PHILIPS

1796 9 AUG -6 A10:40

Philips Medical Systems
Cardiac Care
3000 Minuteman Road
Andover, MA 01810

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: **Petition to Reclassify Automated External Defibrillators (21 CFR § 870.5310)**
Docket No. FDA-2009-M-0101]

Dear Sir/Madam:

Enclosed with this letter is a reclassification petition from Philips Medical Systems requesting that automated external defibrillators (21 CFR § 870.5310) be reclassified from its Class III preamendment status to class II, special controls. The petition is submitted in response to the United States Food and Drug Administration's (FDA's) order published in the *Federal Register* on April 9, 2009 calling for the submission of certain safety and effectiveness information for 25 types of preamendment class III device, including automated external defibrillators, or in lieu of such data, reclassification petitions. *See* 74 Fed. Reg. 16214 (April 9, 2009).

This submission fulfills Philips' requirement to respond to the FDA's April 9 order, and provides valid scientific evidence in support of the company's reclassification request. Submitted herewith are one original and three copies of the petition and attachments.

Sincerely,

Paul Smolenski

Paul Smolenski
Director, Quality and Regulatory Affairs
Philips Cardiac Care
paul.smolenski@philips.com

Enclosures

PHILIPS

Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810

Petition for Reclassification of Automated External Defibrillators From Class III to Class II

[DOCKET NO. FDA-2009-M-0101]

PHILIPS MEDICAL SYSTEMS,

Petitioner

3000 Minuteman Road
Andover, MA 01810
(800) 229-6417

Counsel to Philips Medical Systems:

Mark A. Heller
Louise N. Howe
GOODWIN PROCTER LLP
901 New York Avenue NW
Washington, DC 20001
(202) 346-4000

August 5, 2009

Volume 1 of 2

PHILIPS

Philips Medical Systems
Cardiac Care
3000 Minuteman Road
Andover, MA 01810

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: **Petition to Reclassify Automated External Defibrillators (21 CFR § 870.5310)**
Docket No. FDA-2009-M-0101]

Dear Sir/Madam:

Enclosed with this letter is a reclassification petition from Philips Medical Systems requesting that automated external defibrillators (21 CFR § 870.5310) be reclassified from its Class III preamendment status to class II, special controls. The petition is submitted in response to the United States Food and Drug Administration's (FDA's) order published in the *Federal Register* on April 9, 2009 calling for the submission of certain safety and effectiveness information for 25 types of preamendment class III device, including automated external defibrillators, or in lieu of such data, reclassification petitions. *See* 74 Fed. Reg. 16214 (April 9, 2009).

This submission fulfills Philips' requirement to respond to the FDA's April 9 order, and provides valid scientific evidence in support of the company's reclassification request. Submitted herewith are one original and three copies of the petition and attachments.

Sincerely,

Paul Smolenski
Director, Quality and Regulatory Affairs
Philips Cardiac Care
paul.smolenski@philips.com

Enclosures

RECLASSIFICATION PETITION

TABLE OF CONTENTS

1.0 BACKGROUND AND REGULATORY HISTORY

In response to FDA's April 9, 2009 order, Philips Medical Systems ("Philips") is satisfying its obligation to provide information to the United States Food and Drug Administration ("FDA") regarding its preamendment class III automated external defibrillator ("AED") devices (and relevant accessories) by submitting this reclassification petition. We believe that a premarket approval application ("PMA") approval is unnecessary for AEDs to protect the public health because the device is well characterized, well understood, and its regulation under class II special controls and general controls will provide reasonable assurance of safety and effectiveness. Moreover, class III controls, in particular prospective clinical studies, are largely irrelevant to assuring the safety and effectiveness of currently available AEDs, and those substantially equivalent to them, because the waveforms used in these AEDs were substantiated by clinical data and cleared by the FDA.[1] Below we will identify, through valid scientific evidence, the key performance parameters and risks of the AED generic type of device, and the means of controlling them to provide reasonable assurance of device safety and effectiveness.

Public Health Need for Broad Distribution and Use

There is no doubt among public health organizations, the federal government and all 50 state governments that a need exists to distribute AEDs as widely as possible for immediate use by trained and untrained people. The non-profit American Heart Association ("AHA") estimates that approximately 250,000 deaths are caused every year in the United States by sudden cardiac arrests that occur outside of the hospital, and that the lives of 50,000 cardiac arrest victims could be saved each year if AEDs were widely available.[2] Public health organizations and Congress agree that public access to AEDs can raise the survival rate of persons with cardiac arrest outside of hospitals from below 5% to as high as 50%.[3] An increasing body of data also supports expanded use of AEDs in hospitals, because their hospital-wide placement and use by first responders before the arrival of the CPR team can decrease time to defibrillation and save lives.[4]

---

[1] For AEDs that have new waveforms, *i.e.*, waveforms that are not monophasic or biphasic, clinical data would be appropriate to demonstrate that the new waveform is as safe and effective as previously and clinically substantiated cleared waveforms.

[2] AHA, at http://www.americanheart.org/presenter.jhtml?identifier=3015578.

[3] NSC, "National Safety Council Praises House Passage of the Josh Miller HEARTS Act" (June 3, 2009), at http://www.nsc.org/news/JoshMiller_HEARTS_act.aspx; Pub. L. 107-188, 116 Stat. 634 (2002).

[4] *See* Hanefeld C, Lichte C, Laubenthal H, Hanke E, Mügge A. In-hospital resuscitation. Concept of first-responder resuscitation using semi-automated external defibrillators (AED) *Dtsch Med Wochenschr.* 2006 Sep 29; 131 (39):2139-42; Gombotz H, Weh B, Mitterndorfer W, Rehak P. In-hospital cardiac resuscitation outside the ICU by the nursing staff equipped with automated external defibrillators—The first 500 cases. *Resuscitation.* 2006 Sep; 70(3):416-22. Epub 2006 Aug 14; Kyller M, Johnstone D. A 2-Tiered Approach to In-Hospital Defibrillation: Nurses Respond to a Trial of Using Automated External Defibrillators as Part of a Code-Team Protocol. *Crit Care Nurse.* 2005 Aug; 25(4):25-33; Hanefeld C, Lichte C, Mentges-Schröter I, Sirtl C, Mügge A. Hospital-wide First Responder Automated External Defibrillator Programme: 1 year experience. *Resuscitation.* 2005 Aug; 66(2): 167-70. *See also,* Rossano JW, Jefferson LS, Smith EO, Ward MA, Mott AR. Automated External Defibrillators and Simulated In-hospital Cardiac Arrests. *J Pediatr.* 2009 May; 154(5): 672-6. Epub 2009 Jan 23; Løfgren B, Wahlgreen C, Hoffmann AM, Poulsen TS, Krarup NH. In-hospital resuscitation with automated external defibrillator *Ugeskr Laeger.* 2009 Jan 26; 171(5): 308-10; Ali B, Bloom H, Veledar E, House D, Norvel R, Dudley

Many victims of sudden cardiac arrest experience an abnormal heart rhythm called ventricular fibrillation ("VF"), the only effective treatment for which is defibrillation. Early defibrillation is not only a critical link in AHA's "chain of survival" for victims of VF cardiac arrest,[5] but the most important determinant of survival.[6] For every minute that passes between collapse from cardiac arrest and defibrillation, the survival rate drops by as much as 10%, but in most communities, the time interval from collapse to the arrival of EMS personnel is 7 to 8 minutes or longer.[7] AEDs provide an answer to this public health need and were designed for use by lay rescuers and first responders to reduce time to defibrillation for victims of sudden cardiac arrest.[8] They are user-friendly devices that employ voice, visual and audio prompts to guide users, including untrained users, through the key steps of operation.

Public health organizations, the federal government, and all 50 states have taken measures to encourage greater AED availability and use, including passing "Good Samaritan" laws and establishing funding to support AED purchase and training, thus clearly taking the position that the public health benefits of AEDs – as regulated today under 510(k) – outweigh any risks. The views of these organizations and the federal and state governments are supported by numerous clinical studies and extensive published literature which demonstrate the public health need for broad distribution and use of AEDs.

Specifically, numerous public health organizations, including the AHA, the American Red Cross, the National Safety Council, and others, advocate broad deployment and use of AEDs.[9] These organizations have supported the widespread availability and use of AEDs by pursuing

---

SC, Zafari AM. Automated external cardioversion defibrillator monitoring in cardiac arrest: a randomized trial. *Trials*. 2008 Jun 11; 9:36.

[5] Hazinski MF, Idris AH, Kerber RE et al., "AHA Science Advisory: Lay Rescuer Automated External Defibrillator ("Public Access Defibrillation") Programs," *Circulation*, 111:3336-3340 (2005); *see also* Hallstrom A and Ornato JP, "Public-Access Defibrillation and Survival after Out-of-Hospital Cardiac Arrest," *N Engl J Med*, 351;7:637-646 (2004) (early defibrillation with an AED doubled the number of survivors).

[6] AHA, "ECC Guidelines, Part 4: The Automated External Defibrillator," *Circulation*, 102:1-60 (2000).

[7] Hazinski MF, Idris AH, Kerber RE et al., "AHA Science Advisory: Lay Rescuer Automated External Defibrillator ("Public Access Defibrillation") Programs," *Circulation*, 111:3336-3340 (2005).

[8] AHA, "ECC Guidelines, Part 4: The Automated External Defibrillator," *Circulation*, 102:1-60 (2000).

[9] The American College of Emergency Physicians and the Citizen CPR Foundation support the widespread implementation of PAD programs, noting that research supports "the efficacy of early defibrillation with the reliable technology of automated external defibrillators." The Citizen CPR Foundation, Position Statement, at http://www.citizencpr.org/1position.html; American College of Emergency Physicians, "Automatic External Defibrillators," at http://www3.acep.org/patients.aspx?id=26022. The Sudden Cardiac Arrest Association, which is an organization dedicated to SCA awareness and prevention, supports PAD programs and federal and state legislation that expand AED availability and use. The Sudden Cardiac Arrest Association, "2008 Annual Report on Advocacy, Awareness, Education and Impact." The American College of Occupational and Environmental Medicine supports the establishment of workplace AED programs. ACOEM, "Automated External Defibrillation in the Occupational Setting" (May 2006), at http://www.acoem.org/guidelines.aspx?id=564#.

legislation at the federal and state level, by providing materials, guidance and comprehensive training to lay persons in CPR and AED use, and through other actions.

For example, in the mid-1990s the AHA "launched a public health initiative to promote early CPR and early use of AEDs by trained lay responders in community public access defibrillation ("PAD") programs."[10] However, because a major obstacle was a lack of enabling state legislation, the AHA in 1998 began an organized effort to recommend and pursue legislation at both the state and federal levels to ease personnel certification restrictions (so that non-EMT first responders and lay users could use AEDs), to provide immunity for good faith users of AEDs (Good Samaritan laws), and to ensure wider access to life-saving equipment such as AEDs. [11]

The American Red Cross ("ARC") and the National Safety Council have also taken steps to encourage greater AED access and use. In 2002 the ARC implemented a public service initiative called "Project Lifesaver: Increasing Public Access to Defibrillation" to help communities train and educate their residents in AED use.[12] The ARC has also supported legislation at the federal and state level to increase public access to AEDs.[13] The ARC anticipates a vast deployment of equipped lay responders who would help save lives when emergencies arise, especially in public areas such as shopping malls, airports, stadiums, and worksites.[14] ARC's vision is that all Americans will be within four minutes of an AED and someone trained to use it in the event of sudden cardiac arrest.[15]

The National Safety Council ("NSC") also supports greater availability and use of AEDs, particularly in the workplace and in schools. Since 2003, the NSC and the Occupational Safety and Health Administration have collaborated to improve workplace safety and health by, among other things, providing CPR and AED training in the workplace.[16] The NSC also supported recent federal legislation that, if enacted, would place AEDs in schools.[17]

Undergirding all of these efforts, as well as state initiatives, is the recognition that these devices are safe today under FDA's current level of premarket review.

---

[10] Aufderheide T, Hazinski MF, Nichol G, et al. AHA Policy Recommendation, Community Lay Rescuer Automated External Defibrillation Programs: Key State Legislative Components and Implementation Strategies. *Circulation*. 2006 published online at http://www.americanheart.org/presenter.jhtml?identifier=3004600

[11] *Id.*

[12] American Red Cross, "New Study Results Underscore Need for AEDs in Public Places" (Oct. 22, 2002), at http://www2.redcross.org/news/hs/cpraed/021022aed.html.

[13] ARC, "AED Frequently Asked Questions (External Audiences)," at http://www.redcross.org/www-files/Documents/pdf/Preparedness/AED_FAQs.pdf.

[14] American Red Cross, "New Study Results Underscore Need for AEDs in Public Places" (Oct. 22, 2002), at http://www2.redcross.org/news/hs/cpraed/021022aed.html.

[15] *See* American Red Cross, "Saving a Life Is as Easy as A-E-D," at http://www2.redcross.org/services/hss/courses/aed.html.

[16] NSC, "National Safety Council and Occupational Safety and Health Administration Renew Alliance: (Oct. 15, 2007), at http://www.nsc.org/news/occupational.aspx.

[17] NSC, "National Safety Council Praises House Passage of the Josh Miller HEARTS Act" (June 3, 2009), at http://www.nsc.org/news/JoshMiller_HEARTS_act.aspx.

All 50 states have enacted legislation that encourages the broad availability and use of AEDs.[18] Today, state AED laws include one or more of the following: facilitation of lay persons use of AEDs; immunity for lay rescuers who use AEDs; training requirements for potential users; and mandatory, or grant supported AED placement in various settings, such as government buildings, schools, and fitness centers.[19]

In 2000, the federal government also recognized the highly favorable risk-benefit ratio of AEDs, noted the number of deaths that could be prevented each year if AEDs were more widely available, and enacted the Cardiac Arrest Survival Act ("CASA") and the Rural AED Act.[20] That same year the Federal Aviation Administration issued a rule requiring AEDs on large passenger aircrafts.[21] CASA contains a Good Samaritan provision as well as guidelines for placing AEDs in federal buildings, and the Rural AED Act provides funding to allow communities to purchase AEDs.[22] In enacting CASA, Congress found, among other things, that there is a public health need for AEDs, and AEDs have been demonstrated to be safe and effective, even when used by lay people.[23] In 2002, Congress established a broader grant program through the Community Access to Emergency Devices Act of 2002, noting that in communities that have implemented PAD programs, survival rates have increased dramatically.[24] Congress continues to take action to encourage the widespread availability of AEDs, including 2009 legislation to place AEDs in elementary and secondary schools.[25]

---

[18] National Conference of State Legislatures, "State Laws on Cardiac Arrest & Defibrillators" (Jan. 2, 2009), at http://www.ncsl.org/IssuesResearch/Health/LawsonCardiacArrestandDefibrillatorsAEDs/ tabid/14506/Default.aspx.

[19] *Id.* Notably, the New York legislature passed a law in 2006 that requires the placement of AEDs in places of public assembly. N.Y. Pub. Health Law § 225(5-b).

[20] Both acts are part of the Public Health Improvement Act, Public Law 106-505 (2000).

[21] In 1998 Congress had enacted the Aviation Medical Assistance Act of 1998 which directed the FAA to issue a decision on whether AEDs should be required on passenger aircrafts and at airports. The Act also provided immunity to air carriers for actions arising out of in-flight medical emergencies, with certain exceptions. Pub. L. 105-170, 112 Stat. 48 (2002).To determine whether AEDs should be required, the FAA collected data on cardiac events and AED usage over a one-year period from passenger airlines. Based on this data and further FAA investigation, the FAA decided to issue a rule requiring AEDs on large, passenger aircrafts, noting that more lives could have been saved if AEDs had been aboard every aircraft of each participating air carrier during the data collection period. 65 Fed. Reg. 33720, 33723-24 (May 24, 2000). This rule was finalized in 2001 and took effect in 2004. 66 Fed. Reg. 19028, 19037 (Apr. 12, 2001).

[22] In the HHS Health Resources & Services Administration's 2005 Annual Report, the agency reported that in fiscal year 2005, approximately 8,110 AEDs were placed through the Rural AED Act program, and there were approximately 1,500 AED uses, which resulted in approximately 850 patients having their cardiac rhythm restored. HHS Health Resources & Services Administration, "2005 Annual Report."

[23] Pub. L. 105-505, 114 Stat. 2336 (2000).

[24] Pub. L. 107-188, 116 Stat. 634 (2002). This Act directed HHS to award grants to the states and other political subdivisions to develop and implement PAD programs that would include the purchase and placement of AEDs in public areas and encourage private companies to purchase AEDs and provide CPR and AED training to their employees, as well as grants to develop and implement PAD demonstration projects that would, among other things, maximize community access to AEDs. Congress appropriated $30 million to fund the first year of the program. Pub. L. 107-188, 116 Stat. 634 (2002).

[25] On June 2, 2009, the House of Representatives passed the Josh Miller Helping Everyone Access Responsive Treatment in Schools Act (Josh Miller HEARTS Act), which would help place AEDs in elementary and secondary

In parallel with these activities, the AHA continued its own efforts, issuing scientific statements advocating wider use of AEDs, for example in health fitness facilities.[26] The AED is now considered the standard of care by first responders, and AEDs have been used effectively in many public settings, including casinos, airport terminals and airplanes.[27]

Not satisfied with the progress made in the decade from 1995 to 2005, the AHA published another policy statement in 2006 which aimed "to remove barriers to effective community lay rescuer AED programs" by helping "policymakers develop new legislation or revise existing legislation."[28] One of the components was to provide Good Samaritan limited immunity for untrained rescuers; the thinking was that it is better to have an AED used by a novice than not at all. Clearly, the AHA, state governments and the federal government all recognize the highly favorable benefit to risk ratio of these devices and are interested in removing hurdles to their use. These views are consistent with the information and reasoning herein that the benefit to risk ratio heavily weighs toward wide availability that in the future will be dependent upon reclassification of the AED generic type of device.

History of AED Regulation and Use

Prior to 2003, FDA considered automated external defibrillators to be a combination of class II defibrillators and class III arrhythmia detectors and classified them in class III under 21 CFR § 870.1025 (arrhythmia detectors and alarms).[29] In 2003, FDA reclassified arrhythmia detectors and alarms from class III to class II, but postponed a decision on reclassifying AEDs, instead opting to propose a new identification statement for such devices that was finalized in 21 CFR § 870.5310.[30] In the years since, AEDs have been successfully regulated in effect as class II devices and it is now clear that class II controls are sufficient to ensure the safe and effective use of AEDs. The first over-the-counter AED was cleared in 2004,[31] and the presence and use of public access defibrillators (prescription devices) have become increasingly widespread due to the devices' extremely favorable benefit to risk ratio and the concerted efforts by the non-profit AHA and others to deploy this lifesaving technology as widely as possible. As a matter of public

---

schools, and provide training for schools that have AEDs or acquire them through the program. *See* H.R. 1380, 111th Cong. (2009). The act was named in memory of a teenager from Ohio who suffered SCA during a high school football game and expired before an AED arrived. *See* NSC, "National Safety Council Praises House Passage of the Josh Miller HEARTS Act" (June 3, 2009), at http://www.nsc.org/news/JoshMiller_HEARTS_act.aspx.

[26] Balady G, Chatiman B et al. AHA/ACSM Scientific Statement. Automated External Defibrillators in Health/Fitness Facilities, Supplement to the AHA/ACSM Recommendations for Cardiovascular Screening, Staffing, and Emergency Policies at Health/Fitness Facilities. *Circulation.* 2002; 105; 1147-1150.

[27] Samson RA, Berg RA, Bingham R, et al. ILCOR Advisory Statement, Use of AEDs for Children: An update: An Advisory Statement from the Pediatric Advanced Life Support Task Force, International Liaison Committee on Resuscitation. *Circulation.* 2003; 107; 3250-3255.

[28] Aufderheide T, Hazinski MF, Nichol G, et al. AHA Policy Recommendation, Community Lay Rescuer Automated External Defibrillation Programs: Key State Legislative Components and Implementation Strategies. *Circulation.* 2006 published online at http://www.americanheart.org/presenter.jhtml?identifier=3004600

[29] 67 Fed. Reg. 76706, 76708 (Dec. 13, 2002).

[30] 68 Fed. Reg. 61342 (Oct. 28, 2003).

[31] The HeartStart by Philips, k040904.

health policy, there is no dispute that AEDs should be widely available with as few restrictions on availability and use as possible.[32] Indeed, the authors of the recent Public Access Defibrillator Trial report estimated based on the trial's results that about "2000 to 4000 additional lives would be saved each year in the United States" with widespread implementation of lay rescuer community AED programs.[33] Imposing a PMA requirement would not only undermine this goal, but PMA requirements, in particular the keystone requirement of prospective clinical trials, would have little, if any, applicability to monophasic and biphasic AEDs that essentially represent a combination of two class II devices, *i.e.*, manual defibrillators and arrhythmia detectors, and are clinically demonstrated to be safe and effective. Simply put, based on the record associated with reviewing and clearing AEDs for use through premarket notification, class II regulatory controls are the most appropriate to address the pressing public health need recognized by the AHA and others, while providing reasonable assurance of safety and effectiveness.

Class III Controls are Inappropriate

Class III controls are not only unnecessary, but are inappropriate for AEDs. First, the waveforms used in currently available AEDs and substantially equivalent devices are substantiated by clinical data and cleared by the FDA.[34] Second, unlike PMA devices, a great deal is known about the controls necessary to reasonably assure the safety and effectiveness of AEDs. To reasonably assure that AEDs are effective, controls are available to evaluate: (1) the ability of an AED to reliably detect and analyze heart rhythms; and (2) the device's ability to reliably deliver the appropriate shock in a timely fashion. As the regulation of class II arrhythmia detectors and manual defibrillators illustrates, verification of these performance parameters does not require a clinical trial and PMA approval, but can be done through implementation of a compliant design control process, including software validation, adherence to electrical and environmental standards, and performance testing of the device.[35] The technology necessary for the detection

---

[32] Indeed, federal and state legislation in the last 10-15 years has all trended towards fewer restrictions and greater access to these devices. *See* Cardiac Arrest Survival Act of the Public Health Improvement Act (Public Law 106-505) (2000); Community Access to Emergency Devices Act (Community AED Act) within H.R. 3448 (sections 159, 312 and 313) of the Public Health Security and Bioterrorism Response Act (Public Law 107-188) (2002); Aviation Medical Assistance Act (Public Law 105-170) (1998). *See also* Aufderheide T, Hazinski MF, Nichol G, et al. AHA Policy Recommendation, Community Lay Rescuer Automated External Defibrillation Programs: Key State Legislative Components and Implementation Strategies. *Circulation.* 2006 published online, at http://www.americanheart.org/presenter.jhtml?identifier=3004600

[33] Hallstrom A and Ornato JP, Public Access Defibrillation and Survival after Out-of-Hospital Cardiac Arrest, *New England Journal of Medicine*, 2004; 351 No.7; 637-646. *See also*, Hazinski MF, Idris AH, Kerber RE et al. AHA Science Advisory: Lay Rescuer Automated External Defibrillator ("Public Access Defibrillation") Programs: Lessons Learned from an International Multicenter Trial. Advisory Statement from the American Heart Association Emergency Cardiovascular Committee; the Council on Cardiopulmonary, Perioperative, and Critical Care; and the Council on Clinical Cardiology. *Circulation.* 2005; 111; 3336-3340 (emphasis added).

[34] For AEDs that use a new waveform that has not been reviewed and cleared by the FDA, *i.e.*, waveforms that are not monophasic or biphasic, the inclusion of clinical data in the 510(k) would be appropriate to demonstrate that the new waveform is as safe and effective as a previously cleared waveform.

[35] *See, e.g., Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm,* October 28, 2003. The special controls contained in this guidance document are: software validation, electrical safety and environmental handling, performance testing and labeling. *See also*, ANSI/AAMI DF80:2003 and IEC 60601-2-4.

and analysis of shockable and non-shockable rhythms is regulated in class II in the context of arrhythmia detectors and alarms (21 CFR § 870.1025). Similarly, the particular waveforms and energy levels used to administer therapeutic shocks are regulated in class II in the context of low energy manual defibrillators (21 CFR § 870.5300). Other components of AEDs, such as pads, adaptors, and batteries, are common to these class II devices as well. Special controls already exist to provide reasonable assurance of the safety and effectiveness of these components and features.[36] Indeed, these controls and general controls have resulted in the successful regulation of these devices in class II.

In addition, the attributes of the AED that distinguish it from class II arrhythmia detectors and low energy manual defibrillators can likewise be successfully regulated under class II controls. These attributes are:

- ECG quality and analysis (shockable and non-shockable rhythm detection and artifact detection),
- device readiness and maintenance, because AEDs may remain in standby for years between actual uses, *i.e.*, AED reliability, and
- use by lay persons with no medical background or AED training.

As discussed in this submission, there are general and special controls that can control these attributes as well as the device's other key performance parameters and risks. These attributes do not require class III PMA controls to reasonably assure safety and effectiveness. The first two attributes are controllable with design controls, performance testing and other special and general controls. The third is controllable through usability testing, design and labeling.

In sum, verification of the AED's performance can be done through class II controls, including performance testing standards and design controls, and the Act's general controls. AEDs do not require the product by product clinical evaluation of performance necessary to assure the safety and effectiveness of class III devices. In other words, under the Federal Food, Drug, and Cosmetic Act ("Act"), such evaluations are only necessitated because not enough is known about a device to classify it in class II or I. As discussed below, valid scientific evidence demonstrates that factors determining safety and effectiveness of AEDs are well understood and controllable, and the legal standard for reclassification of the device into class II has been met.

Legal Requirements and Standard for Reclassification

On April 9, 2009, FDA issued an order requiring manufacturers of AEDs, and other preamendment class III devices for which regulations requiring submission of PMAs have not been promulgated by FDA, to submit to the agency information respecting such devices, in order

[36] *See, e.g., Guidance for Industry and Staff, Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm*, October 28, 2003.

for FDA to determine whether to require a PMA.[37] Also, FDA's order allowed device manufacturers to submit reclassification petitions to fulfill their obligation under the order.[38]

For preamendment devices, under section 513(e) of the Act , FDA may change a device's classification based on "new information" respecting that device. Act § 513(e)(1). In addition to newly developed information since the classification of a device type, new analyses of "old" information are considered new information for purposes of reclassification under section 513(e)(1).[39] FDA may reclassify a device into class II if the agency determines that special controls would provide reasonable assurance of the safety and effectiveness of the device and general controls alone would not. Act § 513(e)(2). A device should be classified into class II if "there is sufficient information to establish special controls to provide such assurance." *See* Act § 513(a)(1)(B). FDA is not required to, but may, obtain a panel recommendation during the reclassification process; if it does so, it must publish in the Federal Register any recommendation submitted to it by the panel. Act § 513(e)(1).

Because AEDs may be considered "a device that is purported or represented to be for a use in supporting or sustaining human life" under section 513(a)(1)(B), a manufacturer seeking reclassification must identify the special controls that "are necessary" to provide adequate assurance of safety and effectiveness, and describe how the controls provide that assurance. Act § 513(a)(1)(B).[40] Below, we set forth specific descriptions of the special controls to provide reasonable assurance of the safety and effectiveness of AEDs. Unlike with many other types of preamendment class III devices, numerous special controls for AEDs in the form of well-known voluntary standards exist to ensure effective regulation.

FDA's regulations set forth what must be contained in a reclassification petition, starting with a specification of the generic type of device for which reclassification is requested. *See* 21 CFR § 860.123(a). AEDs are well characterized and share a similar purpose, design, materials, energy source, function and other features related to safety and effectiveness, and thus, a generic type of device can be reasonably described. Moreover, because of the similarity of AEDs, they constitute a group of products that can be successfully regulated by the same set of regulatory controls to provide a reasonable assurance of safety and effectiveness. AEDs use an interpretive ECG analysis algorithm to analyze the heart rhythm and identify shockable and non-shockable cardiac rhythms, and when they detect a rhythm that is likely to respond to an electrical shock, they deliver electrical energy in a fully automated or semi-automated mode. Although devices with AED functionality may differ in various respects, depending upon the environments in which they are indicated for use, nevertheless, AEDs present a uniform profile of performance characteristics and risks that would be amenable to the same class II controls.

The core of a reclassification petition is "a full statement of the reasons, together with supporting data satisfying the requirements of § 860.7, why the device should not be classified into its

---

[37] 74 Fed. Reg. 16214 (April 9, 2009).

[38] 74 Fed. Reg. at 16216.

[39] 72 Fed. Reg. 32170 (June 12, 2007).

[40] Note that 21 CFR § 860.3(c)(2) states that "class II means the class of devices that is or eventually will be subject to special controls."

present classification and how the proposed classification will provide reasonable assurance of the safety and effectiveness of the device." 21 CFR § 860.123.

What is necessary to support the reclassification of a type of device from class III to class II was precisely identified by the district court in the *Ethicon* case:

> In FDA's view, 'sufficient information' for evaluating a device requires that valid scientific evidence in the record correlates the control of performance parameters to safe and effective use of the device. *See* 21 C.F.R. § 860.7(c), .5(f). Thus, the question is whether the administrative record contains sufficient information for the agency to understand the device and sufficient evidence to demonstrate that factors determining the device's safety and effectiveness are controllable.

Ethicon v. FDA, 762 F. Supp. 382, 388 (D.C. 1991). As this petition shows, there is sufficient information to understand the device and its key performance parameters and risks, and to demonstrate that special controls are (or can be) available to control these parameters and risks to provide a reasonable assurance of the device's safety and effectiveness.

The statute identifies the considerations for evaluating this information to determine safety and effectiveness for purposes of reclassification. Specifically, the safety and effectiveness of a device are determined with respect to the (1) persons for whose use the device is intended, (2) conditions of use for the device suggested in labeling, and (3) weighing of probable benefit to health and probable risks of illness or injury. Act § 513(a)(2). In addition to these statutory criteria for assessing safety and effectiveness, FDA's regulations add the criterion of reliability of the device. *See* 21 CFR § 860.7(b).

As stated above, AEDs are intended for pulseless, unresponsive patients who will die unless defibrillation is delivered very quickly. Their status is so dire, and the benefit of the device so great, that the weighing of probable benefit to probable risk is extremely favorable. This conclusion is true even when conditions of use for the device include untrained, nonmedical personnel. The favorable character of AEDs versus any related risk is underlined by the AHA's statement that "Safe and effective use of AEDs that are widely available and easily handled by nonmedical personnel has the potential to dramatically increase survival from cardiac arrest."[41] The PAD trial fully supports this statement.[42] AHA's view and the results of the PAD trial reinforce the conclusion that AEDs have "a reasonable uniform risk-benefit profile," a characteristic important to the District Court in *Ethicon* in affirming FDA's reclassification of

---

[41] Kerber R.E., Becker L, et al. AHA Scientific Statement, Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety. *Circulation.* 1997; 95, 1677-1682.

[42] Hallstrom A and Ornato JP, Public Access Defibrillation and Survival after Out-of-Hospital Cardiac Arrest, *New England Journal of Medicine*, 2004; 351 No.7; 637-646. *See also*, Hazinski MF, Idris AH, Kerber RE et al. AHA Science Advisory: Lay Rescuer Automated External Defibrillator ("Public Access Defibrillation") Programs: Lessons Learned from an International Multicenter Trial. Advisory Statement from the American Heart Association Emergency Cardiovascular Committee; the Council on Cardiopulmonary, Perioperative, and Critical Care; and the Council on Clinical Cardiology. *Circulation.* 2005; 111; 3336-3340 (emphasis added).

PGL sutures. *See Ethicon* at 388. Finally, the major reliability issue related to AEDs is the length of time they remain idle in between uses. Self tests, alerts and other design features help ensure the device's reliability by minimizing the likelihood of use of a non-functioning device on a victim. Moreover, an effective design development process, including the compliant implementation of the design and its translation into the manufacturing process, contributes significantly to device reliability.

In sum, AEDs are a well characterized type of device that is well understood. In this context, sufficient information exists to support reclassification of AEDs into class II, particularly when taking into account the intended patient population, conditions of use and the weighing of benefits and risks. As noted above, FDA has long acknowledged that AEDs are a combination of arrhythmia detectors and low energy defibrillators, both of which are class II devices. The additional attributes of an AED do not present reasons for a different classification than its major components, and these attributes can be controlled by class II special controls and general controls. Simply put, there is sufficient information correlating the control of AED performance parameters and risks to special and general controls, thus providing reasonable assurance of safety and effectiveness under class II controls. Moreover, reclassification of AEDs is in the public health interest and consistent with the policies and recommendations of major public health organizations.

2.0 DEVICE DESCRIPTION

A. Generic Type of Device

AEDs present a readily identifiable and well characterized generic type of device. Specifically, AEDs automatically analyze heart rhythms of non-responsive persons who are not breathing normally, and automatically advise or deliver shocks when they detect pre-specified heart rhythms that may be responsive to an electrical shock.

AEDs use an interpretive arrhythmia analysis algorithm to identify shockable and non-shockable cardiac rhythms and deliver electrical energy in the fully automated or semi-automated mode (where additional operator steps are required). The device analyzes a patient's cardiac rhythm and advises the user as to whether a shock is advisable. Voice and other prompts guide the user through the defibrillation process by providing instructions and patient information. The voice prompts are typically reinforced by messages that appear on the AEDs' display.

AED functionality is present on a range of devices that are intended for different use environments and users. Users and use environments range from untrained lay users in the home and public settings, to trained designated response teams in the workplace and public settings, to professional responders like EMTs and paramedics, to hospital personnel. The simplest AED devices for lay users include AED functionality only; the most complex AED devices have AED functionality as one of many available functions.

AEDs deliver into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy. They include a variety of waveforms, *e.g.*, biphasic or monophasic.

These characteristics define the safety and effectiveness of AEDs, thus constituting a grouping of devices "for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness," 21 CFR § 860.3(i). Through its classification regulations, FDA concurs with this conclusion defining a generic type of device, and accordingly, has identified the generic type of AEDs under 21 CFR § 870.5310.

Intended Use

Currently marketed AEDs are available in prescription and over-the-counter versions, thus necessitating a bifurcated identification statement, although both versions have the same medical purpose.

Prescription

AED Therapy is intended for use for the termination of ventricular tachycardia and ventricular fibrillation. The device is to be used in the presence of a suspected cardiac arrest on patients that are unresponsive and not breathing normally.

Over-the-Counter

An AED is used to treat someone who may be a victim of sudden cardiac arrest. A person in sudden cardiac arrest does not respond when shaken and is not breathing normally.

Materials

The only patient contacting materials are the pads. The materials used in the pads are well known to be biocompatible and appropriate to their use in the context of AEDs. They do not present safety or effectiveness issues in AED related use.

Component Parts/Accessories

The device may include rechargeable or non-rechargeable batteries, battery chargers, various types of pads, including reduced energy pediatric pads, cables and adaptors.

B. Device Description

The current AED classification regulation (21 CFR § 870.5310) defines the type of device as:

> a low energy device with a rhythm recognition detection system that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart. An AED analyzes the patient's electrocardiogram, interprets the cardiac rhythm, and automatically delivers an electrical shock (fully automated AED), or advises the user to deliver the shock (semi-automated or shock advisory AED) to treat ventricular fibrillation or pulseless ventricular tachycardia.

FDA has used two product codes under § 870.5310:

- MKJ – Automated External Defibrillators (Non-wearable)
- NSA – Over-The-Counter Automated External Defibrillator

The MKJ product code is defined as:

> This device is a non-wearable prescription use only AED. These are devices that include automated external defibrillation. Automated external defibrillators use external pad-type electrodes to sense, detect, classify and treat (with an electrical shock) ventricular fibrillation. These devices are intended to be used on suspected victims of sudden cardiac arrest. A person in cardiac arrest is unresponsive and is not breathing normally. The device can be sold with prescription only.

The NSA product code is defined as:

> Automated external defibrillators are devices that use external pad-type electrodes to sense, detect, classify and treat (with an electrical shock) ventricular fibrillation. These devices are intended to be used on suspected victims of sudden cardiac arrest. A person in cardiac arrest is unresponsive and is not breathing normally. The device can be sold over-the-counter without a prescription. The

device is to be used on adults and children who are either > 8 years old or > 55 lbs.

Both prescription and over-the-counter devices are included in the current classification regulation.

3.0 ACTION REQUESTED - PROPOSED CLASSIFICATION REGULATION

We propose changing the classification of the current AED regulation, 21 CFR § 870.5310, from class III to class II, and amending the text to reflect this change.

The following text reflects the change in AED classification from class III to class II:

> **§ 870.5310 Automated external defibrillator.**
>
> (a) *Identification.* An automated external defibrillator (AED) is a low energy device with a rhythm recognition detection system that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart. An AED analyzes the patient's electrocardiogram, interprets the cardiac rhythm, and automatically delivers an electrical shock (fully automated AED), or advises the user to deliver the shock (semi-automated or shock advisory AED) to treat ventricular fibrillation or pulseless ventricular tachycardia. AEDs may include rechargeable or non-rechargeable batteries, various types of pads, including provisions for delivering pediatric energy levels, cables and adaptors and other accessories.
>
> The device may be prescription or over-the-counter. When AED functionality is included on multi-function devices that require the supervision of a licensed practitioner, and for which adequate directions for lay use cannot be prepared, the multi-function device requires a prescription. Single function AEDs require a prescription if they do not comply with the special controls for over-the-counter AEDs.
>
> (b) *Classification.* Class II (special controls).
>
> (1) The special control for this device is FDA's "Class II Special Controls for Automated External Defibrillators."
>
> (2) Automated External Defibrillators with waveforms that are not monophasic or biphasic shall be subject to a clinical trial special control demonstrating the safety and effectiveness of the waveform to defibrillate the atria or ventricles of the heart to restore normal heart rhythm.

4.0 SUPPLEMENTAL DATA SHEET

See *Attachment A*.

5.0 CLASSIFICATION QUESTIONNAIRE

See ***Attachment B***.

6.0 SUMMARY OF REASONS FOR RECLASSIFICATION INTO CLASS II

Reclassifying AEDs into class II is appropriate because:

1. Defibrillation is a well-proven clinical therapy for treating the causes of sudden cardiac arrest ("SCA") and AEDs are a well characterized type of device that is well understood.

2. FDA has long acknowledged that AEDs are a combination of arrhythmia detectors and defibrillators. The low energy (less than 360J) waveforms used in currently marketed AEDs are the same type of waveforms used in class II low energy manual defibrillators (21 CFR § 870.5300; product code LDD), and therefore have been adequately controlled in class II for many years. AEDs also incorporate an arrhythmia detection system upon which the device makes its shock advisory recommendation. Arrhythmia detectors are a well-proven technology, have an extensive safety record, and are successfully regulated as class II devices (21 CFR § 870.1025).

3. The additional attributes of an AED can be adequately controlled by class II special controls[43] and general controls. Specifically, the petition fully defines and documents with valid scientific evidence the device type's performance parameters and risks, and that these characteristics can be controlled by the special controls incorporated in Attachment C. Unlike many other types of preamendment class III devices, numerous potential special controls for AEDs exist in the form of well-known voluntary standards to reasonably assure safety and effectiveness, and sufficient information to support these and other special controls exists to support reclassification of AEDs into class II, particularly when taking into account the intended patient population, conditions of use and the weighing of benefits and risks.

4. Class III premarket and postmarket controls are unnecessary to address the AED-specific risks and performance parameters. In particular, class III premarket controls, including randomized clinical trials and completion of premarket inspections that review Quality System procedures and processes, and class III postmarket controls, including pre-approval of product changes and labeling, and annual reporting to FDA, do not provide additional controls for risks associated with the arrhythmia analysis algorithm and device readiness and usability. General controls, *e.g.*, GMPs, and the proposed special controls, *e.g.* consensus standards, adequately address these concerns.

5. Reclassification of AEDs is in the public health interest and consistent with the policies and recommendations of major public health organizations, the federal government, and all 50 states. Moreover, class III premarket and postmarket controls present an unnecessarily high barrier to access, without public health justification, that would be in direct conflict with the clinical recommendations of numerous public health organizations, such as the American Heart Association and American Red Cross, that widespread availability of AEDs is critical to improving the survivability of SCA, particularly SCA that occurs outside of the hospital. Class III regulation would also

[43] The special controls discussed throughout the reclassification petition are incorporated in Attachment C, "Special Controls Guidance Document."

undercut the legislative measures that have been undertaken and/or implemented by the U.S. Congress and all 50 states to encourage widespread access to AEDs in public places. Further, studies show that AEDs can be made available to, and used by, lay users without introducing new safety issues to SCA victims, users or bystanders, and improve the survival rate of SCA.[44]

In sum, as this petition shows, there is sufficient information to understand the device and its key performance parameters and risks, and to demonstrate that special controls exist to control these parameters and risks to provide a reasonable assurance of the device's safety and effectiveness. In other words, class II controls are effective to ensuring the safe and effective use of the device, and class III controls are unnecessary to do so. Reclassification of AEDs is in the public health interest and consistent with the policies and recommendations of major public health organizations, the federal government, and all 50 states, and Section 513(e)(2) of the Act.

[44] *See* Drezner JA, et al. Effectiveness of Emergency Response Planning for Sudden Cardiac Arrest in United States High Schools with Automated External Defibrillators. *Circulation.* 2009; 120:518-525.

7.0 REASONS AND DATA SUPPORTING THAT CLASS II CONTROLS WILL PROVIDE REASONABLE ASSURANCE OF THE SAFETY AND EFFECTIVENESS FOR THE DEVICE AND WHY CLASS III CONTROLS ARE UNNECESSARY AND INAPPROPRIATE TO PROVIDE SUCH ASSURANCE

In the sections below we identify (A) performance parameters and controls, (B) risks to health and controls, and (C) the favorable benefit to risk ratio of the device that strongly favor reclassification from class III to class II. For each performance parameter and risk, we document and describe special and general controls that provide reasonable assurance of safety and effectiveness.

Importantly, a significant number of the device's performance parameters and risks are coincidental with those presented by arrhythmia detectors and low energy defibrillators, which are class II devices. The agency already made the judgment that for the performance parameters and risks associated with these types of devices there are special controls that provide a reasonable assurance of safety and effectiveness. Below we demonstrate that the performance parameters and risks particular to AEDs are similarly amenable to special controls and regulation in class II.

A. Performance Parameters and Controls

1. Introduction

AED performance depends on the following key parameters: arrhythmia analysis algorithm; defibrillation shock delivery; usability; intended use environment; electrical safety; other AED safety and performance requirements, *e.g.*, electrode performance and battery capacity requirements; and other safety and regulatory requirements, *e.g.*, biocompatibility, software validation and device tracking. As FDA acknowledges, an AED is a combination of a defibrillator and an arrhythmia detector, both of which are class II devices subject to special controls.[45] Consequently, AEDs have many performance parameters in common with arrhythmia detectors and manual defibrillators, and the applicable sections of the standards that apply to these devices, and the general standards applicable to all active medical devices, are likewise special controls for AEDs.[46]

There are also AED-specific standards and guidelines, including ANSI/AAMI DF80:2003, which is the current consensus standard for defibrillators, including AEDs, and the AHA's algorithm performance guidelines for AEDs, that address most of the AED-specific performance parameters and provide further special controls.[47] We encourage FDA to formally recognize

---

[45] *See* 67 Fed. Reg. 76706, 76707 (Dec. 13, 2002) (proposed classification rule for arrhythmia detector and alarm).

[46] *See e.g., Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm,* October 28, 2003 and IEC 60601-2-4:2002 "Medical electrical equipment – Part 2-4: Particular requirements for the safety of cardiac defibrillators."

[47] AHA's guidelines are set forth in Kerber R.E., Becker L, et al. "AHA Scientific Statement, Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety," *Circulation,* 95:1677-1683 (1997) ("AHA Scientific Statement"). From time to time, as AED-specific standards and guidelines are updated, we expect that FDA will keep the AED special controls current with them.

ANSI/AAMI DF80 because it incorporates and updates ANSI/AAMI DF39:1993, which is the AED performance standard currently recognized by the FDA.[48] These AED-specific standards and guidelines include: performance testing of the arrhythmia analysis algorithm; environmental qualification testing to confirm that AEDs are able to withstand the conditions of their intended use environment; other AED-specific safety and performance testing; AED design considerations; and the specific information for AED labeling. We also propose including usability testing as a special control to provide reasonable assurance that AEDs can be used safely and effectively by the intended user population. These special controls, together with the general controls of the Act, *e.g.*, quality system, general labeling, reporting, and premarket notification requirements, would provide a reasonable assurance of AED safety and effectiveness.

What follows are the critical performance parameters and applicable special and general controls that characterize the generic type of device and reasonably assure its safety and effectiveness.

2. *Arrhythmia Analysis Algorithm*

One of the most important AED performance parameters is the ability of the arrhythmia analysis algorithm to accurately interpret a patient's cardiac rhythm and advise the user as to whether a shock is appropriate (or deliver a shock if fully automated). This software application analyzes multiple features of the ECG signal and determines whether a shockable rhythm is present. Indeed, the ability to interpret a patient's cardiac rhythm and advise the user as to whether a shock is appropriate (or deliver a shock if fully automated) is what makes AEDs safe and effective for both medical and non-medical personnel.

The performance of the arrhythmia analysis algorithm can be adequately controlled by both ANSI/AAMI DF80 and the AHA guidelines in the AHA Scientific Statement for the arrhythmia analysis algorithm. ANSI/AAMI DF80 and the AHA guidelines provide adequate special controls for algorithm performance because they define the types of rhythms that are shockable and non-shockable, assure accuracy of the algorithm by establishing high sensitivity and specificity goals, and provide guidance on algorithm validation testing and reporting. Artifacts, which can affect algorithm performance, can be adequately controlled through device design and/or labeling. Moreover, requiring device self testing ensures that any algorithm or other failures are mitigated by notice to users, and immobilization of the device.

Algorithm Performance

In order for the algorithm to detect whether a shockable or non-shockable rhythm is present, the types of rhythms that are shockable and non-shockable must be defined. The AHA guidelines

---

[48] ANSI/AAMI DF80 combines the requirements of earlier ANSI/AAMI DF2 for manual defibrillators and DF39 for automated defibrillators. FDA previously recognized DF39, *see* FDA Recognition Number 3-51 (effective March 8, 2004). The combined standard also includes all of the requirements from IEC standard 60601-2-4:2002 "Medical electrical equipment – Part 2-4: Particular requirements for the safety of cardiac defibrillators," although with additional technical material for the United States. IEC 60601-2-4 details defibrillators under a parent general standard, IEC 60601-1, Medical Electrical Equipment Part 1: General Requirements for Safety. Like the previous standards, DF80 and its parent general standard provide detailed recommendations to specify and test an AED's physical, operational, environmental and safety characteristics.

specify the types of rhythms that are shockable and non-shockable. Specifically, shockable rhythms include coarse VF and rapid (pulseless) VT; non-shockable rhythms include normal sinus rhythm, supraventricular tachycardia, sinus bradycardia, atrial fibrillation and flutter, heart block, idioventricular rhythms, and premature ventricular contractions.[49] Additionally, AHA guidelines classify asystole rhythms as non-shockable to maximize safety in the event of misapplication of the AED pads.[50]

To assure the accuracy of the algorithm, AHA guidelines specify performance goals for the algorithm. The performance goals for the algorithm include attaining high sensitivity and specificity for the different rhythm classes. In particular, AHA recommends that the algorithm recognize VF at a sensitivity level that exceeds 90% in a minimum sample size of 200 and rapid VT at a sensitivity level that exceeds 75% in a minimum sample size of 50.[51] Further, the algorithm should be able to differentiate normal sinus rhythms at a specificity level that exceeds 99% and other non-shockable rhythms at a specificity level that exceeds 95%, in a total minimum sample size of 300.[52] The AHA guidelines meet, and in some cases, exceed the recommendations set forth in ANSI/AAMI DF80:2003. For example, AHA's 99% specificity goal for normal sinus rhythms exceeds that of ANSI/AAMI DF80.[53] Additionally, AHA recommends that validation of algorithm performance be obtained in both the presence and absence of artifacts likely to be encountered in use, although the sensitivity and specificity goals need only be achieved in the absence of artifacts.[54] The manufacturer should provide information on how the device performs and reacts to artifacts. We propose that algorithm performance be evaluated both in the presence and absence of artifacts.

The AHA guidelines and ANSI/AAMI DF80 also provide guidance on algorithm validation testing and reporting. The AHA guidelines specify a format for reporting the algorithm performance and provide other recommendations for validating algorithm performance, for example, the classification of shockable or non-shockable rhythms should be established by agreement among at least three qualified expert reviewers of cardiac arrest rhythms.[55] ANSI/AAMI DF80 provides further input with respect to the ECG database used for validating algorithm performance and the information that should be included in the algorithm performance

---

[49] AHA Scientific Statement. In the late 1990s, the AHA recognized the potential to save large numbers of lives through the widespread deployment of AED technology. Members anticipated that the new AED technology would aim at a very easy-to-use public access model. Forecasting large-scale clinical trials of this model, the AHA saw a need for an additional consensus standard for AED performance. The Scientific Statement referenced above followed an intensive effort by the organization. It offers practical guidance for robust testing and reporting of AED analysis subsystems for shock/no shock decision making.

[50] *Id.*

[51] *Id.*

[52] *Id.*

[53] *Id*; ANSI/AAMI DF80:2003.

[54] Kerber R.E., Becker L, et al. "AHA Scientific Statement, Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety," *Circulation*, 95:1677-1683 (1997) ("AHA Scientific Statement).

[55] *Id.*

test report. At a minimum, ANSI/AAMI DF80 recommends that the ECG database include VF rhythms of varying amplitudes, VT rhythms of varying rates and QRS widths, various sinus rhythms including supraventricular tachycardias, atrial fibrillation and flutter, sinus rhythm with premature ventricular contraction, asystole, and pacemaker rhythms.[56] Moreover, ANSI/AAMI DF80 recommends that all rhythms be collected using electrode systems and ECG signal processing characteristics similar or the same as those incorporated into the device being tested and of appropriate length to allow decisions to be made by the detector system.[57] Additionally, ANSI/AAMI DF80 recommends that the algorithm performance test report not only include the performance data, but also the recording methods, rhythm source, rhythm selection criteria, and annotation methods and criteria.[58]

The proposed AHA statement special control was the result of defibrillator manufacturers, clinicians and the FDA agreeing on the performance for the devices that would be used in the PAD trial. As the PAD trial showed there was 100% specificity and 100% sensitivity.[59] In addition, there are numerous studies that report excellent sensitivity and specificity results for a measurement of an AED's algorithm performance in adults and pediatrics.[60] In addition, the AHA, using evidence-based classification process, has classified Philips waveform as class IIa

---

[56] ANSI/AAMI DF80:2003 clause 6.8.3.

[57] *Id.*

[58] *Id.*

[59] Peberdy, M. A.; Ottingham, L. V.; Groh, W. J.; Hedges, J.; Terndrup, T. E.; Pirrallo, R. G.; Mann, N. C., and Sehra, R. Adverse events associated with lay emergency response programs: The public access defibrillation trial experience. Resuscitation. 2006 Jul; 70(1):59-65.

[60] Bardy, G. H.; Lee, K. L.; Mark, D. B.; Poole, J. E.; Toff, W. D.; Tonkin, A. M.; Smith, W.; Dorian, P.; Packer, D. L.; White, R. D.; Longstreth, W. T. Jr; Anderson, J.; Johnson, G.; Bischoff, E.; Yallop, J. J.; McNulty, S.; Ray, L. D.; Clapp-Channing, N. E.; Rosenberg, Y., and Schron, E. B. Home use of automated external defibrillators for sudden cardiac arrest. N Engl J Med. 2008 Apr 24; 358(17):1793-804; Poole, J. E.; White, R. D.; Kanz, K. G.; Hengstenberg, F.; Jarrard, G. T.; Robinson, J. C.; Santana, V.; McKenas, D. K.; Rich, N.; Rosas, S.; Merritt, S.; Magnotto, L.; Gallagher, J. V. 3rd; Gliner, B. E.; Jorgenson, D. B.; Morgan, C. B.; Dillon, S. M.; Kronmal, R. A., and Bardy, G. H. Low-energy impedance-compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out-of-hospital cardiac arrest. LIFE Investigators. J Cardiovasc Electrophysiol. 1997 Dec; 8(12):1373-85; Gliner, B. E.; Jorgenson, D. B.; Poole, J. E.; White, R. D.; Kanz, K. G.; Lyster, T. D.; Leyde, K. W.; Powers, D. J.; Morgan, C. B.; Kronmal, R. A., and Bardy, G. H. Treatment of out-of-hospital cardiac arrest with a low-energy impedance-compensating biphasic waveform automatic external defibrillator. The LIFE Investigators. Biomed Instrum Technol. 1998 Nov-1998 Dec 31; 32(6):631-44; Page, R. L.; Joglar, J. A.; Kowal, R. C.; Zagrodzky, J. D.; Nelson, L. L.; Ramaswamy, K.; Barbera, S. J.; Hamdan, M. H., and McKenas, D. K. Use of automated external defibrillators by a U.S. airline. N Engl J Med. 2000 Oct 26; 343(17):1210-6; Cecchin, F.; Jorgenson, D. B.; Berul, C. I.; Perry, J. C.; Zimmerman, A. A.; Duncan, B. W.; Lupinetti, F. M.; Snyder, D.; Lyster, T. D.; Rosenthal, G. L.; Cross, B., and Atkins, D. L. Is arrhythmia detection by automatic external defibrillator accurate for children?: sensitivity and specificity of an automatic external defibrillator algorithm in 696 pediatric arrhythmias. Circulation. 2001 May 22; 103(20):2483-8; Caffrey, S. L.; Willoughby, P. J.; Pepe, P. E., and Becker, L. B. Public use of automated external defibrillators. N Engl J Med. 2002 Oct 17; 347(16):1242-7; MacDonald RD et al. Performance and Error Analysis of Automated External Defibrillator Use in the out-of-hospital setting. Ann Emerg Med. 2001;38:262-267; Atkins DL, et al. Sensitivity and specificity of an automated external defibrillator algorithm designed for pediatric patients. Resuscitation. 2008 76, 168-174; Cecchin F, et al. Is arrhythmia detection by automatic external defibrillator accurate for children?: sensitivity and specificity by an automatic external defibrillator algorithm in 696 pediatric arrhythmias. Circulation. 2001. 103:2483-2488; Atkinson E, et al. Specificity and sensitivity of automated external defibrillator rhythm analysis in infants and children. Ann Emerg Med. 2003;42;185-196.

(defined as having "good to very good evidence," a "standard of care," "intervention of choice").[61] The current voluntary practices that AED manufacturers used to develop accurate algorithms, relying on the standards and guidelines referenced herein, will ensure that the practices are continued when the special controls for algorithm performance are implemented.

In sum, the AHA Scientific Statement and ANSI/AAMI standard provide comprehensive special controls, as specified above, to ensure safe and effective performance of AED arrhythmia analysis algorithms. The testing resulting from these standards could be part of premarket notification submissions or could be kept in facilities' files.[62] Importantly, no matter whether reports of results are submitted in a 510(k) or maintained in files, the testing would be required prior to the commercial distribution of the AED.

Artifact Detection

Artifacts such as noise, *e.g.*, electrostatic discharge and electromagnetic interference; motion, *e.g.*, caused by CPR, patient handling and transport; and pacemaker stimuli can interfere with proper rhythm detection and affect the specificity and sensitivity of the AED arrhythmia analysis algorithm. These types of artifacts can also occur during the operation of arrhythmia detectors, and thus, are not unique to AEDs and can be addressed through special controls. Specifically, artifacts can be adequately controlled through device design and/or labeling. AED design could be optimized by including an artifact detection and filtering or removal mechanism to mitigate the effects that artifacts may have on the arrhythmia analysis algorithm.

At a minimum, as recommended in the AHA guidelines, the effects of these various artifacts on algorithm performance, particularly with regard to the detection of shockable and non-shockable rhythms, would be evaluated and included in AED labeling.[63] The AED instructions for use would include information about how the algorithm processes artifacts such as noise and movement and the techniques for controlling such artifacts, and would also provide clear warnings about the effects of such artifacts on AED performance, *e.g.*, motion similar to that caused by CPR or vehicle movement may interfere with the AED function and cause improper analysis of the cardiac rhythm and be more likely to prevent or delay ECG analysis.

In sum, device design and/or labeling provide sufficient special controls to address artifacts which can affect algorithm performance. Indeed, extensive clinical experience shows that AEDs

---

[61] Cummins, RO et al. Guidelines 2000 for cardiopulmonary resuscitation and emergency cardiovascular care. Supplement to Circulation 2000;102(8):I-5, I-63, I-91.

[62] If test results were maintained in facility files, a written certification in the premarket notification for the device would certify that the device would not be distributed prior to the completion of the specified testing with conforming results. This option would lessen the review burdens on the agency

[63] Kerber R.E., Becker L, et al., "AHA Scientific Statement, Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety," *Circulation*, 95:1677-1683 (1997) ("AHA Scientific Statement).

are infrequently affected by patient movement or artifact signals, indicating that currently, AED manufacturers adequately address artifact interference through device design and/or labeling.[64]

3. *Defibrillation Shock Delivery*

The delivery of a proper defibrillation shock is also an important performance parameter because it is critical to successful resuscitation of victims in cardiac arrest. This performance parameter, however, is not unique to AEDs, because the delivery of a proper defibrillation shock is also a key performance parameter for class II manual defibrillators. The safety and effectiveness of the defibrillation shock depends on both the waveform and energy.

Special controls for the delivery of a proper defibrillation shock are the ANSI/AAMI DF80 standard and animal or *in vitro* testing for AEDs that utilize conventional waveforms. ANSI/AAMI DF80 serves as an appropriate special control because it provides standards and guidelines regarding waveform and energy for defibrillators. Specifically, ANSI/AAMI DF80 discusses the types of conventional waveforms that are clinically effective and provides guidance on testing new waveforms. Although ANSI/AAMI DF80 addresses performance testing of new waveforms, it does not address performance testing of conventional waveforms. Performance testing of conventional waveforms, however, can be adequately addressed through animal or *in vitro* testing, when appropriate. With regard to the defibrillation energy, FDA's AED classification regulation establishes an acceptable energy level, and ANSI/AAMI DF80 addresses issues that may affect the delivered energy, including variations in patient impedance.

Waveform

Although ANSI/AAMI DF80 does not recommend a particular waveform for defibrillators, it does discuss the different types of waveforms that have been shown to be effective in clinical studies, including monophasic (damped sinusoid and truncated exponential) and biphasic (truncated exponential) waveforms. Because the safety and effectiveness of these waveforms have been demonstrated clinically,[65] special control requirements for performance testing of these conventional waveforms in animal studies, or alternatively, validated *in vitro* studies will demonstrate the appropriateness of the waveform in the context of a specific AED. The results of such studies can be submitted or certified to in premarket notification submissions.

If animal studies are undertaken, testing should be conducted in a swine model due to the similarity of their cardiovascular systems and defibrillation thresholds to humans. Other animal models may be used if adequate justification is provided for their use. Because humans exhibit wide variation in transthoracic impedance, the entire range of human impedance should be modeled in the animal study. In evaluating safety, the dose should be characterized in terms of the energy delivered to the animal rather than the energy delivered by the AED because the latter may mask toxicity effects as much of the energy delivered by the AED is harmlessly dissipated in the external resistors.[66] Acceptable levels of effectiveness, however, should be described

---

[64] AHA, "ECC Guidelines, Part 4: The Automated External Defibrillator," *Circulation*, 102:1-60 (2000).

[65] ANSI/AAMI DF80:2003, Annex DD.

[66] Snyder, DE et. al., "External series resistors accurately model waveform time course, but not cardiac dose in animal models of defibrillation," *Resuscitation*, 56:238 (2003).

based on the minimal energy dose provided by the device, because the defibrillation threshold (E_{50}) would not adequately characterize AED performance due to variations in the shape of the dose-response curve between different defibrillation waveforms. Further, because studies conducted with healthy animals by delivering shocks to short duration of VF are insensitive to myocardial dysfunction that might be incurred in an ischemic substrate, all ECG abnormalities that occur following shocks should be reported, including but not limited to: post resuscitation myocardial measures of systolic and diastolic function; condition block; S-T segment shift; increased occurrence of premature contractions or idioventricular beats; and T-wave inversion. If a high rate of electrical abnormalities in the ECG is observed in response to defibrillation shock, a study in an ischemic animal model should be conducted, and the study should evaluate and report animal outcome as well as hemodynamic performance and left ventricular function compared with a device of known characteristics. These guidelines for animal testing would be part of a special control for evaluating waveform performance.

If an AED uses a new waveform for which there is insufficient bench-top or clinical data to support its safety and effectiveness, then as recommended by ANSI/AAMI DF80, the safety and effectiveness of the new waveform should be demonstrated in a prospective, randomized, blinded clinical study that compares the new waveform to a conventional waveform (control).[67] The dosing procedures, *e.g.*, electrode placement, energy delivery protocols, for the new waveform should be tested as part of the clinical study.[68] Sufficient statistical power should be employed, and the 95% upper confidence limit on the difference between the control and study waveform defibrillation rates should not exceed 10%.[69]

Energy

FDA's AED classification regulation establishes an acceptable energy level. Specifically, an acceptable energy output is one that does not exceed 360 J in a 50 Ω test load.[70] This energy level criteria is the same for class II manual defibrillators, and is consistent with ANSI/AAMI DF80.[71]

ANSI/AAMI DF80 also addresses issues that may affect the delivered energy, including variations in patient impedance (also referred to as resistance). Specifically, because patient impedance affects the amount of energy delivered to the heart (larger patients have higher transthoracic impedances), ANSI/AAMI DF80 recommends that the effect of changes in load resistance be characterized and described in the labeling.[72] Many AEDs as well as manual defibrillators incorporate technology for optimizing defibrillation output by adjustments based on

---

[67] ANSI/AAMI DF80:2003, Annex DD.

[68] *Id.*

[69] *Id.*

[70] *See* 21 C.F.R. § 870.5310.

[71] *See* 21 C.F.R. § 870.5300; ANSI/AAMI DF80:2003 clause 51.1.

[72] ANSI/AAMI DF80:2003, Annex AA clause 6.8.3.

patient impedance measurements. Whether the AED includes such technology, ANSI/AAMI DF80 recommends that performance data for defibrillation be provided when the device is connected to resistive loads ranging from 25 Ω to 175 Ω and set to its maximum output or according to an automatic protocol for the selected energy.[73] The rated delivered energy (according to equipment settings) into these resistive loads should be specified and the measured delivered energy into these resistive loads should not vary from the delivered energy for that impedance by more than ± 3 J or ± 15%, whichever is greater, at any energy level.[74] Further, the energy accuracy specifications for the delivered energy in a 50 Ω resistor should be provided, and if the AED has a mechanism that inhibits its output when the patient impedance is outside certain limits, these limits should be disclosed.[75] Labeling disclosures capturing this information and requiring compliance with ANSI/AAMI DF80 would provide adequate special controls.

As AEDs have been in use for over 10 years, there is extensive clinical experience demonstrating that waveforms used and the energy they deliver are effective.[76] In addition, the AHA, using evidence-based classification process, has classified the Philips waveform (which energy is a part of the waveform characterization) as class IIa (defined as having "good to very good evidence," a "standard of care", "intervention of choice").[77] We expect that DF80 will provide an effective special control for AED waveforms because that standard combines DF39 and DF2, the standards Philips relied upon to develop its biphasic waveform that is highly effective in treating shockable rhythms and that other manufacturers used to develop effective waveforms. The proposed special controls are grounded in valid scientific evidence and extensive successful clinical use.

In sum, the ANSI/AAMI standard, supplemented by nonclinical testing for defibrillators that use conventional waveforms, provide sufficient special controls for safe and effective defibrillation shock delivery, because together they address waveform and energy, which are critical elements of this performance parameter. Moreover, defibrillation shock delivery has been adequately controlled in class II for many years as evidenced by FDA's class II regulation of low energy manual defibrillators that also are required to meet this performance parameter. All testing of defibrillation waveform and energy could be part of premarket notification submissions or

---

[73] *Id.* at clause 6.8.3.

[74] *Id.* at clause 50.2.

[75] *Id.* at clause 6.8.3.

[76] White RD, Blanton DM. Biphasic truncated exponential waveform defibrillation. *Prehosp Emerg Care* 1999;3:283-9; Schneider T, Martens PR, Paschen H, et al. Multicenter, randomized, controlled trial of 150-J biphasic shocks compared with 200- to 360-J monophasic shocks in the resuscitation of out-of-hospital cardiac arrest victims. *Circulation* 2000;102:1780-1787; White RD, Russell JK. Refibrillation, resuscitation and survival in out-of-hospital sudden cardiac arrest victims treated with biphasic automated external defibrillators. *Resuscitation* 2002 Oct;55(1):17-23; Gliner, BE et al. Treatment of out-of-hospital cardiac arrest with a low-energy impedance-compensating biphasic waveform automatic external defibrillation. Biomedical Instrumentation & Technology. 1998.32:631-644.

[77] Cummins, RO et al. Guidelines 2000 for cardiopulmonary resuscitation and emergency cardiovascular care. Supplement to Circulation 2000;102(8):I-5, I-63, I-91.

maintained in facilities' files.[78] Importantly, regardless of whether test reports are submitted in a 510(k) or maintained in files, the testing would be required prior to the commercial distribution of the AED.

4. Usability

Successful emergency responses with AEDs depend not only on the device functioning properly, but also on the responder's ability to use the device. Usability considerations should be tailored to the respective user group. Users of prescription AEDs, *e.g.*, healthcare professionals and advanced paramedics, generally have a medical background and/or training in AED operation and CPR and use AEDs frequently. On the other end of the spectrum are lay users of OTC AEDs who are expected to have no or little AED or CPR training and who likely never used an AED. Below we discuss the key usability performance parameters associated with AED use, and the special controls to reasonably assure safety and effectiveness.

(1) User ability to determine when to use the AED: Users need to be able to determine when to use an AED as part of the chain of survival. Users of prescription AEDs are likely to recognize the symptoms of cardiac arrest based on their medical background and/or training. Users of OTC AEDs, however, may be unaware of the symptoms of cardiac arrest.

A labeling general control that includes a description of the symptoms of cardiac arrest, combined with a special control requiring prominent instructions to apply pads even when there is doubt whether cardiac arrest occurred, is appropriate for both user populations, although users of OTC AEDs likely are the target group who need direction in this regard. This control would address user uncertainty and ensure that AEDs are used even when doubt exists about whether cardiac arrest has occurred. Because of the already-established high sensitivity and specificity of the algorithms, safety is maintained and effectiveness improved by the application of pads in such cases. The literature shows that there have been no adverse events related to safety in a variety of environments, including public access and private homes, by lay users.[79] In addition, the demonstrated high sensitivity and specificity of the AEDs' algorithm help ensure shockable

---

[78] If test results were maintained in facility files, a written certification in the premarket notification for the device would certify that the device would not be distributed prior to the completion of the specified testing with conforming results. This option would lessen the review burdens on the agency.

[79] *See* Peberdy, M. A.; Ottingham, L. V.; Groh, W. J.; Hedges, J.; Terndrup, T. E.; Pirrallo, R. G.; Mann, N. C., and Sehra, R. Adverse events associated with lay emergency response programs: The public access defibrillation trial experience. Resuscitation. 2006 Jul; 70(1):59-65. Caffrey, S. L.; Willoughby, P. J.; Pepe, P. E., and Becker, L. B. Public use of automated external defibrillators. N Engl J Med. 2002 Oct 17; 347(16):1242-7; Cummins, RO et al. Guidelines 2000 for cardiopulmonary resuscitation and emergency cardiovascular care. Supplement to Circulation 2000;102(8):I-5, I-63, I-91; Valenzuela TD, Roe DJ, Nichol G, et al. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. *N Engl J Med* 2000;343:1206-9; Bardy, G. H.; Lee, K. L.; Mark, D. B.; Poole, J. E.; Toff, W. D.; Tonkin, A. M.; Smith, W.; Dorian, P.; Packer, D. L.; White, R. D.; Longstreth, W. T. Jr; Anderson, J.; Johnson, G.; Bischoff, E.; Yallop, J. J.; McNulty, S.; Ray, L. D.; Clapp-Channing, N. E.; Rosenberg, Y., and Schron, E. B. Home use of automated external defibrillators for sudden cardiac arrest. N Engl J Med. 2008 Apr 24; 358(17):1793-804; Culley LL, et al. Public access defibrillation in out-of-hospital cardiac arrest: a community-based program. Circulation, 2004; 109:1859-1863; Drezner JA, et al. Effectiveness of Emergency Response Planning for Sudden Cardiac Arrest in United States High Schools with Automated External Defibrillators. Circulation.2009; 120:518-525.

rhythms receive a shock recommendation and non shockable rhythms do not.[80] Because AEDs meet an even higher standard for specificity than for sensitivity, the risk of the device shocking on a non-shockable rhythm is extremely low.

(2) Ability to safely and successfully operate the AED: Because the AED user population ranges from users with a medical background and/or training in advanced life support who frequently use AEDs to lay users with little or no prior AED experience, AED manufacturers must clearly characterize the likely users of their devices in assessing usability. The following user needs must be considered in devising a special control:

- Device set up;
- Prompt and proper pad placement;
- Safe shock delivery without interfering with the device's function (for example, users performing CPR while the AED is in the process of analyzing could lead to an inappropriate shock recommendation or delay or prevent the delivery of a shock); and
- Safe use of the device on children.

The following are special controls that would provide reasonable assurance of safe and effective AED use by all users.

a. Product design and evaluation of design through testing

---

[80] Bardy, G. H.; Lee, K. L.; Mark, D. B.; Poole, J. E.; Toff, W. D.; Tonkin, A. M.; Smith, W.; Dorian, P.; Packer, D. L.; White, R. D.; Longstreth, W. T. Jr; Anderson, J.; Johnson, G.; Bischoff, E.; Yallop, J. J.; McNulty, S.; Ray, L. D.; Clapp-Channing, N. E.; Rosenberg, Y., and Schron, E. B. Home use of automated external defibrillators for sudden cardiac arrest. N Engl J Med. 2008 Apr 24; 358(17):1793-804; Poole, J. E.; White, R. D.; Kanz, K. G.; Hengstenberg, F.; Jarrard, G. T.; Robinson, J. C.; Santana, V.; McKenas, D. K.; Rich, N.; Rosas, S.; Merritt, S.; Magnotto, L.; Gallagher, J. V. 3rd; Gliner, B. E.; Jorgenson, D. B.; Morgan, C. B.; Dillon, S. M.; Kronmal, R. A., and Bardy, G. H. Low-energy impedance-compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out-of-hospital cardiac arrest. LIFE Investigators. J Cardiovasc Electrophysiol. 1997 Dec; 8(12):1373-85; Gliner, B. E.; Jorgenson, D. B.; Poole, J. E.; White, R. D.; Kanz, K. G.; Lyster, T. D.; Leyde, K. W.; Powers, D. J.; Morgan, C. B.; Kronmal, R. A., and Bardy, G. H. Treatment of out-of-hospital cardiac arrest with a low-energy impedance-compensating biphasic waveform automatic external defibrillator. The LIFE Investigators. Biomed Instrum Technol. 1998 Nov-1998 Dec 31; 32(6):631-44; Page, R. L.; Joglar, J. A.; Kowal, R. C.; Zagrodzky, J. D.; Nelson, L. L.; Ramaswamy, K.; Barbera, S. J.; Hamdan, M. H., and McKenas, D. K. Use of automated external defibrillators by a U.S. airline. N Engl J Med. 2000 Oct 26; 343(17):1210-6; Cecchin, F.; Jorgenson, D. B.; Berul, C. I.; Perry, J. C.; Zimmerman, A. A.; Duncan, B. W.; Lupinetti, F. M.; Snyder, D.; Lyster, T. D.; Rosenthal, G. L.; Cross, B., and Atkins, D. L. Is arrhythmia detection by automatic external defibrillator accurate for children?: sensitivity and specificity of an automatic external defibrillator algorithm in 696 pediatric arrhythmias. Circulation. 2001 May 22; 103(20):2483-8; Caffrey, S. L.; Willoughby, P. J.; Pepe, P. E., and Becker, L. B. Public use of automated external defibrillators. N Engl J Med. 2002 Oct 17; 347(16):1242-7; MacDonald RD et al. Performance and Error Analysis of Automated External Defibrillator Use in the out-of-hospital setting. Ann Emerg Med. 2001;38:262-267; Atkins DL, et al. Sensitivity and specificity of an automated external defibrillator algorithm designed for pediatric patients. Resuscitation. 2008 76, 168-174; Cecchin F, et al. Is arrhythmia detection by automatic external defibrillator accurate for children?: sensitivity and specificity by an automatic external defibrillator algorithm in 696 pediatric arrhythmias. Circulation. 2001. 103:2483-2488; Atkinson E, et al. Specificity and sensitivity of automated external defibrillator rhythm analysis in infants and children. Ann Emerg Med. 2003;42;185-196.

Requiring a user-specific, functional product design that considers user capabilities is a necessary and effective special control for user success in time-critical emergency situations. For prescription AEDs that are used by responders with a medical background and/or training in advanced life support who frequently use AEDs, the design must maximize the opportunity for user success, taking into consideration the multiple features that can be controlled by the user. For OTC AEDs which are expected to be used by lay users with likely no prior AED experience, the control should require a sufficiently intuitive human factors design that includes clear audible, visual and/or tactile user cues targeted at people with a wide range of ages and abilities. It is important that the design is responsive to the needs of minimally trained or untrained users of the product and makes such users feel comfortable and capable with the technology. Required design features for OTC AEDs should include audible or visual prompts guiding the user through the chain of survival and rescue process. Studies show that usability may be significantly improved through ease of use factors that are related to the human/device interface.[81]

The special control should further require that the device design be evaluated through user testing. Specifically, the objective of the testing would be to ensure that the device conforms to the intended users' needs and that a defined level of human factors requirements be met. These user studies would have two endpoints (safety and effectiveness), would be well designed, and the results of the testing would be described in a test report that is submitted with the 510(k).

i. Safety

For both prescription and OTC AEDs, it should be demonstrated through usability testing that the users do not expose themselves or the victim to unsafe conditions that could result in a life-threatening or serious injury or cause other harm, *e.g.*, testing should reveal design features, including labeling, that effectively warn users not to touch the victim in a way that would be harmful during shock delivery. Such testing is important, particularly for naïve, untrained users, even though there is no documentation showing that AEDs present significant risks to users, and studies show AEDs are generally safe for use.[82] As several usability studies have shown, most lay users, including middle school children, can use AEDs safely and effectively.[83]

The safety aspect of the usability testing should be tailored to the safety issues that are specific to the type of AED, *i.e.*, semi-automatic or fully automatic. Examples of unsafe use for semi-automatic AEDs would be touching the victim while pressing the shock button or interfering with defibrillator function by, for example, performing CPR while the AED is analyzing. An

---

[81] *See, e.g.*, Callejas et al, *Human Factors Impact Successful Lay Person Automated External Defibrillator Use During Simulated Cardiac Arrest*, 32 Crit. Care Med. (2004); *see also* Andre et al., *Automated External Defibrillator Use by Untrained Bystanders: Can the Public Use Model Work?*. 8 Prehosp. Emerg. Care (2004); *see also* Sandroni et al., *Automated External Defibrillation By Untrained Deaf Lay Rescuers*, 63 Resuscitation (2004).

[82] *See generally* Callejas et al, *supra*, *see also* Beckers et al., *Minimal Instructions Improve the Performance of Laypersons in the Use of Semiautomatic and Automatic External Defibrillators*, 9 Crit. Care (2005).

[83] Eames P, et al. Comparison of ease of use of three automated external defibrillators by untrained lay people. Resuscitation. 2003; 58: 25-30; Andre AD, et al. Automated external defibrillator use by untrained bystanders:can the public-use model work. Prehosp Emerg Care. 2004. Jul-Sep; 8(3):284-91; Gundry JW, Comess KA, DeRook FA, et al. Comparaison of naïve sixth-grade children with trained professionals in the use of an automated external defibrillator. *Circulation* 1999;100:1703-1707 ; Fleischhackl R, et al. Differing operational outcomes with six commerically avialable automated external defibrillators. Ressuscitation. 2004. 62 :167-174;

example of unsafe use for fully automatic AEDs would be the risk of energy delivery without adequate warning to the user.

ii. Effectiveness

The effectiveness aspect of the usability testing would demonstrate that the device design permits users to predictably use the device on a simulated victim successfully. For both prescription and OTC AEDs, the design would optimize user success. For prescription devices, the user interface could be maximally stressed by using healthcare providers inexperienced with AEDs, which would focus the assessment on the AED interface design, while taking into account that pre-existing habits of individuals may also be an important concern for device design.[84]

Effectiveness in the usability testing of OTC AEDs must also include an evaluation of the ability of lay users to properly use the AED based upon the design/human interface features alone. The key measurements for usability of AEDs are timely and accurate pad placement. The testing population should be based on the lowest-skilled purchaser of the device, *i.e.*, untrained individuals with no medical background who are unfamiliar with AEDs, under simulated emergency conditions. As several usability studies have shown, most lay users, including middle school children, can use AEDs safely and effectively.[85]

iii. Study Design

FDA should require that the usability studies be well designed and sufficiently statistically powered. For non-professional, *i.e.* basic life saving and public access, prescription devices, the user population should be the labeled intended user group, with at least 10-25 users in both the study and the control groups.[86] Appropriate historical controls may be used. If such testing is appropriate for professionals, a smaller number of subjects may be justified by the assumption that these users will have a medical background or will be subject to oversight that ensures AED training. The testing should occur with the AED in the configuration recommended for an emergency.

For OTC devices, where users may have had no training and likely are unfamiliar with the device's labeling content, testing of the device design, including human factors features, is significantly more important. The study sample size should be such that, with a 95% confidence level, it is demonstrated that a majority of OTC users can safely and successfully use the AED (deliver a shock to a patient) with no prior device training. The study design would randomize subjects to a test group that relies upon the design, and especially the human factors features

---

[84] *See FDA's Do it By Design, An Introduction to Human Factors In Medical Devices.*

[85] Eames P, et al. Comparison of ease of use of three automated external defibrillators by untrained lay people. Resuscitation. 2003; 58: 25-30; Andre AD, et al. Automated external defibrillator use by untrained bystanders:can the public-use model work. Prehosp Emerg Care. 2004. Jul-Sep; 8(3):284-91; Gundry JW, Comess KA, DeRook FA, et al. Comparison of naïve sixth-grade children with trained professionals in the use of an automated external defibrillator. *Circulation* 1999;100:1703-1707; Fleischhakl R, et al. Differing operational outcomes with six commerically avialable automated external defibrillators. Ressuscitation. 2004. 62 :167-174 ;

[86] *See FDA's Do it By Design, An Introduction to Human Factors In Medical Devices, see also FDA Stresses Human Factors Design for Home-Use Devices,* The Silver Sheet, Vol. 13, No. 5 (May 2009).

(such as voice prompts) of the AED alone, *i.e.*, persons with no prior training, and a control group, *i.e.*, persons who received AED training. This comparison would demonstrate the effectiveness and safety of the design, and thus, the device's usability.

The study design requirements should be flexible and correspond to the novelty and/or complexity level of the design features. For example, for a minor alteration to a well-established design feature that has undergone previous testing, the number of testing subjects may be less than for a novel feature. Additionally, if immaterial alterations are made, reliance on previous testing results should be adequate and sufficient to demonstrate usability.

iv. Test report

A part of the testing special control would require that the results of the testing be described in a test report that identifies the use model of the tested device, the testing methodology, and any materials provided to users (such as labeling). The test report would also include a justification of the user group and sample size and would explain user exclusions, device anomalies and user demographics. The report would further describe usability as measured by the successful treating of the simulated victim as well as any safety issues that were observed in the user testing. The elapsed time to completion of the task would be reported. The special control would require the submission of the test report as part of the AED premarket notification.

b. Labeling and user evaluation

i. Labeling

As an additional control, FDA should require labeling that will ensure the responder's ability to use the device in a safe and effective manner, especially for AEDs that are sold OTC to users with no or minimal training in AED use.[87]

Prescription AEDs are mainly used by responders with a medical background and/or training in advanced life support who frequently use AEDs, or are deployed as part of an emergency response program with medical oversight, thereby making it less likely that the users will significantly rely on the labeling to operate the AED. The Act's general labeling controls require that manufacturers provide adequate labeling and materials to ensure the safe and effective use by the intended use population. Because AEDs may be used on small children with pediatric pads, the labeling would also include instructions for use on children and what provisions are implemented to achieve pediatric defibrillation, such as when to switch from adult pads to pediatric pads and how to properly place the pediatric pads.

For OTC AEDs, labeling, together with AED verbal prompts, must be adequate for safe and effective use of the product without additional training or oversight. A special control would specify particular objectives for labeling of OTC AEDs, such as simple instructions that are written for a lay audience to enable purchasers to set up, maintain, and use their AEDs as intended. The special control should also require that the labeling contain appropriate warnings regarding the dangers of electrical shock and user behavior that could be harmful and/or interfere

[87] 21 CFR 801.5

with the device function. In addition, the labeling would contain a warning that collapse in young children is more likely caused by airway obstruction than cardiac arrest.[88]

ii. User evaluation of labeling for OTC AEDs

For OTC AEDs, a special control would require the manufacturer to conduct a user evaluation of the labeling during the product development cycle. Specifically, the major labeling components (such as owner's manual, instructional video and quick reference guide) should be assessed with representative users to ensure that actual responders will be able to use the device based on the labeling, and that the labeling does not interfere with the use of the product. The main criteria in determining the adequacy of the labeling for OTC use will be visibility and user comprehension to permit purchasers to maintain, store, set up and ultimately use their AEDs as intended. FDA could require a specific design for the user evaluation, for example, a written comprehension test and assessment in a mock-rescue scenario of the performance of participants using labeling that would be available during an emergency. The testing should be conducted in a scientifically valid manner, with adequate statistical power addressing target user population factors such as demographic, regional, cultural and educational differences. Manufacturers could consult with FDA regarding the study design to assure that the protocol is adequate. The user evaluation of labeling, which could be part of a usability test, would be submitted as part of the premarket notification.

(3) User awareness of rescue chain: AED users, and especially OTC users who operate an AED outside of a medical environment, should be made aware of the rescue chain, which involves EMS notification and CPR performance, including knowing how to properly time CPR relative to defibrillation.

FDA should establish a special control that requires design features such as voice prompts to guide the user through the rescue chain. Such design features would ensure that users are aware of and appropriately follow the rescue chain. This special control should be imperative for OTC AEDs and could also be useful for prescription devices. As an additional special control, the labeling would address user awareness of the rescue chain by, for example, including reminders to call EMS. As shown in the Public Access Defibrillator Trial and Home Access Trial, lay users activated emergency medical services and performed CPR.[89]

(4) Proper Maintenance and Storage: Proper maintenance of the AED is also important because a device that is not properly maintained may not function when needed. User understanding of the need for and the ability to maintain the device is therefore crucial.

As a special control to ensure that maintenance and storage are satisfactorily done, an AED design special control would include self-testing features (with an alarm if maintenance is

[88] American Heart Association. PALS Provider Manual. 2002. page 44.

[89] Hallstrom A and Ornato JP, Public-Access Defibrillation and Survival after Out-of-Hospital Cardiac Arrest: the public access defibrillation trial investigators. N Engl J Med 2004; 351:637-46; Bardy, G. H.; Lee, K. L.; Mar, D. B.; Poole, J. E.; Toff, W. D.; Tonkin, A. M.; Smith, W.; Dorian, P.; Packer, D. L.; White, R. D.; Longstreth, W. T. Jr; Anderson, J.; Johnson, G.; Bischoff, E.; Yallop, J. J.; McNulty, S.; Ray, L. D.; Clapp-Channing, N. E.; Rosenberg, Y., and Schron, E. B. Home use of automated external defibrillators for sudden cardiac arrest. N Engl J Med. 2008 Apr 24; 358(17):1793-804.

required) and self-calibration to ensure proper maintenance and reliability of the device. While such requirements are important for both OTC and prescription devices, they are especially important for OTC AEDs that may be in stand-by mode for long periods of time. Additionally, this special control would require that the labeling for both OTC and prescription AEDs provide clear instructions on how to properly maintain and store AEDs, including information on when and how to change batteries and other consumable items such as pads, and expected battery life. The amount of detail in the maintenance and storage instructions would correspond to the need to actively maintain the AED, *i.e.*, instructions for prescription AEDs that require a high degree of maintenance due to frequent use would be significantly more detailed than instructions for OTC AEDs.

As shown in the Public Access Defibrillator Trial, adverse events associated with maintenance activities are low.[90]

5. Intended Use Environment

Compatibility with the intended use environment is a key performance parameter because AEDs may be used in a variety of environments, for example hospitals, emergency medical vehicles and medical helicopters, public locations, and in the home, and therefore must be able to withstand the conditions of their intended use environment. For example, AEDs intended for use in the home and hospitals must meet electromagnetic compatibility standards because they will be exposed to multiple interfering electronic sources, including other medical devices, communication devices, etc.

As a special control, environmental qualification testing in accordance with the following standards would be conducted to confirm that the AED is able to operate properly in accordance with its specifications under the stresses that it may encounter in its intended use environment: IEC 60601-1, which provides environmental qualification standards for active medical devices; IEC 60601-1-2, which provides EMC standards for active medical devices; and ANSI/AAMI DF80, which provides environmental qualification standards for defibrillators, including AEDs. These standards address many different environmental conditions such as water ingress, temperature, humidity, and electromagnetic energy.

In particular, ANSI/AAMI DF80's environmental qualification standards for defibrillators, including AEDs, include:

- Water ingress testing. Following the test method described in the standard, defibrillators should be tested to confirm that they meet their performance specifications, and should be inspected to confirm no sign of wetting of any electrical insulation or water in the high voltage circuitry.[91]

---

[90] Peberdy, M. A.; Ottingham, L. V.; Groh, W. J.; Hedges, J.; Terndrup, T. E.; Pirrallo, R. G.; Mann, N. C., and Sehra, R. Adverse events associated with lay emergency response programs: The public access defibrillation trial experience. Resuscitation. 2006 Jul; 70(1):59-65.

[91] ANSI/AAMI DF80:2003 clause 44.6.

- Temperature and humidity testing. Extended temperature and humidity ranges are provided for defibrillators in recognition of the different environments in which these devices may be used, including settings outside of the hospital.[92] Specifically, defibrillators should be tested to confirm that they are able to operate in temperatures between 0°C and +40°C and in relative humidity between 30% and 95% without condensation.[93]

- EMC testing. Because defibrillators are often used in an ambulance or other environments where electromagnetic energy may be particularly severe and could interfere with device performance, ANSI/AAMI DF80 expands on IEC 60601-1-2 in order to provide reasonable assurance that these devices will operate effectively and safely in all of their intended use environments.[94] In particular, ANSI/AAMI DF80 provides test methods for electrostatic discharge, radiated RF electromagnetic fields, and magnetic fields.[95]

The AED labeling would identify the environmental conditions in which the device should be stored and operated based on data from the environmental qualification tests, and specify any environmental limitations regarding storing the device, *e.g.*, in a car or an ambulance under severe climatic conditions, immediately prior to use.[96]

It has been shown that in various environments, including the effect of EMC on AEDs in public locations,[97] train terminals and metro stations,[98] underneath power lines and along side generators,[99] and power plants,[100] and in wet environments[101], AED performance is not compromised.

In sum, the standards specified above provide comprehensive special controls that would reasonably assure that AEDs are able to withstand the conditions of their intended use environment. The test procedures, including the environmental test conditions and the

---

[92] *Id.* at Annex AA clause 10.2.

[93] *Id.* at clause 10.2.1.

[94] ANSI/AAMI DF80:2003, Annex AA clause 36.

[95] *Id.* at clauses 36.202.2 (electrostatic discharge), 36.202.3 (radiated RF electromagnetic fields) and 36.202.8 (magnetic fields).

[96] ANSI/AAMI DF80:2003 clause 6.8.2.

[97] Fleischhackl R, et al. Automated external defibrillators do not recommend false positive shocks under the influence of electromagnetic field present at public locations. Anesth Analg 2006;103:1485-8.

[98] Kanz, KG et al. Susceptibility of automated external defibrillators to training overhead lines and metro third rails. Resuscitation. 2004;62: 189-198.

[99] Fleischhackl R, et al. Influence of electromagnetic fields on function of automated external defibrillators. Academic emergency medicine. 2006:13:1-6.

[100] Stolzenberg BT, et al. Automated external defibrillators appropriately recognize ventricular fibrillation in electromagnetic fields. Prehosp Emerg Care. 2002. Jan-mar;6(1):65-6.

[101] Lyster TS, et al. The safe use of automated external defibrillators in a wet environment. Prehospital Emergency Care. 2003. 7:3, 307-311.

components and accessories, *e.g.*, batteries, electrodes, and cables, included in the test, and the test results could be part of premarket notification submissions or maintained in facilities' files.[102] Importantly, regardless of whether test reports are submitted in a 510(k) or maintained in files, the testing would be required prior to the commercial distribution of the AED.

6. Electrical Safety

Another key performance parameter is electrical safety. In particular, AEDs would be designed and tested to provide adequate protection to patients and users against leakage currents, inadvertent electrical shock, and other potential electrical hazards. Electrical safety is a performance parameter for manual defibrillators as well and thus, is not unique to AEDs; indeed, the standards discussed below apply equally to manual defibrillators.

The electrical safety standards in IEC 60601-1 (or an equivalent standard), which applies to all active medical devices and is recognized by the FDA, and the electrical safety standards in ANSI/AAMI DF80, which applies specifically to defibrillators, provide appropriate special controls for the electrical safety of AEDs, because they are comprehensive and address protection from leaking currents, inadvertent electrical shock, and other potential electrical hazards.

The specific electrical safety standards for defibrillators provided by ANSI/AAMI DF80 include, among other things:

- Testing for separation (isolation) and isolating the electrodes from other components so that during discharge, hazardous electrical energies are excluded from certain components, including the enclosure, all patient connections belonging to other patient circuits, any signal input part and/or signal output part, and a metal foil on which the device is placed and which has an area at least equal to the base of the device.[103]

- Testing for patient leakage current and patient auxiliary current.[104]

- Testing the dielectric strength and insulation resistance of the device's high voltage circuit, *e.g.*, electrodes, charging circuit and switching devices.[105] In particular, the insulation of the device's high voltage circuit should withstand a DC test voltage of 1.5 times the highest peak voltage U occurring between the parts concerned during discharging any mode of normal operation, and the insulation resistance should not be less than 500MΩ.[106] Similarly, the resistance of the cable that connects the defibrillator to the electrodes must not be less than 500MΩ and the dielectic strength of the cable must

---

[102] If test results were maintained in facility files, a written certification in the premarket notification for the device would certify that the device would not be distributed prior to the completion of the specified testing with conforming results. This option would lessen the review burdens on the agency.

[103] ANSI/AAMI DF80:2003 clause 17.

[104] *Id.* at clause 19.1.

[105] ANSI/AAMI DF80:2003 clause 20.3.

[106] *Id.*

be tested using a voltage of 1.5 times the highest voltage occurring between the electrodes in any normal mode of operation.[107]

- Designing the defibrillator so that in the event of a power failure in the internal electrical power source or when the device is turned off, no unintentional energy will be available at the electrodes, and including an internal discharge circuit whereby stored energy that is not delivered through the electrodes can be dissipated without energizing the electrodes.[108] Functional tests should be conducted to confirm that the defibrillator meets these specifications.[109]

As part of the labeling special control, AED labeling would include precautions and/or warnings regarding the dangers of electrical shock and excessive leakage current and procedures for protection against electrical shock to the user or others, *e.g.*, "clear" prior to delivery of an electric shock to the patient, and "do not touch the patient during shock delivery."

In the Public Access Defibrillation Trial[110] and Home Access Trial[111]and in a survey of lay users,[112] there were no adverse events of users, victims or by-standers being shocked or injured during AED use. Furthermore, usability studies have shown that the devices are effective in creating safe use environments for users and by-standers.[113]

In sum, the standards specified above provide adequate special controls to reasonably assure the electrical safety of AEDs. The testing resulting from these standards could be part of premarket notification submissions or could be kept in facilities' files.[114] Importantly, regardless of whether reports of results are submitted in a 510(k) or maintained in files, the testing would be required prior to the commercial distribution of the AED.

7. Other AED Requirements

---

[107] *Id.* at clause 57.10.

[108] *Id.* at clauses 51.102 & 51.103.

[109] *Id.*

[110] Peberdy, M. A.; Ottingham, L. V.; Groh, W. J.; Hedges, J.; Terndrup, T. E.; Pirrallo, R. G.; Mann, N. C., and Sehra, R. Adverse events associated with lay emergency response programs: The public access defibrillation trial experience. Resuscitation. 2006 Jul; 70(1):59-65.

[111] Bardy, G. H.; Lee, K. L.; Mark, D. B.; Poole, J. E.; Toff, W. D.; Tonkin, A. M.; Smith, W.; Dorian, P.; Packer, D. L.; White, R. D.; Longstreth, W. T. Jr; Anderson, J.; Johnson, G.; Bischoff, E.; Yallop, J. J.; McNulty, S.; Ray, L. D.; Clapp-Channing, N. E.; Rosenberg, Y., and Schron, E. B. Home use of automated external defibrillators for sudden cardiac arrest. N Engl J Med. 2008 Apr 24; 358(17):1793-804.

[112] Jorgenson DB, Skarr T, Russell JK, et al. AED use in businesses, public facilities and homes by minimally-trained first responders. *Resuscitation* 2003;59:225-233.

[113] Andre AD, et al. Automated external defibrillator use by untrained bystanders:can the public-use model work. Prehosp Emerg Care. 2004. Jul-Sep; 8(3):284-91.

[114] If test results were maintained in facility files, a written certification in the premarket notification for the device would certify that the device would not be distributed prior to the completion of the specified testing with conforming results. This option would lessen the review burdens on the agency

Other performance parameters include the following defibrillator and AED-specific safety and performance requirements: protection against inadvertent charging or discharging of the defibrillation circuitry; strength and durability of the electrode connections; minimum performance requirements for the electrodes which obtain ECG data from the patient and deliver therapeutic shock to the patient; short defibrillator charging times; rapid recovery of the algorithm following delivery of shock; and minimum battery capacity.

ANSI/AAMI DF80 provides standards for these and other defibrillator and AED-specific requirements, and therefore, would serve as an appropriate special control to provide an acceptable level of safety and performance. In particular, ANSI/AAMI DF80 addresses, among other things:

- Protection against inadvertent charging or discharging of the energy storage device, *e.g.*, capacitor, that may lead to abnormal operation or a fault condition.[115]

- Strength and durability of the electrode connections. Specifically, stress testing procedures are provided for the cables that connect the electrodes to the defibrillator to confirm that the connectors can withstand the pulling forces expected in use.[116]

- Minimum electrode performance requirements. For example, requirements relating to minimum electrode area for both adult and pediatric electrodes, electrode adhesion and contact to patient, and electrode packaging and shelf life are provided.[117]

- Short defibrillator charging time. Because rapid delivery of defibrillation shock is critical to survival and thus, an excessively long charging time would be unacceptable, maximum charging times are specified as follows. If the AED is for frequent use, the maximum charging time should not exceed 40 seconds from turning the power on to the AED being ready to discharge at maximum energy and should not exceed 30 seconds from the activation of the arrhythmia analysis system to the AED being ready to discharge at maximum energy. If the AED is for infrequent use, the maximum charging time should not exceed 45 seconds (or 50 seconds with the battery depleted by delivery of 15 discharges) from turning the power on to the AED being ready to discharge at maximum energy and should not exceed 35 seconds (or 40 seconds with the battery depleted by delivery of 15 discharges) from the activation of the arrhythmia analysis system to the AED being ready to discharge at maximum energy.[118] Procedures for testing maximum charging times are provided.[119] The charging times under best and worst conditions should be detailed in the labeling.[120]

---

[115] *Id.* at clause 52.4.101.

[116] ANSI/AAMI DF80:2003 clause 56.101 and Annex AA clause 56.

[117] *Id.* at clauses 56.101 and 107.

[118] *Id.* at clauses 101.3 and 101.4 and Annex AA clause 101.

[119] *Id.* at clauses 101.

[120] *Id.* at Annex AA clause 6.8.2.

- Rapid recovery of the algorithm following delivery of shock. In order to determine the success or failure of an attempted defibrillation as soon as possible, rapid recovery of the algorithm is necessary. Accordingly, the arrhythmia analysis system should be able to detect a shockable rhythm within 20 seconds after defibrillation.[121] Procedures for testing the recovery of ECG input after defibrillation are specified in the standard.[122]

- Minimum battery capacity. AEDs are typically portable devices that operate on a battery; thus, adequate battery capacity is critical to device operation and performance. Minimum battery capacity for AEDs is defined as follows. For frequent use AEDs, the capacity of a new battery should be such that at 0°C, the device can provide at least 20 defibrillation charges at the maximum delivered energy performed in cycles, each comprising 3 discharges in 105 seconds and 1 minute of rest. For infrequent use AEDs, the capacity of a new battery should be such that at 0°C, the device can provide at least 20 defibrillation charges at the maximum delivered energy performed in cycles, each comprising 3 discharges in 135 seconds and 1 minute of rest.[123] Procedures for testing the battery are provided. [124] Further, AEDs should provide a means to indicate clearly when non-rechargeable batteries require replacement or rechargeable batteries require recharging, and should be capable of delivering 3 defibrillation discharges at the pre-programmed or maximum energy setting once the indication is given.[125]

Additionally, ANSI/AAMI DF80 recommends endurance testing to provide reasonable assurance of the reliability of defibrillators.[126] Specifically, ANSI/AAMI DF80 recommends the following endurance test for defibrillators: for frequent use defibrillators, the device should be charged and discharged 500 times into a 50 Ω load at maximum energy or according to a programmed energy protocol; and for infrequent use defibrillators, 100 times into a 50 Ω load.[127]

The requirements in standards often exceed actual performance requirements. For example, the number of shocks required by the standard are significantly above the clinical requirements. For instance, most victims are converted after a single shock[128] and there are reports in the literature of a victim receiving 21 shocks and surviving.[129] Therefore, by implementing DF80 as a special

---

[121] *Id.* at clauses 105.1 and 105.3 and Annex AA clause 105.

[122] *Id.* at clause 105.

[123] *Id.* at clauses 102.3.1 and 102.3.2.

[124] *Id.* at clauses 102.3.

[125] *Id.* at clauses 102.4.

[126] *Id.* at Annex AA clause 103.

[127] *Id.* at clause 103.

[128] Whitfield R, et al. The department of health national defibrillator programme: analysis of downloads from 250 deployments of public access defibrillators. Resuscitation. 2005; 64: 269-277; van Alem AP, et al. VF recurrence: characteristics and patient outcome in out-of-hospital cardiac arrest. Resuscitation. 2003; 59: 181-188; Hess EP, et al. A high peak current 150-J fixed-energy defibrillation protocol treats recurrent ventricular fibrillation as effectively as initial VF. Resuscitation 2008. 79, 28-83.

[129] Harve H, et al. AED use in a passenger during a long-haul flight: repeated defibrillation with a successful outcome. Aviation, Space and Environmental Medicine, 2009. 80(4) 405-408(4).

control, the devices will continue to operate safely and effectively and exceed clinical performance expectations.

In sum, ANSI/AAMI DF80 addresses these other important aspects of AEDs and defibrillators in general that bear on device safety and performance. This standard, as one of the proposed special controls, is comprehensive, and in conjunction with the other special and general controls identified above would provide a reasonable assurance of safe and effective performance of the generic type of device.

8. Other Device Special Controls

The following controls are applied generally to all software devices and complement the other controls specified above to assure safe and effective device performance: conducting a risk assessment in accordance with EN 14971;[130] software validation in accordance with FDA's guidance (Guidance for the Content of Premarket Submission for Software Contained in Medical Devices) applied in the context of the DF80 and AHA Scientific Statement specifications regarding algorithm validation; and an evaluation of biocompatibility of the patient contacting materials as prescribed in EN 10993 or applicable sections of DF80. These activities are typically part of design development and would be required by the Quality System Regulation to achieve compliance with design controls under 21 CFR § 820.30. Moreover, the current device tracking requirement for AEDs provides a means to ensure prompt responses to any product shortcoming that necessitates field action.

9. Conclusion

In sum, in addition to the safety and performance standards applicable to manual defibrillators, arrhythmia detectors and active medical devices in general, AED-specific standards are provided in ANSI/AAMI DF80 and the AHA AED algorithm guidelines. These standards and guidelines specifically address AED safety and performance testing, device design and labeling, and the key AED performance parameters, including the arrhythmia analysis algorithm, defibrillation shock delivery, intended use environment, electrical safety and other AED safety and performance requirements. Usability testing would be included as a special control to provide reasonable assurance that AEDs can be used safely and effectively by the intended user population, including untrained lay persons. Adherence to these standards, guidelines, and testing requirements provide appropriate special controls for AEDs, and these special controls, together with the general controls applicable to all medical devices, would provide reasonable assurance that AEDs can be used safely and effectively by both medical and non-medical personnel in their intended use environments to resuscitate victims of cardiac arrest.

---

[130] EN14971 is an international standard for manufacturers of medical devices. It specifies a process through which the manufacturer can identify hazards associated with a medical device, estimate and evaluate the risks associated with these hazards, control these risks, and monitor the effectiveness of that control.

B. Risks to Health and Controls

Philips has identified risks unique to AEDs based on a review of the literature, reports or problem databases, including those available from ECRI (Emergency Care Research Institute), clinical evaluation, experience from design and manufacturing activities, use experience, customer complaints, MDRs, and recalls. Because FDA has recognized that an AED is a combination of an arrhythmia detector/alarm and a low energy defibrillator, both of which are class II devices, the agency already has concluded that special controls can provide a reasonable assurance of safety and effectiveness for devices that share these performance parameters and risks. *See* 21 CFR §§ 870.1025, 870.5300(a). As a result, because the risks associated with the arrhythmia detector and low energy defibrillator features of an AED have already been assessed and determined to be mitigated by general and special controls, this discussion focuses primarily on those risks that are unique to AEDs. We note that the risk profile varies for the different AED user populations. However, the risks discussed below represent the worst case and thus, cover all AED user populations.

1. Inappropriate Shock Recommendation by Algorithm

Risk: A potential safety risk is that an AED will provide an inappropriate shock recommendation and either recommend and allow the user (or if fully automatic, the device) to deliver a shock for a non-shockable rhythm (false positive) or fail to identify and allow the user (or if fully automatic, the device) to deliver a shock for a shockable rhythm (false negative).[131]

The risk of either of these occurring is low, because AED algorithms have high sensitivity and specificity in identifying the intended treatment population: persons who are pulseless and unresponsive and require defibrillation. Indeed, experience and testing show there are very few reports of false positives. The few reports of false negatives are due primarily to use and environmental issues common to ECG monitoring including poor pad contact, patient motion and out of range patient impedance that interferes with the ability of the algorithm to obtain an accurate reading. Nevertheless, this risk occurs and there are special controls available to mitigate it.

Causes of Risk: The causes behind this risk help define the appropriate special controls. Lack of adequate sensitivity/specificity of the algorithm, inadequate control of artifacts and lack of device reliability are most likely the potential causes. Accordingly, assuring algorithm accuracy and artifact mitigation, as well as overall device reliability (discussed in the following section, *Therapy Not Delivered, is Delayed or Ineffective*) are the ways to address this risk.

---

[131] While the AED algorithm differs from those in the class II arrhythmia detector, they can be controlled in a similar manner, with the addition of design or labeling controls to address the risk presented by non-expert users in generating or failing to recognize artifacts. The arrhythmia guidance document refers to the "inappropriate shock recommendation" risk as "misdiagnosis and misclassification of arrhythmias" and "incorrect pacemaker pulse detection." The special controls agreed to by the agency to mitigate these risks when presented by arrhythmia detectors are: software validation; electrical safety and environmental handling testing; electromagnetic compatibility; performance testing; and labeling. We agree generally with this approach with minor modifications to fit the AED.

Discussion: Assuring continued algorithm accuracy by requiring compliance with the AHA Scientific Statement and ANSI/AAMI DF80 special controls described above in *Performance Parameters and Controls, Arrhythmia Analysis Algorithm, Algorithm Performance*, will adequately address the risk presented by an inaccurate or less than optimal algorithm. Specifically:

- Clause 6.8.3 aa) 3) of DF80 regarding specificity/sensitivity describes what the ECG database for validation of rhythm recognition performance shall include, what the test report should include and that results of detector performance are to be reported in terms of specificity, true predictive value, sensitivity and false positive rates.

- The AHA Scientific Statement includes guidance on evaluating the accuracy of the arrhythmia analysis algorithms and sets forth sensitivity and specificity parameters for these algorithms. Manufacturers should be required to validate the AED's ability to render shock/no shock decisions in accordance with the methodology in the AHA Scientific Statement. In particular, the following should be reported in detail:

    - How the development and validation rhythm data sets meet the criteria of the AHA Scientific Statement, including data set sizes and data set classification.
    - How algorithm validation testing using the test data was conducted.
    - Test results per Table 2 of the statement; *i.e.*, rhythms, minimum test sample size, performance goal, observed performance and 90% one-sided lower confidence limit.
    - Test results per the requirements of DF-80 for the rhythm recognition detector.

The algorithm performance test reports could be provided in the 510(k) submission or kept in facilities' files. Compliance with these two standards will ensure a highly sensitive and specific algorithm that will recommend and allow the user to deliver a shock for a shockable rhythm and not recommend a shock for a non-shockable rhythm.

Similarly, for artifact mitigation, the controls discussed in *Performance Parameters and Controls, Artifact Detection*, and *Usability, supra*, are appropriate in addressing the risk of inappropriate shock recommendation by the algorithm. Sources of interference include (1) noise, *e.g.*, from electrostatic discharge or electromagnetic interference; (2) motion, *e.g.*, caused by CPR, patient handling, or patient transport; and (3) patient- or user-generated artifacts, *e.g.*, pacemaker stimuli, patient seizures that look like a shockable rhythm, or inappropriate pad contact.

As discussed in the *Performance Parameters* section, *supra*, noise from electrostatic discharge and electromagnetic interference is amenable to special controls. Indeed, the literature indicates that current standards work well, for example, immunity to electromagnetic interference is not a large concern with AEDs. Accordingly, the electromagnetic compatibility and electrical safety controls described, *supra* in *Performance Parameters and Controls, Intended Use Environment*, and *Electrical Safety* are adequate to control these potential areas of risk. For example, DF80

clause 36.202.2 addresses electrostatic discharge, clause 36.202.3 addresses radiated RF electromagnetic fields and clause 36.202.8 addresses magnetic fields, assuring that the devices will work in all of their intended use environments.

Artifacts created by motion and patient- and user-generated artifacts are addressed primarily through product design and labeling pursuant to usability (and use environment) assessments and testing to ensure that the user does not inadvertently create artifacts by moving the patient and understands what to do when a patient is seizing or has a pacemaker. *See Performance Parameters and Controls, Artifact Detection*, and *Usability, supra.*

In Philips' devices, labeling and audible and visual prompts clearly instruct users not to attempt AED analysis while CPR is being performed, or while other sources of patient motion exist and provide the corrective measures to take when an artifact, regardless of source, is detected. Users are instructed to avoid moving or touching the patient during analysis and that the device should be used only with caution in a moving vehicle. Specifically, if the device is being used on a patient in transport, users are instructed to make frequent stops for AED monitoring checks. Similarly, the devices instruct that they should not be used if the patient is seizing.

As a redundant protection, most Philips devices are designed to warn the user when motion or poor contact is detected.

Philips has employed usability principles in its design and labeling of AEDs, has submitted its usability testing in its premarket notification submissions, and the evidence indicates that these controls have successfully mitigated these risks. To ensure continued control of these risks, all AED manufacturers should be required to submit to FDA in 510(k)s their usability specifications and verification and validation evidence showing compliance with these specifications.

Special Controls: In sum, the special controls to address the risk of an inappropriate shock recommendation are as follows.

To ensure algorithm accuracy: ANSI/AAMI DF80 and AHA Scientific Statement. The AHA Scientific Statement guidelines call for validation of algorithm performance in both the presence and absence of artifacts likely to be encountered in use.

To ensure mitigation of artifacts due to:

- Noise: Electromagnetic compatibility and electrical safety controls in IEC 60601-1 and 60601-1-2 and ANSI/AAMI DF80
- Motion: Product design and labeling pursuant to usability (and use environment) assessments and testing. Manufacturers should submit to FDA in a 510(k) what the usability specifications are and evidence that they have been verified and validated
- Patient- and user-generated artifact (seizure, pacemaker, pad contact issues): Labeling.

To ensure device reliability, see discussion in ***Therapy Not Delivered, is Delayed or Ineffective***, *infra.*

Success of Special Controls: The above listed special controls have been successful. The AHA reports that AEDs perform as well as conventional defibrillators used by emergency medical technicians (EMTs), indicating that the accuracy of AED algorithms and their robustness in managing artifacts have been adequately controlled to achieve the standard of care when defibrillation is administered by healthcare professionals.[132] The infrequency of inappropriate shock recommendations by AED algorithms indicates that AED manufacturers are adequately addressing the issues of algorithm accuracy and artifact mitigation through these proposed special controls.[133] Accordingly, the controls for these performance parameters, and associated risks, are appropriate to ensure device performance and mitigate associated risks.

2. *Therapy Not Delivered, is Delayed or Ineffective*

Risk: Another AED risk is that therapy is not delivered, is delayed or is ineffective due to various components or subsystems failures, battery failure, or user error.

Causes of Risk: While manual defibrillators may have similar technical issues with hardware or software failures preventing the device from delivering the appropriate shock, the risk unique to AEDs is device readiness and maintenance, *i.e.*, AED reliability, because AEDs may remain in standby for years between actual uses. In addition, users who are less experienced than those using manual defibrillators may require more instruction through labeling, or audible or visual prompts regarding proper device maintenance and use.

Discussion: The special controls identified in *Performance Parameters, supra*, mitigate the overall risk of therapy not being delivered. Special controls to address the reliability and lay user error risks include: performance testing, usability studies (and concomitant design and labeling to prevent user error) and readiness for use assessments, *i.e.*, device design and testing which incorporate critical self tests and user notifications.

Reliability

AEDs encounter a wide range of actual use frequencies varying from daily or weekly use in hospitals to infrequent use, *i.e.*, standby service, in office buildings or the home. In addition, AEDs may be deployed in standby service in a variety of environments, ranging from benign office buildings to more environmentally challenging situations such as police vehicles. Extended standby time provides opportunities for AED readiness to be compromised through damage, battery depletion, electrode expiration and so forth.

Performance Testing

Performance testing conducted in accordance with ANSI/AAMI DF80 can assist in ensuring reliability. This ANSI/AAMI standard provides minimum safety and reliability requirements. Among other things, DF80 addresses testing related to environmental conditions, labeling requirements including those related to the battery, and requirements for frequent use versus

[132] AHA, "Automated External Defibrillation," in textbook of Advanced Cardiac Life Support (Dallas 1990) at 292.

[133] AHA, "ECC Guidelines, Part 4: The Automated External Defibrillator," *Circulation*, 102:1-60 (2000).

infrequent use (including battery capacity) and related testing. Electromagnetic compatibility and electromagnetic immunity testing conducted in accordance with IEC 60601-1-2 can also assist in addressing this risk.

Usability Studies

Usability studies, or user interface validation tests, are discussed in depth in *Performance Parameters, Usability, supra.* For purposes of the reliability concern, such studies should examine design and labeling to ensure proper device maintenance and storage. (Usability studies to address other causes of lay user error are discussed below.)

Readiness for Use

Most importantly, regardless of deployment situation, AED users should have a means of assessing the readiness for use of their AEDs. As part of a special control, manufacturers would report in their 510(k)s how users should assess their AED's readiness for use. The report would include:

- Intended use model and expected standby times,
- A description of how the device signals its status regarding readiness for use,
- The methods a user must follow to assess readiness of an AED (Automated or manual testing, looking at a readiness indicator or expiration date, etc. If additional tools and equipment are required to assess readiness, they should be described in the report.),
- A description of required procedures to place the AED in service and to maintain it during standby service (setup, battery and/or electrode replacement, etc.),
- A description of any limitations on the assessment of AED readiness for use, *e.g.*, if the AED performs periodic self-testing, whether the testing is suspended during extreme environmental conditions and how readiness or readiness reporting status is compromised, and
- A complete description of the design measures and validations used by the manufacturer to provide assurance of readiness to the user.

In assessing an AED's readiness for use, manufacturers must consider environmental conditions, including storage temperature. This consideration is particularly important for AEDs used by medical first responders, such as emergency medical technicians who store AEDs in ambulances or helicopters. Because these storage environments can be subject to extreme conditions, *e.g.*, very high or low temperatures and humidity, manufacturers need to ensure batteries, pads, and all components of AEDs last for predefined periods associated with environmental conditions (and any necessary restrictions) identified in labeling.

Philips has been successful in addressing the readiness for use issue by designing its AEDs to incorporate thorough self tests and user notifications that can identify the potential for all of the problems listed above. These self tests and notifications are extremely comprehensive. Between

uses, its AEDs perform daily, weekly, and monthly self-tests of their electrical components, subsystems, and battery to help ensure continued reliability and readiness. A pads integrity test, which checks daily that the cartridge is properly installed and that the defibrillator pads are in working order, provides an additional level of assurance for some product lines.

Indeed, the incorporation of self tests and user notifications has been an extremely effective means of ensuring device reliability and readiness for use. For example, a comprehensive independent analysis of recalls and safety alerts between January 1996 and December 2005 concluded that there was an increase in the number of AED advisories, *i.e.*, recalls and safety alerts, and the number of AEDs affected by advisories.[134] FDA commented that while the article stated there was an increase in the number of AEDs affected by device advisories, the agency put that fact in context stating it believes this increase was attributable to "improvements in the devices' ability to self-diagnose hardware and software problems ....before a device is ever used on a patient."[135] The agency further stated that these device advisories occur when there is "the ***potential*** to exhibit a certain failure mode, not only when a device has, in fact, failed." *Id.* (emphasis in original). FDA's comments underline the value of AED self test capabilities.

Usability/User Error

User error can also lead to failures of the device to deliver the proper energy, for example:

- pediatric energy delivered to an adult,
- failure to maintain the device, in particular batteries or pads,
- failure to properly set up the AED,
- poor or erratic pad connections due to the presence of contaminants or other maintenance deficiency,
- incorrect application of another manufacturer's adapter, and
- unintentional or incorrect activation of control buttons, *e.g.*, incorrectly turning the device off by pressing the power button when a shock is advised.

User error is not a common occurrence with AEDs, as the literature overwhelmingly supports user-friendly design of AEDs.[136] The literature and our device experience indicate that these

---

[134] Shah JS, Maisel WH, Recalls and Safety Alerts Affecting Automated External Defibrillators, *JAMA*. 2006 Aug 9;296(6):655-60

[135] FDA News Release, *Journal of American Medical Association Article on Recalls and Safety Alerts Affecting Automated External Defibrillators,* at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108710.htm (Aug. 10. 2006).

[136] *See, e.g.*, Eames P, et al. Comparison of ease of use of three automated external defibrillators by untrained lay people. Resuscitation. 2003; 58: 25-30; Andre AD, et al. Automated external defibrillator use by untrained bystanders:can the public-use model work. Prehosp Emerg Care. 2004. Jul-Sep; 8(3):284-91; Gundry JW, Comess KA, DeRook FA, et al. Comparison of naïve sixth-grade children with trained professionals in the use of an

occurrences are infrequent and can be mitigated by special controls including usability studies to ensure the design and labeling are adequate to provide reasonable assurance of safe and effective use of the device.

Usability Studies

To address the concern that user error may cause a failure to properly deliver defibrillation energy, usability testing should show the ability of users to set up and use the device adequately and safely based upon the device design and the labeling provided with the device, *i.e.*, the testing must demonstrate that the labeling, as well as audible and visual prompts, is complete, clear, and does not compromise user performance. For example, usability studies may examine pad placement. Recent studies of pad placement accuracy viewed in light of real-world defibrillation performance show that there may be more latitude in pad placement than accepted practice dictates.[137] Moreover, most Philips devices are designed to warn the user when poor contact, another pad issue, is detected and to take corrective action. Field experience of Philips AEDs, much of which is acquired in trained BLS (basic life support) environments, show few if any patients who are not defibrillated, suggesting that pad placement and other user errors are not reaching levels of clinical significance. In other words, these errors have not been seen to result in the hazard of delayed or prevented defibrillation. Nonetheless, a usability study control that includes evaluation of pad placement and other potential user issues is important to ensuring predictably appropriate use of the device, particularly OTC AEDs.

Labeling

Labeling also can mitigate risks. For example, to address some of the situations identified above, user manuals should include: recommendations, such as carrying a spare battery or spare pads; cleaning instructions; and specifications of acceptable accessories. To prevent pediatric energy from being delivered to an adult, the labels on the pads must clearly distinguish pediatric from adult pads and the labeling should clarify which pads to use with which patients. Finally, as described above, as part of usability studies labeling must be assessed to ensure it is comprehensive, clear, and understood; results from such studies should be included in 510(k)s.

Special Controls: In sum, the special controls to address the risk of therapy not being delivered, being delayed or ineffective are as follows.

---

automated external defibrillator. Circulation 1999;100:1703-1707; Fleischhackl R, et al. Differing operational outcomes with six commercially available automated external defibrillators. Resuscitation. 2004. 62 :167-174.

[137] Nurmi et al., Adherence to guidelines when positioning the defibrillation electrodes. *Resuscitation* 2004; 61: 143-147 (Nurmi et al. examined pad placement accuracy achieved by a variety of trained responders. Approximately 35% of BLS providers (n=34) placed pads within 5 cm of recommended position, compared with only 22% of nurses (n=81) and 13% of physicians (n=21)); Andre et al., Automated external defibrillator use by untrained bystanders:can the public-use model work? *Prehospital Emergency Care* 2004: 8(3): 284-291 (Andre et al. performed a similar study of untrained bystanders using the HeartStart Home Defibrillator. When scored against the same criteria as Nurmi et al., approximately 50% of users achieved accurate pad placement. By this comparison, untrained users of the HeartStart Home defibrillator studies scored at least as well as trained BLS users of AEDs in pad placement accuracy).

The special controls discussed in *Performance Parameters, supra*, mitigate the overall risk of therapy not being delivered.

The special controls to address the reliability issue are:

- Compliance with DF80, *i.e.*, performance testing to assure minimum safety and reliability, testing related to environmental conditions, labeling requirements including those related to the battery, and requirements for frequent versus infrequent use.

- Compliance with EMC and EMI testing under IEC 60601-1-2.

- Usability (or user interface validation tests), as described in *Performance Parameters and Controls, Usability, supra*, would examine design and labeling to ensure proper device maintenance and storage.

- Readiness for use assessments, *i.e.*, device design and testing which incorporates critical self tests and user notifications, and submission of a report in the 510(k) detailing the design measures and validations used to provide assurance of device readiness to the user.

The special controls to address the lay user error related risks are:

- Usability studies (user interface validation tests) and concomitant design and labeling controls to prevent user error, as described in *Performance Parameters and Controls, Usability, supra*. The studies should examine product design and labeling to ensure that users can properly set up and use the device safely and effectively.

    - Device labeling can include recommendations to carry a spare battery or pads, cleaning instructions and specification of acceptable accessories, among other instructions.

Success of Special Controls: As noted above, AED malfunctions occur only occasionally and the numbers are small compared to the number of lives saved. The malfunctions did not present an additional risk to the sudden cardiac arrest victim. User error is also rare, indicating that device design and labeling are user friendly. The evidence shows that AEDs are reliable, user friendly devices, and self tests have been successful in addressing readiness for use issues presented by devices that spend time in standby mode.

3. Inappropriate shock to patient, user, or bystander

Risk: A third risk is inappropriate shock to the patient, user, or bystander.

Causes of Risk: This risk can result when:

- the patient leakage current is exceeded,

- there are electrical shocks to users or bystanders because of (1) a shock into shorted pads, (2) high voltage on pads connectors pins, (3) high voltage on pads during self test, (4) the

user or bystander is touching the patient or another conductive surface during shock delivery, or (5) conductive shock button.

These risks can be mitigated by performance testing, usability studies and labeling.

Discussion: It is important to appreciate that because of the hands free nature of the AED, it presents less of a risk of these inappropriate shocks to users or bystanders than do manual defibrillators. Indeed a review of MDRs and the literature reveals that this risk is small. Because this risk can be addressed for manual defibrillators through special controls, special controls can also assure AED safety and effectiveness, including when the device is intended for lay users.

Performance testing

Again, compliance with DF80 ensures these risks are mitigated. For example, DF80 addresses patient leakage current, insulation and isolation of the high-voltage circuit, measurements of delivered energy, and output control range. *See* section 50.2 (accuracy of controls) and 51.1 (hazardous limits) of DF80, and discussion of electrical safety *supra*, in *Performance Parameters, Device Requirements.* Performance testing of voice prompts and periodic self-tests also serve to mitigate these risks.

Usability studies and labeling

Usability studies also can help ensure that the device does not shock the user or bystander. As described in *Performance Parameters, Usability*, the studies could include an assessment of what labeling or design features such as audible and visual prompts are necessary to prevent users and bystanders from touching the patient during defibrillator discharge, and to ensure use of the proper pads. Labeling can mitigate these risks by clearly differentiating pediatric pads from adult pads and showing the appropriate weight for pediatric use. Labeling describes what actions to take if an adult energy level is delivered to a pediatric patient. DF80 also sets forth labeling requirements including warning the user not to touch the patient during defibrillation.

Special Controls: In sum, the special controls to address the risk of inappropriate shock to patient, user, or bystander are as follows:

- Performance testing in compliance with DF80, which addresses patient leakage current, insulation and isolation of the high voltage circuit, measurements of delivered energy and output control range.

- Usability studies (user interface validation tests) and concomitant design and labeling to prevent user error, such as touching the patient or incorrect pad usage, as described in *Performance Parameters and Controls, Usability, supra.* The studies should examine product design (audible and visual prompts) and labeling to ensure that users set up and use the device safely and effectively.

- Labeling to differentiate adult from pediatric pads and otherwise ensure proper device use.

Success of Special Controls: Our review of MDRs and the literature indicates that the risk of inappropriate shocks to patients, users or bystanders is very small and is adequately addressed by device performance testing, usability studies and labeling.

4. Conclusion

All of these risks can be effectively mitigated through product design and labeling, which is confirmed through performance testing, usability studies, and compliance with standards, including those set forth in DF80 and the AHA Scientific Statement. The application of general controls, *e.g.*, the submission of a premarket notification (510(k)) and compliance with the Quality System Regulation (QSR), 21 CFR Part 820, in addition to special controls, will provide reasonable assurance of the safety and effectiveness for AEDs. Importantly, the QSR ensures design requirements are appropriately developed and achieved through design controls, which include conducting a hazard or risk analysis and verification and validation of AED design through testing, which can include usability/human factors studies.

C. Favorable Benefit to Risk Ratio of AEDs

The safety and effectiveness of a device for purposes of reclassification are determined with respect to (1) the persons for whose use the device is intended, (2) conditions of use for the device suggested in labeling, and (3) weighing of probable benefit to health and probable risks of illness or injury. Act § 513(a)(2). AEDs are intended for unresponsive, not breathing patients who will likely die unless defibrillation is delivered very quickly. Their status is so dire, and the benefit of the device so great, the weighing of probable benefit to probable risk is extremely favorable. This is even more the case because the device actually presents a very low risk of injury, even when conditions of use for the device include untrained, nonmedical personnel.

Numerous clinical studies and other evaluations conducted in a variety of settings demonstrate that these devices are safe and effective as regulated today, pursuant to 510(k) and other general controls. The addition of the class II special controls proposed herein should provide assurance of a safety and effectiveness threshold that has the force of law. Leading public health organizations, the United States Congress and the legislatures of all 50 states accept the highly favorable benefit to risk ratio of these devices and acted to remove hurdles to their use.

The clinical benefits of AEDs and the low risks associated with their use are supported by numerous clinical studies conducted in a variety of settings. The airline study conducted in the late 1990s demonstrated the accuracy and reliability of the device as well as its strong safety profile.[138] The Chicago airport bystander study similarly demonstrated the device's accuracy and reliability and indicated that untrained bystanders could successfully use the device to resuscitate SCA victims.[139] The extensive, seminal PAD trial demonstrated the device's

---

[138] Page, R.L., "Use of Automated External Defibrillators by a U.S. Airline," N. Engl. J. Med., 343(17);1210-16 (2000) (In this study that evaluated AED use on a major passenger aircraft carrier, the rate of survival to discharge where an AED was used was 40%. No complications occurred from AED use on 200 patients, and the AED properly advised shock on all 14 patients who had VF and properly advised no shock for the remaining patients.)

[139] Caffrey, S. L.; Willoughby, P. J.; Pepe, P. E., and Becker, L. B., "Public Use of Automated External Defibrillators," N. Engl. J. Med., 347(16);1242-47 (2002) (In this prospective clinical study conducted at three

effectiveness – use of an AED doubled the number of survivors – and confirmed that AEDs can be used safely and effectively by trained lay responders in public locations.[140] The survival benefits associated with AED use were also confirmed in a systematic review and meta-analysis study published in 2007.[141] Further, a recent study of AED use at 1,710 high schools in the United States found that the survival rate for SCA victims was 64% for high schools that had an AED onsite and the authors strongly recommended that high schools implement onsite AED programs as part of a comprehensive emergency response plan to SCA.[142] Clearly, AEDs increase survival rates and present a very low risk of injury.

Public health organizations, the federal government, and the states understand and accept the documented benefits of AEDs compared to minimal risks, and took action to maximize AED access and use. Specifically:

- Numerous public health organizations, including the AHA, ARC, the National Safety Council and others, advocate broad deployment and use of AEDs. These organizations support the widespread availability and use of AEDs by pursuing legislation at the federal and state level, by providing materials, guidance and comprehensive training to lay persons in CPR and AED use, and through other actions.

- Congress has enacted several laws that support broader implementation of AEDs, including legislation directing the FAA to consider whether AEDs should be required on passenger aircraft, providing immunity to lay rescuers who use AEDs, mandating guidelines for AED placement in federal buildings, and establishing grant programs that encourage widespread AED availability and use and appropriating significant funding for these programs.

Chicago airports to assess whether random bystanders witnessing out-of-hospital cardiac arrest could successfully use AEDs placed at these airports, the long-term survival rate was 56% among VF SCA victims who received CPR and AED and 67% if these interventions were received within five minutes. In all 18 cases where an AED was used, the device correctly detected the presence of VF or a nonshockable rhythm, and no complications occurred, *i.e.*, there was no inappropriate delivery of shock, failure to deliver shock in response to VF, malfunction of the audible and visual alarms or prompts, inappropriate use of the AED by rescuers, or injury of rescuers or other bystanders as a result of AED use.)

[140] Hallstrom A and Ornato JP, "Public-Access Defibrillation and Survival after Out-of-Hospital Cardiac Arrest," *N Engl J Med*, 351;7:637-646 (2004) (In the PAD trial, which was a large, multicenter, prospective, randomized clinical trial that involved more than 19,000 lay responders from 993 community units (community units were assigned either to a CPR only response system or CPR plus AED response system), including shopping malls, recreation centers, hotels, office buildings, apartment complexes, and other public settings in 24 North American regions, the results showed that the use of an AED doubled the number of survivors of OHCA and confirmed that AEDs can be used safely and effectively by trained lay responders in public locations. Further, no inappropriate shocks were given, and other than the psychological trauma that affected a few rescuers after a resuscitation attempt, the trial documented no clinically significant harm from the deployment of 1,600 AEDs that were accessible to more than 11,000 volunteers in 622 public or residential locations over an average period of 21.5 months.)

[141] Sanna, T *et al.*, "Cardiopulmonary resuscitation alone vs. cardiopulmonary resuscitation plus automated external defibrillator use by non-healthcare professionals: A meta-analysis on 1583 cases of out-of-hospital cardiac arrest," Resuscitation , 76(2):226-32 (2008).

[142] Drezner JA, et al. Effectiveness of Emergency Response Planning for Sudden Cardiac Arrest in United States High Schools with Automated External Defibrillators. Circulation. 2009; 120:518-525

- All 50 states have enacted legislation that encourages the broad availability and use of AEDs.

In conclusion, the highly favorable benefit-to-risk profile of AEDs has been demonstrated in numerous clinical studies and in a variety of settings involving the use of the device by trained and untrained personnel. Public health organizations, the federal government and all 50 states have recognized this reality and taken numerous actions to encourage greater AED availability and use, acknowledging that the benefits of this technology greatly outweigh any risks.

The U.S. Department of Health and Human Services has stated that the AED is one of the most important advances in technology and provides an innovative opportunity to prevent unnecessary disability and death.[143] Because the benefits of AEDs outweigh any risks, and as we discussed in the above sections, special controls and general controls would provide reasonable assurance of the safety and effectiveness of these devices, reclassification of AEDs into class II is appropriate, and continuing them in class III would be unnecessary and inappropriate. Further, class II regulation would be consistent with public efforts to encourage the widespread availability of AEDs, but class III PMA regulation would frustrate these efforts and create a significant barrier to the widespread availability of these devices. Because broader access to AEDs could save many lives, FDA should support the public efforts aimed at maximizing access to this critical, life-saving technology by reclassifying the type of device into class II.

[143] 66 Fed. Reg. 28495, 28496 (May 23, 2001).

8.0 REPRESENTATIVE UNFAVORABLE INFORMATION

Representative unfavorable information consists of literature, recalls and MDRs associated with AEDs. As discussed below, we do not believe that the representative unfavorable information alters the favorable risk-benefit profile of AEDs or justifies class III regulation.

A. Literature

We conducted a search of the literature from late 2003 to May 2009 for unfavorable information associated with AEDs. A comprehensive literature review, including the epidemiology of sudden cardiac arrest, the evolution of defibrillation technology and factors to consider when defibrillators are placed in the hands of lay users, was contained in the HeartStart Home OTC submission (K040904). As such a new search was conducted for articles published since that submission was prepared (late 2003) in order to identify new information, including any potentially unfavorable information. Representative unfavorable published literature known to us is provided in below, organized into six categories (user error or safety, AED design, algorithm related, reliability, training, and use environment) with representative literature in each category and a brief summary of each citation. We also searched for articles related to representative unfavorable information for AED use on pediatric patients (defined as less than 8 years old); however, none were located. Articles may appear in more than one category (as applicable).

In sum, the representative articles fail to reveal any new issues not considered in this petition, and as a result, do not alter our position that the performance parameters and risks associated with AEDs are well known and understood, and that the special controls proposed in this petition, along with general controls under the Act, control these characteristics to provide reasonable assurance of device safety and effectiveness.

Topic	Number	Article Summary	Title	Citation
User Error or Safety				
	1.	Editorial that references perceived device (manual defibrillator) design flaws.	Hazards With Medical Devices: The Role of Design	Fairbanks RJ, Wears RL. Ann Emerg Med. 2008 Nov;52(5):519-21.
	2.	Editorial related to the recent clearance of an over-the-counter defibrillator and questioning its place in addressing public health issues.	Over-the-counter automated external defibrillations: show me the data!	Kellermann AL. Ann Emerg Med. 2005 Jan;45(1):96-7.
	3.	AED rhythm reanalyses, stacked shocks and post shock pulse checks delayed CPR after initial shock delivery and contributed little to return of a pulse.	Automated external defibrillators: to what extent does the algorithm delay CPR?	Rea T, et al. Ann Emerg Med. 2005; 46:132-141.
	4.	Review of prior bystander/operator shocks by defibrillators. Proposes that defibrillators may be safer than previously thought, and that it may be possible to continue CPR wearing	Is external defibrillation an electric threat for bystanders?	Hoke RS, Heinroth K, Trappe HJ, Werdan K. Resuscitation. 2009 Apr;80(4):395-401.

Topic	Number	Article Summary	Title	Citation
		exam gloves during shocks.		
	5.	In the Public Access Defibrillation (PAD) trial, 20,396 lay volunteers trained in AED/CPR or CPR only. 1,716 AEDs placed, 26,389 exposure months to adverse events. For AEDs, 27 related adverse events: 17 thefts of 20 devices, 3 inaccessible AED placements, 4 mechanical problems with the AED not affecting patient safety, 3 AEDs improperly maintained by facility. No inappropriate shocks or failures to shock when indicated.	Adverse events associated with lay emergency response programs: the public access defibrillation trial experience	Peberdy MA, Ottingham LV, Groh WJ, Hedges J, Terndrup TE, Pirrallo RG, Mann NC, Sehra R; PAD Investigators. Resuscitation. 2006 Jul;70(1):59-65.
	6.	In Denmark, 5 of 142 defibrillation attempts by physicians during simulation training, using a manual LifePak 12, inadvertently turned off instead of delivering shocks. Recommend redesign.	Adverse design of defibrillators: turning off the machine when trying to shock	Heyer CS, Christensen EF, Eika B. Ann Emerg Med 2008 Nov; 52(5):512-4.
AED Design				
	7.	Editorial about related articles regarding perceived defibrillator design flaws.	Hazards with medical devices: the role of design.	Fairbanks RJ, Wears RL. Ann Emerg Med. 2008 Nov;52(5):519-21.
	8.	Study through a dental school with lay population versus dental students and other medical professionals showed high failure rates in AED use in untrained general public.	Automated external defibrillator use among the general population.	Roccia WD, Modic PE, Cuddy MA. J Dent Educ. 2003 Dec;67(12):1355-61.
	9.	Nine deaf people attempted to use an AED with visual prompts as well as voice prompts. Most could do so readily without training, all could do so, and faster, with a 6 hour Basic Life Saving (BLS) course.	Automated external defibrillation by untrained deaf lay rescuers.	Sandroni C, Fenici P, Franchi ML, Cavallaro F, Menchinelli C, Antonelli M. Resuscitation. 2004 Oct;63(1):43-8.
	10.	Compared the ability of naive users to operate different AEDs, measuring time to shock, whether CPR was started, etc. Concluded that design detail mattered and varied between devices.	Differing operational outcomes with six commercially available automated external defibrillators.	Fleischhackl R, Losert H, Haugk M, Eisenburger P, Sterz F, Laggner AN, Herkner H. Resuscitation. 2004 Aug;62(2):167-74.
	11.	Extensive review of prior bystander/operator shocks by defibrillators. Proposes that	Is external defibrillation an electric threat for	Hoke RS, Heinroth K, Trappe HJ, Werdan K Resuscitation. 2009

Topic	Number	Article Summary	Title	Citation
		defibrillators may be safer than previously thought, and that it may be possible to continue CPR wearing exam gloves during shocks.	bystanders?	Apr;80(4):395-401.
Algorithm Related				
	12.	Hands-off time, *i.e.*, no CPR, was greater using AEDs than manual defibrillation due to analysis times.	Comparison of hands-off time during CPR with manual and semi-automatic defibrillation in a manikin model.	Pytte M, Pedersen TE, Ottem J, Rokvam AS, Sunde K. Resuscitation. 2007 Apr;73(1):131-6.
	13.	Interval between stopping CPR and delivering a shock shown elsewhere to make a big difference in survival. Shown that AED models vary widely in how long this interval may be. Recommends designing AEDs to minimize this interval.	Wide variation in cardiopulmonary resuscitation interruption intervals among commercially available automated external defibrillators may affect survival despite high defibrillation efficacy.	Snyder D, Morgan C. Crit Care Med. 2004 Sep;32(9 Suppl):S421-4
Reliability				
	14.	Points out time differences in a code review between two different report programs of the same stored event. Suggests a software flaw in post event review being reported.	Who is reviewing the data review systems of automated external defibrillators? Implications of flawed timelines for clinicians and researchers.	Calle PA, Monsieurs KG, De Paepe P. Resuscitation. 2007 Mar;72(3):484-9.
	15.	A review of FDA data on AED recalls or safety alerts and MAUDE reports. Notes advisories occur frequently, although AEDs are useful in saving lives.	Recalls and safety alerts affecting automated external defibrillators.	Shah JS, Maisel WH. JAMA. 2006 Aug 9;296(6):655-60
	16.	Review of prior bystander/operator shocks by defibrillators. Proposes that defibrillators may be safer than previously thought, and that it may be possible to continue CPR wearing exam gloves during shocks.	Is external defibrillation an electric threat for bystanders?	Hoke RS, Heinroth K, Trappe HJ, Werdan K. Resuscitation. 2009 Apr;80(4):395-401.
	17.	In the PAD trial, 20,396 lay volunteers trained in AED/CPR or CPR only. 1,716 AEDs placed, 26,389 exposure months to adverse events. For AEDs, 27 related adverse events: 17 thefts of 20 devices, 3 inaccessible AED placements, 4 mechanical problems w/ AED not affecting patient safety, 3 AEDs improperly maintained by facility. No inappropriate shocks or failures to shock when indicated	Adverse events associated with lay emergency response programs: the public access defibrillation trial experience.	Peberdy MA, Ottingham LV, Groh WJ, Hedges J, Terndrup TE, Pirrallo RG, Mann NC, Sehra R; PAD Investigators. Resuscitation. 2006 Jul;70(1):59-65
	18.	Case study. Patient had a wearable automatic defibrillator while	A fatal device-device interaction between a	LaPage MJ, Canter CE, Rhee EK.

Topic	Number	Article Summary	Title	Citation
		awaiting transplant. He had a VF arrest, but unipolar pacer spikes from an implanted pacer prevented the wearable device from shocking, despite initial rhythm recognition.	wearable automated defibrillator and a unipolar ventricular pacemaker.	Pacing Clin Electrophysiol. 2008 Jul;31(7):912-5
	19.	Contains a history of why AEDs were developed relative to improving maintenance inspections of crash carts and manual defibrillators.	A video based training program improves defibrillator inspection compliance.	Adams BD, Shih H, Stuffel E, Robinson AM. Am J Cardiol. 2006 Feb 15;97(4):578-9
Training				
	20.	Contains a history of why AEDs were developed relative to improving maintenance inspections of crash carts and manual defibrillators.	A video based training program improves defibrillator inspection compliance.	Adams BD, Shih H, Stuffel E, Robinson AM. Am J Cardiol. 2006 Feb 15;97(4):578-9
	21.	Studies retention of resuscitation skills of New Zealand air crews 12 months after training. They did poorly. AED use was safe but not necessarily timely or likely effective.	Retention of knowledge and skills in first aid and resuscitation by airline cabin crew.	Mahony PH, Griffiths RF, Larsen P, Powell D. Resuscitation. 2008 Mar;76(3):413-8.
	22.	Study through a dental school with lay population versus dental students and other medical professionals showed very high failure rates in AED use in untrained general public.	Automated external defibrillator use among the general population.	Roccia WD, Modic PE, Cuddy MA. J Dent Educ. 2003 Dec;67(12):1355-61
	23.	Compared the ability of naive users to operate different AEDs, measuring time to shock, whether CPR was started, etc. Conclusion was that design detail mattered and varied between devices	Differing operational outcomes with six commercially available automated external defibrillators.	Fleischhackl R, Losert H, Haugk M, Eisenburger P, Sterz F, Laggner AN, Herkner H. Resuscitation. 2004 Aug;62(2):167-74
Use Environments				
	24.	Relatively small study of opinions. Reflects AEDs as part of tough end-of-life decisions with mixed opinion of residents.	Do residents want automated external defibrillators in their retirement home?	Woolley DC, Medvene LJ, Kellerman RD, Base M, Mosack V. J Am Med Dir Assoc. 2006 Mar;7(3):135-40
	25.	Related to accuracy of AED clocks for quality assurance of resuscitation attempts in Finnish Emergency Medical Service. Mitigated by design of data software.	Time matters; what is the time in your defibrillator? An observational study in 30 emergency medical service systems.	Castrén M, Kurola J, Nurmi J, Martikainen M, Vuori A, Silfvast T. Resuscitation. 2005 Mar;64(3):293-5
	26.	Slight negative result in post-ischemic patients with AEDs at home. Concludes need to help	Psychological and social impacts of automated external	Cagle AJ, Diehr P, Meischke H, Rea T, Olsen J, Rodrigues D, Yakovlevitch M, Amidon T,

Topic	Number	Article Summary	Title	Citation
		patients with value of AED instead of just how to use it.	defibrillators (AEDs) in the home.	Eisenberg M. Resuscitation. 2007 Sep;74(3):432-8.
	27.	The Home Access Trial (HAT). 7001 post-myocardial infarction (MI) patients not eligible for implantable cardio defibrillators (ICDs) were randomized to an AED plus CPR training versus control of CPR training only. 450 patients died, no difference in mortality between control and study group. Rate of cardiac arrest was less than predicted in study design	Home use of automated external defibrillators for sudden cardiac arrest.	Bardy GH, Lee KL, Mark DB, Poole JE, Toff WD, Tonkin AM, Smith W, Dorian P, Packer DL, White RD, Longstreth WT Jr, Anderson J, Johnson G, Bischoff E, Yallop JJ, McNulty S, Ray LD, Clapp-Channing NE, Rosenberg Y, Schron EB; HAT Investigators. N Engl J Med. 2008 Apr 24;358(17):1793-804.
	28.	Equipped Cincinnati police with AEDs in area already served by a fire dept with AEDs. Did not improve survival. Police almost always arrived at SCA scene after the fire department	Providing automated external defibrillators to urban police officers in addition to a fire department rapid defibrillation program is not effective.	Sayre MR, Evans J, White LJ, Brennan TD. Resuscitation. 2005 Aug;66(2):189-96
	29.	In the PAD trial, 20,396 lay volunteers trained in AED/CPR or CPR only. 1,716 AEDs placed, 26,389 exposure months to adverse events. For AEDs, 27 related adverse events: 17 thefts of 20 devices, 3 inaccessible AED placements, 4 mechanical problems with the AED not affecting patient safety, 3 AEDs improperly maintained by facility. No inappropriate shocks or failures to shock when indicated.	Adverse events associated with lay emergency response programs: the public access defibrillation trial experience	Peberdy MA, Ottingham LV, Groh WJ, Hedges J, Terndrup TE, Pirralio RG, Mann NC, Sehra R; PAD Investigators. Resuscitation. 2006 Jul;70(1):59-65
	30.	Large study of US Gambro hemodialysis sites over several years. 43,200 hemodialysis patients, 729 in-center cardiac arrests. Survival not statistically better in sites with AEDs than in sites that did not have AEDs.	Automated external defibrillators and survival from cardiac arrest in the outpatient hemodialysis clinic.	Lehrich RW, Pun PH, Tanenbaum ND, Smith SR, Middleton JP. J Am Soc Nephrol. 2007 Jan;18(1):312-20.
	31.	Cost analysis showed that equipping everyone over the age of 60 with AEDs is too expensive for the benefits gained. Also noted that slight changes in assumptions made purchase of a home AED more attractive, esp. for high-risk groups.	Cost-effectiveness of in-home automated external defibrillators for individuals at increased risk of sudden cardiac death.	Cram P, Vijan S, Katz D, Fendrick AM. J Gen Intern Med. 2005 Mar;20(3):251-8

B. Recalls

AED Recalls from 1996 to 2005

An independent analysis of the AED recalls from January 1996 to December 2005 was conducted and reported in a peer-reviewed journal.[144] The analysis included both recalls and safety alerts, collectively referred to as "advisories."[145] For the 10-year period, there were 37 AED advisories (approximately 3.5 advisories per year) and 15 AED accessory advisories. The analysis did not include a further assessment of advisories that relate to AED-specific issues, nor did it report the number of advisories for each manufacturer, so it is unclear how many of these advisories relate to AED-specific issues and whether there was a disproportionate number of advisories for certain manufacturers. Of the 37 AED advisories, 84% were class II and 11% were class I advisories.[146] Advisories affecting AEDs were most often issued because of electrical or software-related issues. Although the annual number of AED advisories and the annual number of AEDs affected by advisories increased over the 10-year period, there was also a 10-fold increase in the number of AEDs sold during this period.[147] Additionally, in commenting on the authors' findings, FDA pointed out that "improvements in the devices' ability to self-diagnose hardware and software problems may contribute to this trend" and "may result in users reporting problems before a device is ever used on a patient."[148] In other words, the increase in the number of advisories may be due to technical improvements made to enhance device reliability.[149]

AED Recalls from January 2005 to June 2009

We conducted an analysis of the AED recalls from January 1, 2005 to June 30, 2009 for five major AED manufacturers using information from FDA's recall database. Because it was not uncommon for manufacturers to have several different recalls for the same issue,[150] the chart below presents the recall data according to both the total number of recalls and the number of different recall issues for each manufacturer. We believe that it is more useful to look at the number of distinct recall issues because it better reflects the number of different problems that gave rise to recalls. There were 46 different recall issues from the five AED manufacturers during this period. Although the description of each recall in FDA's recall database is brief and thus, somewhat limited, it is clear that a number of recall issues were not specific to AEDs;

---

[144] Shah, J.S. *et al.*, "Recalls and Safety Alerts Affecting Automated External Defibrillators," *JAMA*, 296(6); 655-660 (2006).

[145] *Id.*

[146] *Id.*

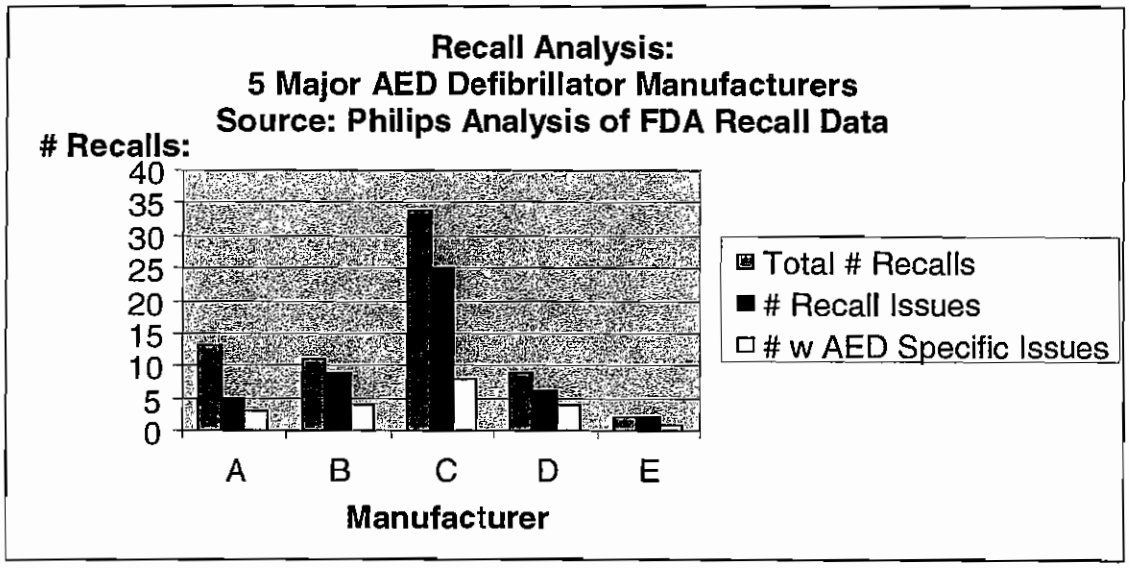
[147] *Id.*

[148] FDA News Release, *Journal of American Medical Association Article on Recalls and Safety Alerts Affecting Automated External Defibrillators*, at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108710.htm (Aug. 10. 2006).

[149] *Id.*

[150] This occurs, for example, because the same defective component is used in several different device models, or because the manufacturer increases the number of affected units.

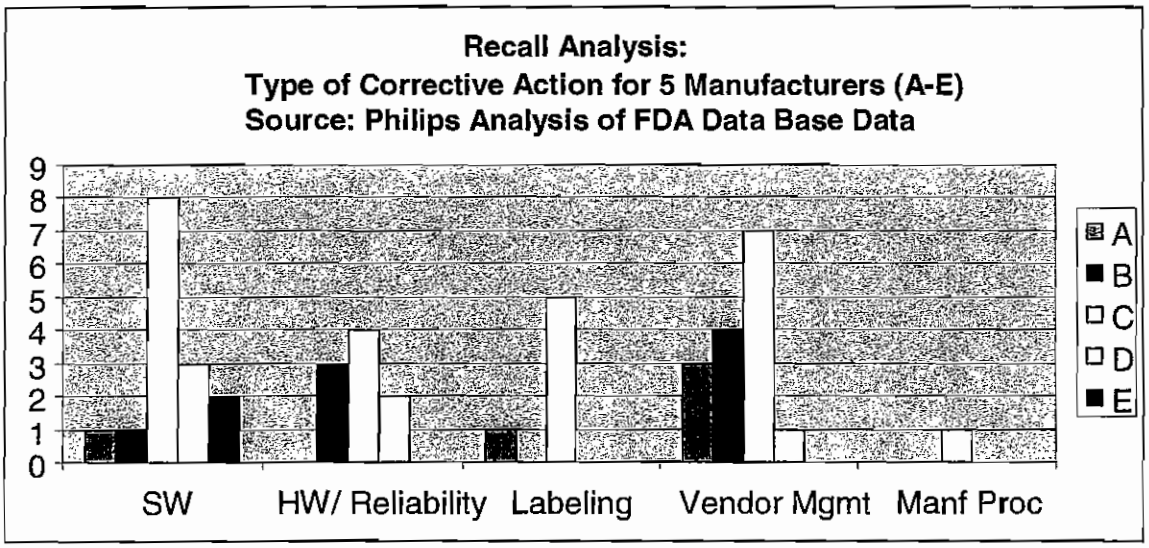
indeed, many of the issues were applicable to manual defibrillators as well. We categorized the recall issues according to those that specifically relate to AEDs and those that relate to defibrillators in general The number of recall issues that specifically relate to AEDs are included in the chart below. As the chart shows, issues that specifically relate to AED functionality are only a small subset of the recalls.



The above chart also shows that one AED manufacturer had a disproportionately large number of recalls compared to the other four AED manufacturers. In particular, 25 of the 46 different recall issues relate to that single manufacturer. If the remaining 21 different recall issues for the other four manufacturers are considered over the four-and-a-half year period, this amounts to approximately one recall issue per manufacturer per year. Because not all of the recall issues specifically relate to AED functionality, the recall rate would be even lower when only AED-specific issues are considered.

In a second analysis of this data, we classified the 46 different recall issues into five categories (software, hardware/reliability, labeling, vendor management, and manufacturing processes)[151] as illustrated in the chart below. The chart also shows for each category, the number of recall issues for each manufacturer, and demonstrates that there are differences in the causes of recalls for the different leading AED manufacturers. For example, while Manufacturer B's recalls relate primarily to hardware/reliability and vendor management issues, Manufacturer E's recalls relate primarily to software issues. In other words, the AED-related issues extracted from FDA's database suggest that recalls are less related to inherent characteristics of AEDs, but instead to individual manufacturers' AED design efforts. This concern is not remedied by class III controls, but instead the special controls described above and the Act's general controls.

[151] Software issues relate to software-related defects/errors; hardware/reliability issues relate to hardware-related failures; labeling issues relate to various labeling problems, such as unclear instructions; vendor management issues relate to defective components and other problems concerning suppliers; and manufacturing processes relate to problems in the manufacturing process, but not necessarily a hardware failure, for example, incorrect configuration of the device.



A review of the above chart further shows that the various causes of the recall issues can be adequately controlled through general controls or class II special controls. Our analysis indicates that 65% of the recalls can be traced to software defects or vendor management issues such as defective components. The recall data show that some software defects only become apparent after several thousand units have shipped, which indicates that the frequency of the failures associated with some software defects is so low that it takes use over a large population and over an extended period of time for the defect to be detectable. Likewise, defective components often become apparent only after several months of device shipments indicating that the frequency of failures associated with defective components is low.

Software issues can be adequately addressed through general or special controls. In other words, there is no advantage to class III controls for software evaluation. Vendor management issues can be adequately addressed through purchasing controls that would include supplier audits. The remaining causes of AED recalls – deficiencies relating to hardware/reliability, labeling and manufacturing processes – also can be adequately controlled through general or special controls. On the whole, class III controls would not mitigate these relatively low frequency postmarket discoveries, and only implementation of class II design controls could have an impact at reducing design-related effects.

In sum, our analysis of the AED recall data for five major AED manufacturers over the past four-and-a-half year period suggests that the number of recalls that relate to AED-specific issues represent only a small subset of the total number of recalls and thus, many of the issues identified in the recalls would apply to manual defibrillators. Further, the various causes of the recall issues may be adequately controlled through general controls or class II special controls. Moreover, the majority of the recall issues related to one manufacturer. Where one manufacturer has a disproportionately higher rate of recalls, greater utilization of FDA's inspection authority with respect to that manufacturer would be appropriate rather than imposing across-the-board unnecessary class III controls on all AED manufacturers.

C. Medical Device Reports (MDRs)

AED MDRs from 1996 to 2005

The authors who reviewed the AED recalls from 1996 to 2005 also evaluated the AED MDRs, specifically MDRs involving patient death, that were reported to the FDA between July 1996 and December 2005.[152] According to the authors, there were 801 AED or AED accessory MDRs involving a patient death over the nine-and-a-half year period, but less than half of these (< 400 total or < 42 per year) were determined to be due to confirmed device malfunctions that occurred during sustained ventricular arrhythmias; the remaining MDRs were determined to not involve device malfunctions or were indeterminate. The authors concluded that the total number of AED malfunctions that occurred during a resuscitation attempt was small compared with the number of lives saved.[153] Indeed, 42 AED malfunctions during resuscitation attempts per year would be small compared to the thousands of lives that are saved each year using AEDs to treat SCA victims.[154]

AED MDRs from January 2005 to June 2009

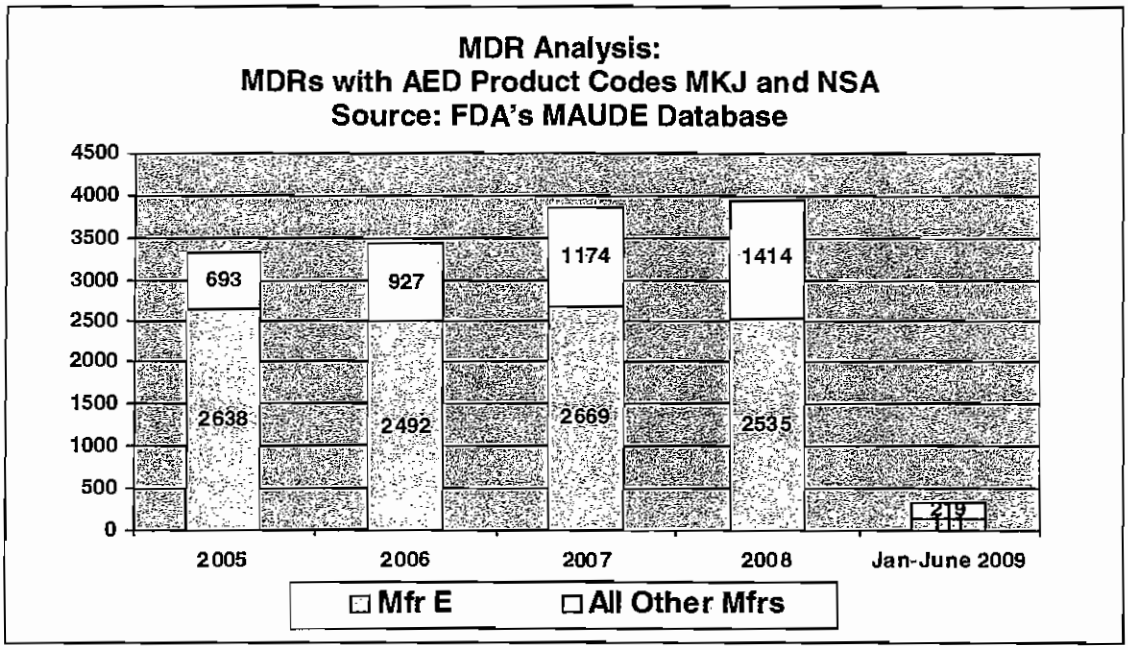
We conducted a search in FDA's Manufacturer and User Facility Device Experience (MAUDE) database of AED MDRs reported between January 1, 2005 to June 30, 2009 by using the device product codes MKJ and NSA. Below, we provide a chart of the AED MDRs by year. Additionally, because a significant number of the AED MDRs relate to one manufacturer, we show the MDRs for that one manufacturer ("Mfr E") and the MDRs relating to all other AED manufacturers. Oddly, Mfr E is not the same manufacturer who reported the highest number of recalls (Mfr C in the first recall chart above). Instead, Mfr E reported the lowest number of AED recalls (as shown in the first recall chart above), suggesting that Mfr E may have grossly over-reported MDRs. This conclusion is reinforced by the dramatic decline in MDR reporting by Mfr E for the time period of January through June 2009.

---

[152] Shah, J.S. *et al.*, "Recalls and Safety Alerts Affecting Automated External Defibrillators," JAMA, 296(6); 655-660 (2006).

[153] *Id.*

[154] *Id.*



For the January 1, 2005 to June 30, 2009 period, over 70% of the AED MDRs reported related to Mfr E. If the MDRs for this manufacturer are excluded, the MDRs for all other AED manufacturers are similar to the number of MDRs for manual defibrillators. Even if the MDRs for Mfr E are included, the total number of AED MDRs represent a very small percentage of the number of AEDs in the field. For example, the total number of AED MDRs for 2005 represent less than 2% of all AEDs sold that year (approximately 180,000 AEDs were sold in 2005).[155]

In sum, we do not believe that the representative unfavorable information discussed above alters the favorable benefit-to-risk profile of AEDs or justifies class III regulation. An independent analysis of the AED recalls and MDRs over a 10-year period concluded that the total number of malfunctions that occurred during a resuscitation attempt was small compared with the number of lives saved. Further, our analysis of the AED recalls and MDRs for the past four-and-a-half years indicates that each of two manufacturers was responsible for the majority of the recalls and MDRs, respectively, and the majority of the recall issues associated with AEDs were not specific to AEDs but would apply equally class II manual defibrillators.

[155] Shah, J.S. et al., "Recalls and Safety Alerts Affecting Automated External Defibrillators," JAMA, 296(6); 655-660 (2006).

9.0 SUMMARY OF NEW INFORMATION

Below is a general summary of the new information submitted to support this petition to reclassify AEDs, a preamendment device, from class III to class II. The new information requirement under section 513(e)(2) of the Act can be satisfied by information that came into existence after the promulgation of the AED classification regulation, or a re-examination of information existing at the time that regulation became final that was considered by FDA in its deliberations.[156]

Petition sections 1, 7 and 8, identify studies, well accepted AED and device-related standards and guidances by highly reputable and expert organizations, federal and state legislative activities and policies, and recall and MDR data and analyses to support AED reclassification.[157] The information presented in the petition is new both because it existed at the time of the promulgation of the AED classification regulation and was either not considered by FDA in its classification decision or it has been reanalyzed in this petition, and because it came into existence since the AED regulation became final. *See Section 11* which contains AED references.

Information in the petition that existed at the time the AED classification rule became final was analyzed, among other ways, in the context of performance parameters, risks, and special controls.[158] This approach was not previously applied to the AED information in context of the arrhythmia detector reclassification. Moreover, this information was not analyzed from the perspective of OTC AEDs or certain prescription uses of AEDs, *e.g.*, the use of AEDs at home.

The petition also contains information that did not exist at the time of the promulgation of the AED classification regulation. For example, the discussion and citation to usability studies

---

[156] *See* 72 Fed. Reg. 32170 (June 12, 2007).

[157] *See e.g.*, National Conference of State Legislatures, "State Laws on Cardiac Arrest & Defibrillators" (Jan. 2, 2009), at http://www.ncsl.org/IssuesResearch/Health/LawsonCardiacArrestandDefibrillatorsAEDs/tabid/14506/Default.aspx (lists the state AED laws for all 50 states); Sanna, T *et al.*, "Cardiopulmonary resuscitation alone vs. cardiopulmonary resuscitation plus automated external defibrillator use by non-healthcare professionals: A meta-analysis on 1583 cases of out-of-hospital cardiac arrest," *Resuscitation*, 76(2):226-32 (2008) (analysis of data on survival to hospital admission and discharge on 1,583 cases of out-of-hospital cardiac arrest (OHCA), collected from three randomized, controlled clinical which compared CPR to CPR plus AED, both delivered by non-medical personnel for the treatment of OHCA, showed that there was a survival benefit associated with AED use, with significant 95% confidence intervals for both survival to hospital admission and discharge); ,Hallstrom A and Ornato JP, "Public-Access Defibrillation and Survival after Out-of-Hospital Cardiac Arrest," *N Engl J Med*, 351;7:637-646 (2004) (the extensive PAD trial demonstrated that AEDs can be used safely and effectively by trained lay responders in public locations – there was no clinically significant harm associated with AED use and the use of an AED doubled the number of survivors); ANSI/AAMI DF80:2003 Medical electrical equipment—Part 2-4: Particular requirements for the safety of cardiac defibrillators (including automated external defibrillators) (approved on Oct. 23, 2003) (current consensus standard for defibrillators including AEDs).

[158] *See, e.g.*, AHA, "ECC Guidelines, Part 4: The Automated External Defibrillator," *Circulation*, 102:1-60 (2000); Kerber R.E., Becker L, et al., "AHA Scientific Statement Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety," *Circulation*, 95:1677-1683 (1997).

reflect information created after the effective date of the AED classification regulation.[159] Also, the MDR literature studies referenced in the petition were completed after the date of the AED classification in 2003.[160] The company's research into the FDA's MDR and recall databases, and the analysis of the research results, likewise reflect information that came into existence years after the October 2003 classification date. [161]

In sum, the petition satisfies section 513(e)(2)'s "new information" requirement, and is based on such information to justify reclassification of the generic type of device, AEDs, from class III to class II.

---

[159] *See, e.g.*, Beckers *et al.*, *Minimal Instructions Improve the Performance of Laypersons in the Use of Semiautomatic and Automatic External Defibrillators*, 9 Crit. Care (2005); Callejas et al, *Human Factors Impact Successful Lay Person Automated External Defibrillator Use During Simulated Cardiac Arrest*, 32 Crit. Care Med. (2004).

[160] *See* Shah, J.S. *et al.*, "Recalls and Safety Alerts Affecting Automated External Defibrillators," Journal of the American Medical Association, 296(6); 655-660 (2006).

[161] *See* Section 8, *infra*.

10.0 CONCLUSION.

Based on the foregoing information and data, PHILIPS MEDICAL SYSTEMS respectfully requests that automated external defibrillators be reclassified from Class III to Cl II.

Respectfully submitted,

Paul Smolenski
Director, Quality and Regulatory Affairs
Philips Cardiac Care
PHILIPS MEDICAL SYSTEMS
3000 Minuteman Road
Andover, MA 01810
(978) 659-3380
paul.smolenski@philips.com

Mark A. Heller
Louise N. Howe
GOODWIN PROCTER LLP
901 New York Avenue NW
Washington, DC 20001
(202) 346-4000

Counsel to Philips Medical Systems

11.0 FINANCIAL CERTIFICATION.

See ***Attachment D***.

12.0 COPIES OF SOURCE DOCUMENTATION

See ***Attachment F***.

PHILIPS

Philips Medical Systems
Cardiac Care
3000 Minuteman Road
Andover, MA 01810

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: **Petition to Reclassify Automated External Defibrillators (21 CFR § 870.5310)**
Docket No. FDA-2009-M-0101]

Dear Sir/Madam:

Enclosed with this letter is a reclassification petition from Philips Medical Systems requesting that automated external defibrillators (21 CFR § 870.5310) be reclassified from its Class III preamendment status to class II, special controls. The petition is submitted in response to the United States Food and Drug Administration's (FDA's) order published in the *Federal Register* on April 9, 2009 calling for the submission of certain safety and effectiveness information for 25 types of preamendment class III device, including automated external defibrillators, or in lieu of such data, reclassification petitions. *See* 74 Fed. Reg. 16214 (April 9, 2009).

This submission fulfills Philips' requirement to respond to the FDA's April 9 order, and provides valid scientific evidence in support of the company's reclassification request. Submitted herewith are one original and three copies of the petition and attachments.

Sincerely,

Paul Smolenski

Paul Smolenski
Director, Quality and Regulatory Affairs
Philips Cardiac Care
paul.smolenski@philips.com

Enclosures

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

SUPPLEMENTAL DATA SHEET

FORM APPROVED: OMB NO. 0910-0138
EXPIRATION DATE: March 31, 2009
(See OMB Statement on Page 2)

Panel Recommendation

1. GENERIC TYPE OF DEVICE
automated external defibrillator

2. ADVISORY PANEL
cardiovascular for Rx (prod. code MKJ); circulatory system devices panel for OTC (NSA)

3. IS DEVICE AN IMPLANT (21 CFR 860.3)?
☐ Yes ☒ No

4. INDICATIONS FOR USE IN THE DEVICE'S LABELING
AED Therapy is intended for use for the termination of ventricular tachycardia and ventricular fibrillation. The device is to be used in the presence of suspected cardiac arrest on patients that are unresponsive and not breathing normally.

5. IDENTIFICATION OF ANY RISKS TO HEALTH PRESENTED BY DEVICE
General (1) Inappropriate shock recommendation by algorithm so that shock is delivered for a non-shockable rhythm or device fails to deliver a shock for a shockable rhythm. (2) Therapy not delivered, is delayed or ineffective. (3) Inappropriate shock to patient, user, or bystander.

6. RECOMMENDED ADVISORY PANEL CLASSIFICATION AND PRIORITY
Classification Class II
Priority (Class II or III Only) N/A- performance standard unnecessary

7. IF DEVICE IS AN IMPLANT, OR IS LIFE-SUSTAINING OR LIFE-SUPPORTING AND HAS BEEN CLASSIFIED IN A CATEGORY OTHER THAN CLASS III, EXPLAIN FULLY, THE REASONS FOR THE LOWER CLASSIFICATION WITH SUPPORTING DOCUMENTATION AND DATA
See petition for a full explanation. In sum, the type of device is well characterized and understood; its performance parameters and risks are identified by valid scientific evidence in the petition; and the petition shows that general and special controls address the device type's performance and safety to provide reasonable assurance of safety and effectiveness. The device has a very favorable benefit to risk ratio, and and should be reclassified into class II, as demonstrated in the petition.

8. SUMMARY OF INFORMATION, INCLUDING CLINICAL EXPERIENCE OR JUDGMENT, UPON WHICH CLASSIFICATION RECOMMENDATION IS BASED
See reclassification petition for a full explanation. In sum, the classification recommendation is based on the published data and information attached to this petition as well as decades of safe and effective use of the device.

9. IDENTIFICATION OF ANY NEEDED RESTRICTIONS ON THE USE OF THE DEVICE *(e.g., special labeling, banning, or prescription use)*
See question 11 of the General Device Questionnaire.

10. IF DEVICE IS RECOMMENDED FOR CLASS I, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM

Justification / Comments

☐ a. Registration / Device Listing Not applicable

☐ b. Premarket Notification Not applicable

☐ c. Records and Reports Not applicable

☐ d. Good Manufacturing Practice Not applicable

11. IF DEVICE IS RECDMMENDED FOR CLASS II, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM PREMARKET NOTIFICATION

☐ a. Exempt

☒ b. Nol Exempt

Justifications/Comments

12. EXISTING STANDARDS APPLICABLE TO THE DEVICE, DEVICE SUBASSEMBLIES *(Components)* OR DEVICE MATERIALS *(Parts and Accessories)*

ANSI/AAMI DF80:2003; AHA "Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating Ncw Waveforms, and Enhancing Safety," Scientific Statement (I997); IEC 60601-1 and applicable collateral and device-specific standards (i.e., IEC 60601-2-4); EN 14971; EN 10993.

13. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs (HFZ-215)
1350 Piccard Drive
Rockville, MD 20850

OMB STATEMENT

Public reporting burden for this collection of information is eslimated to average 1-2 hours per response, including the time for reviewing instructions, searching existing dala sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any olher aspect of this collection of information, including suggeslions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, MD 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE --- FOOD AND DRUG ADMINISTRATION

GENERAL DEVICE CLASSIFICATION QUESTIONNAIRE

FORM APPROVED: OMB NO. 0910-0138
EXPIRATION DATE: March 31, 2009
(See OMB Statement on Page 2)

PANEL MEMBER / PETITIONER
Philips Medical Systems

DATE

GENERIC TYPE OF DEVICE
automated external defibrillator

CLASSIFICATION RECOMMENDATION
Class II

1. IS THE DEVICE LIFE-SUSTAINING OR LIFE-SUPPORTING ?	☒ YES ☐ NO	Go to Item 2.
2. IS THE DEVICE FOR A USE WHICH IS OF SUBSTANTIAL IMPORTANCE IN PREVENTING IMPAIRMENT OF HUMAN HEALTH ?	☒ YES ☐ NO	Go to Item 3.
3. DOES THE DEVICE PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY ?	☐ YES ☒ NO	Go to Item 4.
4. DID YOU ANSWER "YES" TO ANY OF THE ABOVE 3 QUESTIONS ?	☒ YES ☐ NO	If "Yes," go to Item 6. If "No," go to Item 5.
5. IS THERE SUFFICIENT INFORMATION TO DETERMINE THAT GENERAL CONTROLS ARE SUFFICIENT TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☐ YES ☐ NO	If "Yes," Classify in Class I. If "No," go to Item 6.
6. IS THERE SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* IN ADDITION TO *GENERAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☒ YES ☐ NO	If "Yes," Classify in Class II and go to Item 7. If "No," Classify in Class III.
7. IF THERE IS SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS IDENTIFY BELOW THE SPECIAL CONTROL(S) NEEDED TO PROVIDE SUCH REASONABLE ASSURANCE. FOR CLASS II. ☒ Guidance Document ☐ Performance Standard(s) ☒ Device Tracking ☒ Testing Guidelines ☒ Other *(Specify)* The special controls can be set forth in a guidance document and should include: conformance with defibrillator and electrical safety standards, performance testing, usability/ human factors testing, design that considers readiness for use, and labeling. Device tracking is currently performed for devices of this type indicated for use outside a healthcare facility and should continue.		
8. IF A REGULATORY PERFORMANCE STANDARD IS NEEDED TO PROVIDE REASONABLE ASSURANCE OF THE SAFETY AND EFFECTIVENESS OF A CLASS II OR III DEVICE, IDENTIFY THE PRIORITY FOR ESTABLISHING SUCH A STANDARD. ☐ Low Priority ☐ Medium Priority A performance standard is unnecessary; the ☐ High Priority recommended special controls currently exist; ☒ Not Applicable FDA should recognize ANSI/AAMI DF80; 2003.		
9. FOR A DEVICE RECOMMENDED FOR RECLASSIFICATION INTO CLASS II, SHOULD THE RECOMMENDED REGULATORY PERFORMANCE STANDARD BE IN PLACE BEFORE THE RECLASSIFICATION TAKES EFFECT ?	☐ YES ☐ NO ☒ NOT Applicable	
10. FOR A DEVICE RECOMMENDED FOR CLASSIFICATION / RECLASSIFICATION INTO CLASS III, IDENTIFY THE PRIORITY FOR REQUIRING PREMARKET APPROVAL APPLICATION (PMA) SUBMISSIONS. ☐ Low Priority ☐ Medium Priority ☐ High Priority ☒ Not Applicable		

11. IDENTIFY THE NEEDED RESTRICTION(S)

- ☐ Only upon the written or oral authorization of a practitioner licensed by law to administer or use the device
- ☐ Use only by persons with specific training or experience in its use
- ☐ Use only in certain facilities
- ☒ Other *(Specify)* If over-the-counter special controls are not met, then the device requires a prescription.

12. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs (HFZ-215)
1350 Piccard Drive
Rockville, MD 20850

OMB STATEMENT

Public reporting burden for this collection of information is estimated to average 1-2 hours par rasponse, including the time for reviewing instructions, searching existing date sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send commants regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, MD 20857

An agency may not conduct or sponsor, and a person is not required to respond to , a collection of information unless it displays a currently valid OMB control number.

Class II Special Controls for Automated External Defibrillators

Class II Special Controls for Automated External Defibrillators (AEDs); Draft Guidance for Industry and FDA

Table of Contents

Draft Guidance for Industry and FDA Staff

Class II Special Controls for Automated External Defibrillators (AEDs); Draft Guidance for Industry and FDA

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance document.

1. Introduction

This draft guidance document was developed as a special control guidance to support the reclassification of Automated External Defibrillators (AEDs) into class II (special controls). This draft guidance will be issued in conjunction with a Federal Register notice announcing the notice of panel recommendation, which recommends reclassifying AEDs and designating this document as the special control for this device type. This guidance is issued for comment purposes only. If a regulation reclassifying this device type is not issued, this guidance document will not be issued as a special control.

Following the effective date of a regulation reclassifying the device, any firm submitting a 510(k) for an AED will need to address the issues covered in the special control guidance. However, the firm should demonstrate that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.[1]

FDA believes the special controls specified herein, when combined with the general controls, will provide reasonable assurance of the safety and effectiveness of automatic external defibrillators (AEDs). Thus, a manufacturer who intends to market a device of this generic type must (1) conform to the general controls of the Federal Food, Drug, and

[1] We recommend that manufacturers document how they address the recommendations of this guidance in their design history file. Manufacturers must maintain design controls, including a design history file, in accordance with 21 CFR 820.30.

Cosmetic Act (the Act), including the premarket notification requirements described in 21 CFR 807, Subpart E, (2) address the specific performance parameters and risks to health associated with AED devices identified in this guidance, and (3) obtain a substantial equivalence determination from FDA prior to marketing the device.

Although FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities, manufacturers and others who want to commercially distribute AEDs as class II devices must adequately address the content of this document. This guidance describes the Agency's current thinking on AEDs and should be viewed as a series of recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

This draft guidance document reflects our careful review of what we believe are the relevant issues related to AEDs and what we believe would be the least burdensome way of addressing these issues. If you have comments on whether there is a less burdensome approach, however, please submit your comments as indicated on the cover of this document.

2. Background

This special controls guidance document lists the risks to health identified by FDA and describes measures that, if followed by manufacturers and combined with the general controls, will address the risks associated with these automated external defibrillator (AED) devices and lead to a timely review of premarket notification submissions. This document supplements other FDA documents regarding the specific content requirements of a premarket notification submission. You should also refer to 21 CFR 807.87, **Format for Traditional and Abbreviated 510(k)s** at http://www.fda.gov/cdrh/ode/guidance/1567.html, and "**How to Prepare a 510(k) Submission**" on FDA Device Advice at http://www.fda.gov/cdrh/devadvice/314.html.[2]

As described in the guidance entitled, **The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**, http://www.fda.gov/cdrh/ode/parad510.html, a manufacturer may submit a Traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once a special controls guidance document has been issued. Manufacturers considering certain modifications to their own cleared devices may lessen the regulatory burden by

[2] We recommend that you include a table of contents at the front of your submission. Each line listing in the table of contents should refer to major section titles and the page numbers where each section can be found.

submitting a Special 510(k).

3. Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should describe how this special control guidance document was used during the device development and testing and should briefly describe the methods or tests used and a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of section 807.87 as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this special controls guidance document.

Proposed labeling

Proposed labeling must be sufficient to describe the device, its intended use, and the directions for its use (21 CFR 807.87(e)). (Please refer to **Section 11. Labeling** for specific information that should be included in the labeling for devices of the types covered by this guidance document.)

Summary report

We recommend that the summary report contain:

Description of the device and its intended use
We recommend that the description include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. (Please refer to **Section 5. Device Description** for specific information that we recommend you include in the device description for devices of the types covered by this guidance document.) You should also submit an "indications for use" enclosure.[3]

Description of device design requirements
We recommend that you include a brief description of the device design requirements.

Identification of the risk analysis method

[3] Refer to http://www.fda.gov/cdrh/ode/indicate.html for the recommended format.

We recommend that you identify the Risk Analysis method(s) you used to assess the risk profile, in general, as well as the specific device's design, and the results of this analysis.
(Please refer to **Section 6. Risks to Health** for the risks to health generally associated with the use of this device that FDA has identified.)

Discussion of the device characteristics
We recommend that you discuss the device characteristics that address the risks identified in this class II special controls guidance document, as well as any additional risks identified in your risk analysis.

Description of the performance aspects
We recommend that you include a brief description of the test method(s) you have used or intend to use to address each performance aspect identified in **Sections 7-10** of this class II special controls guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply or have applied to your test results.[4] (See also 21 CFR 820.30, Subpart C - Design Controls for the Quality System Regulation.)

Reliance on standards
If you choose to rely on a recognized standard for any part of the device design or testing, you may include either a:
- statement that testing will be conducted and meet specified acceptance criteria before the device is marketed; or
- declaration of conformity to the standard.[5]

Because a declaration of conformity is based on results from testing, we believe you cannot properly submit a declaration of conformity until you have completed the testing the standard describes. For more information, please refer to section 514(c)(1)(B) of the act and the FDA guidance, **Use of**

[4] If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

[5] See Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(K)] Submissions), http://www.fda.gov/cdrh/ode/reqrecstand.html.

Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA, http://www.fda.gov/cdrh/ode/guidance/1131.html.

If it is not clear how you have addressed the risks identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), you can submit a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering modifications to their own cleared devices should consider submitting Special 510(k)s.

The general discussion above applies to any device subject to a special controls guidance document. The following is a specific discussion of how you should apply this special controls guidance document to a premarket notification submission for an automatic external defibrillator (AED).

4. Scope

The scope of this document is limited to the device described under 21 CFR § 878.5310 class II (following this reclassification), product codes MKJ and NSA.

21 CFR § 878.5310 defines an automated external defibrillator:

> (a) *Identification.* An automated external defibrillator (AED) is a low-energy device with a rhythm recognition detection system that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart. An AED analyzes the patient's electrocardiogram, interprets the cardiac rhythm, and automatically delivers an electrical shock (fully automated AED), or advises the user to deliver the shock (semi-automated or shock advisory AED) to treat ventricular fibrillation or pulseless ventricular tachycardia. AEDs may include rechargeable or nonrechargeable batteries, various types of pads, including provisions for delivering pediatric energy levels, cables and adaptors and other accessories.
>
> The device may be prescription or over-the-counter. When AED functionality is included on multi-function devices that require the supervision of a licensed practitioner, and for which adequate directions for lay use cannot be prepared, the multi-function device requires a prescription. Single function AEDs require a

prescription if they do not comply with the special controls for over-the-counter AEDs.

(b) *Classification.* Class II (special controls).

(1) The special control for this device is FDA's "Class II Special Controls for Automated External Defibrillators."

(2) Automated External Defibrillators with waveforms that are not monophasic or biphasic shall be subject to a clinical trial special control demonstrating the safety and effectiveness of the waveform to defibrillate the atria or ventricles of the heart to restore normal heart rhythm.

AEDs are further defined by FDA Product Codes:

Product Code MKJ:

"This device is a non-wearable prescription use only AED. These are devices that include automated external defibrillation. Automated external defibrillators use external pad-type electrodes to sense, detect, classify and treat (with an electrical shock) ventricular fibrillation. These devices are intended for use on suspected victims of sudden cardiac arrest. A person in cardiac arrest is unresponsive and is not breathing normally. The device can be sold with prescription only. "

Product Code NSA:

"Automated external defibrillators are devices that use external pad-type electrodes to sense, detect, classify and treat (with an electrical shock) ventricular fibrillation. These devices are intended for use on suspected victims of sudden cardiac arrest. A person in cardiac arrest is unresponsive and is not breathing normally. The device can be sold over-the-counter without a prescription. The device is to be used on adults and children who are either > 8 years old or > 55 lbs."

If your device is a multifunction monitor-defibrillator that also includes AED functionality, then this document only addresses clearance of the AED features of that product.

Also, please note that this document is limited to *automatic* external defibrillators. Manual external low energy (<360 Joules) defibrillators are Class II devices described in 21 CFR 870.5300, DC Defibrillators (Including Paddles).

5. Device Description

We recommend that you identify your device by regulation number and product code indicated in **Section 4. Scope** and include the information described below.

Intended Use

Automatic external defibrillators have historically been tailored for use in a variety of clinical circumstances. Consequently, training requirements for AED users may vary considerably. We recommend that you clarify the intended use of the submitted device:

Intended Patients:
- For example, is the AED intended for use solely to treat victims of apparent cardiac arrest?
- Are there any patient limitations of the device, such as size or age?

Intended Users:
- Who is intended to operate the AED?
- What training or special skills are required in order to operate the AED?
- Are there specific expectations of non-emergency users of the AED? For example, AEDs deployed throughout a large office building may be maintained by staff who do not expect to respond in the event of a cardiac arrest emergency. These users may nevertheless regularly maintain the AEDs or download use information following an event.

Device Design

We recommend that you identify and describe:

Design features.
- Include size and weight and drawings or photos of the device. Identify and describe all controls and indicators. List and describe everything that is included with the purchase of the device.
- Identify all required accessories, such as batteries and cables.
- Identify any optional accessories that may be used with the device.
- Describe how the device is attached to the patient in order to achieve its intended use.

User Requirements
- Describe what is required of a user of the AED in order to place the device into service.
- Describe what is required of a user of the AED in order to maintain the device in a state of readiness for use.
- Describe what is required in order to use the AED to attempt a rescue of an apparent victim of cardiac arrest. Outline the flow of interactions between device, user and victim as the event proceeds.
- Describe what is required in order to use the device on a pediatric patient, if applicable.
- Describe what is required of a user of the AED following an event in order to place the device back into service and/or retrieve data from the device.

Theory of Operation
- Describe the device's theory of operation. How does the AED achieve its intended use?

• Describe the device's interaction with the AED user and victim during the progress of an event.
• Describe the general theory of the way the AED analyzes a patient's heart rhythm to determine if a shock should be administered. If variables in addition to ECG are factored into a shock/no shock decision, what are the variables and how are they used?
• Describe the electrical therapy is delivered by the AED. In particular, describe similarities and differences with the electrical therapy delivered by a previously cleared AED or manual defibrillator. Note that any substantial difference may require well-substantiated clinical evidence of efficacy. Contact FDA for guidance.

Environmental Limitations
• Describe any environmental limitations on the use of the AED. For example, operational limitations may include operating temperature or vibration limits, or possible limits to operation in wet environments or rain. Possible limits to use may also include, for example, noisy environments that mask voice prompts, or lighting conditions that render displays unviewable.
• Describe any environmental limitation on the AED during shipping, storage or standby. For example, are there temperature extremes beyond the operating range of the AED that may nevertheless be acceptable for a limited exposure during shipping or storage? Are there duration limits to such extremes?
• Are there any unique use, storage or shipping environmental limitations on required AED accessories, such as batteries and electrodes?

Maintenance Expectations
• Describe what is required to set up the AED so that it is ready to use in an emergency.
• Describe what is required to maintain the AED in a state of readiness for use. For example, is there a need for regular testing, inspections or replacement of expiring components such as batteries or electrodes? Are there limits on the service life of the device or its accessories?
• Describe what is required to return the AED to service following use. For example, How is use data extracted (if applicable), what tests may be required, or what components need to be replaced? Is any special cleaning required or does the cleaning process have any limitations?
• Describe what is required to remove the AED or its accessories from service. For example, are there environmental considerations or special procedures for disposal or recycling of the AED or its accessories?

Technical Specifications
Detail the device's specifications and conformance to applicable standards. You should summarize technical specifications to include product, functional, physical and environmental specifications for the device.

Predicate Devices
Under section 513(i) of the Act, you must compare your device with a legally marketed predicate device; in your submission, include its 510(k) number. Show how your device is similar to and differs from the predicate, especially related to identified users, ECG

analysis system, waveform, readiness for use, maintenance and accessories. A side-by-side comparison table is recommended.

6. Risks to Health

The table below identifies risks generally associated with the use of automatic external defibrillators addressed in this document. The table includes measures recommended to mitigate these identified risks, as described in subsequent sections of this guidance document. You should conduct a risk analysis of your product before submitting a 510(k) to identify other risks specific to your device. The 510(k) should describe the risk analysis method you used and the results of your analysis. Use of EN 14971 is recommended. If you elect to use an alternative approach to address a particular risk identified in this document, or to address additional risks you have identified, you should provide sufficient detail to support the approach you have used to address the risk.

Identified Risks	Recommended Mitigation Measures
Inappropriate Shock Recommendation	Section 7. Performance Testing Section 9. Usability Section 11. Labeling
Therapy Not Delivered, Delayed, or Ineffective	Section 7. Performance Testing Section 8. Readiness for Use Section 9. Usability Section 11. Labeling
Inappropriate Shock to Patient, Operator, or Bystander	Section 7. Performance Testing Section 9. Usability Section 11. Labeling
Adverse Tissue Reaction	Section 10. Biocompatibility

7. Performance Testing

General

Bench testing of AEDs should be conducted to meet the requirements of two standards as described below:

1. AAMI/ANSI DF80: 2003, Medical electrical equipment- Part 2-4: Particular requirements for safety for cardiac defibrillators (including automated external defibrillators).

Published by: Association for the Advancement of Medical Instrumentation
1110N. Glebe Road, Suite 220
Arlington, VA 22201-4795

ISBN 1-57020-210-9

Manufacturers should demonstrate compliance with the portions of this Standard applicable to their particular AED design under consideration.

2. AHA Scientific Statement: Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety

A Statement for Health Professionals From the American Heart Association Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy

Kerber, et al, Circulation Vol 95, No 6, March 18, 1997

In particular, all AEDs should demonstrate compliance with the section of this Statement titled "Demonstrating the Accuracy of the Arrhythmia Analysis Algorithm".

AAMI/ANSI DF-80 combines the requirements of earlier AAMI/ANSI standards DF-2 for manual defibrillators and DF-39 for automated defibrillators. The combined standard also aligns with IEC Standard 60601-2-4, although with additional technical material for the United States. IEC 60601-2-4 details defibrillators under a parent general standard, IEC 60601-1, *Medical electrical equipment- Part1: General requirements for safety.* Like the previous standards, DF-80 and its parent general standard provide detailed recommendations to specify and test an AED's physical, operational, environmental and safety characteristics. DF-80 recognizes the rapid evolution in recent years of defibrillation waveform technology. Accordingly, the standard provides only historical perspective on defibrillation waveforms rather than prescriptive waveform specifications. Nevertheless, suggestions are offered on validating the effectiveness of new defibrillation waveform technology. Following the earlier DF-39 standard, DF-80 offers guidance for testing and reporting effectiveness of ECG rhythm analysis systems in AEDs.

In the late 1990s the American Heart Association (AHA) recognized the potential to save large numbers of lives through the widespread deployment of AED technology. Members anticipated that the new AED technology would aim at a very easy-to-use "public access" deployment model. Forecasting large-scale AED clinical trials of this deployment model, the AHA saw the need for an additional consensus standard for AED performance acceptable to the medical community and industry. Following an intensive effort, the resulting Scientific Statement offered practical guidance for robust testing and reporting of AED analysis subsystems for shock/no shock decision-making. In addition, the Scientific Statement offered practical guidelines for demonstrating new defibrillation waveform effectiveness.

Overall Performance Testing

You should test and report AED performance in accordance with the portions of AAMI/ANSI DF-80, above, applicable to your device. We suggest your reports tabulate tests and results per applicable paragraph numbers of the standard.

Arrhythmia Analysis Testing

You should validate and report the your AED's ability to render accurate shock/no shock decisions in accordance with the methodologies detailed in DF-80 and the AHA Scientific Statement described above. In general, the requirements of the AHA Statement are more detailed and stringent. However, the requirements of both standards should be met and reported.

In particular, we recommend that you report in detail:

- How your development and validation rhythm data sets meets the criteria of the Statement, including data set sizes and how the data set was classified.
- How algorithm validation testing using the test data was conducted.
- Test Results per Table 2 of the Statement, i.e., rhythms, minimum test sample size, performance goal, observed performance and 90% one-sided lower confidence limit.
- Test Results per the requirements of DF-80 for the Rhythm Recognition Detector

If the AED's analysis subsystem is to be used on pediatric patients, report in detail how your validation was conducted to assure appropriate operation for this patient category, including any limits to such operation.

In addition, you should describe testing and report test results of your device's ability to cope with adverse circumstances such as data artifact due to patient handling, user error, etc.

Defibrillation Therapy Delivery

We recommend that you describe the electrical waveform delivery characteristics of your device in detail per the requirements of AAMI/ANSI DF-80. Include delivered waveform parameters as a function of resistive loads (representative of patient resistance) across the entire recommended range of the standard.

In particular, provide a detailed side-by-side comparison of the waveform characteristics and delivery accuracy of your AED to a previously cleared AED or manual defibrillator. Comparisons should include waveform electrical parameter variations as a function of load (patient) resistance as required by AAMI/ANSI DF-80. Comparisons should also include shock-to-shock variations, such as escalation (if used), etc. Therapy adjustments for pediatric patients, if applicable, should be described and compared to prior devices.

For minor changes to your AEDs defibrillation waveform parameters, an appropriately designed animal testing series is suggested in order to show that, using a previously cleared waveform as a control, unexpected changes in efficacy or safety have not occurred.

If your AED's electrical therapy characteristics are markedly different from a previously cleared defibrillator product, then appropriate animal and/or clinical safety and efficacy study data may be required. For clinical study design, useful guidance may be found in AAMI/ANSI DF-80 or the AHA Scientific Statement listed above. Clinical studies, if undertaken, should be designed to meet or exceed the statistical confidence recommendations of these standards. (For example, to demonstrate equivalence using the AHA Statement, the upper boundary of the 90% confidence interval of the difference between the new defibrillation therapy and an established control should be ≤10%.) Studies to acquire defibrillation performance data should be coordinated with FDA during design, and are expected to be similar if not identical to those required for approval of new waveforms for manual defibrillators.

Environmental Qualification

The intended use of AEDs may include storage and operation in a wide range of environmental conditions. Your AED should be qualified to perform across the spectrum of environments it may encounter. You should test and report the performance of your AED per the environmental requirements of AAMI/ANSI DF-80 and its parent IEC standards. The Standards provide testing to address the effects of, among other environmental factors:

- Temperature extremes
- Water ingress
- Humidity

- Electromagnetic compatibility

In particular, you should be sure to report the performance of your AED in the environment of its intended use. If the environment of intended use exceeds the requirements of AAMI/ANSI DF-80 or its parent standards, (for example, an AED intended for use in extremely cold temperatures) that environment should be described and performance in that environment reported.

Electrical Safety

Electrical safety for any medical device is important, and for AEDs it is a key performance parameter. AAMI/ANSI DF-80 and its parent IEC standards outline comprehensive testing to assure the safety of both patient and operator from electrical hazards. The standards prescribe testing that addresses, in addition to other internationally recognized electrical safety factors:

- Protection from excessive leakage currents,
- Adequacy of dielectric strength in device construction,

- Protection from accidental discharge.
- Safety assurance in the event of fault conditions..

You should test and report in detail the performance of your AED to the electrical safety requirements of AAMI/ANSI DF-80 and its parent standards.

Additional AED Features

Depending on the intended use model of a particular AED, the device may offer features in addition to automated defibrillation capabilities. For example, devices intended for infrequent users may offer guidance to assist in following resuscitation protocols. Such devices may use voice prompts to remind the operator to alert emergency medical services or to provide cardiopulmonary resuscitation (CPR) guidance at appropriate times.

If your AED provides additional functionality, the functionality should be completely described and the performance of such additional features should be reported.

8. Readiness for Use

Automated external defibrillators encounter a very wide range of actual use frequencies. A hospital monitor /defibrillator with AED functionality may be used often, perhaps daily or weekly. Conversely, other types of AEDs may be widely deployed in situations that call upon any particular device only very infrequently. Such AEDs may be deployed in standby service for months or years before being applied in an emergency. Further, AEDs may be deployed in standby service in a variety of environments. Standby environments may range from relatively benign office buildings to more environmentally challenging situations such as police vehicles. Extended standby time provides opportunities for AED readiness to be compromised through damage, battery depletion, electrode expiration, etc.

Regardless of deployment situations, AED users should have a means of assessing the readiness for use of their AEDs while in standby service.

Manufacturers should report how users should assess their AED's readiness for use during standby periods. The report should include:

- Intended use model and expected standby times.
- A description of how the device signals its status regarding readiness for use.
- The methods a user must follow to assess readiness of an AED. (Automated or manual testing, looking at a readiness indicator or expiration date, etc. If additional tools and equipment are required to assess readiness, they should be described in the report)
- A description of required procedures to place the AED in service and to maintain it during standby service (Setup, battery and/or electrode replacement, etc).

• A description of any limitations on the assessment of AED readiness for use. For example, if the AED performs periodic self-testing, is such testing suspended during adverse environmental conditions such as extreme cold? If so, how is readiness or readiness reporting status compromised?
• A complete description of the design measures and validations used by the manufacturer to provide assurance of readiness to the user.

9. Usability

AED user populations have a wide range of training, skills and experience. An AED in a hospital or EMS setting may be operated by a highly skilled medical professional. Conversely, another AED may be used by a passer-by in an airport who has never responded to a cardiac arrest emergency or handled an AED before.

Accordingly, AED manufacturers should characterize the likely users of their AEDs. Manufacturers should then assure that these users of the their devices can reasonably be expected to successfully employ AEDs for their intended use.

Robust AED usability is achieved through a continuum of appropriate device design coupled with adequate supplemental labeling. For example, if a manufacturer's intended user of an AED includes an airport passer-by, then that user should expect to be guided primarily by AED functional design more than labeling such as instructions manuals. The AED's human interface and sequences of operation (such as voice prompts and primary controls, indicators and labels) should provide the user an adequate chance of successful use. Additional labeling may be useful for the AED program administrator to, for example, set up and maintain the device, or download information about its use.

Useful introductory guidance on usability design and assessment may be found in:

Do It By Design, An Introduction to Human Factors in Medical Devices
by Dick Sawyer, December, 1996
(Available from FDA)

This document provides useful design guidance and advice, but appropriately emphasizes that confidence in usability is only achieved following realistic testing with intended users.

AED manufacturers generally demonstrate and report usability via studies of the AED conducted with an appropriately sized sample of users from the intended user population. These users apply the AEDs being evaluated to manikins simulating cardiac arrest victims. Test administrators score the results for proper application and safe operation of the candidate AED. Usability test requirements may vary as described below.

Automatic External Defibrillators under Product Code MKJ (requires prescription)

AEDs cleared under Product Code MKJ require a prescription for sale. Prescribing authorities are responsible for assuring that adequate programs for training and AED deployment are in place for the intended use of the AEDs.

Manufacturers should provide adequate labeling and other materials as needed to assist prescribing authorities in setting up and maintaining successful AED programs. The materials may include training programs and materials, training videos or computer training aids, wall placards, posters, wall mounts, maintenance kits, etc. If such materials are required to permit an operator to successfully operate an AED, the materials should be submitted during the AED clearance process.

Most AEDs in the past two decades have been prescription devices, and those intended for a public access use model have evolved fairly simple user interfaces. Prescribing authorities have set up many successful AED programs with such devices.

Given the established history of prescription AEDs, manufacturers have considerable experience with the usability of these devices. Accordingly, AED manufacturers submitting prescription AEDs should show in detail how, if appropriate, their interfaces are similar to previously cleared devices with successfully demonstrated usability. In such cases, limited usability studies with representative intended users may be adequate to demonstrate the AED's usability. Nevertheless, changes to the design or use model for new AEDs may require more detailed usability studies with larger user populations to confidently demonstrate to FDA and prescribing authorities that the new devices can be used safely and effectively. Such studies, if performed, should be designed using well-established statistical methodology.

Manufacturers submitting AEDs that include use on children should address the appropriate usability of their AED for adult and pediatric use. For example, how does the design mitigate inappropriate delivery of adult therapy to a pediatric patient, or the delivery of pediatric therapy to an adult patient?

In general, manufacturers should submit adequate user testing to assure that new features can be used safely and reliably.

Also refer to the Labeling section, below.

Automatic External Defibrillators under Product Code NSA (no prescription required)

AEDs cleared under Product Code NSA may be sold without a prescription (over-the-counter, or OTC). In this case, included product labeling must be adequate for safe and effective use of the product without additional training or oversight.

AED labeling under Product Code NSA should be written for use by a lay audience and tested to assure that it can be adequately understood to permit purchasers to set up,

maintain, and ultimately use their AEDs as intended. Refer to the Labeling section, below.

There is no assurance that purchasers of a non-prescription AED will read the labeling. Therefore, to assure safety, the AED's usability should be tested with untrained individuals who are unfamiliar with AEDs. The tests should demonstrate that users are unlikely to cause harm to themselves or others, and that they will have a reasonable chance of successfully treating a simulated victim of cardiac arrest. Tests should be designed and conducted in a scientifically valid manner, with adequate statistical power to assure safety. It is recommended that manufacturers seeking OTC clearance consult with FDA regarding use study design to assure that the usability testing protocol is adequate to demonstrate safe and effective OTC AED use.

10. Biocompatibility

We recommend that you evaluate the biocompatibility of the patient-contacting materials as prescribed in the FDA guidance on **International Standard Organization (ISO) standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing".**

Testing should be in accordance with the expected maximum patient contact duration for your AED's intended use.

We recommend that you provide a list of patient contacting materials in your device. If identical materials are used in a predicate device with the same type and duration of patient contact, you may identify the predicate device in lieu of performing biocompatibility testing. Materials are identical if they have the identical chemical formulation and identical manufacturing processes.

11. Labeling

The premarket notification should include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed assisting you in preparing labels that satisfies the requirements of 21 CFR 807.87 (e).

Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce.

Automatic External Defibrillators under Product Code MKJ (requires prescription)

AEDs cleared under Product Code MKJ require a prescription for sale. Final labeling for prescription devices must comply with 21 CFR 801.109.

Under 21 CFR 807.87(e), Manufacturers should provide clear and concise instructions delineating how the device is to be used on patients, and the technical features of the device.

Manufacturers should provide adequate labeling and other materials as needed to assist prescribing authorities in setting up and maintaining safe and effective AED programs. The materials may include training programs and materials, training videos or computer training aids, wall placards, posters, wall mounts, maintenance kits, etc. If such materials are required to permit an operator to successfully operate an AED, the materials should be submitted during the AED clearance process.

Automatic External Defibrillators under Product Code NSA (no prescription required)

AEDs cleared under Product Code NSA may be sold without a prescription (over-the-counter). In this case, included product labeling must be adequate for safe and effective use of the product without additional training or oversight.

Under 21 CFR 807.87(e), Manufacturers should provide clear and concise instructions delineating how the device is to be used on patients, and the technical features of the device.

AED labeling under Product Code NSA should be written for use by a lay audience to assure that it can be adequately understood to permit purchasers to set up, maintain, and ultimately use their AEDs as intended.

Labeling for over-the counter AEDs should be tested with representative users. The testing should assure that intended users reading the labeling materials achieve sufficient comprehension of the material for the safe and effective use of the AED. Tests should be designed and conducted in a scientifically valid manner, with adequate statistical power to assure reliability of the results. It is recommended that manufacturers consult with FDA regarding label study design to assure that the protocol is adequate to demonstrate safe and effective AED use by users using the device labeling.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: April 30, 2009

DISCLOSURE: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

The following information concerning Lance Becker; Gust Bardy; PAD and HAT trials invs. (*Name of clinical investigator*), who participated as a clinical investigator in the submitted study Human Factors Impact Successful Lay Person AED Use; PAD (*Name of*) trial; HAT trial (*clinical study*) is submitted in accordance with 21 CFR part 54. The named individual has participated in financial arrangements or holds financial interests that are required to be disclosed as follows:

Please mark the applicable check boxes.

☐ any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;

☑ any significant payments of other sorts made on or after February 2, 1999 from the sponsor of the covered study such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;

☐ any proprietary interest in the product tested in the covered study held by the clinical investigator;

☐ any significant equity interest as defined in 21 CFR 54.2(b), held by the clinical investigator in the sponsor of the covered study.

Details of the individual's disclosable financial arrangements and interests are attached, along with a description of steps taken to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.

NAME	TITLE
Tamara Yount	Senior Regulatory Affairs Specialist
FIRM/ORGANIZATION: Philips Medical Systems	
SIGNATURE: Tamara Yount	DATE: 08/05/2009

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 4 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to:

Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14-72
Rockville, MD 20857

Lance Becker

A co-author of the Callejas human factors study, Lance Becker, received more than $25,000, for services unrelated to the trial, during the period of the human factors trial and for one year following the completion of the trial.[1] For this particular study, Philips supplied the defibrillators and accessories, had input on the study design and Philips personnel helped conduct the simulations during the trial. Philips approached Dr. Becker to perform the study. Devices used in the study were returned to Philips. Since Dr. Becker performed his own analysis with the help of independent statisticians, any potential bias of the study results due to the financial arrangement was minimized. In addition, he was only one of several investigators. Payments for Dr. Becker's services were at fair market value and should have had no impact on the results of the study contained herein in which he participated.

PAD and HAT trials

Erring on the side of caution, we have included Philips as a sponsor (under 21 CFR 54.2(h)) because the company provided defibrillators for use in the PAD and HAT trials.[2] The devices were not returned at the end of either of the trials. We are disclosing this support of the trial, although we believe it is unlikely to have constituted a financial arrangement that exceeded $25,000 in payments of other sorts. Although the aggregate value of the AEDs exceeded the reporting threshold of $25,000, we believe that no investigator received more than $25,000 worth of devices, particularly after calculating the value of the devices at the end of the trial (note that the costs of the trial are not to be included in the $25,000 calculation).

PAD trial

Philips was one of the three manufacturers that provided approximately 500-600 defibrillators for a total of 1600 defibrillators as part of the PAD study. The devices supplied retail at a value of approximately $1200. Philips was not involved in the study design, study management or data analysis. Philips was blinded to study results until publication. Because Philips had no control over where or how the devices were distributed or the study publications, we do not believe that any bias resulted from donating the devices, and Philips remoteness from the trial would further minimize bias, assuming any occurred.

HAT trial

For this particular study, Philips supplied approximately 2500 defibrillators (and accessories) for the study. The devices supplied retail at a value of approximately $1200. Philips was blinded to study results until publication. Because the study was overseen by a government entity (NIH) and the analysis and publications were independent of Philips, we do not believe that any bias resulted, and Philips remoteness from the trial would further minimize bias of these financial arrangements on study results, assuming any occurred.

---

[1] Callejas, Barry, Demertsidis, Jorgenson, Becker. "Human Factors Impact Successful Lay Person Automated External Defibrillator Use During Simulated Cardiac Arrest." *Crit. Care Med* 2004, Vol 32.

[2] PAD trial: Public Access Defibrillation and Survival after Out-of-Hospital Cardiac Arrest. NEJM 351; 637-646, August 12, 2004

HAT trial: Home Use of Automated External Defibrillators for Sudden Cardiac Arrest. NEJM 358;17, April 24, 2008.

Gust Bardy

The lead author of the HAT trial, Gust Bardy, received more than $25,000 annually from Philips, for services unrelated to the trial, during the course of the trial plus one year after trial completion. He was only one of numerous investigators. Payments for Dr. Bardy's services were at fair market value. For that reason and due to the study's design as described above, the potential for bias of this financial arrangement is minimized.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: April 30, 2009

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

☑ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators		
	Dr. Anthony D. Andre (AED Use by Untrained Bystanders)	

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Tamara Younl	Senior Regulatory Affairs Specialist
FIRM/ORGANIZATION: Philips Medical Systems	
SIGNATURE: Tamara Younl	DATE: 08/05/2009

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

FORM FDA 3454 (4/06)

ISE Daytec (301)443-1090 EF

AED BIBLIOGRAPHY

1. ACOEM, "Automated External Defibrillation in the Occupational Setting," May 2006, at http://www.acoem.org/guidelines.aspx?id=564#

2. AHA, "ECC Guidelines, Part 4: The Automated External Defibrillator," *Circulation.* 2000;. 102:1-60.

3. AHA, "Every Minute Counts – AED Saves Pflugerville Student's Life," Sept. 24, 2003, at http://www.americanheart.org/presenter.jhtml?identifier=3015578

4. Ali B, Bloom H, Veledar E, House D, Norvel R, Dudley SC, Zafari AM. Automated external cardioversion defibrillator monitoring in cardiac arrest: a randomized trial. *Trials*. 2008 Jun 11; 9:36.

5. American Red Cross, "New Study Results Underscore Need for AEDs in Public Places" (Oct. 22, 2002), at http://www2.redcross.org/news/hs/cpraed/021022aed.html

6. American Red Cross, "Saving a Life Is as Easy as A-E-D," at http://www2.redcross.org/services/hss/courses/aed.html

7. Andre AD, et al. Automated external defibrillator use by untrained bystanders:can the public-use model work? *Prehosp Emerg Care.* 2004 Jul-Sep; 8(3):284-91.

8. ARC, "AED Frequently Asked Questions (External Audiences)," at http://www.redcross.org/www-files/Documents/pdf/Preparedness/AED_FAQs.pdf

9. Atkins DL, et al. Sensitivity and specificity of an automated external defibrillator algorithm designed for pediatric patients. *Resuscitation.* 2008; 76, 168-74.

10. Atkinson E, et al. Specificity and sensitivity of automated external defibrillator rhythm analysis in infants and children. *Ann Emerg Med.* 2003;42;185-196.

11. Aufderheide T, Hazinski MF, Nichol G, et al. AHA Policy Recommendation, Community Lay Rescuer Automated External Defibrillation Programs: Key State Legislative Components and Implementation Strategies. *Circulation.* 2006, available at http://www.americanheart.org/presenter.jhtml?identifier=3004600

12. Balady G, Chatiman B et al. AHA/ACSM Scientific Statement. Automated External Defibrillators in Health/Fitness Facilities, Supplement to the AHA/ACSM Recommendations for Cardiovascular Screening, Staffing, and Emergency Policies at Health/Fitness Facilities. *Circulation.* 2002; 105; 1147-1150.

13. Bardy, G. H.; Lee, K. L.; Mark, D. B.; Poole, J. E.; Toff, W. D.; Tonkin, A. M.; Smith, W.; Dorian, P.; Packer, D. L.; White, R. D.; Longstreth, W. T. Jr; Anderson, J.; Johnson, G.; Bischoff, E.; Yallop, J. J.; McNulty, S.; Ray, L. D.; Clapp-Channing, N. E.; Rosenberg, Y., and Schron, E. B. Home use of automated external defibrillators for sudden cardiac arrest. *N Engl J Med.* 2008 Apr 24; 358(17): 1793-1804.

14. Beckers et al., Minimal Instructions Improve the Performance of Laypersons in the Use of Semiautomatic and Automatic External Defibrillators. *Crit. Care Med.*, 2005; 9:R110-R116.

15. Caffrey, S. L.; Willoughby, P. J.; Pepe, P. E., and Becker, L. B. Public use of automated external defibrillators. *N Engl J Med.* 2002 Oct 17; 347(16):1242-47.

16. Callejas et al, Human Factors Impact Successful Lay Person Automated External Defibrillator Use During Simulated Cardiac Arrest. *Crit. Care Med.*, 2004; 32(9):5406-13.

17. Cecchin, F.; Jorgenson, D. B.; Berul, C. I.; Perry, J. C.; Zimmerman, A. A.; Duncan, B. W.; Lupinetti, F. M.; Snyder, D.; Lyster, T. D.; Rosenthal, G. L.; Cross, B., and Atkins, D. L. Is arrhythmia detection by automatic external defibrillator accurate for children?: Sensitivity and specificity of an automatic external defibrillator algorithm in 696 pediatric arrhythmias. *Circulation.* 2001 May 22; 103(20):2483-88.

18 The Citizen CPR Foundation, Position Statement, at http://www.citizencpr.org/1position.html; American College of Emergency Physicians, "Automatic External Defibrillators," at http://www3.acep.org/patients.aspx?id=26022

19 Culley LL, et al. Public access defibrillation in out-of-hospital cardiac arrest: a community-based program. *Circulation*, 2004; 109:1859-63.

20. Cummins, RO et al. Guidelines 2000 for cardiopulmonary resuscitation and emergency cardiovascular care. Supplement to *Circulation* 2000; 102(8):I-5, I-63, I-91.

21. Drezner JA, et al. Effectiveness of Emergency Response Planning for Sudden Cardiac Arrest in United States High Schools with Automated External Defibrillators. *Circulation.*2009; 120:518-25.

22. Eames P, et al. Comparison of ease of use of three automated external defibrillators by untrained lay people. *Resuscitation.* 2003; 58: 25-30.

23. FDA News Release, *Journal of American Medical Association Article on Recalls and Safety Alerts Affecting Automated External Defibrillators,* August 10, 2006, available at:

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108710.htm

24. *FDA Stresses Human Factors Design for Home-Use Devices,* The Silver Sheet, Vol. 13, No. 5 (May 2009).

25. Fleischhackl R, et al. Differing operational outcomes with six commerically avialable automated external defibrillators. *Resuscitation.* 2004 Aug; 62(2):167-174.

26. Fleischhackl R, et al. Automated external defibrillators do not recommend false positive shocks under the influence of electromagnetic field present at public locations. *Anesth Analg.* 2006; 103:1485-88.

27. Fleischhackl R, et al. Influence of electromagnetic fields on function of automated external defibrillators. *Academic Emergency Medicine.* 2006:13:1-6.

28. Gliner, B. E.; Jorgenson, D. B.; Poole, J. E.; White, R. D.; Kanz, K. G.; Lyster, T. D.; Leyde, K. W.; Powers, D. J.; Morgan, C. B.; Kronmal, R. A., and Bardy, G. H. Treatment of out-of-hospital cardiac arrest with a low-energy impedance-compensating biphasic waveform automatic external defibrillator. The LIFE Investigators. *Biomed Instrum Technol.* 1998 Nov-1998 Dec 31; 32(6):631-44.

29. Gombotz H, Weh B, Mitterndorfer W, Rehak P. In-hospital cardiac resuscitation outside the ICU by the nursing staff equipped with automated external defibrillators—The first 500 cases. *Resuscitation.* 2006 Sep; 70(3):416-22. Epub 2006 Aug 14.

30. Gundry JW, Comess KA, DeRook FA, et al. Comparaison of naïve sixth-grade children with trained professionals in the use of an automated external defibrillator. *Circulation.* 1999; 100:1703-07.

31. Hallstrom A and Ornato JP. Public-Access Defibrillation and Survival after out-of-hospital cardiac arrest: the public access defibrillation trial investigators. *N Engl J Med.* 2004; 351:637-46.

32. Hanefeld C, Lichte C, Mentges-Schröter I, Sirtl C, Mügge A. Hospital-wide First Responder Automated External Defibrillator Programme: 1 year experience. *Resuscitation.* 2005 Aug; 66(2): 167-70.

33. Hanefeld C, Lichte C, Laubenthal H, Hanke E, Mügge A. In-hospital resuscitation. Concept of first-responder resuscitation using semi-automated external defibrillators (AED) *Dtsch Med Wochenschr.* 2006 Sep 29; 131 (39):2139-42.

34. Harve H, et al. AED use in a passenger during a long-haul flight: repeated defibrillation with a successful outcome. *Aviation, Space and Environmental Medicine*, 2009. 80(4) 405-08.

35. Hazinski MF, Idris AH, Kerber RE et al. AHA Science Advisory: Lay Rescuer Automated External Defibrillator ("Public Access Defibrillation") Programs: Lessons Learned from an International Multicenter Trial. Advisory Statement from the American Heart Association Emergency Cardiovascular Committee; the Council on Cardiopulmonary, Perioperative, and Critical Care; and the Council on Clinical Cardiology. *Circulation*. 2005; 111; 3336-40.

36. Hess EP, et al. A high peak current 150-J fixed-energy defibrillation protocol treats recurrent ventricular fibrillation as effectively as initial VF. *Resuscitation* 2008; 79, 28-33.

37. HHS Health Resources & Services Administration, "2005 Annual Report."

38. Jorgenson DB, Skarr T, Russell JK, et al. AED use in businesses, public facilities and homes by minimally-trained first responders. *Resuscitation* 2003; 59:225-33.

39. Kanz, KG et al. Susceptibility of automated external defibrillators to training overhead lines and metro third rails. *Resuscitation*. 2004; 62:189-98.

40. Kerber R.E., Becker L, et al. AHA Scientific Statement, Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety. *Circulation*. 1997; 95, 1677-83.

41. Kyller M, Johnstone D. A 2-Tiered Approach to In-Hospital Defibrillation: Nurses Respond to a Trial of Using Automated External Defibrillators as Part of a Code-Team Protocol. *Crit Care Nurse*. 2005 Aug; 25(4):25-33.

42. Løfgren B, Wahlgreen C, Hoffmann AM, Poulsen TS, Krarup NH. In-hospital resuscitation with automated external defibrillator *Ugeskr Laeger*. 2009 Jan 26; 171(5): 308-10.

43. Lyster TS, et al. The safe use of automated external defibrillators in a wet environment. *Prehospital Emergency Care*. 2003. 7:3, 307-311

44. MacDonald RD et al. Performance and Error Analysis of Automated External Defibrillator Use in the out-of-hospital setting. *Ann Emerg Med*. 2001;38:262-267.

45. National Conference of State Legislatures, "State Laws on Cardiac Arrest & Defibrillators," Jan. 2, 2009, at http://www.ncsl.org/IssuesResearch/Health/LawsonCardiacArrestandDefibrillatorsAEDs/ tabid/14506/Default.aspx

46. NSC, "National Safety Council and Occupational Safety and Health Administration Renew Alliance:," Oct. 15, 2007, at http://www.nsc.org/news/occupational.aspx

47. NSC, "National Safety Council Praises House Passage of the Josh Miller HEARTS Act," June 3, 2009, at http://www.nsc.org/news/JoshMiller_HEARTS_act.aspx

48. Nurmi *et al.*, "Adherence to guidelines when positioning defibrillation electrodes," *Resuscitation.* 2004; 61: 143-47.

49. Page, R. L.; Joglar, J. A.; Kowal, R. C.; Zagrodzky, J. D.; Nelson, L. L.; Ramaswamy, K.; Barbera, S. J.; Hamdan, M. H., and McKenas, D. K. Use of automated external defibrillators by a U.S. Airline. *N Engl J Med.* 2000 Oct 26; 343(17):1210-16.

50. Peberdy, M. A.; Ottingham, L. V.; Groh, W. J.; Hedges, J.; Terndrup, T. E.; Pirrallo, R. G.; Mann, N. C., and Sehra, R. Adverse events associated with lay emergency response programs: The public access defibrillation trial experience. *Resuscitation.* 2006 Jul; 70(1):59-65.

51. Poole, J. E.; White, R. D.; Kanz, K. G.; Hengstenberg, F.; Jarrard, G. T.; Robinson, J. C.; Santana, V.; McKenas, D. K.; Rich, N.; Rosas, S.; Merritt, S.; Magnotto, L.; Gallagher, J. V. 3rd; Gliner, B. E.; Jorgenson, D. B.; Morgan, C. B.; Dillon, S. M.; Kronmal, R. A., and Bardy, G. H. Low-energy impedance-compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out-of-hospital cardiac arrest. LIFE Investigators. *J Cardiovasc Electrophysiol.* 1997 Dec; 8(12):1373-85.

52. Rossano JW, Jefferson LS, Smith EO, Ward MA, Mott AR. Automated External Defibrillators and Simulated In-hospital Cardiac Arrests. *J Pediatr.* 2009 May; 154(5): 672-76. Epub 2009 Jan 23.

53. Samson RA, Berg RA, Bingham R, et al. ILCOR Advisory Statement, Use of AEDs for Children: An update: An Advisory Statement from the Pediatric Advanced Life Support Task Force, International Liaison Committee on Resuscitation. *Circulation.* 2003; 107; 3250-55.

54. Sandroni et al., Automated External Defibrillation By Untrained Deaf Lay Rescuers. *Resuscitation.* 2004; 63:43-48

55. Sanna, T *et al.*, "Cardiopulmonary resuscitation alone vs. cardiopulmonary resuscitation plus automated external defibrillator use by non-healthcare professionals: A meta-analysis on 1583 cases of out-of-hospital cardiac arrest," *Resuscitation.* 2008, 76(2):226-32.

56. Schneider T, Martens PR, Paschen H, et al. Multicenter, randomized, controlled trial of 150-J biphasic shocks compared with 200- to 360-J monophasic shocks in the resuscitation of out-of-hospital cardiac arrest victims. *Circulation* 2000; 102:1780-87.

57. Shah JS, Maisel WH, "Recalls and Safety Alerts Affecting Automated External Defibrillators," *JAMA*. 2006 Aug 9; 296(6):655-60.

58. Snyder, DE *et. al.*, "External series resistors accurately model waveform time course, but not cardiac dose in animal models of defibrillation," *Resuscitation*, 2003; 56:238.

59. Stolzenberg BT, et al. Automated external defibrillators appropriately recognize ventricular fibrillation in electromagnetic fields. *Prehosp Emerg Care*. 2002 Jan-Mar; 6(1):65-66.

60. The Sudden Cardiac Arrest Association, "2008 Annual Report on Advocacy, Awareness, Education and Impact."

61. Valenzuela TD, Roe DJ, Nichol G, et al. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. *N Engl J Med* 2000; 343:1206-09.

62. van Alem AP, et al. VF recurrence: characteristics and patient outcome in out-of-hospital cardiac arrest. *Resuscitation*. 2003; 59: 181-88.

63. White RD, Blanton DM. Biphasic truncated exponential waveform defibrillation. *Prehosp Emerg Care* 1999; 3:283-89.

64. White RD, Russell JK. Refibrillation, resuscitation and survival in out-of-hospital sudden cardiac arrest victims treated with biphasic automated external defibrillators. *Resuscitation* 2002 Oct; 55(1):17-23.

65. Whitfield R, et al. The department of health national defibrillator programme: analysis of downloads from 250 deployments of public access defibrillators. *Resuscitation*. 2005; 64: 269-77.

COPIES OF SOURCE DOCUMENTATION

1. NSC, "National Safety Council Praises House Passage of the Josh Miller HEARTS Act," June 3, 2009, at http://www.nsc.org/news/JoshMiller_HEARTS_act.aspx

2. Hanefeld C, Lichte C, Laubenthal H, Hanke E, Mügge A. In-hospital resuscitation. Concept of first-responder resuscitation using semi-automated external defibrillators (AED) *Dtsch Med Wochenschr.* 2006 Sep 29; 131 (39):2139-42.

3. Gombotz H, Weh B, Mitterndorfer W, Rehak P. In-hospital cardiac resuscitation outside the ICU by the nursing staff equipped with automated external defibrillators—The first 500 cases. *Resuscitation.* 2006 Sep; 70(3):416-22. Epub 2006 Aug 14.

4. Kyller M, Johnstone D. A 2-Tiered Approach to In-Hospital Defibrillation: Nurses Respond to a Trial of Using Automated External Defibrillators as Part of a Code-Team Protocol. *Crit Care Nurse.* 2005 Aug; 25(4):25-33.

5. Hanefeld C, Lichte C, Mentges-Schröter I, Sirtl C, Mügge A. Hospital-wide First Responder Automated External Defibrillator Programme: 1 year experience. *Resuscitation.* 2005 Aug; 66(2): 167-70.

6. Rossano JW, Jefferson LS, Smith EO, Ward MA, Mott AR. Automated External Defibrillators and Simulated In-hospital Cardiac Arrests. *J Pediatr.* 2009 May; 154(5): 672-76. Epub 2009 Jan 23.

7. Løfgren B, Wahlgreen C, Hoffmann AM, Poulsen TS, Krarup NH. In-hospital resuscitation with automated external defibrillator *Ugeskr Laeger.* 2009 Jan 26; 171(5): 308-10.

8. Ali B, Bloom H, Veledar E, House D, Norvel R, Dudley SC, Zafari AM. Automated external cardioversion defibrillator monitoring in cardiac arrest: a randomized trial. *Trials.* 2008 Jun 11; 9:36.

9. Hazinski MF, Idris AH, Kerber RE et al. AHA Science Advisory: Lay Rescuer Automated External Defibrillator ("Public Access Defibrillation") Programs: Lessons Learned from an International Multicenter Trial. Advisory Statement from the American Heart Association Emergency Cardiovascular Committee; the Council on Cardiopulmonary, Perioperative, and Critical Care; and the Council on Clinical Cardiology. *Circulation.* 2005; 111; 3336-40.

10. Hallstrom A and Ornato JP. Public-Access Defibrillation and Survival after out-of-hospital cardiac arrest: the public access defibrillation trial investigators. *N Engl J Med.* 2004; 351:637-46.

11. AHA, "ECC Guidelines, Part 4: The Automated External Defibrillator," *Circulation.* 2000;. 102:1-60.

12. The Citizen CPR Foundation, Position Statement, at http://www.citizencpr.org/1position.html; American College of Emergency Physicians, "Automatic External Defibrillators," at http://www3.acep.org/patients.aspx?id=26022

13. ACOEM, "Automated External Defibrillation in the Occupational Setting," May 2006, at http://www.acoem.org/guidelines.aspx?id=564#

14. Aufderheide T, Hazinski MF, Nichol G, et al. AHA Policy Recommendation, Community Lay Rescuer Automated External Defibrillation Programs: Key State Legislative Components and Implementation Strategies. *Circulation.* 2006, available at http://www.americanheart.org/presenter.jhtml?identifier=3004600

15. ARC, "AED Frequently Asked Questions (External Audiences)," at http://www.redcross.org/www-files/Documents/pdf/Preparedness/AED_FAQs.pdf

16. National Conference of State Legislatures, "State Laws on Cardiac Arrest & Defibrillators," Jan. 2, 2009, at http://www.ncsl.org/IssuesResearch/Health/LawsonCardiacArrestandDefibrillatorsAEDs/ tabid/14506/Default.aspx

17. Balady G, Chatiman B et al. AHA/ACSM Scientific Statement. Automated External Defibrillators in Health/Fitness Facilities, Supplement to the AHA/ACSM Recommendations for Cardiovascular Screening, Staffing, and Emergency Policies at Health/Fitness Facilities. *Circulation.* 2002; 105; 1147-1150.

18. Samson RA, Berg RA, Bingham R, et al. ILCOR Advisory Statement, Use of AEDs for Children: An update: An Advisory Statement from the Pediatric Advanced Life Support Task Force, International Liaison Committee on Resuscitation. *Circulation.* 2003; 107; 3250-55.

19. Kerber R.E., Becker L, et al. AHA Scientific Statement, Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety. *Circulation.* 1997; 95, 1677-83.

20. Drezner JA, et al. Effectiveness of Emergency Response Planning for Sudden Cardiac Arrest in United States High Schools with Automated External Defibrillators. *Circulation.*2009; 120:518-25.

21. Peberdy, M. A.; Ottingham, L. V.; Groh, W. J.; Hedges, J.; Terndrup, T. E.; Pirrallo, R. G.; Mann, N. C., and Sehra, R. Adverse events associated with lay

emergency response programs: The public access defibrillation trial experience. *Resuscitation.* 2006 Jul; 70(1):59-65.

22. Bardy, G. H.; Lee, K. L.; Mark, D. B.; Poole, J. E.; Toff, W. D.; Tonkin, A. M.; Smith, W.; Dorian, P.; Packer, D. L.; White, R. D.; Longstreth, W. T. Jr; Anderson, J.; Johnson, G.; Bischoff, E.; Yallop, J. J.; McNulty, S.; Ray, L. D.; Clapp-Channing, N. E.; Rosenberg, Y., and Schron, E. B. Home use of automated external defibrillators for sudden cardiac arrest. *N Engl J Med.* 2008 Apr 24; 358(17): 1793-1804.

23. Poole, J. E.; White, R. D.; Kanz, K. G.; Hengstenberg, F.; Jarrard, G. T.; Robinson, J. C.; Santana, V.; McKenas, D. K.; Rich, N.; Rosas, S.; Merritt, S.; Magnotto, L.; Gallagher, J. V. 3rd; Gliner, B. E.; Jorgenson, D. B.; Morgan, C. B.; Dillon, S. M.; Kronmal, R. A., and Bardy, G. H. Low-energy impedance-compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out-of-hospital cardiac arrest. LIFE Investigators. *J Cardiovasc Electrophysiol.* 1997 Dec; 8(12):1373-85.

24. Gliner, B. E.; Jorgenson, D. B.; Poole, J. E.; White, R. D.; Kanz, K. G.; Lyster, T. D.; Leyde, K. W.; Powers, D. J.; Morgan, C. B.; Kronmal, R. A., and Bardy, G. H. Treatment of out-of-hospital cardiac arrest with a low-energy impedance-compensating biphasic waveform automatic external defibrillator. The LIFE Investigators. *Biomed Instrum Technol.* 1998 Nov-1998 Dec 31; 32(6):631-44.

25. Page, R. L.; Joglar, J. A.; Kowal, R. C.; Zagrodzky, J. D.; Nelson, L. L.; Ramaswamy, K.; Barbera, S. J.; Hamdan, M. H., and McKenas, D. K. Use of automated external defibrillators by a U.S. Airline. *N Engl J Med.* 2000 Oct 26; 343(17):1210-16.

26. Cecchin, F.; Jorgenson, D. B.; Berul, C. I.; Perry, J. C.; Zimmerman, A. A.; Duncan, B. W.; Lupinetti, F. M.; Snyder, D.; Lyster, T. D.; Rosenthal, G. L.; Cross, B., and Atkins, D. L. Is arrhythmia detection by automatic external defibrillator accurate for children?: Sensitivity and specificity of an automatic external defibrillator algorithm in 696 pediatric arrhythmias. *Circulation.* 2001 May 22; 103(20):2483-88.

27. Caffrey, S. L.; Willoughby, P. J.; Pepe, P. E., and Becker, L. B. Public use of automated external defibrillators. *N Engl J Med.* 2002 Oct 17; 347(16):1242-47.

28. MacDonald RD et al. Performance and Error Analysis of Automated External Defibrillator Use in the out-of-hospital setting. *Ann Emerg Med.* 2001;38:262-267.

29. Atkins DL, et al. Sensitivity and specificity of an automated external defibrillator algorithm designed for pediatric patients. *Resuscitation.* 2008; 76, 168-74.

30. Atkinson E, et al. Specificity and sensitivity of automated external defibrillator rhythm analysis in infants and children. *Ann Emerg Med.* 2003;42;185-196.

31. Cummins, RO et al. Guidelines 2000 for cardiopulmonary resuscitation and emergency cardiovascular care. Supplement to *Circulation* 2000; 102(8):I-5, I-63, I-91.

32. Snyder, DE *et. al.*, "External series resistors accurately model waveform time course, but not cardiac dose in animal models of defibrillation," *Resuscitation*, 2003; 56:238.

33. White RD, Blanton DM. Biphasic truncated exponential waveform defibrillation. *Prehosp Emerg Care* 1999; 3:283-89.

34. Schneider T, Martens PR, Paschen H, et al. Multicenter, randomized, controlled trial of 150-J biphasic shocks compared with 200- to 360-J monophasic shocks in the resuscitation of out-of-hospital cardiac arrest victims. *Circulation* 2000; 102:1780-87.

35. White RD, Russell JK. Refibrillation, resuscitation and survival in out-of-hospital sudden cardiac arrest victims treated with biphasic automated external defibrillators. *Resuscitation* 2002 Oct; 55(1):17-23.

36. Valenzuela TD, Roe DJ, Nichol G, et al. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. *N Engl J Med* 2000; 343:1206-09.

37. Culley LL, et al. Public access defibrillation in out-of-hospital cardiac arrest: a community-based program. *Circulation*, 2004; 109:1859-63.

38. Callejas et al, Human Factors Impact Successful Lay Person Automated External Defibrillator Use During Simulated Cardiac Arrest. *Crit. Care Med.*, 2004; 32(9):5406-13.

39. Andre AD, et al. Automated external defibrillator use by untrained bystanders:can the public-use model work? *Prehosp Emerg Care.* 2004 Jul-Sep; 8(3):284-91.

40. Sandroni et al., Automated External Defibrillation By Untrained Deaf Lay Rescuers. *Resuscitation.* 2004; 63:43-48.

41. Beckers et al., Minimal Instructions Improve the Performance of Laypersons in the Use of Semiautomatic and Automatic External Defibrillators. *Crit. Care Med.*, 2005; 9:R110-R116.

42. Eames P, et al. Comparison of ease of use of three automated external defibrillators by untrained lay people. *Resuscitation.* 2003; 58: 25-30.

43. Gundry JW, Comess KA, DeRook FA, et al. Comparaison of naïve sixth-grade children with trained professionals in the use of an automated external defibrillator. *Circulation.* 1999; 100:1703-07.

44. Fleischhackl R, et al. Differing operational outcomes with six commerically avialable automated external defibrillators. *Resuscitation.* 2004 Aug; 62(2):167-174.

45. *FDA Stresses Human Factors Design for Home-Use Devices,* The Silver Sheet, Vol. 13, No. 5 (May 2009).

46. Fleischhackl R, et al. Automated external defibrillators do not recommend false positive shocks under the influence of electromagnetic field present at public locations. *Anesth Analg.* 2006; 103:1485-88.

47. Kanz, KG et al. Susceptibility of automated external defibrillators to training overhead lines and metro third rails. *Resuscitation.* 2004; 62:189-98.

48. Fleischhackl R, et al. Influence of electromagnetic fields on function of automated external defibrillators. *Academic Emergency Medicine.* 2006:13:1-6.

49. Stolzenberg BT, et al. Automated external defibrillators appropriately recognize ventricular fibrillation in electromagnetic fields. *Prehosp Emerg Care.* 2002 Jan-Mar; 6(1):65-66.

50. Lyster TS, et al. The safe use of automated external defibrillators in a wet environment. *Prehospital Emergency Care.* 2003. 7:3, 307-311

51. Jorgenson DB, Skarr T, Russell JK, et al. AED use in businesses, public facilities and homes by minimally-trained first responders. *Resuscitation* 2003; 59:225-33.

52. Whitfield R, et al. The department of health national defibrillator programme: analysis of downloads from 250 deployments of public access defibrillators. *Resuscitation.* 2005; 64: 269-77.

53. van Alem AP, et al. VF recurrence: characteristics and patient outcome in out-of-hospital cardiac arrest. *Resuscitation.* 2003; 59: 181-88.

54. Hess EP, et al. A high peak current 150-J fixed-energy defibrillation protocol treats recurrent ventricular fibrillation as effectively as initial VF. *Resuscitation* 2008; 79, 28-33.

55. Harve H, et al. AED use in a passenger during a long-haul flight: repeated defibrillation with a successful outcome. *Aviation, Space and Environmental Medicine*, 2009. 80(4) 405-08.

56. Shah JS, Maisel WH, "Recalls and Safety Alerts Affecting Automated External Defibrillators," *JAMA.* 2006 Aug 9; 296(6):655-60.

57. FDA News Release, *Journal of American Medical Association Article on Recalls and Safety Alerts Affecting Automated External Defibrillators,* August 10, 2006, available at:

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108710.htm

58. Nurmi *et al.*, "Adherence to guidelines when positioning defibrillation electrodes," *Resuscitation*. 2004; 61: 143-47.

59. Sanna, T *et al.*, "Cardiopulmonary resuscitation alone vs. cardiopulmonary resuscitation plus automated external defibrillator use by non-healthcare professionals: A meta-analysis on 1583 cases of out-of-hospital cardiac arrest," *Resuscitation*. 2008, 76(2):226-32.

NSC.org

Educate and influence people to prevent accidental injury and death

National Safety Council Praises House Passage of the Josh Miller HEARTS Act

For Immediate Release,
June 3, 2009

Contact:
Meredith Morris
Communications Manager
(630)775-2307
Meredith.morris@nsc.org

Itasca, Ill. – The National Safety Council praises Members of the House of Representatives for their June 2 vote to pass the Josh Miller HEARTS Act, which establishes a grant program through the Department of Education to place automated external defibrillators (AEDs) in elementary and secondary schools. The legislation now heads to the Senate, where Senator George Voinovich (R-OH) plans to introduce companion legislation later this week.

"The National Safety Council praises our nation's lawmakers for passing this lifesaving bill," said Janet Froetscher, NSC President & CEO. "AEDs provide immediate care and can make the difference between life and death. It is important schools are equipped with AEDs to respond quickly to emergency cardiac care situations. I hope the Senate will quickly take up and pass this important legislation."

Introduced by Representative Betty Sutton (D-OH), H.R. 1380, the Josh Miller HEARTS (Helping Everyone Access Responsive Treatment in Schools) Act, is named in memory of Josh Miller, a 15 year old from Ohio who suffered sudden cardiac arrest during a high school football game. By the time an AED arrived, it was too late. Public access to AEDs can raise the survival rate for out-of-hospital cardiac arrests from below 5 percent to as high as 50 percent. The American Heart Association estimates that widespread availability and use of AEDs could save as many as 50,000 Americans each year.

Recognizing National CPR and AED Awareness Week, June 1-7, the NSC is offering free online "First Aid and CPR with AED" training for adults. To register, June 1-7 only visit: http://www.safetyserve.com/firstaidnationalCPRweek/. The NSC offers training in first aid, CPR and AED all year, through its local chapters. Chapter contact information is available at www.nsc.org.

The National Safety Council (www.nsc.org) saves lives by preventing injuries and deaths at work, in homes and communities, and on the roads, through leadership, research, education and advocacy.

1121 Spring Lake Drive
Itasca, IL 60143-3201
(630) 285-1121
(630) 285-1315 fax
Info@nsc.org

1: Dtsch Med Wochenschr. 2006 Sep 29;131(39):2139-42.

Thieme Links

[In-hospital resuscitation. Concept of first-responder resuscitation using semi-automated external defibrillators (AED)]

[Article in German]

Hanefeld C, Lichte C, Laubenthal H, Hanke E, Mügge A.

Medizinische Klinik II/Kardiologie, St. Josef-Hospital, Klinikum der Ruhr-Universität Bochum. christoph.hanefeld@rub.de

BACKGROUND AND OBJECTIVE: The prognosis after in-hospital resuscitation has not significantly improved in the last 40 years. This account presents the results over a three-year period of a hospital-wide emergency plan which implements the use of an automated external defibrillator (AED) by the first responder to the emergency call. BACKGROUND AND OBJECTIVE: 15 "defibrillator points" were installed, which could be reached within 30 s from all wards, out-patient departments and other areas, thus making them accessible for immediate defibrillator application. The hospital personnel is trained periodically in the alarm sequence, cardiopulmonary resuscitation and use of the defibrillator. Data on 57 patients who had sustained a cardiac arrest were prospectively recorded and analysed. RESULTS: In 46 patients (81%) the "on-the-spot" personnel (first-responder) was able to apply AED before arrival of the hospital's resuscitation team. Mean period between arrest alarm and activation of the AED was 2.2 (0.7-4.7) min. Ventricular fibrillation or ventricular tachyarrhythmia was recorded in 40 patients, making immediate shock delivery by AED possible. Restoration of the circulation was achieved in 23 (80%) of the patients and 20 (50%) were discharged home, 17 (43%) without neurological deficit. The high proportion of first-responder AED applications and evaluation of the personnel training indicate a wide acceptance of the emergency plan among the personnel. CONCLUSION: An immediate resuscitation plan consisting of an integrated programme of early defibrillation is feasible and seems to achieve an improved prognosis for patients who have sustained an in-hospital cardiac arrest.

PMID: 16991028 [PubMed - indexed for MEDLINE]

Resuscitation (2006) 70, 416–422

RESUSCITATION

www.elsevier.com/locate/resuscitation

CLINICAL PAPER

In-hospital cardiac resuscitation outside the ICU by nursing staff equipped with automated external defibrillators—The first 500 cases☆,☆☆

H. Gombotz[a,*], B. Weh[a], W. Mitterndorfer[a], P. Rehak[b]

[a] *Department of Anaesthesiology and Intensive Care, General Hospital Linz, Austria*
[b] *Department of Surgery, University of Graz, Austria*

Received 29 September 2005; received in revised form 7 February 2006; accepted 8 February 2006

KEYWORDS
Defibrillation;
Bystander CPR;
Cardiac arrest;
Utstein template;
Ventricular fibrillation;
Return of spontaneous circulation;
Pulse-less electrical activity (PEA)

Summary
Background: Since nursing staff in the hospital are frequently the first to witness a cardiac arrest, they may play a central role in the effective management of in-hospital cardiac arrest. In this retrospective study the first 500 in-hospital cardiac arrests in non-monitored areas, which were treated initially by nursing staff equipped with automated external defibrillators (AEDs) are reported.
Methods and results: Between April 2001 and December 2004, 500 in-hospital cardiac arrest calls were made: there were false arrests in 61 patients, so a total of 439 patients (88%) were evaluated using the Utstein style of data collection. ROSC occurred in 256 patients (58%), 125 (28%) were discharged from hospital and 95 (22%) were still alive 6 months after discharge. Among the 73 patients with VF/VT 63 (86%) had ROSC, 34 (47%) were discharged from hospital and 28 (38%) were alive after 6 months. The chance of survival was not influenced by the time between the call of the arrest team and the 1st defibrillation but was slightly higher with physicians as in-hospital first responders ($p = 0.078$). In contrast, 366 patients with non-VF/VT, 193 (53%) had ROSC, but only 91 (25%) were discharged from hospital and 67 (18%) were alive after 6 months. The risk of dying was significantly higher in patients with non-VF/VT ($p < 0.001$), and there was a trend to a higher risk ratio in patients older than 65 years and in patients with non-witnessed cardiac arrest ($p = 0.056$ and 0.079, respectively).
Conclusion: This observational study supports the concept of hospital-wide first responder resuscitation performed by nursing staff before the arrival of the CPR-team. Among these patients survival rate was higher in those with VF/VT

☆ This paper was presented in part at the annual meeting of the American Society of Anesthesiologists in Las Vegas 2004.
☆☆ A Spanish translated version of the summary of this article appears as Appendix in the online version at doi:10.1016/j.resuscitation.2006.02.006

* Corresponding author. Department of Anaesthesiology and Intensive Care, General Hospital Linz, Krankenhausstraße 9, A-4020 Linz, Austria. Tel.: +43 732 7806 2157; fax: +43 732 7806 2154.
E-mail address: hans.gombotz@akh.linz.at (H. Gombotz).

doi:10.1016/j.resuscitation.2006.02.006

defibrillated at an early stage. Consequently, it may be assumed that patients may die unnecessarily due to sudden cardiac arrest if proper in-hospital resuscitation programmes are not available.

Introduction

Depending on the hospital type, size and the level of medical care the reported annual number of in-hospital cardiac resuscitations ranges from 100 to 300 cases per hospital per year.[1] The outcome of resuscitation following cardiac arrest depends on many factors related to the patient, the environment and the extent of resuscitation efforts. Collapse to shock time is a critical factor.[2] Whereas patients with out-of-hospital cardiac arrest are often relatively healthy, patients with in-hospital cardiac arrest frequently have significant concurrent illness. Seriously ill patients in unmonitored beds are at an increased risk of a non-witnessed cardiac arrest and poor outcome.[3] On the other hand, survival rate after in-hospital resuscitation may be higher due to a shorter interval to the start of treatment and previously prepared selection for resuscitation efforts.[4]

In general, after cardiac arrest in hospital there is an estimated survival rate at hospital discharge of about 13–66%. Patients with ventricular tachycardia or fibrillation are more likely to survive than those with asystole or pulse-less electrical activity (PEA).[1,3,5–26] As a consequence, programmes focusing on early defibrillation have improved the rate of survival to hospital discharge.[8,13,27] Developments in defibrillator technology have made the use of automated external defibrillators (AEDs) by non-medical personnel possible. As a result, the public use of automated external defibrillators has been shown to improve outcome in patients with cardiac arrest in different settings outside hospitals.[28–30] Studies in hospitals have also shown that early defibrillation is important since patients with witnessed arrests, on cardiac monitors, and again in ventricular fibrillation are more likely to survive.[19,31]

Since nursing staff in hospital are frequently the first to witness a cardiac arrest before the arrival of the cardiopulmonary resuscitation (CPR) team, they may play a central role in the effective management of in-hospital cardiac arrest.[32–34] Therefore, the use of AEDs by non-physicians, especially nurses, in medical institutions with a high incidence of cardiac arrests seems to be essential. In this retrospective study the first 500 in-hospital cardiac arrests in non-monitored areas, which were treated initially by nursing staff equipped with AEDs are reported.

Patients and methods

With the exception of paediatric surgery and neurosurgery the General Hospital in Linz (Austria) supplies all medical specialties and has 35 wards and almost 1000 hospital beds for more than 50,000 patients treated per year. As the evaluation of the efficiency of the existing in-hospital CPR programme produced poor results in the year 2000 an in-hospital first responder AED programme was initiated in 2001. Forty biphasic external semi-automatic defibrillators (AEDs) (Philips Heartstream ForeRunner 2, Böblingen, Germany), one for each floor ($n = 16$) and one for each outpatient clinic ($n = 8$) were installed. The external semi-automated defibrillators had no ECG display but verbal instructions to guide the first responder through the resuscitation programme. After all nursing staff were given training for correct application of the device, their performance was evaluated. Then they were delegated independently to perform defibrillation, and one obligatory training course per year together with members of the in-hospital CPR team was mandatory. The training programme consisted of three units: the correct use of the AED device and basic (BLS) and advanced life support (ALS) according to the Guidelines of the European Resuscitation Council.[35,36] Nurses in general wards and in outpatient clinics were trained in BLS and AED, whereas ICU nurses and the CPR-Team were trained BLS, AED and ALS. The continuous obligatory CPR-training was evaluated using a simple questionnaire in 2001 and 2004.

In cases of cardiac arrest the in-hospital CPR team was called via pager and BLS was immediately started by the first person on scene before the arrival of the CPR-team. After arrival of the multidisciplinary CPR team, consisting of one anaesthesiologist, one cardiologist and one ICU-nurse, resuscitation was continued by the CPR team. Finally the patients were transferred to one of the ICU-units for further treatment after successful resuscitation.

After approval by the Ethics Committee demographic and clinical data were investigated retrospectively, event data and ECG were recorded using Code Runner Software (Philips) during resuscitation. Key event information following in-hospital Utstein style for resuscitation was documented.[22,37] Call time to time of 1st defibrillation was documented using the time mark of the 1st phone call and the defibrillation time mark of the defibrillator. In surviving patients follow-up was done by phone 6 months after discharge from hospital. All data were evaluated by an independent investigator.

Statistics

Kaplan–Meier log rank test and Cox proportional hazards regression were used for statistical analysis.

Results

Altogether more than 1000 persons participated in the CPR training. The main results of the CPR-training evaluation in 2002 and 2004 are summarised in Table 1. More than 90% of all people trained reported better competence and self-confidence in performing cardiac resuscitation, but complained about an almost non-existent feedback from the CPR-team. In 2002, 55% of the participants considered the CPR training to be optimal, increasing to 96% in 2004 (Table 1).

The 500 in-hospital cardiac arrest calls reported in this study happened between April 2001 and December 2004. There were false arrests in 61 patients, so a total of 439 patients (88%) could be evaluated using the Utstein style of data collection (Figure 1). Demographic and clinical data are summarised in Table 2 and the initial cardiac rhythm and the number of survivors is listed in Table 3.

The average time between the patients' admission to the hospital and their cardiac arrest was 5.9 (1–65) days and 47% of all resuscitations ($n = 207$) were performed between 19:00 and 07:00 h. Before arrival of the CPR team nurses on duty were on scene as first responders in all cases. The interval between the call and arrival of the CPR-team on scene was 2.42 ± 1.7 min in patients with non-VF/VT and 2.30 ± 0.8 min in patients with VF/VT. All cardiac arrests occurred in non-monitored areas of the hospital. Fifty-six percent of cardiac arrests with VF/VT, and 37% of cardiac arrest with non-VF/VT, were witnessed. Out of 439 patients with in-hospital cardiac arrest ROSC (return of spontaneous circulation) could be obtained in 256 patients (58%), 125 (28%) were discharged from hospital and 95 (22%) were still alive 6 months after discharge. Out of 73 patients with VF/VT, defibrillation was performed by nurses alone in 41, by nurses and physicians in 10, by physician only in 10 and by nurses and other healthcare workers (i.e. midwives, assistant medical technicians) in 6 patients. In the remaining six patients it was not documented who performed the defibrillation. Among the 73 patients with VF/VT 63 (86%) had ROSC, 34 (47%) were discharged from hospital and 28 (38%) were alive after 6 months. In contrast, out of 366 patients with non-VF/VT 193 (53%) had ROSC, but only 91 (25%) were discharged from hospital and 67 (18%) were alive after 6 months (Figure 2). The risk of dying was significantly higher in patients with non-VF/VT, and there was a trend to a higher risk ratio in patients older than 65 years and in patients with non-witnessed cardiac arrest. Survival chance was not influenced by the time

Table 1 Evaluation of the CPR training in 2002 and 2004

Question	2002 (%)	2004 (%)
Increased competence and self confidence (yes)	84	92
The CPR-training was optimal (yes)	55	96
Insufficient feedback from the CPR-team (yes)	94	77

Table 2 Demographics

Number of patients (male/female)	439 (239/200)
Patients	Age (years)—mean (range)
Total	71 (20–98)
Survivors	67 (20–93)
Non-survivors	72 (22–98)
VF/VT	71 (29–92)
VF/VT survivors	65 (29–87)
VF/VT non-survivors	74 (30–92)
Department	*N* (%)
Surgery	190 (43%)
Internal medicine	222 (51%)
Neurology	27 (6%)
Pre-arrest morbidity	*N* (%)
Cardiac disease	346 (79%)
Pulmonary disease	131 (30%)
Metabolic disease	267 (61%)
Other diseases	280 (64%)

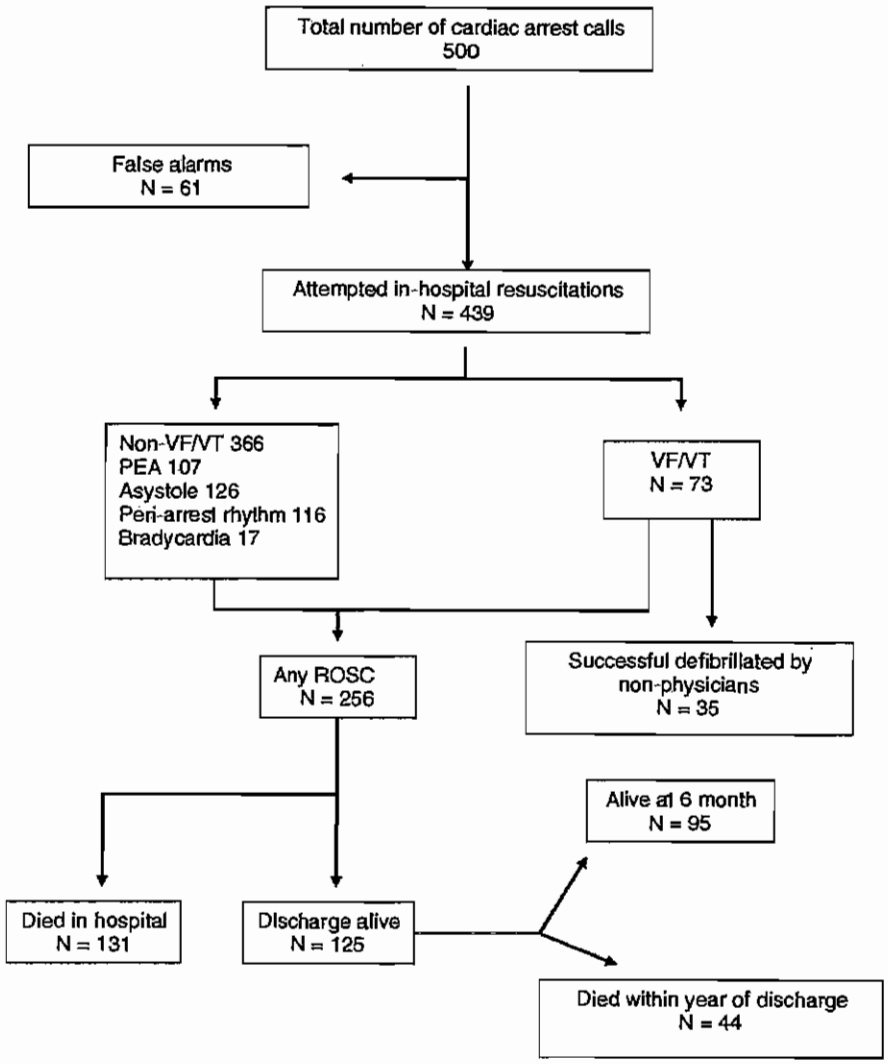


Figure 1 Utstein protocol.

Table 3 Initial rhythm

Initial rhythm	All pts.	ROSC	In hospital death (a)	Discharge (a)	Alive >6 months (a)
VF/VT	73	63 (86%)	29 (46%)	34 (54%)	28 (44%)
Non-VF/VT	366	193 (53%)	102 (53%)	91 (47%)	67 (35%)
Asystole	126	34 (27%)	22 (65%)	12 (35%)	9 (26%)
PEA	107	36 (34%)	28 (78%)	8 (22%)	5 (14%)
Bradycardia	17	15 (88%)	7 (47%)	8 (53%)	7 (47%)
Peri-arrest rhythm	116	108 (93%)	45 (42%)	63 (58%)	46 (43%)
Total	439	256 (58%)	131 (51%)	125 (49%)	95 (37%)

PEA, pulse-less electrical activity.
(a) Percentage of ROSC-patients.

Table 4 Cox proportional hazard regression (risk of no ROSC)

Independent variable	Risk ratio	Lower 95% C.L.	Upper 95% C.L.	p-Value
Non VF/VT	1.87	1.36	2.58	<0.001
Age > 65 years	1.27	0.99	1.63	0.056
No physician	1.28	0.97	1.68	0.078
Non-witnessed	1.22	0.98	1.53	0.079

C.L., confidence limit.

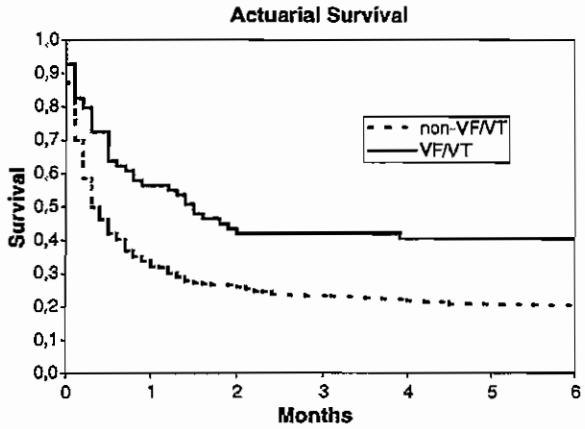


Figure 2 Survival rate after in-hospital cardiac arrest.

from call to 1st defibrillation but slightly higher with physicians as first responders (Table 4).

Discussion

In accordance with the Austrian Federal Law nursing staff of our hospital have been trained continually for BLS and ALS including the usage of AEDs since the year 2000 due to the poor results of the preceding survey. The aim was to improve the survival rate of patients with cardiac arrest outside the ICU. It has been reported that the survival of patients having cardiac arrest in non-monitored in-hospital areas strongly depended on BLS and ALS response provided by the cardiac arrest team where bystander defibrillation was not available.[19] However, the efficiency of the CPR teams was frequently impaired by the lack of staff and equipment and especially due to the poor co-ordination between the responder team and the ward personnel. Therefore, the members of the cardiac arrest team identified a strong need for BLS training and retraining of nursing staff.[38] Also, feedback from the CPR-team to the ward personnel should be improved. In general, the introduction of in-hospital resuscitation teams has been proved to be associated not only with an increase in the number of resuscitations, and in the number of patients experiencing ROSC but also in an increase of the percentage of patients who were discharged from hospital after cardiac arrest.[16] With the introduction of nurse defibrillation the chain of survival was strengthened by a significant increase from 12 to 47% in early defibrillation before the arrival of the CPR-team, although there was no increase in the overall percentage of nurse defibrillations.[12] In contrast, in our survey almost 60% of all patients with VF/VT were defibrillated exclusively by nurses. As with other studies, the nurses who participated in our training programme indicated that they felt well prepared and confident to manage cardiopulmonary resuscitation until the arrival of the CPR team.[39–41] It has been reported in other papers, no obvious difference in skill was found between medically and nursing qualified first responders.[32,42]

Patient survival in the wards is highly dependent on the CPR team arrival time and treatment. Although all cardiac arrests occurred in non-monitored areas of our hospital the CPR-team arrival time was short, because it is based in the very centre of the hospital and—in addition—patients had already been immediately resuscitated by trained ward personnel.[19] Only for prolonged periods of VF/VT, may initial basic life support be superior to immediate defibrillation.[2] However, for our patients the question whether to defibrillate first was not relevant as the criteria for early defibrillation were met in all patients with VF/VT. Wik et al. showed that only patients with ventricular fibrillation and ambulance response intervals longer than 5 min had a better outcome with CPR before defibrillation was attempted.[43] Nevertheless, there was a trend to a poor outcome in our patients with un-witnessed cardiac arrest probably due to prolonged call intervals.[13,19]

Heterogeneity of in-hospital studies, different patient populations and different levels of care make it difficult to compare data collected in published studies.[6,44] In general, there is a wide variety in reported numbers of patients discharged from hospital after cardiac arrest ranging from 5 to 55%.[1,3,8–26,45,46] In the largest registry of in-hospital cardiopulmonary resuscitation with more

than 14,700 cardiac arrests, 44% of adult in-hospital cardiac arrest victims had ROSC and only 17% survived to hospital discharge. In this registry VF/VT was the initial rhythm in only 16% and ROSC occurred in 58% of VF/VT cases, yielding a survival-to-hospital discharge rate of 34% in this subset of patients. To provide initial defibrillation an AED was used in only 1.4% of patients whose initial cardiac arrest rhythm was VF.[1] In contrast an AED was available for all our cardiac arrest patients and all patients with VF/VT were defibrillated leading to a ROSC in 86% of the patients and a survival-to-hospital discharge rate of 54%.

The survival rate after VF/VT is highly dependent on the interval between collapse and the first defibrillation and survival at discharge may reach up to 72%.[47] The lower 54% discharge rate in our patients may at least be partially explained due to the fact that collapse to shock time could not always exactly be determined and that a significant proportion of our patients (44%) had non-witnessed cardiac arrests in the non-monitored areas.[48] In addition, DNAR (do not attempt resuscitation) protocols were not yet in use and it may be speculated that attempts could have been made in patients with a poor prognosis and, as a consequence, could have worsened the overall survival rate.[49,50]

Limitations

Several limitations of the study should be noted. As this is an observational study only limited conclusions can be made about the effectiveness of the resuscitation regime used. Even though we are able to support the concept of first responder rapid defibrillation by nursing staff in the hospital setting, we cannot prove scientifically the superiority of our programme over other in-hospital resuscitation programmes. In addition, the observations reported can only be extrapolated cautiously to other hospitals with different size, structure and different level of care.

Conclusions

In conclusion this observational study supports the concept of hospital-wide first responder resuscitations performed by nursing personnel before the arrival of the CPR-team. Among these resuscitated patients survival rate was higher in those with VF/VT defibrillated. So it may be assumed that patients may die unnecessarily due to sudden cardiac arrest if proper in-hospital facilities and proper in-hospital resuscitation programmes are not available.

Acknowledgments

The authors wish to thank all members of the in-hospital cardiopulmonary resuscitation team of the General Hospital in Linz for their commitment and competent clinical work.

References

1. Peberdy MA, Kaye W, Ornato JP, et al. Cardiopulmonary resuscitation of adults in the hospital: a report of 14720 cardiac arrests from the National Registry of Cardiopulmonary Resuscitation. Resuscitation 2003;58:297–308.
2. Stotz M, Albrecht R, Zwicker G, Drewe J, Ummenhofer W. EMS defibrillation-first policy may not improve outcome in out-of-hospital cardiac arrest. Resuscitation 2003;58:277–82.
3. Dumot JA, Burval DJ, Sprung J, et al. Outcome of adult cardiopulmonary resuscitations at a tertiary referral center including results of "limited" resuscitations. Arch Intern Med 2001;161:1751–8.
4. Herlitz J, Bang A, Ekstrom L, et al. A comparison between patients suffering in-hospital and out-of-hospital cardiac arrest in terms of treatment and outcome. J Intern Med 2000;248:53–60.
5. Saklayen M, Liss H, Markert R. In-hospital cardiopulmonary resuscitation. Survival in 1 hospital and literature review. Medicine (Baltimore) 1995;74:163–75.
6. Ballew KA. Recent advances: cardiopulmonary resuscitation. BMJ 1997;314:1462.
7. De MV, Stiell IG, Wells GA, Spaite DW. Cardiac arrest witnessed by emergency medical services personnel: descriptive epidemiology, prodromal symptoms, and predictors of survival. OPALS study group. Ann Emerg Med 2000;35:138–46.
8. Gwinnutt CL, Columb M, Harris R. Outcome after cardiac arrest in adults in UK hospitals: effect of the 1997 guidelines. Resuscitation 2000;47:125–35.
9. Andreasson AC, Herlitz J, Bang A, et al. Characteristics and outcome among patients with a suspected in-hospital cardiac arrest. Resuscitation 1998;39:23–31.
10. Bedell SE, Delbanco TL, Cook EF, Epstein FH. Survival after cardiopulmonary resuscitation in the hospital. New Engl J Med 1983;309:569–76.
11. Berger R, Kelley M. Survival after in-hospital cardiopulmonary arrest of non-critically ill patients. A prospective study. Chest 1994;106:872–9.
12. Coady EM. A strategy for nurse defibrillation in general wards. Resuscitation 1999;42:183–6.
13. Cohn AC, Wilson WM, Yan B, et al. Analysis of clinical outcomes following in-hospital adult cardiac arrest. Intern Med J 2004;34:398–402.
14. Danciu SC, Klein L, Hosseini MM, Ibrahim L, Coyle BW, Kehoe RF. A predictive model for survival after in-hospital cardiopulmonary arrest. Resuscitation 2004;62:35–42.
15. George Jr AL, Folk III BP, Crecelius PL, Campbell WB. Pre-arrest morbidity and other correlates of survival after in-hospital cardiopulmonary arrest. Am J Med 1989;87:28–34.

16. Henderson SO, Ballesteros D. Evaluation of a hospital-wide resuscitation team: does it increase survival for in-hospital cardiopulmonary arrest? Resuscitation 2001;48:111–6.
17. Herlitz J, Bang A, Alsen B, Aune S. Characteristics and outcome among patients suffering from in hospital cardiac arrest in relation to the interval between collapse and start of CPR. Resuscitation 2002;53:21–7.
18. Keuper W, Brouwer MA, Luijten JE, Uijen GJ, van der WT, Verheugt FW. Resuscitations in the hospital: reporting using the Utstein-style form and a study of 183 patients in the St. Radboud University Medical Center, Nijmegen, The Netherlands, between 1997 and 2000. Ned Tijdschr Geneeskd 2003;147:1222–8.
19. Sandroni C, Ferro G, Santangelo S, et al. In-hospital cardiac arrest: survival depends mainly on the effectiveness of the emergency response. Resuscitation 2004;62:291–7.
20. Schultz SC, Cullinane DC, Pasquale MD, Magnant C, Evans SR. Predicting in-hospital mortality during cardiopulmonary resuscitation. Resuscitation 1996;33:13–7.
21. Skogvoll E, Isern E, Sangolt GK, Gisvold SE. In-hospital cardiopulmonary resuscitation. 5 years' incidence and survival according to the Utstein template. Acta Anaesthesiol Scand 1999;43:177–84.
22. Skrifvars MB, Rosenberg PH, Finne P, et al. Evaluation of the in-hospital Utstein template in cardiopulmonary resuscitation in secondary hospitals. Resuscitation 2003;56:275–82.
23. Tok D, Keles GT, Toprak V, Topcu I. Assessment of in-hospital cardiopulmonary resuscitation using Utstein template in a university hospital. Tohoku J Exp Med 2004;202:265–73.
24. Urberg M, Ways C. Survival after cardiopulmonary resuscitation for an in-hospital cardiac arrest. J Fam Pract 1987;25:41–4.
25. Varon J, Fromm Jr RE. In-hospital resuscitation among the elderly: substantial survival to hospital discharge. Am J Emerg Med 1996;14:130–2.
26. Woog RH, Torzillo PJ. In-hospital cardiopulmonary resuscitation: prospective survey of management and outcome. Anaesth Intens Care 1987;15:193–8.
27. Bunch TJ, White RD, Gersh BJ, et al. Long-term outcomes of out-of-hospital cardiac arrest after successful early defibrillation. New Engl J Med 2003;348:2626–33.
28. Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Public use of automated external defibrillators. New Engl J Med 2002;347:1242–7.
29. Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. New Engl J Med 2000;343:1206–9.
30. Page RL, Joglar JA, Kowal RC, et al. Use of automated external defibrillators by a U.S. airline. New Engl J Med 2000;343:1210–6.
31. Brindley PG, Markland DM, Mayers I, Kutsogiannis DJ. Predictors of survival following in-hospital adult cardiopulmonary resuscitation. CMAJ 2002;167:343–8.
32. Murphy M, Fitzsimons D. Does attendance at an immediate life support course influence nurses' skill deployment during cardiac arrest? Resuscitation 2004;62:49–54.
33. Mancini ME, Kaye W. In-hospital first-responder automated external defibrillation: what critical care practitioners need to know. Am J Crit Care 1998;7:314–9.
34. Kaye W, Mancini ME, Giuliano KK, et al. Strengthening the in-hospital chain of survival with rapid defibrillation by first responders using automated external defibrillators: training and retention issues. Ann Emerg Med 1995;25:163–8.
35. Monsieurs KG, Handley AJ, Bossaert LL. European Resuscitation Council Guidelines 2000 for automated external defibrillation. A statement from the Basic Life Support and Automated External Defibrillation Working Group (1) and approved by the Executive Committee of the European Resuscitation Council. Resuscitation 2001;48:207–9.
36. de LF, Nolan J, Robertson C, Chamberlain D, Baskett P. European Resuscitation Council Guidelines 2000 for Adult Advanced Life Support. A statement from the Advanced Life Support Working Group (1) and approved by the Executive Committee of the European Resuscitation Council. Resuscitation 2001;48:211–21.
37. Jacobs I, Nadkarni V, the ILCOR Task Force on Cardiac Arrest and Cardiopulmonary Resuscitation Outcomes, et al. Cardiac Arrest and Cardiopulmonary Resuscitation Outcome Reports: update and simplification of the Utstein templates for resuscitation registries: a statement for healthcare professionals from a task force of the International Liaison Committee on Resuscitation (American Heart Association, European Resuscitation Council, Australian Resuscitation Council, New Zealand Resuscitation Council, Heart and Stroke Foundation of Canada, InterAmerican Heart Foundation, Resuscitation Councils of Southern Africa). Circulation 2004;110:3385–97.
38. Sandroni C, Cavallaro F, Ferro G, et al. A survey of the in-hospital response to cardiac arrest on general wards in the hospitals of Rome. Resuscitation 2003;56:41–7.
39. Skrifvars MB, Castren M, Kurola J, Rosenberg PH. In-hospital cardiopulmonary resuscitation: organization, management and training in hospitals of different levels of care. Acta Anaesthesiol Scand 2002;46:458–63.
40. O'Higgins F, Ward M, Nolan J. Advanced life support skills undertaken by nurses—UK survey. Resuscitation 2001;50:45–9.
41. Wynne R, Lodder T, Trapani T, Hanlon G, Cleary C. The initiation and administration of drugs for advanced life support by critical care nurses in the absence of a medical practitioner. Aust Crit Care 2002;15:94–100.
42. Hulme J, Perkins GD, Baldock C, MacNamara A. Use of advanced life support skills. Resuscitation 2003;58:59–63.
43. Wik L, Hansen TB, Fylling F, et al. Delaying defibrillation to give basic cardiopulmonary resuscitation to patients with out-of-hospital ventricular fibrillation: a randomized trial. JAMA 2003;289:1389–95.
44. Ebell MH, Smith M, Kruse JA, Drader-Wilcox J, Novak J. Effect of race on survival following in-hospital cardiopulmonary resuscitation. J Fam Pract 1995;40:571–7.
45. Hajbaghery MA, Mousavi G, Akbari H. Factors influencing survival after in-hospital cardiopulmonary resuscitation. Resuscitation 2005;66:317–21.
46. Hanefeld C, Lichte C, Mentges-Schroter I, Sirtl C, Mugge A. Hospital-wide first-responder automated external defibrillator programme: 1 year experience. Resuscitation 2005;66:167–70.
47. Herlitz J, Aune S, Bang A, et al. Very high survival among patients defibrillated at an early stage after in-hospital ventricular fibrillation on wards with and without monitoring facilities. Resuscitation 2005;66:159–66.
48. Kaye W, Mancini ME, Truitt TL. When minutes count—the fallacy of accurate time documentation during in-hospital resuscitation. Resuscitation 2005;65:285–90.
49. Aune S, Herlitz J, Bang A. Characteristics of patients who die in hospital with no attempt at resuscitation. Resuscitation 2005;65:291–9.
50. Niemann JT, Stratton SJ. The Utstein template and the effect of in-hospital decisions: the impact of do-not-attempt resuscitation status on survival to discharge statistics. Resuscitation 2001;51:233–7.

A 2-Tiered Approach to In-Hospital Defibrillation

Nurses Respond to a Trial of Using Automated External Defibrillators as Part of a Code-Team Protocol

Michael Kyller, RN, BSN, CCRN
Donald Johnstone, RN, MBA

A survey was completed at Boston Medical Center to gather data on the attitudes of nurses in non–critical care areas toward using automated external defibrillators (AEDs) to complement a traditional response by a code team that used manual defibrillators. Intensive care nurses on the code team interacted with non–critical care nurses using AEDs when the code team responded to codes during a 1-year study period. We thought that nurses' acceptance of and attitudes toward these new Basic Life Support (BLS) devices were important to the successful integration of such devices into code-response policies (Figure 1). In a 2-tiered approach, when a patient required defibrillation, a nurse in the patient's care unit served as a BLS first responder by using an AED until the code team with critical care nurses arrived and used a manual defibrillator as part of the Advanced Cardiac Life Support (ACLS) response. The use of BLS responders to supplement an ACLS response team in the community is common, and we discuss use of such a 2-tiered system in the hospital.

* This article has been designated for CE credit. A closed-book, multiple-choice examination follows this article, which tests your knowledge of the following objectives:

1. Discuss the initiation of a 2-tiered defibrillation response system in one hospital
2. Discuss the importance of early defibrillation in cardiac arrest
3. Describe the limitations of the study

Background and Significance

The Importance of Early Defibrillation

Early defibrillation is critical to the outcomes of adults in cardiac arrest. Cardiac arrest has a high mortality rate unless defibrillation occurs quickly, usually within 10 minutes of the onset of cardiac arrest. Survival decreases 7% to 10% with each minute that passes; therefore, rapid defibrillation is an essential goal in any protocol for treating patients with life-threatening ventricular arrhythmias.[1,2,3(pp160-161)] The latest guidelines from the American Heart Association (AHA) suggest that defibrillation be administered to patients in the hospital within 3 minutes of the onset of sudden cardiac arrest.[3(p169)] A small body of evidence exists on the use of AEDs in hospitals and the out-

Authors

Michael Kyller is the charge nurse in the cardiac catheterization laboratory at Boston Medical Center, Boston, Mass. He is an American Heart Association Basic Life Support instructor and course coordinator and is Regional Faculty for Basic Life Support and Advanced Cardiac Life Support.

Donald Johnstone is a clinical instructor in the telemetry units at Boston Medical Center, Boston, Mass. He is an American Heart Association Basic Life Support instructor and course coordinator.

Figure 1. Automated external defibrillator with battery and data card.

comes of patients treated with AEDs. Introducing AEDs to hospital teams who respond to codes is a relatively new idea.

Traditional responses to hospitalized patients who are experiencing cardiac arrest vary according to where in the hospital the event occurs. Critical care nurses on code teams often respond from their units to distant inpatient units. At Boston Medical Center, we have many patient floors in many different buildings. This wide distribution of patients may cause delays when a traditional response by a code team is used because the nurses outside the critical care areas do only cardiopulmonary resuscitation (CPR) until a team arrives that can administer defibrillation and perform other advanced measures.[4,5]

Hospital areas where patients are monitored (eg, intensive care, cardiac care, telemetry, and cardiac rehabilitation units) have excellent response times, and survival rates of these patients can be almost 90%.[6,7] In contrast to those rates, survival rates after sudden cardiac arrest in non–critical care areas or areas where patients are not monitored can be as low as 11% to 15%.[8,9]

Outcomes from sudden cardiac arrest in the community have improved remarkably with the institution of initiatives for public access to defibrillators. With recent increased public training in the use of AEDs and CPR, survival rates of 70% and higher have been reported.[10,11] These types of statistics have even prompted *USA Today* to print an article titled "Hospitals A Bad Bet For Heart Jump-Start."[12]

Effects and Use of AEDs

AEDs initially were developed for providers of emergency medical services; subsequently the general public has gained access to AEDs and the training to use the devices. The experiences of these users have led to improvements in design that make AEDs more efficient and easy to use. Even sixth-grade students have been successful in using an AED.[13] Use of AEDs in public is becoming more common, especially in places such as airports, casinos, and golf courses. Similarly, AEDs are beginning to appear in more healthcare facilities, including hospitals.

Resuscitation or code committees must evaluate current hospital protocols and validate response and defibrillation times in all areas, but especially in the non–critical care areas. The addition of AEDs in these areas has proved beneficial in hospitals.[14-16] Understanding and integrating AEDs into current protocols were parts of the process we went through at Boston Medical Center for both critical care nurses and non–critical care nurses. Critical care nurses will continue to encounter AEDs both in their communities and when they respond to sudden cardiac arrest in the hospital. The American Association of Critical-Care Nurses supports funding for public defibrillation programs, as outlined in an action alert on their Web site (http://www.aacn.org).

Operation of AEDs

As previously mentioned, the design of AEDs has been improved so that the devices are very easy to use. At the same time, AEDs have undergone complex technological advances that have improved their efficiency.[17-20] Our devices have "Smart Biphasic" technology that uses advanced algorithms to identify cardiac rhythms and can adjust to a patient's impedance or resistance to the flow of current through the chest. Such adjustments mean that lower energy settings can be used and that the potential for skin burns or myocardial damage is reduced.[21,22] Our older manual defibrillators use monophasic waveform energy and deliver current from one paddle to another in a single direction, whereas these newer biphasic units deliver energy in 2 directions between the pads or paddles. Studies indicate that biphasic energy is more successful than monophasic energy in terminating arrhythmias.[23] We are moving away from using paddles and instead are using pads as our primary mode for defibrillation. The AHA recommends placement of

pads on the right side of a patient's chest to the right of the sternum just below the clavicle and on the left side, laterally at the midaxillary line at a level just below the nipple.[3(p165)] When pads are initially used with an AED, our code team can easily unplug the pad cable and insert the cable into the manual defibrillator without changing the pads that are attached to the patient. Not only is this process quick and easy, but then the pads can be used immediately for monitoring, pacing, cardioversion, or defibrillation as determined by the critical care nurse on the team. An adapter connector may be needed to connect these pads to a manual defibrillator, as was the case for us during the study period. Our new devices do not need an adapter, though, because both the AED and the manual devices have the same connection; thus, disconnection and reconnection can be done quickly without adapters.

Single-Team Versus 2-Tiered Approach

Our code committee discussed the use of AEDs in our non–critical care areas and because it was a new approach, asked us to design a trial to obtain feedback from nurses before implementing the program campuswide. A 2-tiered system was proposed. Hands-free pads would be used as well as standard paddles. The trial would provide information to decide how and if such a system would be instituted. Specific questions related to the new device and the change in protocol would be examined.

We thought that the benefits of adding AEDs and changing to a 2-tiered approach could be significant. Any patient with sudden cardiac arrest would be treated by using the AED with pads, and the initial defibrillation would be delivered by the non–critical care nurse at the bedside. Rapid replacement of the AED by the manual defibrillator would be done by the critical care nurse when the code team arrived. This process was a significant improvement from our previous system. Quicker defibrillation with a smoother, rapid transition of care to the code team would be possible with this 2-tiered system.

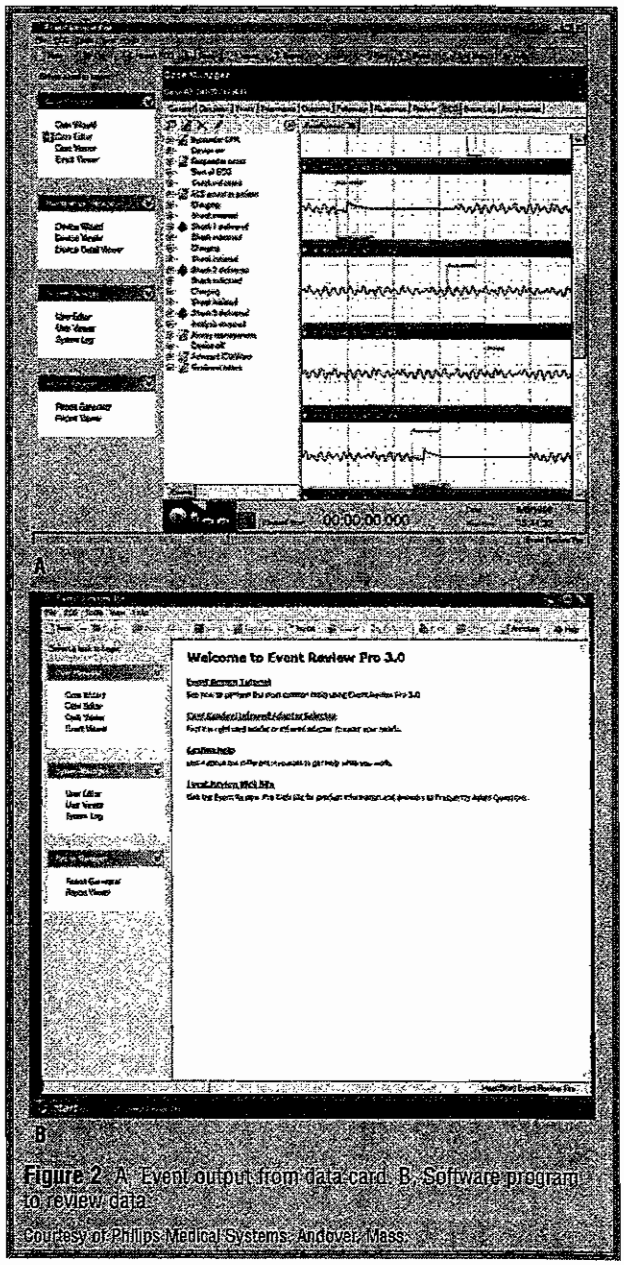


Figure 2. A, Event output from data card. B, Software program to review data.
Courtesy of Philips Medical Systems, Andover, Mass.

Moving to this new technology had other potential benefits. Documentation and data collection could be easier and more reliable because the AEDs contain a data card that can be used to save data automatically, including electrocardiographic tracings and information on events. These data can be downloaded into a computer and printed for later review and use (Figures 2A and 2B). Cardiologists, electrophysiologists, and the code team could use these data to treat patients further and to improve quality of care.

Our past practice had been to place manual defibrillators in every inpatient area, even though many nurses in those areas were not trained to use defibrillators. Often, the devices were used only as monitors. Another potential benefit of a 2-tiered approach is cost savings, because the cost of a manual defibrillator is 2 to 5 times more than the cost of an AED. Prices listed range from $2000 to $3000 for

AEDs and from $7000 to $12 000 for manual units. If personnel in non–critical care areas use more AEDs and fewer manual units, considerable cost savings might be realized for the medical center.

Methods

In response to our code committee's request, an in-hospital AED study was designed to use a 2-tiered protocol (Figure 3) based on the AHA algorithm and guidelines for defibrillation. The study design was submitted to our institution's investigational review board and was approved. A survey questionnaire was developed with a series of questions for the nurses to answer (Figure 4). Our aim was to survey 20 or 30 nurses who used AEDs throughout the 1-year study and report back to the committee about ease of use and the nurses' attitudes toward AEDs and the 2-tiered response. Support for our project was requested and was granted by the Ross Committee for Nursing at Boston Medical Center. We obtained 5 AEDs and selected 2 care units that had large populations of cardiac patients. We hoped to enroll enough patients to use the protocol and the devices and obtain nurses' feedback. We thought that 5 AEDs could be dispersed for quick access by the nursing staff. The devices that we used were Philips Forerunner (FR2) AEDs (Andover, Mass). Each of these units has a screen that displays electrocardiographic rhythms and is visible to all responders. This feature is not available on all AEDs; the advanced practitioners wanted to have a visible indication of a patient's heart rhythm when they arrived. The AEDs were strategically located in 2 non–critical care areas in hallway locations that offered easy access to the devices and proximity to any patient's room. The units were mounted in wall boxes that were custom-made with a clear front panel and a plastic snap lock (Figure 5). The AEDs were secured in this manner to discourage removal except when needed. Our hospital electricians and carpenters agreed to make the boxes for the AEDs. A small battery-powered buzzer was activated when the wall box was opened to alert the staff that the AED had been removed. We also hoped that the noise of the buzzer would be a deterrent to theft. Each AED also included an adapter to connect the AED pads to the manual defibrillators (HP Code Master, Philips Medical, Andover, Mass, and Physio Control Life Pack, Medtronic, Palo Alto, Calif).

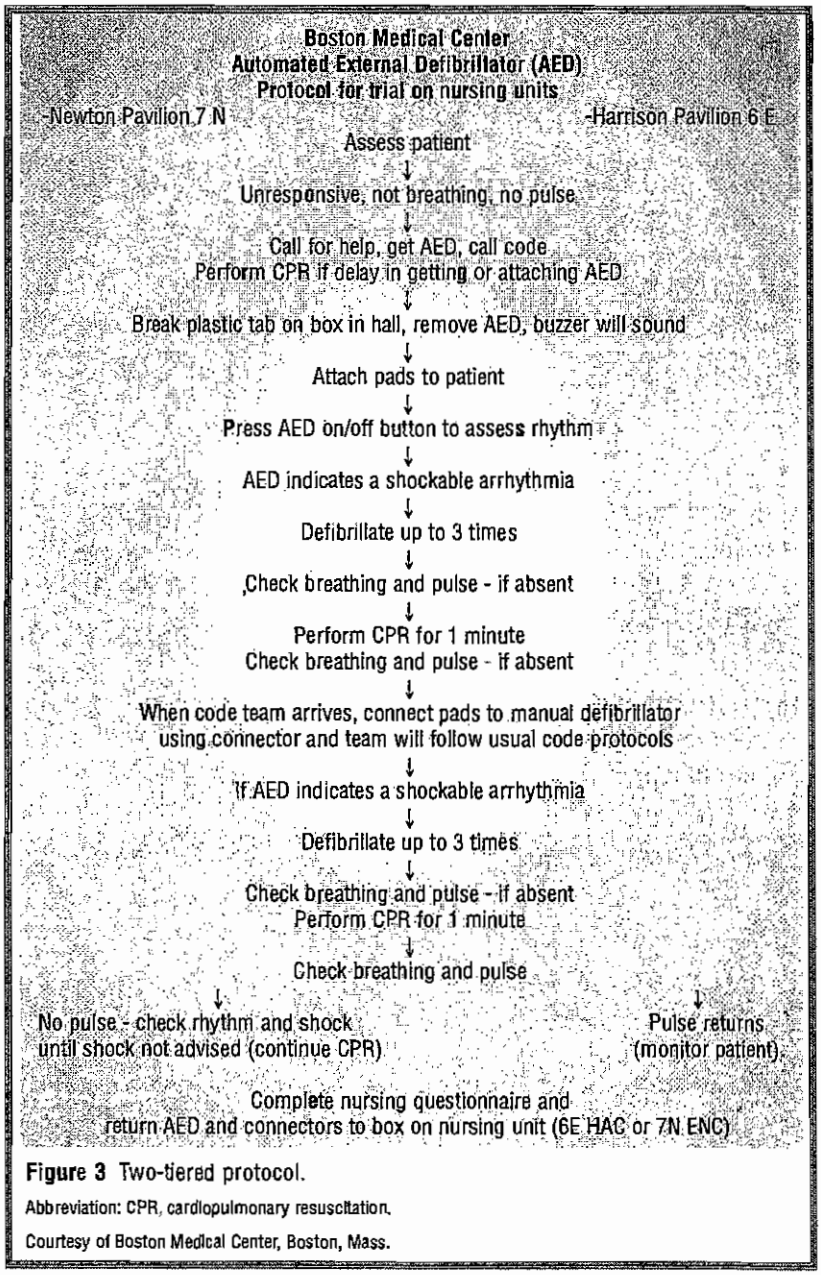


Figure 3 Two-tiered protocol.

Abbreviation: CPR, cardiopulmonary resuscitation.

Courtesy of Boston Medical Center, Boston, Mass.

At Boston Medical Center Date

Location of code 7N (NP) 6E (HP) (circle one)

Nursing role during this (code) event:
Patient's nurse ☐ Code team nurse ☐
Nurse leader ☐ Other _____ ☐

Did you use the AED?	Yes ☐	No ☐
Did you observe the AED being used?	Yes ☐	No ☐
Did a non-nurse use the AED?	Yes ☐	No ☐
Were the "hands-off" pads used with the manual defibrillator?	Yes ☐	No ☐
Did you use the manual defibrillator?	Yes ☐	No ☐
Was a shock delivered prior to code team arrival?	Yes ☐	No ☐
If "yes"- was it with the AED?	Yes ☐	No ☐
Was the switch over from AED to manual defibrillator easy?	Yes ☐	No ☐
Was a shock delivered from the manual defib?	Yes ☐	No ☐
Was the AED easily accessible?	Yes ☐	No ☐
Should we consider the use of AEDs in non-critical care areas?	Yes ☐	No ☐

If "yes" because— ☐ Simple to use
☐ Quicker shock to patient
☐ Other: reason _____

If "no" because— ☐ Complicated to use
☐ No difference in time to shock
☐ Other: reason _____

Other comments _____

Figure 4 Questionnaire for nurses who use an automated external defibrillator (AED).

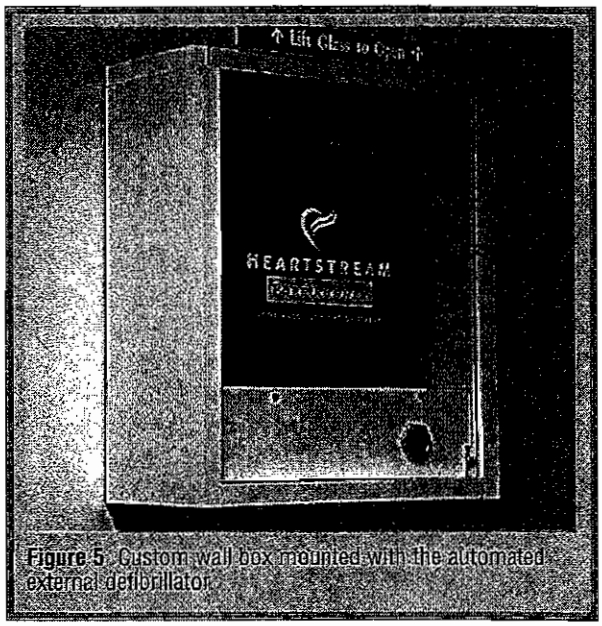


Figure 5 Custom wall box mounted with the automated external defibrillator.

We used the protocol we had developed for defibrillation to provide in-service education by performing mock codes with the AED and a manual defibrillator (Figure 6). Device-specific training on the AEDs was also given to both the non–critical care nurses and the code team nurses by the AED vendor and the study coordinators.

Results

At the conclusion of our trial, we reviewed the nurses' survey responses about their experience with the AED and the 2-tiered system. Overall, the nurses recommended the use of AEDs in non–critical care areas. The data from the surveys collected are contained in the Table.

Twenty-six patients in our study areas had the code team activated for an event during the 1-year duration of our trial. Seventeen nurses who used or observed the AED being used responded to our questionnaire. The hands-off pads were placed on the patient initially with the AED, and 8 patients had the pads connected to the manual defibrillator when the code team arrived. The first nurses to switch the pads from an AED to manual defibrillators said that doing so was not easy. An adapter was used to allow the pads to remain on patients while a nurse connected the pads to the manual device, but some respondents found that switching from an AED to a manual defibrillator was difficult. After the nurses were retrained, it was easier for them to use the adapter and switch from the AED to the manual device.

Our initial training included only nurses because they would be the pri-

Figure 6 In-service education with mock codes and automated external defibrillators.

Survey results, based on 26 calls for code team and 17 survey respondents who used the automated external defibrillator (AED)

17 respondents used an AED
17 respondents observed an AED being used
Only nurses used the AED
8 "hands-off" pads were used with the manual defibrillator
The manual defibrillator was used 3 times
3 patients received defibrillation before the code team arrived
7 respondents stated that switching from the AED to the manual device was easy; 7 respondents stated that it was not easy (before retraining)
19 respondents stated they would consider using AEDs in non–critical care areas
20 respondents considered the AED easily accessible
18 respondents thought that the AED was simple to use
10 respondents thought that defibrillation would be delivered sooner if the AED was used
1 respondent stated that it was difficult to synchronize and pace with the AED

Other data

At least 3 additional patients did not have an AED applied or it was removed because of the house staff's discomfort with the device
3 of 26 patients for whom a code was called had a rhythm that warranted defibrillation (ventricular fibrillation) and received defibrillation
2 of 3 patients who received defibrillation were revived before the code team arrived
The initial switchover from the AED to the manual defibrillator was difficult and retraining was required
7 deaths occurred in the study group

mary users of both the AEDs and the manual defibrillators. Not including the physician house staff in our initial education on AEDs was an oversight. Implementation of the protocol was difficult initially because nurses were asked to remove the AED and set up the manual defibrillator to do a "quick look" with paddles. Our cardiology staff helped us train the house staff about the AEDs and our 2-tiered protocol. This training led to increased compliance of physicians with the use of the AEDs during subsequent codes called in the pilot units. We still received many comments from the house staff and critical care nurses that it seemed like a long time elapsed during which they were not doing anything for the patient while the AED was analyzing the patient's rhythm (that process takes up to 10 seconds).

At the end of the study, the responding nurses concluded that the AEDs were easily accessible, simple to use, and allowed patients to receive defibrillation more quickly than before.

Discussion

Only 3 of the 26 patients who had an AED applied had ventricular tachycardia or ventricular fibrillation that required defibrillation. Upon reviewing other studies of cardiac arrests that occurred in hospitals but outside critical care units, we found that the low incidence of ventricular tachycardia or fibrillation that we noted is consistent with the incidence reported for similar studies.[4,14] We were encouraged, however, that 3 patients received defibrillation, and 2 of them had return of spontaneous circulation before the code team arrived. The third patient died despite a lengthy resuscitation attempt. Seven patients in the group died, consistent with the high mortality rate associated with in-hospital cardiac arrests in non–critical care areas. The patients who died did not have ventricular tachycardia or fibrillation as an initial rhythm.

Limitations

Our survey was developed and designed as a simple means to evaluate nurses' responses to the use of AEDs and a change in practice. We did not measure outcome data, our sample size was small, and the number of patients with ventricular fibrillation was low. Our code committee used the responses on our questionnaire to further pursue a new approach in our hospital. Actual times from cardiac arrest to defibrillation were not noted, but patients who needed defibrillation received it before the code team arrived.

Nursing Implications and Recommendations

Sudden cardiac arrest is not an everyday event, and in most nursing units, it occurs unexpectedly. Delayed defibrillation occurs infrequently in patients who are monitored and in patients in critical care units, but it occurs in non–critical care hospital units and in outpatient and diagnostic facilities, which hundreds of patients enter and leave each day. In areas such as these, centralized response teams can take many minutes to arrive with a defibrillator, attach it, and administer defibrillation.[4,24]

We think that in-hospital practice, like out-of-hospital care, must shift from a focus on CPR as the sole form of BLS to include both CPR and defibrillation. Outside the critical care areas, staff nurses trained in BLS are usually the first to discover that a patient is having a cardiac arrest. They provide CPR until the resuscitation team arrives.

The use of an AED is a BLS skill; in fact, BLS courses now include the use of AEDs for healthcare providers. We think that AED training should

be incorporated into all BLS training programs for hospital personnel expected to respond to patients who are experiencing a cardiac arrest, and rapid defibrillation should be a priority along with immediate CPR. Because the algorithms used by the AEDs to detect arrhythmias are sensitive and specific for recognizing abnormal heart rhythms that can be treated by defibrillation, the operators of AEDs do not require ACLS training or training to recognize arrhythmias. Critical care nurses responding to a patient in cardiac arrest must also be comfortable interacting with and using the AEDs so that the transition to advanced life support is smooth.

In moving from a single-tier structure to a 2-tiered response, our nurses and physicians needed to understand not only how the 2 tiers interact but also what each type of defibrillator can and cannot do (ie, monitoring, defibrillation, synchronization, cardioversion, or pacing). Reinforcement and reeducation of our teams were necessary and beneficial in our 2-tiered approach. Early in our experience with the AED program, some physicians responding to a cardiac arrest in which an AED was being used were eager to remove the device and use conventional manual defibrillation. "Get that thing off!" and "Bring the real defibrillator!" were heard occasionally. Our initial exclusion (inadvertent) of physicians from the AED training was a mistake that we corrected. Now that physicians, especially house staff, are included at the beginning of the training program, their subsequent experience with AEDs has changed their attitudes from disbelief to acceptance. Implementing AHA guidelines with the use of AEDs is a component of our BLS training program for all nurses, including critical care staff. The goal set by the AHA to administer defibrillation within 3 minutes of the onset of cardiac arrest (in-hospital standard) is what we are striving to achieve.

The Joint Commission on Accreditation of Healthcare Organizations has recently required stricter resuscitation documentation, and with new defibrillators that can not only record but also download data, documentation should be easier and more accurate.[25,26(p1.3.1.1)] Many successful community programs use nonlicensed personnel to operate AEDs. Might hospitals be able to do the same? One might envision a secretary, security guard, or patient care assistant using an AED so that the nurse can assist the code team and coordinate the patient's overall care.

Conclusion

AEDs have a useful role in patients with cardiac arrest who are in non–critical care areas of the hospital. The comfort level of all healthcare professionals is critical to the success of AED protocols. Whenever a new program is starting or a new device is being evaluated, difficulties may be encountered and must be addressed. Comprehensive training and practice with all levels of respondents, including physicians, code team nurses, and unit nurses will help create this comfort level. A 2-tiered approach to defibrillation can provide rapid defibrillation and allow better integration between personnel with different levels of training (ie, basic and advanced) who respond to patients who are having cardiac arrest. This approach could also allow hospitals to decrease costs without decreasing (and perhaps even increasing) the quality of patients' care. Costs could be reduced by using the less-expensive AEDs instead of manual defibrillators in some areas. The nurses who used the AEDs and responded to the survey reported a high level of satisfaction and thought that AEDs should be considered for use in non–critical care areas of the hospital. Ventricular fibrillation is infrequent during codes called in the hospital, as it was during our study, despite the high morbidity and mortality in the patients on whom the AED was used. Those patients who did have ventricular fibrillation had a high revival rate and received defibrillation before the code team arrived. The prehospital community at large has expanded use of AEDs and improved response times. At times defibrillation may occur as fast or faster in the prehospital community than in the hospital's non–critical care areas. Our goal is to make response times for defibrillation in non–critical care areas of the hospital as short as or shorter than defibrillation times in the community.

We encourage and support the use of AEDs in hospitals. Our study reemphasized to our code committee that a 2-tiered response to codes in the hospital setting can be effective. When AEDs are deployed in carefully selected areas of a hospital, the potential benefits of rapid defibrillation and improved survival of patients can be realized.

More study is needed to look at specific outcomes for patients according to accurate response times and time to first defibrillation. Our nurses had a positive attitude toward use of AEDs as part of a 2-tiered code-response system in the hospital. Critical care nurses will continue to

see AEDs and must be aware of how the devices work and how they fit into hospital response protocols.

References

1. Marenco JP, Wang P, Link M, Hamond M, Estes M. Improving survival from sudden cardiac arrest. *JAMA.* 2001;285:1193-1200.
2. Cummins RO. From concept to standard of care? Review of the clinical experience with automated external defibrillators. *Ann Emerg Med.* 1989;18:1269-1275.
3. Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiac Care. An International Consensus on Science. *Circulation.* 2000;102(8 suppl):160-161.
4. Kaye W, Nadkarni V, Mancini ME, et al. A national registry of cardiopulmonary resuscitation: a preliminary report of 5030 adult in-hospital cardiac arrests [abstract]. *J Am Coll Cardiol.* 2002;39(suppl 2):335-336.
5. Steill IG, Hebert PC, Wells GA, et al. The Ontario trial of active compression-decompression cardiopulmonary resuscitation for in-hospital and prehospital cardiac arrest. *JAMA.* 1996;275:1417-1423.
6. Carruth JE, Silverman ME. Ventricular fibrillation complicating acute myocardial infarction: reasons against the routine use of lidocaine. *Am Heart J.* 1982;104:545-550.
7. Hossack KF, Hartwig R. Cardiac arrest associated with supervised cardiac rehabilitation. *J Cardiac Rehab.* 1982;2:402-408.
8. Jastremski MS. In-hospital cardiac arrest. *Ann Emerg Med.* 1993;22:113-117.
9. McGrath RB. In-house cardiopulmonary resuscitation: after a quarter of a century. *Ann Emerg Med.* 1987;16:1365-1368.
10. Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hartman RG. Outcomes of rapid defibrillation by security officers after cardiac arrests in casinos. *N Engl J Med.* 2000;343:1206-1209.
11. Page RL, Joglar AJ, Kowal RC, et al. Use of automated external defibrillators by a US airline. *N Engl J Med.* 2000;343:1210-1216.
12. Sternberg S. Hospitals a bad bet for heart jump-start. *USA Today.* November 9, 1999:08.D.
13. Gundry JW, Comess KA, DeRook FA, et al. Comparison of naive sixth grade children with trained professionals in the use of an automated external defibrillator. *Circulation.* 1999;100:1703-1709.
14. Destro A, Marzolini M, Sermasi S, Rossi F. Automated external defibrillators in the hospital as well? *Resuscitation.* 1996;31:39-44.
15. Kenward G, Castle N, Hodgetts TJ. Should nurses be using automated external defibrillators as first responders to improve the outcome from cardiac arrest? *Resuscitation.* 2002;52:31-37.
16. Mancini ME, Kaye W. AEDs: changing the way you respond to cardiac arrest. *Am J Nurs.* May 1999;99:26-30.
17. Bardy GH, Marchlinski AD, Sharma SJ, et al. Multicenter comparison of truncated biphasic shocks and standard damped sine wave monophasic shocks for transthoracic ventricular defibrillation. *Circulation.* 1996;94:2507-2514.
18. White RD. Early out-of-hospital experience with an impedance-compensating low-energy biphasic waveform automatic external defibrillator. *J Intervent Card Electrophysiol.* 1997;1:203-208.
19. Cummins RO, Hazinski MF, Kerber RE, et al. Low-energy biphasic waveform defibrillation: evidence-based review applied to emergency cardiovascular care guidelines: a statement for healthcare professionals from the American Heart Association Committee on Emergency Cardiovascular Care and the Subcommittees on Basic Life Support, Advanced Cardiac Life Support, and Pediatric Resuscitation. *Circulation.* 1998;97:1654-1667.
20. Gliner BE, Jorgenson DB, Poole JE, et al. Treatment of out-of-hospital cardiac arrest with a low-energy impedance-compensating biphasic waveform automatic external defibrillator. The LIFE Investigators. *Biomed Instrum Technol.* 1998;32:631-644.
21. Reddy RK, Gleva MJ, Gliner BE, et al. Biphasic transthoracic defibrillation causes fewer ECG ST-segment changes after shock. *Ann Emerg Med.* 1997;30:127-134.
22. Gazmuri RJ. Effects of repetitive electrical shocks on postresuscitation myocardial function. *Crit Care Med.* 2000;28(11 suppl):N228-N232.
23. Schneider T, Martens PR, Paschen H, et al. Multicenter, randomized, controlled trial of 150-J biphasic shocks compared with 200- to 300-J monophasic shocks in the resuscitation of out-of-hospital cardiac arrest victims. Optimal Response to Cardiac Arrest (ORCA) Investigators. *Circulation.* 2000;102:1780-1787.
24. Lazzam C, McCans JL. Predictors of survival of in-hospital cardiac arrest. *Can J Cardiol.* 1991;7:113-116.
25. In-hospital resuscitation requirements reinstated for hospitals. *Jt Comm Perspect.* November-December 1998;18:5.
26. Joint Commission on Accreditation of Healthcare Organizations. *CAMH 2004 Comprehensive Accreditation Manual for Hospitals: The Official Handbook.* Oakbrook Terrace, Ill: Joint Commission on Accreditation of Healthcare Organizations; 2003.

CE Test Test ID C0542: A 2-Tiered Approach to In-Hospital Defibrillation: Nurses Respond to a Trial of Using Automated External Defibrillators as Part of a Code Team Protocol

Learning objectives: 1. Discuss the initiation of a 2-tiered defibrillation response system in one hospital 2. Discuss the importance of early defibrillation in cardiac arrest 3. Describe the limitations of the study

1. According to the latest guidelines from the American Heart Association, the initial defibrillation for a cardiac arrest iu a hospital shonld be administered within what time frame?
a. 3 minutes
b. 2 minutcs
c. 4 minntes
d. 5 minutes

2. Survival of cardiac arrest in nonmonitored areas of the hospital cau be as low as what percentage?
a. 7% to 11%
b. 11% to 15%
c. 15% to 23%
d. 25% to 30%

3. The American Heart Associatiou recommeuds that defibrillation paddles or pads be placed where on the patient?
a. Just below the left clavicle and at the level of the nipple, left midaxillary line
b. Just below the left clavicle and at the level of the nipple, left anterior axillary line
c. Just below the right clavicle and at the level of the nipple, left anterior midaxillary line
d. Just below the right clavicle and at the level of the nipple, left midaxillary line

4. In the iuitial study, automated external defibrillators (AEDs) were placed iu which non-critical care area?
a. Nurses' station
b. Hallway
c. Elevators
d. Medication rooms

5. What would occur when wall box contaiuing the AED was opened?
a. Hospital engineering was uotified.
b. The hospital operator was notified.
c. A small buzzer attached to the box was activated.
d. A light attached to the box was activated.

6. During the study period of 1 year, how many patients actually received defihrillation from an AED before the code team arrived?
a. 10 patients
b. 8 patients
c. 7 patients
d. 3 patients

7. Which of the following difficulties was au initial complaint that nurses had regarding the AED, which was dealt with by retraining?
a. Switching from the AED to the manual defibrillator
b. Applying the AED pads correctly
c. Remembering the correct AED sequence
d. Doing cardiopulmonary resuscitation around the AED

8. How many patients who received defibrillation with an AED had a spontaneous return of circulation before the code team arrived?
a. 0 patients
b. 2 patients
c. 5 patients
d. 7 patients

9. What were 2 limitations of the study?
a. No statistical analysis of the gathered date and the initial exclusion of physician house staff from the stndy
b. Initial exclusion of physician house staff from the study and a small sample
c. Initial exclusion of physician house staff from the study and a low numbcr of patients with ventricular fibrillation
d. A small sample and a low number of patients with ventricular fibrillation

10. What were 2 recommendations for further study by the authors?
a. Incorporating AED use in all units and teaching AED use to all levels of providers
b. Teaching AED use to all levels of providers and identifying accurate response times
c. Teaching AED use to all levels of providers and identifying time to first defibrillation
d. Identifying accurate response times and time to first defibrillation

11. Survival of a cardiac arrest requiriug defibrillation will be affected by how fast defibrillation can he accomplished, and will decrease how much for each minute that passes?
a. 5% to 7%
b. 7% to 10%
c. 10% to 13%
d. 13% to 16%

12. The price differeutial between AEDs and manual defibrillators can be how large?
a. $10 000
b. $5000
c. $8000
d. $2000

Test answers: Mark only one box for your answer to each question. You may photocopy this form.

1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.
☐a	☐a	☐a	☐a	☐a	☐a	☐a	☐a	☐a	☐a	☐a	☐a
☐b	☐b	☐b	☐b	☐b	☐b	☐b	☐b	☐b	☐b	☐b	☐b
☐c	☐c	☐c	☐c	☐c	☐c	☐c	☐c	☐c	☐c	☐c	☐c
☐d	☐d	☐d	☐d	☐d	☐d	☐d	☐d	☐d	☐d	☐d	☐d

Test ID: C0542 Form expires: August 1, 2007. Contact hours: 1.5 Fee: $11 Passing score: 9 correct (75%) Category: A Test writer: Mike W. Day, RN, MSN, CCRN

AMERICAN ASSOCIATION of CRITICAL-CARE NURSES

Mail this entire page to:
AACN
101 Columbia
Aliso Viejo, CA 92656
(800) 899-2226

Program evaluation

	Yes	No
Objective 1 was met	☐	☐
Objective 2 was met	☐	☐
Objective 3 was met	☐	☐
Content was relevant to my nursing practice	☐	☐
My expectations were met	☐	☐
This method of CE is effective for this content	☐	☐

The level of difficulty of this test was: ☐ easy ☐ medium ☐ difficult

To complete this program, it took me _____ hours/minutes.

Name _____ Member # _____
Address _____
City _____ State ____ ZIP _____
Country _____ Phone _____
E-mail _____
RN Lic. 1/St _____ RN Lic. 2/St _____
Payment by: ☐ Visa ☐ M/C ☐ AMEX ☐ Discover ☐ Check
Card # _____ Expiration Date ____
Signature _____

ELSEVIER

Resuscitation 66 (2005) 167–170

RESUSCITATION

www.elsevier.com/locate/resuscitation

Hospital-wide first-responder automated external defibrillator programme: 1 year experience☆

Christoph Hanefeld[a], Carolin Lichte[a], Ina Mentges-Schröter[b], Clemens Sirtl[c], Andreas Mügge[a,*]

[a] *Clinic of Cardiology ond Angiology, St. Josef-Hospital, University Hospital of the Ruhr-University Bochum, Gudrunstrasse 56, D-44791 Bochum, Germany*

[b] *Nursing Administration, St. Josef-Hospital, University Hospital of the Ruhr-University Bochum, Gudrunstrasse 56, D-44791 Bochum, Germany*

[c] *Clinic of Anesthesiology, St. Josef-Hospital, University Hospital of the Ruhr-University Bochum, Gudrunstrasse 56, D-44791 Bochum, Germany*

Received 23 September 2004; received in revised form 18 November 2004; accepted 28 January 2005

Abstract

The first year experience with a hospital-wide first-responder automated external defibrillator (AED) programme implemented in a 683-bed University Hospital is reported. Throughout the hospital, 14 "AED access spots" were identified which could be easily reached from all wards and diagnostic rooms within 30 s. AEDs were installed (Lifepak 500; Medtronik PhysioControl Corp., Redmond, USA, equipped with a Biolog 3000i portable ECG monitor; Micromedical Industries Ltd., Labrador, Australia). Within 3 months, 120 medical officers, 750 nurses, and 50 administrative or technical staff underwent a 2 h training programme. An AED was applied and activated by nurses/medical staff before the cardiac arrest team arrived in 27 of 33 cases (81.8%) of witnessed cardiac arrest. The median time from onset of the emergency call to the activation of the AED (record of ECG) was on average 2.1 min (range 1.0–4.5 min). In 18 of 27 cases in which the AED was installed promptly, the primary arrest rhythm was either VT or VF, and the AED delivered a shock. For this subgroup, the rate of return of spontaneous circulation and the rate of discharge at home were 88.9 and 55.6%, respectively. This encourages us to extend the concept of first-responder AED-defibrillation throughout our hospital.

Keywords: Automated external defibrillator; In-hospital cardiac arrest; First-responder defibrillation; Cardiopulmonary resuscitation

1. Introduction

Cardiac arrest in patients or visitors outside intensive care areas within the hospital is not an infrequent event [1]. In the pre-hospital situation, there is little doubt that successful resuscitation depends on immediate activation of the chain of survival. Although the aetiology of cardiac arrest inside hospital differs from out of hospital [2,3], and may be more often of non cardiac origin (e.g. metabolic, respiratory, neurological), the best chance of survival is afforded to those with pulseless ventricular tachycardia (VT) or ventricular fibrillation (VF) and mortality clearly increases proportionately with delayed defibrillation [4]. Ideally, the person who is most likely to witness a cardiac arrest, the first-responder, should have the skill and equipment to provide rapid defibrillation. With the introduction of automated external defibrillators (AEDs), the concept of a first-responder AED programme has been increasingly advocated for in-hospital settings by numerous authors [4–10]. The ESC-ERC panel recommended recently that improvement of access to AEDs inside the hospital should have a high priority [11]. Although the use of AEDs can be easily learned even by children [12], hospital staff have to be encouraged to use AEDs at every opportunity, and routine staff training need to be implemented [13–15]. This concept has technical and organisational requirements,

☆ A Spanish translated version of the Abstract and Keywords of this article appears as Appendix at 10.1016/j.resuscitation.2005.01.014.

* Corresponding author.
E-mail address: andreas.muegge@rub.de (A. Mügge).

0300-9572/$ – see front matter © 2005 Published by Elsevier Ireland Ltd.
doi:10.1016/j.resuscitation.2005.01.014

as well as standardized documentation and programme evaluation [5,15]. In the present study, the first year experience with a hospital-wide first-responder AED programme in a medium-size University Hospital is reported.

2. Methods

2.1. Hospital settings

St. Josef-Hospital is a 683-bed hospital, and is part of the Bochum University Hospitals. It takes care of more than 24,000 in-patients/year in 27 wards, covering the following clinical subspecialities: cardiology and angiology (with telemetry facility), gastroenterology, endocrinology, rheumatology, infectious diseases, intensive care, dermatology, neurology, radiation therapy, general surgery, abdominal surgery, orthopaedic surgery, trauma surgery, vascular surgery and anaesthesiology. A children's hospital is separated from the main building, and has its own emergency system. Before the implementation of hospital-wide AEDs, a "cardiac arrest team" was alerted to the scene of the event via a group call paging system initiated by the hospital switchboard upon receipt of the cardiac arrest call. The cardiac arrest team was comprised of three medical staff who supplemented the first-responder at the location of the event and performed cardiopulmonary resuscitation (CPR), including early defibrillation according to the European Resuscitation Council guidelines [16]. With the exception of certain high-risk areas (e.g. intensive care, emergency room, catheterization laboratory), the normal wards were not equipped with defibrillators. After an emergency call, the cardiac arrest team transported a defibrillator to the scene.

2.2. Description and installation of AEDs

With the support of the hospital management, a CPR-AED committee was founded in June 2002 consisting of a nurse leader, cardiologist, anaesthesiologist, technical maintenance leader, and pharmacist. This committee identified 14 "AED access spots" throughout the hospital (the children's hospital not included), which could be easily reached from all wards and diagnostic rooms within 30 s. It was calculated that the interval between the event and AED-guided defibrillation should not be more than 3 min for all areas of the hospital. These "AED access spots" were equipped with an AED, the wall behind the AED was painted in red and furnished with a heart symbol. Four of these access spots (e.g. the patients cafeteria) were also equipped with an advanced resuscitation set and a phone with a direct line to the switchboard operator. In general, the wards were equipped with an advanced resuscitation set ("*Ulmer Notfallkoffer*"). As part of our new resuscitation policy, we included in each advanced resuscitation set a red-coloured "defibrillation bag" containing adrenaline (epinephrine) (two ampoules 1 mg each), amiodarone (two ampoules 150 mg each), NaCl 0.9% ampoules, 16 G and 18 G polyethylene cannulae, 10 ml syringes, and a tourniquet. Furthermore, specific risk areas such as the intensive care units, cardiology ward, stroke unit and cardiac catheterization area were equipped with additional Lifepak 12 (Medtronik PhysioControl Corp., Redmond, USA) defibrillators.

The AEDs installed were Lifepak 500 AEDs from Medtronik PhysioControl Corp. (Redmond, WA, USA) with a biphasic shock waveform. The electrodes used for ECG/defibrillation were disposable Fast-Patch electrodes. Each AED was equipped with a Biolog 3000i portable ECG monitor (Micromedical Industries Ltd., Labrador, Australia) for single-lead simultaneous ECG recording.

2.3. Technical support and maintenance

The Electrical Biomedical Engineering unit supported this programme. On a regular basis, the AEDs were serviced by this unit. After each use, the internal AED protocol was printed out and forwarded to the CRP-AED committee.

2.4. Training programme

Within 3 months (the first quarter of 2003), 120 medical officers, 750 nurses, and 50 administrative or technical servants underwent a 2-h training programme, with a maximum of eight participants in each training group. This training programme consisted of theoretical and practical parts, including training in basic life support. Each participant had to handle a dummy AED. This training programme was evaluated by the participants. Refresher "resuscitation days" were scheduled four times a year, and all employees of the hospital were required to join one such event per year. The participation of each employee was recorded. This training programme encouraged medical staff, nurses and servants to focus on the early use of AEDs as part of basic life support before the cardiac arrest team arrived at the scene.

2.5. Data collection and analysis

Mandatory prospective clinical audit of cardiac arrest using a standardized data sheet commenced in January 2003. Data was collected from 1st April 2003 for 1 year until 31st March 2004. Cardiac arrest calls initiated by the switchboard operator acted as the time index, which was documented on a cardiac arrest log form. The cardiac arrest team completed a resuscitation audit form, and one copy was forwarded to the CPR-AED committee. The outcome measures used for the survival profile were return of spontaneous circulation, and discharge from hospital. Values given are mean ± S.D., if not otherwise noted. This study analyzed the confirmed, audited and witnessed in-hospital cardiac arrests, which occurred outside the intensive care units, emergency department, and operation theatres. The definition criteria used were in accordance to the guidelines of the European Resuscitation Council [16]. Cardiac arrests which occurred in the cardiac catheterization laboratory as part of diagnostic or interven-

tional procedures (primary balloon angioplasty for acute myocardial infarctions) were not included in this analysis.

3. Results

During the period 1st April 2003 to 31st March 2004, there were 138 emergency calls registered from the switchboard operator with the request for the cardiac arrest team. A witnessed in-hospital cardiac arrest event was confirmed in 38 cases. Sufficient data were available for 33 cases, five cases were excluded from analysis (missing patient identification, missing outcome data, missing resuscitation audit form). An AED was applied and activated by nurses or medical staff before the cardiac arrest team arrived in 27 cases. Thus, the medical, nursing or other staffs already present in the wards or departments used the AED as "first-responders" in 81.8% of witnessed cardiac arrest events. The median time from onset of emergency call to the activation of the AED (recording of ECG) was on average of 2.1 min (range 1.0–4.5 min). The median arrival time of the cardiac arrest team was 4.7 min (range 2.0–11.5 min). A technical problem was not reported in any case with the use of AEDs.

In 18 of 27 cases in whom the AED was applied promptly, the primary arrest rhythm was either VT or VF, and the AED delivered a shock. Table 1 lists demographic and clinical data for this subgroup of 18 patients with confirmed pulseless VT/VF. The presumed reasons for VT/VF were as follows (n): acute coronary syndrome (10), coronary artery disease with previous myocardial infarction (3), recent aortic/coronary bypass surgery (2), end-stage congestive heart failure with hypokalaemia (2), and acute pulmonary embolism (1). For this subgroup of 18 patients, the rate of return of spontaneous circulation and the rate of hospital discharge were 88.9 and 55.6%, respectively. In the remaining nine patients in whom the AED was applied but did not deliver a shock, asystolic arrest ($n=7$) or pulseless electrical activity ($n=2$) were recorded.

Table 1
VT/VF cardiac arrest, AED used for early defibrillation

Number of patients	18
Mean age (range) (years)	70.2 (43–94)
Sex (male/female)	5/13
Witnessed cardiac arrest (%)	100
Location of cardiac arrest n (%)	
Wards	11 (61.1)
Diagnostic rooms	5 (27.8)
Other rooms	2 (11.1)
Duration of hospital stay before arrest (days)	8.9 (1–25)
Reason for hospital admission n (%)	
Cardiac diseases	9 (50.0)
Non-cardiac diseases	4 (22.2)
Non-cardiac surgical procedures	5 (27.8)
Time interval between arrest alarm to first defibrillation shock (min)	2.1 (1.0–4.5)
Additional CPR/Ventilation n (%)	8 (44.4)
Return of spontaneous circulation n (%)	16 (88.9)
Discharge from the intensive care unit n (%)	11 (61.1)
Discharge home from the hospital n (%)	10 (55.6)

Equipment and technical maintenance costs of 34,000 Euro and 1500 Euro/year, respectively, were calculated. The medical and non-medical hospital staff ($n=920$) underwent initial training for 2 h (in groups of eight participants), and was required to participate in a refreshing course (2 h) once a year. These training events were scheduled during working hours. The 920 staff members spend 1840 working hours on initial training.

4. Discussion

This study describes the initial experience of widespread implementation of AED supported early defibrillation in a medium-size university hospital. After a training period of 3 months, this concept of first-responder AED defibrillation was accepted and used by medical staff, nurses and other hospital servants in more than 80% of cardiac arrest events before the designated cardiac arrest team arrived at the scene. In an important subgroup of patients with cardiac arrest due to VF/VT, first-responder defibrillation yielded a high rate of ROSC and discharge to home.

Although the concept of first-responder early defibrillation using an AED for in-hospital cardiac arrests has been advocated for several years, only limited data are available in the literature [9]. This early defibrillation programme required considerable effort in training hospital specific solutions in organisation and technology, and a change in the traditional philosophy and responsibility by the nursing staff [10,13,14,17]. To our knowledge no data are available demonstrating that the outcome for in-hospital cardiac arrest is superior when a hospital-wide first-responder AED programme is implemented in addition to a cardiac arrest team. However, there is little doubt that the time to first shock is critical for survival in cardiac arrest in-hospital patients with VT/VF [4]. Reports like ours can at best support this concept of first-responder rapid AED-defibrillation, but cannot give the scientific proof of superiority over other in-hospital CPR programmes.

In an extensive literature search, Kenward et al. [9] identified recently only five studies reporting on outcome data from in-hospital first-responder AED defibrillation programmes. Overall, they noted a survival to discharge rate following rapid AED-defibrillation for VF/VT cardiac arrest of 36.5% (42/115). This number is similar to that published previously from a National Registry of Cardiopulmonary Resuscitation (34%) in which "traditional" cardiac arrest teams performed in-hospital advanced CPR, and AEDs were used to provide first-responder defibrillation in less than 1% of cases [3]. In our study, we observed a survival-to-hospital discharge rate of 55.6% for this subgroup of patients with VT/VF cardiac arrest. This number encourages us to go further with the concept of first-responder rapid AED application throughout our hospital.

Acknowledgements

The authors would like to acknowledge the help and support from B. Milde (Administration Director), E. Hanke (Nursing Director), M. Buddendick, M. Rüther, S. Zombeck, and W. Satzer for the technical maintenance unit, Dr. M. Rivera (Pharmacist) and the medical staff who assisted us in this study.

Referenees

[1] Jastremski MS. In-hospital cardiac arrest. Ann Emerg Med 1993;11:113–7.
[2] Andreasson C, Herlitz J, Bang A, et al. Characteristics and outcomes among patients with a suspected in-hospital cardiac arrest. Resuscitation 1998;39:23–31.
[3] Peberby MA, Kaye E, Ornato JP, et al. Cardiopulmonary resuscitation of adults in the hospital: a report of 14720 cardiac arrests from the National Registry of Cardiopulmonary Resuscitation. Resuscitation 2003;58:297–308.
[4] Spearpoint KG, McLean CP, Zideman DA. Early defibrillation and the chain of survival in "in-hospital" adult cardiac arrest: minutes count. Resuscitation 2000;44:165–9.
[5] Kaye, Mancinci ME, Richards N. Organizing and implementation a hospital-wide first-responder automated external defibrillation program: strengthening the in-hospital chain of survival. Resuscitation 1995;30:151–6.
[6] Destro A, Marzaloni M, Sermasi S, Rossi F. Automatic external defibrillators in the hospital as well? Resuscitation 1996;31:39–44.
[7] Soar J, McKay U. A revised role for the hospital cardiac arrest team? Resuscitation 1998;38:145–9.
[8] Bozzana A, Rossi GP, Marcolin R, Valagussa F, Pesenti A. Organisation of an hospital-wide first-responder AED outside critical care areas. Resuscitation 1998;37:50.
[9] Kenward G, Castle N, Hodgetts TJ. Should ward nurse be using automatic external defibrillators as first-responders to improve the outcome from cardiac arrest? a systematic review of the primary research. Resuscitation 2002;52:31–7.
[10] Dwyer T, Williams LM, Jacobs I. The benefits and use of shock advisory a defibrillators in-hospital. Int J Nurs Pract 2004;10:86–92.
[11] Priori SG, Bossaert LL, Chamberlain DA, et al. ESC-ERC recommendations for the use of automated external defibrillators (AEDs) in Europe. Eur Heart J 2004;25:437–45.
[12] Gundry JW, Comess KA, DeRook FA, Jorgenson D, Bardy GH. Comparison of naïve sixth-grade children with trained professionals in the use of an automated external defibrillator. Circulation 1999;100:1703–7.
[13] Warwick JP, Mackie K, Spencer I. Towards early defibrillation—a nurse training programme in the use of automated external defibrillators. Resuscitation 1995;30:231–5.
[14] Coady EM. A strategy for nurse defibrillation in general wards. Resuscitation 1999;42:183–6.
[15] Bickenbach J, Fries M, Beckers S, Rossaint R, Kuhlen R. Voraussetzungen zur Anwendung von automatischen externen Defibrillatoren in deutschen Krankenhäusern. Anaesthesist 2004;53:555–9.
[16] De Latorre F, Nolan J, Robertson C, et al. European resuscitation council guidelines 2000 for adult advanced life support. Resuscitation 2001;48:211–21.
[17] Stewart JA. A more effective approach to in-hospital defibrillation. J Cardiovasc Nurs 1996;10:37–46.

ELSEVIER

Resuscitation 66 (2005) 167–170

RESUSCITATION

www.elsevier.com/locate/resuscitation

Hospital-wide first-responder automated external defibrillator programme: 1 year experience☆

Christoph Hanefeld[a], Carolin Lichte[a], Ina Mentges-Schröter[b], Clemens Sirtl[c], Andreas Müggе[a,*]

[a] *Clinic of Cardiology and Angiology, St. Josef-Hospital, University Hospital of the Ruhr-University Bochum, Gudrunstrasse 56, D-44791 Bochum, Germany*

[b] *Nursing Administration, St. Josef-Hospital, University Hospital of the Ruhr-University Bochum, Gudrunstrasse 56, D-44791 Bochum, Germany*

[c] *Clinic of Anesthesiology, St. Josef-Hospital, University Hospital of the Ruhr-University Bochum, Gudrunstrosse 56, D-44791 Bochum, Germany*

Received 23 September 2004; received in revised form 18 November 2004; accepted 28 January 2005

Abstract

The first year experience with a hospital-wide first-responder automated external defibrillator (AED) programme implemented in a 683-bed University Hospital is reported. Throughout the hospital, 14 "AED access spots" were identified which could be easily reached from all wards and diagnostic rooms within 30 s. AEDs were installed (Lifepak 500; Medtronik PhysioControl Corp., Redmond, USA, equipped with a Biolog 3000i portable ECG monitor; Micromedical Industries Ltd., Labrador, Australia). Within 3 months, 120 medical officers, 750 nurses, and 50 administrative or technical staff underwent a 2 h training programme. An AED was applied and activated by nurses/medical staff before the cardiac arrest team arrived in 27 of 33 cases (81.8%) of witnessed cardiac arrest. The median time from onset of the emergency call to the activation of the AED (record of ECG) was on average 2.1 min (range 1.0–4.5 min). In 18 of 27 cases in which the AED was installed promptly, the primary arrest rhythm was either VT or VF, and the AED delivered a shock. For this subgroup, the rate of return of spontaneous circulation and the rate of discharge at home were 88.9 and 55.6%, respectively. This encourages us to extend the concept of first-responder AED-defibrillation throughout our hospital.

Keywords: Automated external defibrillator; In-hospital cardiac arrest; First-responder defibrillation; Cardiopulmonary resuscitation

1. Introductiou

Cardiac arrest in patieuts or visitors outside inteusive care areas within the hospital is not an infrequent event [1]. In the pre-hospital situation, there is little doubt that successful resuscitation depends on immediate activation of the chain of survival. Although the aetiology of cardiac arrest inside hospital differs from out of hospital [2,3], and may be more often of non cardiac origin (e.g. metabolic, respiratory, neurological), the best chance of survival is afforded to those with pulseless ventricular tachycardia (VT) or ventricular fibrillation (VF) and mortality clearly increases proportionately with delayed defibrillation [4]. Ideally, the person who is most likely to witness a cardiac arrest, the first-responder, should have the skill and equipment to provide rapid defibrillation. With the introduction of automated external defibrillators (AEDs), the concept of a first-responder AED programme has been increasingly advocated for in-hospital settings by numerous authors [4–10]. The ESC-ERC panel recommended recently that improvement of access to AEDs inside the hospital should have a high priority [11]. Although the use of AEDs can be easily learned even by children [12], hospital staff have to be encouraged to use AEDs at every opportunity, and routine staff training need to be implemented [13–15]. This concept has technical and organisational requirements,

☆ A Spanish translated version of the Abstract and Keywords of this article appears as Appendix at 10.1016/j.resuscitation.2005.01.014.

* Corresponding author.
E-mail address: andreas.muegge@rub.de (A. Müggе).

0300-9572/$ – see front matter © 2005 Published by Elsevier Ireland Ltd.
doi:10.1016/j.resuscitation.2005.01.014

as well as standardized documentation and programme evaluation [5,15]. In the present study, the first year experience with a hospital-wide first-responder AED programme in a medium-size University Hospital is reported.

2. Methods

2.1. Hospital settings

St. Josef-Hospital is a 683-bed hospital, and is part of the Bochum University Hospitals. It takes care of more than 24,000 in-patients/year in 27 wards, covering the following clinical subspecialities: cardiology and angiology (with telemetry facility), gastroenterology, endocrinology, rheumatology, infectious diseases, intensive care, dermatology, neurology, radiation therapy, general surgery, abdominal surgery, orthopaedic surgery, trauma surgery, vascular surgery and anaesthesiology. A children's hospital is separated from the main building, and has its own emergency system. Before the implementation of hospital-wide AEDs, a "cardiac arrest team" was alerted to the scene of the event via a group call paging system initiated by the hospital switchboard upon receipt of the cardiac arrest call. The cardiac arrest team was comprised of three medical staff who supplemented the first-responder at the location of the event and performed cardiopulmonary resuscitation (CPR), including early defibrillation according to the European Resuscitation Council guidelines [16]. With the exception of certain high-risk areas (e.g. intensive care, emergency room, catheterization laboratory), the normal wards were not equipped with defibrillators. After an emergency call, the cardiac arrest team transported a defibrillator to the scene.

2.2. Description and installation of AEDs

With the support of the hospital management, a CPR-AED committee was founded in June 2002 consisting of a nurse leader, cardiologist, anaesthesiologist, technical maintenance leader, and pharmacist. This committee identified 14 "AED access spots" throughout the hospital (the children's hospital not included), which could be easily reached from all wards and diagnostic rooms within 30 s. It was calculated that the interval between the event and AED-guided defibrillation should not be more than 3 min for all areas of the hospital. These "AED access spots" were equipped with an AED, the wall behind the AED was painted in red and furnished with a heart symbol. Four of these access spots (e.g. the patients cafeteria) were also equipped with an advanced resuscitation set and a phone with a direct line to the switchboard operator. In general, the wards were equipped with an advanced resuscitation set ("*Ulmer Notfallkoffer*"). As part of our new resuscitation policy, we included in each advanced resuscitation set a red-coloured "defibrillation bag" containing adrenaline (epinephrine) (two ampoules 1 mg each), amiodarone (two ampoules 150 mg each), NaCl 0.9% ampoules, 16 G and 18 G polyethylene cannulae, 10 ml syringes, and a tourniquet. Furthermore, specific risk areas such as the intensive care units, cardiology ward, stroke unit and cardiac catheterization area were equipped with additional Lifepak 12 (Medtronik PhysioControl Corp., Redmond, USA) defibrillators.

The AEDs installed were Lifepak 500 AEDs from Medtronik PhysioControl Corp. (Redmond, WA, USA) with a biphasic shock waveform. The electrodes used for ECG/defibrillation were disposable Fast-Patch electrodes. Each AED was equipped with a Biolog 3000i portable ECG monitor (Micromedical Industries Ltd., Labrador, Australia) for single-lead simultaneous ECG recording.

2.3. Technical support and maintenance

The Electrical Biomedical Engineering unit supported this programme. On a regular basis, the AEDs were serviced by this unit. After each use, the internal AED protocol was printed out and forwarded to the CRP-AED committee.

2.4. Training programme

Within 3 months (the first quarter of 2003), 120 medical officers, 750 nurses, and 50 administrative or technical servants underwent a 2-h training programme, with a maximum of eight participants in each training group. This training programme consisted of theoretical and practical parts, including training in basic life support. Each participant had to handle a dummy AED. This training programme was evaluated by the participants. Refresher "resuscitation days" were scheduled four times a year, and all employees of the hospital were required to join one such event per year. The participation of each employee was recorded. This training programme encouraged medical staff, nurses and servants to focus on the early use of AEDs as part of basic life support before the cardiac arrest team arrived at the scene.

2.5. Data collection and analysis

Mandatory prospective clinical audit of cardiac arrest using a standardized data sheet commenced in January 2003. Data was collected from 1st April 2003 for 1 year until 31st March 2004. Cardiac arrest calls initiated by the switchboard operator acted as the time index, which was documented on a cardiac arrest log form. The cardiac arrest team completed a resuscitation audit form, and one copy was forwarded to the CPR-AED committee. The outcome measures used for the survival profile were return of spontaneous circulation, and discharge from hospital. Values given are mean ± S.D., if not otherwise noted. This study analyzed the confirmed, audited and witnessed in-hospital cardiac arrests, which occurred outside the intensive care units, emergency department, and operation theatres. The definition criteria used were in accordance to the guidelines of the European Resuscitation Council [16]. Cardiac arrests which occurred in the cardiac catheterization laboratory as part of diagnostic or interven-

tional procedures (primary balloon angioplasty for acute myocardial infarctions) were not included in this analysis.

3. Results

During the period 1st April 2003 to 31st March 2004, there were 138 emergency calls registered from the switchboard operator with the request for the cardiac arrest team. A witnessed in-hospital cardiac arrest event was confirmed in 38 cases. Sufficient data were available for 33 cases, five cases were excluded from analysis (missing patient identification, missing outcome data, missing resuscitation audit form). An AED was applied and activated by nurses or medical staff before the cardiac arrest team arrived in 27 cases. Thus, the medical, nursing or other staffs already present in the wards or departments used the AED as "first-responders" in 81.8% of witnessed cardiac arrest events. The median time from onset of emergency call to the activation of the AED (recording of ECG) was on average of 2.1 min (range 1.0–4.5 min). The median arrival time of the cardiac arrest team was 4.7 min (range 2.0–11.5 min). A technical problem was not reported in any case with the use of AEDs.

In 18 of 27 cases in whom the AED was applied promptly, the primary arrest rhythm was either VT or VF, and the AED delivered a shock. Table 1 lists demographic and clinical data for this subgroup of 18 patients with confirmed pulseless VT/VF. The presumed reasons for VT/VF were as follows (n): acute coronary syndrome (10), coronary artery disease with previous myocardial infarction (3), recent aortic/coronary bypass surgery (2), end-stage congestive heart failure with hypokalaemia (2), and acute pulmonary embolism (1). For this subgroup of 18 patients, the rate of return of spontaneous circulation and the rate of hospital discharge were 88.9 and 55.6%, respectively. In the remaining nine patients in whom the AED was applied but did not deliver a shock, asystolic arrest ($n=7$) or pulseless electrical activity ($n=2$) were recorded.

Table 1
VT/VF cardiac arrest, AED used for early defibrillation

Number of patients	18
Mean age (range) (years)	70.2 (43–94)
Sex (male/female)	5/13
Witnessed cardiac arrest (%)	100
Location of cardiac arrest n (%)	
Wards	11 (61.1)
Diagnostic rooms	5 (27.8)
Other rooms	2 (11.1)
Duration of hospital stay before arrest (days)	8.9 (1–25)
Reason for hospital admission n (%)	
Cardiac diseases	9 (50.0)
Non-cardiac diseases	4 (22.2)
Non-cardiac surgical procedures	5 (27.8)
Time interval between arrest alarm to first defibrillation shock (min)	2.1 (1.0–4.5)
Additional CPR/Ventilation n (%)	8 (44.4)
Return of spontaneous circulation n (%)	16 (88.9)
Discharge from the intensive care unit n (%)	11 (61.1)
Discharge home from the hospital n (%)	10 (55.6)

Equipment and technical maintenance costs of 34,000 Euro and 1500 Euro/year, respectively, were calculated. The medical and non-medical hospital staff ($n=920$) underwent initial training for 2 h (in groups of eight participants), and was required to participate in a refreshing course (2 h) once a year. These training events were scheduled during working hours. The 920 staff members spend 1840 working hours on initial training.

4. Discussion

This study describes the initial experience of widespread implementation of AED supported early defibrillation in a medium-size university hospital. After a training period of 3 months, this concept of first-responder AED defibrillation was accepted and used by medical staff, nurses and other hospital servants in more than 80% of cardiac arrest events before the designated cardiac arrest team arrived at the scene. In an important subgroup of patients with cardiac arrest due to VF/VT, first-responder defibrillation yielded a high rate of ROSC and discharge to home.

Although the concept of first-responder early defibrillation using an AED for in-hospital cardiac arrests has been advocated for several years, only limited data are available in the literature [9]. This early defibrillation programme required considerable effort in training hospital specific solutions in organisation and technology, and a change in the traditional philosophy and responsibility by the nursing staff [10,13,14,17]. To our knowledge no data are available demonstrating that the outcome for in-hospital cardiac arrest is superior when a hospital-wide first-responder AED programme is implemented in addition to a cardiac arrest team. However, there is little doubt that the time to first shock is critical for survival in cardiac arrest in-hospital patients with VT/VF [4]. Reports like ours can at best support this concept of first-responder rapid AED-defibrillation, but cannot give the scientific proof of superiority over other in-hospital CPR programmes.

In an extensive literature search, Kenward et al. [9] identified recently only five studies reporting on outcome data from in-hospital first-responder AED defibrillation programmes. Overall, they noted a survival to discharge rate following rapid AED-defibrillation for VF/VT cardiac arrest of 36.5% (42/115). This number is similar to that published previously from a National Registry of Cardiopulmonary Resuscitation (34%) in which "traditional" cardiac arrest teams performed in-hospital advanced CPR, and AEDs were used to provide first-responder defibrillation in less than 1% of cases [3]. In our study, we observed a survival-to-hospital discharge rate of 55.6% for this subgroup of patients with VT/VF cardiac arrest. This number encourages us to go further with the concept of first-responder rapid AED application throughout our hospital.

Acknowledgements

The authors would like to acknowledge the help and support from B. Milde (Administration Director), E. Hanke (Nursing Director), M. Buddendick, M. Rüther, S. Zombeck, and W. Satzer for the technical maintenance unit, Dr. M. Rivera (Pharmacist) and the medical staff who assisted us in this study.

References

[1] Jastremski MS. In-hospital cardiac arrest. Ann Emerg Med 1993;11:113–7.
[2] Andreasson C, Herlitz J, Bang A, et al. Characteristics and outcomes among patients with a suspected in-hospital cardiac arrest. Resuscitation 1998;39:23–31.
[3] Peberby MA, Kaye E, Ornato JP, et al. Cardiopulmonary resuscitation of adults in the hospital: a report of 14720 cardiac arrests from the National Registry of Cardiopulmonary Resuscitation. Resuscitation 2003;58:297–308.
[4] Spearpoint KG, McLean CP, Zideman DA. Early defibrillation and the chain of survival in "in-hospital" adult cardiac arrest: minutes count. Resuscitation 2000;44:165–9.
[5] Kaye, Mancinci ME, Richards N. Organizing and implementation a hospital-wide first-responder automated external defibrillation program: strengthening the in-hospital chain of survival. Resuscitation 1995;30:151–6.
[6] Destro A, Marzaloni M, Sermasi S, Rossi F. Automatic external defibrillators in the hospital as well? Resuseitation 1996;31:39–44.
[7] Soar J, McKay U. A revised role for the hospital cardiac arrest team? Resuscitation 1998;38:145–9.
[8] Bozzano A, Rossi GP, Marcolin R, Valagussa F, Pesenti A. Organisation of an hospital-wide first-responder AED outside critical care areas. Resuscitation 1998;37:50.
[9] Kenward G, Castle N, Hodgetts TJ. Should ward nurse be using automatic external defibrillators as first-responders to improve the outcome from cardiac arrest? a systematic review of the primary research. Resuscitation 2002;52:31–7.
[10] Dwyer T, Williams LM, Jacobs I. The benefits and use of shock advisory a defibrillators in-hospital. Int J Nurs Pract 2004;10:86–92.
[11] Priori SG, Bossaert LL, Chamberlain DA, et al. ESC-ERC recommendations for the use of automated external defibrillators (AEDs) in Europe. Eur Heart J 2004;25:437–45.
[12] Gundry JW, Comess KA, DeRook FA, Jorgenson D, Bardy GH. Comparison of naïve sixth-grade children with trained professionals in the use of an automated external defibrillator. Circulation 1999;100:1703–7.
[13] Warwick JP, Mackie K, Spencer I. Towards early defibrillation—a nurse training programme in the use of automated external defibrillators. Resuscitation 1995;30:231–5.
[14] Coady EM. A strategy for nurse defibrillation in general wards. Resuscitation 1999;42:183–6.
[15] Bickenbach J, Fries M, Beckers S, Rossaint R, Kuhlen R. Voraussetzungen zur Anwendung von automatischen externen Defibrillatoren in deutschen Krankenhäusern. Anaesthesist 2004;53:555–9.
[16] De Latorre F, Nolan J, Robertson C, et al. European resuscitation council guidelines 2000 for adult advanced life support. Resuscitation 2001;48:211–21.
[17] Stewart JA. A more effective approach to in-hospital defibrillation. J Cardiovasc Nurs 1996;10:37–46.

Automated External Defibrillators and Simulated In-Hospital Cardiac Arrests

JOSEPH W. ROSSANO, MD, LARRY S. JEFFERSON, MD, E. O'BRIAN SMITH, PHD, MARK A. WARD, MD, AND ANTONIO R. MOTT, MD

Objective To test the hypothesis that pediatric residents would have shorter time to attempted defibrillation using automated external defibrillators (AEDs) compared with manual defibrillators (MDs).

Study design A prospective, randomized, controlled trial of AEDs versus MDs was performed. Pediatric residents responded to a simulated in-hospital ventricular fibrillation cardiac arrest and were randomized to using either an AED or MD. The primary end point was time to attempted defibrillation.

Results Sixty residents, 21 (35%) interns, were randomized to 2 groups (AED = 30, MD = 30). Residents randomized to the AED group had a significantly shorter time to attempted defibrillation [median, 60 seconds (interquartile range, 53 to 71 seconds)] compared with those randomized to the MD group [median, 103 seconds (interquartile range, 68 to 288 seconds)] ($P < .001$). All residents in the AED group attempted defibrillation at <5 minutes compared with 23 (77%) in the MD group ($P = .01$).

Conclusions AEDs improve the time to attempted defibrillation by pediatric residents in simulated cardiac arrests. Further studies are needed to help determine the role of AEDs in pediatric in-hospital cardiac arrests. *(J Pediatr 2009;154:672-6)*

Ventricular fibrillation (VF) is the primary cause of sudden cardiac death in adults. Although VF is less common among children, as many as one-quarter of pediatric out-of-hospital arrests are from VF,[1,2] with a similar number from in-hospital cardiac arrests.[3] Additionally, 15% to 20% of pediatric cardiac arrests that develop VF will not have VF as the presenting rhythm.[3,4] Importantly, survival and survival with good neurological outcome are significantly better when VF is the presenting rhythm compared with asystole.[1,5]

Prompt defibrillation is crucial for survival of patients with VF.[6,7] Estimates from adult out-of-hospital arrests suggest that survival decreases as much as 10% for each minute defibrillation is not performed.[8,9] Automated external defibrillators (AEDs) have been successfully used to improve time to defibrillation and survival in many settings including airports, casinos, and other public places.[10-15] Additionally, AEDs have been used to a limited extent in adult hospitals for inpatient cardiac arrests with encouraging results, including reduced time to defibrillation and possibly an increased rate of survival.[16-18]

The American Heart Association (AHA) and the European Resuscitation Council recommend the use of AEDs for pediatric patients >1 year of age for out-of-hospital arrests, and training on the use of AEDs is part of the AHA courses on pediatric basic and advanced life support.[19] There are, however, no studies that have evaluated the use of AEDs for pediatric inpatient cardiac arrests or on the use of AEDs by pediatric residents, who are in many instances the physician leader of code teams. Additionally, there are no studies that have evaluated whether pediatric residents can perform defibrillation correctly and in a timely manner.

Therefore, the purpose of this study was to test the hypothesis that pediatric residents would have shorter time to attempted defibrillation using AEDs compared with manual defibrillators (MDs) in simulated in-hospital VF cardiac arrest. The primary outcome was time to first defibrillation attempt. Secondary outcomes included the frequency of defibrillation attempts at <2 minutes and <5 minutes.

METHODS

The study was approved by the Institutional Review Board of Baylor College of Medicine and Texas Children's Hospital. Subjects were available pediatric residents, recruited from the inpatient services at Texas Children's Hospital and Ben Taub General Hospital from December 2006 to February 2007. Participation was voluntary and there

AED	Automated external defibrillator	PALS	Pediatric Advanced Life Support
AHA	American Heart Association	VF	Ventricular fibrillation
MD	Manual defibrillator		

From the Department of Pediatrics, Lillie Frank Abercrombie Section of Pediatric Cardiology (J.R., A.M.), Section of Pediatric Critical Care Medicine (L.J.), Children's Nutrition Research Center (E.S.), and Section of Emergency Medicine (M.W.), Baylor College of Medicine, Texas Children's Hospital, Houston, TX.

The authors declare no conflicts of interest.

Clinical Trial Registration No. NCT00640354.

Submitted for publication Jul 8, 2008; last revision received Oct 3, 2008; accepted Nov 17, 2008.

Reprint requests Dr Joseph W. Rossano, Lillie Frank Abercrombie Section of Pediatric Cardiology, Texas Children's Hospital, 6621 Fannin, MC 19345-C, Houston, TX 77030. E-mail: jrossano@bcm.tmc.edu.

0022-3476/$ - see front matter

10.1016/j.jpeds.2008.11.051

were no residents that refused to participate. All residents were Pediatric Advanced Life Support (PALS) certified and had received training on the use of AEDs and MDs. The results of individual resident performance were kept confidential and were not used as a part of any performance evaluation.

For the AED, we used the Lifepak CR-T AED Training System (Physio-Control, a division of Medtronic; Redmond, Washington) (Figure 1; available at www.jpeds.com). To perform defibrillation successfully, the resident would only have to open the AED and then voice prompts from the AED guide the resuscitator to place the pads appropriately. The adult-sized defibrillation pads were used for the study. Once the pads are attached, the AED will analyze the rhythm. If the rhythm is a shockable one, the AED will prompt the user to stand clear and a shock will be delivered. The Lifepak CR-T AED is the training device for the Lifepak CR Plus AED, which is the AED located in nonpatient care areas of the hospital. The training device is designed to work as the Lifepak™ CR plus AED does, but will not actually discharge energy into the mannequin.[20] The heart rhythm is not displayed on the AED, and the operator cannot adjust the energy dose delivered.

The MD (Lifepak 20, Physio-Control, a division of Medtronic; Redmond, Washington) provides biphasic shocks with an adjustable dose (Figure 1). The device will default to 200 J if not manually changed. The MD can be discharged using both pads and paddles. To decrease the potential for confusion, appropriate-sized pads were connected to the defibrillator and the paddles were removed. The MD was used with a simulator attachment that would display the appropriate rhythm. With the simulator, the MD could still be used just as it would be used during an actual code and the device could be discharged, but no energy would be delivered into the mannequin. Additionally, the MD used for the study is the same model as the MDs used throughout the study hospitals.

The subjects were informed that they would respond to a simulated code, and that they would be randomized to either having a MD or an AED. Subjects were randomized via block randomization in 6 blocks with 10 subjects in each block. Allocation concealment occurred by placing the group assignment (eg, having a MD or AED available) in a sealed container that was selected by the subject. Subjects were made aware of the group they were randomized to immediately before the scenario started. Subjects were enrolled by one investigator (J.W.R.). There was no blinding of group assignment.

The code scenario was the same for all participants. The scenario was witnessed in-hospital VF arrest. The scenario was described to the subjects as follows:

The patient had a witnessed arrest and is pulseless. He weighs 25 kg, has an intact airway, and is being hand ventilated. The subject is immediately on scene and is the first physician responder.

The patient was not on a monitor, so defibrillation pads would have to be placed on the patient for the subject to determine the rhythm. The only equipment available was the AED or MD in order to decrease other confounding factors that could affect the time to defibrillation attempt.

Subjects were permitted to ask questions before but not during the scenario. The simulated code was ended when the first defibrillation attempt occurred or 5 minutes after the start of the simulated code. The time to defibrillation attempt was considered the time period from the resident stating understanding the instructions with all questions answered to discharge of the device. The simulated codes were attended by and timed by one of the investigators (J.W.R.) and video taped to insure accuracy. Residents were not given feedback at the end of the scenario and were asked not to discuss the study.

The primary outcome was time to the first defibrillation attempt with secondary outcomes being the percentage with a defibrillation attempt at <2 and <5 minutes. For the secondary outcomes, the time of 2 minutes was chosen from adult guidelines that define delayed defibrillation for in-hospital arrests at that time period.[21] The time of 5 minutes was chosen at the other end point with the thought that by that time during an actual code other members of the code team knowledgeable of defibrillation would be available to the resident. There are no data on time to attempted defibrillation in pediatric in-hospital cardiac arrests. It was assumed that a mean time to attempted defibrillation of 3 minutes would be achieved using a MD. To achieve 80% power to detect a 20% improvement in time to shock, a minimum of 40 total subjects would be required. Given the uncertainty of this calculation, the desired number of subjects was increased to 60.

Statistical analysis was performed using SPSS, version 12.0 (Chicago, Illinois). Baseline data are expressed as percentages. A Mann-Whitney U test was utilized to assess for differences in the primary end point between the MD and AED groups. If no defibrillation attempt occurred at 5 minutes, the scenario was stopped and a time of 5 minutes was assigned to the subject. A χ^2 square or Fisher exact text was performed for categorical variables. Analysis of covariance was used to compare AED and MD groups while controlling for differences in baseline characteristics. Statistical significance was defined as a P value of $< .05$.

RESULTS

Sixty residents participated in the study (AED, n = 30); the baseline characteristics were similar among residents randomized to the AED and those randomized to the MD (Table I). Residents randomized to the AED had a significantly shorter time to attempted defibrillation, median 60 seconds (interquartile range, 53 to 71 seconds), compared with those randomized to the MD, median 103 seconds (interquartile range 68 to 288 seconds) ($P < .001$). There was also less variation in the time to attempted defibrillation in the AED group compared with the MD group (Figure 2). There were no significant differences in time to attempted defibrillation based on other characteristics (Table II). Controlling for differences in baseline characteristics also indicated that

Table I. Baseline characteristics

Characteristic	AED (n = 30)	MD (n = 30)	P value
Intern, n (%)	12 (40)	18 (60)	.42
Combined Med-Peds resident, n (%)	3 (10)	3 (10)	1.00
ACLS before residency, n (%)	11 (37)	14 (47)	.43
PALS (active), n (%)	30 (100)	30 (100)	NA
Prior cardiology rotation, n (%)	14 (47)	18 (60)	.30
Prior PICU rotation, n (%)	10 (33)	9 (30)	.78
Anticipated career: Card, EM, PCCM, n (%)	15 (50)	17 (57)	.61
Anticipated career: Primary care, n (%)	5 (17)	4 (13)	1.00

AED, automated external defibrillator group; *MD*, manual defibrillator group; *Med-Peds*, medicine-pediatric resident; *ACLS*, advanced cardiac life support certified; *PALS*, pediatric advanced life support certified; *PICU*, pediatric intensive care unit; *Card*, cardiology; *EM*, emergency medicine; *PCCM*, pediatric critical care medicine.

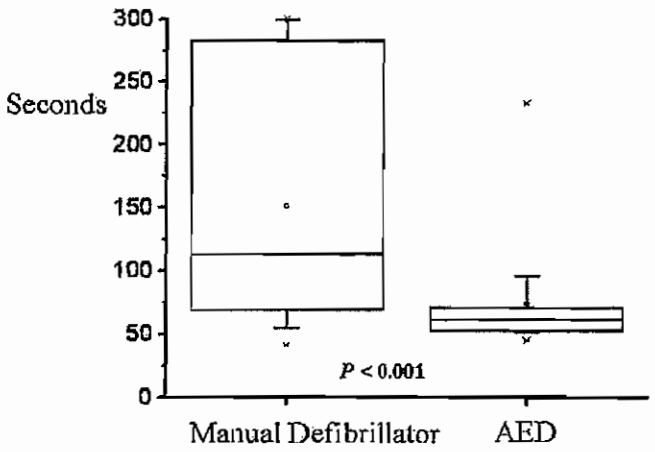


Figure 2. Time to attempted defibrillation in AED vs manual defibrillator. Horizontal lines in box denote 25th, 50th, and 75th percentile values. Error bars denote the 5th and 95th percentile values. Symbol below the 5th percentile error bar denotes 1st percentile value. Symbol above the 95th percentile error bar denotes the 99th percentile. Square symbol in box denotes mean of the column of data. AED, automated external defibrillator.

the AED group had significantly improved time to defibrillation ($P < .001$).

More residents randomized to the AED attempted defibrillation in <2 minutes (n = 27, 90%) compared with residents randomized to the MD (n = 16, 53%) ($P = 0.003$), and all of the residents randomized to the AED attempted defibrillation in <5 minutes compared with 23 (77%) in the MD group ($P = .01$).

The AED will deliver a preprogrammed energy dose protocol of 200 J for the first shock, using adult-sized pads. The median energy dose delivered from residents randomized to the MD was 200 J (interquartile range, 50 to 200 J) or 8 J/kg (interquartile range, 2 to 8 J/kg). Only 7 (30%) of the residents correctly adjusted the energy dose to 2 J/kg, and 13 (43%) defibrillated with the default setting of 200 J (8 J/kg).

Table II. Time to attempted defibrillation

Variable	Median time, s (IQR)	P value
Intern	65 (55 to 109)	.41
Senior resident	71 (56 to 132)	
Categorical pediatric resident	69 (55 to 127)	.32
Combined medicine-pediatric resident	92 (60 to 300)	
ACLS before residency	65 (55 to 105)	.47
No ACLS before residency	75 (54 to 195)	
Prior cardiology rotation	70 (54 to 118)	.92
No prior cardiology rotation	70 (55 to 175)	
Prior PICU rotation	65 (53 to 120)	.36
No prior PICU rotation	75 (56 to 161)	
Anticipated career primary care	67 (56 to 131)	.79
Anticipated career subspecialty care	74 (54 to 126)	

IQR, interquartile range; *ACLS*, advanced cardiac life support; *PALS*, pediatric advanced life support; *PICU*, pediatric intensive care unit.

DISCUSSION

This study documented the performance of pediatric residents in simulated pediatric VF arrests and evaluated the use of AEDs in this situation. In our study, residents randomized to the MD group did not consistently defibrillate in a timely manner, but residents randomized to the AED group consistently defibtillated in a timely mannet. This has impottant ptactical implications, as many hospitals have pediatric residents serve as the code team leader. There are no hospitals, to our knowledge, that currently use AEDs for inpatient resuscitations of pediatric patients.

Although pediatric residents demonstrated proficiency with the use of AEDs in our study, this level of proficiency was not demonstrated by pediatric residents that used MDs. Steps should be taken to improve the training and performance of residents on this important task. However, it is also known that skills taught in resuscitation courses quickly erode with time after the course in both health professionals[22-24] and lay responders.[25,26] Additionally, pediatric residency training requirements have limited the amount of time spent in critical care areas to more time spent in outpatient settings.[27] Thus, residents have less time to reinforce resuscitation skills in the clinical setting. Additionally, a survey of internal medicine residents revealed that almost 50% perceived their training in code scenarios to be inadequate to lead a resuscitation team.[28] Inadequate training combined with lack of clinical reinforcement and practice may place unrealistic expectations on residents. PALS type courses may be insufficient to insure prompt defibrillation by residents in the in-hospital setting. This is evidenced by all pediatric residents in the study being PALS certified, but almost half of the residents randomized to the MD group failed to perform defibrillation at <2 minutes.

The Institute of Medicine, interested in improving patient outcomes, have advocated the use of existing technology

in order assess and improve inefficiencies in care delivery.[29] For example, the decline in chest compression skills may be attenuated by the use of aids that incorporate technological advancements to assist the resuscitator with feedback on performance.[30] AEDs are another technological advantage that assists the resuscitator in rhythm identification and treatment. Even though there are limited data on the use of AEDs in pediatric patients, they have been used successfully for pediatric out-of-hospital arrests.[31-33] The algorithms used by AEDs have high sensitivity and specificity in detecting shockable rhythms in pediatric patients.[34,35] AEDs do provide higher than recommended energy doses for many children; however, the doses actually used in out-of-hospital arrest are similar to what AEDs provide,[4] and similar to what was delivered by the MD group in this study. Designing hospital systems that do not rely on relatively inexperienced personnel to perform complicated tasks in emergency situations should lead to improved outcomes. Whether AEDs should be a part of these systems is unresolved, but this study provides support for the concept.

This study has several limitations. It is a single-center study of a cohort of residents and the findings may not be applicable to residents from other training centers. However, the study institution is a large academic institution that is probably similar to other large academic institutions in training residents to respond to cardiac arrests. Additionally, the environment of a simulated cardiac arrest is quite different from that of a true cardiac arrest. The code scenario was designed to be simple to limit potential cofounders that may affect the time to attempted defibrillation. However, in the "real world," there are many factors which may affect the time to attempted defibrillation. It is likely that the time to attempted defibrillation would be higher in both groups in a "real world" situation. There could potentially be some recall bias based on prior training; however, as PALS courses include both AEDs and manual defibrillator, it is not clear that any recall bias would favor one device over the other. Lastly, although time to attempted defibrillation is a very important component of successful resuscitation for VF arrests, other important factors, such as performing high quality chest compressions and avoiding hyperventilation, are also important determinants.[36,37] These were not assessed in our study, and there are some data to suggest that the performance of chest compressions may be impacted when AEDs are used compared with MD.[38]

AEDs improved the time to defibrillation by pediatric residents in simulated pediatric cardiac arrests. Importantly, pediatric residents were not able to reliably use the MD for prompt defibrillation. Further studies are needed to determine the role of AEDs for pediatric in-hospital cardiac arrests.

We would like to thank the pediatric residents of Baylor College of Medicine for their participation in the study. They received no compensation other than helping to improve the understanding of pediatric resuscitations.

REFERENCES

1. Mogayzel C, Quan L, Graves JR, Tiedeman D, Fahrenbruch C, Herndon P. Out-of-hospital ventricular fibrillation in children and adolescents: causes and outcomes. Ann Emerg Med 1995;25:484-91.
2. Hickey RW, Cohen DM, Strausbaugh S, Dietrich AM. Pediatric patients requiring CPR in the prehospital setting. Ann Emerg Med 1995;25:495-501.
3. Samson RA, Nadkarni VM, Meaney PA, Carey SM, Berg MD, Berg RA. Outcomes of in-hospital ventricular fibrillation in children. N Engl J Med 2006;354:2328-39.
4. Rossano JW, Quan L, Kenney MA, Rea TD, Atkins DL. Energy doses for treatment of out-of-hospital pediatric ventricular fibrillation. Resuscitation 2006;70:80-9.
5. Young KD, Seidel JS. Pediatric cardiopulmonary resuscitation: a collective review. Ann Emerg Med 1999;33:195-205.
6. Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Part 6: advanced cardiovascular life support: section 2: defibrillation. The American Heart Association in collaboration with the International Liaison Committee on Resuscitation. Circulation 2000;102:I-90-4.
7. Deakin CD, Nolan JP. European Resuscitation Council guidelines for resuscitation 2005. Section 3. Electrical therapies: automated external defibrillators, defibrillation, cardioversion and pacing. Resuscitation 2005;67(Suppl 1):S25-37.
8. Larsen MP, Eisenberg MS, Cummins RO, Hallstrom AP. Predicting survival from out-of-hospital cardiac arrest: a graphic model. Ann Emerg Med 1993; 22:1652-8.
9. Waalewijn RA, de Vos R, Tijssen JG, Koster RW. Survival models for out-of-hospital cardiopulmonary resuscitation from the perspectives of the bystander, the first responder, and the paramedic. Resuscitation 2001;51:113-22.
10. O'Rourke MF, Donaldson E, Geddes JS. An airline cardiac arrest program. Circulation 1997;96:2849-53.
11. Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Public use of automated external defibrillators. N Engl J Med 2002;347:1242-7.
12. Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. N Engl J Med 2000;343:1206-9.
13. Capucci A, Aschieri D, Piepoli MF, Bardy GH, Iconomu E, Arvedi M. Tripling survival from sudden cardiac arrest via early defibrillation without traditional education in cardiopulmonary resuscitation. Circulation 2002;106:1065-70.
14. Hallstrom AP, Ornato JP, Weisfeldt M, Travers A, Christenson J, McBurnie MA, et al. Public-access defibrillation and survival after out-of-hospital cardiac arrest. N Engl J Med 2004;351:637-46.
15. Culley LL, Rea TD, Murray JA, Welles B, Fahrenbruch CE, Olsufka M, et al. Public access defibrillation in out-of-hospital cardiac arrest: a community-based study. Circulation 2004;109:1859-63.
16. Hanefeld C, Lichte C, Laubenthal H, Hanke E, Mugge A. [In-hospital resuscitation. Concept of first-responder resuscitation using semi-automated external defibrillators (AED)]. Dtsch Med Wochenschr 2006;131:2139-42.
17. Zafari AM, Zarter SK, Heggen V, Wilson P, Taylor RA, Reddy K, et al. A program encouraging early defibrillation results in improved in-hospital resuscitation efficacy. J Am Coll Cardiol 2004;44:846-52.
18. Gombotz H, Weh B, Mitterndorfer W, Rehak P. In-hospital cardiac resuscitation outside the ICU by nursing staff equipped with automated external defibrillators: the first 500 cases. Resuscitation 2006;70:416-22.
19. Samson RA, Berg RA, Bingham R, Biarent D, Coovadia A, Hazinski MF, et al. Use of automated external defibrillators for children: an update: an advisory statement from the pediatric advanced life support task force, International Liaison Committee on Resuscitation. Circulation 2003;107:3250-5.
20. Beckers SK, Fries M, Bickenbach J, Skoruing MH, Derwall M, Kuhlen R, et al. Retention of skills in medical students following minimal theoretical instructions on semi and fully automated external defibrillators. Resuscitation 2007;72:444-50.
21. Chan PS, Krumholz HM, Nichol G, Nallamothu BK. Delayed time to defibrillation after in-hospital cardiac arrest. N Engl J Med 2008;358:9-17.
22. Semeraro F, Signore L, Cerchiari EL. Retention of CPR performance in anaesthetists. Resuscitation 2006;68:101-8.
23. Young R, King L. An evaluation of knowledge and skill retention following an in-house advanced life support course. Nurs Crit Care 2000;5:7-14.
24. Nadel FM, Lavelle JM, Fein JA, Giardino AP, Decker JM, Durbin DR. Assessing pediatric senior residents' training in resuscitation: fund of knowledge, technical skills, and perception of confidence. Pediatr Emerg Care 2000;16:73-6.
25. Chamberlain D, Smith A, Woollard M, Colquhoun M, Handley AJ, Leaves S, et al. Trials of teaching methods in basic life support (3): comparison of simulated CPR performance after first training and at 6 months, with a note on the value of re-training. Resuscitation 2002;53:179-87.
26. Reder S, Cummings P, Quan L. Comparison of three instructional methods for teaching cardiopulmonary resuscitation and use of an automatic external defibrillator to high school students. Resuscitation 2006;69:443-53.

27. Tenner PA, Dibrell H, Taylor RP. Improved survival with hospitalists in a pediatric intensive care unit. Crit Care Med 2003;31:847-52.
28. Hayes CW, Rhee A, Detsky ME, Leblanc VR, Wax RS. Residents feel unprepared and unsupervised as leaders of cardiac arrest teams in teaching hospitals: a survey of internal medicine residents. Crit Care Med 2007;35:1668-72.
29. Bates DW, Gawande AA. Improving safety with information technology. N Engl J Med 2003;348:2526-34.
30. Wik L, Myklebust H, Auestad BH, Steen PA. Twelve-month retention of CPR skills with automatic correcting verbal feedback. Resuscitation 2005;66:27-30.
31. Atkins DL, Hartley LL, York DK. Accurate recognition and effective treatment of ventricular fibrillation by automated external defibrillators in adolescents. Pediatrics 1998;101:393-7.
32. Divekar A, Soni R. Successful parental use of an automated external defibrillator for an infant with long-QT syndrome. Pediatrics 2006;118:e526-9.
33. Bar-Cohen Y, Walsh EP, Love BA, Cecchin F. First appropriate use of automated external defibrillator in an infant. Resuscitation 2005;67:135-7.
34. Cecchin F, Jorgenson DB, Berul CI, Perry JC, Zimmerman AA, Duncan BW, et al. Is arrhythmia detection by automatic external defibrillator accurate for children? Sensitivity and specificity of an automatic external defibrillator algorithm in 696 pediatric arrhythmias. Circulation 2001;103:2483-8.
35. Atkinson E, Mikysa B, Conway JA, Parker M, Christian K, Deshpande J, et al. Specificity and sensitivity of automated external defibrillator rhythm analysis in infants and children. Ann Emerg Med 2003;42:185-96.
36. Aufderheide TP, Lurie KG. Death by hyperventilation: a common and life-threatening problem during cardiopulmonary resuscitation. Crit Care Med 2004;32:S345-51.
37. Yannopoulos D, Aufderheide TP, Gabrielli A, Beiser DG, McKnite SH, Pirrallo RG, et al. Clinical and hemodynamic comparison of 15:2 and 30:2 compression-to-ventilation ratios for cardiopulmonary resuscitation. Crit Care Med 2006;34:1444-9.
38. Berg RA, Hilwig RW, Kern KB, Sanders AB, Xavier LC, Ewy GA. Automated external defibrillation versus manual defibrillation for prolonged ventricular fibrillation: lethal delays of chest compressions before and after countershocks. Ann Emerg Med 2003;42:458-67.

50 Years Ago in *The Journal of Pediatrics*

PURE RED-CELL ANEMIA

Smith CH. J Pediatr 1959;54:609-16

In the 1930s, 6 children with pure red cell aplasia were described by Josephs, Diamond, and Blackfan[1,2]; this disorder is known today as Diamond Blackfan anemia (DBA). Carl Smith, in his 1959 article, reviewed the clinical and therapeutic options for children with this rare disorder. At that time, researchers recognized the early clinical presentation, but hypothesized a noxious in utero event or some deficiency state to explain infant red cell anemia. Patients received corticosteroids as frontline therapy, followed by transfusions in steroid-resistant patients. Other available therapies such as adrenocorticotropic hormone, cobalt, B-complex vitamins, and splenectomy were later abandoned because of morbidity or lack of efficacy. DBA was recognized as a progressive anemia with fatal outcome, most often from chronic transfusion complications, including cardiac or liver failure. Complications of transfusional iron overload were known, but chelation therapy was not yet available.

The recent identification of a 19q abnormality and discovery of RPS19 gene mutations represent a breakthrough in DBA research.[3] RPS19 plays a key role in ribosome synthesis within hematopoietic cells; mutations are found in 25% of DBA patients, and additional ribosomal genes are now implicated. Patients still receive corticosteroids and periodic or chronic transfusions; safer transfusions and iron chelation have reduced fatal complications. Hematopoietic stem cell transplantation provides a curative option, particularly in young patients receiving a matched sibling donor transplant.

In 1993, the Diamond Blackfan Anemia Registry (www.dbar.org) was established to centralize clinical and demographic data on DBA patients and their families. With approximately 25 to 30 new cases identified annually in the United States and Canada, the DBA registry provides education to families and clinicians, promotes research in DBA genetics and cancer predisposition, and helps determine its natural history in the modern era. DBA is a paradigm for inherited bone marrow failure syndromes, and its scientific and clinical lessons should help our understanding of normal hematopoiesis. With ongoing collaborative gene discoveries, biological studies, and therapeutic clinical trials, the next 50 years should be equally enlightening.

Jeffrey Lebensburger, DO
Russell E. Ware, MD, PhD
Department of Hematology
St. Jude Children's Research Hospital
Memphis, Tennessee
10.1016/j.jpeds.2008.11.001

REFERENCES

1. Josephs HW. Anaemia of infancy and early childhood. Medicine 1936;15:307.
2. Diamond LK, Blackfan KD. Hypoplastic anemia. Am J Dis Child 1938;56:464.
3. Draptchinskaia N, Gustavsson P, Andersson B, Pettersson M, Willig T-N, Dianzani I, et al. The gene encoding ribosomal protein S19 is mutated in Diamond-Blackfan anaemia. Nat Genet 1999;21:169.

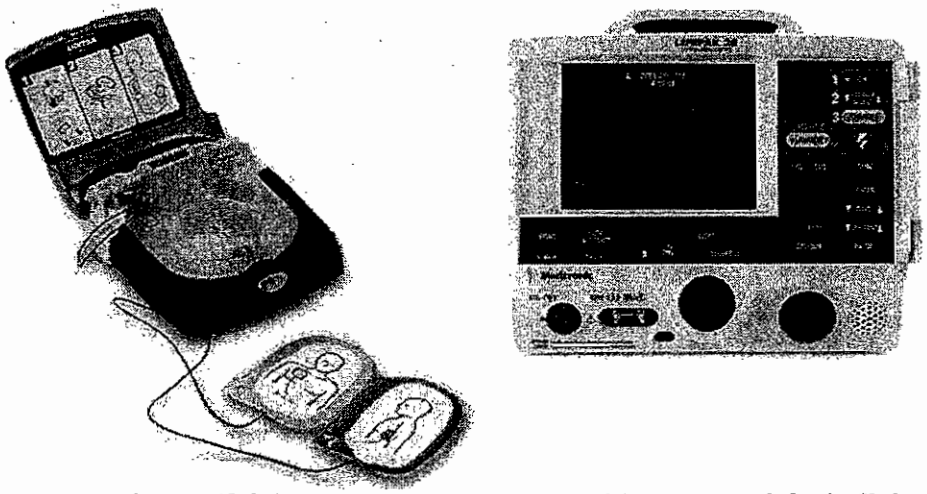


Figure 1. Lifepak CR-T AED (Physio-Control, a division of Medtronic, Redmond, Washington) and Lifepak 20 manual defibrillator (Physio-Control, a division of Medtronic, Redmond, Washington).

8/4/2009
download
T. Grant
8/4/09

Research article summary (published 24 Jan 2009):

[In-hospital resuscitation with automated external defibrilliator]

(Genoplivning med automatisk ekstern defibrillator på hospital.)

Full Abstract

Early defibrillation is a determinant of survival in cardiac arrest. We report a Danish case of successful in-hospital resuscitation using an automated external defibrillator (AED). This case illustrates important aspects of implementation of in-hospital use of an AED, i.e. location of the AED, education of the staff, systematic registration and data collection and technical aspects of AED use. If in-hospital AED implementation is carefully executed, its use may provide a safe and effective way of obtaining early defibrillation.

Author information

Author/s: Løfgren, Bo (B); Wahlgreen, Claus (C); Hoffmann, Anne Mette (AM); Poulsen, Tina Svenstrup (TS); Krarup, Niels Henrik (NH);

Affiliation: Hjertemedicinsk Afdeling B, Arhus Universitetshospital, Skejby, DK-8200 Arhus N. bo.loefgren(-atsign-)kl.au.dk

Journal and publication information

Publication Type: Case Reports; English Abstract; Journal Article

Journal: Ugeskrift for laeger (Ugeskr Laeger), published in Denmark. (Language: dan)

Reference: 2009-Jan; vol 171 (issue 5) : pp 308-10

Dates: Created 2009/01/29; Completed 2009/02/06; Revised 2009/02/11;

PMID: 19176157, status: MEDLINE (last retrieval date: 2/18/2009, IMS Date:)

External Links for this article (including full text providers, if available):

Trials

BioMed Central

Study protocol

Open Access

Automated external cardioversion defibrillation monitoring in cardiac arrest: a randomized trial

Bakhtiar Ali[1], Heather Bloom[1,2], Emir Veledar[2], Dorothy House[1], Robert Norvel[1], Samuel C Dudley[3] and A Maziar Zafari*[1,2]

Address: [1]Atlanta Veterans Affairs Medical Center, Decatur, Georgia, USA, [2]Emory University School of Medicine, Division of Cardiology, Atlanta, Georgia, USA and [3]University of Illinois at Chicago, Section of Cardiology and the Jesse Brown VA Medical Center, Chicago, Illinois, USA

Email: Bakhtiar Ali - bakhtiar02@yahoo.com; Heather Bloom - hbloom@emory.edu; Emir Veledar - eveleda@emory.edu; Dorothy House - Dorothy.House2@va.gov; Robert Norvel - rnorvel@hotmail.com; Samuel C Dudley - scdudley@uic.edu; A Maziar Zafari* - azafari@emory.edu

* Corresponding author

Published: 11 June 2008

Trials 2008, 9:36 doi:10.1186/1745-6215-9-36

Received: 25 April 2008
Accepted: 11 June 2008

This article is available from: http://www.trialsjournal.com/content/9/1/36

Abstract

Background: In-hospital cardiac arrest has a poor prognosis despite active electrocardiography monitoring. The initial rhythm of approximately 25% of in-hospital cardiopulmonary resuscitation (CPR) events is pulseless ventricular tachycardia/ventricular fibrillation (VT/VF). Early defibrillation is an independent predictor of survival in CPR events caused by VT/VF. The automated external cardioverter defibrillator (AECD) is a device attached by pads to the chest wall that monitors, detects, and within seconds, automatically delivers electric countershock to an appropriate tachyarrhythmia.

Study Objectives: • To evaluate safety of AECD monitoring in hospitalized patients.

• To evaluate whether AECDs provide earlier defibrillation than hospital code teams.

Methods: The study is a prospective trial randomizing patients admitted to the telemetry ward to standard CPR (code team) or standard CPR plus AECD monitoring (PowerHeart CRM). The AECD is programmed to deliver one 150 J biphasic shock to patients in sustained VT/VF. Data is collected using the Utstein criteria for cardiac arrest. The primary endpoint is time-to-defibrillation; secondary outcomes include neurological status and survival to discharge, with 3-year follow-up.

Results: To date, 192 patients have been recruited in the time period between 10/10/2006 to 7/20/2007. A total of 3,655 hours of telemetry data have been analyzed in the AECD arm. The AECD has monitored ambulatory telemetry patients in sinus rhythm, sinus tachycardia, supraventricular tachycardia, atrial flutter or fibrillation, with premature ventricular complexes and non-sustained VT without delivery of inappropriate shocks. One patient experienced sustained VT during AECD monitoring, who was successfully defibrillated (17 seconds after meeting programmed criteria). There are no events to report in the control arm. The patient survived the event without neurological complications. During the same time period, mean time to shock for VT/VF cardiac arrest occurring outside the telemetry ward was 230 ± 50 seconds.

Conclusion: AECD monitoring is safe and likely results in earlier defibrillation than standard telemetry monitoring.

Trial Registration: National Institutes of Health registration ID: NCT00382928

Background

In-hospital cardiac arrest has a poor prognosis despite active electrocardiography monitoring. Part of the poor prognosis may be explained by slow response to a lethal arrhythmia.[1] The National Registry of Cardiopulmonary Resuscitation (NRCPR) has reported delayed defibrillation, which was defined as greater than 2 minutes, in more than 30% of cases of in-hospital cardiac arrest. This delay in defibrillation resulted in significantly lower probability of surviving to hospital discharge.[1]

The initial rhythm in about 25% of in-hospital cardiac arrest is ventricular tachycardia or fibrillation (VT/VF).[2] Early provision of good quality CPR and rapid defibrillation have the highest impact on survival for the victims of VT/VF cardiac arrest.[3] Early defibrillation is an independent predictor of survival in CPR events caused by VT/VF.[4,5] Delay in provision of defibrillation for 10 minutes renders CPR ineffective.[4] Each minute of delay in defibrillation increases the likelihood of death by 7% to 10% in cardiac arrest.[5] If defibrillation is provided within 3 minutes in in-hospital cardiac arrest, 38% survival to discharge is reported versus 21%, if defibrillation is provided after 3 minutes.[2] Addressing this delay, a program encouraging early defibrillation using automated external defibrillators (AED) in the hospital resulted in a 14-fold increase in survival for VT/VF cardiac arrest.[6]

Automated External Cardioverter Defibrillator (AECD; The PowerHeart CRM, Cardiac Science Inc., Seattle, WA) is a device attached to the chest wall by pads, monitors the electrocardiogram, and is capable of automatically delivering electric countershock to appropriate rhythms without operator intervention. Automated external cardioverter defibrillators have been studied in a few non-randomized clinical trials. [7-9] They performed with a sensitivity of 100% and a specificity of 98.8% in a study conducted in the United States (n = 79) and a sensitivity of 100% and a specificity of 97.6% in an European study (n = 117).[7,8] We designed the current randomized trial to test the safety of AECDs in hospitalized patients and the performance compared to standard telemetry response.

Methods

This study is a single center, randomized, prospective, trial in which, all patients admitted to the emergency department and telemetry unit of the Atlanta Veterans Affairs Medical Center (AVAMC), Decatur, Georgia are screened. Patient recruitment started in October 2006. Inclusion and exclusion criteria are presented in Table 1. Patients consenting to participate in the study are randomized to either standard electrocardiographic telemetry or standard

Table 1: Inclusion and Exclusion Criteria

Inclusion Criteria:
1. All patients admitted to telemetry ward and ER.
2. Age > 18 years.
Exclusion Criteria:
1. Pregnant women.
2. Patients with R wave less than 0.5 mV in lead II.
3. Patients with functioning ICDs.
4. Patients with cardiac pacemakers if oversensing by AECD is demonstrated (double counting of pacer spikes).
5. Patients with visible chest lesions that would prevent AECD pad placement.
6. Patients who are designated DNR.
7. Right bundle branch block.
8. Patients with Parkinson's disease.
9. Patients with seizure disorders.
Additional Exclusion Criteria for Emergency Room:
10. Patients with dementia and/or delirium.
11. Patients presenting with psychiatric complaints.
12. Patients who are agitated.
13. Patients presenting with trauma.
14. Patients unable to participate in the informed consent process.
15. Patients with respiratory rate greater than twenty.
16. Patients who report pain greater than four out of ten in the visual analog scale.

ER = emergency room; ICD = internal cardioverter defibrillator; AECD = automated external cardioverter defibrillator; DNR = do not resuscitate

Table 2: Cerebral Performance Categories/CPC scale

CPC 1: Good cerebral performance – conscious, alert, able to work, might have mild neurologic or psychological deficit.
CPC 2: Moderate cerebral disability – conscious, sufficient cerebral function for independent activities of daily life. Able to work in sheltered environment.
CPC 3: Severe cerebral disability – conscious, dependent on others for daily support because of impaired brain function. Ranges from ambulatory state to severe dementia or paralysis.
CPC 4: Coma or vegetative state – any degree of coma without the presence of all brain death criteria. Unawareness, even if appears awake (vegetative state) without interaction with environment; may have spontaneous eye opening and sleep/awake cycles. Cerebral unresponsiveness.
CPC 5: Brain death – apnea, areflexia, EEG silence, etc.

EEG = electroencephalogram

telemetry augmented by AECD monitoring (Figure 1). Patients randomized to AECD monitoring have the AECD attached for the duration of their hospitalization while undergoing simultaneous telemetry monitoring. A log book is used to record the time of AECD attachment and to record whenever the AECD is detached from the patient. The AECD is programmed to deliver a single 150 Joule shock to VT/VF rhythms presenting above the rate of 170 beats per minute, after a 30 second delay. Study enrollment terminates when telemetry is discontinued. The primary endpoint is time-to-defibrillation in VT/VF cardiac arrest. The AECDs have the ability to measure the precise time of initiation of cardiac arrhythmias and of delivery of defibrillation. The secondary outcomes are survival to discharge and cerebral outcomes as measured by cerebral performance category scale (Table 2). Patients who survive cardiac arrest while participating in the trial will be followed for a period of three years for survival, internal cardioverter defibrillator (ICD) placement and cerebral performance. The Emory University Institutional Review Board (IRB) and the AVAMC Research and Development Committee approved the study.

Data collection

Demographic and arrest data is collected according to Utstein guidelines and stored in a database designed with Microsoft access software (Microsoft Inc., Redmond, WA).

Sample size

A total sample size of 40 patients per group will be recruited. There are approximately 40 true cardiac arrests per year on the telemetry ward. The expected time to defibrillation in the AECD group is to be 30 ± 30 seconds, whereas time to defibrillation in the standard of care group is 180 ± 180 seconds. The expected time to defibrillation in the AECD group will be programmed into the device. Time to defibrillation will be coded continuously in both groups. Using a two-tailed t-test to compare time to defibrillation between the groups, a sample size of 12 patients per group affords 81% power at alpha = 0.05. A total sample size of 40 patients per group will yield over 99% power for a two-tailed test at alpha = 0.05.

Statistical analysis

The primary outcome will be time-to-defibrillation. Demographic and clinical categorical and continuous variables are compared for patients in the standard of care versus the AECD group at cardiac arrest. Baseline data will be expressed as mean ± SD for continuous variables, and frequencies for categorical variables. Differences in baseline characteristics between the groups will be examined by the use of χ^2 tests and two-sample t-tests, or, if assumptions are not met, by Fisher's Exact and Mann-Whitney tests for categorical and continuous variables, respectively. Time to defibrillation will be measured continuously in both the standard of care and the AECD group,

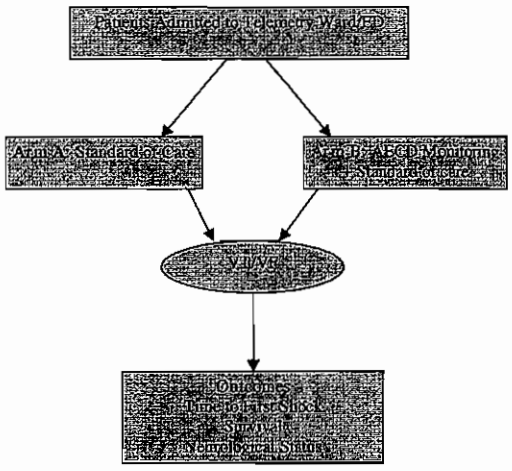


Figure 1
Design of the AECD Trial. ED = emergency department; AECD = automated external cardioverter defibrillator; VT/VF = ventricular tachycardia/ventricular fibrillation.

Table 3: Demographic and Clinical Characteristics of Study Subjects

	AECD n = 95	Control n = 97	P Value
Age ± SD	61.7 ± 3.4	62 ± 3.4	0.7
Gender			0.98
Male	92 (96.8%)	94 (96.9%)	
Female	3 (3.2%)	3 (3.1%)	
Race			0.15
Hispanic	2 (2.1%)	0	
White	42 (44.2%)	53 (54.6%)	
Black	51 (53.7%)	44 (45.4%)	
History of HF	25 (26.3%)	20 (20.6%)	0.39
New Diagnosis of HF	6 (6.3%)	4 (4.1%)	0.53
Diabetes mellitus	46 (48.4%)	35 (36.1%)	0.11
History of CAD	35 (36.8%)	42 (43.3%)	0.38
Hypertension	79 (84%)	74 (76.3%)	0.28
Hyperlipidemia	55 (57.9%)	53 (54.6%)	0.66
EKG on admission			0.62
NSR	84 (88.4%)	81 (83.5%)	
Atrial fibrillation/flutter	9 (9.5%)	11 (11.3%)	
SVT	0	2 (2.1%)	
Other	2 (2.1%)	3 (3.1%)	

SD = standard deviation; HF = heart failure; CAD = coronary artery disease; NSR = normal sinus rhythm; SVT = supraventricular tachycardia

then compared using a two-tailed t-test. Assumptions will be checked and analyses will be adjusted accordingly.

In addition a multiple logistic model will be used to analyze the secondary endpoints (survival of cardiac arrest, survival to discharge), considering all the available variables. The total sample size will limit this analysis; however, an exploratory forward stepwise selection procedure will be used with a p-value of at least 0.10 for entry and 0.05 for removal. All pairwise interactions between AECD use and the other variables in the final stepwise model will be tested. A Hosmer-Lemeshow test will be used to test goodness of fit. Odds ratios will be presented with 95% confidence intervals. Pearson residuals, deviance residuals, and influence statistics will be examined to assess model fit. Statistical analyses will be performed using SAS version 9.1.3.

Cerebral performance state (Table 2) will be measured using the cerebral performance categorization (CPC) scale and analyzed initially using χ^2 tests. If cell counts warrant, the 2 × 3 contingency table will be analyzed using exact methods and the mean score statistics (Q) will be used to compare cerebral performance status between the groups.

Preliminary results

One hundred and ninety two patients were recruited in the time period between 10/10/2006 to 7/20/2007. The demographic and clinical characteristics of the patients are presented in Table 3. Patients in the control and treatment arms had similar characteristics. The majority of patients (> 90%) in both arms were men, reflecting the demographics of the AVAMC. A total of 3,655 hours of telemetry data has been analyzed by the AECDs. The AECDs monitored ambulatory patients with normal sinus rhythm, sinus tachycardia, atrial fibrillation or flutter, supraventricular tachycardia, premature ventricular complexes and non-sustained ventricular tachycardia without inappropriately delivering a shock (Table 4). Of the 95 patients randomized to the AECD arm, total of ten patients had to be taken off the AECD, two due to adverse events, two due to anxiety, two due to skin irritation by the pads, and four due to alarming of the AECD, as the pads detached from the chest wall during their sleep.

Only one event of sustained VT occurred in the experimental arm, which was defibrillated by the AECD 17 seconds after programmed criteria were met (Figure 2). There are no events to report in the control arm. During the same time period mean time to shock for VT/VF cardiac arrest occurring outside the telemetry ward was 230 ± 50 seconds.

There were two false positive events in which, the shocks were delivered inappropriately. In the first case, the AECD delivered the shock when a patient was eating an apple.

Table 4: Frequency of Abnormal Rhythms Monitored by the AECD

Atrial Fibrillation/Flutter	9 (9.5%)
Supraventricular Tachycardia	1 (1.1%)
Premature Ventricular Complexes	10 (10.5%)
Non-Sustained Ventricular Tachycardia	5 (5.3%)

AECD = automated external cardioverter defibrillator

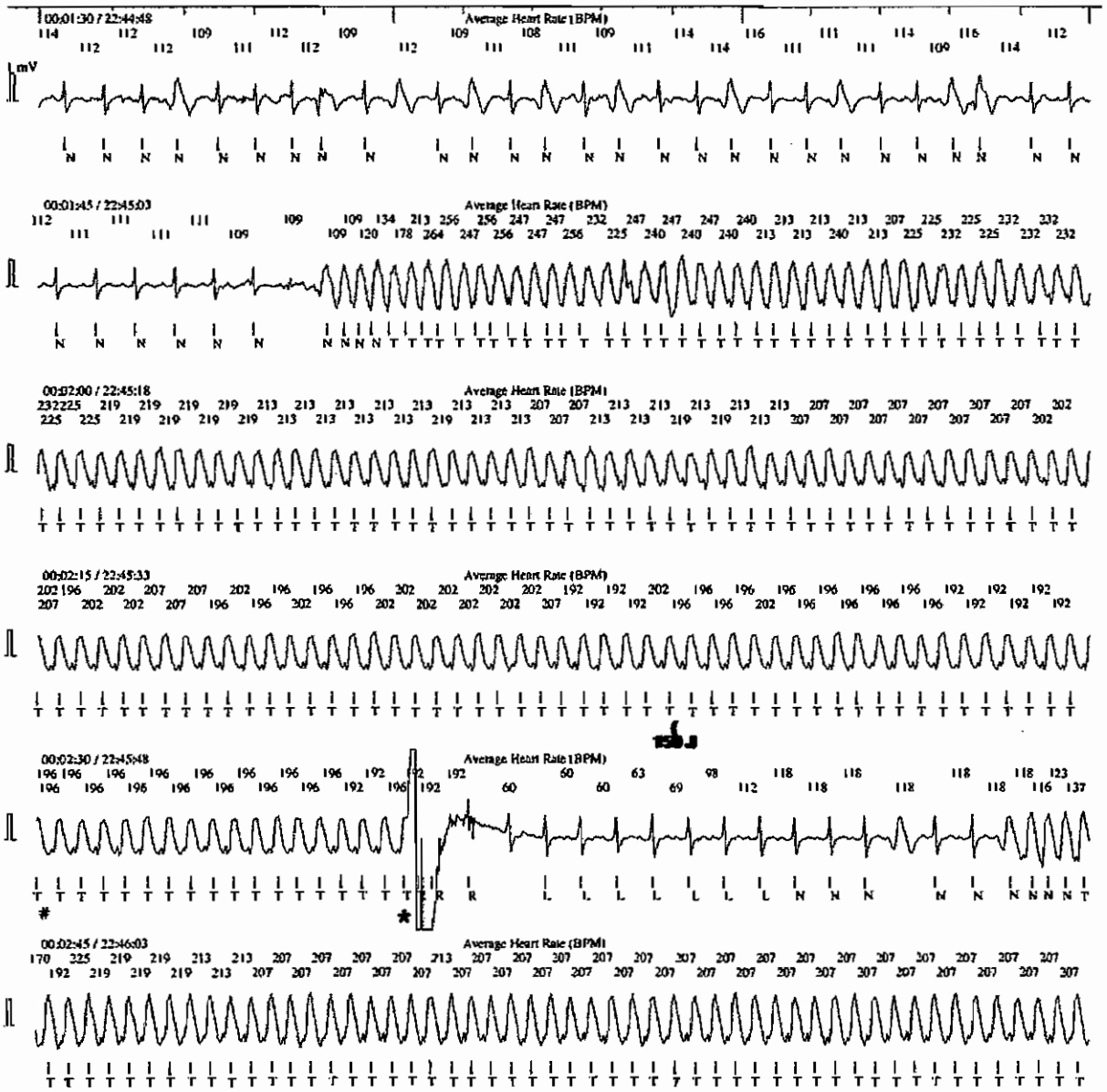


Figure 2
The AECD correctly recognized sustained monomorphic ventricular tachycardia and delivered a 150 Joule shock after 47 seconds. The rhythm is converted to sinus rhythm but reverts to ventricular tachycardia after 10 seconds. (= capacitor charging; # = capacitor charged; * = therapy delivered to patient.

The AECD showed ventricular fibrillation at the same time the telemetry monitor showed sinus rhythm. This occurred in the setting of a reduced R wave amplitude on his 12-lead EKG, which was less than 0.5 mV. In the second case, discharge was the result of deliberate action of the patient. Neither patient had any other complications related to the delivery of the shocks.

Discussion

In-hospital cardiac arrest remains a major health problem with high mortality rates.[2] Most important determinants of survival in both out-of-hospital and in-hospital cardiac arrest are early CPR and defibrillation.[1-3,10-12] Previously three clinical studies evaluated the application of AECD technology in hospitalized patients. [7-9] Mattioni et al. and Martinez-Rubio et al. both demonstrated high sensitivity and specificity for the AECD in the treatment of tachyarrhythmias.[7,8] The two studies demonstrated time-to-shock in the range of 14 to 22 seconds in patients admitted to the intensive care units and the cardiac electrophysiology laboratory.[7,8] In another study in patients with cardiovascular diagnoses admitted to the emergency department, a 94.4% success rate, with a mean time-to-shock of 33.4 seconds for VT/VF arrhythmias was found.[9] These studies, while demonstrating effectiveness of AECDs in highly specialized settings, did not establish efficacy in an ambulatory group, where the possibility of inappropriate discharges are increased. In addition, none of the studies were randomized; there were no control groups with standard of care; and finally, none of the previous studies evaluated the impact of AECDs on survival and cerebral outcomes.

In the one arrest monitored by AECD, we showed a defibrillation time of 17 seconds. This is consistent with previous AECD trials. On the other hand, Chan and his coauthors reported that in 30% of in-hospital cardiac arrest, defibrillation is delayed using standard therapy, resulting in lower survival to discharge (22.2% vs 39.3%, P =< 0.001).[1] After hours (5 p.m. to 8 a.m.), weekends and unmonitored beds were predictors of delayed defibrillation, suggesting that manpower considerations were a critical determinant of response.[1,13] It would seem likely that routine use of automated strategies would help addressing these delays.[14] This idea is supported by findings that AEDs can improve outcomes in in-hospital cardiac arrest.[6]

Our trial thus far, has established the safety and practicality of continuous monitoring by AECDs in a high risk, ambulatory, inpatient population. Having established efficacy, continuation of the trial will allow a comparison of outcomes between the two strategies.

Abbreviations

AECD: automatic external cardioverter defibrillator; AED: automated external defibrillator; AVAMC: Atlanta Veterans Affairs Medical Center; CPC: cerebral performance categories; CPR: cardiopulmonary resuscitation; IRB: Institutional Review Board; NRCPR: National Registry of Cardiopulmonary Resuscitation; SD: standard deviation; VT/VF: pulseless ventricular tachycardia/ventricular fibrillation

Competing interests

Dr. Zafari reports receiving an investigator-initiated grant from Cardiac Science, Inc.

References

1. Chan PS, Krumholz HM, Nichol G, Nallamothu BK, American Heart Association National Registry of Cardiopulmonary Resuscitation Investigators: **Delayed time to defibrillation after in-hospital cardiac arrest.** *N Engl J Med* 2008, **358**:9-17.
2. Peberdy MA, Kaye W, Ornato JP, Larkin GL, Nadkarni V, Mancini ME, *et al.*: **Cardiopulmonary resuscitation of adults in the hospital: a report of 14720 cardiac arrests from the national registry of cardiopulmonary resuscitation.** *Resuscitation* 2003, **58**:297-308.
3. Hazinski MF, Nadkarni VM, Hickey RW, O'Connor R, Becker LB, Zaritsky A: **Editorial: major changes in the 2005 AHA Guidelines for CPR and ECC: reaching the tipping point for change.** *Circulation* 2005, **112(suppl IV)**:IV-206-IV-211.
4. Valenzuela TD, Roe DJ, Cretin S, Spaite DW, Larsen MP: **Estimating effectiveness of cardiac arrest interventions.** *Circulation* 1997, **96**:3308-13.
5. Larsen MP, Eisenberg MS, Cummins RO, Hallstrom AP: **Predicting survival from out-of-hospital cardiac arrest: a graphic model.** *Ann Emerg Med* 1993, **22**:1652-8.
6. Zafari AM, Zarter SK, Heggen V, Wilson P, Taylor RA, Reddy K, *et al.*: **A program encouraging early defibrillation results in improved in-hospital resuscitation efficacy.** *J Am Coll Cardiol* 2004, **44**:846-52.
7. Mattioni TA, Nademanee K, Brodsky M, Fisher J, Riggio D, Allen B, *et al.*: **Initial clinical experience with a fully automatic in-hospital external cardioverter defibrillator.** *PACE* 1999, **22**:1648-55.
8. Martinez-Rubio A, Kanaan N, Borggrefe M, Block M, Makijarvi M, Fedele F, *et al.*: **Advances for treating in-hospital cardiac arrest: safety and effectiveness of a new automatic external cardioverter-defibrillator.** *J Am Coll Cardiol* 2003, **41**:627-32.
9. Bento AM, Cardoso LF, Timerman S, Moretti MA, Peres ED, de Paiva EF, *et al.*: **Preliminary in-hospital experience with a fully automatic external cardioverter-defibrillator.** *Resuscitation* 2004, **63**:11-6.
10. Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG: **Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos.** *N Engl J Med* 2000, **343**:1206-9.
11. Swedish Cardiac Arrest Registry: **Factors modifying the effect of bystander cardiopulmonary resuscitation on survival in out-of-hospital cardiac arrest patients in Sweden.** *Eur Heart J* 2001, **22**:511-9.
12. White RD, Bunch TJ, Hankins DG: **Evolution of a community-wide early defibrillation program experience over 13 years using police/fire personnel and paramedics as responders.** *Resuscitation* 2005, **65**:279-83.
13. Peberdy MA, Ornato JP, Larkin GL, Braithwaite RS, Kashner TM, Carey SM, *et al.*: **Survival from in-hospital cardiac arrest during night and weekends.** *JAMA* 2008, **299**:785-92.
14. Saxon LA: **Survival after tachyarrhythmic arrest-what are we waiting for?** *N Engl J Med* 2008, **358**:77-79.

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

Lay Rescuer Automated External Defibrillator ("Public Access Defibrillation") Programs: Lessons Learned From an International Multicenter Trial: Advisory Statement From the American Heart Association Emergency Cardiovascular Committee; the Council on Cardiopulmonary, Perioperative, and Critical Care; and the Council on Clinical Cardiology

Mary F. Hazinski, Ahamed H. Idris, Richard E. Kerber, Andrew Epstein, Dianne Atkins, Wanchun Tang and Keith Lurie

Circulation 2005;111;3336-3340
DOI: 10.1161/CIRCULATIONAHA.105.165674
Circulation is published by the American Heart Association. 7272 Greenville Avenue, Dallas, TX 72514
 Print ISSN: 0009-7322. Online ISSN: 1524-4539

Lay Rescuer Automated External Defibrillator ("Public Access Defibrillation") Programs

Lessons Learned From an International Multicenter Trial

Advisory Statement From the American Heart Association Emergency Cardiovascular Committee; the Council on Cardiopulmonary, Perioperative, and Critical Care; and the Council on Clinical Cardiology

Mary F. Hazinski, RN, MSN; Ahamed H. Idris, MD; Richard E. Kerber, MD; Andrew Epstein, MD; Dianne Atkins, MD; Wanchun Tang, MD; Keith Lurie, MD

Abstract—Lay rescuer automated external defibrillator (AED) programs may increase the number of people experiencing sudden cardiac arrest who receive bystander cardiopulmonary resuscitation (CPR), can reduce time to defibrillation, and may improve survival from sudden cardiac arrest. These programs require an organized and practiced response, with rescuers trained and equipped to recognize emergencies, activate the emergency medical services system, provide CPR, and provide defibrillation. To determine the effect of public access defibrillation (PAD) programs on survival and other outcomes after SCA, the National Heart, Lung, and Blood Institute, the American Heart Association (AHA), and others funded a large prospective randomized trial. The results of this study were recently published in *The New England Journal of Medicine* and support current AHA recommendations for lay rescuer AED programs and emphasis on planning, training, and practice of CPR and use of AEDs. The purpose of this statement is to highlight important findings of the Public Access Defibrillation Trial and summarize implications of these findings for healthcare providers, healthcare policy advocates, and the AHA training network. (***Circulation.* 2005;111:3336-3340.)**

Key Words: AHA Science Advisory ■ defibrillation ■ heart arrest ■ fibrillation ■ cardiopulmonary resuscitation

Since 1995, the American Heart Association (AHA) has promoted the development of lay rescuer automated external defibrillator (AED) programs to improve survival from out-of-hospital sudden cardiac arrest (SCA).[1–3] These programs are also known as "public access" defibrillation (PAD) programs. The AHA has emphasized the importance of organization, planning, and training to maximize effectiveness of these programs.[4]

To determine the effect of PAD programs on survival and other outcomes after SCA, the National Heart, Lung and Blood Institute (NHLBI), the AHA, and others funded a large prospective randomized trial. The results of this study were published recently in *The New England Journal of Medicine*.[5] The purpose of the present statement is to highlight important findings of the Public Access Defibrillation (PAD) trial and summarize implications of these findings for healthcare providers, healthcare policy advocates, and the AHA training network.

Background

Although estimates of the annual number of deaths caused by out-of-hospital SCA in the United States vary widely,[6–9] the AHA estimates that ≈250 000 people die in the United States each year from SCA outside the hospital setting.[10] At the time of first heart rhythm analysis, ≈40% of SCA victims demonstrate ventricular fibrillation (VF), an abnormal heart rhythm that causes the heart to quiver so that it is unable to pump blood effectively.[8] It is likely that an even higher proportion of people with SCA have VF at the time of collapse. Many people who experience sudden VF cardiac arrest can

Circulation is available at http://www.circulationaha.org

DOI: 10.1161/CIRCULATIONAHA.105.165674

survive if bystanders act immediately. If VF is untreated, then cardiac standstill will develop, and successful resuscitation will be unlikely.[11]

The AHA has traditionally used 4 links in a chain to illustrate the important actions that can create a "chain of survival" for victims of VF SCA.[12] These links are as follows:

1. Early recognition of the emergency and activation of the emergency medical services (EMS) system ("9-1-1").
2. Early bystander cardiopulmonary resuscitation (CPR).
3. Early delivery of a shock with a defibrillator.
4. Early advanced life support.

Bystanders can now perform 3 of the links in this chain. Bystander recognition of the emergency and EMS activation are critical first steps in response to an SCA, ensuring that basic and advanced life support providers are dispatched to the site of the arrest. In most communities, the time interval from collapse to the arrival of EMS personnel is 7 to 8 minutes or longer. This means that the victim depends on the actions of bystanders and local rescuers to perform the first 2 or 3 links in the chain of survival during the first minutes after SCA.

Bystanders need to provide immediate CPR for victims of SCA. CPR provides blood flow to the heart and brain. In addition, CPR increases the likelihood that a shock delivered by a defibrillator will terminate the VF and that the heart will resume an effective rhythm after defibrillation. These effects of CPR appear to be particularly important if shock delivery does not occur for ≥4 minutes after collapse.[13] Defibrillation does not "restart" the heart; defibrillation stops VF and allows the heart to resume a normal rhythm. In the first few minutes after defibrillation, the heart rhythm may be slow and the heart may not pump blood effectively. CPR may be needed for several minutes after defibrillation until adequate heart function resumes.[14]

Lay rescuers can use computerized devices called AEDs to deliver a shock to victims of VF cardiac arrest. The rescuer attaches the AED to the victim with adhesive pads or electrodes. The AED records and analyzes the victim's ECG rhythm, informs the rescuer if a shock is needed, and provides voice and audio prompts to guide the rescuer through all steps of AED use. The AED computerized algorithms that are used to analyze the victim's heart rhythm are accurate. AEDs will deliver a shock only when VF or its precursor, rapid ventricular tachycardia, is present and will not deliver a shock to a person with a normal heart rhythm.[15]

The success of the actions of rescuers at the scene of an SCA is time critical. Several studies have documented the effects of time to defibrillation and the effects of bystander CPR on survival from SCA. For every minute that passes between collapse and defibrillation, survival from witnessed VF SCA falls 7% to 10% if no CPR is provided.[11] When bystander CPR is provided, the fall in survival is more gradual and averages 3% to 4% per minute from collapse to defibrillation.[11,16] CPR can double[11,16] or triple[17] survival from witnessed SCA at any interval to defibrillation.

Lay rescuer AED programs may increase the number of SCA victims who receive bystander CPR and can reduce time to defibrillation. These programs require an organized and practiced response with rescuers trained and equipped to recognize emergencies, activate the EMS system, provide CPR, and provide defibrillation. Small studies of lay rescuer AED programs in airports[18] and casinos[19,20] and with police officers[14,21–23] have demonstrated a 49% to 74% survival rate from out-of-hospital witnessed VF SCA when immediate bystander CPR is provided and defibrillation occurs within 3 to 5 minutes of collapse. These high survival rates, however, are attained only in programs that reduce time to defibrillation.[24]

The PAD Trial

The PAD trial involved 993 facilities in 24 urban and suburban regions in North America and reported outcomes from 239 episodes of out-of-hospital SCA with attempted resuscitation.[5] A facility was included if it had a history of at least 1 out-of-hospital cardiac arrest every 2 years or if at least 1 out-of-hospital cardiac arrest was predicted during the study period. Each study site was required to have clearly defined geographic boundaries and a typical EMS response interval of 3 to 15 minutes.

Methods

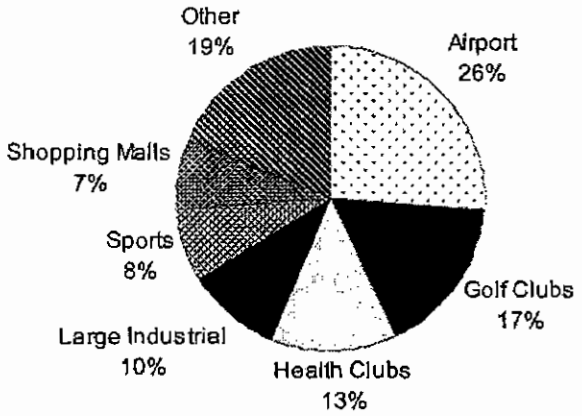
Participating sites were urban and suburban communities served by EMS systems that provide advanced life support. Each site identified distinct units within their service area (eg, buildings, public areas). These units were randomly allocated to train and equip volunteers to provide either CPR only or CPR plus AED response. All of the volunteer rescuers received rigorous, standard training to recognize SCA, phone 9-1-1, and perform CPR according to AHA recommendations. Volunteers at the sites offering CPR plus AED response also were trained and equipped to use AEDs. At CPR-plus-AED sites, AEDs were placed to enable volunteers to retrieve and deliver an AED to a victim of SCA within 3 minutes of collapse.

The trial was conducted from July 2000 through September 2003. Approximately 20 000 volunteers received training in programs that offered frequent retraining and refresher drills. More than 1600 AEDs were placed to conduct the trial. Most (84%) of the study facilities were in public locations such as recreational facilities and shopping centers. Additional details of the study design and methodology have been published.[25]

Results

In the units providing only bystander CPR, 15 of 107 persons experiencing definite cardiac arrest (ie, an arrest of cardiac origin with rhythm identification) survived to hospital discharge. In the units providing bystander CPR plus AED response, 30 of 128 victims of definite cardiac arrest survived to discharge. This increase in the number of survivors of definite cardiac arrest in units with CPR plus AED response compared with the number of survivors in the units providing CPR response alone was statistically significant ($P<0.05$).[26]

In this study, nearly two thirds of all victims of SCA in both groups received bystander CPR. Compared with sites with CPR-only response, sites with CPR plus AED response had a shorter interval from collapse to first rhythm assess-



Public locations with high incidence of SCA in Seattle and King County, Washington, 1990 to 1994 (n=134). Adapted with permission from Becker et al.[27] Copyright 1998 American Heart Association.

ment (6 versus 8.7 minutes) and a higher incidence of VF (57% versus 47%). These differences were statistically significant. No inappropriate shocks were delivered. Adverse events were rare and consisted chiefly of stolen AEDs and transient psychological stress among rescuers.

It is important to note that residential sites represented ≈16% of the study sites and accounted for 28% of the cardiac arrests but <5% of the survivors. The study lacked statistical power to detect whether lay rescuer AED programs increase survival from SCA in residential settings.

Implications for Public Policy

Estimates of the incidence of SCA in the United States vary widely because SCA is not a reportable disease or cause of death. In the PAD study, the observed number of cardiac arrests during the study period was substantially lower (<50%) than the number predicted. This correlates with recent data suggesting that the incidence of SCA may be 0.5 per 1000 adults >35 years old.[6,7] To quantify the problem and evaluate the effect of any interventions designed to reduce death from SCA, this cause of death must be reportable.

EMS databases may enable the identification of sites of cardiac arrests to better pinpoint priority sites for lay rescuer AED programs. Although the organization of information in state EMS databases varies widely, recent attempts to collect national EMS data have been encouraging.

The PAD trial[5] confirms the value of the elements of the chain of survival in improving the outcome of SCA. The trial supports current AHA recommendations for lay rescuer AED programs and the emphasis on planning, training, practice of CPR, and use of AEDs. Early recognition, early CPR, and early defibrillation all contribute to an increased chance of survival from out-of-hospital SCA. The authors note that if the increased number of survivors from the PAD trial is extrapolated to all episodes of out-of-hospital SCA that occur in public locations annually in the United States, then ≈2000 to 4000 additional lives can be saved every year with widespread implementation of lay rescuer community AED programs. This would require the placement of AEDs in those public locations with a high incidence or likelihood of SCA (see the Figure).[27]

In the PAD trial, survival with structured lay rescuer programs that included bystander CPR response was higher than previously reported by traditional EMS systems.[5] This implies that public sites that do not provide AED programs may still improve survival from SCA by training volunteers to recognize cardiac arrest, phone 9-1-1, and give bystander CPR before the arrival of EMS providers.

Lay rescuer AED programs will be most cost effective if they are present at sites where at least 1 witnessed SCA is likely to occur every few years. In the PAD trial, sites were enrolled if there were at least 250 adults >50 years old present at the site during waking hours (≈16 hours per day). Other criteria (eg, presence of high-risk persons) that can be used to select AED program sites are posted on the AED website (http://www.americanheart.org/ecc/PAD).

It is important to note that the PAD trial was not designed to evaluate home defibrillation or defibrillation provided by untrained rescuers. A national study is under way to evaluate home defibrillation, and the results of this study are expected to provide additional information about the potential benefits of home AED programs.

The AHA recommends critical elements for lay rescuer AED programs: healthcare provider oversight and planning, training of anticipated rescuers in CPR and use of the AED, link with the EMS system, and a plan for maintenance and quality improvement monitoring.[4] The AHA has particularly emphasized the importance of training rescuers and the development and practice of a structured response plan. Even in the PAD trial, with rescuers trained to respond to SCA, resuscitation was attempted for only half of the witnessed SCA victims, and the on-site AED was used for only about one third of SCA victims. These findings suggest that rescuers may need more training or practice than that offered in the study and document that the mere presence of an AED does not ensure that it will be used when SCA occurs.

The selection of sites for potential lay rescuer AED programs and the placement of the AEDs within the site are important in the planning for the program. Published data about the most likely sites of SCA in the community[27] can be used to identify potential sites for these lay rescuer AED programs (see the Figure). The AHA recommends that the AEDs be placed in the site so that they can be reached within a 1- to 1.5-minute brisk walk from any location.

Implications for Future AHA Activities

The promotion of PAD programs is an important component of the AHA's comprehensive strategy to prevent heart disease and stroke through risk factor prevention, identification and control, early identification and treatment of acute events, and prevention of recurrent events. The PAD trial results validate the importance of the AHA chain of survival in improving outcome from out-of-hospital witnessed SCA. The results document the importance of program planning, rescuer training, the link with the local EMS system, and a system of device maintenance and quality improvement monitoring in lay rescuer AED programs to improve outcome from SCA.

All states have passed legislation or regulations that allow lay rescuer AED programs, but the heterogeneity of the state laws has created confusion for lay rescuers and has complicated attempts to establish lay rescuer AED programs. An AHA scientific statement is being developed that will delineate critical state legislative components and implementation strategies for lay rescuer AED programs.

The PAD trial results are being carefully reviewed by AHA resuscitation experts to refine recommendations for resuscitation and lay rescuer AED programs. In addition, the researchers gained experience in obtaining community informed consent and institutional review board approval.[28] For further information about lay rescuer AED programs, see http://www.americanheart.org/ecc/PAD.

Writing Group Disclosures

Writing Group Member	Employment	Research Grant	Other Research Support	Speakers Bureau/Honoraria	Ownership Interest	Consultant/ Advisory Board	Other
Mary F. Hazinski	Vanderbilt University	None	None	None	None	Paid AHA consultant/senior science editor	None
Ahamed H. Idris	University of Texas–Southwestern	Medtronic; Laerdal; Medcool; NASA; Department of Defense	None	None	None	Philips SAB member	Holds patent for mouth-to-mouth ventilation device
Richard E. Kerber	University of Iowa Hospital	Philips Medical Systems; Guidant	None	None	None	None	None
Andrew Epstein	University of Alabama–Birmingham	Boston Scientific; Irvine Biomedical; Biosense; Medtronic; Guidant; St. Jude Medical	None	Speakers bureau: AstraZeneca, Reliant, GlaxoSmithKline, Medtronic, Guidant, St. Jude Medical	None	None	None
Dianne Atkins	University of Iowa	Philips Medical Systems; Zoll Medical Corporation; Wyeth-Ayerst; Berlex Medical (latter 2 completed 2001)	None	None	None	None	None
Wanchun Tang	Institute of Critical Care Medicine	American Heart Association; Philips; Zoll Medical Corporation	None	None	None	None	None
Keith Lurie	University of Minnesota	None	None	None	Founder and Chief Medical Officer, Advanced Circulatory Systems (manufacturer of CPR devices and CPR device technology)	None	None

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit.

Reviewer Disclosures

Reviewer	Employment	Research Grant/Other Research Support	Speakers Bureau/Honoraria	Ownership Interest	Consultant/Advisory Board	Other
Dr Robert Berg	University of Arizona Health Sciences Center	Medtronic	None	None	None	None
Dr Mickey Eisenberg	University of Washington	Medtronic; Philips Medical Systems; Laerdal	None	None	None	None
Dr Terry Vanden Hoek	University of Chicago	None	None	None	None	None

This table represents the relationships of reviewers that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Reviewer Disclosure Questionnaire, which all reviewers are required to complete and submit.

References

1. Weisfeldt M, Kerber R, McGoldrick RP, Moss AJ, Nichol G, Ornato JP, Palmer DG, Riegel B, Smith SC Jr. Public access defibrillation: a statement for healthcare professionals from the American Heart Association Task Force on Automatic External Defibrillation. *Circulation*. 1995;92:2763.
2. Weisfeldt ML, Kerber RE, McGoldrick RP, Moss AJ, Nichol G, Ornato JP, Palmer DG, Riegel B, Smith SC Jr. American Heart Association Report on the Public Access Defibrillation Conference December 8–10, 1994. Automatic External Defibrillation Task Force. *Circulation*. 1995; 92:2740–2747.
3. Nichol G, Hallstrom AP, Kerber R, Moss AJ, Ornato JP, Palmer D, Riegel B, Smith S Jr, Weisfeldt ML. American Heart Association report on the second public access defibrillation conference, April 17–19, 1997. *Circulation*. 1998;97:1309–1314.
4. Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Part 4: the automated external defibrillator: key link in the chain of survival. The American Heart Association in Collaboration with International Liaison Committee on Resuscitation. *Circulation*. 2000;102(suppl 1):I-60–I-76.
5. PAD Trial Investigators. Public-access defibrillation and survival after out-of-hospital cardiac arrest. *N Engl J Med*. 2004;351:637–646.
6. Rea TD, Eisenberg MS, Sinibaldi G, White RD. Incidence of EMS-treated out-of-hospital cardiac arrest in the United States. *Resuscitation*. 2004;63:17–24.
7. Chugh SS, Jui J, Gunson K, Stecker EC, John BT, Thompson B, Ilias N, Vickers C, Dogra V, Daya M, Kron J, Zheng ZJ, Mensah G, McAnulty J. Current burden of sudden cardiac death: multiple source surveillance versus retrospective death certificate-based review in a large U.S. community. *J Am Coll Cardiol*. 2004;44:1268–1275.
8. Cobb LA, Fahrenbruch CE, Olsufka M, Copass MK. Changing incidence of out-of-hospital ventricular fibrillation, 1980–2000. *JAMA*. 2002;288: 3008–3013.
9. Zheng ZJ, Croft JB, Giles WH, Mensah GA. Sudden cardiac death in the United States, 1989 to 1998. *Circulation*. 2001;104:2158–2163.
10. American Heart Association. *Heart Disease and Stroke Statistics—2005 Update*. Dallas, Tex: American Heart Association; 2004.
11. Larsen MP, Eisenberg MS, Cummins RO, Hallstrom AP. Predicting survival from out-of-hospital cardiac arrest: a graphic model. *Ann Emerg Med*. 1993;22:1652–1658.
12. Cummins RO, Ornato JP, Thies WH, Pepe PE. Improving survival from sudden cardiac arrest: the "chain of survival" concept: a statement for health professionals from the Advanced Cardiac Life Support Subcommittee and the Emergency Cardiac Care Committee, American Heart Association. *Circulation*. 1991;83:1832–1847.
13. Cobb LA, Fahrenbruch CE, Walsh TR, Copass MK, Olsufka M, Breskin M, Hallstrom AP. Influence of cardiopulmonary resuscitation prior to defibrillation in patients with out-of-hospital ventricular fibrillation. *JAMA*. 1999;281:1182–1188.
14. White RD, Russell JK. Refibrillation, resuscitation and survival in out-of-hospital sudden cardiac arrest victims treated with biphasic automated external defibrillators. *Resuscitation*. 2002;55:17–23.
15. Kerber RE, Becker LB, Bourland JD, Cummins RO, Hallstrom AP, Michos MB, Nichol G, Ornato JP, Thies WH, White RD, Zuckerman BD. Automatic external defibrillators for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety: a statement for health professionals from the American Heart Association Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. *Circulation*. 1997;95:1677–1682.
16. Valenzuela TD, Roe DJ, Cretin S, Spaite DW, Larsen MP. Estimating effectiveness of cardiac arrest interventions: a logistic regression survival model. *Circulation*. 1997;96:3308–3313.
17. Holmberg M, Holmberg S, Herlitz J. Effect of bystander cardiopulmonary resuscitation in out-of-hospital cardiac arrest patients in Sweden. *Resuscitation*. 2000;47:59–70.
18. Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Public use of automated external defibrillators. *N Engl J Med*. 2002;347:1242–1247.
19. Valenzuela TD, Bjerke HS, Clark LL, Hardman R, Spaite DW, Nichol, G. Rapid defibrillation by nontraditional responders: the Casino project. *Acad Emerg Med*. 1998;5:414–415. Abstract.
20. Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. *N Engl J Med*. 2000;343:1206–1209.
21. White R, Asplin B, Bugliosi T, Hankins D. High discharge survival rate after out-of-hospital ventricular fibrillation with rapid defibrillation by police and paramedics. *Ann Emerg Med*. 1996;28:480–485.
22. White RD. Early out-of-hospital experience with an impedance-compensating low-energy biphasic waveform automatic external defibrillator. *J Interv Card Electrophysiol*. 1997;1:203–210.
23. White RD, Hankins DG, Bugliosi TF. Seven years' experience with early defibrillation by police and paramedics in an emergency medical services system. *Resuscitation*. 1998;39:145–151.
24. Groh WJ, Newman MM, Beal PE, Fineberg NS, Zipes DP. Limited response to cardiac arrest by police equipped with automated external defibrillators: lack of survival benefit in suburban and rural Indiana—the police as responder automated defibrillation evaluation (PARADE). *Acad Emerg Med*. 2001;8:324–330.
25. Ornato JP, McBurnie MA, Nichol G, Salive M, Weisfeldt M, Riegel B, Christenson J, Terndrup T, Daya M; PAD Trial Investigators. The Public Access Defibrillation (PAD) trial: study design and rationale. *Resuscitation*. 2003;56:135–147.
26. Sayre MR, Travers AH, Daya M, Greene HL, Salive ME, Vijayaraghavan K, Craven RA, Groh WJ, Hallstrom AP; PAD Investigators. Measuring survival rates from sudden cardiac arrest: the elusive definition. *Resuscitation*. 2004;62:25–34.
27. Becker L, Eisenberg M, Fahrenbruch C, Cobb L. Public locations of cardiac arrest: implications for public access defibrillation. *Circulation*. 1998;97:2106–2109.
28. Moscesso VN Jr, Brown LH, Greene HL, Schmidt TA, Auffderheide TP, Sayre MR, Stephens SW, Travers A, Craven RA, Weisfeldt ML; PAD Trial Investigators. Conducting research using the emergency exception from informed consent: the Public Access Defibrillation (PAD) Trial experience. *Resuscitation*. 2004;61:29–36.

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 AUGUST 12, 2004 VOL. 351 NO. 7

Public-Access Defibrillation and Survival after Out-of-Hospital Cardiac Arrest

The Public Access Defibrillation Trial Investigators*

ABSTRACT

BACKGROUND

The rate of survival after out-of-hospital cardiac arrest is low. It is not known whether this rate will increase if laypersons are trained to attempt defibrillation with the use of automated external defibrillators (AEDs).

METHODS

We conducted a prospective, community-based, multicenter clinical trial in which we randomly assigned community units (e.g., shopping malls and apartment complexes) to a structured and monitored emergency-response system involving lay volunteers trained in cardiopulmonary resuscitation (CPR) alone or in CPR and the use of AEDs. The primary outcome was survival to hospital discharge.

RESULTS

More than 19,000 volunteer responders from 993 community units in 24 North American regions participated. The two study groups had similar unit and volunteer characteristics. Patients with treated out-of-hospital cardiac arrest in the two groups were similar in age (mean, 69.8 years), proportion of men (67 percent), rate of cardiac arrest in a public location (70 percent), and rate of witnessed cardiac arrest (72 percent). No inappropriate shocks were delivered. There were more survivors to hospital discharge in the units assigned to have volunteers trained in CPR plus the use of AEDs (30 survivors among 128 arrests) than there were in the units assigned to have volunteers trained only in CPR (15 among 107; P=0.03; relative risk, 2.0; 95 percent confidence interval, 1.07 to 3.77); there were only 2 survivors in residential complexes. Functional status at hospital discharge did not differ between the two groups.

CONCLUSIONS

Training and equipping volunteers to attempt early defibrillation within a structured response system can increase the number of survivors to hospital discharge after out-of-hospital cardiac arrest in public locations. Trained laypersons can use AEDs safely and effectively.

Alfred Hallstrom, Ph.D. (University of Washington, Seattle), and Joseph P. Ornato, M.D. (Virginia Commonwealth University Medical Center, Richmond), assume responsibility for the content of this article. Address reprint requests to the Public Access Defibrillation Clinical Trial Center, University of Washington, School of Public Health and Community Medicine, Department of Biostatistics, 1107 NE 45th St., Room 505, Seattle, WA 98105, or at padctc@u.washington.edu.

*The investigators and coordinators participating in the Public Access Defibrillation (PAD) Trial are listed in the Appendix.

N Engl J Med 2004;351:637-46.

SUDDEN OUT-OF-HOSPITAL CARDIAC ARrest is a leading cause of death and disability and a leading source of health care costs in the United States.[1,2] When out-of-hospital cardiac arrest is caused by ventricular fibrillation, defibrillation is an effective treatment; however, its effectiveness diminishes with each passing minute.[3,4] Automated external defibrillators (AEDs) are safe and effective when used by trained public-safety personnel who have a duty to respond to medical emergencies.[5-10] However, it is unclear whether trained volunteer laypersons who do not have a duty to act could save additional lives by using AEDs in addition to cardiopulmonary resuscitation (CPR) in patients who have had an out-of-hospital cardiac arrest.

In this study, we sought to determine whether the use of AEDs by response teams composed of volunteer laypersons trained in CPR would increase the number of survivors to hospital discharge among patients with out-of-hospital cardiac arrest due to cardiac causes.

METHODS

The Public Access Defibrillation (PAD) Trial was a community-based, prospective, randomized trial conducted from July 2000 through September 2003. In this trial, the number of patients who survived to hospital discharge after out-of-hospital cardiac arrest at a community facility where trained volunteers were able to recognize the event, telephone 911, and perform CPR was compared with the number of patients who survived to hospital discharge after out-of-hospital cardiac arrest at a community facility where volunteers could also provide early defibrillation with an on-site AED. An independent data and safety monitoring board, appointed by the National Heart, Lung, and Blood Institute, monitored patient safety, adverse events, and the conduct of the study. Details of the study design and methods have been described previously.[11]

STUDY CENTERS AND PARTICIPATING FACILITIES

The protocol was approved by the institutional review boards at 21 research centers in the United States and 3 in Canada. A diverse sample of community facilities (e.g., shopping malls, recreation centers, hotels, and apartment complexes) was recruited to participate. The facilities had to have a pool of potential volunteer responders and the ability to deliver an AED within three minutes to a person having a cardiac arrest. Facilities having on-site personnel with a duty to respond to medical emergencies (e.g., law-enforcement officers, firefighters, nurses, and physicians) and facilities with existing AED programs were excluded. Communitywide police programs involving the use of AEDs were permitted. Physical facilities were eligible for randomization as a community unit, either singly or in groups, if they could expect at least one out-of-hospital cardiac arrest during the study period (specifically, if the equivalent of at least 250 adults more than 50 years of age were present for 16 hours a day or if the facilities had a history of at least one witnessed out-of-hospital cardiac arrest every two years, on average). Eighty-three percent of the community units were single facilities. Eligible units were required to have clearly defined geographic boundaries and a typical emergency-medical-services system response time to defibrillation of 3 to 15 minutes.

STUDY POPULATIONS

Two populations with prespecified characteristics were studied: volunteer responders and patients having out-of-hospital cardiac arrest.

Patients

Because of the nature of out-of-hospital cardiac arrest, the patients were unable to give their consent before receiving the study treatment. Thus, the study was conducted under the regulations governing exceptions to informed consent for emergency research.[12] Written informed consent was obtained either from the patient or from a family member for the follow-up of survivors.

The primary patient population consisted of persons at least eight years of age with out-of-hospital cardiac arrest from cardiac causes. Patients with out-of-hospital cardiac arrest due to trauma, drug overdose, or other noncardiac causes were excluded from the primary comparison but not from the evaluation of safety.[13]

Volunteer Responders

Volunteer responders were laypersons whose primary job descriptions did not include the responsibility to provide medical assistance in emergencies. They gave written, informed consent before participation and were trained to competency according to current American Heart Association guidelines.[14] Retraining was scheduled to take place after three to six months and at one or more additional times during the course of the study. Additional volun-

teers were recruited to fill vacancies due to attrition (which typically resulted from job changes).

AED DEVICES

The AEDs used in the study were approved by the Food and Drug Administration and produced by three manufacturers. All the devices provided voice prompts and had electrocardiographic and sound-recording capabilities. Device checks were scheduled to take place monthly.

STUDY DESIGN

Eligible community units were randomly assigned to a CPR-only response system or to a CPR-plus-AED response system. The randomized groups were stratified according to center and stratified within each center according to location (residential vs. public).

A broad net of events triggered the data-collection process. Among the triggering events were syncope, seizure, choking, AED activation or electrode attachment not generated by emergency medical services, or dispatch of emergency-medical-services personnel to a unit for an apparently unresponsive person. Volunteers were alerted to events in various ways (e.g., overhead paging and security notification), depending on the facility's response plan. Events were classified as "presumed cardiac arrests" when more than two ventilations or more than five chest compressions were performed, when any defibrillation shock was delivered by volunteers or by emergency-medical-services personnel, or when the unresponsive person was found dead (even if emergency medical services had not been notified).

An events-adjudication committee, blinded with respect to the treatment group, classified all presumed cardiac arrests as one of the following: definite out-of-hospital cardiac arrest (an arrest of cardiac origin with rhythm identification [identification of ventricular fibrillation, ventricular tachycardia, pulseless electrical activity, or asystole] that was treated by emergency-medical-services personnel), probable out-of-hospital cardiac arrest (one in which only CPR was performed by emergency-medical-services personnel and the patient died), uncertain out-of-hospital cardiac arrest (one in which emergency-medical-services personnel provided treatment, there was no shockable rhythm, and the patient survived), or an event other than out-of-hospital cardiac arrest or an out-of-hospital cardiac arrest of noncardiac causes.[13] The committee reviewed a masked narrative report of each event, including rhythm strips and notations as appropriate. Sham masking (i.e., blacking out or altering reports to disguise whether emergency medical services or volunteer responders used an AED) was used to obscure the treatment group.[15]

STATISTICAL ANALYSIS

Traditional survival rates were initially considered a potential primary outcome measure but then rejected. The numerator of a survival rate would be the number of patients who survived to discharge after definite out-of-hospital cardiac arrest. However, it was unclear whether a reliable denominator could be identified. The logical denominator — all episodes of definite out-of-hospital cardiac arrest — is subject to both ascertainment bias and classification bias. Ascertainment bias is a consideration because volunteers might be more likely to report an event involving AED use or to respond to an event because of increased confidence based on the availability of an AED or because emergency-medical-services personnel may be more likely to continue treatment when an AED is already in place; classification bias is a consideration because an early electrocardiogram would more often be available in the CPR-plus-AED group (and rhythm strips are the best means of observing ventricular fibrillation and diagnosing cardiac arrest). These artifacts could result in a falsely low denominator (and hence a falsely high survival rate) for the CPR-only group. Other candidate denominators were also potentially flawed.[13]

Therefore, the prespecified primary outcome chosen was the number of survivors of definite out-of-hospital cardiac arrest in each community unit. A secondary outcome was the number of survivors of definite or uncertain out-of-hospital cardiac arrest. The unit of analysis was the community unit, and the primary comparison between treatment groups involved the use of a two-sample, stratified t-test with which the mean number of survivors per unit within strata were compared. With this approach, the comparison of survival rates composed of noncomparable denominators could be avoided.

A secondary analytic approach involved the use of log-linear (Poisson) generalized-linear-model regression, which permitted adjustment for the risk of out-of-hospital cardiac arrest (estimated as the population at risk multiplied by the years of exposure), as well as adjustments for center and unit type. A priori subgroup analyses were specified for

Table 1. Characteristics of the Community Units and the Volunteer Responders.*

Characteristic	CPR Only	CPR plus AED	P Value
Community units			
No. of units	497	496	
Residential — no. (%)	80 (16.1)	77 (15.5)	0.86†
Public — no. (%)	417 (83.9)	419 (84.5)	
No. of facilities	638	622	
Public facilities — no. (%)	547 (85.7)	527 (84.7)	
Recreational facilities	146 (26.7)	154 (29.2)	
Shopping centers	149 (27.2)	149 (28.3)	
Entertainment complexes	56 (10.2)	55 (10.4)	
Community centers	34 (6.2)	55 (10.4)	
Large office buildings	56 (10.2)	32 (6.1)	
Other (e.g., hotels, factories, transit centers)	106 (19.4)	82 (15.6)	
Noncompliant facilities — no. (%)	63 (9.9)	33 (5.3)	0.003†
Crossed over	34 (5.3)	5 (0.8)	<0.001†
Never trained	22 (3.4)	25 (4.0)	0.66†
Trained but not active	7 (1.1)	3 (0.5)	0.34†
No. of AEDs per unit			
Mean	NA	3.2	
Range	NA	0–17	
Events			
Expected cardiac arrests — no./unit‡			
Mean	1.23±1.19	1.20±0.91	0.71§
Range	0.01–12.88	0.06–7.79	
Expected cardiac arrests — total no.	611	597	
Observed presumed cardiac arrests — no.	266	260	0.004¶
Residential units	169	121	
Public units	97	139	
Observed attempted resuscitations — no.	133	162	0.26¶
Residential units	45	39	
Public units	88	123	

residential as compared with public units. Facilities that crossed over or that chose to discontinue participation were followed for events by review of responses from emergency medical services to the facility or by monthly queries to personnel at the facility. All discovered events were included in the analyses on an intention-to-treat basis.

The cerebral performance category at the time of hospital discharge was used to assess the functional outcome of survivors. Comparisons between treatment groups were made with the use of a chi-square test.

The study was designed to have 80 percent power to detect a 2.1-fold difference in the number of survivors between the CPR-only and the CPR-plus-AED groups, assuming 7 percent survival in the CPR-only group. One interim analysis was planned, with the interim stopping boundary specified at a P value of less than 0.005. The P value that was considered to indicate significance overall was 0.05.

RESULTS

The study randomly assigned 993 community units. The units were involved in the study a mean (±SD) of 21.5±5.5 months. The majority of the facilities (85 percent) were in public locations, most of which were recreational facilities and shopping centers

Table 1. (Continued.)

Characteristic	CPR Only	CPR plus AED	P Value
Volunteers			
Total no. of volunteers trained	8361	11,015	
Attrition rate — %/yr	18.7	18.8	0.52‖
No. per trained unit			<0.001§
Mean	17.6±15.3	23.0±17.3	
Range	1–149	1–115	
Age — yr			0.70§
Mean	39.8±9.0	39.6±9.4	
Range	17.3–72.0	19.4–69.1	
Male sex — %			0.50§
Mean	55.0±24.7	56.0±22.2	
Range	0–100	0–100	
High-school education or less — %			0.51§
Mean	31.6±21.1	30.8±19.1	
Range	0–100	0–100	

* Plus–minus values are means ±SD. Because of rounding, not all percentages total 100. NA denotes not applicable.
† The P value was calculated by Fisher's exact chi-square test.
‡ The expected number of cardiac arrests in a unit was calculated as the expected monthly rate of all out-of-hospital cardiac arrests (on the basis of the population or historical rate in the unit), multiplied by the number of months the unit participated in the trial.
§ The P value was calculated by the t-test with respect to unit-level summary measures.
¶ The P values are associated with the interaction between treatment group and unit type (residential vs. public). The P value was calculated by adding treatment group and public or residential interaction terms to log-linear (Poisson) generalized-linear-model regression analyses with the use of the natural log of the expected number of cardiac arrests as offset and with adjustments for center, treatment group, and unit type (public or residential).
‖ The P value was calculated by the Kaplan–Meier estimator and log-rank statistics.

(Table 1). Although the proportions of facilities that dropped out were similar in the two groups, more CPR-only facilities than CPR-plus-AED facilities crossed over. The observed numbers of arrests were substantially lower than anticipated from the prerandomization unit-enrollment data; however, the survival rate in the CPR-only units was higher than anticipated. After the interim analysis, information regarding the frequency of cardiac arrests and the survival rate in the CPR-only units was used to extend the data-collection period by six months to maintain the specified power level. A significantly larger number of volunteers participated in units that were randomly assigned to CPR plus AED than in units that were assigned to CPR only.

Table 2 outlines the characteristics of the events. The anticipated reporting bias was observed: the reported event incidence was higher in the CPR-plus-AED group than in the CPR-only group (2.02 vs. 1.81 events per unit per year), and among the reported events, activation of the volunteer system was more frequent in the CPR-plus-AED group. However, CPR-only residential units reported disproportionately more cardiac arrests (P=0.004 for the treatment-by-location [public vs. residential] interaction) (Table 1). When only cardiac arrests where resuscitation was attempted were considered, the interaction disappeared (P=0.26). Adverse events were rare and consisted mostly of transient psychological trauma to the volunteers and stolen AEDs. No inappropriate shocks were given. There were 526 presumed cardiac arrests or, on average, 1 presumed cardiac arrest per unit every 3.4 years. After blinded review, only 4 events were classified as probable or uncertain out-of-hospital cardiac arrests, and 235 were classified as definite out-of-hospital cardiac arrests, for a total of 239 events, or 1 per unit every 7.4 years.

Table 3 provides the characteristics of out-of-hospital cardiac arrests of cardiac cause. Treated patients were younger and were more likely to have been treated in a public facility than were those who

Table 2. Characteristics of the Events.*

Characteristic	Total	CPR Only	CPR plus AED	P Value
All events				
No. of events	3413	1591	1822	0.001†
Incidence — no./unit/yr		1.81	2.02	
No. of units with ≥1 events		330	349	
Adverse events — no. (%)				
Serious		1 (0.1)	0	0.47‡
Mild or moderate		1 (0.1)	6 (0.3)	0.13‡
Volunteer system activated — mean % of events per unit		53.2±42.5	60.9±40.5	0.02§
Patients				
Age — yr				0.16§
Mean of unit means		52.6±18.6	54.7±18.7	
Range		12–100	8–95	
Male sex — %				0.99§
Mean per unit		50.7±35.5	50.8±35.8	
Range		0–100	0–100	
Presumed out-of-hospital cardiac arrest				
Total — no.	526	266	260	0.59†
Dead on arrival (no EMS treatment) — no.	231	133	98	0.04†
With do-not-attempt-resuscitation orders	49	26	23	
Without do-not-attempt-resuscitation orders	182	107	75	
Cardiac cause	148	86	62	
Noncardiac cause	32	19	13	
Unknown cause	2	2	0	
Other event or an arrest of noncardiac cause — no.	56	24	32	0.22†
Arrest of noncardiac cause treated by bystander CPR only¶	18	8	10	
Respiratory arrest treated by EMS‖	17	6	11	
Arrest of noncardiac cause treated by EMS**	21	10	11	
Treated arrest of cardiac cause — no.	239	109	130	0.09†
Probable or uncertain	4	2	2	
Definite	235	107	128	

* Plus–minus values are means ±SD. EMS denotes emergency medical services.
† The P value was calculated by log-linear (Poisson) generalized-linear-model regression at the unit level, with adjustments for the natural log of the expected number of cardiac arrests, the center, and the location (residential vs. public).
‡ The P value was calculated by Fisher's exact chi-square test.
§ The P value was calculated by the t-test with respect to unit-level summary measures.
¶ Ventilations or compressions were given only by bystanders and not by EMS personnel.
‖ Ventilations with or without intubation, but no cardiac compressions, were given.
** Among the causes of arrest were drowning, suicide, drug overdose, trauma, choking, and cerebrovascular accident.

were dead on arrival. Table 4 provides the characteristics of the events classified as definite out-of-hospital cardiac arrests, according to treatment group. The characteristics of the patients did not differ according to treatment group. Volunteer-system activation occurred more frequently in the CPR-plus-AED group, but the frequency of CPR performed by volunteers or other bystanders was similar in the two groups. Shocks were delivered with a public-access defibrillator or other non–emergency-medical-services defibrillator in 34.4 percent of the definite out-of-hospital cardiac arrests (48.4 percent of the events in which a shock was administered) in the CPR-plus-AED group and 1.9 percent in the CPR-only group. The rate of hospital admission was higher in the CPR-plus-AED group.

Table 5 provides results with respect to the primary study outcome: survival to hospital discharge. The number of definite out-of-hospital cardiac arrest events was lower in the CPR-only group than in the CPR-plus-AED group (107 vs. 128, P=0.09). This difference characterized the public units more than it did the residential units. Twice as many patients in the CPR-plus-AED group as in the CPR-only group survived after a definite cardiac arrest, yielding a twofold difference in survival (95 percent confidence interval, 1.07 to 3.77; P=0.03). There was only 1 survivor of definite cardiac arrest in each group in the residential units; when uncertain cardiac arrests were included, the numbers were 31 in the CPR-plus-AED group and 16 in the CPR-only group. There was no difference between the two treatment groups in the cerebral performance category of survivors of definite cardiac arrest; however, it should be noted that the study was not powered to detect small-to-moderate differences in neurologic outcomes.

Table 3. Characteristics of the Out-of-Hospital Arrests of Cardiac Cause.*

Characteristic	Arrest in Persons Dead on Arrival without Known Advance Directives	Arrest Treated by EMS†
Arrests		
No. of events	148	239
Public	9	167
Residential	139	72
Average interval between arrests per unit — yr	12.0	7.4
Public	168.9	9.1
Residential	1.8	3.5
No. of events — no. of units		
0 events	921	814
1 event	42	140
≥2 events	30	39
Public unit — no./total no. (%)	9/148 (6.1)	167/239 (69.9)
Volunteer system activated — no./total no. (%)	40/148 (27.0)	148/238 (62.2)
Witnessed — no./total no. (%)‡	4/82 (4.9)	136/188 (72.3)
Bystander CPR — no./total no. (%)	8/125 (6.4)	143/227 (63.0)
Patients		
Age — yr		
Mean	75.7±13.8	69.8±15.2
Range	35–97	24–100
Male sex — no./total no. (%)	70/140 (50.0)	160/238 (67.2)
White race — no./total no. (%)‡	30/55 (54.5)	66/90 (73.3)
Sedentary before arrest — no./total no. (%)‡	28/34 (82.4)	61/177 (34.5)
Treated by EMS and had advance directives§	—	2/239 (0.8)

* Plus–minus values are means ±SD. EMS denotes emergency medical services.
† EMS-treated arrests include those classified as definite, probable, or uncertain.
‡ This characteristic was determined according to the EMS incident report but frequently had not been recorded.
§ The advance directive was found after the resuscitation attempt.

DISCUSSION

This study shows that enhancing a well-developed, monitored, layperson-enacted CPR-response plan by adding AEDs and AED training can increase the number of survivors of out-of-hospital cardiac arrest in public locations. This increase in survival does not come at the expense of increased neurologic deficit. In the trial, all volunteers received CPR training; thus, both groups included active interventions. This design tested a strategy of supervised public AED implementation under the condition of an "optimally" trained layperson-enacted response plan and should not be extrapolated to implementation without a response plan. Such extrapolation could underestimate or overestimate the incremental value of AED distribution without a planned response strategy.[16,17]

Choosing the number of survivors as the primary measure provided an arguably unbiased comparison at the cost of a small loss in power (2.6 percent) had an unbiased denominator been available. The anticipated bias in obtaining data pertaining to all episodes of out-of-hospital cardiac arrest was observed. After blinded review, there was a clear trend toward an increased frequency of the diagnosis of definite out-of-hospital cardiac arrest in public community units that had been assigned to CPR and AED. The opposite trend, noted in residential units, was probably due to a chance imbalance in unmeasured characteristics of the community units; however, the excess cardiac arrests were largely untreatable (i.e., cardiac arrests in patients who were dead on arrival or who had do-not-attempt-resuscitation orders). Therefore, this imbalance probably did not bias the results.

Comparing survivor counts is not a unique approach, but it does differ from the typical method of assessing survival after out-of-hospital cardiac arrest, which generally involves survival rates. The

Table 4. Characteristics of the Definite Out-of-Hospital Cardiac Arrests.*

Characteristic	CPR Only (N=107)	CPR plus AED (N=128)	P Value†
Volunteer response activated — no. (%)‡	57 (53.8)	89 (69.5)	0.06
Bystander CPR — no. (%)§	62 (62.0)	81 (64.8)	0.55
Shock delivered with non-EMS AED — no. (%)	2 (1.9)	44 (34.4)	<0.001
Interval between call to EMS and first rhythm assessment — min ¶	8.7±5.5	6.0±4.7	<0.001
Ventricular fibrillation or ventricular tachycardia as first rhythm — no. (%)‖	43 (47.3)	71 (57.7)	0.66
Interval between call to EMS and arrival of EMS — min	5.6±3.4	5.7 (3.3)	0.63
Patient admitted to hospital — no. (%)	29 (27.1)	50 (39.1)	0.07

* Plus–minus values are means ±SD. EMS denotes emergency medical services.
† P values were calculated by the t-test with respect to unit-level summary measures.
‡ Data were unavailable for one patient in the CPR-only group.
§ Data were unavailable for seven patients in the CPR-only group and three patients in the CPR-plus-AED group.
¶ The data shown include those pertaining to non-EMS rhythm identification with an AED. When non-EMS assessments with an AED were excluded, there was no difference between the two groups in the interval between the call to EMS and the first rhythm identification.
‖ Data were unavailable for 16 patients in the CPR-only group and 5 patients in the CPR-plus-AED group. The data shown include those pertaining to non-EMS rhythm identification with an AED. When non-EMS assessments with an AED were excluded, there was no difference between the two groups in the interval between the call to EMS and the first rhythm identification.

comparison of rates among jurisdictions is problematic, because ascertainment of the denominator is very system-sensitive.[11] Comparing rates within a jurisdiction reduces the problem, although even within a jurisdiction, event ascertainment may change over time. In this trial, it was possible to estimate survival rates that were comparable to those reported by other sources. To do so, we chose denominators that most closely reflected events that would be detected by the average emergency-medical-services system. For comparison with rates reported by emergency medical services with respect to all cardiac arrests, the most reasonable denominator was probably the number of presumed cardiac arrests in the CPR-only group. Similarly, for the comparison with rates reported by emergency medical services with respect to treated cardiac arrests, the number of treated arrests of cardiac cause in the CPR-only group was probably a reasonable denominator. This approach suggests, for the CPR-plus-AED group, overall survival rates of 29.9 percent in public locations (since there were 29 survivors of definite cardiac arrest in this group and 97 presumed cardiac arrests in the CPR-only group) and 0.6 percent in the residential complexes (1 and 169, respectively); likewise, it suggests rates of survival after treated cardiac arrest of 40.8 percent in public locations (29 and 71) and 2.6 percent in residential complexes (1 and 38), respectively. Though imperfect, these estimates may be useful for comparing the results of this trial with the results of analyses of survival rates in public settings.

Out-of-hospital cardiac arrests were uncommon in the public units; less than half the number expected were reported. This finding emphasizes the difficulty of prospectively identifying locations where out-of-hospital cardiac arrest might occur. The paucity of survivors of out-of-hospital cardiac arrest in large, multiunit, residential locations was striking in both the treatment groups. Although such units represented approximately 16 percent of the study locations and were the site of 28 percent of the cardiac arrests in which resuscitation was attempted, they accounted for less than 5 percent of the survivors of definite out-of-hospital cardiac arrest. Delays in diagnosis and in the mobilization of volunteers at these locations were likely. In these units, volunteers were summoned and responded to potential out-of-hospital cardiac arrests by way of centralized response systems; AEDs were not located in individual households. Thus, the trial was not, by design, a test of AED use in the home.

Our results show that use of AEDs by trained volunteers is safe and effective when initiated in public locations where there is at least a moderate likelihood of a witnessed out-of-hospital cardiac arrest (one every nine years). However, caution must be used when these results are extrapolated to broad, nationwide efforts. The actual effect of widespread implementation of public AED programs on survival after out-of-hospital cardiac arrest in such locations is likely to be moderate overall, since the majority of out-of-hospital cardiac arrests (79 to 84 percent) occur in the home.[18,19] For example, if widespread implementation of public AED programs resulted in a doubling of survival (such as that seen with this trial), approximately 2000 to 4000 additional lives would be saved each year in the United States.[11,18,19] However, additional measures are needed to affect the survival of persons who have a cardiac arrest at home.

This trial provides important confirmation that AEDs can be used safely and effectively by trained

lay responders. Where emergency-medical-services response times are very prolonged (as they may be in rural communities), public-access defibrillation may hold promise for survival after out-of-hospital cardiac arrest. Other than the psychological trauma that affected a few rescuers after a resuscitation attempt, the trial documented no clinically significant harm from the deployment of 1600 AEDs that were accessible to more than 11,000 volunteers in 622 public or residential locations over an average period of 21.5 months. This observation encourages wider use of AEDs.

The study had several limitations. Training programs, emergency-medical-services systems, or hospital care may have varied among the nearly 1000 units, but such heterogeneity should have been equalized by the randomization process. Crossovers were infrequent but were more common in the CPR-only group than in the CPR-plus-AED group. However, the analysis was performed on an intention-to-treat basis. This imbalance in crossovers would be expected to decrease the observed differences between the two groups.

The results of the trial pertain only to the implementation of layperson-based defibrillation systems in public settings with an organized emergency-response system in place. Furthermore, the results only apply to locations with a defined window of emergency-medical-services response times (i.e., 3 to 15 minutes). Locations where responses may be delayed (e.g., aircraft, boats, and trains) were excluded because randomization to the CPR-only group would almost completely remove any possibility of defibrillation. Locations with very rapid emergency-medical-services response times were not included because public AED implementation could not be expected to have a large effect in such places.

In public locations, where approximately 20 percent of out-of-hospital cardiac arrests occur, implementing an organized emergency-response plan and training and equipping volunteers to provide early defibrillation with an AED doubled the number of survivors to hospital discharge after out-of-hospital cardiac arrest. The PAD Trial supports the concept that trained volunteers can use AEDs safely and effectively in a variety of public locations.

Supported by a contract (N01-HC-95177) with the National Heart, Lung, and Blood Institute and by the American Heart Association, Guidant Foundation, and Medtronic. AEDs were provided by Cardiac Science Survivalink, Medtronic Physio-Control, and Philips Medical Systems Heartstream. CPR barrier devices were provided by Laerdal Medical.

Table 5. Number of Survivors of Out-of-Hospital Cardiac Arrest.

Characteristic	CPR Only	CPR plus AED	P Value	
			Unadjusted	Adjusted
Definite cardiac arrests — no.	107	128	0.09*	
Residential units	37	33		
Public units	70	95		
Survivors of definite arrest — no.	15	30	0.03†	0.03*‡
Residential units	1	1		
Public units	14	29		
Survivors of definite or uncertain arrest — no.	16	31		0.03*‡
Cerebral performance category of survivors of definite arrest — no. (%)§			0.90¶	
Normal	10 (71.4)	22 (73.3)		
Mildly impaired	3 (21.4)	5 (16.7)		
Moderately impaired	1 (7.1)	3 (10.0)		

* The P value was calculated by generalized-linear-model (Poisson) regression with the use of the natural log of the expected number of cardiac arrests as offset and with adjustments for center and unit type (public or residential). A treatment-by-location (public or residential) interaction term was not statistically significant for either definite cardiac arrests (P=0.42) or survivors (P=0.74).

† The groups were stratified according to center and were stratified within center according to location (residential vs. public). The nominal P value resulting from the stratified, two-sample t-test was adjusted for sequential monitoring by adding 0.005.

‡ The analysis was adjusted for sequential monitoring.

§ Data were unavailable for 1 of the 15 survivors in the CPR-only group. Patients whose cerebral performance category was considered "normal" were conscious, alert, and able to lead a normal life; they may have had minor psychologic or neurologic deficits, such as mild dysphasia or nonincapacitating hemiparesis. Those whose category was considered "mildly impaired" were conscious and had sufficient cerebral function for part-time work in a sheltered environment or independent activities of daily life; they may have had hemiplegia, seizures, ataxia, dysarthria, dysphasia, or permanent memory or mental changes. Those whose category was considered "moderately impaired" were conscious and had at least limited cognition but were dependent on others for daily support (i.e., in an institution or at home with exceptional family effort); they may have had severe memory disturbances, dementia, or the "locked-in" syndrome.

¶ The P value was calculated by Pearson's chi-square test.

Dr. Christenson reports having received research support from Medtronic Physio-Control, and Dr. Becker research support from Philips Medical Systems and support from Laerdal Medical.

We are indebted to the participating volunteers and facilities for their sustained commitment to the trial; to the emergency-medical-services systems serving the participating facilities for their assistance with data collection; to the numerous local organizations that donated personnel and supplies for training volunteers; and to Costas T. Lambrew, M.D., David C. Goff, Jr., M.D., Ph.D., Laurence McCullough, Ph.D., Louis Gonzales, E.M.T.-P., Henry A. Feldman, Ph.D., and Allan Braslow, Ph.D., for serving on the data and safety monitoring board.

APPENDIX

The investigators and coordinators participating in the PAD Trial were as follows: Writing Committee — A.P. Hallstrom, J.P. Ornato, M. Weisfeldt, A. Travers, J. Christenson, M.A. McBurnie, R. Zalenski, L.B. Becker, E.B. Schron, and M. Proschan. Investigators and Coordinators — *Arizona Heart Institute, Phoenix:* K. Vijayaraghavan, T. Mattioni, and C. Williams. *Calgary Emergency Medical Services, Calgary, Alta., Canada:* A.R. Anton, C.D. Jones, S. Yahn, and D. Rabel. *Christiana Health Care Services, Newark, Del.:* R.E. O'Connor, P. McGraw, M. Bollinger, and R.E. Megargel. *East Coast Clinical Research, Virginia Beach, Va.:* R.A. Craven, L.A. Bosken, M.P. Burke, J. Paulsen, and G. Newton. *Hennepin County Medical Center, Minneapolis:* B.D. Mahoney, R. Knudson-Ballard, and G. Vasquez. *Indiana University, Indianapolis:* W.J. Groh, D. Cordes, and S.J. Bondurant. *Intermountain Injury Control Research Center, Department of Pediatrics, University of Utah School of Medicine, Salt Lake City:* N.C. Mann, B. Shaum, K. Brown, and K. Jacobsen. *Medical College of Wisconsin, Milwaukee:* T.P. Aufderheide, R.G. Pirrallo, C.J. Conrad, D.J. Kitscha, C.W. Sparks, C. von Briesen, K.A. Deja, M.M. LeStarge, R.W. Janisch, S.S. Schmidt, L. Parmenter, and L. Grabowski. *Mission Hospital, Mission Viejo, Calif.*, and *Orange County Emergency Medical Services, Orange County, Calif.:* S. Ehrlich, B. Haynes, L. Asbury, and M. Amaya. *Mount Sinai School of Medicine, New York:* L.D. Richardson, F. Ehlert, C. Freyberg, N. Richmond, C. Shields, I. Wilets, and J. Holohan. *Oregon Health and Science University, Portland:* M. Daya, M.D. Gunnels, J.R. Hedges, J. Jui, T. Schmidt, L. Wittwer, H. Brooks, C. Burke, and D. Griffiths. *Riverside County Emergency Medical Services, Riverside, Calif.:* M. Osur, B. MacGavin, and B. Myrin. *Institute of Critical Care Medicine, Palm Springs, Calif.:* M.H. Weil. *Loma Linda University Medical Center, Loma Linda, Calif.:* R. Sehra. *University of Washington, Seattle:* R.O. Cummins, A. Doherty, S. Thompson, and S. Wood. *St. Paul's Hospital, Vancouver, B.C., Canada:* J. Christenson, S. Pennington, A. Holmes, H. Payne, R. Wehb, N. Douglas, and P. Lawson. *Stony Brook University, Stony Brook, N.Y.:* M.C. Henry, S. Johnson, H. Thode, and E.R. Stapleton. *SUNY Upstate Medical University Hospital, Syracuse, N.Y.:* D.B. Reed, L.H. Brown, and L.M. Evans. *George Washington University Medical Center, Washington, D.C.:* P.J. Varghese and R. Lucas. *University of Alabama at Birmingham, Birmingham:* T.E. Terndrup, S. Stepbens, S. Nafziger, and J. Sanford. *University of Alberta–City of Edmonton Emergency Response Department, Edmonton, Alta., Canada:* A. Travers, A. Panylyk, K. Irwin, and B. Heisz. *University of Chicago Hospitals, Chicago:* L.B. Becker, A. Barry, and E. Demertsidis. *University of Cincinnati, Cincinnati:* J. Van Zile, C. Grimmelsman, and L. Nolting. *University of Pittsburgh School of Medicine, Pittsburgh:* V.N. Mosesso, Jr., B.K. Slater, V.J. Campbell, and D. Hostler. *Virginia Commonwealth University Health System, Richmond:* J.P. Ornato (Steering Committee chair), M.A. Peherdy, J. Overton, and K. Schaffer. *Wayne State University, Detroit:* R. Zalenski, S. Compton, R. Dunne, R. Swor, R. Welch, L.M. Mango, and K. Bilicki. *Johns Hopkins University School of Medicine, Baltimore:* M. Weisfeldt. *Ohio State University, Columbus:* M.R. Sayre. *School of Nursing, University of Pennsylvania, Philadelphia:* B. Riege*L National Heart, Lung, and Blood Institute, Bethesda, Md.:* E.B. Schron, J. Fleg, M.J. Domanski, M. Proschan, Y. Rosenberg, L. O'Neill, and the following former project officers: D. Simons-Morton and M.E. Salive. *Economic Center, University of Ottawa, Ottawa, Ont., Canada:* G. Nichol, G. Wells, E. Huszti, J. Rokosh, and D. Morris. *Harvard University, Boston:* K. Kuntz. *University of Alberta, Edmonton, Alta., Canada:* D. Feeny. *Clinical Trial Center, University of Washington, Seattle:* A.P. Hallstrom, H.L. Greene, M.A. McBurnie, J. Powell, L. Van Ottingham, A. Birnbaum, R.B. Ledingham, R. Moore, M. Morris, M. Scholz, and A. Kerr.

REFERENCES

1. Rosamond WD, Chambless LE, Folsom AR, et al. Trends in the incidence of myocardial infarction and in mortality due to coronary heart disease, 1987 to 1994. N Engl J Med 1998;339:861-7.
2. State-specific mortality from sudden cardiac death — United States, 1999. MMWR Morb Mortal Wkly Rep 2002;51:123-6.
3. Cummins RO, Ornato JP, Thies WH, Pepe PE. Improving survival from sudden cardiac arrest: the "chain of survival" concept: a statement for health professionals from the Advanced Cardiac Life Support Subcommittee and the Emergency Cardiac Care Committee, American Heart Association. Circulation 1991;83:1832-47.
4. Valenzuela TD, Roe DJ, Cretin S, Spaite DW, Larsen MP. Estimating effectiveness of cardiac arrest interventions: a logistic regression survival model. Circulation 1997;96:3308-13.
5. White RD, Hankins DG, Bugliosi TF. Seven years' experience with early defibrillation by police and paramedics in an emergency medical services system. Resuscitation 1998;39:145-51.
6. Mosesso VN Jr, Davis EA, Auble TE, Paris PM, Yealy DM. Use of automated external defibrillators by police officers for treatment of out-of-hospital cardiac arrest. Ann Emerg Med 1998;32:200-7.
7. Page RL, Joglar JA, Kowal RC, et al. Use of automated external defibrillators by a U.S. airline. N Engl J Med 2000;343:1210-6.
8. Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Public use of automated external defibrillators. N Engl J Med 2002;347:1242-7.
9. Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. N Engl J Med 2000;343:1206-9.
10. Myerburg RJ, Fenster J, Velez M, et al. Impact of community-wide police car deployment of automated external defibrillators on survival from out-of-hospital cardiac arrest. Circulation 2002;106:1058-64.
11. Ornato JP, McBurnie MA, Nichol G, et al. The Public Access Defibrillation (PAD) Trial: study design and rationale. Resuscitation 2003;56:135-47.
12. Mosesso VN Jr, Brown LH, Greene HL, et al. Conducting research using the emergency exception from informed consent: the Public Access Defibrillation (PAD) Trial experience. Resuscitation 2004;61:29-36.
13. Sayre MR, Travers AH, Daya M, et al. Measuring survival rates from sudden cardiac arrest: the elusive definition. Resuscitation 2004;62:25-34.
14. Guidelines 2000 for cardiopulmonary resuscitation and emergency cardiovascular care. 4. The automated external defibrillator: key link in the chain of survival. Circulation 2000;102:Suppl I:I-60–I-76.
15. Antiarrhythmics Versus Implantable Defibrillators (AVID) — rationale, design, and methods. Am J Cardiol 1995;75:470-5.
16. Stiell IG, Wells GA, Field BJ, et al. Improved out-of-hospital cardiac arrest survival through the inexpensive optimization of an existing defibrillation program: OPALS study phase II: Ontario Prehospital Advanced Life Support. JAMA 1999;281:1175-81.
17. Becker LB, Ostrander MP, Barrett J, Kondos GT. Outcome of CPR in a large metropolitan area — where are the survivors? Ann Emerg Med 1991;20:355-61.
18. Becker L, Eisenberg M, Fahrenbruch C, Cobb L. Public locations of cardiac arrest: implications for public access defibrillation. Circulation 1998;97:2106-9.
19. Pell JP, Sirel JM, Marsden AK, Ford I, Walker NL, Cobbe SM. Potential impact of public access defibrillators on survival after out of hospital cardiopulmonary arrest: retrospective cohort study. BMJ 2002;325:515.

Circulation. 2000;102:I-60-I-76 « Previous Article | Table of Contents | Next Article »

(*Circulation.* 2000;102:I-60.)

ECC Guidelines

Part 4: The Automated External Defibrillator

Key Link in the Chain of Survival

Major Guidelines Changes

Following are the major guidelines changes related to use of automated external defibrillators (AEDs) in basic life support:

1. Early defibrillation (shock delivery within 5 minutes of EMS call receipt) is a high-priority goal.
2. Healthcare providers with a duty to perform CPR should be trained, equipped, and authorized to perform defibrillation (Class IIa).
3. For in-hospital defibrillation: a. Early defibrillation capability, which is defined as having appropriate equipment and trained first responders, should be available throughout hospitals

and affiliated outpatient facilities (Class IIa).

4. b. The goal of early defibrillation by first responders is a collapse-to-shock interval, when appropriate, of <3 minutes in all areas of the hospital and ambulatory care facilities (Class I).
5. c. Response time intervals for in-hospital resuscitation events are often inaccurate and must be corrected before documented times to defibrillation can be considered reliable (Class IIa).
6. Evidence supports establishment of public access defibrillation (PAD) programs in the following cases: a. The frequency of cardiac arrest events is such that there is a reasonable probability of one AED use in 5 years (estimated event rate of 1 sudden cardiac arrest per 1000 person-years).
7. b. An EMS call–to-shock time interval of <5 minutes cannot be reliably achieved with conventional EMS services. In many communities, this EMS call–to-shock time interval can be achieved by training and equipping laypersons to • Function as first responders in the community • Recognize cardiac arrest • Activate the EMS system (phoning 911 or another appropriate emergency response number) at appropriate times • Provide CPR • Attach/operate an AED safely.

1. c. For BLS responders such as police, firefighters, security personnel, sports marshals, ski patrol members, ferryboat crews, and airline flight attendants (referred to as level I responders in this document), education in CPR and the use of an AED is a Class IIa recommendation. For level 2 targeted responders such as citizens at worksites or in public places, this is a Class Indeterminate recommendation at this time. Likewise, for level 3 responders (family and friends of persons at high risk) this is a Class Indeterminate recommendation.
2. Usc of AEDs in children ≥8 years of age (approximately >25 kg body weight) is a Class IIb recommendation.
3. Use of AEDs in infants and children <8 years of age is not recommended (Class Indeterminate).
4. Biphasic waveform defibrillation with shocks ≤200 J is safe and has equivalent or higher efficacy for termination of ventricular fibrillation (VF) compared with higher-energy escalating monophasic-waveform shocks (Class IIa).

Introduction

Public access defibrillation, which places AEDs in the hands of trained laypersons, has the potential to be the single greatest advance in the treatment of VF cardiac arrest since the development of CPR.[1 2 3 4 5 6 7 8 9 10 11] Time to defibrillation is the most important determinant of survival from cardiac arrest.[1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16] PAD provides the opportunity to defibrillate victims of cardiac arrest within a few minutes, even at sites remote from traditional EMS responders. Extraordinary survival rates—as high as 49%—have been reported in PAD programs.[17 18 19 20 21 22 23 24] These rates are twice those previously reported for the most effective EMS systems.[25]

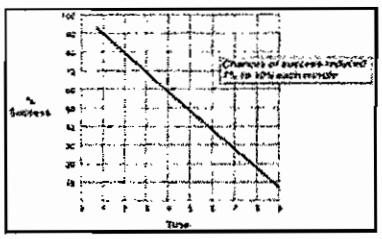
AEDs are sophisticated, computerized devices that are reliable and simple to operate, enabling lay rescuers with minimal training to administer this lifesaving interven-tion.[1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 26] Flight attendants, security personnel, sports marshals, police officers, firefighters, lifeguards, family members, and many other trained laypersons have used AEDs successfully.[15 16 17 18 19 20 21 22 23 24] AEDs are located in airports, airplanes, casinos, high-rise office buildings, housing complexes, recreational facilities, shopping malls, golf courses, and numerous other public locations.[15 16 23 24 27 28 29] AEDs are also used by healthcare professionals in ambulances, hospitals, dental clinics, and physicians' offices.[29 30 31 32 33 34]

With the inclusion of AED use as a BLS skill, BLS now encompasses the first 3 links in the Chain of Survival (early access, early CPR, and early defibrillation).[35] AEDs widely used by the public and distributed throughout the community significantly advance the concept proposed more than 2 decades ago: the community should become the "ultimate coronary care unit."[36]

Principle of Early Defibrillation

Early defibrillation is critical to survival from cardiac arrest for several reasons: (1) the most frequent initial rhythm in witnessed sudden cardiac arrest is VF; (2) the most effective treatment for VF is electrical defibrillation; (3) the probability of successful defibrillation diminishes rapidly over time; and (4) VF tends to convert to asystole within a few minutes.[25 37 38 39 40 41 42 43 44 45 46] Many adults in VF can survive neurologically intact even if defibrillation is performed as late as 6 to 10 minutes after sudden cardiac arrest, particularly if CPR is provided.[25 37 38 39 40 41 42 43 44 45 46] The performance of CPR while awaiting the arrival of the AED appears to prolong VF, contributing to preservation of heart and brain function.[39 40] Basic CPR, however, is unlikely to convert VF to a normal rhythm.

The speed with which defibrillation is performed is the major determinant of the success of resuscitative attempts for treatment of VF cardiac arrest.[38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56] Survival rates after VF cardiac arrest decrease approximately 7% to 10% with every minute that defibrillation is delayed.[25 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52] (See Figure 1[41]) A survival rate as high as 90% has been reported when defibrillation is achieved within the first minute of collapse.[43 44 45 46] When defibrillation is delayed, survival rates decrease to approximately 50% at 5 minutes, approximately 30% at 7 minutes, approximately 10% at 9 to 11 minutes, and approximately 2% to 5% beyond 12 minutes.[25 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52] One historical observational study suggests that survival may be improved if CPR is performed by first responders for 1 minute before defibrillation when defibrillation is delayed ≥4 minutes[57] and no bystander CPR is performed.



View larger version (27K):
[in this window]
[in a new window]

Figure 1. Composite data illustrating relationship between probability of survival to hospital discharge (indicated as "success" in figure) after VF cardiac arrest and interval between collapse and defibrillation. Based on data from Reference [41].

Survival rates from cardiac arrest can be remarkably high if the event is witnessed. For example, when people in supervised cardiac rehabilitation programs experience a witnessed cardiac arrest, defibrillation is usually performed within minutes; in 4 studies of cardiac arrest in this setting, 90 of 101 victims (89%) were resuscitated.[43 44 45 46] This is the highest survival rate reported for a defined out-of-hospital population.

Communities with no out-of-hospital ACLS services but with early defibrillation programs have reported improved survival rates among patients with cardiac arrest when survival rates for EMT care with and without AEDs were compared.[47 48 49 50 51] The most impressive results were reported by King County, Washington, where the survival rate of patients with VF improved from 7% to 26%,[47] and rural Iowa, where the survival rate rose from 3% to 19%.[48] More modest results have been observed in rural communities in southeastern Minnesota,[49] northeastern

Minnesota,[50] and Wisconsin.[51] After implementation of early defibrillation programs by EMS personnel in 5 European regions, survival to discharge from VF cardiac arrest was as high as 27% to 55%.[58]

Clearly the earlier defibrillation occurs, the better the prognosis.[38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56] Emergency personnel have only a few minutes after a victim's collapse to reestablish a perfusing rhythm. CPR can sustain a patient for a short time but cannot directly restore an organized rhythm. Restoration of an adequate perfusing rhythm requires defibrillation and advanced cardiovascular care, which must be administered within a few minutes of the initial arrest.[37] The use of AEDs increases the range of personnel who can use a defibrillator, shortening the time between collapse and defibrilla-tion.[47 48 49 50 51 53 54 55 56] This exciting prospect accounts for the addition of this intervention as an integral component of BLS.

Early defibrillation (shock within 5 minutes of EMS call receipt) is a high-priority goal of EMS care. Every community should assess its capability to provide this intervention and institute whatever measures are necessary to make this recommendation a reality.

History of AEDs

In a prophetic report of what was to follow in the next 2 decades, Diack and colleagues[59] described experimental and clinical experience with the first AED. Subsequently, other studies provided supportive evidence for the potential role of such a device for widespread provision of rapid defibrillation.[60 61 62]

In the ensuing years, clinical studies have documented various aspects of AED performance, confirming the high sensitivity and specificity of the AED algorithms as well as the safety and efficacy of the devices.[62 63 64 65 66 67 68 69 70 71 72 73 74 75 76]

Another major advance in the use of AEDs was the development of a small (6.25-lb) AED specifically designed for home use. This AED delivered up to 3 nonescalating 180-J monophasic damped sinusoidal shocks and instructed the operator with easy-to-follow audible prompts. New AED models and manufacturers soon entered the field. Clinical evaluation confirmed the safety and efficacy of this AED in termination of out-of-hospital VF arrest.[72 76 77] Home trials were conducted and reported, but the concept of home defibrillation for patients at high risk was not yet ready for acceptance.[15 16 78 79 80 81]

In the last few years there has been a significant increase in the use of AEDs in early defibrillation programs in a variety of settings, including EMS systems, police departments, casinos, airport terminals, and commercial aircraft, among others.[12 13 17 18 20 21 22 23 24 82 83 84] In most of these settings, use of AEDs by BLS ambulance providers or first responders (PAD level 1 responders) in early defibrillation programs has been associated with a significant increase in survival rates. In some cases no benefit from such early defibrillation has been observed, usually in rural areas or systems in which EMS response is rapid enough to preclude benefit.[14 85 86] Also, improved survival will not be likely when infrequent bystander CPR and delays in dispatch impose weaknesses in other aspects of the Chain of Survival.[87] Long arrest-to-shock times (mean 23.8 minutes) and a low occurrence of bystander CPR (9%) were accompanied by a low survival rate (6%) from VF after introduction of AEDs in a large Asian city.[88] These and similar studies suggest that the introduction of AEDs into ambulance services may not significantly improve outcome unless other links in the Chain of Survival are optimized.[87] Guidelines for implementation of early

defibrillation programs have been published that emphasize the components that are likely to result in improved patient outcomes, especially the critical links in the Chain of Survival.[89] [90] [91]

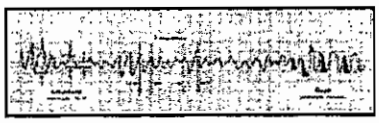
Advances in defibrillation waveform technology have been incorporated into AEDs, following the transition from monophasic to biphasic waveforms with implantable cardioverter-defibrillators (ICDs).[91A] Experimental and clinical evidence supporting the transition to biphasic waveforms in ICDs was abundant and consistent.[92] [93] [94] [95] [96] [97] [98] [99] [100] [101] The use of biphasic defibrillation waveforms permits a reduction in the size and weight of AEDs, a major consideration in many settings, such as aircraft. Recommendations for specifying algorithm performance and demonstrating the equivalence of alternative waveforms were published by the American Heart Association Subcommittee on AED Safety and Efficacy in 1997.[102]

Contemporary AEDs

The term "AED" refers to an automated external defibrillator that incorporates a rhythm analysis system and a shock-advisory system.[103] [104] The AED "advises" a shock and the operator must take the final action (press the SHOCK button) to deliver the shock. Fully automated external defibrillators do not require pressing the SHOCK button, and they are available only for special situations.

Automated Analysis of Cardiac Rhythms

Current AEDs are highly sophisticated, microprocessor-based devices that analyze multiple features of the surface ECG signal, including frequency, amplitude, and some integration of frequency and amplitude, such as slope or wave morphology (Figure 2). Various filters check for QRS-like signals, radio transmission, or 50- or 60-cycle interference as well as loose electrodes and poor electrode contact. Some intermittent radio transmissions can produce an ECG artifact if a transmitter or receiver is used within 6 feet of a patient during rhythm analysis. Some devices are programmed to detect spontaneous movement by the patient or movement of the patient by others.[103] [104]



View larger version (63K):
[in this window]
[in a new window]

Figure 2. Features of an ECG analyzed by an AED.

AEDs have been extensively tested, both in vitro against libraries of recorded cardiac rhythms[105] and clinically in numerous field trials.[59] [60] [62] [63] [64] [67] [68] [72] Their accuracy in rhythm analysis is high.[62] [63] [64] The rare errors noted in field trials have been almost solely errors of omission (sensitivity) in which the device failed to recognize certain varieties of VF or tachycardia or when operators failed to follow recommended operating procedures, such as avoidance of patient movement.[66]

Inappropriate Shocks or Failure to Shock

Extensive clinical experience has revealed that AEDs are infrequently affected by movement of the patient (eg, seizures and agonal respirations), repositioning of the patient, or artifactual signals, although some rare difficulties have been reported.[59] [60] [62] [63] [64] [66] [67] [68] [72] Failure to follow the manufacturer's instructions for use of a fully automated external defibrillator has in rare instances (<0.1%) resulted in delivery of inappropriate electrical countershocks.[12] AEDs should be placed in the analysis mode only when full cardiac arrest has been confirmed and *only* when all movement, particularly patient transport, has ceased. Agonal respiration poses a problem because some devices may not be able to complete analysis cycles if the patient continues to have gasping respirations. Use of radio receivers and transmitters should be avoided during rhythm analysis. The major errors reported in clinical trials have been occasional failures to deliver shocks to rhythms that may benefit from electrical therapy, such as extremely fine or coarse VF.[62] [64] [66] Occasionally the analysis and treatment cycles of implanted and automated defibrillators can conflict.[64] [66] [106]

Ventricular Tachycardia

Although AEDs are not designed to deliver synchronized shocks, all AEDs will shock monomorphic and polymorphic ventricular tachycardia (VT) if the rate exceeds preset values. AEDs should be operated *only* on patients who are unresponsive, not breathing, and have no signs of circulation.

With this approach, the operator serves as a second verification system to confirm that the patient has suffered a cardiac arrest. In an apneic patient without signs of life, electrical shocks are indicated whether the rhythm is supraventricular tachycardia (SVT), VT, or VF. There have been rare reports of shocks delivered to responsive patients with perfusing ventricular or supraventricular arrhythmias.[12] [62] These are operator errors, not device errors, and are preventable when rescuers are well trained and possess good patient assessment skills.[67]

Throughout this chapter, for laypersons the term "signs of circulation" means quickly evaluating the victim for normal breathing, coughing, or movement. For healthcare professionals the term "signs of circulation" means quickly performing a pulse check while simultaneously evaluating the victim for breathing, coughing, or movement.

Waveforms and Energy Levels

The energy settings for defibrillators are designed to provide the lowest effective energy needed to terminate VF. If energy and current are too low, the shock will not terminate the arrhythmia; if energy and current are too high, myocardial damage may result.[107] [108] [109] [110] [111] There is no clear relation between body size and energy requirements for defibrillation in adults. Modern AEDs fall into 2 broad categories of waveforms: monophasic and biphasic. Energy levels vary by type of device. Monophasic waveforms deliver current that is primarily of 1 polarity (ie, direction of current flow). They are further subdivided by the rate at which the current pulse decreases to zero; namely, either gradually (damped sinusoidal or instantaneously (truncated exponential). The waveforms of biphasic defibrillators indicate a sequence of 2 current pulses; the polarity of the second is opposite that of the first.

In a prospective out-of-hospital study of monophasic manual defibrillators, defibrillation rates and the proportion of patients resuscitated and later discharged from the hospital were virtually identical in patients who received initial monophasic damped sine (MDS) waveform shocks of 175 J and 320 J.[112] The recommended first-shock energy for monophasic waveform defibrillation is 200 J.[112] For monophasic devices the recommended second shock is 200 to 300 J; the recommended third shock is 360 J.[112] The intent of this escalating energy dosage protocol is to maximize shock success (termination of VF) while minimizing shock toxicity.[107] [108] [109] [110] [111]

The first biphasic waveform for use in an AED was approved in the United States in 1996. This impedance-compensating biphasic truncated exponential (BTE) waveform was incorporated into an AED that discharged

nonescalating 150-J shocks. Impedance compensation was achieved by adjusting first-phase tilt, relative duration of the 2 phases, and total duration to a maximum of 20 ms. Experimental work in animals suggested the superiority of this waveform over monophasic truncated exponential (MTE) waveforms.[113] In-hospital studies during ICD testing compared 115-J and 130-J shocks using the BTE waveform with MDS waveform shocks of 200 J and 360 J.[114] [115] This in-hospital data indicated that for short-duration VF, BTE shocks at low energy (115 J and 130 J) were as effective as the 200-J MDS shocks traditionally used for the first shock.[114] [115] Fewer ST-segment changes were observed after transthoracic defibrillation of short-duration VF with the 115- and 130-J BTE shocks compared with those after 200-J MDS shocks.[116]

Another in-hospital study comparing an MDS waveform with a damped sinusoidal version of a biphasic waveform ("Gurvich") concluded that this biphasic waveform was likewise superior to the MDS waveform in terminating short-duration VT and VF.[117]

Early clinical experience with the 150-J, impedance-compensated BTE waveform for treatment of out-of-hospital long-duration VF was also positive.[118] [119] This experience, along with in-hospital clinical data, formed the basis for the AHA evidence-based review of this low-energy biphasic waveform defibrillation, which led to an initial Class IIb recommendation.[120] Since then, cumulative experience with this waveform in 100 patients with VF was reported, confirming its efficacy in terminating VF arrest outside the hospital.[121] The aggregate data with this waveform in VF arrest from one EMS system (Rochester, Minn) also affirmed the efficacy of this waveform for terminating VF.[82] This experience was compared retrospectively with that of the MDS waveform in the same EMS system.[82] The growing body of evidence is now considered sufficient to support a Class IIa recommendation for this low-energy, BTE waveform.

Other versions of biphasic waveforms have been introduced and have undergone initial evaluation during electrophysiology study and ICD implantation and testing. Experience with short-duration VF, in which a low-energy (120- to 170-J), constant-current, rectilinear biphasic waveform was used has recently been reported.[122] This waveform has also been very effective in terminating atrial fibrillation during elective cardioversion with energies as low as 70 J.[123] At this time no studies have reported experience with other biphasic waveforms in long-duration VF in out-of-hospital arrest. When such data becomes available, it will need to be assessed by the same evidence-evaluation process as used for the biphasic AED and this guidelines process.

The data indicates that biphasic waveform shocks of relatively low energy (≤200 J) are safe and have equivalent or higher efficacy for termination of VF compared with higher-energy escalating monophasic waveform shocks (Class IIa). The safety and efficacy data related to specific biphasic waveforms must be evaluated on an individual basis in both in-hospital (electrophysiology studies, ICD testing) and out-of-hospital settings.

Evaluation of Defibrillation Waveform Performance

The evaluation of defibrillation shock waveform efficacy requires the adoption of standard descriptors of defibrillation and postshock rhythms.[124] Clinical investigators should uniformly apply such descriptors in the assessment of defibrillation waveforms. The term "defibrillation" means reversal of the action of fibrillation. Defibrillation is not a synonym for "shock." Thus, defibrillation should be understood to mean termination of fibrillation and should not be confused with other resuscitation outcomes, such as restoration of a perfusing rhythm, admission to hospital, or discharge survival.[125] These additional end points may occur during resuscitation as a consequence of many variables, including time from collapse to shock and other interventions, such as CPR and drug therapy.

In several recent studies,[82] [119] [126] a successful defibrillatory shock was defined as the absence of VF 5 seconds after shock delivery. This definition of shock outcome was one of several considered by the 1999 Evidence Evaluation experts as acceptable to define "success" in evaluation of defibrillator waveforms. Thus, asystole or non-VF electrical activity at the postshock end point constitutes "success" because VF has been terminated. This is consistent with data from electrophysiological mapping studies confirming the time course of termination of VF after shock delivery, and clinically it is an easily measurable point in time after a shock.[127] [128] At this point the direct effect of the shock on VF is not influenced by many other interventions that may ensue after shock delivery, such as chest compressions, ventilation, and administration of drugs, which themselves have an impact on cardiac rhythm after shocks. Examining the rhythm 5 seconds after each of the first series of shocks, before any drugs or other advanced life support interventions are initiated, will yield the most useful specific information about shock efficacy. In addition, tracking the postshock rhythm during the first minute after shock delivery will provide additional data, such as whether an organized rhythm is supraventricular or idioventricular and whether or not a perfusing rhythm accompanies restoration of organized electrical activity.

As new defibrillation waveforms evolve and are evaluated in out-of-hospital arrest, it is essential that standardized definitions of shock efficacy be accepted and uniformly applied by clinical investigators engaged in waveform research. The definitions proposed here help meet that need.

Operation of the AED

Before attaching the AED, the operator should first determine whether special situations exist that contraindicate the use of the AED or require additional actions before its use.

Special Situations That May Require Additional Actions

While preparing to use the AED, the operator must identify 4 possible circumstances (special situations) that may require rescuers to modify their actions before or during AED use. These situations include victims in water, those <8 years of age or <25 kg, those with transdermal medication patches, and those with implanted pacemakers or ICDs. Metal surfaces are *not* included as a special circumstance because they pose no shock hazard to either victim or rescuer.

Water

Water is a good conductor of electricity and may provide a pathway for energy from the AED to rescuers and bystanders treating the victim. There is a small possibility that rescuers or bystanders may receive shocks or minor burns if they are within such a pathway. Water on the skin of the chest can also provide a direct path of energy from one electrode pad to the other (arcing) and can decrease the effectiveness of the shock delivered to the heart. It is critical to quickly remove the victim from freestanding water and dry the victim's chest before using the AED. If the victim has a diving injury or other possible spinal injury, care should be taken to maintain cervical spine immobilization while moving the victim and performing resuscitation.

Children

Cardiac arrest is less common in children than adults, and its causes are more diverse.[129] [130] [131] [132] Approximately 50% of pediatric cardiac arrests occur in children <1 year old.[129] Most of these are caused by sudden infant death syndrome and respiratory disease.[129] [130] [131] [132] Beyond the first 6 months of life, injuries and drowning are the

major causes of cardiac arrest.[129] [130] [131] [132] The most common terminal rhythm observed in patients ≤17 years of age is asystole or pulseless electrical activity.[129] [131] [132] [133] [134] [135] [136] [137] When pediatric cardiac arrest rhythms are reported, estimates of VF range from 7% to 15%.[129] [131] [133] [134] [135] [138] In some studies, pediatric patients with VF who receive defibrillation at the scene have a higher initial resuscitation rate and are more likely to be discharged from the hospital with good neurological outcomes than pediatric patients who present with non-VF rhythms.[131] [133]

Experience with AEDs in children is very limited. The sensitivity and specificity for children of the AED algorithm need further study. The data suggests that AEDs can accurately detect VF in children of all ages (sensitivity),[139] [140] [141] but there is inadequate data on the ability of AEDs to correctly identify nonshockable tachycardic rhythms in infants (specificity).[141] Although the available data is encouraging, more data in larger pediatric populations is needed to define AED algorithm sensitivity and specificity.

More studies are also needed to determine AED energy doses that are safe and effective for children. In adults, clinical reports of biphasic waveform AED use have described energy doses as low as 120 J, with success rates equal to 200-J monophasic shocks for termination of VF; less postresuscitation myocardial dysfunction was observed after lower-energy shocks.[122] [142] [143] Currently available AEDs deliver energy doses that exceed the recommended monophasic dose of 2 to 4 J/kg in most children <8 years of age. The median weight of children more than 8 years of age is typically >25 kg; therefore, the delivered *initial* dose from a monophasic or biphasic AED (150 to 200 J) will be <10 J/kg for this age group. Data from animals suggests that this may be a safe dose, although human pediatric data is extremely limited.[144] At this time attempted defibrillation of VF/pulseless VT detected by an AED may be considered in older children (≥8 years old, approximately >25 kg body weight), particularly in the out-of-hospital setting. A weight of 25 kg corresponds to a body length of approximately 50 in (128 cm) using a Broselow color-coded tape.[144A]

In summary, although VF is not a common arrhythmia in children, it is observed in as many as 15% of pediatric and adolescent arrests.[129] [131] [133] [134] [135] [137] In these patients rapid defibrillation may improve outcomes.[131] [133] [138] Multicenter or controlled studies of AED algorithm sensitivity and specificity are needed, as well as a clearer definition of appropriate energy doses for children of all ages and sizes.

For these reasons, use of AEDs in children ≥8 years old (approximately >25 kg body weight) is a Class IIb recommendation. Use of AEDs in infants and children <8 years old is not recommended, primarily because of the lack of data concerning sensitivity, specificity, safety, and efficacy (Class Indeterminate). Healthcare providers who routinely care for children at risk for arrhythmias and cardiac arrest (eg, in-hospital settings) should continue to use defibrillators capable of appropriate energy adjustment. For infants and children <8 years old who are in cardiac arrest, the initial priorities continue to be support of the airway, oxygenation, and ventilation.

Transdermal Medications

AED electrodes should not be placed directly on top of a transdermal medication patch (eg, nitroglycerin, nicotine, analgesics, hormone replacements, antihypertensives), because the patch may block delivery of energy from the electrode pad to the heart and may cause small burns to the skin.[145] The only problems reported with shocks over a transdermal patch have involved patches with a metal backing. Metal backing for patches is no longer being used, so this potential problem has been eliminated. Medication patches should be removed and the area wiped clean before the AED electrode pad is attached.

Implanted Pacemakers/ICDs

Defibrillators that deliver a limited number of low-energy shocks directly to the myocardium have been implanted in selected patients with a history of malignant arrhythmias. These devices create a hard lump beneath the skin of the upper chest or abdomen (usually on the victim's left side). The lump is about half the size of a pack of cards and usually has a small overlying scar. Placement of an AED electrode pad directly over an implanted medical device may reduce the effectiveness of defibrillation attempts.[146] Instead, place the pad at least 1 inch (2.5 cm) away from the implanted device. Then follow the usual steps for operating an AED.[146] However, if the ICD is delivering shocks to the patient (ie, the patient's muscles contract in a manner like that observed during external defibrillation), allow 30 to 60 seconds for the ICD to complete the treatment cycle. Occasionally the analysis and shock cycles of automatic ICDs and AEDs will conflict.[106] (See "Part 6, Section 2: Defibrillation" for guidelines for management of patients with ICDs.)

The "Universal AED": Common Steps to Operate All AEDs

It is recommended that AEDs used in PAD programs (eg, large buildings, shopping malls, or homes) be stored next to a telephone. This allows the rescuer to activate the EMS system (by phoning 911 or another appropriate emergency telephone number) and retrieve the AED quickly. In some settings (eg, airports), security personnel or the local EMS system are automatically notified when the AED is retrieved from its storage case.

Position the AED close to the supine victim's ear. Performing defibrillation protocols from the victim's *left* side allows better access to the AED controls and easier placement of electrode pads. The left-side position also provides space for a second rescuer to perform CPR from the victim's right side. This position, however, may not be accessible in all clinical settings. Alternative positions and operator roles may be used with equal success.

AEDs are available in several models. There are small differences from model to model, but all AEDs operate in basically the same way.[103,104] The 4 universal steps of AED operation are as follows:

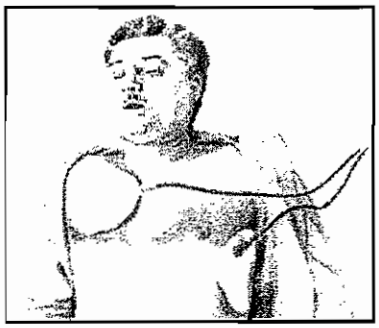
Step 1: POWER ON the AED

The first step in operating an AED is to turn the power on. This initiates voice prompts, which guide the operator through subsequent steps. To turn the AED on, press a power switch or lift the monitor cover or screen to the "up" position.

Step 2: Attach electrode pads

Quickly open and attach the self-adhesive monitor-defibrillator electrode pads directly to the skin of the victim's chest. In some models the pads and cables are preconnected to the AED. Other devices may require a connection between the cable and AED or between the cable and electrode pads.

Place the electrode pads on the upper-right sternal border (directly below the clavicle) and lateral to the left nipple, with the top margin of the pad a few inches (approximately 7 cm) below the axilla (Figure 3⊞). The correct position of the electrode pads is often illustrated on the pads themselves or another part of the AED. Stop CPR just before attaching the pads.



View larger version (89K):
[in this window]
[in a new window]

Figure 3. AED electrode pad placement on the victim.

If the victim is noticeably diaphoretic, dry the chest with a cloth or towel before attaching the electrode pads.

If the victim has a hairy chest, the adhesive electrode pads may stick to the hair on the chest, preventing effective contact with the skin of the chest and causing transthoracic impedance to be high,[147] leading to a *"check electrodes"* or *"check electrode pads"* message from the AED. This problem may be resolved by pressing firmly on each pad. If the error message continues, briskly remove the original pads (this will remove the hair under the pad) and apply a second set of electrodes. If the problem continues, shave the chest in the area of the pads before attaching a third set of electrodes. Alternatively, clip hair close to the chest or shave the chest hair before applying the second set of electrodes.

Step 3: Analyze the rhythm

Clear rescuers and bystanders from the victim and ensure that no one is touching the victim. To prevent artifactual errors, avoid all movement affecting the patient during rhythm analysis.[12] [52] In some devices the operator presses an ANALYZE button to initiate rhythm analysis. Other devices automatically begin analysis when the electrode pads are attached to the chest. Rhythm analysis requires from 5 to 15 seconds, depending on the brand of AED. If VF is present, the device will announce it through a displayed message, visual or auditory alarm, or voice-synthesized statement that a shock is indicated.

Step 4: Clear the victim and press the SHOCK button

Before pressing the SHOCK button, ensure that no one is touching the victim. Always loudly state a "Clear the patient" message, such as "I'm clear, you're clear, everybody clear" or simply "Clear." At the same time perform a visual check to ensure that no one is in contact with the patient. In most devices, the capacitors charge automatically if a treatable rhythm is detected. A tone, voice-synthesized message, or light indicates that charging has started. Delivery of a shock should occur only after the victim is "cleared."[148] The shock will produce a sudden contraction of the patient's musculature (like that seen with a conventional defibrillator).

After the first shock, do not restart CPR. Some AED models require that the rescuer immediately press the ANALYZE button. In other models the AED will automatically begin rhythm analysis after shock delivery. If VF persists, the AED will indicate it, and the *"shock indicated"* and *"charging"* sequence will repeat for a second and, if needed, third shock. The AED is programmed to reanalyze the victim's rhythm and provide a shock as quickly as possible after each shock, to a total of 3 shocks. The purpose of this cluster or series of 3 shocks is to identify and treat a shockable rhythm as quickly as possible. Therefore, during the series of 3 shocks the rescuer should not

interrupt or interfere with the rapid analysis and shock pattern. AEDs are programmed to pause after each group of 3 shocks to allow 1 minute for CPR. Therefore, after 3 shocks, check signs of circulation and prepare to provide chest compressions and continue compressions and ventilations for 1 minute (see below).

Outcomes and Actions After Attempted Defibrillation

"Shock Indicated" Message: Recurrent VF

If signs of circulation do not return after 3 shocks, rescuers without immediate ACLS backup should resume CPR for 60 seconds. After 60 seconds most devices will prompt a check for signs of circulation. If VF continues, deliver additional rounds of 3 "stacked" shocks after appropriate analysis. Provide sets of 3 stacked shocks followed by 1 minute of CPR until the AED gives a *"no shock indicated"* message or ACLS is available.

Do not check for signs of circulation between stacked shocks, ie, after shocks 1 and 2, 4 and 5, 7 and 8, etc. Checking for signs of circulation between shocks will delay rapid identification and shocking of persistent VF. The rapid sequence of shocks has the additional advantage of modestly reducing transthoracic impedance; this reduction will increase the effective energy delivered.

"No Shock Indicated" Message

Signs of Circulation Absent

When the AED gives a *"no shock indicated"* message, check for signs of circulation, and if there are no signs of circulation, resume CPR. Three *"no shock indicated"* messages suggest that there is a low probability that the rhythm can be successfully defibrillated. Therefore, rhythm analysis should be repeated only after 1- to 2-minute intervals of CPR. CPR should then be discontinued during rhythm analysis. No one should touch the victim during analysis.

Signs of Circulation Present

If signs of circulation are present, check breathing. If the victim is not breathing, provide rescue breathing at a rate of 10 to 12 breaths per minute. If the victim is breathing adequately, place him or her in a recovery position. The AED should always be left attached. If VF recurs, most AEDs will prompt the rescuer to check for signs of circulation (or *"check patient"*). The device will then charge automatically and advise the rescuer to deliver an additional shock.

AEDs in a Moving Ambulance

AEDs can be left in place during transport of the patient in a moving vehicle. But never push the ANALYZE button while the patient is in transport, because the movement of the ambulance can interfere with rhythm assessment and artifact can simulate VF.[12] [52] Some devices continuously analyze the patient. If rhythm analysis is necessary during transport or if the AED prompts the rescuer to check the patient or recommends a shock, stop the vehicle, then reanalyze.

One Rescuer With an AED

In some situations, 1 rescuer with immediate access to an AED may respond to a cardiac arrest. The rescuer should quickly activate the EMS system or the emergency medical response system on the premises (eg, airport security personnel or the hospital resuscitation team) to summon ACLS providers. The recommended BLS rescue sequence for adults is as follows:

1. Verify unresponsiveness.
2. Activate EMS (or the emergency medical response system) at the appropriate time.
3. Open the airway, check breathing.
4. If the victim is not breathing, provide initial ventilations (2 in the United States; up to 5 in other countries).
5. Check for signs of circulation. If there are no signs of circulation, attach the AED and follow the AED treatment algorithm.

Reasonable variations in this sequence are acceptable.

Integration of CPR and AED Use

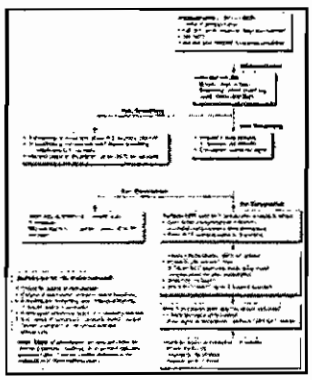
When arriving at the scene of a suspected cardiac arrest, rescuers must rapidly integrate CPR with use of the AED. In most out-of-hospital and in-hospital situations, rescuers will have the benefit of having 1 or more additional rescuers to assist with the multiple actions needed to resuscitate a victim of sudden cardiac death. In general, 3 actions must occur simultaneously at the scene of a cardiac arrest: (1) activation of the EMS system (or emergency medical response system, such as the hospital resuscitation team), (2) CPR, and (3) operation of the AED. When 2 or more rescuers are present, these functions can be initiated simultaneously. AED operators should be trained in scene leadership and team management to ensure timely and effective actions by multiple rescuers.[149]

Care After Successful Defibrillation

When signs of circulation and breathing return, place the patient in a recovery position and leave the AED attached. Continue to monitor the victim. Many AEDs monitor rhythm continuously and advise the operator if fibrillation recurs. It is important to check breathing and signs of circulation frequently.

AED programs should coordinate with the local EMS system to ensure seamless transfer of care after the arrival of BLS or ACLS healthcare providers.

The AED treatment algorithm (Figure 4⊞) summarizes the approach to the cardiac arrest victim while using an AED.



View larger version (51K):
[in this window]
[in a new window]

Figure 4. The AED treatment algorithm for ECC pending arrival of emergency medical personnel.

Device Maintenance and Quality Assurance

Appropriate maintenance of the AED is vital for proper operation.[150] [151] AED manufacturers provide specific recommendations for maintenance and readiness, which should be followed carefully. Checklists have been developed to help identify and prevent maintenance deficiencies and suggest methods of uniform device testing. Use of these checklists will increase user familiarity with the equipment.[152] Newer AED models require almost no maintenance. These devices conduct a self-check of operation and indicate "readiness to use." Nonetheless, operators trained to use an AED must still ensure that the AED is ready to use at any time.

Medical Direction

Legislation and regulations regarding EMS authority and the use of AEDs vary from country to country and even from one EMS system to another. In general, ambulance providers can perform some medical procedures in emergencies, but only with a physician's medical authorization.[153] The authorizing physician assumes medical direction and takes legal responsibility for the activity of BLS ambulance providers, including the use of AEDs. The authorizing physician for a PAD program oversees implementation of the program, issues standing orders for BLS personnel who operate AEDs, and monitors the system to ensure continuous quality improvement. In areas such as the United States, where AEDs are considered medical equipment, the rescuer must operate the AED under the authority of either the medical director or administrative codes of the state or commonwealth.[153]

Case-by-Case Review

Ideally the medical director or designated representative should review every event in which an AED is used (or could have been used). This means every incident in which CPR was performed or an AED used should undergo a medical review to establish whether the patient was treated according to professional standards and local standing orders. Medical reviews should also determine whether VF and other rhythms were treated appropriately with defibrillation and BLS. Other dimensions of performance that can be evaluated include command of the scene, safety, efficiency, speed, professionalism, ability to troubleshoot, completeness of patient care, and interactions with other professionals and bystanders.[65]

Quality Assurance

Organized collection and review of patient data can identify systemwide problems and allow assessment of each link in the Chain of Survival for the adult victim of sudden cardiac death. The Utstein Guidelines for reporting out-of-hospital cardiac arrest data present the recommended data to enable quality assurance monitoring for EMS and resuscitation programs (see also "Part 12: From Science to Survival").[154] This data collection constitutes quality assurance activities and as such should not expose clinical providers or organizations to increased risk of liability. Adult victims of witnessed cardiac arrest of presumed cardiac etiology caused by VF appear to be the best group on which to focus. A lower-than-expected hospital discharge rate in this group may be explained by long ambulance response times, delayed activation of EMS, infrequent witnessed arrests, rare bystander CPR, or slow on-scene times to defibrillation. Each of these problems can be addressed with a specific programwide effort. Continued systematic and uniform data collection will determine whether the new efforts succeed.

Emergency Cardiovascular Care Systems and the AED

The ECC Systems Concept

The term "Chain of Survival"[35] provides a useful metaphor for the elements of the ECC systems concept, summarizing the best approach to treatment of persons in sudden cardiac arrest.[155] The 4 links in the chain are early access to the EMS system, early CPR, early defibrillation, and early advanced cardiovascular life support. Epidemiological and clinical research have established that effective emergency cardiovascular care, whether in or out of hospital, requires that each of these links be strong, yet all are interconnected.[35 41 156 157] The effectiveness of early defibrillation and PAD programs also depends on a strong Chain of Survival in the community.

Early Defibrillation

Early defibrillation with an AED has established benefit. The principle of early defibrillation[53 54 55 56] suggests that the first person to arrive at the scene of a cardiac arrest should have a defibrillator.[52] This principle is now internationally accepted.[89] Healthcare providers with a duty to perform CPR should be trained, equipped, and authorized to attempt defibrillation[155] (Class IIa). Healthcare providers who may be first responders include BLS ambulance providers,[58 158 159 160] hospital-based healthcare providers,[30 31 32 33 34] and trained laypersons in PAD programs.[161 162]

Out-of-Hospital BLS Providers and AEDs

BLS emergency medical responders have different names in different countries, but BLS providers are the most common type of emergency responder in the world. These rescuers provide BLS but do not provide invasive interventions such as tracheal intubation, IV access, or IV medications. In Europe, BLS providers are often called "ambulancemen," "ambulance drivers," or "ambulance personnel." In the United States they are usually called "emergency medical technicians" (EMTs). In these Guidelines they are referred to as "BLS personnel," "BLS rescuers," "BLS providers," or "BLS ambulance personnel." Because BLS providers are typically the first emergency personnel to reach the scene of an out-of-hospital cardiac arrest, they can provide rapid defibrillation with an AED.

Early studies demonstrated a trend to superior survival rates with the use of AEDs in out-of-hospital cardiac arrest by BLS ambulance providers.[42 72] These studies also established many practical advantages of AED use by BLS ambulance providers, including easy, brief, and inexpensive initial training and continuing education, as well as evidence that AEDs can be operated more quickly than conventional defibrillators.[64 66 72] Subsequent studies have confirmed these findings, including AED accuracy,[163] shorter times to defibrillation,[69 70 164] faster application of subsequent ACLS interventions,[69] and comparable[165 166 167] or improved[12 71 168 169 170 171] survival. Taken together, these studies stand as powerful confirmation of the value of early defibrillation by out-of-hospital emergency personnel.[172]

The clinical benefits and practical superiority of the AED are well established. Early defibrillation is recommended as a standard of care for EMS[28 90 172] except in sparsely populated and remote settings, where the frequency of cardiac arrest is low and rescuer response times are excessively long.[173 174 175]

In-Hospital Use of AEDs

An approach pioneered by William Kaye and others[30 31 32 33 34] is now being used by many hospitals: general care nurses are being trained to use AEDs in resuscitation attempts. Hospital records were examined in several hospitals before AED placement to determine the average in-hospital time to first shock. This examination documented an

unexpected and disturbing performance problem in many medical facilities: long delays (5 to 10 minutes) before conventional in-hospital response teams first attempt defibrillation.[176] [177] Delayed defibrillation occurs infrequently in monitored beds and critical care units, but it occurs more often in unmonitored hospital beds and outpatient and diagnostic facilities, which hundreds of patients enter and leave each day. In such areas several minutes may elapse before centralized response teams arrive with a defibrillator, attach it, and deliver shocks.[176] Resuscitation committees may inappropriately place more emphasis on arrival of the resuscitation team than on delivery of the first defibrillatory shock.[30] As with out-of-hospital care, in-hospital practice must shift from a focus on CPR as the core of BLS care.[30] [178]

In recognition of the new AED technology, BLS has expanded to include CPR *and* defibrillation. An unacceptably high percentage of hospitals lack methods to assess resuscitation performance, underuse personnel in resuscitative efforts, and have not made significant attempts to improve the availability of early defibrillation by placing AEDs in non–critical care areas.[179] [180]

Several obstacles must be overcome before a quality early defibrillation program in which AEDs are used can be successfully implemented in the hospital. Nurses can be trained to use an AED and retain the skills needed for its safe and effective operation.[30] [181]

Strategic deployment of AEDs throughout hospital areas and authorization and training of first-responding personnel in their use is necessary to bring in-hospital use of AEDs up to the level of the out-of-hospital setting.[32] [33]

Documentation of in-hospital resuscitation events is often inaccurate and therefore unreliable in making quantitative assessments of such critical components as time to defibrillation and other interventions during resuscitation. This must be corrected before any data can be considered reliable enough to provide accurate assessment of resuscitation practices.

The absence of in-hospital early defibrillation programs is evident in the scarcity of data related to deployment of AEDs in hospital and its impact on patient outcome.[32] Some studies have documented the components of a successful program such as acquisition and retention of skills in AED use by nurses, including a recommendation that AED use be incorporated into BLS training of all hospital personnel expected to respond to a cardiac arrest.[30] Early defibrillation capability should be available in ambulatory care facilities as well as throughout hospital inpatient areas.

The International Liaison Committee on Resuscitation and the European Resuscitation Council have included in their guidelines formal recommendations for establishing in-hospital early defibrillation programs.[89] [90] [182]

One regulatory organization is attempting to improve systemwide response to resuscitation. In the United States, the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) altered its standards for individual in-hospital resuscitation capabilities by evaluating the following characteristics[183] :

1. Appropriate policies, procedures, processes, or protocols for provision of resuscitation services
2. Appropriate equipment placed strategically throughout the hospital close to areas where patients are likely to need resuscitation services
3. Ongoing review of outcomes related to resuscitation in the aggregate to identify opportunities for improvement of resuscitative efforts
4. Appropriate staff trained and competent to recognize the need for and use of designated equipment in

resuscitative efforts

5. Appropriate data collection related to the process and outcomes of resuscitation, particularly the ability to track trends and changes over several years

The AHA has established the National Registry of Cardiopulmonary Resuscitation to assist participating hospitals with systematic data collection of resuscitative efforts. The objectives of the registry are to develop a well-defined database documenting resuscitation performance of hospitals over time. This information can establish a hospital's baseline performance, target problem areas, and identify opportunities for improvement in data collection and the resuscitation program in general. The registry is also the largest repository of information on in-hospital cardiopulmonary arrest. Patterned after the highly respected British Resuscitation Study (Bresus), the registry is based on the Utstein Guidelines for collecting and reporting information from in-hospital resuscitation events.[184] Further guidelines for in-hospital resuscitation will emerge from future analyses of the large database provided by the registry. Participation in the registry will also allow hospitals to fully comply with the new JCAHO standards.

The capability to provide early defibrillation within patient-care areas is an obligation of the modern hospital. Early defibrillation is achieved by having defibrillators (including AEDs), ventilation equipment, and trained responders available throughout hospitals and affiliated outpatient facilities (Class IIa). The goal for all hospitals should be to have first responders provide *early* defibrillation to collapsed patients in VF in all areas of the hospital and ambulatory care facilities (Class I). The principle of early defibrillation should be "the earlier the better," and evaluation and intervention should occur when prolonged collapse-to-shock intervals are documented. Experts at the international Guidelines 2000 Conference endorsed a goal of 3±1 minutes for the collapse-to-shock interval for a high percentage of in-hospital arrests.

When medical quality assurance monitoring is instituted, it is important to note that recorded response-time intervals for in-hospital resuscitation events are notoriously inaccurate. The most common methods used to time events are unsynchronized wristwatches and wall and bedside clocks. This asynchrony must be corrected before documentation of times to defibrillation will be consistently reliable. In many countries AEDs could easily be equipped with a timing mechanism that is synchronized with governmental atomic clock satellites. The AED clock could then become the gold standard for timing resuscitation events. Accurate time-interval data must be obtained because it is the key to future high-quality research (Class IIa).

Public Access Defibrillation

The concept of early defibrillation with AEDs was originally developed and explored by Douglas Chamberlain in Brighton, England, where AEDs were placed in train stations and commercial aircraft, and by Mickey Eisenberg in King County, Washington, who placed AEDs with families of high-risk patients. To develop strategies to implement programs of *early* defibrillation in the community, the AHA Task Force on Early Defibrillation hosted 2 conferences (in 1994 and 1997) on the subject of PAD.[27] [28]

The recommendations that emerged from those conferences included the recognition that AEDs are the most promising method for achieving rapid defibrillation and that AEDs and training in their use should be accessible to the community.[27] [28] Advisory statements from ILCOR (1997)[185] and the European Resuscitation Council (1998)[182] affirmed the importance of early defibrillation programs.

Placement of AEDs in selected locations for immediate use by trained laypersons may be the key intervention to significantly increase survival from out-of-hospital cardiac arrest. The demonstrated safety and effectiveness of the AED make it an ideal source of early defibrillation by trained laypersons.[52] [62] Conceptually the AED and rescuer

function as a sharp diagnostic and therapeutic probe searching for just 1 phenomenon—VF/pulseless (no circulation) VT—and providing a potentially lifesaving therapy over just a few seconds. AEDs are of no value for non-VF/pulseless VT arrest and provide no benefit after VF/pulseless VT has been terminated. Therefore, the rescuer must also be trained to open the airway and support ventilation and circulation with chest compressions as needed. For this reason, all persons who operate an AED still must be trained to recognize emergencies, including cardiac arrest, and to provide effective CPR.

PAD Rescuers

PAD implies expanded use of AEDs in the community to the broadest possible number of rescuers while maintaining safety and effectiveness.[27] [28] [186] Within the next few years an increasing range of laypersons and healthcare professionals will learn the combined skills of CPR and AED use. These diverse groups can be roughly categorized into 3 levels of PAD responders, although the number and type of such responders change daily.

Level 1: Nontraditional Responders

Nontraditional responders are persons other than healthcare personnel, such as police, firefighters, security personnel, sports marshals, ski patrol members, ferryboat crews, and flight attendants, whose job duties require them to respond to an emergency. Traditionally, however, they have not been asked or expected to take any action other than to perform basic CPR.

Level 2: Targeted Responders

Targeted, or worksite, responders, who may also be called "citizen responders," frequently participate in PAD programs. These responders are employees of companies, corporations, or public facilities with established PAD programs. Their location at the worksite (eg, central reception area staff) makes them a natural choice to be the primary responder with the AED. PAD programs can shorten the time to defibrillation and improve the chance of survival from sudden cardiac death in the workplace or community.

Level 3: Responders to Persons at High Risk

Family members and friends living with or visiting persons at high risk for cardiac emergencies are another potential category of responders. They often participate in early defibrillation programs and are taught CPR and use of an AED when a friend or loved one is at high risk for sudden cardiac death.

Deployment Strategies for PAD Programs

Before deploying AEDs, PAD program directors should determine whether the population in the geographic area covered by the program will be likely to benefit from it. Some PAD planners target locations with a large concentration of persons >50 years old, such as senior citizen centers.[187] Implementation of AED programs in places where >10 000 people gather has been recommended for consideration.[188] Ideally program planners should review communitywide cardiac arrest data, identify sites with the highest incidence of cardiac arrest, and target those locations for AED placement.

Location

Some data is available on the location and frequency of cardiac arrest events in metropolitan areas. In Seattle and King County, Washington, for example, the incidence of cardiac arrest is greatest at the international airport, then (in decreasing order of frequency) county correctional facilities, shopping malls, public sports venues, industrial sites, golf courses, shelters, ferries/train terminals, health clubs/gyms, and community/senior centers.[189] The site-specific incidence and need for specific distribution of AEDs within those sites is likely to vary with each community. To optimize the benefit of limited healthcare resources in each community, program planners must provide AEDs and make trained rescuers available in locations with the highest incidence of cardiac arrest.

Accordingly, the evidence supports establishment of PAD programs at sites in which

1. The frequency of cardiac arrest events is such that there is a reasonable probability of AED use (an estimated event rate of 1 sudden cardiac arrest per 1000 person-years).
2. An EMS call–to-shock time interval of <5 minutes cannot be reliably achieved with conventional EMS services.
3. An EMS call–to-shock time interval of <5 minutes can be reliably achieved (in >90% of cases) by training and equipping laypersons to function as first responders in the community EMS system, recognizing cardiac arrest, phoning 911 (or another appropriate emergency telephone number), initiating CPR, and attaching/operating an AED.

For level 1 responders, such as police, firefighters, security personnel, ski patrol members, ferryboat crews, and flight attendants, this is a Class IIa recommendation. For level 2 targeted responders, such as citizens at worksites or in public places, this is a Class Indeterminate recommendation at this time. It is hoped that data from a prospective, randomized multicenter trial regarding PAD will justify a change in this class of recommendation. For level 3 responders (family and friends of persons at high risk), the above recommendation is a Class Indeterminate recommendation.

Coordination With EMS Systems

PAD program planners should attempt to coordinate PAD programs with the local EMS system. This may include but is not limited to medical direction, assistance in planning AED deployment and AED protocols, training, continuous quality improvement, monitoring, and review of AED events. Integration with the local EMS dispatch system is important because many dispatch systems use phone-directed protocols to assist rescuers in the use of the AED if needed and will notify EMS en route that an AED is being used at the scene.[190] [191] The American College of Emergency Physicians has issued a policy statement endorsing coordination with EMS systems to ensure medical direction of AED programs, including those in which bystanders use AEDs.[192] Many other international organizations have issued similar recommendations.[89] [90] [182]

Elements of Successful PAD Programs

Objective data on details of successful PAD programs is lacking. Nonetheless, rational conjecture plus data extrapolated from other sources have identified many elements as keys to successful PAD programs. There must be a strong Chain of Survival within the community. Innovative methods of providing effective, quality training to laypersons in the use of AEDs is important.[149] Incorporating EMS dispatch into PAD programs allows dispatchers to direct a caller to the nearest AED location and provide instruction by telephone if needed. It also allows the EMS personnel to learn to operate specific types of AEDs in advance, enabling seamless patient care.[190] [191]

Careful planning, training, communication with the EMS system, and continuous quality improvement are vital to a successful PAD program. The program director should carefully select AED users who are motivated, available during the expected response period, and capable of performing their duties. A specific response plan should be implemented within each site, targeting a collapse-to-defibrillation time ≤4 to 5 minutes (eg, AEDs located throughout the facility so that the walk to retrieve an AED is no more than 1.5 minutes). Frequent unannounced practice drills and evaluations of performance and response time are recommended.

The most frequent cause of AED malfunction is lack of maintenance.[150] [151] Maintaining the device according to the manufacturer's specifications is essential.[152] Regular system evaluations should be conducted.

PAD program directors must also attend to the emotional needs of lay rescuers, who are not accustomed to providing lifesaving care in an emergency.[193] Case-by-case review with laypersons and critical incident stress debriefing provide important support for PAD program participants.[193] Medical direction includes responsibility for quality of training and medical care provided by PAD lay responders. PAD programs must comply with local or regional regulation and legislation.

Effectiveness of PAD Programs

Several studies have demonstrated the cost-effectiveness of AED use by BLS ambulance providers and PAD programs compared with other medical interventions.[53] [187] [194] [195] This data establishes the substantial survival benefits and attractive cost-effectiveness of a well-designed and well-implemented PAD program.

The National Heart, Lung, and Blood Institute (NHLBI), in partnership with the AHA and industry, has embarked on a multisite, controlled, prospective clinical trial to determine the efficacy and cost-effectiveness of placing AEDs in a variety of public settings. Such definitive scientific evidence is essential for decision making related to the potentially huge PAD initiative. Final results from the PAD trial are not expected for at least 3 years. The results of a large, controlled, randomized, multicenter, prospective clinical trial will eventually be needed for PAD to be considered a Class I recommendation.

Education and Training

Skills Maintenance

Survey results and experience in rural communities have demonstrated that emergency responders may go several years without treating a patient in cardiac arrest.[173] [174] [175] Therefore, every program director must determine how to ensure correct performance of BLS and automated external defibrillation. Principles of adult education suggest that frequent practice of psychomotor skills such as use of an AED in a simulated cardiac arrest offers the best opportunity for skills maintenance.

Frequency of Practice

The frequency and content of these practice sessions have been established by several successful programs.[6] [51] [173] At present many programs provide practice drills every 3 to 6 months and have found this interval satisfactory. Many EMS personnel and systems drill as often as once a month. The most successful long-term skills maintenance occurs when individual rescuers perform a quick check of the equipment frequently and regularly. This check includes a visual inspection of the defibrillator components and controls and a mental review of the steps to take and controls to operate during a cardiac arrest.

The AHA ECC Committee and international expert panels encourage routine skills review and practice sessions at least every 6 months.

Future of PAD

The future of PAD is likely to include further improvements in device design, making AEDs easier to use, lighter, and less expensive. Public access to AEDs is increasing, and implementation of AEDs in a diversity of settings is growing as well. Automated external defibrillation will continue to increase survival from VF if AED programs are well implemented and AEDs are used within the first few minutes after cardiac arrest.

References

▲ Top

1. Atkins JM. Emergency medical service systems in acute cardiac care: state

of the art. *Circulation.* 1986;74(suppl IV):IV-4–IV-8.

2. Cummins RO, Eisenberg MS, Stults KR. Automatic external defibrillators: clinical issues for cardiology. *Circulation.* 1986;73:381–385.[Medline]

3. White RD. EMT-defibrillation: time for controlled implementation of effective treatment. *AHA Emergency Cardiac Care Newsletter.* 1986;8:1–3.

4. Atkins JM, Murphy D, Allison EJ, Graves JR. Toward earlier defibrillation: first responders are next. *J Emerg Med Serv.*. 1986;11:50–57.

5. Eisenberg MS, Cummins RO. Defibrillation performed by the emergency medical technician. *Circulation.* 1986;74(suppl IV):IV-9–IV-12.

6. Cummins RO. EMT-defibrillation: national guidelines for implementation. *Am J Emerg Med.* 1987;5:254–257.[Medline]

7. Ruskin JN. Automatic external defibrillators and sudden cardiac death[editorial]. *N Engl J Med.*. 1988;319:713–715.[Medline]

8. Cummins RO, Eisenberg MS. EMT-defibrillation: a proven concept. *American Heart Association Emergency Cardiac Care National Faculty Newsletter.* 1984;1:1–3.

9. Cummins RO, Eisenberg MS, Moore JE, Hearne TR, Andresen E, Wendt R, Litwin PE, Graves JR, Hallstrom AP, Pierce J. Automatic external defibrillators: clinical, training, psychological, and public health issues. *Ann Emerg Med.* 1985;14:755–760.[Medline]

10. Newman MM. National EMT-D study. *J Emerg Med Serv.* 1986;11:70–72.

11. Newman MM. The survival advantage: early defibrillation programs in the fire service. *J Emerg Med Serv.* 1987;12:40–46.

12. Sedgwick ML, Watson J, Dalziel K, Carrington DJ, Cobbe SM. Efficacy of out of hospital defibrillation by ambulance technicians using automated external defibrillators: the Heartstart Scotland Project. *Resuscitation.* 1992;24:73–87.[Medline]

13. Mols P, Beaucarne E, Bruyninx J, Labruyere JP, De Myttenaere L, Naeije N, Watteeuw G, Verset D, Flamand JP. Early defibrillation by EMTs: the Brussels experience. *Resuscitation.* 1994;27:129–136.[Medline]

14. Stapczynski JS, Svenson JE, Stone CK. Population density, automated external defibrillator use, and survival in rural cardiac arrest. *Acad Emerg Med.* 1997;4:552–558.[Abstract]

15. Cummins RO, Eisenberg MS, Bergner L, Hallstrom A, Hearne T, Murray JA. Automatic external defibrillation: evaluations of its role in the home and in emergency medical services. *Ann Emerg Med.* 1984;13:798–801.[Medline]

16. Jacobs L. Medical, legal, and social implications of automatic external defibrillators[editorial]. *Ann Emerg Med.*. 1986;15:863–864.

17. White RD, Vukov LF, Bugliosi TF. Early defibrillation by police: initial experience with measurement of critical time intervals and patient outcome. *Ann Emerg Med.* 1994;23:1009–1013.[Medline]

18. White RD, Asplin BR, Bugliosi TF, Hankins DG. High discharge survival rate after out-of-hospital ventricular fibrillation with rapid defibrillation by police and paramedics. *Ann Emerg Med.* 1996;28:480–485.[Medline]

19. White RD, Hankins DG, Bugliosi TF. Seven years' experience with early defibrillation by police and paramedics in an emergency medical services system. *Resuscitation.* 1998;39:145–151.[Medline]

20. Davis EA, Mosesso VN Jr. Performance of police first responders in utilizing automated external defibrillation on victims of sudden cardiac arrest. *Prehosp Emerg Care.* 1998;2:101–107.[Medline]

21. Mosesso VN Jr, Davis EA, Auble TE, Paris PM, Yealy DM. Use of automated external defibrillators by police officers for treatment of out-of-hospital cardiac arrest. *Ann Emerg Med.* 1998;32:200–207.[Medline]

22. Davis EA, McCrorry J, Mosesso VN Jr. Institution of a police automated external defibrillation program: concepts and practice. *Prehosp Emerg Care.* 1999;3:60–65.[Medline]

23. O'Rourke MF, Donaldson E, Geddes JS. An airline cardiac arrest program [see comments]. *Circulation..* 1997;96:2849–2853.[Abstract/Full Text]

24. Wolbrink A, Borrillo D. Airline use of automatic external defibrillators: shocking developments [see comments]. *Aviat Space Environ Med..* 1999;70:87–88.[Medline]

25. Eisenberg MS, Horwood BT, Cummins RO, Reynolds-Haertle R, Hearne TR. Cardiac arrest and resuscitation: a tale of 29 cities. *Ann Emerg Med.* 1990;19:179--186.[Medline]

26. Gundry JW, Comess KA, DeRook FA, Jorgenson D, Bardy GH. Comparison of naive sixth-grade children with trained professionals in the use of an automated external defibrillator. *Circulation.* 1999;100:1703–1707. [Abstract/Full Text]

27. Nichol G, Hallstrom AP, Kerber R, Moss AJ, Ornato JP, Palmer D, Riegel B, Smith S Jr, Weisfeldt ML. American Heart Association report on the Second Public Access Defibrillation Conference, April 17–19, 1997. *Circulation.* 1998;97:1309–1314.[Full Text]

28. Weisfeldt ML, Kerber RE, McGoldrick RP, Moss AJ, Nichol G, Ornato JP, Palmer DG, Riegel B, Smith SC Jr. Public access defibrillation: a statement for healthcare professionals from the American Heart Association Task Force on Automatic External Defibrillation. *Circulation.* 1995;92:2763.[Full Text]

29. Wassertheil J, Keane G, Fisher N, Leditschke GF. Cardiac arrest outcomes at the Melbourne Cricket Ground and Shrine of Remembrance, using a tiered response strategy: a forerunner to public access defibrillation. *Resuscitation..* 2000;44:97–104.[Medline]

30. Kaye W, Mancini ME, Giuliano KK, Richards N, Nagid DM, Marler CA, Sawyer-Silva S. Strengthening the in-hospital chain of survival with rapid defibrillation by first responders using automated external defibrillators: training and retention issues. *Ann Emerg Med.* 1995;25:163–168.[Medline]

31. Kaye W, Mancini ME, Richards N. Organizing and implementing a hospital-wide first-responder automated external defibrillation program: strengthening the in-hospital chain of survival. *Resuscitation.* 1995;30:151–156. [Medline]

32. Destro A, Marzaloni M, Sermasi S, Rossi F. Automatic external defibrillators in the hospital as well? *Resuscitation.* 1996;31:39–43; discussion 43–44.[Medline]

33. Kaye W, Mancini ME. Improving outcome from cardiac arrest in the hospital with a reorganized and strengthened chain of survival: an American view [editorial]. *Resuscitation..* 1996;31:181–186.[Medline]

34. Mancini ME, Kaye W. In-hospital first-responder automated external defibrillation: what critical care practitioners need to know. *Am J Crit Care.* 1998;7:314–319.[Medline]

35. Cummins RO, Ornato JP, Thies WH, Pepe PE. Improving survival from sudden cardiac arrest: the "chain of survival" concept. A statement for health professionals from the Advanced Cardiac Life Support Subcommittee and the Emergency Cardiac Care Committee, American Heart Association. *Circulation.* 1991;83:1832–1847.[Medline]

36. McIntyre KM. Cardiopulmonary resuscitation and the ultimate coronary care unit[editorial] *JAMA.*. 1980;244:510–511.[Medline]

37. Eisenberg MS, Cummins RO, Damon S, Larsen MP, Hearne TR. Survival rates from out-of-hospital cardiac arrest: recommendations for uniform definitions and data to report. *Ann Emerg Med.* 1990;19:1249–1259.[Medline]

38. Eisenberg MS, Copass MK, Hallstrom A, Cobb LA, Bergner L. Management of out-of-hospital cardiac arrest: failure of basic emergency medical technician services. *JAMA.* 1980;243:1049–1051.[Medline]

39. Eisenberg MS, Hallstrom AP, Copass MK, Bergner L, Short F, Pierce J. Treatment of ventricular fibrillation: emergency medical technician defibrillation and paramedic services. *JAMA.* 1984;251:1723–1726.[Medline]

40. Weaver WD, Copass MK, Bufi D, Ray R, Hallstrom AP, Cobb LA. Improved neurologic recovery and survival after early defibrillation. *Circulation.* 1984;69:943–948.[Abstract]

41. Larsen MP, Eisenberg MS, Cummins RO, Hallstrom AP. Predicting survival from out-of-hospital cardiac arrest: a graphic model. *Ann Emerg Med.* 1993;22:1652–1658.[Medline]

42. Eisenberg MS, Bergner L. Paramedic programs and cardiac mortality: description of a controlled experiment. *Public Health Rep.*. 1979;94:80–84.[Medline]

43. Fletcher GF, Cantwell JD. Ventricular fibrillation in a medically supervised cardiac exercise program: clinical, angiographic, and surgical correlations. *JAMA.* 1977;238:2627–2629.[Medline]

44. Haskell WL. Cardiovascular complications during exercise training of cardiac patients. *Circulation.* 1978;57:920–924.[Abstract]

45. Hossack KF, Hartwig R. Cardiac arrest associated with supervised cardiac rehabilitation. *J Cardiac Rehab.* 1982;2:402–408.

46. Van Camp SP, Peterson RA. Cardiovascular complications of outpatient cardiac rehabilitation programs. *JAMA.* 1986;256:1160–1163.[Medline]

47. Eisenberg MS, Copass MK, Hallstrom AP, Blake B, Bergner L, Short FA, Cobb LA. Treatment of out-of-hospital cardiac arrests with rapid defibrillation by emergency medical technicians. *N Engl J Med.* 1980;302:1379–1383.[Medline]

48. Stults KR, Brown DD, Schug VL, Bean JA. Prehospital defibrillation performed by emergency medical technicians in rural communities. *N Engl J Med.* 1984;310:219–223.[Medline]

49. Vukov LF, White RD, Bachman JW, O'Brien PC. New perspectives on rural EMT defibrillation. *Ann Emerg Med.* 1988;17:318–321.[Medline]

50. Bachman JW, McDonald GS, O'Brien PC. A study of out-of-hospital cardiac arrests in northeastern Minnesota. *JAMA.* 1986;256:477–483.[Medline]

51. Olson DW, LaRochelle J, Fark D, Aprahamian C, Aufderheide TP, Mateer JR, Hargarten KM, Stueven HA. EMT-defibrillation: the Wisconsin experience [see comments]. *Ann Emerg Med.*. 1989;18:806–811.[Medline]

52. Cummins RO. From concept to standard-of-care? Review of the clinical experience with automated external defibrillators. *Ann Emerg Med.* 1989;18:1269–1275.[Medline]

53. Valenzuela TD, Roe DJ, Cretin S, Spaite DW, Larsen MP. Estimating effectiveness of cardiac arrest interventions: a logistic regression survival model. *Circulation.* 1997;96:3308–3313.[Abstract/Full Text]

54. Holmberg M, Holmberg S, Herlitz J, Gardelov B. Survival after cardiac arrest outside hospital in Sweden: Swedish Cardiac Arrest Registry. *Resuscitation.* 1998;36:29–36.[Medline]

55. Valenzuela TD, Spaite DW, Meislin HW, Clark LL, Wright AL, Ewy GA. Case and survival definitions in out-of-hospital cardiac arrest: effect on survival rate calculation [see comments]. *JAMA.*. 1992;267:272–274.[Medline]

56. Valenzuela TD, Spaite DW, Meislin HW, Clark LL, Wright AL, Ewy GA. Emergency vehicle intervals versus collapse-to-CPR and collapse-to-defibrillation intervals: monitoring emergency medical services system performance in sudden cardiac arrest. *Ann Emerg Med.* 1993;22:1678–1683.[Medline]

57. Cobb LA, Fahrenbruch CE, Walsh TR, Copass MK, Olsufka M, Breskin M, Hallstrom AP. Influence of cardiopulmonary resuscitation prior to defibrillation in patients with out-of-hospital ventricular fibrillation [see comments]. *JAMA.*. 1999;281:1182–1188.[Medline]

58. Herlitz J, Bahr J, Fischer M, Kuisma M, Lexow K, Thorgeirsson G. Resuscitation in Europe. a tale of five European regions. *Resuscitation.* 1999;41:121–131.[Medline]

59. Diack AW, Welborn WS, Rullman RG, Walter CW, Wayne MA. An automatic cardiac resuscitator for emergency treatment of cardiac arrest. *Med Instrum.* 1979;13:78–83.[Medline]

60. Jaggarao NS, Heber M, Grainger R, Vincent R, Chamberlain DA, Aronson AL. Use of an automated external defibrillator-pacemaker by ambulance staff. *Lancet.* 1982;2:73–75.[Medline]

61. Rozkovec A, Crossley J, Walesby R, Fox KM, Maseri A. Safety and effectiveness of a portable external automatic defibrillator-pacemaker. *Clin Cardiol.* 1983;6:527–533.[Medline]

62. Cummins RO, Eisenberg M, Bergner L, Murray JA. Sensitivity, accuracy, and safety of an automatic external defibrillator. *Lancet.* 1984;2:318–320.[Medline]

63. Cummins RO, Eisenberg MS, Litwin PE, Graves JR, Hearne TR, Hallstrom AP. Automatic external defibrillators used by emergency medical technicians: a controlled clinical trial. *JAMA.* 1987;257:1605–1610. [Medline]

64. Stults KR, Brown DD, Kerber RE. Efficacy of an automated external defibrillator in the management of out-of-hospital cardiac arrest: validation of the diagnostic algorithm and initial clinical experience in a rural environment. *Circulation.* 1986;73:701–709.[Abstract]

65. Cummins RO, Austin D Jr, Graves JR, Hambly C. An innovative approach to medical control: semiautomatic defibrillators with solid-state memory modules for recording cardiac arrest events. *Ann Emerg Med.* 1988;17:818–824.[Medline]

66. Dickey W, Dalzell GW, Anderson JM, Adgey AA. The accuracy of decision-making of a semi-automatic defibrillator during cardiac arrest. *Eur Heart J.* 1992;13:608–615.[Medline]

67. Jakobsson J, Nyquist O, Rehnqvist N. Effects of early defibrillation of out-of-hospital cardiac arrest patients by ambulance personnel. *Eur Heart J.* 1987;8:1189–1194.[Medline]

68. Gray AJ, Redmond AD, Martin MA. Use of the automatic external defibrillator-pacemaker by ambulance personnel: the Stockport experience. *Br Med J.* 1987;294:1133–1135.

69. Hoekstra JW, Banks JR, Martin DR, Cummins RO, Pepe PE, Stueven HA, Jastremski M, Gonzalez E, Brown CG, the Multicenter High Dose Epinephrine Study Group. Effect of first-responder automated defibrillation on time to therapeutic interventions during out-of-hospital cardiac arrest. [see comments]. *Ann Emerg Med.*. 1993;22:1247–1253.[Medline]

70. Shuster M, Keller JL. Effect of fire department first-responder automated defibrillation. *Ann Emerg Med.* 1993;22:721–727.[Medline]

71. Auble TE, Menegazzi JJ, Paris PM. Effect of out-of-hospital defibrillation by basic life support providers on cardiac arrest mortality: a metaanalysis [see comments]. *Ann Emerg Med.*. 1995;25:642–648.[Medline]

72. Weaver WD, Hill D, Fahrenbruch CE, Copass MK, Martin JS, Cobb LA, Hallstrom AP. Use of the automatic external defibrillator in the management of out-of-hospital cardiac arrest. *N Engl J Med.* 1988;319:661–666. [Medline]

73. Kroll MW, Brewer JE. Automated external defibrillators: design considerations. *New Horiz.* 1997;5:128–136. [Medline]

74. Niskanen RA. Automated external defibrillators: experiences with their use and options for their further development. *New Horiz.* 1997;5:137–144.[Medline]

75. Sunde K, Eftestol T, Askenberg C, Steen PA. Quality assessment of defibrillation and advanced life support using data from the medical control module of the defibrillator. *Resuscitation.* 1999;41:237–247.[Medline]

76. Weaver WD, Copass MK, Hill DL, Fahrenbruch C, Hallstrom AP, Cobb LA. Cardiac arrest treated with a new automatic external defibrillator by out-of-hospital first responders. *Am J Cardiol.* 1986;57:1017–1021.[Medline]

77. Weaver WD, Hill DL, Fahrenbruch C, Cobb LA, Copass MK, Hallstrom AP, Martin J. Automatic external defibrillators: importance of field testing to evaluate performance. *J Am Coll Cardiol.* 1987;10:1259–1264. [Medline]

78. Moore JE, Eisenberg MS, Andresen E, Cummins RO, Hallstrom A, Litwin P. Home placement of automatic external defibrillators among survivors of ventricular fibrillation. *Ann Emerg Med.* 1986;15:811–812.[Medline]

79. Moore JE, Eisenberg MS, Cummins RO, Hallstrom A, Litwin P, Carter W. Lay person use of automatic external defibrillation. *Ann Emerg Med.* 1987;16:669–672.[Medline]

80. Eisenberg MS, Moore J, Cummins RO, Andresen E, Litwin PE, Hallstrom AP, Hearne T. Use of the automatic external defibrillator in homes of survivors of out-of-hospital ventricular fibrillation. *Am J Cardiol.* 1989;63:443–446.[Medline]

81. Cummins RO, Schubach JA, Litwin PE, Hearne TR. Training lay persons to use automatic external defibrillators: success of initial training and one-year retention of skills. *Am J Emerg Med.* 1989;7:143–149. [Medline]

82. Gliner BE, White RD. Electrocardiographic evaluation of defibrillation shocks delivered to out-of-hospital sudden cardiac arrest patients. *Resuscitation.* 1999;41:133–144.[Medline]

83. Karch SB, Graff J, Young S, Ho CH. Response times and outcomes for cardiac arrests in Las Vegas casinos. *Am J Emerg Med.* 1998;16:249–253.[Medline]

84. Page RL, Hamdan MH, McKenas DK. Defibrillation aboard a commercial aircraft. *Circulation.*. 1998;97:1429–1430.[Full Text]

85. Kellermann AL, Hackman BB, Somes G, Kreth TK, Nail L, Dobyns P. Impact of first-responder defibrillation in an urban emergency medical services system [see comments]. *JAMA.*. 1993;270:1708–1713.[Medline]

86. Joyce SM, Davidson LW, Manning KW, Wolsey B, Topham R. Outcomes of sudden cardiac arrest treated with defibrillation by emergency medical technicians (EMT-Ds) or paramedics in a two-tiered urban EMS system. *Prehosp Emerg Care.* 1998;2:13–17.[Medline]

87. Sweeney TA, Runge JW, Gibbs MA, Raymond JM, Schafermeyer RW, Norton HJ, Boyle-Whitesel MJ. EMT defibrillation does not increase survival from sudden cardiac death in a two-tiered urban-suburban EMS system. *Ann Emerg Med.* 1998;31:234–240.[Medline]

88. Liu JCZ. Evaluation of the use of automatic external defibrillation in out-of-hospital cardiac arrest in Hong Kong. *Resuscitation.* 1999;41:113–119.[Medline]

89. Bossaert L, Handley A, Marsden A, Arntz R, Chamberlain D, Ekstrom L, Evans T, Monsieurs K, Robertson C, Steen P. European Resuscitation Council guidelines for the use of automated external defibrillators by EMS providers and first responders: a statement from the Early Defibrillation Task Force, with contributions from the Working Groups on Basic and Advanced Life Support, and approved by the Executive Committee. *Resuscitation.* 1998;37:91–94.[Medline]

90. Kloeck W, Cummins RO, Chamberlain D, Bossaert L, Callanan V, Carli P, Christenson J, Connolly B, Ornato JP, Sanders A, Steen P. Early defibrillation: an advisory statement from the Advanced Life Support Working Group of the International Liaison Committee on Resuscitation. *Circulation.* 1997;95:2183–2184.[Full Text]

91. McDowell R, Krohmer J, Spaite DW, Benson N, Pons P, American College of Emergency Physicians. Guidelines for implementation of early defibrillation/automated external defibrillator programs. *Ann Emerg Med.* 1993;22:740–741.[Medline]

91. Gurvich NL, Makarychev VA. Defibrillation of the heart with biphasic electrical impulses. *Kardiologiya.* 1967;7:109–112.

92. Jones JL, Jones RE, Balasky G. Microlesion formation in myocardial cells by high-intensity electric field stimulation. *Am J Physiol.* 1987;253:H480–H486.[Medline]

93. Walcott GP, Walcott KT, Knisley SB, Zhou X, Ideker RE. Mechanisms of defibrillation for monophasic and biphasic waveforms. *Pacing Clin Electrophysiol.* 1994;17:478–498.[Medline]

94. Bardy GH, Ivey TD, Allen MD, Johnson G, Mehra R, Greene HL. A prospective randomized evaluation of biphasic versus monophasic waveform pulses on defibrillation efficacy in humans. *J Am Coll Cardiol.* 1989;14:728–733.[Medline]

95. Kwaku KF, Dillon SM. Shock-induced depolarization of refractory myocardium prevents wave-front propagation in defibrillation. *Circ Res.* 1996;79:957–973.[Abstract/Full Text]

96. Jones JL, Tovar OH. The mechanism of defibrillation and cardioversion. *Proc IEEE.* 1996;84:392–403.

97. Jones JL, Tovar OH. Threshold reduction with biphasic defibrillator waveforms: role of charge balance. *J Electrocardiol.* 1995;28(suppl):25–30.

98. Tovar OH, Jones JL. Biphasic defibrillation waveforms reduce shock-induced response duration dispersion

between low and high shock intensities. *Circ Res.* 1995;77:430–438.[Abstract/Full Text]

99. Jones JL, Swartz JF, Jones RE, Fletcher R. Increasing fibrillation duration enhances relative asymmetrical biphasic versus monophasic defibrillator waveform efficacy. *Circ Res.* 1990;67:376–384.[Abstract]

100. Winkle A, Mead R, Ruder M, Gaudiani V, Buch W, Pless B, Sweeney M, Schmidt P. Improved low energy defibrillation efficacy in man with the use of a biphasic truncated exponential waveform. *Am Heart J.* 1989;117:122–127.[Medline]

101. Sweeney RJ, Gill RM, Steinberg MI, Reid PR. Ventricular refractory period extension caused by defibrillation shocks [see comments]. *Circulation..* 1990;82:965–972.[Abstract]

102. Kerber R, Becker L, Bourland J, Cummins R, Hallstrom A, Michos M, Nichol G, Ornato J, Thies W, White R, Zuckerman B. Automatic external defibrillators for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis, algorithm performance, incorporating new waveforms, and enhancing safety. *Circulation.* 1997;95:1677–1682.[Full Text]

103. Stults KR, Cummins RO. Fully automatic versus shock advisory defibrillators: what are the issues? *J Emerg Med Services.* 1987;12:71–73.

104. Stults KR, Brown DD, Cooley F, Kerber RE. Self-adhesive monitor/defibrillation pads improve prehospital defibrillation success. *Ann Emerg Med.* 1987;16:872–877.[Medline]

105. Cummins RO, Stults KR, Haggar B, Kerber RE, Schaeffer S, Brown DD. A new rhythm library for testing automatic external defibrillators: performance of three devices. *J Am Coll Cardiol.* 1988;11:597–602.[Medline]

106. Monsieurs KG, Conraads VM, Goethals MP, Snoeck JP, Bossaert LL. Semiautomatic external defibrillation and implanted cardiac pacemakers: understanding the interactions during resuscitation. *Resuscitation..* 1995;30:127–131.[Medline]

107. Kerber RE, Martins JB, Kienzle MG, Constantin L, Olshansky B, Hopson R, Charbonnier F. Energy, current, and success in defibrillation and cardioversion: clinical studies using an automated impedance-based method of energy adjustment. *Circulation.* 1988;77:1038–1046.[Abstract]

108. Geddes LA, Tacker WA, Rosborough JP, Moore AG, Cabler PS. Electrical dose for ventricular defibrillation of large and small animals using precordial electrodes. *J Clin Invest.* 1974;53:310–319.[Medline]

109. Gutgesell HP, Tacker WA, Geddes LA, Davis S, Lie JT, McNamara DG. Energy dose for ventricular defibrillation of children. *Pediatrics.* 1976;58:898–901.[Abstract]

110. Dahl C, Ewy G, Warner E, et al. Myocardial necrosis from direct current countershock. *Circulation.* 1974;50:956.[Medline]

111. Pantridge JF, Adgey AA, Webb SW, Anderson J. Electrical requirements for ventricular defibrillation. *BMJ.* 1975;2:313–315.

112. Weaver WD, Cobb LA, Copass MK, Hallstrom AP. Ventricular defibrillation: a comparative trial using 175-J and 320-J shocks. *N Engl J Med.* 1982;307:1101–1106.[Medline]

113. Gliner B, Lyster T, Dillion S, Bardy G. Transthoracic defibrillation of swine with monophasic and biphasic waveforms. *Circulation.* 1995;92:1634–1643.[Abstract/Full Text]

114. Bardy GH, Gliner BE, Kudenchuk PJ, Poole JE, Dolack GL, Jones GK, Anderson J, Troutman C, Johnson G.

Truncated biphasic pulses for transthoracic defibrillation. *Circulation.* 1995;91:1768–1774.[Abstract/Full Text]

115. Bardy GH, Marchlinski FE, Sharma AD, Worley SJ, Luceri RM, Yee R, Halperin BD, Fellows CL, Ahern TS, Chilson DA, Packer DL, Wilber DJ, Mattioni TA, Reddy R, Kronmal RA, Lazzara R, Transthoracic Investigators. Multicenter comparison of truncated biphasic shocks and standard damped sine wave monophasic shocks for transthoracic ventricular defibrillation. *Circulation.* 1996;94:2507–2514.[Medline]

116. Reddy RK, Gleva MJ, Gliner BE, Dolack GL, Kudenchuk PJ, Poole JE, Bardy GH. Biphasic transthoracic defibrillation causes fewer ECG ST-segment changes after shock. *Ann Emerg Med.* 1997;30:127–134.[Medline]

117. Greene HL, DiMarco JP, Kudenchuk PJ, Scheinman MM, Tang AS, Reiter MJ, Echt DS, Chapman PD, Jazayeri MR, Chapman FW, et al, for the Biphasic Waveform Defibrillation Investigators. Comparison of monophasic and biphasic defibrillating pulse waveforms for transthoracic cardioversion. *Am J Cardiol.* 1995;75:1135–1139.[Medline]

118. White RD. Early out-of-hospital experience with an impedance-compensating low- energy biphasic waveform automatic external defibrillator. *J Intervent Card Electrophysiol.*. 1997;1:203–208; discussion 209–210.

119. Poole JE, White RD, Kanz KG, Hengstenberg F, Jarrard GT, Robinson JC, Santana V, McKenas DK, Rich N, Rosas S, Merritt S, Magnotto L, Gallagher JV III, Gliner BE, Jorgenson DB, Morgan CB, Dillon SM, Kronmal RA, Bardy GH, LIFE Investigators. Low-energy impedance-compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out-of-hospital cardiac arrest. *J Cardiovasc Electrophysiol.* 1997;8:1373–1385. [Medline]

120. Cummins RO, Hazinski MF, Kerber RE, Kudenchuk P, Becker L, Nichol G, Malanga B, Aufderheide TP, Stapleton EM, Kern K, Ornato JP, Sanders A, Valenzuela T, Eisenberg M. Low-energy biphasic waveform defibrillation: evidence-based review applied to emergency cardiovascular care guidelines: a statement for healthcare professionals from the American Heart Association Committee on Emergency Cardiovascular Care and the Subcommittees on Basic Life Support, Advanced Cardiac Life Support, and Pediatric Resuscitation. *Circulation.* 1998;97:1654–1667.[Full Text]

121. Gliner BE, Jorgenson DB, Poole JE, White RD, Kanz KG, Lyster TD, Leyde KW, Powers DJ, Morgan CB, Kronmal RA, Bardy GH, LIFE Investigators. Treatment of out-of-hospital cardiac arrest with a low-energy impedance-compensating biphasic waveform automatic external defibrillator. *Biomed Instrum Technol.* 1998;32:631–644.[Medline]

122. Mittal S, Ayati S, Stein KM, Knight BP, Morady F, Schwartzman D, Cavlovich D, Platia EV, Calkins H, Tchou PJ, Miller JM, Wharton JM, Sung RJ, Slotwiner DJ, Markowitz SM, Lerman BB, ZOLL Investigators. Comparison of a novel rectilinear biphasic waveform with a damped sine wave monophasic waveform for transthoracic ventricular defibrillation. *J Am Coll Cardiol.* 1999;34:1595–1601.[Medline]

123. Mittal S, Ayati S, Stein KM, Schwartzman D, Cavlovich D, Tchou PJ, Markowitz SM, Slotwiner DJ, Scheiner MA, Lerman BB. Transthoracic cardioversion of atrial fibrillation: comparison of rectilinear biphasic versus damped sine wave monophasic shocks. *Circulation.*. 2000;101:1282–1287.[Abstract/Full Text]

124. White RD. External defibrillation: the need for uniformity in analyzing and reporting results [editorial; comment]. *Ann Emerg Med.*. 1998;32:234–236.[Medline]

125. Cummins RO, Eisenberg MS, Hallstrom AP, Hearne TR, Graves JR, Litwin PE. What is a "save"? Outcome measures in clinical evaluations of automatic external defibrillators. *Am Heart J.* 1985;110:1133–1138.[Medline]

126. White RD, Blanton DM. Biphasic truncated exponential waveform defibrillation. *Prehosp Emerg Care.* 1999;3:283–289.[Medline]

127. Chen PS, Shibata N, Dixon EG, Wolf PD, Danieley ND, Sweeney MB, Smith WM, Ideker RE. Activation during ventricular defibrillation in open-chest dogs: evidence of complete cessation and regeneration of ventricular fibrillation after unsuccessful shocks. *J Clin Invest.* 1986;77:810–823.[Medline]

128. Usui M, Callihan RL, Walker RG, Walcott GP, Rollins DL, Wolf PD, Smith WM, Ideker RE. Epicardial sock mapping following monophasic and biphasic shocks of equal voltage with an endocardial lead system. *J Cardiovasc Electrophysiol.* 1996;7:322–334.[Medline]

129. Eisenberg M, Bergner L, Hallstrom A. Epidemiology of cardiac arrest and resuscitation in children. *Ann Emerg Med.* 1983;12:672–674.[Medline]

130. Kuisma M, Suominen P, Korpela R. Paediatric out-of-hospital cardiac arrests: epidemiology and outcome. *Resuscitation.* 1995;30:141–150.[Medline]

131. Hickey RW, Cohen DM, Strausbaugh S, Dietrich AM. Pediatric patients requiring CPR in the prehospital setting [see comments]. *Ann Emerg Med..* 1995;25:495–501.[Medline]

132. Sirbaugh PE, Pepe PE, Shook JE, Kimball KT, Goldman MJ, Ward MA, Mann DM. A prospective, population-based study of the demographics, epidemiology, management, and outcome of out-of-hospital pediatric cardiopulmonary arrest [see comments] [published erratum appears in *Ann Emerg Med..* 1999;33:358]. *Ann Emerg Med.* 1999;33:174–184.

133. Mogayzel C, Quan L, Graves JR, Tiedeman D, Fahrenbruch C, Herndon P. Out-of-hospital ventricular fibrillation in children and adolescents: causes and outcomes [see comments]. *Ann Emerg Med..* 1995;25:484–491. [Medline]

134. Appleton GO, Cummins RO, Larson MP, Graves JR. CPR and the single rescuer: at what age should you "call first" rather than "call fast"? [see comments]. *Ann Emerg Med.* 1995;25:492–494.[Medline]

135. Ronco R, King W, Donley DK, Tilden SJ. Outcome and cost at a children's hospital following resuscitation for out-of-hospital cardiopulmonary arrest. *Arch Pediatr Adolesc Med.* 1995;149:210–214.[Medline]

136. Walsh CK, Krongrad E. Terminal cardiac electrical activity in pediatric patients. *Am J Cardiol.* 1983;51:557–561.[Medline]

137. Safranek DJ, Eisenberg MS, Larsen MP. The epidemiology of cardiac arrest in young adults. *Ann Emerg Med.* 1992;21:1102–1106.[Medline]

138. Losek JD, Hennes H, Glaeser P, Hendley G, Nelson DB. Prehospital care of the pulseless, nonbreathing pediatric patient. *Am J Emerg Med.* 1987;5:370–374.[Medline]

139. Atkins DL, Hartley LL, York DK. Accurate recognition and effective treatment of ventricular fibrillation by automated external defibrillators in adolescents. *Pediatrics.* 1998;101:393–397.[Abstract/Full Text]

140. Cecchin F, Perry JC, Berul CI, Jorgenson DB, Brian DW, Lyster T, Snider DE, Zimmerman AA, Lupinetti FM, Rosenthal GL, Rule D, Atkins DL. Accuracy of automatic external defibrillator analysis algorithm in young children. *Circulation.* 1999;100(suppl I):I-663. Abstract.

141. Hazinski MF, Walker C, Smith J, Deshpande J. Specificity of automatic external defibrillator (AED) rhythm analysis in pediatric tachyarrhythmias. *Circulation.* 1997;96(suppl I):I-561. Abstract.

142. Clark CB, Davies LR, Kerber RE. Pediatric defibrillation: biphasic vs. monophasic waveforms in an experimental model. *Circulation.* 1999;200(suppl I):I-90. Abstract.

143. Tang W, Weil MH, Sun S, Yamaguchi H, Povoas HP, Pernat AM, Bisera J. The effects of biphasic and conventional monophasic defibrillation on postresuscitation myocardial function. *J Am Coll Cardiol.* 1999;34:815–822.[Medline]

144. Babbs CF, Tacker WA, VanVleet JF, Bourland JD, Geddes LA. Therapeutic indices for transchest defibrillator shocks: effective, damaging, and lethal electrical doses. *Am Heart J.* 1980;99:734–738.[Medline]

144. Lubitz DS, Seidel JS, Chameides L, Luten RC, et al. A rapid method for estimating weight and resuscitation drug dosages from length in the pediatric age group. *Ann Emerg Med.*. 1988;17:576–581.[Medline]

145. Panacek EA, Munger MA, Rutherford WF, Gardner SF. Report of nitropatch explosions complicating defibrillation. *Am J Emerg Med.* 1992;10:128–129.[Medline]

146. Calle PA, Buylaert W. When an AED meets an ICD... automated external defibrillator: implantable cardioverter defibrillator. *Resuscitation.* 1998;38:177–183.[Medline]

147. Bissing JW, Kerber RE. Effect of shaving the chest of hirsute subjects on transthoracic impedance to self-adhesive defibrillation electrode pads. *Am J Cardiol.* In press.

148. Gibbs W, Eisenberg M, Damon SK. Dangers of defibrillation: injuries to emergency personnel during patient resuscitation. *Am J Emerg Med.* 1990;8:8:101–104.

149. Aufderheide T, Stapleton ER, Hazinski MF, Cummins RO. *Heartsaver AED for the Lay Rescuer and First Responder*. Dallas, Tex: American Heart Association; 1999.

150. Emergency Care Research Institute. Hazard: user error and defibrillator discharge failures. *Health Devices.* 1986;15.

151. Cummins RO, Chesemore K, White RD, Defibrillator Working Group. Defibrillator failures: causes of problems and recommendations for improvement. [see comments]. *JAMA.*. 1990;264:1019–1025.[Medline]

152. White RD. Maintenance of defibrillators in a state of readiness. *Ann Emerg Med.* 1993;22:302–306.[Medline]

153. White RD. AED (automated external defibrillators): a physician's responsibility. *J Emerg Med Serv.* 1992;17:8–9.

154. Cummins RO. The Utstein style for uniform reporting of data from out-of-hospital cardiac arrest. *Ann Emerg Med.* 1993;22:37–40.[Medline]

155. Emergency Cardiac Care Committees and Subcommittees AHA. Guidelines for cardiopulmonary resuscitation and emergency cardiac care. *JAMA.* 1992;268:2171–2302.[Medline]

156. Murphy DM. Rapid defibrillation: fire service to lead the way. *J Emerg Med Serv.* 1987;12:67–71.

157. Newman M. Chain of Survival concept takes hold. *J Emerg Med Serv.* 1989;14:11–13.

158. Walters G, Glucksman E, Evans TR. Training St John Ambulance volunteers to use an automated external defibrillator. *Resuscitation.* 1994;27:39–45.[Medline]

159. Weaver WD, Sutherland K, Wirkus MJ, Bachman R. Emergency medical care requirements for large public assemblies and a new strategy for managing cardiac arrest in this setting. *Ann Emerg Med.* 1989;18:155–160.[Medline]

160. Watts DD. Defibrillation by basic emergency medical technicians: effect on survival [see comments]. *Ann Emerg Med.*. 1995;26:635–639.[Medline]

161. Fenner P, Leahy S. Successful defibrillation on a beach by volunteer surf lifesavers. *Med J Aust.* 1998;168:169. [Medline]

162. Riegel B. Training nontraditional responders to use automated external defibrillators. *Am J Crit Care.* 1998;7:402–410.[Medline]

163. Herlitz J, Bang A, Axelsson A, Graves JR, Lindqvist J. Experience with the use of automated external defibrillators in out of hospital cardiac arrest. *Resuscitation.* 1998;37:3–7.[Medline]

164. Calle P, Van Acker P, Buylaert W, Quets A, Come L, Delooz H, Bossaert L, Martens P, Mullie A, the Belgian Cerebral Resuscitation Study Group. Should semi-automatic defibrillators be used by emergency medical technicians in Belgium? *Acta Clin Belg.* 1992;47:6–14.[Medline]

165. Calle PA, Verbeke A, Vanhaute O, Van Acker P, Martens P, Buylaert W. The effect of semi-automatic external defibrillation by emergency medical technicians on survival after out-of-hospital cardiac arrest: an observational study in urban and rural areas in Belgium. *Acta Clin Belg.* 1997;52:72–83.[Medline]

166. Martens P, Calle P, Mullie A. Do we know enough to introduce semi-automatic defibrillation by ambulancemen in Belgium? *Eur J Med.* 1993;2:430–434.[Medline]

167. Richless LK, Schrading WA, Polana J, Hess DR, Ogden CS. Early defibrillation program: problems encountered in a rural/suburban EMS system. *J Emerg Med.* 1993;11:127–134.[Medline]

168. Ho J, Held T, Heegaard W, Crimmins T. Automatic external defibrillation and its effects on neurologic outcome in cardiac arrest patients in an urban, two-tiered EMS system. *Prehospital Disaster Med.* 1997;12:284–287.[Medline]

169. Herlitz J, Bang A, Holmberg M, Axelsson A, Lindkvist J, Holmberg S. Rhythm changes during resuscitation from ventricular fibrillation in relation to delay until defibrillation, number of shocks delivered and survival. *Resuscitation.* 1997;34:17–22.[Medline]

170. Hamer DW, Gordon MW, Cusack S, Robertson CE. Survival from cardiac arrest in an accident and emergency department: the impact of out of hospital advisory defibrillation. *Resuscitation.* 1993;26:31–37.[Medline]

171. Arntz HR, Oeff M, Willich SN, Storch WH, Schroder R. Establishment and results of an EMT-D program in a two-tiered physician-escorted rescue system: the experience in Berlin, Germany. *Resuscitation.* 1993;26:39–46. [Medline]

172. National Heart Attack Alert Program Coordinating Committee Access to Care Subcommittee. Staffing and equipping emergency medical services system: rapid identification and treatment of acute myocardial infarction. *Am J Emerg Med.* 1995;13:58–66.[Medline]

173. Stults KR, Brown DD. Special considerations for defibrillation performed by emergency medical technicians in small communities. *Circulation.* 1986;74(suppl IV):IV-13–IV-17.

174. Ornato JP, McNeill SE, Craren EJ, Nelson NM. Limitation on effectiveness of rapid defibrillation by emergency medical technicians in a rural setting. *Ann Emerg Med.* 1984;13:1096–1099.[Medline]

175. Cummins RO, Eisenberg MS, Graves JR, Damon SK. EMT-defibrillation: is it right for you? *J Emerg Med Serv.* 1985;10:60–64.

176. Lazzam C, McCans J. Predictors of survival of in-hospital cardiac arrest. *Can J Cardiol.* 1991;7:113–116. [Medline]

177. Dickey W, Adgey A. Mortality within hospital after resuscitation from ventricular fibrillation outside the hospital. *Br Heart J.* 1992;67:334–338. [Abstract]

178. Cummins RO, Sanders A, Mancini E, Hazinski MF. In-hospital resuscitation: a statement for healthcare professionals from the American Heart Association Emergency Cardiac Care Committee and the Advanced Cardiac Life Support, Basic Life Support, Pediatric Resuscitation, and Program Administration Subcommittees. *Circulation.* 1997;95:2211–2212. [Full Text]

179. Nelson ME, Zenas CS. Losing the race to resuscitate. *Nurs Management.* 1998;29:36D–36E, 36G.

180. Mancini ME, Kaye W. AEDs: changing the way you respond to cardiac arrest : automatic external defibrillators. *Am J Nurs..* 1999;99:26–30; quiz 31.

181. Warwick JP, Mackie K, Spencer I. Towards early defibrillation: a nurse training programme in the use of automated external defibrillators [see comments]. *Resuscitation..* 1995;30:231–235. [Medline]

182. Bossaert EL. *European Resuscitation Council Guidelines for Resuscitation.* Amsterdam, Netherlands: Elsevier Science; 1998.

183. Anonymous Joint Commission on Accreditation of Healthcare Organizations. In-hospital resuscitation requirements reinstated for hospitals. *Joint Commission Perspectives.* 1998;18:5. [Medline]

184. Cummins RO, Chamberlain D, Hazinski MF, Nadkarni V, Kloeck W, Kramer E, Becker L, Robertson C, Koster R, Zaritsky A, Bossaert L, Ornato JP, Callanan V, Allen M, Steen P, Connolly B, Sanders A, Idris A, Cobbe S. Recommended guidelines for reviewing, reporting, and conducting research on in-hospital resuscitation: the in-hospital "Utstein style": a statement for healthcare professionals from the American Heart Association, the European Resuscitation Council, the Heart and Stroke Foundation of Canada, the Australian Resuscitation Council, and the Resuscitation Councils of Southern Africa. *Resuscitation.* 1997;34:151–183. [Medline]

185. Kloeck W, Cummins RO, Chamberlain D, Bossaert L, et al. Early defibrillation: an advisory statement from the advanced life support working group of the International Liaison Committee on Resuscitation. *Circulation.* 1997;95:2183–2184. [Full Text]

186. Stoddard FG. Public access defibrillation comes of age. *Currents.* 1997;7:1–3.

187. Nichol G, Hallstrom AP, Ornato JP, Riegel B, Stiell IG, Valenzuela T, Wells GA, White RD, Weisfeldt ML. Potential cost-effectiveness of public access defibrillation in the United States. *Circulation.* 1998;97:1315–1320. [Abstract/Full Text]

188. Cobb LA, Eliastam M, Kerber RE, Melker R, Moss AJ, Newell L, Paraskos JA, Weaver WD, Weil M, Weisfeldt ML. Report of the American Heart Association Task Force on the Future of Cardiopulmonary Resuscitation. *Circulation..* 1992;85:2346–2355. [Medline]

189. Becker L, Eisenberg M, Fahrenbruch C, Cobb L. Public locations of cardiac arrest: implications for public access defibrillation. *Circulation.* 1998;97:2106–2109. [Abstract/Full Text]

190. Zachariah BS, Pepe PE. The development of emergency medical dispatch in the U S A: a historical perspective. *Eur J Emerg Med.* 1995;2:109–112. [Medline]

191. Rossi R. The role of the dispatch centre in preclinical emergency medicine. *Eur J Emerg Med.* 1994;1:27–30.

[Medline]

192. American College of Emergency Physicians. Early defibrillation programs. *Ann Emerg Med.* 1999;33:371. [Medline]

193. Axelsson A, Herlitz J, Karlsson T, Lindqvist J, Reid Graves J, Ekstrom L, Holmberg S. Factors surrounding cardiopulmonary resuscitation influencing bystanders' psychological reactions. *Resuscitation.* 1998;37:13–20. [Medline]

194. Ornato JP, Craren EJ, Gonzalez ER, Garnett AR, McClung BK, Newman MM. Cost-effectiveness of defibrillation by emergency medical technicians. *Am J Emerg Med.* 1988;6:108–112.[Medline]

195. Stiell IG, Wells GA, Field BJ, Spaite DW, De Maio VJ, Ward R, Munkley DP, Lyver MB, Luinstra LG, Campeau T, Maloney J, Dagnone E. Improved out-of-hospital cardiac arrest survival through the inexpensive optimization of an existing defibrillation program: OPALS study phase II. Ontario Prehospital Advanced Life Support. [see comments]. *JAMA.*. 1999;281:1175–1181.[Medline]

This article has been cited by other articles:

Patient Center

Automatic External Defibrillators

Main Points

- AEDs are easy to use and becoming more available in public places, such as shopping malls.
- When a person suffers a cardiac arrest, the chances of survival decrease for each minute that passes without defibrillation. A victim's best chance for survival is when there is revival within 4 minutes.
- An AED is automatic. It automatically detects breathing and how much shock is needed — and it delivers the shock. Having more people aware of the locations of AEDs and being willing and trained to use them will greatly increase the survival rates for people having heart attacks.
- The American College of Emergency Physicians supports increased public access to AEDs that is coordinated with community EMS systems and with appropriate training.

Q. What is an Automated External Defibrillator?

A. An Automated External Defibrillator (AED) is a small, lightweight device used to assess e person's heart rhythm. If necessary, it administers an electric shock to restore a normal rhythm in victims of sudden cardiac arrest. Built-in computers assess the patient's heart rhythm, judge whether defibrillation is needed, and then administer an appropriate level of shock. Audible and/or visual prompts guide the user through the process. AEDs can be used and maintained by anyone with a few hours of training, like a fire extinguisher or CPR. They are most effective when standards are in place for appropriate training, equipment maintenance and ongoing monitoring of the quality of care.

Q. How does an AED work?

A. A microprocessor inside the defibrillator analyzes the victim's heart rhythm through adhesive electrodes (some AED models require the person to press an ANALYZE button). The computer then advises the operator whether a shock is needed. When the operator responds to the prompt to give a shock, an electric current is delivered through the victim's chest wall through adhesive electrode pads.

Q. Why are AEDs important?

A. AEDs can restore a normal heart rhythm in victims of sudden cardiac arrest, which may be a heart attack or sudden death. New, portable AEDs enable more people to respond to a medical emergency that requires defibrillation.

When a person suffers a sudden cardiac arrest, the chance of survival decreases by 7 percent to 10 percent for each minute that passes without defibrillation. The American Red Cross estimates that 50,000 lives could be saved each year if AEDs were widely used.

Q. Who can use an AED?

A. Anyone trained to use cardiopulmonary resuscitation (CPR) can be trained to use an AED. Most AEDs are designed to be used by people without medical backgrounds, such as police, firefighters, flight attendants, security guards, and lay rescuers. AEDs are most effective when standards are in place for appropriate training, equipment maintenance and ongoing quality-of-care monitoring.

Q. When a person's heart stops beating, why should an AED be used?

A. When a heart's rhythm goes into an uncoordinated electrical activity called fibrillation, the heart twitches ineffectively and can't pump blood. This condition often accompanies severe heart attacks when the patient's heart appears to have stopped beating.

The AED delivers electric current to the heart muscle, momentarily stunning the heart, stopping all activity. This gives the heart an opportunity to resume beating effectively.

Q. Will an AED always resuscitate someone in cardiac arrest?

A. No. The AED treats only a heart in ventricular fibrillation, an irregular heart rhythm. In cardiac arrest without ventricular fibrillation, the heart does not respond to electric currents, but needs medications. The victim also needs breathing support. AEDs are less successful when the victim has been in cardiac arrest for more than a few minutes, especially if no CPR was provided.

Q. Should AEDs be available on airplanes and in other public places?

Related Resources

Browse Content by Topic

» Clinical Topics

» Practice Resources

Bookstore

ACEP recommends the following books and resources:

Electrocardiography in Emergency Medicine

Special Events

Scientific Assembly 2009
October 5 - 8, 2009
Boston, MA

Advanced EMS Medical Directors Forum
October 4, 2009
Boston, MA

A. Yes. Since seconds count when a person experiences a heart attack, ACEP supports widespread distribution of AEDs, as long as it is coordinated with existing EMS systems and includes proper training. Logical places for AEDs include police cars, theaters, sports arenas, public buildings, business offices and airports. An increasing number of commercial airplanes are now equipped with AEDs and enhanced medical kits.

- Approximately 200,000 people die from cardiac arrest every year. The broad deployment of a new generation of portable defibrillators for use by trained lay rescuers can help to save countless lives from this deadly and unpredictable event. The sudden death of newsman Tim Russert in 2008 brought attention to the need to educate people about using AEDs in life-threatening situations.

Chicago's O'Hare International and Midway Airports were the first airports in the United States to provide defibrillators to employees. Some companies may be concerned about liability from employees using AEDs, but many states already have passed Good Samaritan laws to protect laypersons. Most states have such laws.

Q. Do AEDs replace the use of CPR?

A. No. When a person experiences cardiac arrest, CPR will help keep oxygen flowing to the brain, but the electric shock of an AED vastly improves the chances of restarting the heart. AEDs can be used as part of cardiopulmonary resuscitation. CPR is still needed, starting with determining whether a person is unconscious, breathless, or pulseless.

To help spread the use of AEDs, the American Red Cross has incorporated AED training into standard CPR training for the nation's businesses. The American Red Cross trains approximately 6 million people each year in lifesaving first aid and CPR.

Q. What's the difference between an AED and the defibrillators used in hospitals?

A. In-hospital defibrillators are manual, larger than AEDs, and designed to be used only by qualified medical personnel with special training to use the device and to recognize heart rhythms. Medical personnel who use the device must decide whether or not to shock the person. Manual defibrillators also have additional capabilities such as pacing and cardioversion.

AEDs are programmed to recognize different heart rhythms and to make the shock/no shock decision, so that users don't have to. They were designed so that lifesaving defibrillation could be performed as quickly as possible.

For additional information, see Tips on Recognizing and Preventing Heart Attacks and policy statements on Public Training in Cardiopulmonary Resuscitation and Public Access Defibrillation and Early Defibrillation Programs.

Print Forward to a Friend

American College of Occupational and Environmental Medicine

Download to PDF

Automated External Defibrillation in the Occupational Setting (reaffirmed May 2006)

Introduction

On November 13, 2000, President Clinton signed into law H.R. 2498, the Cardiac Arrest Survival Act (CASA), designed to expand the availability of automated external defibrillators (AEDs) in public settings. The new legislation requires the Secretary of the Department of Health and Human Services (HHS) to establish guidelines for the placement of AEDs in buildings owned or leased by the federal government.

The American College of Occupational and Environmental Medicine (ACOEM), while applauding this legislation urges the consideration of AEDs in selected workplaces, beyond the scope of federal buildings. The College has thus developed this guideline to increase the awareness of the value of AEDs and has presented recommendations to encourage and provide guidance on their use in the workplace. This guideline reviews the following topics: (1) epidemiology, morbidity, and mortality of cardiovascular diseases in the workplace; (2) the "chain of survival" paradigm; (3) history and descriptions of AEDs; (4) standard-of-care interventions and guidelines; (5) public-access defibrillation and federal initiatives; and (6) recommendations for establishing and managing a workplace AED program.

Epidemiology, Morbidity and Mortality

Heart disease is a significant public health concern. The American Heart Association estimates that in 1997 alone, 7,700,000 Americans experienced myocardial infarctions and 6,300,000 suffered from angina pectoris.[1]

During 1996, reported incidence rates in the United States for the combination of ischemic heart disease and heart rhythm disorders, including tachycardia and other unspecified rhythm disorders, were 78.1 per 1000 persons.[2] Among working-age adults, incidence rates were 39.3 per 1000 persons for those 18-44 years, and 116.4 per 1000 persons for those 45-64 years.[3]

The Occupational Safety and Health Administration reported that from 1991-1993, 15% of workplace deaths were due to sudden cardiac arrest (SCA)[4] Data collected from Calgary, Alberta, from 1992-1996, revealed that 13% of cardiac arrest deaths occurred in public or commercial sites, 5% were in large buildings (> 250 people), and 8% in small buildings (< 250 people).[5] Data reported from a 1990-1994 Seattle area retrospective cohort study found 16% of cardiac arrests occurred in public places.[6]

SCA and the Chain of Survival

There are several electrical abnormalities that result in SCA, but the majority of deaths begin with an initial rhythm of ventricular fibrillation (VF).[7-9] If VF is not treated quickly, this potentially reversible dysrhythmia typically degenerates into asystole, which is generally fatal.[10] The standard medical protocol to correct VF and pulseless ventricular tachycardia (VT) is the application of electric shock with a controlled dose and duration of energy. If the initial shocks fail to convert the rhythm, advanced cardiac life support (ACLS) protocols call for a series of medications to be given in a medication-shock, medication-shock sequence.

Factors contributing to out-of-hospital survival following SCA have been described primarily in terms of the time-related "chain of survival" paradigm.[11] The four links of the chain include: (1) early recognition and call for emergency medical services; (2) initiation of basic life support CPR; (3) defibrillation; and (4) advanced cardiac life support (ACLS) drug intervention. Survival depends on the availability of the links – although more advanced applications may jump ahead of lesser ones. For example, if community emergency medical service (EMS) responders – or medical providers at the scene – are not qualified or prepared to deliver ACLS, this link may not be available until the patient arrives at a medical center. If a workplace has basic life support providers equipped with an AED and an ACLS-level medical department, the timing between these links may be shorter.

Without intervention, survival following SCA decreases rapidly. Several studies have reported that for each minute of untreated cardiac arrest, the probability of successful rhythm conversion decreases by 7% to 10%, producing an equivalent per-minute-death rate.[12,13] Conversely, survival rates as high as 90% have been reported when the collapse-to-defibrillation time is within one minute.[14-16] To better define each the contribution of each link in the "chain of survival," data were examined between 1976 and 1991 in Seattle.[17] A best fit model demonstrated a fit with the following equation:

> Survival rate = 67% at collapse – 2.3% per minute to CPR – 1.1% per minute to defibrillation – 2.1% per minute to ACLS

As noted by the authors:

> "The regression constant, 67%, represents the probability of survival in the hypothetical situation in which all treatments are delivered immediately on collapse to patients with prehospital cardiac arrest ... With delays in CPR, defibrillatory shock, and definitive care, the magnitude of the decline in survival rate per minute is the sum of the three coefficients (-2.2%, -1.1%, -2.1%), or –5.5%."[17]

It is clear that while some variation in the time/survival equation exists, the sooner VF is treated, the more likely a positive outcome. Moreover, data show that some adults in VF remain neurologically intact even when defibrillation is delayed for up to 10 minutes after arrest if CPR is provided.[14,18,19] Indeed, performing CPR prior to defibrillation seems to prolong VF, which may "buy time" until an AED can convert the rhythm, thereby helping to preserve heart and brain function.[17,20] CPR without electric therapy may sustain a patient in VF for a short time but only rarely restores an organized rhythm. As return of an adequate perfusing rhythm requires immediate application of the combination of CPR, defibrillation, and ACLS within a few minutes of arrest, establishing controls to permit smooth and fast support of the chain of survival enhances the probability of survival.

History and Descriptions of AED

While conventional, manual external defibrillators have been used in clinical settings and some emergency medical services (EMS) for nearly 50 years, the automated external defibrillator (AED) did not make its debut until 1979.[21] Utilizing solid-state circuitry and micro-computer technologies, the modern AED identifies VF, voice prompts a user to prepare to deliver a shock, and when a button is pushed, delivers the electric charge. Many studies have shown that AEDs are nearly error-free[22] and effective when used by hospital-wide resuscitation teams,[23] EMTs,[24-26] fire department rescuers,[23] police officers,[27,28] and non-medical, first-aid responders in the workplace.[29-31] In the last decade, there has been a remarkable increase in the placement and use of AEDs. Reasons include the accumulation of additional clinical studies confirming the safety, efficacy, and accuracy of these devices;[32-34] the development of a smaller and lighter batteries and cases (less than 5 lbs); and the easy-to-follow audio prompt instructions.

Types of AEDs

The term "AED" commonly refers to any device that analyzes cardiac rhythm and prompts a user to deliver a shock when necessary. These devices only require a user to attach pads to a patient's chest, turn the device on, and follow audio instructions. They do not require any decision-making or interpretation of symptoms. Most AEDs, therefore, are "automated" in that they analyze and advise. "Fully automated" or "automatic" external defibrillators that deliver a shock without a prompt to press a shock button are available for special situations.

Analysis of Rhythms

AEDs utilize microprocessors to analyze several characteristics of the surface ECG signal. Wave frequency, amplitude, and some integrated features such as slope or morphology are identified and compared to preset values. In an unresponsive, non-breathing, pulseless patient, an AED will advise shocks for monomorphic and polymorphic ventricular tachycardia (VT), supraventricular tachycardia (SVT), or VF. When shock advisories have been reported for patients with perfusing ventricular or supraventricular arrhythmias,[35] these were confirmed as due to interpretation, reporting and response errors of operators not device, errors.[36]

Device "Errors"

An AED should be used for management of full cardiac arrest, and only when all movement is absent. Any patient movement (e.g., patient transport, seizures, or agonal respirations) can disrupt the ability of the device to complete rhythm analysis. Occasional errors have also been reported due to failure to deliver shocks in cases of extremely fine or course VF,[37] incomplete cycles of analysis,[24,31] failure to follow the AED manufacturer's instructions,[34] and conflicts with an implanted defibrillator.[38]

Waveforms and Energy Levels

Although there is no clear relationship between adult body size and energy requirements, the dose and duration of AED energy must be appropriate. When energy or current is too high, there is a risk of cardiac injury and myocardial infarction; when too low, the shock may fail to terminate VF or other arrhythmias.[39-41]

Modern AEDs provide one of two categories of waveforms: monophasic or biphasic. Monophasic waveforms provide current flows in a single direction (polarity). When the rate at which the pulse falls to zero is gradual, they are referred to as monophasic damped sinusoidal (MDS). When the rate is instantaneous, they are called monophasic truncated exponential (MTE). Biphasic waveform defibrillators deliver a sequence of two pulses in which the second is of opposite polarity to the first. While biphasic damped sinusoidal (BDS) and biphasic truncated exponential (BTE) are both technically possible, current manufacturers only market BTE devices. To maximize the success of the shock, monophasic AEDs use an escalating energy sequence. The recommended energy for the first shock is 200 J, followed by 200 J to 300 J in the second, and 360 J in the third.[42] Studies have shown that BTE low shocks energy (200 J or less) are equal or superior to 200 J MTE shocks in terminating short duration VT and VF, and produce fewer ST segment changes.[43,44,45]

Public Access Defibrillation and Federal Initiatives

The concept of public access defibrillation (PAD) gained momentum when the American Heart Association Task Force on the Future of CPR challenged the medical device industry to create AEDs that would make early defibrillation accessible to the public.[46] The rationale for PAD was based on the concern that in many densely populated areas, traditional EMS responders cannot respond in sufficiently short time to perform resuscitation and maximize survival. It was determined that the training and equipping of non-traditional (non-EMS) responders to use AEDs and provide resuscitation until arrival of EMS was a practical and appropriate solution to that problem.

To date, 48 states have passed legislation describing the process of acquisition and use of an AED by lay responders. Since the Food and Drug Administration regulates AEDs as prescription devices, acquisition requires medical involvement. However, details of such requirements for medical involvement vary across states. Elements commonly addressed in state legislation include immunity for rescuers, acquirers, and enablers; training requirements for users; medical supervision or involvement; and EMS notification.

Supporting PAD are three federal initiatives:

- The aforementioned Cardiac Arrest Survival Act (CASA) which instructs the Secretary of Health and Human Services to make

recommendations to promote public access to defibrillation programs in federal and other public buildings. The Act also extends Good Samaritan protections to AED users and the acquirers of the devices in any states without such immunities.

- "Guidelines for Public Access Defibrillation in Federal Facilities"[47] issued by the Department of Health and Human Services (HHS) and General Services Administration (GSA) to "provide a general framework to initiate a design process for a public access defibrillation (PAD) program in federal facilities."
- Finally, on April 21, 2001, the Department of Transportation, Federal Aviation Administration issued "Emergency Medical Equipment; Final Rule"[48] which requires an AED and other associated first-aid supplies for all passenger-carrying aircraft with at least one flight attendant.

Guidelines for the use of automated external defibrillators (AEDs) in workplace settings

The American College of Occupational and Environmental Medicine (ACOEM) supports the establishment of programs by employers to use automated external defibrillators (AEDs) to manage sudden cardiac arrest in workplace settings. In establishing a workplace AED program, it is important to obtain support for the program from the organization's leadership, including agreement about the goals, implementation requirements and costs of the program.

ACOEM recommends that employer-sponsored programs for the use of AEDs in workplaces and public settings, include all of the following elements:

1. ***Establishment of a centralized management system for the AED program***
   It is recommended that a centralized management system be established for the workplace AED program within each organization. It is important that clear lines of responsibility be established for the program, and that roles are defined for those who oversee and monitor the program.

2. ***Medical direction and control of the workplace AED program***
   It is recommended that all workplace AED programs be under the direction and control of an appropriately qualified physician. It is recommended that all workplace AED programs be medically supervised by an appropriately qualified physician or health care provider licensed for independent practice and be in compliance with medical control requirements of the administrative code of the state where the AED is provided. It is recommended that the responsibilities of the program medical director include helping to develop and/or approving medical aspects of the program. Specific areas where medical direction is important include providing the written authorization required in most locations to acquire an AED, ensuring provisions are made for appropriate initial and continued AED training, and performing a case-by-case review each time an AED is used at the site. It is recommended that additional responsibilities include establishing or integrating the AED program with a quality control system, compliance with regulatory requirements (see recommendation #3) and ensuring proper interface with EMS.

   It is recommended that administrative coordination of workplace AED programs be provided by a licensed health care professional or an appropriately qualified health or safety professional responsible for workplace emergency programs. It is recommended that the day-to-day management of the AED program be supervised by the administrative coordinator in consultation with the program medical director for issues of medical control.

3. ***Awareness of and compliance with federal and state regulations***
   It is important that both the AED program medical director and management responsible for the worksite AED program identify and comply with relevant state legislation[49] on public access defibrillation (PAD) and the federal Cardiac Arrest Survival Act.[50] These regulations may impose specific requirements that vary from state to state; therefore, a single corporate policy may be insufficient unless it meets the most stringent requirements imposed by all jurisdictions where a workplace AED program is in place.

   As federal and state AED legislation requires that every person expected to use an AED be properly trained, it is recommended that training be recognized and standardized. Course content must include CPR, use of the AED, and should be integrated with other first aid responder programs at the workplace. It is recommended that CPR and AED skills review and practice be conducted at least annually, and encouraged semi-annually.[51]

4. ***Development of written AED program description for each location***
   It is recommended that a written document describing the workplace AED program be prepared for each location where an AED will be placed. It is recommended that such a written document address all of the 12 recommended program elements stated in this guideline.

5. ***Coordination with local emergency medical services***
   As is required by many state PAD regulations, it is important that information about each workplace AED program be communicated to community emergency medical services (EMS) providers and coordinated with EMS response protocols.

6. ***Integration with an overall emergency response plan for the worksite***
   It is recommended that the workplace AED program should be a component of a more general medical emergency response plan, rather than a freestanding program. It is important that the emergency medical response plan describe in sufficient detail the continuum of personnel, equipment, information, and site activities associated with managing the range of anticipated occupational injuries and illnesses for a patient who is breathing or in sudden cardiac arrest. It is recommended that all employees be informed about the medical emergency response plan including the proper means for notifying trained internal and community emergency responders in the event of a suspected cardiac arrest, or other medical emergency. It is recommended that, when a workplace AED program is in place, the part of the workplace medical emergency response plan dealing with suspected cardiac events included specific recommendations about the following:

a. notification of workplace medical personnel and first aid responders during all operating times of the site;
b. assessment of the situation by the first trained responders at the scene;
c. notification of the community emergency medical service (EMS) system;
d. appropriate first aid including body substance isolation procedures and use of CPR and AEDs by first aid responders if indicated;
e. clinically appropriate patient transport from workplace to medical facility, including how appropriate continuation of care will be ensured;
f. responder debriefing and equipment replacement; and
g. methods to review the follow-up care received by the patient.

7. ***Selection and technical consideration of AEDs*** It is recommended that selection of AED equipment be based on the most current recommendations of the American Heart Association (AHA), available in Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.[51] These AHA guidelines state that compared to higher-energy escalating (200 J, 300 J, 360 J) monophasic-waveform defibrillators, relatively low energy level (= 200 J) biphasic waveform defibrillation devices have been shown to be "safe and of equivalent or higher efficacy for termination of VF."[51] It is also recommended that if a higher-energy escalating monophasic defibrillator has been previously acquired, it may be utilized so long as training of responders adequately addresses particular aspects of such devices.

8. ***Ancillary medical equipment and supplies for the workplace AED program***
In addition to the AED, other medical equipment and supplies are required to support the safe and complete management of workplace cardiac emergencies. Therefore, it is recommended that the following supplies be provided in addition to the defibrillator as part the AED program:

   - bloodborne pathogens responder and clean-up kits[52] to ensure compliance with body substance isolation procedures
   - CPR barrier masks with oxygen port to permit delivery of supplemental oxygen[51]
   - AED responder kits to support electrode pad connections. Items include a razor (to shave chest hair) and towel (to dry sweat from the chest or after removal of a nitroglycerine transdermal patch);[53]
   - appropriate portable emergency oxygen equipment[51,54] to increase oxygen during resuscitation and to support inhalation following restoration of breathing; and
   - a CPR audio prompting device[51] to guide action and timing sequences of CPR ventilations and compressions.

9. ***Assessment of the proper number and placement of AEDs and supplies***
It is recommended that when practical, AEDs be placed in locations throughout a workplace that will allow initiation of resuscitation and use of the AEDs (the "drop-to-shock" interval) within 5 minutes of recognized cardiac arrest. Estimating time needed for transport and set up the AED for various work areas can help determine if a proposed location for AED placement is appropriate.

10. ***Scheduled maintenance and replacement of AED and ancillary equipment***
It is important that AEDs be maintained in optimal working condition. It is recommended that, at a minimum, the AED manufacturer's recommended service schedule be followed, and that records of all servicing and testing be maintained. It is also recommended that any workplace AED program ancillary medical equipment and supplies (e.g., emergency oxygen) used be maintained as recommended by the manufacturers or suppliers. It is recommended that all emergency equipment be evaluated, serviced, or replaced as necessary following use. It is recommended that records be maintained of the dates and details of servicing or replacement of AEDs or ancillary equipment and supplies used.

11. ***Establishment of an AED quality assurance program***
It is recommended that an AED quality assurance program be established that includes at least the following components:
    a. Medical Review:
    A case-by-case review for every use of each AED to treat a human by an appropriately qualified physician. (See also the recommendation above on "Medical Direction and Control.")
    b. Record keeping:
    1) records of all AED-related training including names of instructors, workplace personnel trained, courses completed, and dates of initial, review, renewal, or skill practice classes;
    2) records of all AED locations, service and updates; and
    3) records of medical reviews of AED implementation.
    c. Program evaluation:
    Standardized methods to assess the efficacy of the program, and a system to remediate or improve components as necessary.

12. ***Periodic review and modification of the Workplace AED program protocols***
It is recommended that all components of the workplace AED program be reviewed at least annually and modified as appropriate. As personnel or work practices evolve, there may be need to change the location, means of access, or procedures used to implement AEDs in the workplace.

Summary

ACOEM supports ongoing efforts to enhance emergency response to medical emergencies in the occupational environment. Development of programs to utilize AEDs is a reasonable and appropriate aspect of such programs to manage sudden cardiac arrest, an important cause of morbidity and mortality among working age adults. Implementation of such an AED program, which should be a component of a more general worksite emergency response plan, requires clearly defined medical direction and medical control.

Acknowledgements

This ACOEM guideline was prepared by Larry M. Starr, PhD, under the auspices of the Council on Scientific Affairs. It was peer-reviewed by the members of the Council and approved by the ACOEM Board of Directors on February 11, 2001.

The guideline was reaffirmed in its entirety by the ACOEM Board of Directors on May 6, 2006.

References

1. American Heart Association, Cardiovascular Disease Statistics, 2000, http://americanheart.org/Heart_and_Stroke_A_Z_Guide/cvds.html.
2. Centers for Disease Control, National Vital Statistics Reports, Series 10, No. 200, June 30, 2000.
3. Centers for Disease Control, National Vital Statistics Reports, Volume 47, No. 19, June 30, 2000.
4. Altmann M. 10 frequently asked questions about automated external defibrillators. Occup Hazards. 1999;61(9):85-87.
5. Millard W, De Maio VJ, Grant PT, Yahn S. Locations of cardiac arrest in a large urban center. Acad Emerg Med. 2000; 7(5):430-431.
6. Omato JP, Hankins DG. Public-access defibrillation. Prehosp Emerg Care. 1999;3:297-302.
7. Cummins RO. Textbook of Advanced Life Support. Dallas, TX. 1994, p. 4-1.
8. Stults KR, Brown DD, Schug VL, et al. Prehospital defibrillation performed by emergency medical technicians in rural communities. N Engl J Med. 1984;310:219-223.
9. Eisenberg MS, Copass MK, Hallstrom AP, et al. Treatment of out-of-hospital cardiac arrests with rapid defibrillation by emergency medical technicians. N Engl J Med. 1980:302:1379-1383.
10. Bailey ED. Position Paper, National Association of EMS Physicians. Termination of resuscitation in the prehospital setting for adult patients suffering nontraumatic cardiac arrest. Prehosp Emerg Care. 2000;4:190-195.
11. Cummins RO, Ornato JP, Theis WH. Improving survival from sudden cardiac arrest: The "chain of survival." Circulation. 1991;83:1832-1847.
12. Eisenberg, MS, Hartwig, RT, Cummins, RO, et al. Cardiac arrest and resuscitation: A tale of 29 cities. Ann Emerg Med. 1990;19:179-186.
13. Sedgwick, ML Dalziel, L. Watson, L, et al. Performance of an established system of first responder out-of-hospital defibrillation. The results of the second year of the Heartstart Scotland Project in the 'Utstein Style.' Resuscitation. 1993;26:75-88.
14. Fletcher, GF, Cantwell, JD. Ventricular fibrillation in a medically supervised cardiac exercise program: clinical, angiographic, and surgical correlations. JAMA. 1977;238:2627-2629.
15. Hossack KF, Hartwig R. Cardiac arrest associated with supervised cardiac rehabilitation. J Cardiac Rehabilitation. 1982;2:402-408.
16. Van Camp SP, Peterson, RA. Cardiovascular complications of outpatient cardiac rehabilitation programs. JAMA. 1986:256:1160-1163.
17. Larsen, MP, Eisenberg MS, Cummins RO, Hallstrom AP. Predicting survival from out-of-hospital cardiac arrest: A graphic model. Ann Emerg Med. 1993;22(11):1652-1658.
18. Weaver, WE, Copass, MK, Bufi D, Ray, R, Hallstrom AP, Cobb, LA. Improved neurological recovery and survival after early defibrillation. Circulation. 1984;69:943-948.
19. Eisenberg MS, Cummins RO, Damon S, Larsen MP, Hearne TR. Survival rates from out-of- hospital cardiac arrest: recommendations for uniform definitions and data to report. Ann Emerg Med. 1990;19:1249-1259.
20. Eisenberg, MS, Hallstrom AP, Cobb LA, Bergner L. Short F, Pierce J. Treatment of ventricular fibrillation: emergency medical technicians, defibrillation and paramedic services. JAMA. 1984;251:1723-1726.
21. Diak AW, Welbom WS, Rullman RG, Walter CW, Wayne MA. An automatic cardiac resuscitator for emergency treatment of cardiac arrest. Med Instrumentation. 1979;13:78-83.
22. Cummins RO. Automated external defibrillators: Where we've been and where we're going. Resident Staff Physician. 1994;40:61-67.
23. Kaye W, Mancini ME, Richards N. Organizing and implementing a hospital-wide first-responder automated external defibrillation program: strengthening the in-hospital chain of survival. Resuscitation. 1995;30:151-156.
24. Weaver WD, Hill D, Fahrenbuch CE, et al. Use of the automatic external defibrillator in the management of out-of-hospital cardiac arrest. N Engl J Med. 1988;319:661-666.
25. Cummins RO, Eisenberg MS, Letwin PE, et al. Automatic external defibrillators used by emergency medical technicians: A controlled clinical trial. JAMA. 1987;257:1605-1610.

26. Stults K, Brown D, Kerber R. Efficacy of an automated external defibrillator in the management of out-of-hospital cardiac arrest: Validation of the diagnostic algorithm and initial experience in a rural environment. Circulation. 1986;73:701-709.

27. Mosesso VN, Davis EA, Carlin RE, et al. Use of automated defibrillators by police first responders for treatment of out-of-hospital cardiac arrest. Ann Emerg Med. 1993;22:920.

28. White RD, Vukov LF, Bugliosi TF. Measurement of critical time intervals in a police department early defibrillation study. Ann Emerg Med. 1993;22:901.

29. Cummins RO, Schubach JA, Litwin PE, Hearne TR. Training lay persons to use automatic external defibrillators: Success of initial training and one-year retention of skills. Am J Emerg Med. 1989;7:143-149.

30. Riegel, B. for the American Heart Association External Defibrillator Task Force. Training nontraditional responders to use automated external defibrillators. Am J Crit Care. 1998;7(6):402-410.

31. Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW. Casino project: Implications for public access defibrillation. Acad Emerg Med. 2000;7(5):426.

32. Cummins RO, Eisenberg M, Bergner L, Murray JA. Sensitivity, accuracy and safety of an automatic external defibrillator. Lancet. 1984;2:318-320.

33. Cummins RO, Austin D Jr., Graves JR, Hambly C. An innovative approach to medical control: semiautomatic defibrillators with solid-state memory modules for recording cardiac arrest events. Ann Emerg Med. 1988;17:818-824.

34. Sunde K, Eftestol T, Asenberg C, Steen PA. Quality assessment of defibrillation and advanced life support using data from the medical control module of the defibrillator. Resuscitation. 1999;41:237-247.

35. Sedgwick ML, Watson J, Dalziel K, Carrington DJ, Cobbe SM. Efficacy of out of hospital defibrillation by ambulance technicians using automated external defibrillators: the Heartstart Scotland Project. Resuscitation. 1992;24:73-87.

36. Jakobsson K, Nyquist O, Rehnqvist N. Effects of early defibrillation of out-of-hospital cardiac arrest patients by ambulance personnel. European Heart J. 1987;8:1189-1194.

37. Dickey W, Dalzell GW, Anderson JM, Adgey AA. The accuracy of decision-making of a semi- automatic defibrillator during cardiac arrest. European Heart J. 1992;13:608-615.

38. Jaggarao NS, Heber M, Grainger R, Vincent R, Chamberlain DA, Aronson AL. Use of an automated external defibrillator-pacemaker by ambulance staff. Lancet. 1982;2:73-75.

39. Kerber RE, Martins JB, Kienzle MG, Constantin L, Olshanky B, Hopson R, Charbonnier F. Energy, current and success in defibrillation and cardioconversion: clinical studies using an automated impedance-based method of energy adjustment. Circulation. 1988;77:1038-1046.

40. Geddes LA, Tacker WA, Rosborough JP, Moore AG, Cabler PS. Electrical dose for ventricular fibrillation of large and small animals using precordial electrodes. J Clin Investigation. 1974;53:31-319.

41. Dahl C, Ewy G, Warner E, et al. Myocardial necrosis from direct current countershock. Circulation. 1974;50:956.

42. Weaver WD, Cobb LA, Copass MK, Hallstrom AP. Ventricular defibrillation: a comparison trial using 175 J and 320 J shocks. New England Journal of Medicine. 1982;307:1634-1643.

43. Bardy GH, Gliner, BE, Kudenchuk, PJ, Poole, JE, Dolack, GL, Jones, GK, Anderson, J, Troutman, C, Johnson, G. Truncated biphasic pulses for transthoracic defibrillation. Circulation. 1995;91:1768-1774.

44. Bardy GH, Marchlinski FE, Sharma AD, et al. Transthoracic Investigators. Multicenter comparison of truncated biphasic shocks and standard damped sine wave monophasic shocks for transthoracic ventricular fibrillation. Circulation. 1996;94:2507-2514.

45. Higgins SL, Herre JM, Epstein AE, et al. A comparison of biphasic and monophasic shocks for external defibrillation. Prehospital Emergency Care. 2000;4:305-313

46. Weisfeldt ML, Kerber RE, McGoldrisk RP, et al. for the Automatic Defibrillation Task Force. Public access to defibrillation. Am J Emerg Med. 1966;14:684-692.

47. Guidelines for Public Access Defibrillation Programs in Federal Facilities. Federal Register. 66FR28495, May 23, 2001.

48. Emergency Medical Equipment: Final Rule. Federal Register. 66FR19027, April 21, 2001.

49. National Conference on State Legislatures, Washington, DC. State laws on heart attacks and defibrillators: Encouraging a community access response, February 2001. http://www.ncsl.org/programs/health/aed.htm.

50. Cardiac Arrest Survival Act. http://frwebgate.access.gpo.gov/cgibin/getdoc.cgi?dbname=106_cong_public_laws&docid=f:publ505.106.

51. Guidelines 2000 for cardiopulmonary resuscitation and emergency cardiovascular care. International consensus on science. Circulation. 2000;102(suppl):1-384.

52. Bloodborne Pathogens Standard. Occupational Safety and Health Administration. CFR 1910.1030.

53. American Heart Association Heartsaver AED for the Lay Rescuer and First Responder. Dallas, TX, 1998.

54. American Heart Association Advanced Cardiac Life Support Provider Manual. Dallas, TX, 2001.

Return to Policies and Position Statements

Close Window

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

Community Lay Rescuer Automated External Defibrillation Programs. Key State Legislative Components and Implementation Strategies. A Summary of a Decade of Experience for Healthcare Providers, Policymakers, Legislators, Employers, and Community Leaders From the American Heart Association Emergency Cardiovascular Care Committee, Council on Clinical Cardiology, and Office of State Advocacy

Tom Aufderheide, Mary Fran Hazinski, Graham Nichol, Suzanne Smith Steffens, Andrew Buroker, Robin McCune, Edward Stapleton, Vinay Nadkarni, Jerry Potts, Raymond R. Ramirez, Brian Eigel, Andrew Epstein, Michael Sayre, Henry Halperin and Richard O. Cummins

Circulation published online Jan 16, 2006;
DOI: 10.1161/CIRCULATIONAHA.106.172289
Circulation is published by the American Heart Association. 7272 Greenville Avenue, Dallas, TX 72514
 Print ISSN: 0009-7322. Online ISSN: 1524-4539

Community Lay Rescuer Automated External Defibrillation Programs

Key State Legislative Components and Implementation Strategies

A Summary of a Decade of Experience for Healthcare Providers, Policymakers, Legislators, Employers, and Community Leaders From the American Heart Association Emergency Cardiovascular Care Committee, Council on Clinical Cardiology, and Office of State Advocacy

Tom Aufderheide, MD; Mary Fran Hazinski, RN, MSN; Graham Nichol, MD, FAHA; Suzanne Smith Steffens; Andrew Buroker, JD; Robin McCune; Edward Stapleton, EMT-P; Vinay Nadkarni, MD, FAHA; Jerry Potts, PhD, FAHA; Raymond R. Ramirez, MA, JD; Brian Eigel, PhD; Andrew Epstein, MD, FAHA; Michael Sayre, MD; Henry Halperin, MD, FAHA; Richard O. Cummins, MD, MPH, MSc

Abstract— Cardiovascular disease is a leading cause of death for adults ≥40 years of age. The American Heart Association (AHA) estimates that sudden cardiac arrest is responsible for about 250 000 out-of-hospital deaths annually in the United States. Since the early 1990s, the AHA has called for innovative approaches to reduce time to cardiopulmonary resuscitation (CPR) and defibrillation and improve survival from sudden cardiac arrest. In the mid-1990s, the AHA launched a public health initiative to promote early CPR and early use of automated external defibrillators (AEDs) by trained lay responders in community (lay rescuer) AED programs. Between 1995 and 2000, all 50 states passed laws and regulations concerning lay rescuer AED programs. In addition, the Cardiac Arrest Survival Act (CASA, Public Law 106-505) was passed and signed into federal law in 2000. The variations in state and federal legislation and regulations have complicated efforts to promote lay rescuer AED programs and in some cases have created impediments to such programs. Since 2000, most states have reexamined lay rescuer AED statutes, and many have passed legislation to remove impediments and encourage the development of lay rescuer AED programs. The purpose of this statement is to help policymakers develop new legislation or revise existing legislation to remove barriers to effective community lay rescuer AED programs. Important areas that should be considered in state legislation and regulations are highlighted, and sample legislation sections are included. Potential sources of controversy and the rationale for proposed legislative components are noted. This statement will not address legislation to support home AED programs. Such recommendations may be made after the conclusion of a large study of home AED use. (*Circulation.* 2006;113:0000-0000.)

Key Words: AHA Scientific Statements ■ fibrillation ■ defibrillation ■ resuscitation ■ sudden cardiac arrest

Cardiovascular disease is a leading cause of death for adults ≥40 years of age.[1,2] The American Heart Association (AHA) estimates that sudden cardiac arrest is responsible for ≈250 000 out-of-hospital deaths annually in the United States.[3] Since the early 1990s, the AHA has called for innovative approaches to reduce time to cardiopulmonary resuscitation (CPR) and defibrillation and improve outcome from sudden cardiac arrest.[4] In the mid-1990s, the AHA launched a public health initiative to promote early CPR and early use of automated external defibrillators (AEDs) by trained lay responders in community public access defibrillation (PAD) programs.[5–7] In 1998, in response to requests

The American Heart Association makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest.

This statement was approved by the American Heart Association Science Advisory and Coordinating Committee on November 4, 2005. A single reprint is available by calling 800-242-8721 (US only) or writing the American Heart Association, Public Information, 7272 Greenville Ave, Dallas, TX 75231-4596. Ask for reprint No. 71-0352. To purchase additional reprints: up to 999 copies, call 800-611-6083 (US only) or fax 413-665-2671; 1000 or more copies, call 410-528-4121, fax 410-528-4264, or e-mail kramsay@lww.com. To make photocopies for personal or educational use, call the Copyright Clearance Center, 978-750-8400.

Expert peer review of AHA Scientific Statements is conducted at the AHA National Center. For more on AHA statements and guidelines development, visit http://www.americanheart.org/presenter.jhtml?identifier=3023366.

Circulation is available at http://www.circulationaha.org

DOI: 10.1161/CIRCULATIONAHA.106.172289

from its training network, the AHA circulated an internal report to assist in developing legislation that would remove barriers to these programs.[8]

Between 1995 and 2000, all 50 states passed laws and regulations governing lay rescuer AED programs. In 2000, the Cardiac Arrest Survival Act (CASA) was passed and signed into federal law (Public Law 106-505). CASA called for the development of guidelines for establishing AED programs in federal buildings. CASA provides limited immunity from civil liability for the emergency AED user and the AED acquirer if the state has not otherwise granted immunity for such persons under other statutes. Since 2000, most states have reexamined lay rescuer AED statutes, and many have passed legislation giving grants to local governments to obtain AEDs and to require AEDs or AED programs in certain venues (eg, state buildings, health clubs).

The AHA applauds state and federal policymakers and advocates across the country for enacting lifesaving legislation to promote lay rescuer AED programs. After a decade of experience, the AHA has collected information about policies, legislation, and regulations and their impact on the establishment and success of community lay rescuer AED programs.

The purpose of this policy statement is to help policymakers develop new legislation or revise existing legislation to remove barriers to effective community lay rescuer AED programs. Important areas that should be considered in state legislation and regulations are highlighted, and examples of model legislation are included. Potential sources of controversy and the rationale for proposed legislative components are noted. This statement will not address legislation to support home AED programs. Such recommendations may be made after the conclusion of a large study of home AED use.

Background

As noted above, the AHA estimates that ≈250 000 deaths are caused by coronary artery disease in the out-of-hospital setting annually in the United States.[3] This number is commonly accepted as a surrogate for the number of sudden cardiac arrests that occur in the out-of-hospital setting annually. The median published rate of survival to hospital discharge for witnessed sudden cardiac arrest in the United States is 6.4%.[9–11]

In the first minutes after collapse, many victims of witnessed sudden cardiac arrest demonstrate an abnormal heart rhythm called ventricular fibrillation (VF), which causes the heart to quiver so that it does not pump blood effectively.[12] Treatment of VF requires delivery of a shock with a defibrillator. Delivery of a shock can stop VF (defibrillation), allowing the victim's normal heart rhythm to resume. The victim needs CPR to maintain blood flow to the heart and brain until a defibrillator is available and often requires CPR in the first minutes *after* defibrillation until the heart is able to pump blood effectively.[13,14] CPR is important both before[15] and after[16] defibrillation for improving survival from VF sudden cardiac arrest. Even a brief interruption of chest compression can be detrimental.[17]

AEDs are highly accurate, user-friendly computerized devices with voice and audio prompts that guide the user through the critical steps of operation. AEDs were designed for use by lay rescuers and first responders to reduce time to defibrillation for victims of VF sudden cardiac arrest.[18] The rescuer turns the AED on and attaches it to the victim with adhesive electrodes or pads. The AED records and analyzes the victim's cardiac rhythm. If a shock is indicated, the AED charges to the appropriate energy level and prompts the rescuer to deliver a shock. If the device is fully automated and a shock is indicated, the AED can deliver a shock without further action by the rescuer. AEDs require little maintenance and are relatively inexpensive (<$2000).

As of August 8, 2005, the US Food and Drug Administration (FDA) classified AEDs as Class 3 medical devices, with most requiring a prescription. This means that AEDs require "special controls" to ensure their safety and effectiveness. One goal of the prescription requirement is to ensure that AEDs are used in organized programs with appropriate planning and oversight, appropriate training of anticipated rescuers, and appropriate monitoring of the quality of care associated with use of these devices. Although the AHA strongly supports these program elements, it could find no published evidence that the prescription requirement itself increased the likelihood of rescuer training or effective AED use. In 2004, the FDA cleared the labeling of one commercially available AED without a prescription. It is anticipated that similar labeling will be cleared for more AEDs in the near future. Such labeling may make AEDs available for home use. At this time there is insufficient evidence for the AHA Emergency Cardiovascular Care (ECC) Committee to make recommendations about home AED programs.

Successful lay rescuer AED programs should increase the survival rate of victims of witnessed VF sudden cardiac arrest. Two factors have a significant impact on adult survival from VF sudden cardiac arrest: the time from collapse to defibrillation and the time from collapse to CPR. If no CPR is provided, for every minute of delay between collapse and defibrillation, the victim's chance of survival from VF sudden cardiac arrest falls by 7% to 10%.[19,20] If bystander CPR begins immediately after collapse, the fall in survival is more gradual, decreasing ≈3% to 4% for every minute between collapse and defibrillation.[19,20] Survival-to–hospital discharge rates of 49% to 74% have been reported in airports,[21] commercial airlines,[22,23] casinos,[24] and community police AED programs[16,25–28] when a victim of witnessed VF sudden cardiac arrest receives immediate bystander CPR and shock delivery within 3 to 5 minutes of collapse. Bystander CPR can double[19,20] or triple[29] survival rates at many intervals to defibrillation. AED programs that fail to shorten time to defibrillation and time to bystander CPR have not documented any improvement in survival rates.[30]

In 2000, to determine the effectiveness of community lay rescuer AED programs on survival from out-of-hospital sudden cardiac arrest in a large prospective study, the AHA joined the National Heart, Lung, and Blood Institute (NHBLI) and others to fund a randomized controlled trial of community lay rescuer AED programs. In this study, the Public Access Defibrillation (PAD) trial,[31] nearly 20 000 rescuers were trained in 993 facilities in 24 urban and suburban regions in North America. The trial reported the

outcome of attempted resuscitation in 239 episodes of out-of-hospital sudden cardiac arrest. In this study, all lay rescuers in all study units were trained to recognize emergencies, phone 9-1-1, and provide CPR. Lay rescuers in half of the study sites were also trained and equipped to use AEDs. Fifteen victims of VF sudden cardiac arrest treated in lay rescuer CPR programs without AEDs survived to hospital discharge. During the same period, 30 victims of VF sudden cardiac arrest who were treated in programs that also included early defibrillation with AEDs survived to hospital discharge.[31] The differences between the programs were statistically significant and supported the authors' conclusion that promotion of organized lay rescuer AED programs could save thousands of lives in the United States every year.

Grassroots support for community lay rescuer AED programs has been strong, but placement of AEDs and their use by lay rescuers have raised concerns about legal liability for rescuers, owners of the premises on which AEDs are placed, buyers of AEDs, physician prescribers (if appropriate) of AEDs, public defibrillation program directors, and persons responsible for rescuer training. These nonrescuer program participants are referred to as "facilitators" in this statement.

Questions also have been raised about the amount of training and support required to establish the programs. In the PAD trial, even when extensive initial training was provided to anticipated rescuers, bystander CPR was performed for only ≈65% of the victims of sudden cardiac arrest, and AEDs delivered shocks to only 34% of victims at sites where rescuers were trained and equipped to use AEDs.[31] These results show that even in a well-designed lay rescuer AED program, training in CPR as well as AED use is needed.

Successful community lay rescuer programs require attention to planning as well as training. For example, AEDs must be placed in conspicuous locations, and rescuers must rehearse early recognition of an emergency, early call to the emergency medical services (EMS) system, early CPR, and early defibrillation. The program must be linked with the EMS system and must have a plan for retraining and ongoing quality improvement.

Legislative Efforts to Support Community Lay Rescuer AED Programs

As noted above, all states have legislation or regulations to facilitate lay rescuer AED programs, but these laws and regulations and their components vary widely from state to state. A complete list of existing state legislation and regulations is available at the AHA Web site (www.americanheart.org/statepolicy).

The passage of CASA in 2000 played an important role in triggering the acceptance of AEDs as lifesaving devices and setting the standards for immunity protection for AED use. As noted above, CASA provides limited immunity for rescuers and, under some conditions, for those who acquire AEDs. CASA "supersedes the law of the state" if the state "has no statute or regulations to provide persons in such class with immunity from civil liability for. . .[the use]. . .of automated external defibrillator devices in emergency situations." At the time CASA was enacted, it filled the gap in liability protection for AED acquirers in ≈12 states.

Essential Elements of Community AED Programs

The AHA has identified 4 essential elements of AED programs.[32,33] These elements have been ratified by experts of the AHA ECC Committee as important for increasing survival from witnessed prehospital VF sudden cardiac arrest. These program elements are briefly described below, and they are further explained in the subsequent discussion of key legislation elements.

1. **Planned and practiced response.** The AHA recommends planning and oversight of community lay rescuer AED programs by a person with experience and expertise in resuscitation programs. Such a person is typically a health-care professional with experience in occupational health, emergency, or cardiovascular care. The program director decides on the number and location of AEDs placed. AEDs should be placed where there is a high likelihood of sudden cardiac arrest. In the PAD trial, such locations had the equivalent of ≥250 adults >50 years of age present for 16 hours per day or a history of an average of ≥1 witnessed sudden cardiac arrest every 2 years.[31] The local EMS agency may provide useful information on placement of AEDs (see below). When possible, AEDs should be placed where they can be reached within a short (1 to 1½ min) brisk walk from all areas in the program site. The program director helps to decide whether AEDs should be placed in a highly visible location to facilitate their use by bystanders who are not part of the organized response plan. The program director also oversees the training and retraining of anticipated rescuers, confirms that devices are properly maintained, develops a mechanism to report AED use, establishes a link to the local EMS service, evaluates AED use, and supports a process of quality improvement.
2. **Training of anticipated rescuers in CPR and use of the AED.** This element does not require training of every *potential* rescuer but does require the training of *anticipated* rescuers. Thus, rescuers who are likely to be present should be trained, but the site should not be expected to train every person who could possibly be present. The goal is to ensure that a trained rescuer is present at all times (eg, during business hours). In training, high priority should be placed on recognizing the emergency; phoning 9-1-1; providing CPR and early defibrillation; and using an AED in a safe, appropriate, and effective manner. CPR training should stress that rescuers must deliver effective chest compressions with minimal interruption.[33] Training should include practice in response to a simulated arrest at regular intervals so that responders are familiar with their roles in the resuscitation effort.
3. **Link to the local EMS system.** At a minimum, the program director should inform the local EMS dispatcher that an AED program has been established and give the type and location of AED(s) on site. The AED program must develop a reporting procedure with the EMS system to share patient information. The EMS system also may be able to give information about public locations where sudden cardiac arrest has occurred or provide personnel or other resources to help establish the program and the process of ongoing quality improvement (see below). Each community must decide on the best course of action for its members.
4. **A process of continuous quality improvement, including a plan for on-site AED maintenance and readiness-**

for-use checks. Quality improvement protocols should be used to evaluate the program response to any cardiac arrest. The *Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care* recommended that programs establish a goal of ≤90 seconds from arrival of the AED at the victim's side to delivery of the first shock.[32] Program directors and participants must identify and eliminate factors that cause delay in CPR or delivery of the first shock with the AED. In airports[21] and casinos,[24] high rates of survival to hospital discharge after witnessed VF arrest have been documented when immediate CPR was provided and defibrillation occurred within 3 to 5 minutes of the victim's collapse. In the casino study, the rate of survival from witnessed VF sudden cardiac arrest was 74% when the first shock was delivered within 3 minutes but fell to 49% when the first shock was delivered between 3 and 5 minutes after collapse.[20] In the airport study,[21] the rate of survival from witnessed VF sudden cardiac arrest was 74%; all victims received bystander CPR, and a shock was delivered within 5 minutes of collapse. In that study, AEDs were located within a brisk 1-minute walk from any location.

Additional information on AED program implementation is available at http://www.americanheart.org/presenter.jhtml?identifier=3027304.

Recommended State AED Legislation

In general, advocates for AED legislation will need to adapt legislation for each state, but all AED legislation should be broad enough to be "permissive" or "facilitating." The AHA has a policy Web site (www.americanheart.org/statepolicy) to assist policymakers in developing legislation tailored to their state's needs.

The legislation typically begins with a preamble to document the need for the legislation and its potential benefits. Specific sections within the legislation should recommend important program components without "micromanaging" implementation. The AHA recommends addressing these 4 key components in AED legislation:

1. Good Samaritan limited immunity (without qualification) for rescuers and program facilitators
2. CPR and AED training for anticipated rescuers
3. Link with the EMS system
4. Support of the following program elements to increase the likelihood of successful resuscitation of victims of sudden cardiac arrest:
   a. Planned and practiced response
   b. Plan for training of anticipated rescuers in CPR and use of an AED
   c. Plan for link with EMS system
   d. Plan for ongoing process of quality improvement, including evaluation of each episode of sudden cardiac arrest, on-site maintenance, and readiness-for-use checks

State AED Legislation Preamble

Simple yet powerful statistics support this type of AED legislation. First, the legislation should note the approximate number of state deaths from sudden cardiac arrest. The number of state deaths can be found in state reports, or advocates can use the population of the state to estimate this number (see Table 1). The estimated incidence of sudden cardiac arrest reported in the United States is 0.55 per 1000 (55 per 100 000).[1,2,31,34,35]

TABLE 1. Preamble for State Legislation Supporting Community Lay Rescuer Automated External Defibrillation Programs

- Whereas out-of-hospital sudden cardiac arrest results in the death of approximately 55 persons/100 000 population per year and approximately 20% of these arrests are caused by sudden ventricular fibrillation that occurs in the presence of witnesses (so-called "witnessed ventricular fibrillation sudden cardiac arrest"), and
- Whereas, in the population of (state), approximately (state population* divided by 1818) citizens will die of cardiac arrest every year, and
- Whereas lay rescuer programs that provide early recognition, early cardiopulmonary resuscitation, and early defibrillation within the first minutes of a cardiac arrest can increase survival of victims of witnessed ventricular fibrillation sudden cardiac arrest by 7 times or more and so should save an estimated (the state population* divided by 27 750) or more additional victims of sudden cardiac arrest every year in this state, and
- Whereas automated external defibrillators are extremely accurate computerized devices that can be operated by laypersons with minimal training, and
- Now, therefore, be it enacted by the ____ of the State of ____, etc.

Note: This increase in survival rate is derived from the estimated frequency of sudden cardiac arrest in the population (55/100 000 population per year) and predicted improvement in survival of witnessed VF sudden cardiac arrest with activation of a community lay rescuer AED program. An estimated 20% of all episodes of sudden cardiac arrest are witnessed VF arrests (most in public places). The estimated increase in survival is conservatively calculated as an increase from ≈6% survival of victims of witnessed VF sudden cardiac arrest with delayed CPR and defibrillation to survival of ≥40% of victims of witnessed VF sudden cardiac arrest with prompt recognition, early CPR, and early defibrillation. Therefore, of the 11 people who die of witnessed VF sudden cardiac arrest per year per 100 000 population, ≥40% (4.4 per 100 000 per year) would be expected to survive with establishment of community lay rescuer AED programs.

Key Components in Legislation to Facilitate Successful Community Lay Rescuer AED Programs

Good Samaritan Limited Immunity for Rescuers and Program Facilitators

Key: Good Samaritan Limited Immunity for Rescuers

A major impediment to lay rescuer use of AEDs is the failure to provide Good Samaritan limited immunity to lay rescuers who use AEDs in emergencies. Good Samaritan legislation is intended to protect rescuers from civil liability as long as the rescuer provides reasonable and prudent care in good faith. The AHA recommends that state legislation extend Good Samaritan limited immunity to any AED user, without conditions such as a requirement for training. Good Samaritan limited immunity should extend to anyone who acts in good faith, without specific compensation, as a reasonable and prudent person with the same level of training would respond. Although training of anticipated rescuers is recommended, Good Samaritan limited immunity should cover serendipitous or unexpected users who act in good faith.

Many states have removed an important impediment to the establishment of community lay rescuer AED programs by

TABLE 2. Sample Wording of Legislation to Address Good Samaritan Limited Immunity for AED Users

Wording That May Create an Impediment (Not Recommended)*	Wording That May Facilitate Legislation (Recommended)†
"Any person who has attended and successfully completed a course in cardiopulmonary resuscitation that has been approved by the State Board of Health, who in good faith and without compensation, renders or administers emergency cardiopulmonary resuscitation, cardiac defibrillation, including, but not limited to, the use of an automated external defibrillator . . . shall not be liable."	"Any person who in good faith and without compensation renders or administers emergency cardiopulmonary resuscitation, cardiac defibrillation, including, but not limited to, the use of an automated external defibrillator . . . shall not be liable."

*From House Bill 2097, General Assembly of Virginia, 1999 (amended in 2003). The 1999 legislation was amended because it required training as a condition for Good Samaritan limited immunity. This created an expectation for serendipitous rescuers that is more stringent than for any other Good Samaritan acts.

†From House Bill 1860, General Assembly of Virginia, 2003.

extending Good Samaritan limited immunity to lay rescuers who use the AED as part of gratuitous service in an emergency. CASA also provides limited immunity for lay rescuers in federal buildings. Some states, however, have added conditions to the limited immunity provision for lay rescuers, even when rescuers operate as Good Samaritans. Such conditions can create impediments to establishment of community AED programs (see Table 2).

As noted above, Good Samaritan laws typically require that emergency care be rendered gratuitously, or they differentiate Good Samaritan care from that delivered by healthcare professionals in the context of employment. Responders such as police officers and firefighters who are required to provide CPR and use AEDs in the course of their duties still can be considered Good Samaritans if they are not specifically paid for the attempted resuscitation itself. For example, the Good Samaritan statute may state, "For purposes of this section, the term 'compensation' shall not be construed to include the salaries of police, fire, or other public officials or personnel who render such emergency service." These potential rescuers are typically paid the same salary whether or not they are called on to render aid on a given day: They receive no specific compensation for the emergency response or rescue, so their response is considered gratuitous.

Corporations may attempt to maintain Good Samaritan status for their employees who are AED rescuers by requesting that employees volunteer for resuscitation training and rescue "duty" and be trained and equipped to provide CPR and use an AED. Whether this approach is helpful for a specific entity must be assessed on the basis of local laws and after consultation with competent counsel and risk-management professionals.

Some corporations have added insurance riders to existing policies to cover AED use by their personnel. The Las Vegas gaming casinos, for example, took this approach to their AED program, in which security officers were trained in AED use.[24] The purchase of insurance riders for lay rescuers is not the norm, however.

In recent years, some insurance carriers have advised policyholders that placement of AEDs on a property is covered under a general liability plan. In fact, some insurance companies offer resources to encourage the development of community lay rescuer AED programs. For example, some insurers offer grants for the purchase of AEDs.[36]

In some states, opposition to broadening of the Good Samaritan legislation raises the concern that actions beyond ordinary and simple negligence (ie, *gross negligence, willful or wanton behavior, flagrant indifference to safety, intent to harm*, and other standards set out by specific states) will be protected by such amendments to the Good Samaritan legislation. However, Good Samaritan *limited* immunity means that immunity is limited to simple negligence.

The definition of misuse of the AED that constitutes an action beyond simple negligence will need to be determined by the courts. Risk of negligent use of an AED is reduced by recommended program components, such as approved training of designated or likely (anticipated) rescuers in CPR and use of the AED, course supervision, and skills review—a classic risk-management approach. A standard, broad-based Internet search and a search by legal search services for reported cases[37] and news stories about allegations of or awards for negligent use of AEDs did not reveal any such claims at the time this statement went to press. Although these search techniques have inherent limitations, we are unaware at this time of any claims alleging negligent use of AEDs. This information is not intended to provide legal advice or endorsements of any specific services. A lawyer should be consulted about the application of this information to particular situations.

Recommended: Good Samaritan Limited Immunity for AED Program Facilitators

Another impediment to development and implementation of AED programs has been the lack of limited immunity from legal action for several groups involved in AED programs. These groups include premises owners, AED acquirers, program directors, and trainers; these are referred to collectively as program facilitators.

Limited Immunity for Premises Owners and AED Acquirers. Major insurance carriers now routinely provide liability insurance without additional charge for sites or buildings where AEDs are placed. Some insurers offer discounts in liability insurance premiums when AED programs are established, and some insurance carriers have developed educational materials to support the establishment of community lay rescuer AED programs. Although premises owners may fear liability resulting from the use of an AED, such liability is likely to be very limited. We are aware of no lawsuits filed against lay rescuers or premises owners related to the attempted use of an AED in a Good Samaritan effort to save the life of a victim of prehospital cardiac arrest. The only lawsuits identified[37] cited failure to have AEDs on the premises. As

TABLE 3. Sample Wording of Legislation to Address Good Samaritan Limited Immunity for AED Owners/Acquirers

Example of Recommended Wording for Facilitating Legislation
Section 1. Article 1B of Chapter 90 of the General Statutes is amended by adding a new section to read: § 90–21.15. Emergency treatment using automated external defibrillator; immunity. (a) It is the intent of the General Assembly that, when used in accordance with this section, an automated external defibrillator may be used during an emergency for the purpose of attempting to save the life of another person who is in or who appears to be in cardiac arrest. . .(d) . . . the person responsible for the site where the automated external defibrillator is located when the person has provided for a program of training. . .shall be immune from civil liability arising from the use of an automated external defibrillator.

Modified from Senate Bill 1269, North Carolina General Assembly, 2000.

noted above, CASA provides limited immunity for the AED acquirer if not already provided or specified under state legislation. The AED acquirer can be a tenant or property manager of a building owned by another entity. In such cases, although the manager may have limited immunity, the building owner may not. CASA limited immunity may not apply if harm to the victim arises from one of the following:

- Failure to establish a link with the local EMS system
- Failure to properly maintain the AED
- Failure to train expected responders in the use of the AED

Ideally, state legislation will extend Good Samaritan limited immunity to premises owners (see Table 3) and the AED owner/acquirer, even in the event of the failures listed above.

Limited Immunity for Physician Prescribers and Facilitators. In recent years, the price of malpractice coverage for AED program prescription and oversight has fallen. If this trend continues, it is anticipated that there will be no additional cost of medical malpractice insurance for physicians who prescribe AEDs. In addition, if the FDA clears more AEDs for use without a prescription, the prescription requirement may gradually be eliminated. As noted above, the AED program is most likely to improve survival from witnessed VF sudden cardiac arrest if the program includes a planned and practiced response, appropriate training and equipment, a link with the local EMS system, and a process of ongoing quality improvement. Whether or not a prescription is required, it is helpful if a healthcare provider or resuscitation expert oversees the planning and implementation of the program, including training, monitoring of quality

TABLE 4. Sample Wording of Legislation to Address Limited Immunity for Physician Facilitators and Program Directors

Example of Recommended Wording to Address Limited Immunity for Physician Facilitators and Program Directors
"Immunity from civil liability will be provided to: (3) Any physician or other medical professional who authorizes, directs, or supervises the installation or provision of automated external defibrillator equipment in or on any premises or conveyance other than a medical facility."

Modified from Senate Bill 51, Georgia House of Representatives, 2001; GA Code 51–1-29.3.

TABLE 5. Sample Wording of Legislation to Address Limited Immunity for Trainers of Anticipated AED Rescuers

Example of Recommended Wording to Address Limited Immunity for Trainers
"No person or entity which teaches or provides a training program for cardiopulmonary resuscitation that includes training in the use of automated external defibrillators shall be held liable for any civil damages as a result of such training or use if such person or entity has provided such training in a manner consistent with the usual and customary standards for the providing of such training."

Modified from Senate Bill 132, Kansas State Legislature, 2003; K.S.A. 65–6149a.

improvement, device maintenance, and link to the EMS system. If limited immunity is provided to physician facilitators (eg, prescribers where applicable) or program directors, the wording may follow that in Table 4.

Limited Immunity for Trainers. Trainers of anticipated AED program rescuers have not been granted limited immunity in most states, and they are not mentioned in CASA. When state legislation provides Good Samaritan limited immunity for trainers, the immunity typically specifies that the trainer must deliver training in accordance with the guidelines and policies of an approved or national training organization and the trainer must be authorized to deliver that course or curriculum (see Table 5).

Key: CPR and AED Training for Anticipated Lay Rescuers

Although limited immunity for lay rescuers should not be contingent on training, the AHA strongly recommends that AED programs ensure the training of anticipated rescuers in CPR and use of AEDs. This training should include early recognition of signs of cardiac arrest; indications for phoning 9-1-1; and training in rescue breathing, chest compressions, and safe and efficient use of an AED. These rescuer actions are time critical and require not only initial training but frequent retraining to maintain effective responses. Many community lay rescuer AED programs have documented the link between prompt rescuer actions (recognition of the emergency, early CPR, and shock delivery within 3 to 5 minutes) and survival from VF sudden cardiac arrest.[16,21,24,26,28,30,38]

Although AEDs are user friendly and the steps in their operation are often intuitively obvious, the effectiveness of an AED for cardiac arrest requires more than simple operation. The rescuer must know when to use an AED (ie, recognize cardiac arrest), how to operate it, how to troubleshoot it (eg, a hairy or sweaty chest may prevent good contact between the skin and electrode pads), and how to combine AED use with CPR.

CPR remains a critical component of a successful AED program for several reasons. First, the rescuer must recognize sudden cardiac arrest (ie, the victim is unresponsive and not breathing). Because immediate bystander CPR improves survival from VF sudden cardiac arrest,[15,19,20,29,39] the rescuer also should be able to perform CPR until the AED is available and after a shock ends VF. In a prospective analysis of VF waveform during resuscitation of victims of VF cardiac

arrest, predicted survival from VF was increased when the interval between interruption of chest compressions and delivery of the shock was kept to ≤15 seconds.[17] The efficient integration of CPR with AED use requires training and frequent practice. In addition, improvements in AED rhythm recognition and function are needed to minimize the time required for the AED to analyze the victim's rhythm, recommend shock delivery, charge, and deliver a shock. Such improvements will reduce interruptions in chest compressions. Additional improvements may also include the ability of AEDs to perform analysis with CPR in progress.

Recent studies have also shown that both prehospital[40] and in-hospital[41] healthcare providers deliver compressions of insufficient depth and interrupt compressions too often during CPR. Such reports support the need for stringent CPR training and frequent practice to ensure that rescuers can deliver compressions of correct depth and can minimize interruptions of chest compressions during CPR.

It is important to note that few victims with VF cardiac arrest demonstrate an organized rhythm at 60 seconds after elimination of VF by shock.[13,42] Many demonstrate pulseless electrical activity in the first minutes after successful defibrillation.[14,42] The victim of VF cardiac arrest requires CPR until the heart is able to pump blood effectively.

For all of these reasons, anticipated rescuers should be trained in a course that integrates CPR and use of the AED. It is important to include the recommendation for training and frequent retraining of anticipated rescuers in community lay rescuer AED legislation.

Key: Link With EMS System

The director of a community lay rescuer AED program should inform the EMS system that an AED is on site. State EMS lead agencies request this notification, and it should be listed as an expectation. The owner "shall" notify rather than "is requested to" or "is encouraged to" in state AED legislation.

Notification of the EMS system is helpful for several reasons. The EMS agency can serve as the interface between the AED program and the public service answering agency. If the dispatcher knows the type and location of an AED at the site of the emergency, the dispatcher can direct the rescuer to get the AED and can coach the rescuer in both CPR and AED use. If the EMS agency wants to be more involved, the agency may help train expected AED users and may play an important role in the continuous quality improvement process of the program. Finally, EMS notification is important because EMS providers will need to obtain data from any AED used to treat cardiac arrest.

Some states have legislated the establishment of an AED "registry," requiring that AED programs be registered with the local EMS agency. The purpose of such registries is to ensure that EMS dispatchers know where AEDs are placed so that they can direct a 9-1-1 caller to get and use an AED that is on site. Some states, such as Utah (Senate Bill 95/2003) and New Hampshire (Senate Bill 386/2002), have established statewide registries for the collection and distribution of information on the location of commercially owned devices. If state EMS agencies support the term "registration," it can be used. A formal registration system may be too costly and burdensome for small volunteer EMS programs, though, so for this reason, the term "notification" is recommended.

Recommended: Support of "Best Practice" Program Elements

The program director should evaluate any episode of sudden cardiac arrest at the program site and evaluate the performance of rescuers and the use of the AED. This is done to reduce time to CPR and time to delivery of a shock, helping the program achieve the goal of improving the rate of survival from sudden cardiac arrest. The continuous quality improvement process should include EMS personnel if possible.

The AED should be stored and maintained according to the manufacturer's recommendations and the recommendations provided in nationally accepted courses in CPR and use of AEDs.[43,44] Newer AEDs conduct internal battery and circuitry checks continuously and visually indicate when service or a battery change is needed. This "design for dormancy" means that minimal maintenance is necessary, such as a "readiness-for-use" visual check for "service needed" or other status indicator, confirmation of the physical integrity of the device, and a check of the contents of the carrier case. A checklist from the AED manufacturer can be copied and posted near the AED and initialed and dated to confirm that the device is checked at appropriate intervals.

The AHA recommends that the AED be stored in a carrying case near a telephone so that the device can be retrieved when 9-1-1 is phoned.[43,44] Placing the AED near a telephone shortens the time to EMS call and AED retrieval and simplifies teaching and EMS instructions. Consistent use of these common-sense recommendations will facilitate training and dispatcher instructions.

Related AHA Public Policy Initiatives

On any given day, up to 20% of the combined US adult and child population can be found in school. Although sudden cardiac arrest is much less common in children than in adults, it can occur in children and adolescents. Parents of children who have died suddenly have started a strong grassroots effort to create AED programs in schools. In response to questions about such programs and the increasing potential for medical emergencies in schools, the AHA issued a scientific statement that recommends that schools develop a medical emergency response plan[45] to deal with a variety of life-threatening conditions, including sudden cardiac arrest. The complete statement is available on the AHA Web site (http://circ.ahajournals.org/cgi/content/full/109/2/278).

The AHA recommends that school medical emergency response plans have the following components: an effective and efficient system of campus-wide communication, a coordinated and practiced response plan, risk reduction, training and equipment for first aid and CPR, and a lay rescuer AED program in schools with an established need.[45] After considering several factors, some schools may decide that a need exists for a lay rescuer AED program. For example, schools with a large number of adult employees, volunteers, and visitors or schools with large, sprawling campuses that are not quickly accessible to EMS systems may wish to establish a lay rescuer AED program.

TABLE 6. Key Program Components to Recommend in State AED Legislation

1. Limited immunity for rescuers (key) and facilitators (recommended):

- *Good Samaritan limited immunity for rescuers that is not dependent on training.* The statute should confer *limited immunity to lay rescuers who use AEDs.* This limited immunity should not be conditional on nor require training for the good faith effort to be covered.
- Good Samaritan limited immunity for program facilitators, including premises owners, AED acquirers, trainers, and physician prescribers (where applicable).

2. Recommendation for training of anticipated/expected rescuers. Training should integrate both CPR and AED skills. Note that this does not affect serendipitous AED users/bystanders who happen upon the scene.

The statute *should require training of expected rescuers in an approved course that integrates both CPR and AED skills.* To maintain utmost flexibility with the training requirement, the statute should not prescribe a specific number of hours needed for a rescuer to be considered "trained."

3. Link with EMS systems: The statute should require that the local EMS system be notified about AEDs placed within its response area. Some EMS systems may wish to require registration, but not all EMS systems have the resources to establish a registry.

4. Support of elements that contribute to effective lay rescuer AED programs:

The statute should require a planned and practiced response. Typically this requires

- A planned and practiced response (can specify delegation of authority to a healthcare provider program director).
- Training of anticipated rescuers in CPR and AED use with a practice goal of immediate CPR and delivery of the first shock to victims of VF sudden cardiac arrest within 3 minutes of the victim's collapse.
- A link with the EMS system (see above).
- A process of ongoing quality improvement. The program director should evaluate each episode of sudden cardiac arrest and decide what steps are needed to improve response and minimize time to CPR and time to delivery of the first shock with an AED. The program director should implement a plan for on-site maintenance and readiness-for-use checks of the AED.

In 2002, the state of New York enacted a law requiring school districts, county vocational education and extension boards, and charter schools to provide and maintain at least 1 AED on site and in each instructional school facility. In addition, Assembly Bills 8779 and 10577 required that at least 1 staff member trained in CPR and the use of an AED be present at all school-sponsored activities.

In 2002, the AHA published an update to a 1998 statement recommending the development of AED programs in health clubs with >2500 members.[46] The statement encouraged the development of AED programs in facilities of sufficient size that an episode of sudden cardiac arrest might be predicted to occur there within a several-year period. The statement is available on the AHA Web site (http://circ.ahajournals.org/cgi/content/full/105/9/1147).

Some states have filed legislation requiring or encouraging the establishment of lay rescuer AED programs in health clubs. Illinois enacted a law (HB 4232) that requires physical fitness facilities to have at least 1 AED, a trained AED user, and a written plan for managing medical emergencies. New York State enacted a law (2004: S 6803/A.5084) requiring all health clubs, fitness centers, health spas, health studios, gyms, weight control studios, and martial arts/self-defense schools with a membership ≥500 to have at least 1 AED and at least 1 person (employee or volunteer) on the premises during the hours of operation who is trained in CPR and use of an AED. Other states, such as Michigan (2003: SB 50), New Jersey (2003: S. 1106/A. 453), and Rhode Island (2004: SB 2948) have acted on similar legislation in the past few years.

The PAD trial documented the lifesaving effect of well-organized lay rescuer AED programs in public places,[31] but at least two thirds of all out-of-hospital episodes of sudden cardiac arrest occur in homes.[47,48] A study is underway to determine the effectiveness of home AED programs. The results of this study may support further legislative efforts. At this time there is insufficient data for the AHA ECC Committee to make recommendations about home AED programs.

Summary

This statement describes the key program components to include in state legislation and regulations addressing community lay rescuer AED programs. The goal of the legislation should be to reduce deaths from sudden cardiac arrest by encouraging the development of programs that will increase the likelihood of immediate bystander CPR and defibrillation being provided within 3 to 5 minutes of the victim's collapse. Table 6 lists the key components recommended for community lay rescuer AED programs.

Additional Resources

The AHA has prepared additional support materials and guidelines for AED initiatives. The following materials may be helpful:

- Model AED legislation, AED Policy Toolkit: www.americanheart.org/statepolicy
- State-by-state policy analysis (review of state actions): www.ncsl.org/programs/health/aed.htm
- AED programs Q & A: http://www.americanheart.org/presenter.jhtml?identifier =3011859#training
- AED program implementation resources: http://www.americanheart.org/presenter.jhtml?identifier =3027304
- Medical Emergency Response Plan for Schools statement: http://circ.ahajournals.org/cgi/content/full/109/2/278

Writing Group Disclosures

Writing Group Member	Employment	Research Grant	Other Research Support	Speakers' Bureau	Honoraria	Ownership Interest	Consultant/ Advisory Board	Other
Aufderheide, Tom	Medical College of Wisconsin	NHLBI PAD Trial Award Recipient†	Marquette Medical Systems 16-Lead ECG Trial*	Ress and ECCG speaker*	None	None	Past consultant for Medtronic Physio-Control—terminated July 2005†	Volunteer National AHA BLS Subcommittee
Buroker, Andrew	Krieg DeVault LLP	None	None	None	None	None	None	None
Cummins, Richard	University of Washington	None	None	None	None	None	None	None
Eigel, Brian	AHA	None	None	None	None	None	None	None
Epstein, Andrew	The University of Alabama at Birmingham	Biotronik Guidant Corp Medtronic Inc St Jude Medical*	None	Guidant Corp Medtronic Inc St Jude Medical*	Guidant Corp Medtronic Inc St Jude Medical*	None	Guidant Corp St Jude Medical*	None
Halperin, Henry	Johns Hopkins University	Revivant—PI†	None	None	None	None	Revivant—Consultant† Medtronic—Consultant*	None
Hazinski, Mary Fran	Vanderbilt University Medical Center	None	None	None	None	None	Compensated editor for American Heart Association	None
McCune, Robin	AHA	None	None		None	None	None	None
Nadkarni, Vinay	Children's Hospital of Philadelphia	None	None	None	None	None	None	None
Nichol, Graham	University of Washington	Medtronic ERS, Inc Cardiac Science, Inc Zoll, Inc*	None	None	None	None	None	None
Potts, Jerry	AHA	None	None	None	None	None	None	None
Ramirez, Raymond	AHA	None	None	None	None	None	None	None
Sayre, Michael	The Ohio State University	Zoll/Revivant*	Medtronic*	None	None	None	Philips-Medical*	None
Smith Steffens, Suzanne	AHA	None	None	None	None	None	None	None
Stapleton, Edward	SUNY Stony Brook	Laerdal Med grant to study CPR*	None	None	None	None	*Currents*, AHA publications	None

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives $10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns $10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest conflict of interest.

†Significant conflict of interest.

Reviewers' Disclosures

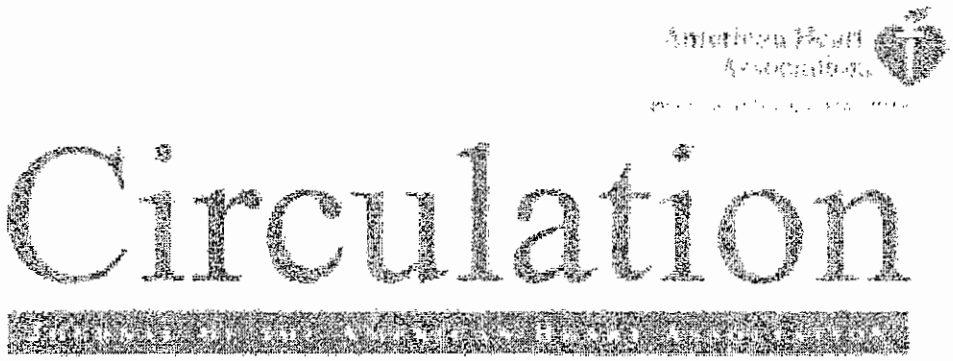
Reviewer Name	Employment	Research Grant	Speakers Bureau/ Honoraria	Stock Ownership	Consultant/ Advisory Board	Other
Wanchun Tang, MD, FCCP, FCCM	None	Philips Medical, Zoll Medical, AHA	None	None	None	None
Richard E. Kerber	University of Iowa	Philips Medical Systems*	None	None	None	Laerdal Foundation for Acute Medical Care,* NHLBI†

*Modest conflict of interest.
†Significant conflict of interest.

References

1. Chugh SS, Jui J, Gunson K, Stecker EC, John BT, Thompson B, Ilias N, Vickers C, Dogra V, Daya M, Kron J, Zheng ZJ, Mensah G, McAnulty J. Current burden of sudden cardiac death: multiple source surveillance versus retrospective death certificate–based review in a large US community. *J Am Coll Cardiol*. 2004;44:1268–1275.
2. Zheng ZJ, Croft JB, Giles WH, Mensah GA. Sudden cardiac death in the United States, 1989 to 1998. *Circulation*. 2001;104:2158–2163.
3. *Heart Disease and Stroke Statistics—2005 Update*. Dallas, Tex: American Heart Association; 2005.
4. Kerber RE. Statement on early defibrillation from the Emergency Cardiac Care Committee, American Heart Association. *Circulation*. 1991; 83:2233.
5. Weisfeldt ML, Kerber RE, McGoldrick RP, Moss AJ, Nichol G, Ornato JP, Palmer DG, Riegel B, Smith SC Jr. Public access defibrillation: a statement for healthcare professionals from the American Heart Association Task Force on Automatic External Defibrillation. *Circulation*. 1995;92:2763.
6. Weisfeldt ML, Kerber RE, McGoldrick RP, Moss AJ, Nichol G, Ornato JP, Palmer DG, Riegel B, Smith SC Jr. American Heart Association Report on the Public Access Defibrillation Conference, December 8–10, 1994. American Heart Association Task Force on Automatic External Defibrillation. *Resuscitation*. 1996;32:127–138.
7. Weisfeldt ML, Kerber RE, McGoldrick RP, Moss AJ, Nichol G, Ornato JP, Palmer DG, Riegel B, Smith SC Jr. Statement on public access defibrillation. American Heart Association Task Force on Automatic External Defibrillation. *Resuscitation*. 1996;32:125–126.
8. Hazinski MF, Cummins RO, Bowser P, Gilpin B, Potts J. State legislation to enable public access defibrillation: essential elements and suggested strategies: recommendations for advocacy staff and volunteers from the American Heart Association's Emergency Cardiovascular Care Committee. 1998:1–26.
9. Nichol G, Valenzuela T, Wells GA, Tang ASL, Stiell IG. Potential cost-effectiveness of early defibrillation by nontraditional responders for treatment of out-of-hospital cardiac arrest. *Circulation*. 1999;100(suppl I):I-868.
10. Nichol G, Stiell IG, Hebert P, Wells GA, Vandemheen K, Laupacis A. What is the quality of life for survivors of cardiac arrest? A prospective study. *Acad Emerg Med*. 1999;6:95–102.
11. Nichol G, Stiell IG, Laupacis A, Pham B, De Maio VJ, Wells GA. A cumulative meta-analysis of the effectiveness of defibrillator-capable emergency medical services for victims of out-of-hospital cardiac arrest. *Ann Emerg Med*. 1999;34(pt 1):517–525.
12. Martin DR, Brown CG, Dzwonczyk R. Frequency analysis of the human and swine electrocardiogram during ventricular fibrillation. *Resuscitation*. 1991;22:85–91.
13. Carpenter J, Rea TD, Murray JA, Kudenchuk PJ, Eisenberg MS. Defibrillation waveform and post-shock rhythm in out-of-hospital ventricular fibrillation cardiac arrest. *Resuscitation*. 2003;59:189–196.
14. White RD, Russell JK. Refibrillation, resuscitation and survival in out-of-hospital sudden cardiac arrest victims treated with biphasic automated external defibrillators. *Resuscitation*. 2002;55:17–23.
15. Cobb LA, Fahrenbruch CE, Walsh TR, Copass MK, Olsufka M, Breskin M, Hallstrom AP. Influence of cardiopulmonary resuscitation prior to defibrillation in patients with out-of-hospital ventricular fibrillation. *JAMA*. 1999;281:1182–1188.
16. White RD, Hankins DG, Atkinson EJ. Patient outcomes following defibrillation with a low energy biphasic truncated exponential waveform in out-of-hospital cardiac arrest. *Resuscitation*. 2001;49:9–14.
17. Eftestol T, Sunde K, Steen PA. Effects of interrupting precordial compressions on the calculated probability of defibrillation success during out-of-hospital cardiac arrest. *Circulation*. 2002;105:2270–2273.
18. Cummins RO, Eisenberg M, Bergner L, Murray JA. Sensitivity, accuracy, and safety of an automatic external defibrillator. *Lancet*. 1984;2: 318–320.
19. Larsen MP, Eisenberg MS, Cummins RO, Hallstrom AP. Predicting survival from out-of-hospital cardiac arrest: a graphic model. *Ann Emerg Med*. 1993;22:1652–1658.
20. Valenzuela TD, Roe DJ, Cretin S, Spaite DW, Larsen MP. Estimating effectiveness of cardiac arrest interventions: a logistic regression survival model. *Circulation*. 1997;96:3308–3313.
21. Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Public use of automated external defibrillators. *N Engl J Med*. 2002;347:1242–1247.
22. Robertson RM. Sudden death from cardiac arrest—improving the odds. *N Engl J Med*. 2000;343:1259–1260.
23. Page RL, Joglar JA, Kowal RC, Zagrodzky JD, Nelson LL, Ramaswamy K, Barbera SJ, Hamdan MH, McKenas DK. Use of automated external defibrillators by a US airline. *N Engl J Med*. 2000;343:1210–1216.
24. Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. *N Engl J Med*. 2000;343:1206–1209.
25. White RD, Asplin BR, Bugliosi TF, Hankins DG. High discharge survival rate after out-of-hospital ventricular fibrillation with rapid defibrillation by police and paramedics. *Ann Emerg Med*. 1996;28:480–485.
26. White RD, Hankins DG, Bugliosi TF. Seven years' experience with early defibrillation by police and paramedics in an emergency medical services system. *Resuscitation*. 1998;39:145–151.
27. Bunch TJ, White RD, Gersh BJ, Meverden RA, Hodge DO, Ballman KV, Hammill SC, Shen WK, Packer DL. Long-term outcomes of out-of-hospital cardiac arrest after successful early defibrillation. *N Engl J Med*. 2003;348:2626–2633.
28. White RD, Bunch TJ, Hankins DG. Evolution of a community-wide early defibrillation programme experience over 13 years using police/fire personnel and paramedics as responders. *Resuscitation*. 2005;65:279–283.
29. Holmberg M, Holmberg S, Herlitz J. Effect of bystander cardiopulmonary resuscitation in out-of-hospital cardiac arrest patients in Sweden. *Resuscitation*. 2000;47:59–70.
30. Groh WJ, Newman MM, Beal PE, Fineberg NS, Zipes DP. Limited response to cardiac arrest by police equipped with automated external defibrillators: lack of survival benefit in suburban and rural Indiana—the police as responder automated defibrillation evaluation (PARADE). *Acad Emerg Med*. 2001;8:324–330.
31. The Public Access Defibrillation Trial Investigators. Public-access defibrillation and survival after out-of-hospital cardiac arrest. *N Engl J Med*. 2004;351:637–646.
32. American Heart Association in collaboration with International Liaison Committee on Resuscitation. Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care: International Consensus on Science, Part 4: the Automated External Defibrillator: Key Link in the Chain of Survival. *Circulation*. 2000;102(suppl I):I-60–I-76.
33. 2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation*. 2005; 112(suppl IV):IV-1–IV-211.
34. Cobb LA, Fahrenbruch CE, Olsufka M, Copass MK. Changing incidence of out-of-hospital ventricular fibrillation, 1980–2000. *JAMA*. 2002;288: 3008–3013.

35. Rea TD, Eisenberg MS, Sinibaldi G, White RD. Incidence of EMS-treated out-of-hospital cardiac arrest in the United States. *Resuscitation*. 2004;63:17–24.
36. Searcy K. Debunking the myths about automated external defibrillators. *Nurs Spectrum*. 2000;17.
37. Petersen KF. Legal implications of lay use of automatic external defibrillators in non-hospital settings. *J Contemp Health Law Policy*. 2000;17:275–320.
38. White RD, Vukov LF, Bugliosi TF. Early defibrillation by police: initial experience with measurement of critical time intervals and patient outcome. *Ann Emerg Med*. 1994;23:1009–1013.
39. Wik L, Hansen TB, Fylling F, Steen T, Vaagenes P, Auestad BH, Steen PA. Delaying defibrillation to give basic cardiopulmonary resuscitation to patients with out-of-hospital ventricular fibrillation: a randomized trial. *JAMA*. 2003;289:1389–1395.
40. Wik L, Kramer-Johansen J, Myklebust H, Sorebo H, Svensson L, Fellows B, Steen PA. Quality of cardiopulmonary resuscitation during out-of-hospital cardiac arrest. *JAMA*. 2005;293:299–304.
41. Abella BS, Alvarado JP, Myklebust H, Edelson DP, Barry A, O'Hearn N, Vanden Hoek TL, Becker LB. Quality of cardiopulmonary resuscitation during in-hospital cardiac arrest. *JAMA*. 2005;293:305–310.
42. Berg MD, Clark LL, Valenzuela TD, Kern KB, Berg RA. Post-shock chest compression delays with automated external defibrillator use. *Resuscitation*. 2005;64:287–291.
43. Aufderheide T, Stapleton E, Hazinski MF, Cummins RO. *Heartsaver AED Handbook for Lay Rescuers*. Dallas, Tex: American Heart Association; 1998.
44. *Heartsaver AED*. Dallas, Tex: American Heart Association; 2003.
45. Hazinski MF, Markenson D, Neish S, Gerardi M, Hootman J, Nichol G, Taras H, Hickey R, O'Connor R, Potts J, van der Jagt E, Berger S, Schexnayder S, Garson A Jr, Doherty A, Smith S. Response to cardiac arrest and selected life-threatening medical emergencies: the medical emergency response plan for schools: a statement for healthcare providers, policymakers, school administrators, and community leaders. *Ann Emerg Med*. 2004;43:83–99.
46. Balady GJ, Chaitman B, Foster C, Froelicher E, Gordon N, Van Camp S. Automated external defibrillators in health/fitness facilities: supplement to the AHA/ACSM Recommendations for Cardiovascular Screening, Staffing, and Emergency Policies at Health/Fitness Facilities. *Circulation*. 2002;105:1147–1150.
47. Becker LB, Ostrander MP, Barrett J, Kondos GT. Outcome of CPR in a large metropolitan area: where are the survivors? *Ann Emerg Med*. 1991; 20:355–361.
48. Holmberg M, Holmberg S, Herlitz J. Incidence, duration and survival of ventricular fibrillation in out-of-bospital cardiac arrest patients in Sweden. *Resuscitation*. 2000;44:7–17.



American Red Cross

FAQ
Health and Safety Services

AED Frequently Asked Questions (External Audiences)

Q What is sudden cardiac arrest?
A Sudden cardiac arrest (SCA), one of the leading causes of death in the United States, strikes over 300,000 victims each year, of which about five percent survive.
Sudden cardiac arrest cases are usually due to abnormal heart rhythms called arrhythmias, the vast majority of which are ventricular fibrillation. Ventricular fibrillation is a condition in which the heart's electrical impulses suddenly become chaotic; causing the heart's pumping action to stop abruptly. Victims collapse and quickly lose consciousness, often without warning. Unless a normal heart rhythm is restored, death follows within a matter of minutes. The cause of sudden cardiac arrest is not well understood. Many victims have no history of heart disease, or if heart disease is present, it has not functionally impaired the victim. Unlike a heart attack, which is the death of muscle tissue from loss of blood supply, many victims of SCA have no prior symptoms. SCA can strike anyone, at any time, anywhere.

Q What is the current treatment for SCA?
A A series of four critical steps, called the "Cardiac Chain of Survival," have been identified for the treatment of SCA:
□ Early access to care (i.e., calling 911 or another emergency number);
□ Early cardiopulmonary resuscitation (CPR);
□ Early defibrillation; and
□ Early institution of advanced cardiac life support.
A break in any of the four links in the chain can compromise the victim's chance for survival; however, early defibrillation is recognized as the most critical step in restoring cardiac rhythm and resuscitating a victim of SCA.

Q What is defibrillation?
A Defibrillation is the treatment of irregular, sporadic or absent heart rhythms by an electrical current to the heart. It is the only definitive treatment for SCA. Defibrillation administered within four minutes after collapse is most successful. Every minute a victim is unconscious translates to approximately a ten percent decrease in the likelihood of resuscitation. After ten minutes, very few resuscitation attempts are successful. Thus, the most important element in the treatment of SCA is providing rapid defibrillation therapy. CPR may help prolong the window of survival, but it cannot reverse SCA.

Q What is the American Red Cross doing to increase public access to AEDs?
A In addition to being the leading training agency for first aid, CPR and AED information and skills, the Red Cross is committed to strengthening existing state and federal legislation that extends the reach of AEDs into the community. For the last several years, the American Red Cross has championed legislation to increase public access to defibrillation.

Q If treatment for SCA exists, why are survival rates low?
A Time. Only one out of every 20 SCA victims survives - though many of these lives

could be saved through early defibrillation. With a brief window of opportunity for effective treatment, it is vital that responders reach the victim and defibrillate within the first ten minutes of SCA.

Despite announcements from the American Red Cross, the American Heart Association and others calling for the broad deployment of AEDs, the penetration of AEDs among emergency responders is remarkably low. Because of other outside influences, response times and survival rates vary from one location to another. Metropolitan and rural areas are the hardest hit. Improved access to early defibrillation will greatly improve the national survival rate, which is presently about five percent.

Q Why do we need AEDs in the workplace? Do my employees need to be trained to use an AED?
A Approximately 150 million Americans go to work every day where they spend more than half of their waking hours. The American Red Cross advocates CPR and AED training in the workplace to help keep American workers safe. The Red Cross believes that proper training in CPR and AED and quick activation of the EMS system combined can help to save more lives. When CPR and defibrillation are used together, as outlined in the Cardiac Chain of Survival, a better outcome can be obtained. The Red Cross also advocates increased public access to AEDs in places such as corporate offices, shopping malls, airports, sports stadiums and other places where large groups of people gather and the risk of an SCA incident is very likely.

Q: Do all AEDs work the same?
A: All AEDs direct the rescuer to either give a shock or perform CPR. However, each device has its own method of communicating with the potential rescuer. The potential rescuer should follow the manufacturer's directions and device prompts when operating an AED.

Q Is a prescription from a physician necessary to purchase an AED in a workplace environment?
A According to FDA rules, a physician prescription is needed in order to purchase an AED.

Q Is a medical director needed to purchase an AED?
A It varies by state. The majority of states have a requirement for a medical director or medical oversight.

Q What is the relationship between the American Red Cross and AED manufacturers?
A To help the Red Cross meet its mission of saving lives, agreements have been established with AED manufacturers to allow Red Cross chapters the opportunity to facilitate the purchase of AED units and provide CPR and AED training to customers. Many chapters have taken advantage of the opportunity. If a chapter is not eligible to coordinate the purchase of AEDs, it can provide the customer with information on how to obtain a device.

American Red Cross

FAQ

Health and Safety Services

Q Why not rely on traditional emergency caregivers?
A Outside of a controlled medical environment, paramedics and EMTs are traditionally the first to arrive on the scene of a sudden cardiac arrest. Both groups are trained in basic first aid and emergency care, but they may or may not be equipped with and trained to use AEDs. Congested urban streets, high-rise office buildings and remote or heavily secured worksites can all slow traditional emergency medical responders from reaching SCA victims within the critical first ten minutes after SCA occurs.

Q Why are so few emergency responders equipped with AEDs?
A Older generations of defibrillation technology made the deployment of AEDs among many groups of potential responders impractical. Older devices were large, heavy (weighing as much as 20 lbs.), expensive and it was necessary for the operator to perform daily maintenance checks. These devices also required highly skilled operators, who needed frequent retraining to maintain skills. Taken together, these factors have prevented this lifesaving technology from being broadly deployed.

Q Could a responder deliver an unnecessary shock?
A An AED is designed to allow the operator to deliver a shock only when the device has detected the presence of a life-threatening arrhythmia, and with some AEDs, the device will detect the need to provide a shock and then proceed to administer it. If it does not detect a shockable rhythm, it will instruct the rescuer to perform chest compressions and rescue breaths as needed.

Q Is it safe to use an AED on a metal surface?
A Recent research findings released by AED manufacturers support that it is indeed safe to defibrillate a victim on a metal surface as long as the appropriate safety precautions are taken. Specifically, care should be taken that the defibrillation electrodes do not contact the conductive surface and that no one is touching the victim when the discharge button is pressed.

Q Is it safe to use AEDs around water?
A Generally, the victim should not be in a puddle of water, nor should the rescuer be kneeling in a puddle of water when operating an AED. AEDs can be used in a variety of environments including rain and snow. Always use common sense when using an AED and follow the manufacturer's recommendations.

Q Are AEDs easily portable?
A Yes. An AED is about the size of a laptop computer or smaller. It is light and easy to carry.

Q How much does an AED cost?
A A defibrillator costs approximately $3,000 in the United States.

NCSL
NATIONAL CONFERENCE of STATE LEGISLATURES

GO

Health Program

State Laws on Cardiac Arrest & Defibrillators

Encouraging or requiring community access and use

Updated January 2, 2009

Each year, more than 250,000 Americans die from sudden cardiac arrest. According to medical experts, the key to survival is timely initiation of a "chain of survival", including CPR (cardiopulmonary resuscitation). Because of recent technological advances a portable lifesaving device, called an "automated external defibrillator" or "AED" has recently become an important medical tool. Trained non-medical personnel can use these simplified electronic machines to treat a person in cardiac arrest. The AED device "guides the user through the process by audible or visual prompts without requiring any discretion or judgment."[1] The American Heart Association notes that at least 20,000 lives could be saved annually by prompt use of AEDs. Ultimately, with broad deployment of AEDs among trained responders, as many as 50,000 deaths due to sudden cardiac arrest could be prevented each year.

Advocates of this approach envision placement of AEDs in public buildings, transportation centers and even large offices and apartment buildings. Meanwhile, the commercial market has expanded substantially, with machines that once sold for $3,000 and up now advertised at under $1,000 for small office, personal or home use.

State Legislators have become actively involved with this issue in the past six years. Most commonly, the recent state laws encourage broader availability, rather than creating new regulatory restrictions. Most of the bills enacted from 1997 to 2001 included one or more provisions to:

automated external defibrillator

- **Establish legislative intent that an "automatic external defibrillator may be used by any person for the purpose of saving the life of another person in cardiac arrest."**
- **Encourage or require training in the use of AED devices by potential users.**
- **Require AED devices to be maintained and tested to manufacturer's standards.**
- **Create a registry of the location of all such defibrillators, or notification of a local emergency medical authority.**
- **Allow a "Good Samaritan" exemption from liability for any individual who renders emergency treatment with a defibrillator.**
- **Authorize a state agency to establish more deteiled requirements for training and registration.**

Florida was the first state to enact such a broad public access law in April 1997 (Chapter 34 of 1997). As of 2001, all fifty states, listed below, had enacted defibrillator laws or adopted regulations.

In 2002, Arizona, California, New Hampshire and New York enacted legislation, all amending existing provisions concerning the regulation of automated external defibrillators. Arizona enacted a measure that will require any state building constructed or renovated at a cost of at least $250,000 to be equipped with automated external defibrillators. SB 1070 requires that the Joint Legislative Budget Committee and the Governor's Office of Strategic Planning and Budgeting should include funding for the placement of automated external defibrillators in capital budgets for new state buildings each fiscal year. The provisions in the act become effective after June 30, 2003. New York legislators enacted new requirements for public school facilities with more than 1000 persons to provide and maintain on-site AED equipment. AB 8779 of 2002 requires that all school sponsored activities have at least one staff person who has been trained in the use of the device present.

In 2003, Utah updated its AED law by establishing a statewide registry; while Virginia updated AED laws by deleting the requirement for registration. Alabama, Alaska, Colorado, Connecticut, Indiana, Kansas, Nebraska, Nevada, Tennessee and Texas also changed or expanded their AED laws.

In 2004, AED laws were changed or expanded in Connecticut, Florida, Hawaii, Idaho, Illinois, Louisiana, Maine, Michigan, Missouri, New York, Ohio, Oklahoma and Rhode Island. The Illinois law (H. 4232) requires every physical fitness facility to have at least one AED on premises, by mid-July 2006, with exceptions.

In 2005-06, Maryland added a requirement that every high school and school-sponsored athletic events have an AED available. California required health clubs to have at least one AED. Florida authorized state and local police vehicles to carry an AED. Indiana and Virginia repealed filing and training requirements. New York required places of public assembly to maintain an AED. Oregon updated Good Samaritan protection for trained AED providers, employers, property-owners and sponsoring agencies. Arizona, Colorado, Florida, Illinois, Maryland, Massachusetts, Nebraska, New Jersey, Pennsylvania, and Wisconsin also enacted AED laws.

In 2007, Texas added a requirement for AEDs not approved for over-the-counter sales.

In 2008 laws were enacted in Georgia, Idaho, Ilinois, Indiana, Iowa, Massachusetts, New Hampshire, New York, South Carolina, Tennessee, West

Virginia, Wisconsin and the District of Columbia (as of July 8, 2008).

AED Location	States Requiring or Supporting AED Placement
Schools	**Colorado** (donations), **Florida, Georgia** (2008), **Illinois, Maryland, Michigan, Nevada, New York, Ohio, Pennsylvania, South Carolina** (2008) **and Virginia** require some schools to have portable defibrillators; actual extent varies. **Tennessee** "encourages" placement in schools (2008.)
Health Clubs	**California, Illinois, Indiana** (2007, 2008), **Massachusetts** (2007), **Michigan, New Jersey, New York, Rhode Island** and the **District of Columbia** (2008) laws now require health clubs to have at least one AED. *Definition example (Michigan)*: "Health club" means an establishment that provides, as its primary purpose, services or facilities that are purported to assist patrons in physical exercise, in weight control, or in figure development, including, but not limited to, a fitness center, studio, salon, or club. A health club does not include a hotel or motel that provides physical fitness equipment or activities, an organization solely offering training or facilities for an individual sport, or a weight reduction center.
Day Care Centers	**Wisconsin** (2008) requires dentists and day care center personnel to have AED proficiency.
Places of Public Assembly	**New York** (2006)
Swimming Pools	**New York** (2008)

Congress Acts on AEDs:

In 2002, Congress incorporated the Community Access to Emergency Devices Act (Community AED Act) into H.R. 3448 of 2002(sections 159, 312 and 313) of the Public Health Security and Bioterrorism Response Act. The President signed the bill on June 12, 2002 as Public Law 107-188. The provisions authorize $30 million in federal grants in year one of the five-year measure. The grants, to be made available to applying states and localities, would be used for the purchase and placement of automated external defibrillators (AEDs) in public places where cardiac arrests are likely to occur. Grant funds would also be used to train first responders to administer immediate life-saving care, including AED use and cardiopulmonary resuscitation (CPR). The bill also encourages private companies to purchase AEDs and to train employees in CPR and emergency defibrillation.

TABLE OF STATE LAWS:

Notes: The following references are to signed, enacted legislation in the 50 states. They reflect examples and actions at a particular time and are not intended as a comprehensive review of history and current statutes. Law citations in color are links directly to bill text or summaries on state legislative web sites.

NOTE: NCSL provides links to other Web sites from time to time for information purposes only. Providing these links does not necessarily indicate NCSL's support or endorsement of the site.These links are not maintained by NCSL and we can not guanrentt

Chart codes:
A = allow lay persons to use AEDs; terms and conditions
L = provide limited immunity for trained lay persons under state Good Samaritan law.
M = mandated or required installation
$ = funding & distribution

State	Law /Year/Sponsor	Codes	Comments
AL	S 5; S 351	A / L	Use plus $3 million funding *(Enacted 6/9/99)*
AL	SB 373 (1998)	$	Appropriation: $3 million for purchase of AED
AL	H 325 Of 2001	$	Appropriates $300,000 for AEDs *(Signed 5/7/01)*
AL	HJR 504	$	Non-binding resolution requests that the Alabama Council of Emergency Medical Services and the Alabama Chapter of the American Heart Association contact the manufacturers of automated external defibrillators urging them to establish a registry of automated external defibrillators. *(Signed 6/18/03)*
AK	H 395 of 1998 Rep. Bunde S 160 of 2003 Sen. Olson	A / L L	(H 395 Signed 5/14/98) Expands protections for AED users from civil liability. A person who uses or attempts to use an AED device on a victim of a perceived medical emergency is not liable for civil damages resulting from the use or attempted use of the device. *(signed 6/03)*
AR	Act 101 of '99 HB 1006 (1999) Rep. Laverty	A / L	*(Signed by Governor 2/18/99)*
AZ	SB 1070 of 2002 HB 2091 of 2006 NEW	$ A / L	Will require any state building constructed or renovated at a cost of at least $250,000 to be equipped with automated external defibrillators. Requires future budgets to include funding. HB 2091 concerns limited volunteer liability and automated external defibrillators. *(Signed 4/17/06)*
AZ	HB 2475 of 1999	A / L	*(Signed 5/12/99 as Chapter 217 of 1999)*

CA	Statute: Health & Safety Code 1797.190 SB 911 of 1999 AB 2041 of 2002 ACR 57 of 2005 Assm. Pavley	A L L $	"Only those individuals who meet the training and competency standards established by the authority shall be approved for, and issued a prescription authorizing them to use AED." SB 911 - added exemption from liability. AB 2041 changes liability provisions. Urges all State public schools maintaining kindergarten or any of grades 1 to 12, inclusive, to implement an automated external defibrillator program
CA	AB 1507 of 2005	M	Health and Safety Code §104113 - Requires every health studio to acquire an AED. Exempts hotels.
CO	HB 1283 of 1999 Rep. Spence HJR04-1090 (2004) Rep. Spradley SB 170 of 2005 Sen. Spence	A / L A $ A / L	"Expected AED users receive training... through a course approved by the department of public health and environment" *(signed 4/16/99)* COMMENDING THE AED DONATION PARTNERSHIP BETWEEN THE AMERICAN HEART ASSOCIATION AND KAISER PERMANENTE. Requires schools to accept donated AEDs or cash donations toward purchase of an AED for each district and school athletic facility. Encourages placement in each public school; provides good samaritan exemption from liability. *(Signed 4/26/05)*
CT	S 318 of 1998 Rep. Flaherty H S650 of 2000	A / L A	User must be trained *(signed 5/19/98)* H S650 allows paramedics to use AEDs *(signed 5/3/2000)*
CT	H 7505 of 2001 (in § 37)	A	Trained emergency personnel "shall not be subject to additional requirements" *(signed 7/2/01)*
CT	H 5627 of 2003	A/ $	Requires the Dept, of Public Health to develop strategies for training, and to availability and use for "cardiac arrest victims in public settings, including, but not limited to, state facilities, municipal facilities and mass public gatherings" with report due 1/1/04. *(signed 5/23/03)*
CT	H S631 of 2004	A	Directs the state to (1) Identify placement and use of automatic external defibrillators within the emergency medical services system; (2) establish guidelines for providing emergency medical services during mass gathering;.
DE	H.332 of 1999 Rep. Ennis H.430 of 2000	A	Requires the Office of Emergency Medical Services to coordinate a statewide effort to promote and implement widespread use of semi-automatic external defibrillators (SAEDs) and to maintain a minimum number of individuals trained to use SAEDs. [see note #3]
DE	FY'02 Budget FY'03 Budget	$	The state allocated $752,000 for 2001 and $375,000 for 2002 to buy defibrillators at a cost of $2,500 to $3,500 each as part of the *First State, First Shock!* Public Access Defibrillation Program. For FY'03 an additional $141,400 has been allocated from tobacco settlement funds. Schools, businesses and other public places must apply to the state Emergency Medical Services office, which determines how many defibrillators are needed based on the number of athletic programs or people congregating at a particular location. [article]
DC	D.C. Law 13-279; D.C. Official Code Section 44-233). (2001) B 738 of 2008 NEW B867 of 2008 NEW	L $ L	Signed as Act Number 392 of '08.
FL	H. 411 of 1997	A / L	Use by any person who has had appropriate training; must complete basic AED course; must activate emergency medical services system upon use. *(Signed 4/97 as Ch 34 of 1997)*
FL	H. 1429 of 2001 Rep. Byrd SB 1436 of 2005 (Chapter No. 2005-109) SB 772 of 2006 (Chapter 2006-301) Sen. Constantine	L $ M	Expands immunity from civil liability for any person who uses or attempts to use an AED on a victim of a "perceived medical emergency." Authorizes state and local law enforcement vehicles to carry an AED; authorizes local governments to use forfeiture funds for purchasing such defibrillators. Requires AEDs in all public schools with high school athletics; encourages public & private partnerships to cover costs. *(Signed 6/26/06; effective 7/1/06)*
GA	S. 566 of 1998 Sen. Hill	A / L	Use by "any appropriately trained person"; owners must be subject to direct supervision of a physician. *(Signed 4/6/98)*
GA	S. 51 of 2001 Sen. Thomas	A / L	Updates standards for training and use; provides definitions for immunity from civil liability. *(Signed 4/26/01)*

	H 1031 of 2008 NEW	M	No later than July 1, 2008, each public high school with an interscholastic athletics program shall have at least one functional automated external defibrillator on site at such school at all times and easily accessible during any school related function.
HI	H.2598 of 1998 Rep. Kawakami	A / L	User who completes training by physician is immune from civil liability. *(Signed 7/14/98)*
IA	Reg.: Public Health 641-132.1(147A) S 505 of 2008 NEW	A / L L	Public Health administrative regulation. Amends the law to clarify the entities that are not liable for civil damages.
ID	S 1185 of 1999 S 1420 of 2008 NEW	A / L L	Section 5-337, Idaho Code (passed as *Chapter 351 of 1999; effective 3/25/99)* S. 1420 revises the requirements for those persons or entities who acquire a defibrillator as a result of a prescription, to provide immunity for any civil damages. *(Chapter 299, signed 3/28/08)*
IL	Public Act 90-746 HB 1217 (1998) Public Act 91-524 SB 458 (1999). HB 43 (2003) Public Act 93-910; HB 4232 of 2004 Public Act 94-876, H.B. 542 of 2006 H 1279 of 2008 NEW	A / L $; M M $ M	- SB 458 expands AED - (Signed 8/13/1999) HB 43 Requires each fitness facility, including those in schools, to have on its premises at least one automated external defibrillator (AED) and a trained AED user *(passed 6/25/03)* H. 4232 requires every physical fitness facility to have at least one AED on premises, by mid-July 2006, with exceptions. Also requires a trained user on premises. *(Signed as Public Act 93-910 8/12/04; Cite as* 210 ILCS 74 /15 *)* Public Act No. 94-876 creates a state income tax checkoff for the Heartsaver AutoMated External Defibrillator (AED) Fund. *(Signed 6/19/06)* H 1279: A physical fitness facility must ensure that there is a trained AED user on staff and present during all physical fitness activities.
IN	S. 171 (1998) Sen. Adams HB 1106 of 2006 SB 134 of 2007, Sen. Miller HB 1137 of 2008 NEW	A / L A / L M	(IC 16-31-6.5) Owners shall ensure that "expected users" complete a training course. Removes the requirements that an entity that acquires a defibrillator have an "AED certificate" or ensure that the users have completed AED courses or have enlisted a physician for medical direction. *(Signed as Public Law 74 of 2006 on 3/17/06)* A health club "shall ensure that a defibrillator" is located on the premises and must employ at least one trained operator on location during all business hours. *(Signed as Public Law 3 of 2008, on 3/13/08)*
KS	SB 535 Senator Steineger	A / L	(K.S.A. 1997 Supp. 65-6144, §19) AED "may be used by any person who has ...obtained training and demonstrated proficiency in use..." (signed 5/98)
KY	HB49 Rep. J. Coleman	A / L	(signed 2/2000)
LA	S 100 Senator Hines	A / L	Law: R.S. 40:1236.11 (Signed 7/2/99)
ME	LD1432 Rep. Bumps	A	*(Signed by Governor, 6/6/01)*
MD **MD**	S. 294 Del. Hollinger HB 1200; S.249 Del. Lee	A / L M	Adds MD Education Code §13-517 - Requires facilities to have a certificate before making AEDs available; users should have training and authorization before use; requires reports and records. *(enacted 4/27/99)* Requires every school in the state to have an AED on the premises and at all school-sponsored athletic events, as well as someone trained and certified to use it. *(HB 1200 signed by the Governor as Chapter 203, effective June 2006)* [article 6/15/06]
MA **MA**	S 2164 (chapter 137) signed 1998 Sen. Morrissey Chapter 142 of 1999 S 2581 of 2006 (Chapter 420) MGL Ch. 93, §88 H 4900, item #4S10-0793 (2008) NEW	A / L L M $	Any person trained in AED or basic cardiac life support is immune from civil liability. 1999 law adds definition of AED Provider. 2006 law requires AEDs in health clubs; provides for volunteer exemption from liability. Effective date 2008 for facilities with 6+ employees and 2009 for facilities with 1-5 employees. (Signed 1/3/07) Appropriated $22,532 for a federally funded grant entitled, RURAL AEDs.

MI	H.4420 Rep. Gerald Law SB 310 of 2006 (Public Act 23 '06); - SB 1085 of 2006 (Public Act 332 '06) ; SB 1095 of 2006 (Public Act 342 '06)	A / L M $ $	Extends MI §691.1504, the Good Samaritan law on CPR, to include immunity for AED use. *(Signed; Effective date 11/16/99)* SB 310 requires AEDs in all health clubs. Requires "obvious and ready accessibility" to AED by staff, members, and guests and one or more trained employees. Fines of $250-$1,000 for violations. *(Signed & effective 2/21/2006)* *SB 1085 states the state* "should work with districts" to secure a bulk-purchase discount onAEDs. *(signed & effective 8/30/2006)* SB 1095, Sec. 99d. appropriates up to $100,000 for school AEDs in FY2006-07; providing that districts provide a 50% local match; and requiring that high schools and lower-income districts be served first. *(signed & effective 8/30/2006)*
MN	S.2861 (1998, Chapter 329) S 3345 of 1998	A / L $	Non-professional user is exempt from civil liability. Appropriates $450,000 for distribution to law enforcement.
MS	H 954	A / L	Appropriate training "required"; A Mississippi licensed physician must exercise medical control authority. *(Signed 3/30/99)*
MO	HB 1668 (section 190.092] Rep. Hosmer SB 1107 (2002) HB 1195 (2004)	A / L	Use by emergency personnel or any person who has completed a course certified by the American Red Cross or American Heart Association that includes CPR. *(Signed 1998, 2002, 2004)*
MT	H 126 of 1999	A / L	*(Enacted 4/19/99)*
NE	L 498 of 1999 Sen. Wickersham	A / L	*(Enacted 3/30/99)*
NE	L 667 of 2003 Sen. Jensen L 176 of 2006	A A	Requires owners of AEDs to notify the local emergency medical service of the existence, location, and type of the defibrillator unless the defibrillator was acquired for use in a private residence, a health care facility, or a health care practitioner facility. *(Signed 5/13/03)* Changes provisions relating to automated external defibrillator use *(Signed 3/9/06)*
NH	S. 67 of 1999 S 386 of 2002 H 1136 of 2008 NEW	A / L A A / L	*(Signed 7/16/99)* S 386 establishes an AED registry and requires all commercial owners to register their devices with the department within 30 days of acquisition. *Effective July 2002.* H 1136 limits the training requirement for AED use to "anticipated responders" and permits use by others. *(Signed as Chapter 207, 6/26/08; effective date 8/25/08)*
NJ	Chapter 34 of 1999, formerly A 2321 S 2567 of 2004-0S Sen. Vitale S 3000 of 200S Sen. Bryant	A M $	A person shall not use a defibrillator unless trained. *(signed 3/8/99)* Requires health clubs to acquire and maintain at least one automated external defibrillator and store it in an accessible location within the health club. Requires one or more AED trained employees. *(Signed 1/12/06 as Chapter 346)* Appropriates $1,000,000 for the "AED Grant"
NM	S. 1a of 2002	$	Appropriates $100,000 for automatic external defibrillators in state buildings, from the tobacco settlement program fund. *(Became law by veto override 5/24/02)*
NM	H. 375	A / L	*(Enacted 4/1/99)*
NV	AB 147; Ch. 474 of 1997 AB 409 of 1999 AB 441 of 2003 (Act # 402 of '03)	A / L M	(AB 409) Use is allowed by "any person who has successfully completed the training requirements." Encourages employers to hire a person trained in CPR and AED use. *(Enacted 5/20/99)* AB 441 - NRS 450B.600 requires AEDs in public high schools for all districts with 100,000+ students; all sporting events connected to the University of Nevada, all larger airports and larger county and state offices buildings.
NY	A 8779 of 2002 A 5084 of 2004 (General Business § 627-a) A 236 of 2006	M M A, M	Requirements for public school facilities with more than 1000 persons to provide and maintain on-site AED equipment. Also requires that all school sponsored activities have at least one AED trained staff person present. A 5084 requires health clubs with a membership of 500 or more to have at least one AED. *(Signed 7/20/04 as Chapter 186)* *A 236* requires that CPR and the use of AEDs be taught in health class at senior high schools by teachers that possess valid certification in the operation of AEDs.

	S 7001 of 2006	M	*(Signed 7/26/06 as Chapter 315)* Requires places of public assembly to maintain an AED and to have at least one employee who is trained. *(Signed 9/13/06)*
	AR 1184 of 2008 NEW	/	
	S 6807 of 2008 NEW	$	Memorializing Governor Eliot Spitzer to proclaim 2008 as the Year of the Defibrillator in the State of New York. (Signed 1/23/08)
	A 2988 of 2008 NEW	M	Providing a tax credit for purchase of an AED by a new business in New York.
			Requires recreational swimming facilities to maintain an AED. (Signed 9/4/08 as Chapter 500)
NY	S 5477 of 1998 (Public Health Law § 3000-B) Sen. Goodman	A / L	Only a person who has completed training in CPR & AED operation may use. Authorizes possession & use after obtaining written agreement w/ emergency health care provider. *(Signed 8/5/98)*
NC	S1269 (text) Sen. Warren	A / L	Provides immunity for AED users, as well as trainers, owners and physicians who write prescription for AED purchase. *(Signed 7/14/2000, effective date 10/1/2000)*
ND	H 1242 of 1999	A / L	Requires notification of Dept. of Health of location of AEDs. See agency description of *Chapter 300 of 1999 (Enacted 3/99)*
OH	HB 717 of 1998	A / L	*(Signed 12/17/98; Effective 12/98)*
	HB 434 of 2004 Rep. Calvert	$, M	HB 434 appropriates $2.5 million for AEDs in public schools for FY 2005-06 from Tobacco Settlement funds; allows public, charter and community school districts to require AEDs. *(Signed & effective 5/28/04)*
OK	HB 1190 of 1999 by Rep. Stanley	A / L	*(Enacted 4/26/99)*
OR	SB 313;	A / L	States use of AED is "medical care." (signed 6/4/99; replaced by HB 3482 below). Urges agencies to place AEDs in state buildings, public places, and local government sites. Does not provide funds. *(passed 4/01)*
	SJR 32 of 2001 *Sen. Nelson*		
OR	HB 3482 of 2005	*A / L*	Updates Good Samaritan protection for trained AED providers, employers, property-owners, or agencies who make AEDs available for use, physicians who oversee AED programs, and training providers. AED providers must maintain necessary training and ensure that deployed AEDs have current batteries and electrode pads. The new law, Oregon Revised Statutes 30.802, superseded Oregon's previous AED Good Samaritan law, ORS 30.801. (Detail provided by Tualatin Valley Fire & Rescue, 2007)
PA	HB 4 of 2001	$	Established a one-time program to assist school entities to acquire AEDs. The funds were appropriated by the General Assembly and after a bidding process the statewide contract for two AEDs per school district was awarded - each school district was offered two free AEDs and each intermediate unit and area vocational-technical school was offered one free AED. In addition, AEDs are made available to other school entities including non-public, private, charter and independent schools that meet program requirements. PA program details online
	SB 5	$	SB 5 appropriated $2.4 million for school AEDs.
PA	H.1897 of 1998	A / L	§11 of bill provides AED civil immunity *(Signed 12/15/98)*
RI	*S.2239 of 1998 &*	-	*S.239 mandates distribution of AED devices to every city, town and public college in R.I. Allows use by state police.*
	S.920 of 1999	$	*S.920 funds 35 AEDs to State Police. (signed 6/99)*
	H.7336 of 2000 RI §23-6.2-2 Sen. Polisena Sen. Kelly Rep. Fox		*H.7336 requires AED placement in every city, town, college campus and judicial office. (signed 7/00)*
SC	S 728 of 1999	A / L	(Enacted 6/1/99) Also see S 71 below.
	H 3723 of 2008 NEW	M	(Section 59-17-155) Subject to state appropriations, requires that each school district shall develop and implement an AED program including placing and AED in each school and requiring training for all employees "reasonably expected" to use it. *(Vetoed by governor; became law by veto override as Acts 206 & 278 of 2008, 6/17/08)*
	S 71 of 2008 NEW		> *S 71* provides expanded immunity from civil immunity for use of AEDs.

SD	S 83 of 2000 Sen. Hainje	A / L	Requires a physician to authorize in writing placement, training and maintenance; users also must activate emergency services. *(Signed, 2/00)*
TN	H.2970; Ch. 963 of 1998 Rep. Halteman-Harwel H.1218 of 1999	A / L	Expected users shall complete AED course; maintain & test device; users also must activate emergency services. *(Signed 5/11/98)*
TN	S 281 of 2003 Sen. Williams H 2775 of 2008 NEW	A M	Strengthens registration requirement from "encouraged" to "required" within a reasonable time. *(Signed 5/03)* The "General Assembly encourage(s) local educational agencies to provide, within existing budgetary limits, automated external defibrillators in schools to provide additional safeguards against loss of life from sudden cardiac incidents. *(Signed as Chapter 795, 4/23/08)*
TX	HB 580 of 1999 Rep. Kyle Janek	A / L	*(Enacted 6/99)*
TX **TX**	HB 1 of 2003 Appropriations Bill HB 92	$ A	FY 04 budget requires the Department of Health to allocate for the purchase and placement of AEDs in state-owned and leased buildings. "The department shall establish criteria to identify up to 100 key locations for placement" by December 31, 2003. *(Signed 6/22/03)* Requires that a person or entity that acquires an automated external defibrillator that has not been approved by the United States Food and Drug Administration for over-the-counter sales shall ensure that it has been delivered to the person or entity by a licensed practitioner in the course of their professional practice or upon a prescription or other order lawfully issued in the course of professional practice, or if the equipment is for sale or lease, the person or entity meet certain requirements. Signed 5/8/07 NEW
UT	HB 98 of 1998 Rep.Valentine HB 50 of 1999 Rep. Siddoway SB 86 of 2000 Sen.Valentine SB 95 of 2003 Sen. Valentine	A L L	Allows use by trained persons w/o a license. H.B. 50, now Chapter 285 of 1999, expands Good Samaritan liability exemption S.B. 86, liability exemption extended to laypersons S.B. 95 establishes a statewide database for the collection and distribution of information regarding the location of commercially owned fully automated external defibrillators, including mandatory registration.
VA	HB 2097 of 1999 HB 1049 of 2000 HB 1860 of 2003 Del. O'Bannon SB 1146 of 2006 NEW	A / L L A / L A	HB 1049 clarifies and expands immunity (*Signed as Chapter 928, effective 7/00*) *SB 1146 eliminated the registration program for automated external defibrillators* HB 1860 further defines immunity, and lifts restrictions on public use, eliminates the requirement for registration of automated external defibrillators. *Effective 4/03.*
VT	S 283 of 2000 Senator Illuzzi	A / L	Prohibits any person from operating an AED unless the person has successfully completed a training course in the operation of the AED. Users providing emergency care will not be liable for civil damages. *(Signed 5/2000)*
WA	H 2998 of 1998 Rep. Sheahan	A / L	Owners shall ensure "expected users" complete a training course.
WI	AB 239 of 1999 AB 521 of 2000 Senator Johnsrud SB 186 of 2006 SB 142 of 2008 NEW	A / L A / L A / L A / M	AB 239 *(Signed 7/99)* AB 521 redefines first responders and clarifies required training *(Signed 4/13/2000)* SB 186 provides immunity from civil liability for users, owners, and providers of AEDs for acts or omissions in rendering emergency care in good faith. *(Signed 5/30/06 as Act 486)* *SB 142* Approves individuals, organizations, or institutions of higher education to provide instruction in the use of an AED. Requires all dentists and all day care center licensees, and all employees of a day care center, who provide care and supervision for children have current proficiency in the use of an AED. *(Signed as Act 104 of 2008, 3/14/08)*
WV	H.2269 of 1999 S 619 of 2008 NEW	A L	Section 16-4D-3 Requires registration of AED owners and locations; training and testing; also provides liability exemption for trainined users. *(enacted 4/99)* (Section 16-4D-2) adds definitions for anticipated and unanticipated users of AEDs and limits liability toward unanticipated users who render aid.

WY	H. 178 Rep. Diercks	A / L	Any person acquiring an AED required to ensure that "expected defibrillator users" receive training." *(enacted 3/99)*

FEDERAL ACTION:

Congress Acts on AEDs: In May 2002 President Bush signed into law the Community Access to Emergency Devices Act (Community AED Act) within H.R. 3448 (sections 159, 312 and 313) of the Public Health Security and Bioterrorism Response Act. The President signed the bill on June 12, 2002 as Public Law 107-188. The provisions authorize $30 million in federal grants in year one of the five-year measure. The grants, to be made available to applying states and localities, would be used for the purchase and placement of automated external defibrillators (AEDs) in public places where cardiac arrests are likely to occur. Grant funds would also be used to train first responders to administer immediate life-saving care, including AED use and cardiopulmonary resuscitation (CPR). The bill also encourages private companies to purchase AEDs and to train employees in CPR and emergency defibrillation.

On November 13, 2000 President Clinton signed the federal "Cardiac Arrest Survival Act", in H.R.2498, now Public Law 106-505, regarding the placement of AEDs in federal buildings and providing civil immunity for authorized users. If a Good Samaritan, building owner, or renter acts in good faith to purchase or use an AED to save a life, this law will provide protection from unfair lawsuits. It appropriates $25,000,000 for fiscal years 2001 through 2003 for local grants to purchase AEDs. The federal bill does not preempt state laws on immunity. Many of the 49 states with existing laws cover additional issues not addressed in this bill. U.S. Rep. Cliff Stearns (R-FL) and 132 cosponsors sponsored H.R. 2498.

The Aviation Medical Assistance Act, Public Law 105-170, was the first federal law addressing the positive use of AEDs, signed April 24, 1998 by President Clinton. It declares that air carriers and individuals "shall not be liable for damages" in attempting to obtain or provide assistance on airplanes. It directs the FAA Administrator to "evaluate regulations" and decide on future required use of AEDs on passenger aircraft and in airports.

RELATED WEB RESOURCES:

Sudden Cardiac Arrest Foundation - Information on state and federal laws and bills on CPR and AED use. Updated 2008.

State CPR and AED laws enacted between 2002 and 2006. **(Statescape data)**

State AED and CPR Bills for 2007-2008 **- 432 measures as of 2/7/08 (Statescape data)**

NY: After another saved life, new effort on school defibrillators - AP article 3/7/07.

CT: Bill would require defibrillators in health clubs - article 1/25/07.

"Community Safety: AEDs" - Example of a user-friendly, informative local distict web site, by Tualatin Valley Fire & Rescue, 2007. NEW

Public Access to Defibrillators | Adobe Version - NCSL LegisBrief, October 2002 [members only-password required]

American Heart Association - details on emergency cardiac care and AEDs.

American Red Cross - AED web information

"The Current State of U.S. AED Laws: Risk and Uncertainty for Community-Based AED Programs" - By Richard Lazar, President and CEO, AED Risk Insights, Inc. - 2007

The AED Law Collection - a commercial publication, features "comprehensive AED Law Insights summaries for each state." Available by subscription from AED Risk Insights, Inc.

Public Access Defibrillation League (PADL) - more resources and information on state programs.

AEDs for sale to the general public - link to Amazon.com "click and buy" examples *[intended as a policy tool, not an offer to purchase]* -updated 2/07. NEW

Chain of Survival web site - sponsored by Agilent Technologies and Laerdal Medical Corporation.

MERGInet - Medical, Emergency, Rescue and Global Information Network.

"Shocks to Save Lives" - NCSL *State Legislatures Magazine* article, October-November, 1999 by Richard Cauchi, Health Care Program.

Ordinary People Save Lives with Defibrillators - by Cheryl Runyon, NCSL

Details on cardiac arrest, defibrillation and CPR, on-line facts courtesy of the Washington State legislative staff. [2]

Notes

1 - CT: Quote from summary of CT S 318 of 1998.

2 - WA: "Final Bill Report, SHB 2998: Synopsis as Enacted" Washington State Legislature.

3 - DE: The Delaware Health & Social Services, Division of Public Health, Office of Emergency Medical Services promulgated: "The Delaware Early Defibrillation Program Administrative Policy", Protocol revised 5/6/98. §9 Provider Training Program "shall be under the direction and supervision of the American Heart Association".

For a more detailed discussion of the medical and social implications of this issue see "Is It Time for Over-the-Counter Defibrillators?" by Mickey Eisenberg, M.D., and "The Shocking Truth about AEDs" by Jeremy Brown, M.D., both published in JAMA, September 20, 2000.

portable AED, 2003

Definitions - cardiac arrest or heart attack?

Sudden cardiac arrest occurs when the heart fibrillates - a chaotic, abnormal electrical activity of the heart -- which causes the heart to quiver in an uncontrollable fashion. The person loses consciousness very quickly and unless the condition is reversed, death follows in a matter of minutes. Heart attack, on the other hand, occurs when the blood supply to part of the heart muscle itself is severely reduced or stopped because of an obstruction in an artery. A heart attack can trigger sudden cardiac arrest, but they are not the same things.

Mixing up the terms "heart attack" and "cardiac arrest" is quite common. In the media, reporters often mis/eport people dying from a "massive heart attack." Chances are, the reporter is actually referring to sudden cardiac arrest. Making the distinction is important because, while both heart attack and cardiac arrest are medical emergencies, a person suffering cardiac arrest literally has minutes to live and responding with an AED within those minutes will mean the difference between life and death for the victim.

- Source: American Heart Association, 1999

Disclaimer: The descriptions of state laws provided in this memorandum are abbreviated for ease of use. Use the links or citations to full text of the laws for a more complete understanding of individual state's laws and procedures. NCSL is not responsible for interpretation or local application of these laws and regulations.

NCSL Contacts - for legislators and legislative staff:

Dick Cauchi, **Health Program-Denver, Colorado;** Kae Warnock, **Legislative Management.**

American Heart Association/American Stroke Association Contact:

Jill Birnbaum, jill.birnbaum@heart.org, **AHA National Advocacy Department, Minneapolis, MN 952-278-7902.**

Visit this site again: www.ncsl.org/programs/health/aed.htm

NCSL Health Menu

: December 2008 hzlv

Denver Office
Tel: 303-364-7700 | Fax: 303-364-7800 | 7700 East First Place | Denver, CO 80230

Washington Office
Tel: 202-624-5400 | Fax: 202-737-1069 | 444 North Capitol Street, N.W., Suite 515 | Washington, D.C. 20001

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

Automated External Defibrillators in Health/Fitness Facilities: Supplement to the AHA/ACSM Recommendations for Cardiovascular Screening, Staffing, and Emergency Policies at Health/Fitness Facilities

Gary J. Balady, Bernard Chaitman, Carl Foster, Erika Froelicher, Neil Gordon and Steven Van Camp

Circulation 2002;105;1147-1150
DOI: 10.1161/hc0902.105998
Circulation is published by the American Heart Association. 7272 Greenville Avenue, Dallas, TX 72514
 Print ISSN: 0009-7322. Online ISSN: 1524-4539

AHA/ACSM Scientific Statement

Automated External Defibrillators in Health/Fitness Facilities

Supplement to the AHA/ACSM Recommendations for Cardiovascular Screening, Staffing, and Emergency Policies at Health/Fitness Facilities

Writing Group
Gary J. Balady, MD, Chair; Bernard Chaitman, MD; Carl Foster, PhD; Erika Froelicher, PhD; Neil Gordon, MD; Steven Van Camp, MD

In 1998, the American Heart Association (AHA) and American College of Sports Medicine (ACSM) published recommendations[5,6] for health/fitness facilities regarding the screening of clients for the presence of cardiovascular disease, appropriate staffing, emergency policies, equipment, and procedures relative to the client base of a given facility. Accordingly, health/fitness facilities are defined as organizations that offer exercise-based health and fitness programs as their primary or secondary service or that promote moderate- to vigorous-intensity recreational physical activity. These range from level 1 (unsupervised exercise room) to level 5 (medically supervised exercise program), and their specific characteristics are outlined in Table 1. Details regarding emergency readiness are provided in the AHA/ACSM recommendations[5,6] and emphasize that all health/fitness facilities must have written emergency policies and procedures that are reviewed and practiced regularly, and that in all supervised facilities, exercise leaders must be trained in basic cardiopulmonary resuscitation (CPR). Because of the publication of the 1998 AHA/ACSM recommendations, 47 states have since passed Good Samaritan legislation, and the federal government has passed the Cardiac Arrest Survival Act and the Rural Access to Emergency Devices Act as components of the federal Public Health Improvement Act of 2000.[7] These state and federal laws now serve to expand Good Samaritan legal protections to users of automated external defibrillators (AEDs) throughout the nation. Therefore, the purpose of this statement is to supplement the 1998 AHA/ACSM recommendations[5,6] regarding the purchase and use of AEDs in health/fitness facilities. Similar to the parent document,[5,6] these recommendations are based on a review of the literature and consensus of the writing group after having undergone extensive peer review and final approval by AHA and ACSM. The recommendations are not mandatory or all encompassing, nor do they limit provision of individualized care by health/fitness facilities exercising independent judgment.

Role of AEDs in the Chain of Survival

An AED is a device that incorporates a rhythm-analysis system and a shock-advisory system for victims of cardiac arrest.[1] The AED advises a shock, and the operator must take the final action to deliver the shock. The International Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care[2] conclude that early CPR is the best treatment for cardiac arrest until the arrival of an AED and advanced cardiac life support care. The chain of survival includes a series of actions designed to reduce mortality associated with cardiac arrest. Early CPR plays an important role in the chain of survival that includes the following links: 1) early recognition of cardiopulmonary arrest, 2) early CPR, 3) early defibrillation when indicated, and 4) early advanced cardiac life support care.[3] Early CPR can prevent ventricular fibrillation from deteriorating to asystole, may increase the chance of successful defibrillation, contributes to the preservation of heart and brain function, and significantly improves survival.[4] Importantly, for victims of sudden, shockable cardiac arrest (ventricular fibrillation or pulseless ventricular tachycardia), the single greatest determinant of survival is the time from collapse to defibrillation. A recent review[17] summarizes the data comparing the time-to-shock between first responders (i.e., firefighters, police, and emergency medical system (EMS) basic life support personnel) versus paramedics and demonstrates significantly shorter times among first responders in three of five studies. A survival rate, among victims of witnessed ventricular fibrillation cardiac arrest, as high as 90% has been reported when defibrillation is achieved within the first minute of collapse.[8,11,14,15,21] Survival rates decline 7–10% with every minute that defibrillation is delayed, such that a cardiac arrest victim without defibrillation beyond 12 minutes has only a 2–5% chance of survival.[1] The highest survival rates for out of hospital cardiac arrest have been reported in cardiac rehabilitation programs equipped with defibrillators (i.e., Table 1: level-5 facilities), where survival approaches 90%.[8,11,14,15,21] The International Guidelines[2] conclude that public access to defibrillation (PAD) accomplished by the placement of AEDs in selected locations for immediate use by trained laypersons may be the key

"Automated External Defibrillators in Health/Fitness Facilities" was approved by the American Heart Association Science Advisory and Coordinating Committee in December 2001.

This statement is being published simultaneously in *Medicine and Science in Sports and Exercise*.

(*Circulation*. 2002;105:1147-1150.)

Health/Fitness Facilities—Emergency Plans and Equipment*

	Level 1	Level 2	Level 3	Level 4	Level 5
Type of facility	Unsupervised exercise room (e.g., those in hotels, commercial buildings, and apartment complexes)	Single exercise leader	Fitness center for general membership	Fitness center offering special programs for clinical populations	Medically supervised clinical exercise program (e.g., cardiac rehabilitation)
Personnel†	None	Exercise leader Recommended: medical liaison	General manager Health/fitness instructor Exercise leader Recommended: medical liaison	General manager Exercise specialist Health/fitness instructor Medical liaison	General manager Exercise specialist Health/fitness instructor Medical liaison
Emergency plan	Present	Present	Present	Present	Present
Emergency equipment	Telephone in room Signs Encouraged: PAD plan with AED as part of the composite PAD plan in the host facility (e.g., hotel, commercial building, apartment complex)	Telephone Signs Encouraged: blood pressure kit, stethoscope, PAD plan with AED	Telephone Signs Encouraged: blood pressure kit, stethoscope, PAD plan with AED (the latter are strongly encouraged in facilities with membership >2500 and those in which EMS response time is expected to be >5 minutes from recognition of arrest)	Telephone Signs Blood pressure kit Stethoscope Strongly encouraged: PAD plan with AED	Telephone Signs Blood pressure kit Stethoscope Oxygen Crash cart Defibrillator‡

AED, automatic external defibrillator; PAD, public access to defibrillation.

*This table should replace the bottom half of Table 5 of the AHA/ACSM Recommendations.[5,6]

†Detailed definitions and competencies for personnel positions are outlined in the ACSM Guidelines.[10]

‡Standard equipment in level 5 facilities includes a defibrillator.[5,6,22]

intervention to significantly increase survival from an out-of-hospital cardiac arrest. Two recent observational studies report impressive results regarding the effectiveness of PAD in persons with witnessed cardiac arrest, who are in ventricular fibrillation, with AED placement in casinos[20] and on airplanes.[19] The cardiac arrest survival rates to discharge from the hospital were 53% and 40%, respectively.

Cardiovascular Risks of Exercise

The AHA/ACSM Recommendations[5,6] provide details regarding the cardiovascular risks of exercise. It is clear that the risk of adverse cardiovascular events including death is greater among those individuals with cardiovascular disease than among presumably healthy individuals.[5,6,9] As the demographics of the more than 30 million individuals who exercise at health/fitness facilities demonstrate a steady increase in the number of members older than 35 yr (approximately 55% of current membership),[16] it is reasonable to presume that the number of members with cardiovascular disease (and other comorbidities) is rising as well. Although there are no data regarding the incidence of cardiac arrest at health/fitness facilities, two recent surveys provide some important insight. A large database consisting of more than 2.9 million members of a large commercial health/fitness facility chain demonstrates 71 deaths (mean age 52 ± 13 yr; 61 men, 10 women) occurring over a 2-year period, yielding a rate of 1 death/100,000 members/year. The death rate was highest among those members who exercised less frequently, such that nearly half of exercise-related deaths were in those who exercised less than once/week.[12] The cardiac arrest rate was not reported but was presumably higher than the death rate. A recent survey of 65 randomly chosen health/fitness facilities in Ohio[18] reports the occurrence of sudden cardiac arrest or heart attack in 17% of facilities during a 5-year period. Notably, only 3% of facilities had an AED on site. Thus, it is prudent to conclude that health/fitness facilities should be considered among the sites in which PAD programs should be established.

Recommendations

It is essential to acknowledge that emergency equipment alone does not save lives. The ACSM/AHA Recommendations[5,6] emphasize the importance of written emergency policies and procedures that are reviewed and practiced regularly. Well-trained health/fitness facility staff members are essential to maintain strong links in the chain of survival for their clients. Effective placement and use of AEDs at all health/fitness facilities (Table 1: levels 1–5) is encouraged, as permitted by law, to achieve the goal of minimizing the time between recognition of cardiac arrest and successful defibrillation. Until further definitive data are available, AED placement is strongly encouraged in those health/fitness facilities with a large number of members (i.e., membership > 2500; (> median size health/fitness facility[16])); those that offer special programs to clinical populations (i.e., programs for the elderly or those with medical conditions (level 4)) (note that in level-5 facilities, current equipment standards require defibrillators[5,6,22]; and those health/fitness facilities in which the time from the recognition of cardiac arrest until the first shock is delivered by the EMS is anticipated to be > 5

minutes. In unsupervised exercise rooms (level-1 facilities), such as those that might be located in hotels, apartment complexes, or office buildings, the AED should be part of the overall PAD plan for the host facility. At the least, an unsupervised exercise room should have a telephone available in the room with clearly posted numbers to call in case of emergency. In supervised settings, it is essential that designated health/fitness facility staff members who are trained in CPR be present during all hours of operation. CPR should be initiated as soon as a cardiac arrest is recognized and should be continued until the AED is placed on the victim and is activated. In cases of cardiac arrest not due to ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT), AEDs are of no value, and CPR must be maintained. Also, after successful termination of VF/pulseless VT, the rescuer must be able to open the airway and support ventilation and circulation with chest compressions as needed until the arrival of EMS personnel.

Therefore, the establishment of a PAD at all health/fitness facilities is encouraged. This plan should include the following:

- Have written emergency policies and procedures that are practiced regularly (i.e., at least once every 3 months).
- Designate staff members who are trained in CPR and function as first responders in the health/fitness facility setting during all hours of operation.
- Train staff to recognize cardiac arrest.
- Activate EMS—assign staff to meet the emergency response team at the entrance of the facility so that they can be promptly guided to the victim.
- Provide CPR.
- Attach/operate AED (detailed instructions are provided by the specific equipment manufacturer and general recommendations are outlined in the Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.[1])
- The use of AEDs in infants and children < 8 yr of age is not recommended.[1]

Health/fitness facilities should coordinate their PAD program with the local EMS, because many dispatch systems use local phone-directed protocols to assist rescuers in the use of AED and may notify local EMS en route that an AED is being used at the scene. Moreover, the local EMS may assist with program planning and quality improvement, including medical direction, AED deployment and protocols, training, monitoring, and review of AED events.[1] Emergency drills should be practiced at least once every 3 months or more often when staff changes occur.[5,6] When new staff are hired, new team arrangements may be necessary. The simulated use of AEDs in drills offers the best opportunity for skills maintenance. Maintaining the AED device in proper working condition according to the manufacturer's recommendations is essential. PAD programs must comply with local or regional regulation and legislation.

Costs

Details regarding the technical aspects of AEDs are available elsewhere.[1,17] At present, the cost of an AED is approximately $3000–$4500 per unit. It is expected that the price of AEDs will likely decrease as their use becomes more widespread. The National Heart Lung and Blood Institute (NHLBI), in partnership with the AHA and industry, is conducting a multisite, controlled, prospective study to determine the efficacy and cost-effectiveness of placing AEDs in a variety of public settings. A recent independent study[13] has demonstrated that a program of placing AEDs on large (>200 passenger) and medium (>100 passenger) capacity aircraft attain generally accepted levels of cost-effectiveness. However, the cost-effectiveness of AED deployment on smaller aircraft is, at this time, less certain. Similarly, as the cost-effectiveness of AED placement in health/fitness facilities is unknown, it is expected that these recommendations will be reviewed and updated when such data become available. At this time, individual health/fitness facilities are encouraged to maintain data on the utility of their PAD programs and perhaps engage in a collaborative effort with other health/fitness facilities to assess the success of their programs.

Summary of Key Points

- The Cardiac Arrest Survival Act and the Rural Access to Emergency Devices Act, as components of the federal Public Health Improvement Act of 2000, as well as Good Samaritan laws passed in 47 states, expands Good Samaritan legal protections to users of AEDs throughout the nation.
- The placement of AEDs in selected locations for immediate use by trained laypersons may be the key intervention to significantly increase survival from an out-of-hospital cardiac arrest.
- The chain of survival includes a series of actions designed to reduce mortality associated with cardiac arrest and includes the following links: 1) early recognition of cardiopulmonary arrest, 2) early CPR, 3) early defibrillation when indicated, and 4) early advanced cardiac life support care.
- Well-trained health/fitness facility staff members are essential to maintain strong links in the chain of survival for their clients.
- Effective placement and use of AEDs at all health/fitness facilities (Table 1: levels 1–5) is encouraged, as permitted by law, to achieve the goal of minimizing the time between recognition of cardiac arrest and successful defibrillation. Until further definitive data are available, AED placement is strongly encouraged in those health/fitness facilities with a large number of members (i.e., membership > 2500); those that offer special programs to clinical populations (i.e., programs for the elderly or those with medical conditions (level 4)); and those health/fitness facilities in which the time from the recognition of cardiac arrest until the first shock is delivered by the EMS is anticipated to be > 5 minutes. In unsupervised exercise rooms (level-1 facilities), such as those that might be located in hotels, apartment complexes, or office buildings, the AED should be part of the overall PAD plan for the host facility.

- Health/fitness facilities should coordinate their PAD program with the local EMS.
- Emergency drills should be practiced at least once every 3 months or more often when staff changes occur.
- PAD programs must comply with local or regional regulation and legislation.

Acknowledgments

This work is a supplement to the AHA/ACSM Recommendations for Cardiovascular Screening, Staffing, and Emergency Policies at Health/Fitness Facilities.[5,6]

References

1. American Heart Association and International Liaison Committee on Resuscitation. Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation* 102(Suppl. 1):I60–76, 2000.
2. American Heart Association and International Liaison Committee on Resuscitation. Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation* 102(Suppl. I):II–375, 2000.
3. American Heart Association and International Liaison Committee on Resuscitation. Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation* 102(Stppl. 1):I358–370, 2000.
4. American Heart Association and International Liaison Committee on Resuscitation. Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation* 102(Suppl. 1):122–59, 2000.
5. Balady, G. J., B. Chaitman, D. Driscoll, et al. American Heart Association/American College of Sports Medicine Joint Scientific Statement: Recommendations for Cardiovascular Screening, Staffing, and Emergency Policies at Health/Fitness Facilities. *Circulation* 97:2283–2293, 1998.
6. Balady, G. J., B. Chaitman, D. Driscoll, et al. American Heart Association/American College of Sports Medicine Joint Scientific Statement: Recommendations for Cardiovascular Screening, Staffing, and Emergency Policies at Health/Fitness Facilities. *Med. Sci. Sports Exerc* 30:1009–1018, 1998.
7. Cardiac Arrest Survival Act of 2000. Public Law 106–505, Sec. 401–404.
8. Fletcher, G.F., and J.D. Cantwell. Ventricular fibrillation in a medically supervised cardiac exercise program: clinical, angiographic and surgical correlations. *JAMA* 238:2627–2629, 1977.
9. Fletcher, G.F., G.J. Balady, V.F. Froelicher, L.H. Hartley, W.H. Haskell, and M.L. Pollock. Exercise Standards: A Statement for Health Professionals from the American Heart Association. *Circulation* 91:580–615, 1995.
10. Franklin, B. (Ed.). *American College of Sports Medicine Guidelines for Exercise Testing and Prescription* (6th Ed.). Baltimore: Williams & Wilkins, 2000, pp. 322–351.
11. Franklin, B.A., K. Bonzheim, S. Gordon, and G.C. Timmis. Safety of medically supervised outpatient cardiac rehabilitation exercise therapy: a 16 year follow-up. *Chest* 114:902–906, 1998.
12. Franklin, B.A., J.M. Conviser, B. Stewart, J. Lasch, and G.C. Timmis. Sporadic exercise: a trigger for acute cardiovascular events? (Abstract). *Circulation* 102(Suppl. 2):II612, 2000.
13. Groeneveld, P.W., J.L. Kwong, Y. Liu, et al. Cost-effectiveness of automated external defibrillators on airlines. *JAMA* 286:1482–1489, 2001.
14. Haskell, W.L. Cardiovascular complications during exercise training of cardiac patients. *Circulation* 57:920–924, 1978.
15. Hossack, K.F., and R. Hartwig. Cardiac arrest associated with supervised cardiac rehabilitation. *J. Cardiac Rehabil.* 2:402–408, 1982.
16. International Health, Racquet, and Sportsclub Association. 2000 Profiles in Success. Boston, 1999.
17. Marenco, J.P., P.J. Wang, M.S. Link, M.K. Homoud, and N.A.M. Estes. Improving survival from sudden cardiac arrest: the role of the automated external defibrillator. *JAMA* 285:1193–1200, 2001.
18. McInnis, K.J., W. Herbert, D. Herbert, J. Herbert, P. Ribisl, and B. Franklin. Low compliance with national standards for cardiovascular emergency preparedness at health clubs. *Chest* 120:283–288, 2000.
19. Page, R.L., J.A. Joglar, R.C. Kowal, et al. Use of automated external defibrillators by a U.S. airline. *N. Engl. J. Med.* 343:1210–1216, 2000.
20. Valenzuela, T. D., D.J. Roe, G. Nichol, L.L. Clark, D.W. Spaite, and R.G. Hardman. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. *N. Engl. J. Med.* 343:1206–1209, 2000.
21. Van Camp, S.P., and R.A. Peterson. Cardiovascular complications of outpatient cardiac rehabilitation programs. *JAMA* 256:1160–1163, 1986.
22. Williams, M (Ed.). *American Association for Cardiovascular, and Pulmonary Rehabilitation: Guidelines for Cardiac Rehabilitation and Secondary Prevention Programs.* Champaign, IL: Human Kinetics, 1999.

KEY WORDS: AHA Scientific Statements ■ automated external defibrillators ■ exercise ■ resuscitation ■ cardiac arrest ■ defibrillation

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

Use of Automated External Defibrillators for Children: An Update: An Advisory Statement From the Pediatric Advanced Life Support Task Force, International Liaison Committee on Resuscitation

R.A. Samson, R.A. Berg, R. Bingham, D. Biarent, A. Coovadia, M.F. Hazinski, R.W. Hickey, V. Nadkarni, G. Nichol, J. Tibballs, A.G. Reis, S. Tse, D. Zideman, Jerry Potts, K. Uzark and D. Atkins

Circulation 2003;107;3250-3255
DOI: 10.1161/01.CIR.0000074201.73984.FD
Circulation is published by the American Heart Association. 7272 Greenville Avenue, Dallas, TX 72514
 Print ISSN: 0009-7322. Online ISSN: 1524-4539

ILCOR Advisory Statement

Use of Automated External Defibrillators for Children: An Update

An Advisory Statement From the Pediatric Advanced Life Support Task Force, International Liaison Committee on Resuscitation

Writing Group

R.A. Samson, MD*; R.A. Berg, MD*; R. Bingham, MBBS, FRCA†

Members of the PALS Task Force

D. Biarent, MD†; A. Coovadia, MD‡; M.F. Hazinski, RN, MSN*; R.W. Hickey, MD*; V. Nadkarni, MD*; G. Nichol, MD, MPH§; J. Tibballs, MBBS‖; A.G. Reis, MD¶; S. Tse, MD§; D. Zideman, MBBS†

Additional Contributors

Jerry Potts, PhD*; K. Uzark, PhD, CPNP*; D. Atkins, MD*

ILCOR Recommendations

On the basis of the published evidence to date, the Pediatric Advanced Life Support (PALS) Task Force of the International Liaison Committee on Resuscitation (ILCOR) has made the following recommendation (October 2002):

- Automated external defibrillators (AEDs) may be used for children 1 to 8 years of age who have no signs of circulation. Ideally the device should deliver a pediatric dose. The arrhythmia detection algorithm used in the device should demonstrate high specificity for pediatric shockable rhythms, ie, it will not recommend delivery of a shock for nonshockable rhythms (Class IIb).

In addition:

- Currently there is insufficient evidence to support a recommendation for or against the use of AEDs in children <1 year of age.
- For a lone rescuer responding to a child without signs of circulation, the task force continues to recommend provision of 1 minute of CPR before any other action, such as activating the emergency medical services (EMS) system or attaching the AED.
- Defibrillation is recommended for documented ventricular fibrillation (VF)/pulseless ventricular tachycardia (VT) (Class I).

Introduction

This statement expands and clarifies the 2000 ILCOR recommendations about the potential use of AEDs in children. The need for this update has become critical. A growing number of AEDs for adults are being placed in public access settings, and the use of AEDs by nontraditional responders is increasing. The likelihood for use of AEDs in smaller (<25 kg), younger (<8 years of age) patients is now a reality. This statement provides the rationale for development of AEDs, outlines questions about the efficacy and safety of AEDs used in smaller, younger children, and summarizes recent efforts to justify the use of existing or modified AEDs in smaller, younger children.

Rationale for AED Use

The primary determinant of survival from VF cardiac arrest is the time interval from collapse until defibrillation. Out-of-hospital defibrillation within the first 3 minutes of witnessed adult VF arrest results in survival rates >50%. But the success of resuscitative efforts decreases dramatically with

---

The American Heart Association makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest.

This statement was approved by the American Heart Association Science Advisory and Coordinating Committee on February 11, 2003. A single reprint is available by calling 800-242-8721 (US only) or writing the American Heart Association, Public Information, 7272 Greenville Ave, Dallas, TX 75231-4596. Ask for reprint No. 71-0256. To purchase additional reprints: up to 999 copies, call 800-611-6083 (US only) or fax 413-665-2671; 1000 or more copies, call 410-528-4426, fax 410-528-4264, or e-mail klbradle@lww.com. To make photocopies for personal or educational use, call the Copyright Clearance Center, 978-750-8400.

From the *American Heart Association, †European Resuscitation Council, ‡Resuscitation Council of Southern Africa, §Heart and Stroke Foundation of Canada, ‖Australia and New Zealand Resuscitation Councils, and ¶InterAmerican Heart Foundation.

This statement has been copublished in the July 2003 issue of *Pediatrics* and in the June 2003 issue of *Resuscitation*.

(*Circulation.* 2003;107:3250-3255.)

Circulation is available at http://www.circulationaha.org DOI: 10.1161/01.CIR.0000074201.73984.FD

the passage of time. For every 1-minute delay in defibrillation, the survival rate may decrease by 7% to 10%, although this number is influenced by the presence and quality of bystander CPR. After >12 minutes of VF, the survival rate of adults is <5%.[1]

Therefore, ILCOR encourages the placement of simple AEDs for use by first responders in public settings. In some settings AED use has substantially improved the rate of survival from VF in adults.[2,3] The AED is the only defibrillator available for use by first-responding EMS personnel, and it is now considered the standard of care by first responders. ILCOR has become a strong advocate for greater use of public access defibrillation, calling for and supporting widespread availability of AEDs. Trained responders have effectively used AEDs in many public settings, including casinos, airport terminals, and airplanes.[4–6]

The Conundrum of Pediatric VF and AEDs for Use in Adults

All commercially available AEDs use algorithmic rhythm analysis programs derived from in vitro rhythm libraries of adult shockable and nonshockable rhythms. AED developers use an empirical, iterative process to create and adjust filters, measurements, and decision rules. This process enables the AED to "decide" to recommend a shock for the highest possible percentage of shockable rhythms (maximum sensitivity) and to avoid shocking the highest possible percentage of nonshockable rhythms (maximum specificity).

All currently available AEDs are programmed to deliver adult-dose shocks with energies ranging from 150 to 360 J when adult pads/cables are used. These adult doses of energy were selected to be safe and effective for adult victims only. At the time of publication of the *ILCOR Guidelines 2000*, no devices were designed for use in children <8 years of age, and none was approved or cleared by the United States Food and Drug Administration (FDA) for use in children. Moreover, there were no data regarding the safety and efficacy of either (1) an AED diagnostic rhythm analysis program to differentiate shockable from nonshockable rhythms in children or (2) an appropriate defibrillation dose or dosing sequence for children <8 years of age. Therefore, the Class of Recommendation for use of AEDs in children <8 years of age was necessarily Indeterminate.[7]

As a result, children with VF in the prehospital setting have been "orphans" with respect to this effective technology. This issue was highlighted as one of the most pressing problems for pediatric cardiac arrest victims at ILCOR'S 1999 Emergency Cardiovascular Care Evidence Evaluation Conference and the 1998 AHA conference "Ventricular Fibrillation: A Pediatric Problem."[8]

Basis for Pediatric Defibrillation Dosage

In the mid 1970s various authoritative sources recommended initial shock doses of 200 J for all children and 60 to 100 J for all infants in VF.[9,10] Use of the same defibrillation dose in both children and adults seemed potentially dangerous despite clinical experience that indicated the effectiveness of such doses. These concerns were supported by only limited animal data, some of which suggested that histopathologic myocardial damage may begin to occur with doses as low as >10 J/kg.[11–14] In addition, further animal data suggested that doses of 0.5 to 10 J/kg were generally adequate for defibrillation in a variety of species.[14]

Gutgesell and colleagues[15] conducted the largest clinical study of an effective defibrillation dose for children. They retrospectively evaluated the efficacy of defibrillation attempts at energy doses of 2 J/kg. The authors reviewed 71 transthoracic defibrillation attempts in 27 children whose ages ranged from 3 days to 15 years and who weighed from 2.1 to 50 kg. The authors reported that 91% of shocks within 10 J of the standard 2 J/kg dose successfully terminated VF.

The task force recommendation of 2 J/kg is derived entirely from this study, although it included only 27 children with short-duration VF and the definition of success was electrical defibrillation with no reference to postshock clinical outcomes, such as a sustained stable perfusing rhythm. Although decades of clinical use confirm that 2 J/kg is effective, no research to date has confirmed it as the most effective dose.

Incidence of VF in Children

VF is an uncommon cause of out-of-hospital pediatric cardiac arrest in infants (<1 year of age), but its occurrence increases with growing age. Two studies reported VF as the initial rhythm in 19% to 24% of out-of-hospital pediatric cardiac arrests if sudden infant death syndrome (SIDS) deaths were excluded.[16,17] In studies that included SIDS victims, however, the frequency dropped to 6% to 10%.[18–20] The rationale for exclusion of SIDS patients is that SIDS is not amenable to treatment, so patients with SIDS should not be included in studies that may influence potential treatment strategies for cardiac arrest. A recent report, however, documented VF in a 3-month-old infant with SIDS who was subsequently diagnosed with prolonged QT syndrome.[21]

Recent data suggest that VF is not a rare rhythm in pediatric arrest. This is encouraging because VF is the arrest arrhythmia associated with improved survival rate in most studies of children.[16,17,22,23] For example, Mogayzel and colleagues[16] reported that 5 of 29 children (17%) who presented with VF in a prehospital setting survived with good neurological outcome versus only 2 of 128 (2%) who presented with asystole/pulseless electrical activity ($P<0.01$).

In-hospital studies of pediatric CPR also indicate that VF is not a rare rhythm among children in cardiac arrest. Two recent comprehensive studies report the incidence of VF as the initial rhythm and the incidence of VF at some time during the arrest. Suominen et al[24] reported initial VF in 11% of children in cardiac arrest and VF in 20% of children some time during the arrest. In a much larger study,[25] cardiac arrest data submitted to the National Registry of CardioPulmonary Resuscitation reveal initial VF/VT in 12% of children and VF/VT at some time during 25% of the pediatric arrests.

Factors That Affect Effectiveness of Transthoracic Shocks

The success of defibrillation depends on delivery of sufficient current flow (amperes) for a sufficient length of time to

depolarize a critical mass of myocardium. In the 1970s, animal studies established that inadequate current through the myocardium led to unsuccessful defibrillation, whereas too much current resulted in postresuscitation myocardial damage.[11,14] These studies further established that the density of current through the myocardium* determined the balance between effectiveness of the shock and myocardial damage.

The basic principles of electrical cardiac defibrillation have been reviewed.[26] For any given waveform, current flow increases with higher shock energy (J) and decreases with higher impedance or resistance (ohms). Several factors increase impedance along the path between defibrillator paddles or electrode pads and decrease current through the myocardium. These factors include a paddle or electrode pad that is too small, large lung volumes, and lack of conducting gel between the skin and defibrillator paddles or electrode pads.

Factors that decrease impedance and thus increase current through the myocardium include the use of electrical conducting gel and increased paddle pressure (reduces impedance by improving skin/electrode contact and squeezing air from the lungs). Impedance may also be reduced by repeated shocks (partly due to increased flow of blood after each shock), although the degree of this reduction is unclear.[27] Increased paddle or electrode pad size does reduce impedance and therefore increases total current flow. But this does not necessarily increase the amount of current delivered to the myocardium (current density), because if the paddles or electrode pads are larger than the cross section of the heart, much of the current bypasses its target—the myocardium—through extramyocardial pathways.

Studies of transthoracic impedance in animals, children, and adults suggest nonlinear relationships among size, weight, and thoracic impedance.[28–31] Additional acceptable evidence is needed to resolve these contemporary inconsistencies. The theme of the evidence suggests that children have higher thoracic impedance than would be expected on the basis of weight alone. This suggests that the present dose of 2 J/kg may need an upward adjustment in smaller patients, or, equally valid, the chance of myocardial damage from any particular dose is less than previously feared. Another important factor influencing shock effectiveness is the shock waveform. In recent years biphasic waveforms have been introduced into external defibrillators and have been shown in clinical studies to have advantages over conventional monophasic waveforms. With biphasic waveforms, a smaller shock will defibrillate effectively yet larger energies are well tolerated, so that a single energy delivery may be applicable across a wider age or size range.[32–34]

Why Adult AEDs May Not Be Appropriate for Use in Children

Young children are much smaller than adults and therefore require a much lower energy setting for delivery of the same defibrillation dose (J/kg) used in an adult. AEDs designed for use in adults have energy levels (or a single energy level) capable of delivering a substantially higher dose (J/kg) to young children. Another concern is that infants and small children with sinus tachycardia or supraventricular tachycardia can have very high heart rates that might be misinterpreted as "shockable" rhythms by an AED with a diagnostic program developed for analyzing adult arrhythmias.

Current Recommendations in Pediatric Guidelines for Use of AEDs

The *2000 International Guidelines* recommend use of AEDs for rhythm identification in children ≥8 years of age (Class IIb). Attempted defibrillation of VF/pulseless VT detected by an AED may be considered in these older children (Class Indeterminate). Attempted defibrillation of children less than approximately 8 years of age is not recommended, however.[6]

The average 8-year-old child weighs 25 kg. The current recommended initial dose of 150 to 200 J would provide 6 to 8 J/kg for the average 8-year-old. If the initial shock fails to eliminate VF, some AEDs are programmed to provide escalating doses to a maximum dosage of up to 360 J. Thus, second and subsequent doses deliver 150 to 360 J, resulting in a shock of 1 to 4 J/kg in an adult who weighs 80 to 125 kg and 6 to 15 J/kg in an 8-year-old child who weighs 25 kg.

Criteria for Changing the Recommendations for Use of AEDs in Children

First, it is necessary to determine whether the rhythm analysis system of a particular AED is safe and effective for children. This means that the rhythm analysis system must be evaluated to determine its capability to safely differentiate between shockable and nonshockable rhythms in children. Every effort must be made to confirm that the AED is safe when attached to and used in a child who does not have a shockable rhythm and who could be harmed by an inappropriate shock. Second, it is necessary to demonstrate that each AED delivers shocks that effectively defibrillate a child's heart and at the same time avoids any myocardial damage.

Clinical Data

One case report describes the successful use of a biphasic AED for adults in a 3-year-old child (level of evidence [LOE]=5).[35] The child was successfully defibrillated with a single shock of 150 J (9 J/kg). Postresuscitation serum creatine kinase (216 IU/L) and troponin I (0.4 ng/mL) concentrations were normal. A postresuscitation echocardiogram showed no change in ventricular function compared with previous examinations.

Rhythm Analysis

A recently published report[36] suggests that the rhythm analysis program of one AED system generally satisfies the sensitivity criterion of the AHA AED performance goals (ie, the device shocks a shockable rhythm) for VF, 1 of the 2 shockable rhythms. The same system also satisfies the AHA specificity criterion (ie, the device will not shock a nonshockable rhythm) for the nonshockable rhythms: sinus rhythm, supraventricular arrhythmias, ventricular ectopic beats, idioventricular rhythms, and asystole (this study contains LOE=3

*Current density (amperes/cm^2) in the myocardium is the total amount of current flow that passes through an area defined by a plane perpendicular to the path of the current and the myocardium that intersects with that plane.

and LOE=4).[36,37] The sensitivity for VF was 96%, which satisfies the AHA recommendation of >90%. The sensitivity for identification of rapid VT was 71%, which is below the AHA criterion of >75% sensitivity to shock rapid VT. The study reported 100% specificity for shockable rhythms (ie, the device never recommended a shock for a nonshockable rhythm). Most of the ECG rhythms (and all of the nonshockable rhythms) in that study were prospectively acquired (in hospital) using a modified AED. About 12%, however, were retrospectively collected (from in-hospital and out-of-hospital sources) and digitized from paper strips, then subjected to analysis by the AED's rhythm recognition algorithm. Those ECG test signals therefore lacked the fidelity of the ECGs acquired directly by an AED. Nevertheless, these initial findings are encouraging.

Another study prospectively examined the accuracy of a rhythm analysis program with an AED by another manufacturer. In this study the AED pads were used to directly record all of the ECG signals that were subsequently analyzed by an AED (LOE=3),[38] which more realistically simulated the signal that would be analyzed by an AED in clinical use. Sensitivity for shockable VF was 94%. Sensitivity for shockable rapid VT was 60%, once again falling below the AHA criterion for rapid VT. Overall specificity was >99% (ie, the device correctly recommended no shock for 99% of the nonshockable rhythms analyzed) among a wide variety of sinus rhythms, sinus tachycardias, and supraventricular arrhythmias. In addition, this study investigated the effects of pad position on ECG rhythm analysis and found no significant differences in specificity between pads placed in the sternal-apical position and those placed in the anterior-posterior position.

On the basis of these 2 published studies, it seems that AED algorithms developed for detection of adult arrhythmias can provide highly specific and reasonably sensitive rhythm analysis in infants and children, especially given the relative rarity of rapid VT in this patient population.[39] Because AED manufacturers use different arrhythmia detection algorithms, however, each manufacturer's algorithm should be tested against a pediatric arrhythmia database to demonstrate its efficacy in this population.

Delivered Energy

One recent development addresses concern about the level of energy delivered to a child by an AED designed for use in adults. Several AED manufacturers have designed new pediatric pad/cable systems for use with AEDs designed for use in adults to reduce the energy delivered to patients under 8 years of age.[40] These modifications essentially raise impedance of the pad/cable system and also divert some of the delivered current away from the patient so that the adult energy dose delivered by the AED is reduced to about 50 to 75 J. The rationale was that with biphasic waveforms, the lower energy dose would be adequate for defibrillation yet reduce the possibility of myocardial damage to pediatric hearts. No changes were made in the AED rhythm analysis program, which continues to use algorithms for defibrillation in adults.

The FDA has ruled that AEDs, with these pediatric pad/cable systems, are composed of components that are "substantially equivalent" to components previously cleared by the FDA. Thus, several AED manufacturers have been cleared by the FDA to advertise, distribute, and sell to physicians (or physicians' agents) this new system, which accommodates both adult pad/cable pads for use in patients ≥8 years of age and pediatric pad/cable systems that reduce the delivered energies for use in patients <8 years of age.

The FDA clearance was based on the agency's conclusion that the new device is "substantially equivalent" to currently marketed devices. Because directly relevant clinical data are not yet available, the agency likely drew this conclusion by extrapolations from animal data and information similar to that included in this statement. FDA-cleared devices are subject to postmarket clinical surveillance for the purpose of accumulating further clinical data on device safety or efficacy. The ILCOR PALS Task Force is not responsible for determining whether a device should or should not be marketed, nor are its classes of recommendation meant to be a quantitative measure of clinical efficacy. Rather, these recommendations reflect the quality of published data in support of a therapy.

ILCOR Recommendations

ILCOR recently examined (October 2002) the literature regarding the use of AEDs in children. The consensus was:

- AEDs may be used for children 1 to 8 years of age with no signs of circulation. Ideally the device should deliver a pediatric dose. The arrhythmia detection algorithm used in the device should demonstrate high specificity for pediatric shockable rhythms, ie, the device will not recommend a shock for nonshockable rhythms (Class IIb).
- Currently the evidence is insufficient to support a recommendation for or against the use of AEDs in children <1 year of age.
- For a lone rescuer responding to a child without signs of circulation, provision of 1 minute of CPR is still recommended before any other action such as activating EMS or attaching the AED.
- Defibrillation is recommended for documented VF/pulseless VT (Class I).

Limitations

One important limitation that arose during task force deliberations on this topic was the lack of data on *clinical use* of newly developed pediatric pad/cable systems that reduce the energy delivered by AEDs designed for use in the adult. This was especially problematic when discussing the risks and benefits of use of AEDs in very young infants. Relevant points of discussion included the following:

1. The experimental data in the Atkinson study[38] examining sensitivity and specificity included infants, but the sample size diminished with decreasing age, and thus there is less confidence in the data from that study analyzing sensitivity/specificity in the youngest patients.
2. Very small infants might receive doses demonstrated to cause myocardial damage in animal studies.

3. The incidence of shockable rhythms as a clinical cause of unresponsiveness in young infants is lower than in older children.

The last 2 points suggest that the number needed to harm and the number needed to treat would move in unfavorable directions with decreasing age, and thus there is consensus in the task force that the recommendations for very young infants be more conservative. The task force recognized that there were insufficient clinical data to determine the *best* appropriate lower age (the age at which the number needed to harm exceeds number needed to treat). Therefore, a pragmatic decision was made to limit the recommendation to children 1 to 8 years of age because many resuscitation councils use 1 year as the transition from infant to child CPR. Linking the recommendation to 1 year of age will facilitate training and retention.

Until clinical data from pediatric AED use becomes available, the task force recommends that institutions that routinely care for children at risk for arrhythmias and cardiac arrest (eg, in-hospital settings) should continue to use defibrillators capable of energy adjustment for weight-based doses.

Because there is insufficient evidence to determine the best placement of AED pads (ie, anterior/posterior versus sternal/apical), the task force has not recommeuded a preferred position for pad placement.

Conclusion

The AED is becoming widely available and may be the first device available for defibrillation in the prehospital setting. Current evidence suggests that AEDs are capable of appropriate sensitivity and specificity for pediatric arrhythmias and are both safe and effective for defibrillation of children 1 to 8 years of age. Ideally pediatric pads/cables should be used, whenever available, to deliver a child dose. Each specific AED model must be tested against a library of pediatric arrhythmias to document its efficacy in detection of shockable and nonshockable rhythms. The task force strongly encourages industry to continue to develop pediatric rhythm diagnostic programs and investigate appropriate pediatric AED energy doses. The task force applauds efforts in this area and will conduct a comprehensive review of new data as they become available.

References

1. Larsen MP, Eisenberg MS, Cummins RO, et al. Predicting survival from out-of-hospital cardiac arrest: a graphic model. *Ann Emerg Med.* 1993; 22:1652–1658.
2. White RD, Vukov LF, Bugliosi TF. Early defibrillation by police: initial experience with measurement of critical time intervals and patient outcome. *Ann Emerg Med.* 1994;23:1009–1013.
3. Mosesso VN Jr, Davis EA, Auble TE, et al. Use of automated external defibrillators by police officers for treatment of out-of-hospital cardiac arrest. *Ann Emerg Med.* 1998;32:200–207.
4. Valenzuela TD, Roe DJ, Nichol G, et al. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. *N Engl J Med.* 2000; 343:1206–1209.
5. O'Rourke MF, Donaldson E, Geddes JS. An airline cardiac arrest program. *Circulation.* 1997;96:2849–2853.
6. Page RL, Joglar JA, Kowal RC, et al. Use of automated external defibrillators by a US airline. *N Engl J Med.* 2000;343:1210–1216.
7. American Heart Association in collaboration with International Liaison Committee on Resuscitation. Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care: International Consensus on Science, Part 9: Pediatric Basic Life Support. *Circulation.* 2000; 102(suppl I):I-253–I-290.
8. Quan L, Franklin WH, eds. *Ventricular Fibrillation: A Pediatric Problem.* New York, NY: Futura Publishing; 2000.
9. Swan HJC. Cardiac catheterization. In: Moss AJ, Adams FH, eds. *Heart Disease in Infants, Children and Adolescents.* Baltimore, Md: Williams & Wilkins; 1968:287.
10. Goldberg AH. Cardiopulmonary arrest. *N Engl J Med.* 1974;290: 381–385.
11. Dahl CF, Ewy GA, Warner ED, et al. Myocardial necrosis from direct current countershock: effect of paddle electrode size and time interval between discharges. *Circulation.* 1974;50:956–961.
12. Gaba DM, Talner NS. Myocardial damage following transthoracic direct current countershock in newborn piglets. *Pediatr Cardiol.* 1982;2: 281–288.
13. Killingsworth CR, Melnick SB, Chapman FW, et al. Defibrillation threshold and cardiac responses using an external biphasic defibrillator with pediatric and adult adhesive patches in pediatric-sized piglets. *Resuscitation.* 2002;55:177–185.
14. Babbs CF, Tacker WA, VanVleet JF, et al. Therapeutic indices for transchest defibrillator shocks: effective, damaging and lethal electrical doses. *Am Heart J.* 1980;99:734–738.
15. Gutgesell HP, Tacker WA, Geddes LA, et al. Energy dose for ventricular defibrillation of children. *Pediatrics.* 1976;58:898–901.
16. Mogayzel C, Quan L, Graves JR, et al. Out-of-hospital ventricular fibrillation in children and adolescents: causes and outcomes. *Ann Emerg Med.* 1995;25:484–491.
17. Hickey RW, Cohen DM, Strausbaugh S, et al. Pediatric patients requiring CPR in the prehospital setting. *Ann Emerg Med.* 1995;25:495–501.
18. Eisenberg M, Bergner L, Hallstrom A. Epidemiology of cardiac arrest and resuscitation in children. *Ann Emerg Med.* 1983;12:672–674.
19. Sirbaugh PE, Pepe PE, Shook JE, et al. A prospective population-based study of the demographics, epidemiology, management and outcome of out-of-hospital pediatric cardiopulmonary arrest. *Ann Emerg Med.* 1999; 33:174–184.
20. Young KD, Seidel JS. Pediatric cardiopulmonary resuscitation: a collective review. *Ann Emerg Med.* 1999;33:195–205.
21. Schwartz PJ, Priori SG, Dumaine R, et al. A molecular link between the sudden infant death syndrome and the long-QT syndrome. *N Engl J Med.* 2000;343:262–267.
22. Losek JD, Hennes H, Glaeser PW, et al. Prehospital countershock treatment of pediatric asystole. *Am J Emerg Med.* 1980;7:571–575.
23. Quan L, Wentz KR, Gore EJ, et al. Outcome and predictors of outcome in pediatric submersion victims receiving prehospital care in King County, Washington. *Pediatrics.* 1990;86:586–593.
24. Suominen P, Olkkola KT, Voipio V, et al. Utstein style reporting of in-hospital paediatric cardiopulmonary resuscitation. *Resuscitation.* 2000; 45:17–25.
25. Nadkarni VM, Berg RA, Kaye W, et al. Survival outcome for in-hospital pulseless cardiac arrest reported to the National Registry of CPR is better for children than adults. *Crit Care Med.* 2003;31:A14.
26. Atkins DL. Pediatric defibrillation: optimal techniques. In: Tacker WA Jr, ed. *Defibrillation of the Heart: ICDs, AEDs, and Manual.* St Louis, Mo: Mosby-Year Book; 1994:169–181.
27. Walker RG, Chapman FW. Revisiting assumptions underlying defibrillation shock protocols: how much does impedance change between first and second shocks? *Prehosp Emerg Care.* 2002;6:146.
28. Tang W, Weil MH, Jorgenson D, et al. Fixed-energy biphasic waveform defibrillation in a pediatric model of cardiac arrest and resuscitation. *Crit Care Med.* 2002;30:2736–2741.
29. Clark CB, Zhang Y, Davies LR, et al. Pediatric transthoracic defibrillation: biphasic versus monophasic waveforms in an experimental model. *Resuscitation.* 2001;51:159–163.
30. Samson RA, Atkins DL, Kerber RE. Optimal size of self-adhesive preapplied electrode pads in pediatric defibrillation. *Am J Cardiol.* 1995;75: 544–545.
31. Kerber RE, Kouba C, Martins J, et al. Advance prediction of transthoracic impedance in human defibrillation and cardioversion: importance of impedance in determining the success of low-energy shocks. *Circulation.* 1984;70:303–308.

32. Tang W, Weil MH, Sun S, et al. The effects of biphasic and conventional monophasic defibrillation on postresuscitation myocardial function. *J Am Coll Cardiol.* 1999;34:815–822.
33. Schneider T, Martens PR, Paschen H, et al. Multicenter, randomized, controlled trial of 150-J biphasic shocks compared with 200- to 360-J monophasic shocks in the resuscitation of out-of-hospital cardiac arrest victims. Optimized Response to Cardiac Arrest (ORCA) Investigators. *Circulation.* 2000;102:1780–1787.
34. Leng CT, Paradis NA, Calkins H, et al. Resuscitation after prolonged ventricular fibrillation with use of monophasic and biphasic waveform pulses for external defibrillation. *Circulation.* 2000;101:2968–2974.
35. Gurnett CA, Atkins DL. Successful use of a biphasic waveform automated external defibrillator in a high-risk child. *Am J Cardiol.* 2000; 86:1051–1053.
36. Cecchin F, Jorgenson DB, Berul CI, et al. Is arrhythmia detection by automatic external defibrillator accurate for children? Sensitivity and specificity of an automatic external defibrillator algorithm in 696 pediatric arrhythmias. *Circulation.* 2001;103:2483–2488.
37. Kerber RE, Becker LB, Bourland JD, et al. Automatic external defibrillators for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety: a statement for health professionals from the American Heart Association Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. *Circulation.* 1997;95:1677–1682.
38. Atkinson E, Mikysa B, Conway JA, et al. Specificity and sensitivity of automated external defibrillator rhythm analysis in infants and children. *Ann Emerg Med.* 2003;41. In press.
39. MacDonald RD, Swanson JM, Mottley JL, et al. Performance and error analysis of automated external defibrillator use in the out-of-hospital setting. *Ann Emerg Med.* 2001;38:262–267.
40. Jorgenson D, Morgan C, Snyder D, et al. Energy attenuator for pediatric application of an automated external defibrillator. *Crit Care Med.* 2002; 30:S145–S147.

KEY WORDS: AHA Scientific Statements ■ pediatrics ■ defibrillation ■ cardioversion ■ heart arrest

Circulation. 1997;95:1677-1682

« Previous Article | Table of Contents | Next Article »

(*Circulation.* 1997;95:1677-1682.)

Articles

Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety

A Statement for Health Professionals From the American Heart Association Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy

Richard E. Kerber, MD, Chair; Lance B. Becker, MD; Joseph D. Bourland, EE, PhD; Richard O. Cummins, MD, MPH; Alfred P. Hallstrom, PhD; Mary B. Michos, RN; Graham Nichol, MD; Joseph P. Ornato, MD; William H. Thies, PhD; Roger D. White, MD; Bram D. Zuckerman, MD,;

Members *Endorsed by the Board of Trustees of the American College of Cardiology*

Key Words: diagnosis • cardiopulmonary resuscitation • AHA Medical/Scientific Statements • defibrillation • myocardial infarction

Introduction

Automatic external defibrillators (AEDs) that accurately analyze cardiac rhythms and, if appropriate, advise/deliver an electric countershock were introduced in 1979. AEDs are widely used by trained emergency personnel (emergency medical technician [EMT]-paramedics, EMT-B's, EMT-I's, and first responders, such as firefighters and police personnel). In such hands, AEDs have proved accurate and effective and have become an essential link in the "chain of survival" as defined by the American Heart Association.[1]

A logical extension of the AED concept is "public access defibrillation" or widespread distribution and use of AEDs by nonmedical, minimally trained personnel (eg, security guards, spouses of cardiac patients).[2] Public access defibrillation poses unique challenges. AEDs must be simple to operate, because in many cases the operator is a first-time user with minimal training. The device must accurately diagnose lethal arrhythmias under unfavorable conditions that may degrade performance. It could be misused, either inadvertently (eg, the patient is conscious and breathing) or deliberately. Safety must be emphasized, and the risk of injury to patient and rescuer minimized. An existing standard for AED construction and performance recognizes the challenges inherent in the various potential uses of AEDs.[3]

Purpose

The purpose of this statement is to recommend strategies to the appropriate regulatory agencies to assist in evaluating

The accuracy of the arrhythmia analysis algorithms incorporated into AEDs

New or alternative defibrillation techniques, especially waveforms

The safety of AEDs when used by minimally trained lay rescuers (public access defibrillation).

This is a consensus document, reflecting the views of the members of the American Heart Association Task Force on Automatic External Defibrillation, its Subcommittee on AED Safety and Efficacy, and the AED Manufacturers' Panel. This document is intended to supplement existing documents concerning AEDs, such as ANSI/Association for the Advancement of Medical Instrumentation (AAMI) DF39,[3] the

AHA Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care,[1] and the AHA *Textbook of Advanced Cardiac Life Support*.[4] All AEDs, whether public access or not, should meet similar algorithm performance specifications.

Demonstrating Accuracy of the Arrhythmia Analysis Algorithm

An arrhythmia analysis algorithm should respond in one of two ways to an electrocardiographically recorded rhythm: it should advise (or in a fully automated system, deliver) a shock, or it should advise no shock (and not deliver a shock). An AED can also notify the operator of suspected artifact in the electrocardiographic (ECG) signal. Similarly, cardiac rhythm disturbances can be divided into three broad categories (Table 1⊞):

View this table: **Table 1.** Rhythm Categories
[in this window]
[in a new window]

Shockable rhythms: lethal rhythms that terminate in the patient's death unless defibrillation is delivered very quickly. These rhythms include coarse ventricular fibrillation (VF) and rapid ventricular tachycardia (VT) and are always (VF) or almost always (rapid VT) associated with a pulseless, unresponsive patient.

Nonshockable rhythms: benign (or even normal) rhythms that must not be shocked, *especially in patients with a pulse,* because no benefit will follow and deterioration in rhythm may result. Nonshockable rhythms include normal sinus rhythm, supraventricular tachycardias, sinus bradycardia, atrial fibrillation and flutter, heart block, idioventricular rhythms, premature ventricular contractions, and other rhythms accompanied by a palpable pulse and/or occurring in a conscious patient. To maximize safety in the event of misapplication of the device/electrodes, asystole is included in this group. The AHA Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care discourage shocks for asystole.[1]

Intermediate rhythms: Rhythms for which the benefits of defibrillation are limited or uncertain. These include fine VF (associated with pulselessness and low survival rates) and VT that does not meet all criteria for inclusion in the shockable VT rhythm category.

Various cardiac rhythms are categorized in Table 1⊞.

Reporting Algorithm Performance

The task force divided arrhythmias into three categories: shockable, nonshockable, and intermediate (Table 2). Patients with shockable rhythms (VF, rapid VT) potentially receive the greatest benefit (survival) from defibrillation at essentially no risk. High *sensitivity* for AED analysis (Table 3) is required for this group. Patients with nonshockable rhythms derive no benefit from defibrillation and are at maximum risk. For reasons of safety, asystole is included in this group. High *specificity* is required. Patients with intermediate rhythms are unlikely to derive benefit or be at risk from defibrillation, making performance requirements inappropriate. Reporting arrhythmia analysis algorithm specificity or sensitivity is sufficient for this group.

View this table: [in this window] [in a new window] **Table 2.** Performance Goals for Arrhythmia Analysis Algorithms (Artifact Free)[1]

View this table: [in this window] [in a new window] **Table 3.** Calculation of Sensitivity, Specificity, and Accuracy[1] : Rhythm Classification[2]

Table 2 shows desired performance goals for each rhythm category. These goals reflect a consensus among the participants on ANSI/AAMI (DF39) standards.[3]

Performance during developmental testing is an indication of what to expect during validation. During developmental testing of automatic rhythm analysis systems, the performance goal should be met or exceeded. This maximizes chances of equaling or exceeding the goal during validation testing, which should be performed with at least the minimum sample size per category given in Table 2. (A sample consists of data required to make a single shock/no-shock decision.) The sizes selected in Table 2 reflect a balance between reasonable confidence in performance and realistic limits on data available to demonstrate it. These are minimum sample sizes and may be exceeded. Data may be acquired from prehospital or in-hospital events. The size and geometry of the electrodes used to acquire the data should be reported.

For each category, the observed test results must equal or exceed the performance goal. For each rhythm category, the exact single-sided 90% lower confidence limit should be calculated, based on test results. This process will give a 90% probability that the actual performance is greater than the lower confidence limit calculated.

Table 2 provides an example of calculation of lower confidence limit for observed performance equal to performance goals for each rhythm with specified performance goals.

Differences in ECG data acquisition preclude the development of a common (single) database against which every AED arrhythmia analysis algorithm could be tested. Therefore, the task force recommends that AED manufacturers report the performance of arrhythmia analysis algorithms of their own devices to the Food and Drug Administration (FDA), using the format in Table 2. Appropriate electronic and/or hard copy documentation should be available for inspection on request.

Validating Performance

The data used for algorithm development must be different from the data used for testing and validation. Validation of performance should be obtained in both the presence and absence of artifacts likely to be encountered in field use.

The signal characteristics of the data acquisition system used to gather the validation data set should be specified (bandwidth, phase characteristics, dynamic range).

The waveforms may include a discharge deflection and a postdischarge recovery period, making the timing of playback into a separate device critical, so that the device being tested is not required to analyze these discharge artifacts introduced during recording. If additional non-ECG signals are used (eg, respirometer, impedance detector), their acquisition characteristics should also be specified.

Algorithms may examine different rhythms recorded from the same patient. However, there can be only one sample of each specific rhythm from each patient.

Because many ECG rhythm segments may be classified differently by different physicians, the task force recommends that classification of segments as shockable, nonshockable, or intermediate require agreement among at least three qualified expert reviewers of cardiac arrest rhythms. Rhythm segments on which reviewers fail to reach 100% agreement can be classified, but the expert disagreement should be reported. The reviewers should use ECG criteria on which they have previously agreed. They should reach a consensus on the distinction between fine VF (an intermediate rhythm that should be shocked) and asystole (which should not be shocked) by employing the same criteria used by the AED being tested.

Effects of Artifacts

In real world situations in which AEDs are used, it is inevitable that artifacts will corrupt ECG data to varying degrees, potentially degrading specificity and sensitivity. Manufacturers should determine the effects of various artifacts, with emphasis on diagnosis of shockable and nonshockable rhythms. The effect of artifacts on diagnosis of intermediate rhythms is of less concern.

The most commonly encountered artifacts are motion artifacts, which are typically generated by cardiopulmonary resuscitation, agonal breathing or seizures, handling of the patient, and transport by stretcher and vehicle. Pacemaker stimuli can also interfere with algorithm performance. Static electric fields (commonly present in dry environments) exacerbate these artifacts.

Because there is no standard database of ECG signals or noise signals for testing AED algorithms, manufacturers should determine how to test their devices for reasonable performance in the presence of noise and specify in detail how this testing was done.

Alternative Waveforms for Defibrillation

The two presently accepted waveforms for transthoracic defibrillation in the United States are the damped sinusoidal waveform (Edmark, Lown, Pantridge) and the truncated exponential waveform. Alternative wave forms for transthoracic defibrillation such as biphasic waveforms, in clinical use in the former Soviet Union, have been introduced in the United States. Studies in animals have demonstrated the superiority of various alternative waveforms.[5,6,7] More recently three studies in humans in the United States have reported comparisons of biphasic and monophasic waveforms.[8,9,10] Patients undergoing provocative electrophysiological studies and implantation of an automatic implantable cardioverter-defibrillator received transthoracic biphasic waveform rescue shocks. These studies suggest that biphasic or other alternative waveforms may achieve equivalent shock success rates at substantially lower energies (or higher success rates at the same energies) when compared with damped sinusoidal waveforms. This in turn suggests the prospect of a reduction in size and weight of AEDs (an important consideration for public access) and/or higher success rates than can be presently achieved using available waveforms.

At present there are no published data on prehospital transthoracic defibrillation using alternative waveforms. The *absolute* success rate of any waveform for termination of VF will be lower in the prehospital setting (in which VF is often present for a prolonged period before shocks are administered) than in the rapid-shock environment of the electrophysiology laboratory or the coronary/intensive care unit. However, there is no a priori reason to suspect that the *relative* advantage of alternative waveforms over monophasic waveforms will not be maintained in prehospital use if such an advantage is demonstrated in hospital. In fact, in vitro studies by Jones et al[11] and a study of intact dogs by Walcott et al[12] have suggested that the superiority of biphasic waveforms may actually be increased over monophasic waveforms when shocks are delivered after longer durations of VF.

It is the consensus of the task force (with the exception of one manufacturer) that if alternative waveforms for transthoracic defibrillation are convincingly demonstrated to be equivalent or superior to standard waveforms in the electrophysiology laboratory or other hospital or prehospital settings, they should be provisionally approved for use in AEDs, pending acquisition of prehospital data. Performance of waveforms tested in the electrophysiology laboratory or other in-hospital or prehospital settings and incorporated into AEDs should be monitored as part of a postmarket surveillance program designed to carefully observe total system performance of these devices in their intended settings.

The task force recommends the following as a minimum standard for demonstrating equivalence of an alternative waveform versus standard waveforms: the upper boundary of the 90% confidence interval (with 5% in each tail) of the difference between standard and alternative waveform efficacy must be ≤ 10%, which permits a slight (5%) chance of acceptance of a waveform that is >10% less effective than the standard waveform. Similarly, the task force suggests that to demonstrate superiority of an alternative waveform over standard waveforms, the upper boundary of the 90% confidence interval of the difference between standard and alternative waveforms must be <0% (ie, alternative is greater than standard). If the standard waveform efficacy equals 90%, and the true (or hypothesized) alternative waveform efficacy is 95%, approximately 52 patients per group would be required to demonstrate equivalence, and 471 patients per group would be required to demonstrate superiority with a power of 0.9. These sample sizes are based on statistical tests of equivalence of new treatments described by Blackwelder.[13]

Postmarket Surveillance

- Top
- Introduction
- Purpose
- Demonstrating Accuracy of the...
- Alternative Waveforms for...
- Postmarket Surveillance
- Enhancing Safety
- Summary
- Appendix 1
- References

Postmarket surveillance should be maintained on any device introduced for in-hospital, emergency medical services, or public access defibrillation. It is important to document both failures and successes; reporting only problems or failures may give a distorted picture of performance. A well-designed postmarket surveillance study should allow observation of the total performance of an AED and its effectiveness in its intended environment. As part of such studies, the task force recommends that manufacturers obtain and submit to the FDA sufficient field data to demonstrate that AEDs incorporating an alternative waveform maintain satisfactory performance when used in the target population for AEDs. The performance reports should state the measured sensitivity and specificity for rhythm categories as well as the upper and lower bounds of the 80% confidence interval (10% per tail). This will allow accurate, prospective tracking of actual field performance.

Enhancing Safety

- Top
- Introduction
- Purpose
- Demonstrating Accuracy of the...
- Alternative Waveforms for...
- Postmarket Surveillance
- Enhancing Safety
- Summary
- Appendix 1
- References

Public access AEDs will be used by minimally trained personnel. The potential for misuse is high: use of AEDs is inappropriate in persons who are conscious and breathing or persons who are in true cardiac arrest but are receiving artifact-generating cardiopulmonary resuscitation during analysis of the rhythm. Deliberate misuse of an AED with an intent to cause harm may also be encountered.

To overcome these potential problems, the task force recommends that AEDs be specifically designed to prevent injury in the event of misuse. Innovative features that enhance safety are encouraged, such as voice chips that deliver a series of prompts to a rescuer who is opening or activating an AED (eg, "Shake the victim. If he or she groans or moves, do not attach the electrodes—call the emergency number."). Alternatively, after the arrhythmia analysis algorithm has been satisfied, an AED might administer an unpleasant but low-strength "wake-up" shock; if the algorithm diagnosis was incorrect and the patient was not in cardiac arrest but merely in a deep sleep or intoxicated, such a preliminary shock would stimulate the patient to move or respond, alerting the rescuer not to deliver a defibrillation-strength shock. These suggestions are intended as examples only; other innovations/approaches may be even more effective.

The task force also encourages the design of devices that enhance rapid and effective deployment in conjunction with local emergency medical services, integrating AEDs into the AHA chain of survival. This can be accomplished through advanced communication technology. For example, AEDs could be designed to automatically activate the local emergency medical services system when the device is removed from its holder or its cover is opened. Other approaches and innovations may be even more effective.

Summary

These recommendations are presented to enhance the safety and efficacy of AEDs intended for public access. The task force recommends that manufacturers present developmental and validation data on their own devices, emphasizing high sensitivity for shockable rhythms and high specificity for nonshockable rhythms. Alternative defibrillation waveforms may reduce energy requirements, reducing the size and weight of the device. The highest levels of safety for public access defibrillation are needed. Safe and effective use of AEDs that are widely available and easily handled by nonmedical personnel has the potential to dramatically increase survival from cardiac arrest.

Acknowledgments

The authors gratefully acknowledge the assistance of Patricia Bowser, AED Task Force Coordinator.

Footnotes

"Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying

and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety" was approved by the American Heart Association Science Advisory and Coordinating Committee in October 1996. It is being published concurrently with the *Annals of Noninvasive Electrocardiology* and *Biomedical Instrumentation and Technology*.

A single reprint is available by calling 800-242-8721 (US only) or writing the American Heart Association, Public Information, 7272 Greenville Avenue, Dallas, TX 75231-4596. Ask for reprint No. 71-0104. To purchase additional reprints: up to 999 copies, call 800-611-6083 (US only) or fax 413-665-2671; 1000 or more copies, call 214-706-1466, fax 214-691-6342, or To make photocopies for personal or educational use, call the Copyright Clearance Center, 508-750-8400.

Appendix 1

Automatic External Defibrillation Task Force
Myron L. Weisfeldt, MD, Chair

Richard E. Kerber, MD

R. Pat McGoldrick

Arthur J. Moss, MD

Graham Nichol, MD

Joseph P. Ornato, MD

David G. Palmer, Esq

Barbara Riegel, DNSc

Sidney C. Smith, Jr, MD

AED Safety and Efficacy Subcommittee
Richard E. Kerber, MD, Chair

Lance B. Becker, MD

Joseph D. Bourland, EE, PhD

Richard O. Cummins, MD, MPH

Bram D. Zuckerman, MD

Mary B. Michos, RN, Fire Chief

Joseph P. Ornato, MD

Roger D. White, MD

AED Research Subcommittee
Joseph P. Ornato, MD, Cochair

Barbara Riegel, DNSc, Cochair

Alfred P. Hallstrom, PhD

Graham Nichol, MD

AED Manufacturers Panel
Carlton B. Morgan, Heartstream, Inc.

William L. Post, Hewlett-Packard Company

John E. Kuphal, Laerdal Medical Corporation

Donald E. Brodnick, Marquette Electronics, Inc.

Robert A. Niskanen, Physio-Control Corporation

Kenneth F. Olson, SurVivaLink Corporation

Gary A. Freeman, Zoll Medical Corporation

References

- Top
- Introduction
- Purpose
- Demonstrating Accuracy of the...
- Alternative Waveforms for...
- Postmarket Surveillance
- Enhancing Safety
- Summary
- Appendix 1
- References

1. Guidelines for cardiopulmonary resuscitation and emergency cardiac care. Emergency Cardiac Care Committee and Subcommittees, American Heart Association. *JAMA.*. 1992;268:2171-2302. [Abstract/Free Full Text]

2. Weisfeldt ML, Kerber RE, McGoldrick RP, Moss AJ, Nichol G, Ornato JP, Palmer DG, Riegel B, Smith SC Jr. American Heart Association Report on the Public Access Defibrillation Conference, December 8-10, 1994: Automatic External Defibrillation Task Force. *Circulation.* 1995;92:2740-2747. [Free Full Text]

3. Association for the Advancement of Medical Instrumentation. *DF39, Automatic External Defibrillators and Remote-Control Defibrillators.* Arlington, Va: AAMI; 1993.

4. American Heart Association. *Textbook of Advanced Cardiac Life Support.* Dallas, Tex: AHA; 1994.

5. Schuder JC, Gold JH, Stoeckle H, McDaniel WC, Cheung KN. Transthoracic ventricular defibrillation in the 100 kg calf with symmetrical one-cycle bidirectional rectangular wave stimuli. *IEEE Trans Biomed Eng.* 1983;30:415-422. [Medline] [Order article via Infotrieve]

6. Schuder JC, McDaniel WC, Stoeckle H. Defibrillation of 100 kg calves with asymmetrical, bidirectional, rectangular pulses. *Cardiovasc Res.* 1984;18:419-426.[Medline] [Order article via Infotrieve]

7. Kerber RE, Spencer KT, Kallok MJ, Birkett C, Smith R, Yoerger D, Kieso RA. Overlapping sequential pulses: a new waveform for transthoracic defibrillation. *Circulation..* 1994;89:2369-2379. [Abstract/Free Full Text]

8. Bardy GH, Gliner BE, Kudenchuk PJ, Poole JE, Dolack GL, Jones GK, Anderson J, Troutman C, Johnson G. Truncated biphasic pulses for transthoracic defibrillation. *Circulation.* 1995;91:1768-1774. [Abstract/Free Full Text]

9. Greene HL, DiMarco JP, Kudenchuk PJ, Scheinman MM, Tang ASL, Reiter MJ, Echt DS, Chapman PD, Jazayeri MR, Chapman FW, Ahmed M, Johnson JL, Niskanen RA, and the Biphasic Waveform Defibrillation Investigators. Comparison of monophasic and biphasic defibrillating pulse waveforms for transthoracic cardioversion. *Am J Cardiol.* 1995;75:1135-1139. [Medline] [Order article via Infotrieve]

10. Bardy GH, Marchlinski FE, Sharma AD, Worley SJ, Luceri RM, Yee R, Halperin BD, Fellows CL, Ahern TS, Chilson DA, Packer DL, Wilber DJ, Mattioni TA, Reddy R, Kronmal RA, Lazzara R, for the Transthoracic Investigators. Multicenter comparison of truncated biphasic shocks and standard damped sine wave monophasic shocks for transthoracic ventricular defibrillation. *Circulation.* 1996;94:2507-2514. [Abstract/Free Full Text]

11. Jones JL, Swartz JF, Jones RE, Fletcher R. Increasing fibrillation duration enhances relative asymmetrical biphasic versus monophasic defibrillator waveform efficacy. *Circ Res.* 1990;67:376-384. [Abstract/Free Full Text]

12. Walcott GP, Melnick SB, Chapman FW, Jones JL, Ideker RE. Comparison of monophasic and biphasic waveforms for external defibrillation in an animal model of cardiac arrest and resuscitation. *J Am Coll Cardiol.* 1995;25:405A. Abstract.

13. Blackwelder WC. `Proving the null hypothesis' in clinical trials. *Controlled Clin Trials.* 1982;3:345-353.[Medline] [Order article via Infotrieve]

This article has been cited by other articles:

Effectiveness of Emergency Response Planning for Sudden Cardiac Arrest in United States High Schools With Automated External Defibrillators

Jonathan A. Drezner, MD; Ashwin L. Rao, MD; Justin Heistand, MD;
Megan K. Bloomingdale; Kimberly G. Harmon, MD

Background—US high schools are increasingly adopting automated external defibrillators (AEDs) for use in campus settings. We analyzed the effectiveness of emergency response planning for sudden cardiac arrest (SCA) in a large cohort of US high schools that had onsite AED programs.

Methods and Results—A cohort of US high schools with at least 1 onsite AED was identified from the National Registry for AED Use in Sports. A school representative completed a comprehensive survey on emergency planning and provided details of any SCA incident occurring within 6 months of survey completion. Surveys were completed between December 2006 and July 2007. In total, 1710 high schools with an onsite AED program were studied. Although 83% (1428 of 1710) of schools have an established emergency response plan for SCA, only 40% practice and review the plan at least annually with potential school responders. A case of SCA was reported by 36 of 1710 schools (2.1%). The 36 SCA victims included 14 high school student athletes (mean age, 16 years; range, 14 to 17 years) and 22 older nonstudents (mean age, 57 years; range, 42 to 71 years) such as employees and spectators. No cases were reported in student nonathletes. Of the 36 SCA cases, 35 (97%) were witnessed, 34 (94%) received bystander cardiopulmonary resuscitation, and 30 (83%) received an AED shock. Twenty-three SCA victims (64%) survived to hospital discharge, including 9 of the 14 student athletes and 14 of the 22 older nonstudents.

Conclusions—School-based AED programs provide a high survival rate for both student athletes and older nonstudents who suffer SCA on school grounds. High schools are strongly encouraged to implement onsite AED programs as part of a comprehensive emergency response plan to SCA. (***Circulation.*** **2009;120:518-525.)**

Key Words: death, sudden ■ defibrillation ■ resuscitation ■ schools ■ students

Sudden cardiac arrest (SCA) is the leading cause of death in the United States and afflicts ≈300 000 persons annually.[1] The single greatest determinant of survival after SCA is the time from collapse to defibrillation, with survival rates declining 7% to 10% per minute with every minute that defibrillation is delayed.[2,3] Historically, survival rates to hospital discharge from out-of-hospital SCA in US cities using conventional emergency response systems are <5%.[4–6] Several studies of early defibrillation [illegible] automated external defibrillators (AEDs) have demonstrated a survival benefit for out-of-hospital SCA. In these studies, use of AEDs by trained or untrained bystanders and nontraditional responders produces survival rates from 41% to 74% if cardiopulmonary resuscitation (CPR) is provided and defibrillation occurs within 3 to 5 minutes of collapse.[7–15]

Editorial see p 461
Clinical Perspective on p 525

SCA is also the leading cause of death in exercising young athletes, accounting for more than half of all deaths.[16–18] Sudden cardiac death in a young athlete is a devastating event with tremendous impact on the family, local community, school, and athletic team. An athlete's tragic death during sports training or competition frequently stimulates debate on the adequacy of emergency planning at athletic events. Survival after exercise-related SCA in young persons is poor; the survival rate measured during a 7-year period in the United States was only 11%.[19] Thus, many schools and athletic programs have recognized that emergency response planning for SCA and implemented onsite school AED programs.

The presence and timely access of AEDs in schools and at sporting venues provide a means of early defibrillation not only for student athletes but also for spectators, coaches, officials, event staff, and other attendees on campus in the event of an unexpected SCA. Through education and training, school-based AED programs also may lead to improved recognition of SCA by school staff, a greater number of trained responders on school grounds, and an increased likelihood of providing early CPR and early defibrillation in

Received February 2, 2009; accepted May 26, 2009.
From the Departments of Family Medicine (J.A.D., A.L.R., M.K.B., K.G.H.) and Pediatrics (J.H.), University of Washington, Seattle.
The online-only Data Supplement is available with this article at http://circ.ahajournals.org/cgi/content/full/CIRCULATIONAHA.109.855890/DC1.
Correspondence to Jonathan A. Drezner, MD, Associate Professor, Department of Family Medicine, 4245 Roosevelt Way NE, University of Washington, Box 354775, Seattle, WA 98105. E-mail jdrezner@fammed.washington.edu

DOI: 10.1161/CIRCULATIONAHA.109.855890

Table 1. Proportion of US High Schools With AED Programs That Train School Staff in CPR or AED Use and Include Staff in Annual Practice of the EAP for SCA

	CPR Trained, %	AED Trained, %	Practice EAP, %
Coaches	80	72	34
School nurses	75	71	22
Administrators	64	63	30
Teachers	49	45	22

the management of SCA. However, prior studies suggest that high schools often acquire AEDs without developing a corresponding emergency response plan for SCA, and the efficacy of early defibrillation in young competitive athletes remains uncertain.[20,21] Overall, little is known about the effectiveness of early defibrillation programs to treat SCA in the school setting. Therefore, we examined the adequacy of emergency response planning and the effectiveness of AED use for SCA in US high schools with onsite AED programs.

Methods

This study was a cross-sectional survey using the National Registry for AED Use in Sports (http://www.aedsports.com). This registry consists of a Web-based questionnaire and database management system, including a comprehensive survey on emergency planning for SCA and specific questions about AED prevalence, location, cost, use, and outcomes and the details of any resuscitation for SCA. The registry aims to monitor emergency response planning and AED use in the school and athletic setting.

Letters requesting participation in the study were sent to 18 974 member high schools from the National Federation of High Schools in December 2006 and again in March 2007. A school representative (principal, athletic director, or certified athletic trainer) was invited to complete a comprehensive survey on emergency response planning for SCA and to provide details and outcomes of any AED use for SCA occurring within 6 months of survey completion.

Of the 18 974 high schools recruited, 2084 (11%) completed the survey. Of the 2084 responding high schools, 1710 (82%) had at least 1 AED on school grounds, and 356 (17%) had no AED (<1% unknown). The high proportion of schools with AED programs responding to this survey likely reflects a responder bias toward schools with AEDs being more willing or interested to participate in the study and may represent, in part, a growing trend toward school-based AED programs. Although the overall response rate was low, the substantial total number of high schools responding with AEDs (n=1710) allows analysis of an important subgroup of US high schools most likely to have an established emergency response plan for SCA. Close examination of this large cohort of schools with AED programs has the potential to identify existing deficiencies in school emergency response plans that can be improved.

All responding schools with at least 1 onsite AED were included for examination of the adequacy of their emergency response planning for SCA and review of past incidents of AED use. The elements defining an adequate emergency response plan for SCA were based on national consensus recommendations.[22–24] We included only cases of AED use for SCA that occurred within 6 months of survey completion. Additional analyses were directed toward the details of resuscitation in cases of SCA. Any school reporting a case of SCA in a student athlete was also contacted by phone to review survey responses and to clarify the details of resuscitation. All surveys were completed between December 2006 and July 2007.

The primary outcome measure for effectiveness was survival to hospital discharge after SCA. Secondary outcome measures relative

Table 2. Case Details of SCA in 14 High School Student Athletes

Case	Age, y	Gender	Race	Sport	Duration of Exercise Before SCA, min	Exercise Intensity	Witnessed Collapse	Location of Defibrillator
1	17	M	White/Caucasian	Basketball	7.5	Easy	Yes	At venue, accessible to public
2	16	M	White/Caucasian	PE class	10–15	Easy	Yes	At venue, accessible to public
3	15	M	White/Caucasian	Baseball	60–90	Intense	Yes	At venue, accessible to athletic trainer and medical personnel
4	14	F	White/Caucasian	Volleyball	45–60	Moderate	Yes	At venue, accessible to athletic trainer and medical personnel
5	17	M	White/Caucasian	Football	45–60	Intense	Yes	At venue, accessible to public
6	15	F	White/Caucasian	Track/cross-country	45–60	Moderate	Yes	At venue, accessible to athletic trainer and medical personnel
7	15	M	White/Caucasian	Basketball	Unknown	Moderate	Yes	At venue, accessible to public
8	17	M	Asian/Pacific Islander	PE class	10–15	Easy	Yes	Brought to site from nearby venue/building
9	16	M	Black/African American	Basketball	Unknown	Unknown	Yes	At venue, accessible to athletic trainer and medical personnel
10	17	M	White/Caucasian	Crew	45–60	Moderate	Yes	At venue, accessible to public
11	17	M	White/Caucasian	Basketball	60–90	Easy	Yes	Brought by responding EMS
12	16	M	White/Caucasian	Football	15–30	Moderate	Yes	Brought by responding EMS
13	14	M	Black/African American	Basketball	30–45	Intense	Yes	At venue, accessible to public
14	16	M	White/Caucasian	Wrestling	45–60	Moderate	Yes	Brought by responding EMS

NOS indicates not otherwise specified; PE, physical education; HCM, hypertrophic cardiomyopathy; CPVT, catecholaminergic polymorphic ventricular tachycardia; ARVC, arrhythmogenic right ventricular cardiomyopathy; LQTS, long-QT syndrome; ER, emergency room; AV, aortic valve; and LVH, left ventricular hypertrophy.

*Survived indicates survival to hospital discharge.

†Reported as immediate CPR after SCA.

to the adequacy of emergency response planning included the proportion of schools with an established emergency action plan (EAP) for SCA, CPR and AED training for coaches and other school staff members, and review and practice of the EAP at least once annually. Secondary outcome measures in cases of SCA included the presence of seizure-like activity after collapse, provision of bystander CPR, reported time to CPR and to initial shock deployment, and cause of SCA. This study was approved by the Human Subjects Division at the University of Washington.

The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

Results

Demographics

We identified 1710 high schools with at least 1 AED on school grounds from the National Registry for AED Use in Sports. The mean number of AEDs per school was 2.9. The mean number of student athletes reported at each school was 371. High schools were distributed across all 50 states, with 85% public schools and 14% private schools (not reported in 1%). Forty-six percent of schools were located in a rural community, 34% were suburban, 13% were urban, and 5% were inner city. Funding for the AED program was provided by a donation or grant in 49% of the schools, the school board or school district in 30% of schools, the athletic department in 10% of schools, and the school budget itself in 4%.

Adequacy of Emergency Response Planning

Eighty-three percent (1428 of 1710) of the high schools with an on-site AED program also have an established EAP for SCA, and 60% (861 of 1428) of the schools developed their EAP in consultation with their local emergency medical services (EMS). Eighty-eight percent (1518 of 1710) of schools have an established communication system at all athletic facilities to activate EMS (ie, call 9-1-1), but only 18% (263 of 1428) of schools post a written EAP at each athletic venue.

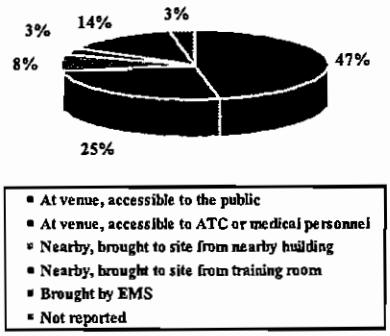


Figure 1. Location and access to AED. ATC indicates certified athletic trainer.

Table 1 shows the proportion of schools that train their coaches, school nurses, administrators, and teachers in CPR or AED use. Athletic coaches were the most likely to receive CPR training (80%) and AED training (72%). Only 40% (684 of 1710) of schools practice and review their EAP to a SCA at least once annually with potential school first responders. Coaches were included in the rehearsal of the EAP in only 34% of schools (Table 1).

Table 2. Continued

Seizure-Like Activity After Collapse	Time From Arrest to CPR, s	Time From Arrest to First Shock, s	Shock Deployed	Total Shocks, n	Outcome	Diagnosis
No	75	105	Yes	5	Survived*	Cardiomyopathy NDS
No	0†	135	Yes	1	Survived	HCM
Yes	105	150	Yes	1	Survived	CPVT
No	0	165	Yes	1	Survived	ARVC
Yes	30	195	Yes	1	Survived	Presumed primary arrhythmia
Yes	30	75	Yes	2	Survived	LQTS
Unknown	Unknown	Unknown	Unknown	Unknown	Lived 5 d, died in hospital	Viral myocarditis
Yes	105	165	Yes	4	Died at scene	Presumed primary arrhythmia
Yes	345	45	Yes	2	Survived	Presumed primary arrhythmia
Yes	105	105	Yes	1	Died in ER	Presumed primary arrhythmia
No	300	660	Yes	1	Survived	HCM
Unknown	0	Unknown	Yes	1	Died at scene	HCM
No	30	75	Yes	1	Died at scene	AV stenosis
Yes	30	690	Yes	1	Survived	Idiopathic LVH

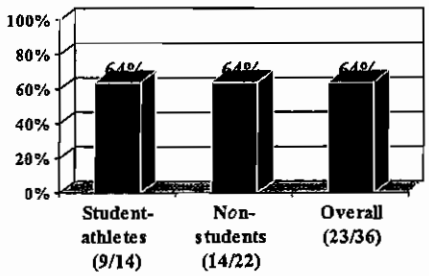


Figure 2. Survival to hospital discharge after SCA in high schools with AEDs.

AED Use for SCA

Thirty-six of the 1710 schools (2.1%) reported an incident of SCA within 6 months of completing the survey (July 2006 through July 2007). The 36 SCA victims included 22 older nonstudents (ie, spectators, teachers, staff, coaches, or officials) with a mean age of 57 years (range, 42 to 71 years) and 14 high school student athletes with a mean age of 16 years (range, 14 to 17 years). No SCA cases in a student nonathlete were reported. Twelve of the 14 cases of SCA in student athletes occurred during organized sports activity, and 2 cases occurred during recreational exercise in a physical education class (Table 2). The victims in these 2 cases were also members of a high school sports team and were reported as occurring in student athletes.

Thirty-three of the 36 schools (92%) with an incident of SCA had an established EAP, although only 18 of 36 (50%) reported practicing their EAP at least once annually. The SCA occurred at a basketball facility in 10 cases (28%), recreation/fitness facility in 7 cases (19%), classroom building in 5 cases (14%), football facility in 5 cases (14%), baseball facility in 3 cases (8%), and theater, official's locker room, cafeteria, main office, and hallway near an athletic facility in 1 case each (not reported in 1 case). Fifteen of the 36 cases (42%) occurred during an official athletic game or competition, 8 (22%) during an organized practice or athletic training session, 3 (8%) during recreational exercise, and 9 (25%) during or after school hours unrelated to a sporting event (not reported in 1 case).

Thirty-five of the 36 cases (97%) of SCA were witnessed, and 34 of 36 (94%) received bystander CPR. The first responder(s) to the SCA victim were a certified athletic trainer in 47% of cases, coach in 33%, teacher in 17%, team physician in 14%, and school nurse in 11%. The AED used in the resuscitation was located at the venue and accessible to the public or medical personnel in 72% of cases and brought to the site from a nearby building or the athletic training room in an additional 11% of cases (Figure 1). In 14% of cases, arriving EMS personnel provided the defibrillator despite the school having an AED on school grounds.

Survival

The AED deployed a shock in 30 of 36 cases (83%), and 12 victims received multiple shocks (mean, 1.7 shocks; range, 1 to 5 shocks). Of the 30 SCA victims who received defibrillation, 20 (67%) survived to hospital discharge. Overall, 23 of 36 SCA victims (64%) survived to hospital discharge, including 9 of 14 student athletes and 14 of 22 older nonstudents (Figure 2).

Details of Resuscitation in Student Athletes With SCA

Twelve male and 2 female student athletes suffered SCA within 6 months of survey completion. Given a mean of 371 student athletes at the 1710 schools, the total number of high school student athletes in this cohort was ≈634 410 over a 6-month period, or 14 SCA events in 317 205 person-years. Thus, the annual incidence of SCA in a high school student athlete estimated from this study is 4.4 in 100 000.

The specific activity at the time of SCA was basketball (n=5), football (n=2), physical education class (n=2), baseball (n=1), jogging (n=1), volleyball (n=1), rowing (n=1), and wrestling (n=1). The duration of exercise before SCA was reported in 12 cases, with a mean of 42 minutes and median of 52.5 minutes (range, 7.5 to 90 minutes). The intensity of exercise before SCA was reported as easy (ie, warm-up) in 4 cases, moderate (ie, practice) in 6 cases, and intense (ie, competition) in 3 cases and was not reported in 1 case.

All 14 cases of SCA in a student athlete were witnessed. Brief seizure-like activity was reported in 7 of 14 athletes (50%) after collapse, and a pulse and/or respirations were perceived after collapse in 8 of 14 cases (57%) for a mean duration of 2.2 minutes and median of 1.25 minutes (range, 0.25 to 5.25 minutes). Thirteen of 14 cases (93%) received bystander CPR. In 3 cases, the AED was applied before the initiation of CPR. The time from SCA to initiation of CPR was reported in 13 cases, with a mean of 1.5 minutes and median of 0.5 minutes (range, 0 to 5.75 minutes). Thirteen of the 14 student athletes (93%) with SCA received a shock. Although ECG data were not available for review, AED shock deployment in 13 of the 14 cases suggests that the initial rhythm after collapse in student athletes with SCA was predominantly ventricular fibrillation or ventricular tachycardia. The time from SCA to initial shock deployment was reported in 12 cases, with a mean of 3.6 minutes and median of 2.4 minutes (range, 0.75 to 11.5 minutes). Multiple shocks were required in 4 cases, with a mean of 1.7 shocks and median of 1 shock (range, 1 to 5 shocks).

EMS personnel were not on site before the SCA in any case. The time to EMS arrival at the site of arrest was reported in 11 cases, with a mean of 8.2 minutes and median of 8 minutes (range, 5.5 to 13.5 minutes). A structural cardiac disorder was reported in 8 of 14 cases (57%), hypertrophic cardiomyopathy in 3 cases, and myocarditis, aortic stenosis, arrhythmogenic right ventricular cardiomyopathy, cardiomyopathy not otherwise specified, and idiopathic left ventricular hypertrophy in 1 case each. A primary electric disorder was reported in 6 of 14 cases (43%), presumed primary arrhythmia (autopsy or structural workup negative) in 4 cases, long-QT syndrome in 1 case, and catecholaminergic polymorphic ventricular tachycardia in 1 case. The details of each case, the outcome, and the cause of the arrest in student athletes with SCA are shown in Table 2.

Details of Resuscitation in Older Nonstudents With SCA

Twenty-two cases of SCA (19 male, 3 female victims) occurred in older persons on school grounds. Fourteen of the

Table 3. Comparison of Case Details of SCA in High School Student Athletes and Older Nonstudents

SCA Victims	Age (Range), y	Witnessed Collapse, n/N (%)	Seizure-Like Activity After Collapse, n/N (%)	Bystander CPR, n/N (%)	Time From Arrest to CPR, Mean; Median; Range, min	Shock Deployed, n/N (%)	Time From Arrest to First Shock, Mean; Median; Range, min	Survival to Hospital Discharge, n/N (%)
High school student athletes (n=14)	16 (14–17)	14/14 (100)	7/12 Reported (58)	13/14 (93)	1.5; 0.5; 0–5.75	13/14 (93)	3.6; 2.4; 0.75–11.5	9/14 (64)
Older nonstudents (n=22)	57 (42–71)	21/22 (95)	5/17 Reported (29)	21/22 (95)	0.8; 0.75; 0–1.75	19/22 (86)	1.8; 1.75; 0.5–3.25	14/22 (64)

22 cases (64%) occurred during an official school-sponsored athletic game or competition. The SCA victims included 9 spectators, 3 teachers, 2 coaches, 2 athletic officials, 1 secretary, 1 support staff member, and 4 other attendees on campus.

Twenty-one of the 22 cases (95%) were witnessed. Brief seizure-like activity was reported in 5 of 22 individuals (23%) after collapse. Twenty-one of the 22 cases (95%) received bystander CPR. The time from SCA to initiation of CPR was reported in 15 cases, with a mean of 0.8 minutes and median of 0.75 minutes (range, 0 to 1.75 minutes). Nineteen of the 22 older nonstudents with SCA (86%) received a shock, suggesting that the initial rhythm shortly after collapse was predominantly ventricular fibrillation or ventricular tachycardia. The time from SCA to initial shock deployment was reported in 13 cases, with a mean of 1.8 minutes and median of 1.75 minutes (range, 0.5 to 3.25 minutes). Multiple shocks were required in 8 cases, with a mean of 1.8 shocks and median of 1 shock (range, 1 to 3 shocks).

EMS personnel were on site before the SCA in 4 of the 22 cases (18%). The reported time to EMS arrival at the site of arrest for the other 18 cases was a mean of 6.8 minutes (median, 5.5 minutes; range, 0.5 to 15 minutes). Coronary artery disease or acute myocardial infarction was reported as the cause of SCA in 7 cases. Aortic valve stenosis, congestive heart failure, and an anomalous coronary artery were reported as the cause of SCA in 1 case each. The cause of SCA was unknown or not reported in 12 cases; however, given the age of this group, it is likely that the majority of these cases were due to coronary artery disease. The details of each case of SCA in older nonstudents are shown in Table I of the online-only Data Supplement. Table 3 summarizes the details of resuscitation in both high school student athletes and older nonstudents with SCA.

Discussion

This is the largest study of emergency response planning for SCA in US high schools. Although some deficiencies in emergency response planning were identified, a high survival rate for both student athletes and older nonstudents with SCA was reported in high schools with onsite AED programs. Several studies have demonstrated a survival benefit through public-access defibrillation programs through early CPR and rapid availability of an AED for use by trained or untrained rescuers. In all of these studies, the survival rate for an SCA victim with ventricular fibrillation or ventricular tachycardia if treated promptly with defibrillation is consistently >60% (Table 4).[7,9–11]

This is also the first study to suggest an apparent survival benefit from early defibrillation in young athletes with SCA. Prior reports have shown a lower-than-expected survival rate in young athletes with SCA.[11,19,21,25] In a small cohort of 9 collegiate athletes with SCA, only 1 athlete survived (11%) despite early reported defibrillation in most cases.[21] The lower survival rate reported in collegiate athletes may be accounted for in part by the smaller proportion of SCA victims treated with onsite AEDs and the smaller proportion of victims who received defibrillation. EMS was not on school grounds at the time of SCA in any student athlete, and the average reported time to EMS arrival was >8 minutes, suggesting that defibrillation would have been significantly delayed if schools did not have AEDs.

Collapse of a young athlete during practice or competition is a relatively uncommon event, but delayed recognition of SCA by first responders can lead to critical delays in initiating CPR and defibrillation. This study suggests that half of young athletes with SCA have brief myoclonic activity after collapse that could be mistaken for a seizure. In addition, athletes with SCA were perceived to have either ongoing respirations or a pulse for an average of 2 minutes after collapse in more than half of the cases. Although it is not possible to determine whether these reports are accurate, it is well established that rescuers may mistake agonal or occasional gasping for normal breathing or may falsely identify

Table 4. Comparison of Public-Access Defibrillation Studies

	Casinos[10]	Airlines[9]	Airports[7]	NCAA Division I Universities[11]	US High Schools
Cases of SCA, n	148	36	21	35	36
Immediate resuscitation rate, % (n/N)	48 (71/148)	36 (13/36)	52 (11/21)	54 (19/35)	64 (23/36)
Cases of VF/VT, n	105	15	18	21*	30*
Resuscitation rate if shock deployed, % (n/N)	63 (66/105)	87 (13/15)	61 (11/18)	71 (15/21)	67 (20/30)

NCAA indicates National Collegiate Athletic Association; VF/VT, ventricular fibrillation/ventricular tachycardia.
*Presumed VF/VT because AED deployed a shock.

the presence of a pulse.[26,27] Thus, a high suspicion of SCA must be maintained for any collapsed and unresponsive athlete and an AED applied as soon as possible for rhythm analysis and defibrillation if indicated.[22]

Public access to AEDs in schools provides a means of early defibrillation and improved survival not only for student athletes but also for other persons on school grounds who suffer SCA. This study found that ≈2 in 50 high schools can expect an SCA event each year. This finding is consistent with prior studies in which the annual probability of SCA occurring in a high school ranged from 0.8% to 2.1%.[20,28,29] This study also demonstrated that the majority of SCA events occur in older persons such as employees, spectators, and other visitors on campus rather than in students or student athletes and that the majority of SCA events occur during a school-sponsored athletic game, competition, or practice.

The exact incidence of SCA in young athletes is unknown. In the United States, estimates are limited by the lack of a mandatory reporting system for juvenile sudden death, and past studies vary widely as a result of differences in the methods of data collection and the age and population studied. Previous estimates of the incidence of sudden cardiac death in young competitive athletes in the United States range from 0.3 to 0.6 per 100 000 athletes per year and have relied heavily on search of public media reports, other electronic databases, and catastrophic insurance claims.[18,30] These studies have potentially underestimated the true incidence of sudden cardiac death because of incomplete detection of all cases. This study found an annual incidence of SCA in high school student athletes of 4.4 in 100 000. Although this estimate may be influenced by responder bias, it is consistent with recent findings from a prospective, population-based study of pediatric out-of-hospital cardiac arrest in which the incidence of SCA caused by cardiovascular disease in adolescents (age, 14 to 24 years) was found to be 3.75 in 100 000.[31] It is also consistent with findings from the Veneto region of Italy, which uses a regional registry for juvenile sudden death and where a baseline incidence of sudden cardiac death in young competitive athletes (age, 12 to 35 years) of 3.6 in 100 000 was found before the implementation of a national screening program.[32]

Comprehensive emergency planning is needed in high schools to ensure an efficient and structured response to SCA. Several national guidelines have provided recommendations for emergency preparedness for SCA in schools and advocated for placement of AEDs in the school and athletic setting.[22-24,33] In 2002, the National Athletic Trainers' Association released a position statement recommending any organization or institution sponsoring athletic activities to develop and implement a written emergency plan for SCA, including acquisition of necessary emergency equipment and training of involved personnel in CPR and AED use.[23] In 2004, the American Heart Association issued consensus recommendations for the Medical Emergency Response Plan in Schools, stating that every school that cannot reliably achieve an EMS call-to-shock interval of <5 minutes should have an AED program.[24] In 2005, the American College of Cardiology 36th Bethesda Conference suggested that every school that sponsors scholastic sports activities should have access to a defibrillator within 5 minutes of collapse.[33] In addition, in 2007, an interassociation task force provided consensus recommendations for emergency preparedness for SCA in high school and college athletic programs, strongly recommending access to AEDs with a target goal of <3 to 5 minutes from collapse to first shock.[22]

Essential elements of emergency planning for SCA include training anticipated responders in CPR and AED use, establishing an effective communication system, ensuring access to early defibrillation, coordinating and integrating onsite responder and AED programs with the local EMS system, and practicing and reviewing the response plan.[22] Although all of the high schools in this study had an onsite AED, many deficiencies in emergency planning were identified and could be improved. Only 60% of schools in this study developed their emergency plan in consultation with their local EMS, and fewer than half of schools actually practice and review their plan with school staff and potential onsite responders. In addition, half of school-based AEDs were funded by donations or a grant. It is critical that schools that receive donated AEDs also develop and implement a comprehensive emergency plan for SCA.

The presence of AEDs in US high schools is a growing trend.[20,34] The desire to protect student athletes from a catastrophic event also has prompted many states, including New York, Texas, Ohio, and Georgia, to pass legislation mandating that every school have at least 1 working AED on site.[35] It appears that the success of public-access defibrillation and school-based AED programs supports an evolving standard in favor of school AED programs.

Study Limitations

This study involved a cross-sectional survey of US high schools with at least 1 onsite AED. Only schools with AEDs were included to investigate a cohort of schools most likely to have developed an emergency response plan for SCA. Although survey questions were carefully worded in an attempt to capture all cases of SCA (both deaths and survivors), it is possible that schools with an SCA event or those with a good outcome from SCA were more likely to respond to the survey.

The use of self-reported data is another limitation in evaluating the details and timing of resuscitation efforts after SCA. The time frame for SCA cases was limited to within 6 months of survey completion in an attempt to reduce recall bias. Still, details of the resuscitation and time estimates may have been misreported. However, in 83% of cases, an AED was available on site or within close proximity, and it is likely that early defibrillation was achieved given the high survival rate.

At present, there is no universally accepted monitoring system of SCA in schools or young athletes in the United States. Thus, cases of SCA may have gone undetected in this study, and there was no comparison group of high schools without AEDs that would be more dependent on a conventional EMS response. A large, prospective study of US high schools is currently underway through the National Registry for AED Use in Sports to further investigate emergency

planning and outcomes of SCA in US high schools with and without onsite AED programs.

Conclusions

School-based AED programs provide a high survival rate for both students and nonstudents who suffer SCA on school grounds. SCA can be effectively treated through prompt recognition of SCA, a coordinated emergency response, the presence of a trained rescuer to initiate CPR, and early defibrillation. Myoclonic activity is common after SCA in young athletes and should not be mistaken for a seizure. High schools are in a unique situation to have trained targeted responders such as athletic trainers, coaches, and other school staff present during school hours and at school-sponsored athletic practices and competitions where the majority of SCA cases occur. Increased efforts should be made to ensure adequate emergency response planning for SCA in schools, including CPR and AED training for likely first responders, access to early defibrillation through onsite AEDs, and routine practice and review of the response plan. Prompt availability to AEDs is the evolving standard and should be encouraged in US high schools.

Acknowledgments

The investigators are grateful to the National Operating Committee on Standards for Athletic Equipment for partially funding the National Registry for AED Use in Sports and the study of emergency response planning for SCA in the school and athletic setting. The opinions expressed herein are those of the authors and do not necessarily reflect the opinions of the National Operating Committee on Standards for Athletic Equipment.

Source of Funding

This work was supported by the National Operating Committee on Standards for Athletic Equipment.

Disclosures

None.

References

1. Rosamond W, Flegal K, Furie K, Go A, Greenlund K, Haase N, Hailpern SM, Ho M, Howard V, Kissela B, Kittner S, Lloyd-Jones D, McDermott M, Meigs J, Moy C, Nichol G, O'Donnell C, Roger V, Sorlie P, Steinberger J, Thom T, Wilson M, Hong Y. Heart disease and stroke statistics–2008 update: a report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation.* 2008;117: e25–e146.
2. Larsen MP, Eisenberg MS, Cummins RO, Hallstrom AP. Predicting survival from out-of-hospital cardiac arrest: a graphic model. *Ann Emerg Med.* 1993;22:1652–1658.
3. American Heart Association in Collaboration with the International Liaison Committee on Resuscitation. Guidelines 2000 for cardiopulmonary resuscitation and emergency cardiovascular care, part 4: the automated external defibrillator: key link in the chain of survival. *Circulation.* 2000;102(suppl): I-60–I-76.
4. Becker LB, Ostrander MP, Barrett J, Kondos GT. Outcome of CPR in a large metropolitan area: where are the survivors? *Ann Emerg Med.* 1991; 20:355–361.
5. Gallagher EJ, Lombardi G, Gennis P. Effectiveness of bystander cardiopulmonary resuscitation and survival following out-of-hospital cardiac arrest. *JAMA.* 1995;274:1922–1925.
6. Bobrow BJ, Clark LL, Ewy GA, Chikani V, Sanders AB, Berg RA, Richman PB, Kern KB. Minimally interrupted cardiac resuscitation by emergency medical services for out-of-hospital cardiac arrest. *JAMA.* 2008;299:1158–1165.
7. Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Public use of automated external defibrillators. *N Engl J Med.* 2002;347:1242–1247.
8. Hallstrom AP, Ornato JP, Weisfeldt M, Travers A, Christenson J, McBurnie MA, Zalenski R, Becker LB, Schron EB, Proschan M. Public-access defibrillation and survival after out-of-hospital cardiac arrest. *N Engl J Med.* 2004;351:637–646.
9. Page RL, Joglar JA, Kowal RC, Zagrodzky JD, Nelson LL, Ramaswamy K, Barbera SJ, Hamdan MH, McKenas DK. Use of automated external defibrillators by a U.S. airline. *N Engl J Med.* 2000;343:1210–1216.
10. Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. *N Engl J Med.* 2000;343:1206–1209.
11. Drezner JA, Rogers KJ, Zimmer RR, Sennett BJ. Use of automated external defibrillators at NCAA Division I universities. *Med Sci Sports Exerc.* 2005;37:1487–1492.
12. Weaver WD, Hill D, Fahrenbruch CE, Copass MK, Martin JS, Cobb LA, Hallstrom AP. Use of the automatic external defibrillator in the management of out-of-hospital cardiac arrest. *N Engl J Med.* 1988;319: 661–666.
13. White RD, Asplin BR, Bugliosi TF, Hankins DG. High discharge survival rate after out-of-hospital ventricular fibrillation with rapid defibrillation by police and paramedics. *Ann Emerg Med.* 1996;28:480–485.
14. Myerburg RJ, Fenster J, Velez M, Rosenberg D, Lai S, Kurlansky P, Newton S, Knox M, Castellanos A. Impact of community-wide police car deployment of automated external defibrillators on survival from out-of-hospital cardiac arrest. *Circulation.* 2002;106:1058–1064.
15. White RD, Bunch TJ, Hankins DG. Evolution of a community-wide early defibrillation programme experience over 13 years using police/fire personnel and paramedics as responders. *Resuscitation.* 2005;65:279–283.
16. Maron BJ. Sudden death in young athletes. *N Engl J Med.* 2003;349: 1064–1075.
17. Maron BJ, Doerer JJ, Haas TS, Tierney DM, Mueller FO. Sudden deaths in young competitive athletes: analysis of 1866 deaths in the United States, 1980–2006. *Circulation.* 2009;119:1085–1092.
18. Van Camp SP, Bloor CM, Mueller FO, Cantu RC, Olson HG. Nontraumatic sports death in high school and college athletes. *Med Sci Sports Exerc.* 1995;27:641–647.
19. Drezner JA, Chun JS, Harmon KG, Derminer L. Survival trends in the United States following exercise-related sudden cardiac arrest in the youth: 2000–2006. *Heart Rhythm.* 2008;5:794–799.
20. Rothmier JD, Drezner JA, Harmon KG. Automated external defibrillators in Washington State high schools. *Br J Sports Med.* 2007;41:301–305.
21. Drezner JA, Rogers KJ. Sudden cardiac arrest in intercollegiate athletes: detailed analysis and outcomes of resuscitation in nine cases. *Heart Rhythm.* 2006;3:755–759.
22. Drezner JA, Courson RW, Roberts WO, Mosesso VN Jr, Link MS, Maron BJ. Inter-association task force recommendations on emergency preparedness and management of sudden cardiac arrest in high school and college athletic programs: a consensus statement. *Heart Rhythm.* 2007;4: 549–555.
23. Andersen J, Courson RW, Kleiner DM, McLoda TA. National Athletic Trainers' Association position statement: emergency planning in athletics. *J Athl Train.* 2002;37:99–104.
24. Hazinski MF, Markenson D, Neish S, Gerardi M, Hootman J, Nichol G, Taras H, Hickey R, OConnor R, Potts J, van der Jagt E, Berger S, Schexnayder S, Garson A Jr, Doherty A, Smith S. Response to cardiac arrest and selected life-threatening medical emergencies: the medical emergency response plan for schools: a statement for healthcare providers, policymakers, school administrators, and community leaders. *Circulation.* 2004;109:278–291.
25. Maron BJ, Gohman TE, Kyle SB, Estes NA III, Link MS. Clinical profile and spectrum of commotio cordis. *JAMA.* 2002;287:1142–1146.
26. ECC Committee, Subcommittees, and Task Forces of the American Heart Association. 2005 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation.* 2005;112(suppl):IV-1–IV-203.
27. Eberle B, Dick WF, Schneider T, Wisser G, Doetsch S, Tzanova I. Checking the carotid pulse check: diagnostic accuracy of first responders in patients with and without a pulse. *Resuscitation.* 1996;33:107–116.
28. Jones E, Vijan S, Fendrick AM, Deshpande S, Cram P. Automated external defibrillator deployment in high schools and senior centers. *Prehosp Emerg Care.* 2005;9:382–385.
29. Lotfi K, White L, Rea T, Cobb L, Copass M, Yin L, Becker L, Eisenberg M. Cardiac arrest in schools. *Circulation.* 2007;116:1374–1379.
30. Maron BJ, Gohman TE, Aeppli D. Prevalence of sudden cardiac death during competitive sports activities in Minnesota high school athletes. *J Am Coll Cardiol.* 1998;32:1881–1884.

31. Atkins DL, Everson-Stewart S, Sears GK, Daya M, Osmond MH, Warden CR, Berg RA, for the Resuscitation Outcomes Consortium Investigators. Epidemiology and outcomes from out-of-hospital cardiac arrest in children: the Resuscitation Outcomes Consortium Epistry–Cardiac Arrest. *Circulation*. 2009;119:1484–1491.
32. Corrado D, Basso C, Pavei A, Michieli P, Schiavon M, Thiene G. Trends in sudden cardiovascular death in young competitive athletes after implementation of a preparticipation screening program. *JAMA*. 2006;296:1593–1601.
33. Myerburg RJ, Estes NA III, Fontaine JM, Link MS, Zipes DP. Task Force 10: automated external defibrillators. *J Am Coll Cardiol*. 2005;45:1369–1371.
34. Berger S, Utech L, Hazinski MF. Lay rescuer automated external defibrillator programs for children and adolescents. *Pediatr Clin North Am*. 2004;51:1463–1478.
35. England H, Weinberg PS, Estes NA III. The automated external defibrillator: clinical benefits and legal liability. *JAMA*. 2006;295:687–690.

CLINICAL PERSPECTIVE

Sudden cardiac arrest is the leading cause of death in exercising young athletes. Several US guidelines provide recommendations for emergency planning for sudden cardiac arrest and advocate for the placement of automated external defibrillators in the school and athletic setting. Many schools have not implemented automated external defibrillator programs because of financial limitations, liability concerns, or both. Of the 11% of high schools responding to this survey, 82% had an automated external defibrillator on school grounds. Of those with automated external defibrillators, 82% had an emergency action plan in place, and 2.1% had had a sudden cardiac arrest event within the preceding 6 months. Victims were older nonstudents, including teachers, staff, and spectators, or student athletes. No arrests were reported in student nonathletes. The majority of victims survived to hospital discharge. This study provides further support for the implementation of automated external defibrillators programs in US high schools.

American Heart Association

Circulation

JOURNAL OF THE AMERICAN HEART ASSOCIATION

Resuscitation (2006) 70, 59–65

ELSEVIER

RESUSCITATION

www.elsevier.com/locate/resuscitation

CLINICAL PAPER

Adverse events associated with lay emergency response programs: The public access defibrillation trial experience

Mary Ann Peberdy[a,*], Lois Van Ottingham[b], William J. Groh[c], Jerris Hedges[d], Thomas E. Terndrup[e], Ronald G. Pirrallo[f], N. Clay Mann[g], Ruchir Sehra[h], and the PAD Investigators[1]

[a] *Virginia Commonwealth University Health System, Box 908204, Richmond, VA 23298, USA*
[b] *Clinical Trial Center, University of Washington, Seattle, WA, USA*
[c] *Indiana University School of Medicine, Indianapolis, IN, USA*
[d] *Oregon Health and Science University, Portland, OR, USA*
[e] *University of Alabama, Birmingham, AB, USA*
[f] *Medical College of Wisconsin, Milwauke, WI, USA*
[g] *University of Utah, School of Medicine, Salt Lake City, UT, USA*
[h] *Loma Linda Medical Center, Loma Linda, CA, USA*

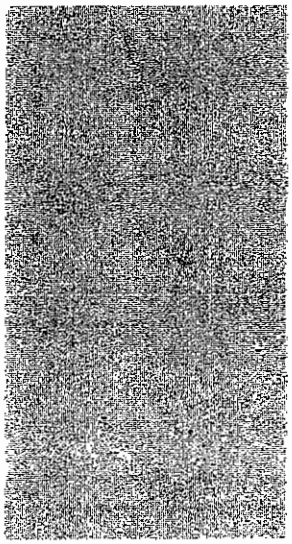
Received 25 July 2005; received in revised form 27 October 2005; accepted 27 October 2005

KEYWORDS
Cardiac arrest;
Automated external defibrillator;
Defibrillation;
Cardiopulmonary Resuscitation;
Emergency treatment

Summary The adverse event (AE) profile of lay volunteer CPR and public access defibrillation (PAD) programs is unknown. We undertook to investigate the frequency, severity, and type of AE's occurring in widespread PAD implementation.
Design: A randomized-controlled clinical trial.
Setting: One thousand two hundred and sixty public and residential facilities in the US and Canada.
Participants: On-site, volunteer, lay personnel trained in CPR only compared to CPR plus automated external defibrillators (AEDs).
Intervention: Persons experiencing possible cardiac arrest receiving lay volunteer first response with CPR + AED compared with CPR alone.
Main outcome measure: An AE is defined as an event of significance that caused, or had the potential to cause, harm to a patient or volunteer, or a criminal act. AE data were collected prospectively.

* Corresponding author. Tel.: +1 804 828 4571; fax: +1 804 828 7710.
E-mail address: mpeberdy@aol.com (M.A. Peberdy).
[1] The PAD Trial investigators and coordinators are listed in Ref. 15.

0300-9572/$ – see front matter
doi:10.1016/j.resuscitation.2005.10.030



Results: Twenty thousand three hundred and ninety six lay volunteers were trained in either CPR or CPR + AED. One thousand seven hundred and sixteen AEDs were placed in units randomized to the AED arm. There were 26,389 exposure months. Only 36 AE's were reported. There were two patient-related AEs: both patients experienced rib fractures. There were seven volunteer-related AE's: one had a muscle pull, four experienced significant emotional distress and two reported pressure by their employee to participate. There were 27 AED-related AEs: 17 episodes of theft involving 20 devices, three involved AEDs that were placed in locations inaccessible to the volunteer, four AEDs had mechanical problems not affecting patient safety, and three devices were improperly maintained by the facility. There were no inappropriate shocks and no failures to shock when indicated (95% upper bound for probability of inappropriate shock or failure to shock = 0.0012).

Conclusions: AED use following widespread training of lay-persons in CPR and AED is generally safe for the volunteer and the patient. Lay volunteers may report significant, usually transient, emotional stress following response to a potential cardiac arrest. Within the context of this prospective, randomized multi-center study, AEDs have an exceptionally high safety profile when used by trained lay responders.

Introduction

Sudden, unexpected cardiac arrest is a leading cause of death and disability. Studies estimate nearly a quarter to a half a million episodes of out-of-hospital cardiac arrest occur annually in the US.[1–3] Survival to hospital discharge is less than 5% in most cities, and has been reported as low as 1–2% in large metropolitan areas, despite ongoing scientific advances in resuscitation practice.[4,5] Early defibrillation is the single most important intervention for improving survival from adult OOH-CA.[6]

The concept of early defibrillation by medical and, more recently, lay first-responders using automated external defibrillators (AEDs) is almost a decade old.[7] Many communities have integrated first responder early defibrillation programs into their emergency medical services (EMS) systems, fire and police first response, and have targeted large venue public places such as airports and casinos using trained flight attendants and security guards.[8–12] The success of these programs in improving time to defibrillation, return of spontaneous circulation, and overall survival has prompted more widespread implementation of early defibrillation by trained lay responders in a variety of public settings.

Weisfeldt and Becker[13] described three phases of resuscitation after cardiac arrest. The electrical phase, when defibrillation is most beneficial, only lasts for approximately 4 min. It is impractical for a typical EMS system to be activated quickly enough to reach the victim's side and provide defibrillation to the vast majority of patients in this timeframe. Public access defibrillation (PAD) offers a way for lay responders to provide early defibrillation using AEDs while awaiting traditional EMS personnel. Many high volume public settings, such as casinos and airports, have demonstrated improved survival when non-medical employees are trained in CPR and AED use.[9,11,12] Because of the small size of these earlier case series, safety data related to the use of AEDs by trained lay responders are limited. The purpose of this study was to determine the frequency, type, and severity of adverse events in patients, volunteers, and AED devices occurring in the large, prospective, multi-center public access defibrillation trial.

Methods

The PAD trial was a prospective, multi-center, randomized clinical trial which demonstrated that volunteer, non-medical responders can improve survival from OOH-CA by using AEDs in addition to performing CPR and calling 911. Twenty-four research centers in the United States and Canada recruited 1260 individual public and residential facilities, which were combined to form a total of 993 randomized "community units" meeting specified cardiac arrest risk criteria. On-site lay volunteers without a contractual duty to act in a medical emergency participated as first responders. Facilities were randomized to have volunteer responders trained in CPR alone (CPR-only) or CPR with AED (CPR + AED). The sites randomized to the AED intervention arm received an adequate number of AEDs to respond to all areas in the facility within 3 min. All participating facilities received the standard emergency medical services (EMS)

care typically provided in their community. The study protocol was approved by the Institutional Review Board of the University of Washington as well as the Boards at each participating site. Detailed methods and results of the PAD trial have been published previously.[14,15]

All lay volunteers were trained in CPR or CPR + AED using American Heart Association (AHA), American Red Cross, Canadian Heart and Stroke Foundation or similar programs that closely followed the AHA guidelines. All volunteers were required to demonstrate proficiency in assessing unresponsiveness, accessing 911, providing ventilation with chest rise, correct hand placement, and adequate chest compression depth. Volunteers trained to operate the AED were also required to demonstrate proficiency in baring the chest, placing and attaching the defibrillation pads correctly, clearing themselves and others, and delivering a shock safely within 90 s.

An emergency episode was defined as any of the following: EMS dispatch to the facility for unconsciousness, any activation of the volunteer system for a presumed cardiac arrest, attempted CPR, any shock delivered within unit boundaries, and any death within unit boundaries. An adverse event was defined prospectively as any event that caused, or had the potential to cause, harm to a patient or volunteer, or the commission of a criminal act.

Collection of possible adverse events occurred by several systematic mechanisms throughout the trial. Volunteers were instructed during their initial training to report any adverse event, problem, or unusual occurrence to the study coordinator or investigator. Coordinators and investigators kept in close contact with volunteers by regular phone contact, faxes, emails and personal site visits to elicit information on system-wide issues or problems. Participating facilities were required to check AEDs monthly and report their findings to the study coordinator by either fax or verbal communication. Volunteer responders were debriefed after each episode in order to gather data relevant to potential adverse effects. Finally, patient EMS and hospital records were reviewed carefully for any possible adverse events. If unclear whether an incident qualified as an AE, the coordinator or investigator communicated with the PAD Coordinating Center for assistance in making the determination. An AE subcommittee, consisting of study investigators and coordinators also reviewed incidents for determination of AE's. All AE data were collected as part of the IRB approved study design and were also reviewed by the study's data safety monitoring board.

Adverse events were collected under three main categories: patient, volunteer, and AED device related. Patient related adverse event categories include rib fractures, liver laceration, pneumothorax, head trauma, neck and back trauma, and resuscitation attempts despite the patient having a do not attempt resuscitation (DNAR) status. Postmortem examinations were not required. Surviving patients were not evaluated for the presence of trauma by study staff. All emergency department and hospital records were reviewed for potential patient AEs but, if not noted in the records, an AE would remain unknown. These findings were noted to be present only if documented at some point in the patient record. Patient related adverse events were collected for both CPR-only trained lay responders and CPR + AED trained lay responders to determine if such events were associated more frequently with resuscitation performed with AEDs.

Volunteer related adverse event categories included the occurrence of any physical injury or emotional trauma. Our protocol required the clinical centers to conduct a volunteer debriefing after each event. The volunteer was asked to rate his or her stress level on a scale of 0–5 immediately after the event. They received follow-up if the score suggested moderate to severe stress defined as scale 4–5. If the volunteer experienced loss of sleep, physical symptoms, or difficulty with daily activities due to the event that did not resolve within a brief period, the site provided or referred the volunteer for psychological follow-up. Data were also collected on whether or not the volunteer responders could feel the AED shock being delivered to the patient.

AED device-related adverse event categories include any device malfunction, including shocks delivered to a non-arrest patient, AED use by a non-trained person, a criminal or inappropriate use of the device, whether or not retrieval of the device caused a substantial delay in accessing EMS, and AED theft. An independent committee reviewed all AED recordings for rhythm determination and appropriateness of shocks.

Ninety-five percent confidence intervals were computed for adverse event rates based on exposure years. For the case where no adverse events were observed a 95% upper bound was computed.

Results

A total of 20,396 lay volunteer responders were trained in CPR alone or CPR plus the use of an AED. One thousand seven hundred and sixteen AEDs were

placed in public and multi-family residential facilities. There were 26,389 months of public availability evaluated for adverse events during the duration of the trial. Of the 3952 emergency episodes captured during the trial, 649 were presumed cardiac arrests. Data on adverse events (AEs) were collected from 20 July 2000 through 30 September 2003. Thirty-six AEs were confirmed.

Patient-related AEs

There were two patient-related AEs (95% CI per exposure-year = [0.0, 0.0022]) consisting of two patients with rib fractures discovered on autopsy after both volunteer and EMS CPR. No patient with a known DNAR order had resuscitation started inappropriately. No patient-related adverse event was related to the use of an AED.

Volunteer related AEs

There were seven (95% CI per exposure-year = [0.0008, 0.0055]) volunteer related adverse events consisting of one volunteer who developed a muscle pull after responding to an emergency, four volunteers with increased emotional stress levels requiring intervention, and two volunteers who felt pressured by their employer to participate as a first responder. The majority of rescuers with initially elevated stress levels returned to normal by the following day but four required further follow up or interventions. One volunteer was tearful, nauseated, and had difficulty sleeping after performing CPR on a victim that was well known to them. This volunteer was upset at seeing the patient cyanotic and was uncomfortable with being labelled a hero, however had complete resolution of their symptoms in 2 days and continued to participate as a volunteer first responder. Another volunteer responded to a traumatic injury to a child. This volunteer had difficulty in school after the event, was referred to a counsellor and was subsequently reported to be "all right" by a family member after counseling. A third volunteer experienced nausea and vomiting for 20 min after the episode and rated their stress level as a four out of five. The stress resolved by the following day. Finally, a fourth volunteer was involved in two episodes, and knew both of the victims. This volunteer reported a stress level was a "five" after the second event and additional follow-up with study personnel was refused. The volunteer left their job at the unit, reportedly due to a number of reasons not solely related to the arrests.

No volunteer was harmed by the use of an AED. The AED was retrieved from its storage site in 690 episodes and placed on 128 patients. A shock was delivered to 58 patients. The AED was never operated by an untrained person.

Device-related AEs

There were 27 (95% CI per exposure year = [0.0076, 0.0169]) AED device-related AE's. There were seventeen incidents of theft involving 20 devices. On three occasions, the AEDs were moved to locations not readily accessible to the first responder. There were four incidents of mechanical difficulty or battery failure that did not affect patient safety. One AED developed a failed circuit board, another displayed a service message, a third showed an electrode warning and the fourth was found to have a dead battery that was not indicated by the AED. Three AEDs were maintained inappropriately by the facility. Two were found to have the battery ajar and the third involved an episode where the lid to the AED box was closed over the electrode wires making it difficult to re-open the device. None of these episodes affected patient safety because another AED was available promptly in each setting. During this study, there were no inappropriate shocks and no device failed to shock when indicated (95% upper bound for probability of inappropriate shock or failure to shock = 0.0012).

Discussion

Survival from OOH-CA is poor, yet when sudden death occurs, if defibrillation and CPR are available immediately (e.g., in cardiac rehabilitation or in the electrophysiology laboratory), survival has the potential to be greater than 90%.[6] The opportunity for significant public benefit from increased survival is huge considering the large difference between what is theoretically possible and what actually occurs in our communities. The results of the PAD trial indicate that trained lay rescuers can use modern generation shock-advisory AEDs effectively and safely. There were no severe adverse events detected in a carefully monitored system of significant size in North American communities.

A similar lack of problems has been noted in other published series. Valenzuela et al. trained security officers in CPR and AED use and significantly improved survival from cardiac arrest in numerous casinos without reporting any adverse events.[12] Many communities have developed law enforcement agency AED programs and, similarly, have not reported any patient, device, or rescuer adverse events related to the provision of early

defibrillation.[8,10,16–21] Two United States airline companies have published their experience with training flight attendants to use AEDs with an exceptional safety record.[11,22] Caffrey et al.'s[9] report of experience in the Chicago airport authority was the first publication of AED use by untrained first responders. Even though this program was designed to have only security personnel respond, in 19 of 21 episodes of cardiac arrest, Good Samaritan lay responders used the AED without harm to themselves or the victim. Despite over 20 years of experience with lay responder AED use, the literature reporting adverse events is scarce.

In the United States, the Food and Drug Administration (FDA) has the responsibility for assuring the safety and efficacy of all regulated marketed medical products. The FDA developed the Safety Information and Adverse Event Reporting Program (MedWatch) to provide health care professionals and consumers a mechanism to report serious problems that are associated with use of a drug or device. Although MedWatch provides vital safety information to the FDA, the database has a limited perspective related to devices such as AEDs. It collects only data specifically reported to the system and links the device with the outcome. Death and poor neurological outcomes in survivors are common outcomes from cardiac arrest, regardless of up to date treatment. This association can be interpreted erroneously as a cause and effect relationship, when in fact the AED may have nothing to do with the poor outcome.

Data from the PAD trial provides a different perspective on AED safety than the FDA MedWatch program. The FDA's medical device reporting system has no denominator. Thus, everything reported to the FDA must be considered to be a potential device problem without any balancing information on the extent to which the device contributed to an adverse patient outcome. The PAD trial experience provides an objective assessment of the true frequency of AED related adverse events as determined by rigorous, prospective surveillance techniques.

Device problems in this trial were all relatively minor, never affecting the safety of the patient or lay responder. Rhythm recognition tests performed in the laboratory and in clinical trials in the mid 1980's validated the accuracy of AEDs. Most device errors were due to a lack of arrhythmia recognition. These devices re-analyzed the rhythm every several seconds so the lack of appropriate detection on one analysis typically did not result in a markedly delayed shock delivery. Stults et al.[23] reported two cases in 122 in which coarse VF was consistently not recognized as VF by the AED and resulted in several minutes delay of defibrillation. Ornato et al.[24] reported an inappropriate automated shock of a patient in sinus rhythm. In this instance, the EMS responders did not follow the device's instructions and analyzed the rhythm in a moving vehicle. The motion artifact was misinterpreted as a shockable rhythm and two shocks were delivered resulting in ventricular tachycardia. The device then appropriately detected VT and restored sinus rhythm with a third shock. Reports such as these were all early devices that were unable to detect motion artifact and, in some cases, were fully automatic, not giving the responder control of shock delivery. Newer devices with advanced technology have nearly eliminated these types of adverse events.

All AEDs used in the PAD trial performed self-checks that were helpful in the early identification of potential problems. Since some of the device-related adverse events were secondary to improper maintenance or location selection, human factors clearly play a role in the ultimate success of these programs. Education on proper maintenance and accessibility is crucial for developing lay first responder AED programs.

The most common adverse event identified in the PAD trial was AED theft. Interestingly, the majority of stolen devices were removed from locked locations as opposed to those kept unlocked and visible, suggesting that restricting access of AEDs to the general public may not be an important factor in preventing AED theft.

The only patient related problems were related primarily to CPR. No patient was harmed by an AED during the trial. DNAR status is becoming increasingly frequent in the pre-hospital setting. A theoretical concern for PAD programs is that resuscitation may be started on those who do not want it. Assisted and independent living facilities for the elderly not only have an exceptionally high-risk population but also have a significant percentage of residents who do not want to be resuscitated should they suffer a cardiac arrest. The PAD trial demonstrated that it is possible to implement widespread lay responder early defibrillation programs in public and residential locations without unwanted resuscitations.

Psychological issues represented the most significant adverse events in the volunteer responder group. A small number of volunteers developed stress levels severe and sustained enough to require intervention. Although they represent a very small fraction of all the volunteers who participated in the trial, the concept of psychological stress on the part of the first responder has not been reported previously. The PAD trial, unlike other reported case series of lay first responder

AED programs, specifically evaluated volunteer stress using a prospective surveillance system. The psychological stress seen in the PAD trial was indigenous to the entire resuscitation response and was not specific to AED use. PAD programs should consider having procedures in place to identify and deal with responder stress levels based on these findings. Employers also need to be sensitive to an employee's willingness to participate in such a program. Volunteers who feel pressured to participate by their employer may interpret this erroneously as a threat to their employment.

The most obvious limitation of this trial was that it included only trained responders in a limited number of public and residential venues. Thus, it is not appropriate to extrapolate these low adverse event rates to PAD programs that might use untrained lay responders. Other limitations include the fact that adverse events were self-reported and, despite significant efforts to collect a comprehensive list of adversities, some data may have been missed. Volunteers and clinical coordinators may have been apprehensive or unwilling to report AEs, but they were encouraged and regularly questioned about reporting. There was variability in the amount of contact each investigator and coordinator had with her/his respective facilities. This may have affected either the occurrence or reporting of adverse events. Despite these limitations, AEDs appear to be safe devices in the hands of trained laypersons using them in settings similar to those used in the PAD trial.

The Food and Drug Administration made a landmark decision in September 2004 in allowing a single manufacturer's AED to be available for purchase by the public without a prescription. This was a crucial step in removing a potentially large barrier to the public's access to AEDs. The results of this study are particularly relevant, given the increased availability of AEDs and the decrease in mandated physician supervision over PAD programs and lay responders that will result from "over the counter" availability of devices.

Conclusion

Our data confirms the safety of AEDs in a culturally diverse, appropriately instructed, supervised lay responder population throughout widespread geographical areas in a variety of public and multifacility residential settings. Further research is needed to determine whether safety is similar for untrained lay responders and those not participating in supervised programs.

Acknowledgements

Funding support: supported by contract #N01–HC–95177 from the National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD. Additional support by: American Heart Association, Dallas, TX; Medtronic, Incorporated, Minneapolis, MN; Guidant Foundation, Indianapolis, IN; Cardiac Science/Survivalink, Incorporated, Minneapolis, MN; Medtronic Physio-Control Corporation, Redmond, WA; Philips Medical Systems, Heartstream, Seattle, WA; and Laerdal Medical Corporation, Wappingers Falls, NY.

References

1. Centers for Disease Control and Prevention (CDC). State-Specific Mortality from Sudden Cardiac Death, United States, 1999, MMWR, 2002; 51(6):123–6.
2. Chugh SS, Jui J, Gunson K, et al. Current burden of sudden cardiac death: multiple source surveillance versus retrospective death certificate-based review in a large U.S. community. J Am Coll Cardiol Sep 15 2004;44(6):1268–75.
3. Rea TD, Eisenberg MS, Sinibaldi G, White RD. Incidence of EMS-treated out-of-hospital cardiac arrest in the United States. Resuscitation Oct 2004;63(1):17–24.
4. Lombardi G, Gallagher J, Gennis P. Outcome of out of hospital cardiac arrest in New York City. The Pre Hospital Arrest Survival Evaluation (PHASE) Study. JAMA 1994;271(9):678–83.
5. Becker LB, Ostrander MP, Barrett J, Kondos GT. Outcome of CPR in a large metropolitan area, where are the survivors? Ann Emerg Med 1991;20(4):355–61.
6. Cummins RO, Ornato JP, Thies WH, Pepe PE. Improving survival from sudden cardiac arrest: the "chain of survival" concept. A statement for health professionals from the Advanced Cardiac Life Support Subcommittee and the Emergency Cardiac Care Committee, American Heart Association. Circulation 1991;83(5):1832–47.
7. Weisfeldt ML, Kerber RE, McGoldrick RP, et al. Public access defibrillation: A statement for healthcare professionals from the American Heart Association Task Force on Automatic External Defibrillation. Circulation 1995;92:2763.
8. White RD, Hankins DG, Bugliosi TF. Seven years' experience with early defibrillation by police and paramedics in an emergency medical services system. Resuscitation Dec 1998;39(3):145–51.
9. Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Public use of automated external defibrillators. N Engl J Med 17 Oct 2002;347(16):1242–7.
10. Mosesso Jr VN, Newman MM, Ornato JP, et al. Law enforcement agency defibrillation (LEA-D). Proceedings of the National Center for Early Defibrillation Police AED Issues Forum. Prehosp Emerg Care, Jul to 6 Sep, 3 2002:273–82.
11. Page RL, Joglar JA, Kowal RC, et al. Use of automated external defibrillators by a US airline. N Engl J Med 26 Oct 2000;343(17):121D–6.
12. Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. N Engl J Med 26 Oct 2000;343(17):1206–9.

13. Weisfeldt ML, Becker LB. Resuscitation after cardiac arrest: a 3-phase time-sensitive model. JAMA 2002;288(23):3035–8.
14. Ornato JP, McBurnie MA, Nichol G, et al. The Public Access Defibrillation (PAD) trial: study design and rationale. Resuscitation Feb 2003;56(2):135–47.
15. The PAD Trial Investigators. Public-access defibrillation and survival after out-of-hospital cardiac arrest. N Engl J Med 2004;351(7):637–46.
16. Myerburg RJ, Fenster J, Velez M, et al. Impact of community-wide police car deployment of automated external defibrillators on survival from out-of-hospital cardiac arrest. Circulation 27 Aug 2002;106(9):1058–64.
17. Groh WJ, Lowe MR, Overgaard AD, Neal JM, Fishburn WC, Zipes DP. Attitudes of law enforcement officers regarding automated external defibrillators. Acad Emerg Med Jul 2002;9(7):751–3.
18. Ross P, Nolan J, Hill E, Dawson J, Whimster F, Skinner D. The use of AEDs by police officers in the City of London. Automated external defibrillators. Resuscitation Aug 2001;50(2):141–6.
19. Groh WJ, Newman MM, Beal PE, Fineberg NS, Zipes DP. Limited response to cardiac arrest by police equipped with automated external defibrillators: lack of survival benefit in suburban and rural Indiana, the police as responder automated defibrillation evaluation (PARADE). Acad Emerg Med Apr 2001;8(4):324–30.
20. Davis EA, McCrorry J, Mosesso Jr VN. Institution of a police automated external defibrillation program: concepts and practice. Prehosp Emerg Care Jan to Mar 1999;3(1):60–5.
21. Mosesso Jr VN, Davis EA, Auble TE, Paris PM, Yealy DM. Use of automated external defibrillators by police officers for treatment of out-of-hospital cardiac arrest. Ann Emerg Med Aug 1998;32(2):200–7.
22. O'Rourke MF, Donaldson E, Geddes JS. An airline cardiac arrest program. Circulation 1997;96(9):2849–53.
23. Stults KR, Brown DD, Kerber RE. Efficacy of an automated external defibrillator in the management of out-of-hospital cardiac arrest: validation of the diagnostic algorithm and initial clinical experience in a rural environment. Circulation 1986;73(4):701–9.
24. Ornato JP, Shipley J, Powell RG, Racht EM. Inappropriate electrical countershocks by an automated external defibrillator. Ann Emerg Med 1992;21(10):1278–82.

ORIGINAL ARTICLE

Home Use of Automated External Defibrillators for Sudden Cardiac Arrest

Gust H. Bardy, M.D., Kerry L. Lee, Ph.D., Daniel B. Mark, M.D., M.P.H., Jeanne E. Poole, M.D., William D. Toff, M.D., Andrew M. Tonkin, M.D., Warren Smith, M.B., Ch.B., Paul Dorian, M.D., Douglas L. Packer, M.D., Roger D. White, M.D., W.T. Longstreth, Jr., M.D., Jill Anderson, R.N., B.S.N., George Johnson, B.S.E.E., Eric Bischoff, B.A., Julie J. Yallop, Ph.D., Steven McNulty, M.S., Linda Davidson Ray, M.A., Nancy E. Clapp-Channing, R.N., M.P.H., Yves Rosenberg, M.D., and Eleanor B. Schron, R.N., Ph.D., for the HAT Investigators*

ABSTRACT

BACKGROUND

The most common location of out-of-hospital sudden cardiac arrest is the home, a situation in which emergency medical services are challenged to provide timely care. Consequently, home use of an automated external defibrillator (AED) might offer an opportunity to improve survival for patients at risk.

METHODS

We randomly assigned 7001 patients with previous anterior-wall myocardial infarction who were not candidates for an implantable cardioverter–defibrillator to receive one of two responses to sudden cardiac arrest occurring at home: either the control response (calling emergency medical services and performing cardiopulmonary resuscitation [CPR]) or the use of an AED, followed by calling emergency medical services and performing CPR. The primary outcome was death from any cause.

RESULTS

The median age of the patients was 62 years; 17% were women. The median follow-up was 37.3 months. Overall, 450 patients died: 228 of 3506 patients (6.5%) in the control group and 222 of 3495 patients (6.4%) in the AED group (hazard ratio, 0.97; 95% confidence interval, 0.81 to 1.17; P=0.77). Mortality did not differ significantly in major prespecified subgroups. Only 160 deaths (35.6%) were considered to be from sudden cardiac arrest from tachyarrhythmia. Of these deaths, 117 occurred at home; 58 at-home events were witnessed. AEDs were used in 32 patients. Of these patients, 14 received an appropriate shock, and 4 survived to hospital discharge. There were no documented inappropriate shocks.

CONCLUSIONS

For survivors of anterior-wall myocardial infarction who were not candidates for implantation of a cardioverter–defibrillator, access to a home AED did not significantly improve overall survival, as compared with reliance on conventional resuscitation methods. (ClinicalTrials.gov number, NCT00047411.)

From the Seattle Institute for Cardiac Research (G.H.B., J.A., G.J., E.B.) and the University of Washington (J.E.P., W.T.L.) — both in Seattle; the Duke University Clinical Research Institute, Durham, NC (K.L.L., D.B.M., S.M., L.D.R., N.E.C.-C.); the University of Leicester, Leicester, United Kingdom (W.D.T.); the Department of Epidemiology and Preventive Medicine, Monash University, Melbourne, Victoria, Australia (A.M.T., J.J.Y.); Auckland City Hospital, Auckland, New Zealand (W.S., J.J.Y.); the University of Toronto, Toronto (P.D.); the Mayo Clinic, Rochester, MN (D.L.P., R.D.W.); and the National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD (Y.R., E.B.S.). Address reprint requests to Dr. Bardy at the Seattle Institute for Cardiac Research, 7900 E. Green Lake Dr. N., #302, Seattle, WA 98103-4819, or at gbardy@sicr.org.

*Investigators in the Home Automated External Defibrillator Trial (HAT) are listed in the Supplementary Appendix, available with the full text of this article at www.nejm.org.

This article (10.1056/NEJMoa0801651) was published at www.nejm.org on April 1, 2008.

N Engl J Med 2008;358:1793-804.

SUDDEN CARDIAC ARREST REMAINS AN unsolved public health problem, with approximately 166,200 out-of-hospital cardiac arrests occurring annually in the United States.[1] The use of automated external defibrillators (AEDs) by trained lay responders in community-based public-access defibrillation programs has been shown to increase survival after sudden cardiac arrest. However, what effect the use of the device has on overall mortality for the community at risk is unknown.[2-5] Particularly impressive results have been reported when sudden cardiac arrest is witnessed and an AED is immediately available, as on airplanes and in casinos and airports.[6-8] However, the effect of such programs is limited, since about three quarters of sudden cardiac arrests occur in the home,[9,10] where successful resuscitation is typically achieved in only 2% of cases.[11]

The combination of ease of use, low cost, and negligible maintenance makes home AED therapy a potentially attractive approach to a major public health problem. The purpose of the Home Automated External Defibrillator Trial (HAT) was to test whether an AED in the home of patients at intermediate risk of sudden cardiac arrest could improve survival.

METHODS

STUDY DESIGN

Our international, multicenter clinical trial was sponsored by the National Heart, Lung, and Blood Institute (NHLBI).[12] AEDs were provided free of charge by Philips Medical Systems and Laerdal Medical as a subsidiary distributor. Both companies also provided funding for research meetings. The corporate sponsors had no role in the design of the trial, the collection or analysis of the data, the writing of the manuscript, or the decision to publish the results. The trial was approved by the institutional review board at each participating center and was performed with the oversight of an NHLBI-appointed data and safety monitoring board.

PATIENTS

Patients whose medical condition was stable and who had had a previous anterior-wall Q-wave or non–Q-wave myocardial infarction were selected for enrollment because such patients represent a sizable group known to be at increased risk for sudden cardiac arrest.[13-15] Patients were excluded from the study if they were candidates for implantable cardioverter–defibrillator therapy, according to published guidelines.[16-19] Contemporary evidence-based drug therapy after myocardial infarction was encouraged for all patients. Patients were required to have a spouse or companion who was willing and able to call for assistance from emergency medical services, perform cardiopulmonary resuscitation (CPR), and use an AED. Patients with an implantable cardioverter–defibrillator, with their own AED, or with a do-not-resuscitate order were excluded. Written informed consent was provided by all patients and their spouses or companions.

GROUP ASSIGNMENTS

Patients who had received conventional training to respond to a cardiac arrest were randomly assigned in equal proportions to receive either an AED for home use or no AED. Randomization was performed with the use of permuted blocks, stratified according to clinical center.

The goal for the control group after sudden cardiac arrest was an immediate telephone request for assistance from emergency medical services and prompt initiation of CPR, in accordance with published guidelines for basic life support.[20] Patients and their spouses or companions in the control group received a video, specifically scripted to educate laypersons on how to call for assistance and perform CPR.[21]

The goal in the AED group was to use the AED first, in accordance with published guidelines for AED use.[22] The AED that was selected for this trial, the Home HeartStart (Philips), is the only device that is approved by the Food and Drug Administration for home use. Spouses or companions were instructed to call emergency medical services and perform CPR, as in the control group. However, in the AED group, spouses or companions placed the call for assistance and performed CPR after the application of the AED. If two or more rescuers were present, the call to emergency medical services was to occur simultaneously with the use of the AED. Patients in the AED group received a video that was specifically scripted to educate laypersons on how to use the AED, call for assistance, and perform CPR.[21] Patients and their spouses or companions were advised to keep the AED in a prominent location in the home to facilitate ease of access and regular visual confirmation of the AED's readiness.

TRAINING AND FOLLOW-UP

In both study groups, video-based training was used to standardize instruction and facilitate refresher training at intervals of 3 months. Investigators were also encouraged to offer hands-on training at enrollment and during annual follow-up visits. A telephone call between annual visits was used to obtain information on vital status and encourage viewing of the video.

DEFINITION AND ADJUDICATION OF OUTCOMES

The primary outcome was death from any cause. Secondary outcomes included death from sudden cardiac arrest, survival from witnessed sudden cardiac arrest in the home, and the outcome after the use of an AED.

All deaths and sudden cardiac arrests were adjudicated with the use of prespecified criteria by a clinical events committee whose members were unaware of study-group assignments. Death was classified as being due to cardiac causes or noncardiac causes according to the most proximate cause. Cardiac arrest was defined as a sudden loss of consciousness requiring CPR or transthoracic defibrillation. Death and cardiac arrest were classified as sudden if they occurred within 1 hour after the onset of major accelerating symptoms; cardiac arrest was classified as witnessed if the patient was seen or heard within 5 minutes before collapse. Resuscitated cardiac arrest was defined as survival for more than 48 hours. In the event of use of an AED, the electrocardiographic data were retrieved whenever possible, and rhythms were categorized as ventricular fibrillation, asystole, or organized rhythm.[23,24]

STATISTICAL ANALYSIS

The trial was designed to have a power of 90% to detect a 20% reduction in the relative risk of death from any cause, with a target recruitment of 7000 patients during a 2.5-year period and a minimum follow-up of 2 years.[12] We assumed an annual rate of death of 4% in the control group, a crossover rate of less than 2%, and a loss of partner or companion of less than 5%. The anticipated reduction in mortality was based on the assumption that half the number of deaths would be due to sudden cardiac arrest and that the use of an AED would reduce the rate of death from sudden cardiac arrest by 40%, with the expectation that patients would be at home and in the presence of their spouses or companions more than 50% of the time.

We performed all major study-group comparisons according to the intention-to-treat principle. All statistical tests were two-tailed. Cumulative event rates were calculated with the use of the Kaplan–Meier method.[25] Event times for all patients were measured from the time of randomization. A log-rank test was used for the comparison of the AED group with the control group with respect to the primary outcome.[26] Hazard ratios with associated confidence intervals were derived with the use of a Cox proportional-hazards model.[27] The Cox model was also used to assess the consistency of the treatment effect by testing for interactions between treatment and prespecified baseline characteristics. The log-rank test and Cox model were also used in the assessment of study-group differences and analyses for secoudary outcomes.

Five interim analyses of the data were performed and reviewed by the data and safety monitoring board. Interim comparisons between study groups used two-sided, symmetric O'Brien–Fleming boundaries that were generated with the alpha-spending-function approach to group-sequential testing.[28,29]

RESULTS

STUDY POPULATION

From January 23, 2003, to October 20, 2005, a total of 7001 patients underwent randomization at 178 clinical sites in seveu countries; 3506 patients were assigned to the control group, and 3495 were assigned to the AED group. The patients were enrolled at centers in the United States (29.1%), Canada (27.0%), Australia (20.9%), the United Kingdom (14.6%), New Zealand (8.1%), the Netherlands (0.1%), and Germany (0.1%).

The median age of the patients was 62 years; 17.4% were women, and 12.9% were members of a racial or ethnic minority group (Table 1). At baseline, all patients had an anterior-wall myocardial infarction; 64.4% had a Q-wave event, and 35.6% had a non–Q-wave event. The median interval between the date of the qualifying myocardial infarction and trial enrollment was 1.7 years.

The designated rescuers were younger than the patients (median age, 58 years) and predominantly female (82.5%); most were married to the patient (87.8%) (Table 1). In 33.3% of households, there were two or more potential rescuers. A total of 42.6% of the patients and 48.8% of the spouses

Table 1. Characteristics of the Patients and Their Spouses or Companions.*

Characteristic	Control Group (N=3506)	AED Group (N=3495)
Patients		
Age — yr		
Median	62.0	62.0
Interquartile range	54.0–70.0	54.0–70.0
Female sex — no. (%)	626 (17.9)	594 (17.0)
Racial or ethnic minority — no. (%)†	478 (13.6)	428 (12.2)
Time since most recent anterior myocardial infarction — no. (%)‡		
≤1 Mo	290 (9.7)	272 (9.2)
>1 Mo to 3 mo	284 (9.5)	300 (10.1)
>3 Mo to 6 mo	284 (9.5)	261 (8.8)
>6 Mo to 1 yr	331 (11.1)	354 (11.9)
>1 Yr	1798 (60.2)	1780 (60.0)
Employment status — no. (%)		
Full-time	1123 (32.0)	1161 (33.2)
Part-time	329 (9.4)	368 (10.5)
Not employed	2054 (58.6)	1966 (56.3)
Estimated daily time alone at home — hr		
Median	1.5	1.5
Interquartile range	0.5–4.0	0.5–4.0
Estimated daily time away from home — hr		
Median	4.0	4.0
Interquartile range	2.0–8.0	2.0–8.0
Previous procedures — no. (%)		
Percutaneous coronary revascularization	1890 (53.9)	1852 (53.0)
Coronary-artery bypass grafting	907 (25.9)	960 (27.5)
Coexisting conditions — no. (%)		
Hypertension	1931 (55.1)	1838 (52.6)
Diabetes	792 (22.6)	712 (20.4)
Hypercholesterolemia	2804 (80.0)	2753 (78.8)
Stroke	217 (6.2)	220 (6.3)
Measured ejection fraction — no. (%)	2803 (79.9)	2821 (80.7)
Left ventricular ejection fraction — %		
Median	45.0	45.0
Interquartile range	35.0–55.0	35.0–55.0
Atrial fibrillation or flutter — no. (%)	361 (10.3)	377 (10.8)
Systolic blood pressure — mm Hg		
Median	124.0	124.0
Interquartile range	112.0–136.0	112.0–136.0
Diastolic blood pressure — mm Hg		
Median	73.0	73.0
Interquartile range	66.0–80.0	68.0–80.0
Heart rate — beats/min		
Median	65.0	65.0
Interquartile range	60.0–72.0	60.0–72.0

Table 1. (Continued.)

Characteristic	Control Group (N=3506)	AED Group (N=3495)
Body-mass index		
Median	27.8	27.7
Interquartile range	25.1–30.9	24.9–30.9
NYHA class — no. (%)		
I	2307 (65.8)	2263 (64.7)
II	1016 (29.0)	1037 (29.7)
III	174 (5.0)	193 (5.5)
IV	9 (0.3)	2 (<0.1)
Left ventricular hypertrophy — no. (%)§	165 (4.7)	166 (4.8)
Duration of QRS interval — msec		
Median	91.0	92.0
Interquartile range	80.0–100.0	80.0–100.0
Type of myocardial infarction — no. (%)		
Anterior Q-wave	2237 (63.8)	2272 (65.0)
Anterior non–Q-wave	1269 (36.2)	1222 (35.0)
Use of medication — no. (%)		
Beta-blocker (other than sotalol or amiodarone)	2793 (79.7)	2738 (78.3)
ACE inhibitor or angiotensin-receptor blocker	2853 (81.4)	2866 (82.0)
Statin	3141 (89.6)	3100 (88.7)
Daily use of aspirin	3047 (86.9)	3016 (86.3)
Digoxin	240 (6.8)	249 (7.1)
Warfarin	600 (17.1)	649 (18.6)
Any antiarrhythmic drug	138 (3.9)	160 (4.6)
Spouse or companion		
Relationship to patient — no. (%)		
Spouse	3055 (87.1)	3095 (88.6)
Companion	451 (12.9)	400 (11.4)
Age — yr		
Median	58.0	58.0
Interquartile range	49.0–67.0	50.0–66.0
Employment status — no. (%)		
Full-time	1110 (31.7)	1113 (31.8)
Part-time	619 (17.7)	577 (16.5)
Not employed	1777 (50.7)	1805 (51.6)
Estimated daily time away from home — hr		
Median	4.0	4.0
Interquartile range	2.0–7.5	2.0–8.0
Completed secondary school — no. (%)	2851 (81.3)	2831 (81.0)

* ACE denotes angiotensin-converting enzyme, AED automated external defibrillator, and NYHA New York Heart Association. The body-mass index is the weight in kilograms divided by the square of the height in meters.
† Race or ethnic group was self-reported.
‡ Percentages are based on 2987 patients in the control group and 2967 in the AED group.
§ Percentages are based on 3485 patients in the control group and 3477 in the AED group.

or companions worked either full-time or part-time. The median estimated time that patients were alone at home was 1.5 hours per day; other persons at home with the patient may or may not have included the study rescuer. The patients reported a median estimated time away from home of 4.0 hours.

Patients were followed through September 30, 2007. The median duration of follow-up was 37.3 months (range, 20.4 to 55.6). Data regarding vital status, current to within 3 months before study closure, were obtained for 100% of the patients who underwent randomization.

COMPLIANCE AND CROSSOVERS

In the AED group, 167 patients (4.8%) had a spouse or companion who was unable or unwilling to use the AED during follow-up. The corresponding number in the control group was 132 of 3272 patients (4.0%) for whom follow-up data were available. Crossover to therapy with an implantable cardioverter–defibrillator during follow-up occurred in 145 of 3435 patients in the AED group (4.2%) and in 155 of 3371 patients in the control group (4.6%).

PRIMARY OUTCOME

A total of 450 patients died. Of these patients, 228 (6.5%) were in the control group, and 222 (6.4%) were in the AED group. As compared with the control group, the AED group had a similar risk of death (hazard ratio, 0.97; 95% confidence interval, 0.81 to 1.17; P=0.77). The mean annual mortality during 4 years of follow-up was 2.1% in the control group and 2.0% in the AED group (Fig. 1). The primary outcome did not differ among the major prespecified subgroups according to the following factors: age (≥65 years vs. <65 years), sex, Q-wave versus non–Q-wave myocardial infarction, and nationality (United States vs. all other countries) (Fig. 2). Treatment comparisons within subgroups were consistent with the overall study results, although the difference in treatment effect in patients with diabetes, as compared with those without diabetes, was statistically significant (P=0.04).

CAUSE, MODE, AND CIRCUMSTANCE OF DEATH

The adjudicated cause and mode of death in each of the study groups are shown in Table 2. Only 169 of the 450 deaths (37.6%) were deemed to be caused by tachyarrhythmia (i.e., consistent with ventricular fibrillation or ventricular tachycardia). Death was attributed to heart failure or nonarrhythmic cardiac causes in 96 patients (21.3% of deaths) and to noncardiac causes in 170 patients (37.8%). Thirteen deaths (2.9%) could not be classified because of insufficient data. There were

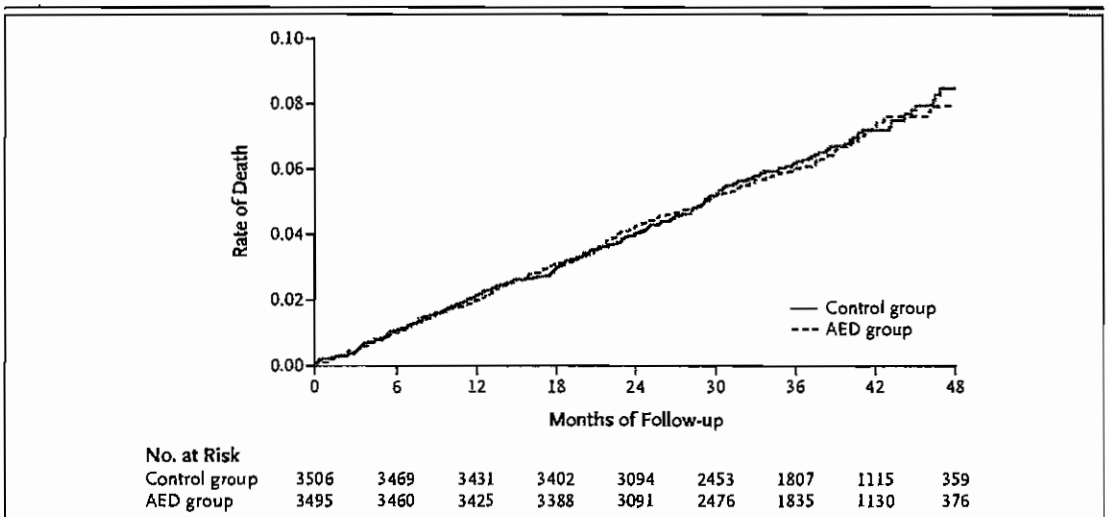


Figure 1. Kaplan–Meier Curves for Death from Any Cause.

Among 7001 patients who had previously survived anterior-wall myocardial infarction, there were 228 deaths in the control group (which was trained in calling emergency medical services and performing cardiopulmonary resuscitation [CPR]) and 222 deaths in the group that was instructed in the home use of an automatic external defibrillator (AED), followed by calling emergency medical services and performing CPR (hazard ratio for the AED group, 0.97; 95% confidence interval, 0.81 to 1.17; P=0.77). Vital status was known for 100% of patients within 3 months before the end of the trial.

no differences between the control group and the AED group in the adjudicated mechanisms of death for any category.

Of the 169 deaths from cardiac tachyarrhythmia, 160 were from sudden cardiac arrest. The initial place of collapse was the home for 117 patients, a public place for 9 patients, a hospital or long-term care facility for 18 patients, and another or an unknown location for 16 patients (Table 2). Only 58 of the 117 sudden cardiac deaths from tachyarrhythmia occurring in the home (49.6%) were witnessed. Sudden cardiac

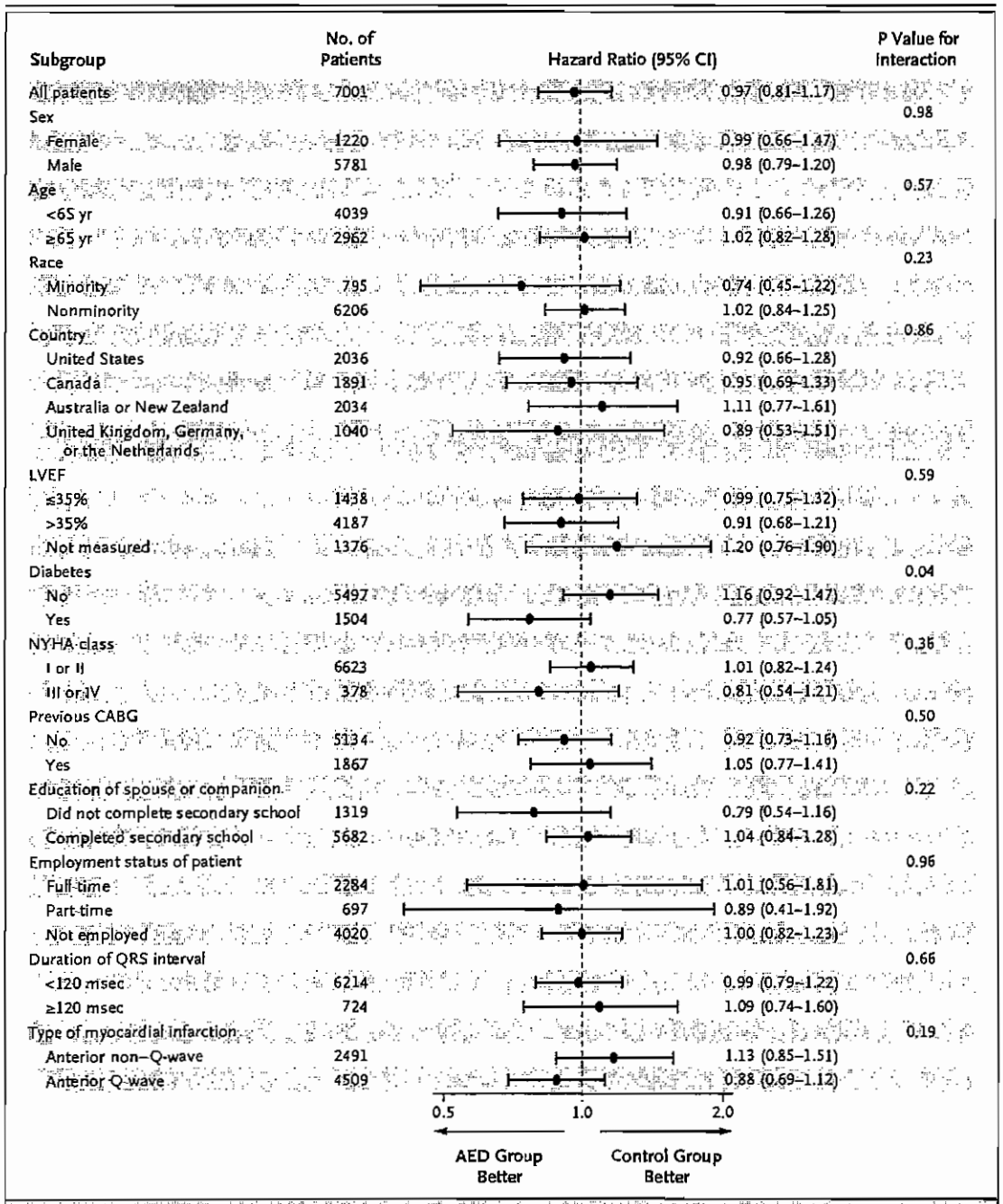


Figure 2. Hazard Ratios for Major Subgroups of Patients.

No subgroup was identified in which the outcome differed significantly from the primary findings. CABG denotes coronary-artery bypass grafting, LVEF left ventricular ejection fraction, and NYHA New York Heart Association.

Table 2. Frequency of Events and Hazard Ratios, According to the Classified Mode of Death and Resuscitated Cardiac Arrest.*

Variable	Control Group (N=3506)	AED Group (N=3495)	Hazard Ratio (95% CI)†
Death from all causes — no. (%)	228 (6.5)	222 (6.4)	0.97 (0.81–1.17)
Onset at home	93 (40.8)	91 (41.0)	
Witnessed	51 (22.4)	54 (24.3)	
Tachyarrhythmia	34 (14.9)	29 (13.1)	
Cause of death — no. (%)			
Cardiac plus unknown events	139 (61.0)	141 (63.5)	1.01 (0.80–1.28)
Cardiac	129 (56.6)	138 (62.2)	1.07 (0.84–1.36)
Tachyarrhythmia	84 (36.8)	85 (38.3)	1.01 (0.75–1.37)
Heart failure	28 (12.3)	36 (16.2)	1.28 (0.78–2.10)
Nonarrhythmia	16 (7.0)	16 (7.2)	1.00 (0.50–2.00)
Not classifiable	1 (0.4)	1 (0.5)	
Noncardiac	89 (39.0)	81 (36.5)	0.91 (0.67–1.23)
Vascular	22 (9.6)	15 (6.8)	
Nonvascular	67 (29.4)	65 (29.3)	
Not classifiable	0	1 (0.5)	
Unknown cause	10 (4.4)	3 (1.4)	
Death from tachyarrhythmia — no.			
Sudden	78	82	
Onset location			
Home	60	57	
Home, witnessed	31	27	
Public place or work	5	4	
Hospital or long-term care facility	8	10	
Other or unknown	5	11	
Nonsudden	5	3	
Unknown	1	0	
Resuscitated cardiac arrest — no.			
Total events	19	19	
Onset location			
Home	8	8	
Home, witnessed	6	7	
Public place or work	2	1	
Hospital or long-term care facility	6	9	
Other or unknown	3	1	

* Percentages are based on the number of deaths. AED denotes automated external defibrillator, and CI confidence interval.
† The hazard ratio is for the AED group as compared with the control group.

deaths from tachyarrhythmia that occurred at home and were witnessed comprised 12.9% of all deaths and 36.3% of the sudden cardiac deaths from tachyarrhythmia. There were no significant differences between the study groups in the location of the patient at the time of death.

RESUSCITATED CARDIAC ARREST

Thirty-eight patients were resuscitated from sudden cardiac arrest and survived for at least 48 hours (Table 2). Among 19 resuscitations in the control group, 8 occurred at home, 2 in a public place, 6 in a hospital or chronic care facility, and

3 in another or an unknown location. Among 19 resuscitations in the AED group, 8 occurred at home, 1 in a public place, 9 in a hospital or chronic care facility, and 1 in another location.

USE OF AN AED

During the trial, a study AED was applied to 32 patients in the AED group; of these patients, 29 were found unresponsive by a spouse, companion, or other household member. Correlative documentation of AED rhythms was available for 21 of 29 unresponsive patients (Fig. 3).

A shock was advised for confirmed ventricular fibrillation in 13 patients and was delivered in 12 of them. Of the 12 patients, 4 were long-term survivors, and another survived to hospital admission but died several days later. No shock was delivered in 1 of the 13 patients with ventricular fibrillation because a household member (not a spouse or companion) accidentally turned off the AED after the shock advisory. (This advisory was a verbal prompt from the AED to press the shock button; the power button was depressed inadvertently instead.) Of the remaining seven patients with ventricular fibrillation who died, AED shocks terminated ventricular fibrillation either to asystole or to a nonshockable rhythm. Monomorphic ventricular tachycardia was not identified in any patient.

A no-shock advisory was confirmed on the AED for eight of the unresponsive patients; of these patients, seven died, with a rhythm documented as asystole in five, complete heart block in one, and sinus tachycardia in one. One of the eight patients had sinus bradycardia and survived.

Of the 29 patients who were unresponsive, 8 did not have correlative AED rhythm information, but clinical information confirmed that an AED shock was delivered in 2 patients, both of whom died. Of the remaining 6 patients, 3 died and 3 had syncope from noncardiac causes and survived.

A no-shock advisory was given in the three patients who did not lose consciousness. There were no documented inappropriate shocks. Overall, 4 of the 14 patients with ventricular fibrillation (28.6%) who received an AED shock were long-term survivors.

GOOD SAMARITAN USE OF AED

Over the course of the trial, the AED was known to have been used in seven persons having sudden cardiac arrest who were not participating in the HAT trial but were neighbors or visitors to the patients' homes. In three such cases, no shock was advised and all three persons died. In four cases, a shock was advised and terminated ventricular fibrillation, with two persons surviving beyond hospital discharge.

DISCUSSION

In the HAT trial, we found that a strategy of placing an AED in the home did not reduce overall mortality in patients with a previous anterior-wall myocardial infarction who did not have an indication for implantation of a cardioverter–defibrillator, as compared with standard response training for cardiac arrest. Several factors may explain this finding. First, the overall mortality and the incidence of sudden cardiac arrest were much lower than predicted from historical data.[13-15] This factor is probably a reflection of the efficacy and high level of use of modern drug therapy and the high rate of previous revascularization (72.2%) in the trial patients. As a result of these factors, the trial had substantially less power than initially projected. These effects were so profound that even a doubling in the population size would not have been sufficient to show an overall mortality benefit with home AED therapy. Remarkably, the enrolled patients were as likely to die from noncardiac causes (37.8% of deaths) as from sudden cardiac arrest from tachyarrhythmia (35.6%), with an annual risk of sudden cardiac arrest of less than 1% per year.

The training of the patients and their spouses or companions may have been an additional factor limiting the likelihood of a demonstrable benefit. All participants in the control group received resuscitation training, with frequent reminders; such education is not reflective of real-world instruction after myocardial infarction. At the same time, less than half the patients with sudden cardiac arrest at home had a witnessed event, and not all of them had the AED applied. This latter finding is particularly disconcerting, given the effort to inform partners or companions of the significance of AED use. Although the reasons for failure to deploy the AED are unclear, it is possible that a more aggressive AED reminder and retraining program might be required to ensure that lay rescuers would use the AED in a highly stressful situation. Such a program, how-

ever, would exceed the practical limits of a public health study, both in terms of personnel time and cost. Furthermore, to contend with events occurring when the patient is asleep or alone, it is conceivable that some form of a home automated alert system might be of value, but no such system is currently available.[30]

The successful delivery of a defibrillating shock in 14 patients and in 4 neighbors resulted in long-term survival for 6 (33%). This confirms that the use of an AED in the home or environs on loved ones or neighbors by lay users with minimal training is feasible, terminates ventricular fibrillation, and appears to carry no risk of inappropriate shock. The observed overall survival after sudden cardiac arrest in the home of 12.0% (18.3% for witnessed events) was significantly better than the figure of 2% that has previously been reported in the general population at home[11] and better than the 6% performance provided by emergency medical services in general.[31] However, the low event rate and the neutral outcome with respect to death from any cause suggest that the placement of AEDs in homes would be an inefficient strategy in public health terms, despite the value to patients who are fortunate enough to have the event witnessed and the AED applied.

It is important to recognize that our trial results may not apply to the use of AEDs in higher-risk populations. Candidates for implantation of a cardioverter–defibrillator were excluded from our trial, although physicians' judgment and a variety of practice patterns in the enrolling countries resulted in the inclusion of some patients who might otherwise have satisfied criteria for use of an implantable cardioverter–defibrillator in the Sudden Cardiac Death in Heart Failure trial or the Multicenter Automatic Defibrillator Implantation Trial II (Table 1).[16-19] It is nonetheless possible that a population with a higher event rate and a greater proportion of sudden deaths from tachyarrhythmia might benefit from access to a home AED.

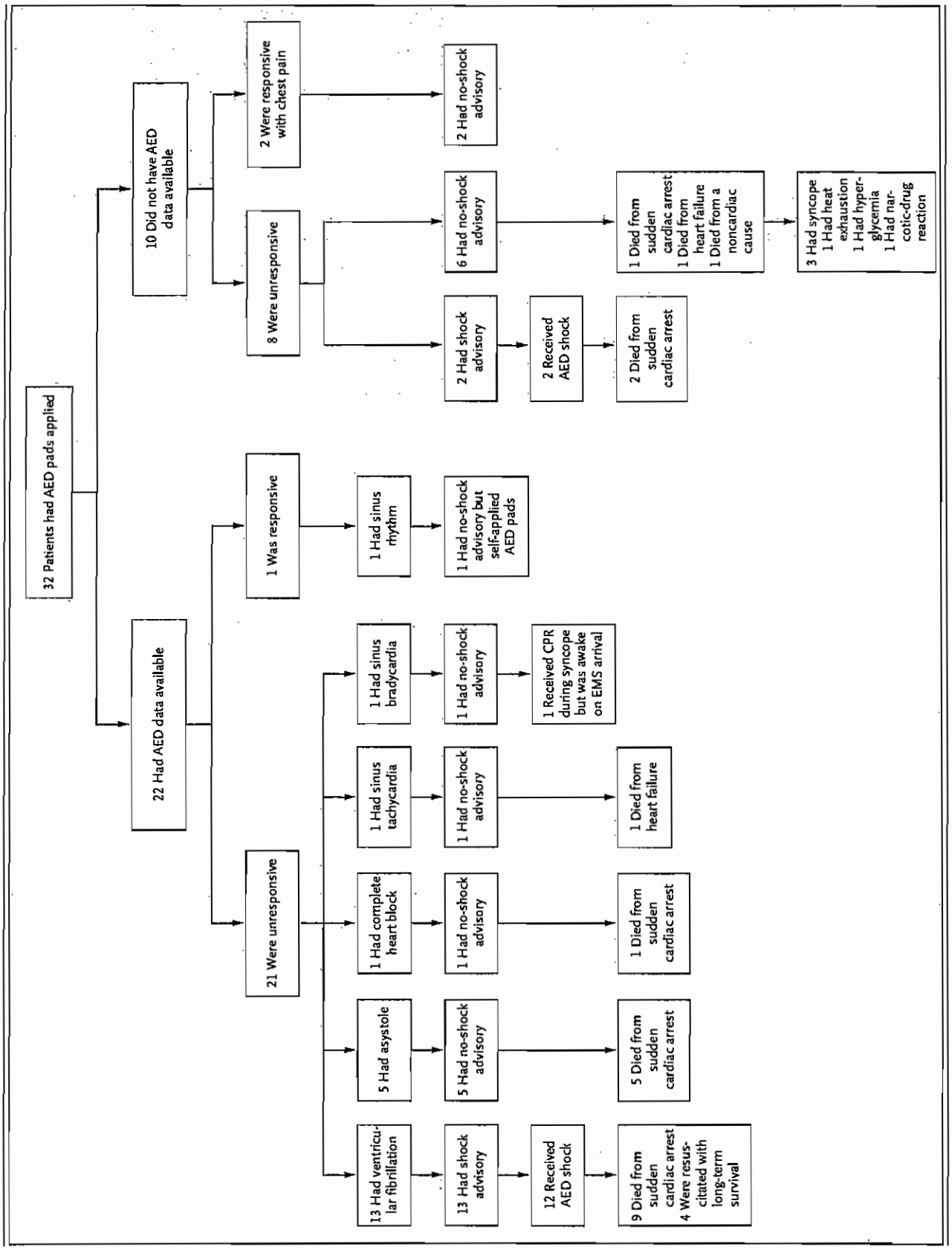
Although the performance of AEDs in this trial may seem at odds with that reported for public-access defibrillation, one must remember that the denominator of patients in our trial was precisely defined, whereas that for public-access defibrillation was not clear. For example, the annual passenger volume in Chicago's O'Hare airport now exceeds 76 million, and this massive cohort is exposed to AEDs placed throughout the airport at a distance of 1 minute's walk apart.[8] No clinical trial of the use of AEDs could assemble a denominator representing even 1% of that volume. Furthermore, in a public venue, there is the opportunity to use an AED in treating any one of many persons at risk. This factor contrasts with the home AED strategy, in which there is the opportunity to treat only those in the immediate household or environs.

Figure 3 (facing page). Events and Outcomes Associated with the Use of an Automatic External Defibrillator (AED) in 32 Patients.

Of the 32 patients for whom an AED was applied, 29 were unresponsive. Of these patients, 13 were documented to be in ventricular fibrillation by review of the AED electrogram, and a shock was advised by the AED in each case. Two patients who were found in cardiac arrest had a shock advisory, apparently for ventricular fibrillation, although no recordings were available for review. Shocks terminated ventricular fibrillation in all 12 patients for whom an AED shock was given. (One rescuer who was not a spouse or companion accidentally turned off the device.) Of 14 patients for whom an AED shock was advised and delivered, 4 (28.6%) survived long term. Of 17 patients who had a no-shock advisory, 14 were unresponsive: 7 died from cardiac arrest, 2 died from heart failure, 1 died from a noncardiac cause, and 4 had syncope and survived. Three patients never lost consciousness, and either they applied the pads to themselves or a spouse applied them. In patients for whom data regarding the AED were unavailable, the AED status was determined by data forms and event narratives from site personnel. EMS denotes emergency medical services.

The survival of some patients with sudden cardiac arrest who were treated early with AEDs in public settings is generally taken as proof of concept that the therapy is effective, since sudden cardiac arrest is known to have a rate of death approaching 100% with conventional resuscitation methods. However, such uses of AEDs are not an efficient attack on the public health problem of sudden cardiac arrest in moderate-risk populations, since most at-risk patients do not spend a sufficient portion of each day in public locations.

In conclusion, our trial evaluated the benefit of the availability of AEDs in the homes of patients with a previous anterior-wall myocardial infarction who were not otherwise candidates for implantation of a cardioverter–defibrillator. There was no significant reduction in death from any cause with a home AED. The very low event rate,



the high proportion of unwitnessed events, and the underuse of AEDs in emergencies, rather than a lack of device efficacy, appear to explain these results.

Supported by a grant (UO1-HL67972) from the National Heart, Lung, and Blood Institute.

Dr. Bardy reports receiving grant support from Philips Medical and Laerdal Medical and consulting fees from Philips Medical, having intellectual-property rights with Medtronic and Cameron Health, and having an equity interest in and serving on an advisory board for Cameron Health; Dr. Mark, receiving research support from Medtronic; Dr. Poole, receiving consulting fees from Philips Medical and lecture fees from Medtronic; Dr. Toff, receiving research support from Laerdal Medical and Cameron Health; Dr. Smith, receiving research support from and having an equity interest in Cameron Health; Dr. Dorian, receiving research support from Medtronic and St. Jude Medical and lecture fees from Medtronic, St. Jude Medical, and Boston Scientific; and Dr. Packer, receiving consulting fees and research support from and serving on an advisory board for Medtronic and receiving research support from Transoma and St. Jude Medical. No other potential conflict of interest relevant to this article was reported.

REFERENCES

1. Rosamond W, Flegal K, Furie G, et al. Heart disease and stroke statistics — 2008 update: a report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Circulation 2008;117(4):e25-e146.
2. Capucci A, Aschieri D, Piepoli MF, Bardy GH, Iconomu E, Arvedi M. Tripling survival from sudden cardiac arrest via early defibrillation without traditional education in cardiopulmonary resuscitation. Circulation 2002;106:1065-70.
3. Hallstrom AP, Ornato JP, Weisfeldt M, et al. Public-access defibrillation and survival after out-of-hospital cardiac arrest. N Engl J Med 2004;351:637-46.
4. Cappato R, Curnis A, Marzollo P, et al. Prospective assessment of integrating the existing emergency medical system with automated external defibrillators fully operated by volunteers and laypersons for out-of-hospital cardiac arrest: the Brescia Early Defibrillation Study (BEDS). Eur Heart J 2006;27:553-61.
5. White R, Bunch J, Hankins D. Evolution of a community-wide early defibrillation programme: experience over 13 years using police/fire personnel and paramedics as responders. Resuscitation 2006;65: 279-83.
6. Page RL, Joglar JA, Kowal RC, et al. Use of automated external defibrillators by a U.S. airline. N Engl J Med 2000;343: 1210-6.
7. Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. N Engl J Med 2000;343:1206-9.
8. Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Public use of automated external defibrillators. N Engl J Med 2002;347: 1242-7.
9. Eisenberg MS, Mengert TJ. Cardiac resuscitation. N Engl J Med 2001;344:1304-13.
10. Pell JP, Sirel JM, Marsden AK, Ford I, Walker NL, Cobbee SM. Potential impact of public access defibrillators on survival after out of hospital cardiopulmonary arrest: retrospective cohort study. BMJ 2002; 325:515.
11. Norris RM, UK Heart Attack Study (UKHAS) Collaborative Group. Circumstances of out of hospital cardiac arrest in patients with ischaemic heart disease. Heart 2005;91:1537-40.
12. Bardy GH, Lee KL, Mark DB, et al. Rationale and design of the Home Automatic External Defibrillator Trial (HAT). Am Heart J 2008;155:445-54.
13. Califf RM, White HD, Van der Werf F, et al. One-year results from the Global Utilization of Streptokinase and t-PA for Occluded Coronary Arteries (GUSTO-I) trial. Circulation 1996;94:1233-8.
14. Singh M, White J, Hasdai D, et al. Long-term outcome and its predictors among patients with ST-segment elevation myocardial infarction complicated by shock: insights from the GUSTO-I trial. J Am Coll Cardiol 2007;50:1752-8.
15. Furman MI, Dauerman HL, Goldberg RJ, Yarzebski J, Lessard D, Gore JM. Twenty-two year (1975 to 1997) trends in the incidence, in-hospital and long-term case fatality rates from initial Q-wave and non-Q-wave myocardial infarction: a multihospital, community-wide perspective. J Am Coll Cardiol 2001;37:1571-80.
16. Zipes DP, Camm AJ, Borggrefe M, et al. ACC/AHA/ESC 2006 Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: a report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death): developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. Circulation 2006; 114(10):e385-e484.
17. Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N Engl J Med 2002;346:877-83.
18. Goldenberg I, Vyas AK, Hall WJ, et al. Risk stratification for primary implantation of a cardioverter-defibrillator in patients with ischemic left ventricular dysfunction. J Am Coll Cardiol 2008;51: 288-96.
19. Bardy GH, Lee KL, Mark DB, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. N Engl J Med 2005;352:225-37. [Erratum, Engl J Med 2005;352:2146.]
20. American Heart Association. Guidelines 2000 for cardiopulmonary resuscitation and emergency cardiovascular care. Part 2: ethical aspects of CPR and ECC. Circulation 2000;102:Suppl I:12-22.
21. Home Use AED Trial (HAT) training videos. (Accessed March 28, 2008, at http://hat.sicr.org/media/.)
22. American Heart Association. Guidelines 2000 for cardiopulmonary resuscitation and emergency cardiovascular care. Part 4: the automated external defibrillator, key link in the chain of survival. Circulation 2000;102:Suppl I:60-76.
23. Poole JE, White RD, Kanz KG, et al. Low-energy impedance-compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out-of-hospital cardiac arrest. J Cardiovasc Electrophysiol 1997;8:1373-85.
24. Gliner BE, White RD. Electrocardiographic evaluation of defibrillation shocks delivered to out-of-hospital sudden cardiac arrest patients. Resuscitation 1999;41: 133-44.
25. Kaplan EL, Meier P. Nonparametric estimation from incomplete observations. J Am Stat Assoc 1958;53:457-81.
26. Kalbfleisch JD, Prentice RL. The statistical analysis of failure time data. 2nd ed. New York: John Wiley & Sons, 2002.
27. Cox DR. Regression models and life-tables. J R Stat Soc [B] 1972;34:187-220.
28. O'Brien PC, Fleming TR. A multiple testing procedure for clinical trials. Biometrics 1979;35:549-56.
29. Lan KKG, DeMets DL. Discrete sequential boundaries for clinical trials. Biometrika 1983;79:659-63.
30. Saxon LA. Survival after tachyarrhythmic arrest — what are we waiting for? N Engl J Med 2008;358:77-9.
31. Nichol G, Stiell IG, Laupacis A, Pham B, De Maio VJ, Wells GA. A cumulative meta-analysis of the effectiveness of defibrillator-capable emergency medical services for victims of out-of-hospital cardiac arrest. Ann Emerg Med 1999;34: 517-25.

Reprinted with permission from
JOURNAL OF CARDIOVASCULAR ELECTROPHYSIOLOGY, Volume 8, No. 12, December 1997

Low-Energy Impedance-Compensating Biphasic Waveforms Terminate Ventricular Fibrillation at High Rates in Victims of Out-of-Hospital Cardiac Arrest

JEANNE E. POOLE, M.D., ROGER D. WHITE, M.D., KARL-GEORG KANZ, M.D., FRIEDERIKE HENGSTENBERG, M.D., G. TRUETT JARRARD, M.D., JACK C. ROBINSON, VALERIE SANTANA, R.N., DAVID K. McKENAS, M.D., NATHAN RICH, M.D., STEVEN ROSAS, M.D., SALLY MERRITT, LUKE MAGNOTTO, M.D., JOHN V. GALLAGHER, III, M.D., BRADFORD E. GLINER, DAWN B. JORGENSON, PH.D., CARLTON B. MORGAN, STEPHEN M. DILLON, PH.D., RICHARD A. KRONMAL, PH.D.; and GUST H. BARDY, M.D., FOR THE LIFE INVESTIGATORS

From The University of Washington, Seattle, Washington

Biphasic Waveform Defibrillation. *Introduction:* New automatic external defibrillators (AEDs), which are smaller, lighter, easier to use, and less costly make the goal of widespread AED deployment and early defibrillation for out-of-hospital cardiac arrest feasible. The objective of this study was to observe the performance of a low-energy impedance-compensating biphasic waveform in the out-of-hospital setting on 100 consecutive victims of sudden cardiac arrest.

Methods and Results: AEDs incorporating a 150-J impedance-compensating biphasic waveform were used by 12 EMS systems. Data were obtained from the AED PC card reporting system. Defibrillation was defined as conversion to an organized rhythm or to asystole. Endpoints included: defibrillation efficacy for ventricular fibrillation (VF); restoration of an organized rhythm at the time of patient transfer to an advanced life support (ALS) team or to the emergency department (ED); and time from AED power-on to first defibrillation. The AED correctly identified 44 of 100 patients presenting in VF as requiring a shock (100% sensitivity) and 56 of 100 patients not in VF as not requiring a shock (100% specificity). The time from 911 call to first shock delivery averaged 8.1 ± 3.0 minutes. A single 150-J biphasic shock defibrillated the initial VF episode in 39 of 44 (89%) patients. The average time from power-on to first defibrillation was 25 ± 17 seconds. At patient transfer to ALS or ED care, an organized rhythm was present in 34 of 44 (77%) patients presenting with VF. Asystole was present in 7 (16%) and VF in 3 (7%).

Conclusions: Low-energy impedance-compensating biphasic waveforms terminate long-duration VF at high rates in out-of-hospital cardiac arrest. Use of this waveform allows AED device characteristics consistent with widespread AED deployment and early defibrillation. *(J Cardiovasc Electrophysiol, Vol. 8, pp. 1373-1385, December 1997)*

sudden cardiac arrest, defibrillation, automatic external defibrillators

Introduction

Each year in the United States, 150,000 to 300,000 people become victims of sudden cardiac arrest (SCA), with only a few percent surviving.[1,2] The majority of these deaths are caused by ventricular fibrillation (VF),[3] with the time from collapse to defibrillation the critical determinant of

Dr. Bardy serves as a consultant for Heartstream, Inc.

Address for correspondence: Jeanne E. Poole, M.D., Division of Cardiology, Box 356422, University of Washington, 1959 N.E. Pacific St., Seattle, WA 98195. Fax: 206-616-6069; E-mail: jpoole@u.washington.edu

Manuscript received 16 September 1997; Accepted for publication 20 October 1997.

survival.[4,5] Other factors affecting survival include witnessed arrest, prompt access to emergency medical services (EMS), and bystander cardiopulmonary resuscitation (CPR).[6-9] Reported survival rates from out-of-hospital cardiac arrest (OHCA) caused by VF vary widely, from 2% to 49%, with lower survival rates primarily a result of delays in defibrillation.[10-14] Early defibrillation programs with widespread deployment of automatic external defibrillators (AEDs) are a reasonable response to this problem and are encouraged by the European Resuscitation Council (ERC), the International Liaison Committee on Resuscitation (ILCOR), and the American Heart Association (AHA)[15] to become part of the standard care for OHCA.

Because of technological issues that affect size, weight, cost, and ease of use, dissemination of AEDs has been limited. These problems derive in part because AEDs, until now, have relied on high energies and monophasic waveforms. For reasons described in this report, this makes them less acceptable for early defibrillation programs. Low-energy biphasic truncated exponential (BTE) waveforms offset many of the technological constraints of previous generation AEDs and so permit smaller, lighter, easier to use, and less costly devices.

BTE waveforms have been shown unequivocally to be superior to monophasic waveforms for internal defibrillation by reducing energy requirements.[16-18] Low-energy BTE waveforms are now standard in implantable cardioverter defibrillators (ICDs), and monophasic waveforms are no longer used in these devices. Similarly, low-energy BTE waveforms seem poised to displace high-energy monophasic waveforms in external defibrillators. BTE waveforms, specifically those designed to compensate for individual patient variation in transthoracic shock impedance, are thought to be best suited to this purpose.[19] Use of lower energies has the added benefit of reducing postshock cardiac dysfunction.[20-24]

Incorporating low-energy impedance-compensating BTE waveforms into AEDs results in devices that are smaller, lighter, easier to use, and less costly compared with previous generation AEDs, thus enabling the goal of widespread AED deployment and early defibrillation. The safety and efficacy of the impedance-adjusting BTE waveform used in the AED under study have been demonstrated in the electrophysiology lab using the methods outlined by the AHA (Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy).[25] The purpose of this study was to validate the defibrillation effectiveness of such an AED in the out-of-hospital setting.

Methods

AEDs incorporating 150-J impedance-compensating BTE waveforms (ForeRunner® AEDs, SMART Biphasic™, Heartstream, Inc., Seattle, WA, USA) were placed into service in 12 EMS systems. Data were obtained from the PC data card recording system within the AEDs in the first 100 consecutive OHCA victims on whom this was the first AED applied. These sites were the first to supply data on this AED's performance. Continuous digitized ECG data (0.1 to 80 Hz) were obtained in all cases and were reviewed on a PC Windows application (CodeRunner®, Heartstream, Inc.). Similarly, shock data, including resistance, delivered energy, peak voltage, peak current, and waveform duration, were obtained from the PC data cards, along with ancillary event timing data for calculation of critical time intervals.

Defibrillation Waveform Description

The AEDs delivered 150-J impedance-compensating BTE shocks from 100-μF capacitors charged to 1790 V. The adhesive defibrillation pads used (Heartstream, Inc.) had a surface area of 100 cm^2 and were applied in the anterior-anterior position. In response to a real-time measurement made during each shock delivery in the first 2 msec of decay of the waveform, the AEDs automatically adjusted the duration of the first and second phases of the waveform, thus delivering an optimized biphasic waveshape for each shock to each patient (impedance-compensation).[26] Phasic duration, i.e., the first phase percentage of the total duration, was 50% for patient resistance $< 60\ \Omega$ and 60% for patient resistances $\geq 60\ \Omega$. Similarly, tilt was adjusted upward for low-impedance patients and downward, in combination with waveform truncation, in high-impedance patients. Therefore, the total waveform duration could vary from 5 to 20 msec, without compromising defibrillation efficacy across a broad range of transthoracic shock resistances (25 to 180 Ω, Fig. 1).

Rhythm Analysis

In examining ECG recordings, defibrillation success was assessed by three physician reviewers experienced in cardiac resuscitation. Termination of VF into an organized rhythm or asystole for 5 seconds postshock was considered a successful defibrillation, whereas the presence of VF at that time was considered a failed attempt. Defining a shock that results in an organized rhythm or

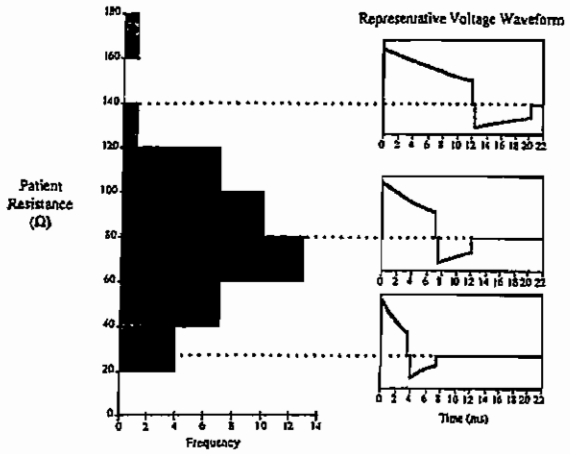


Figure 1. *Distribution of shock resistances for the 44 patients presenting in ventricular fibrillation and representative low-energy impedance-compensating biphasic voltage waveforms.*

asystole as a successful shock is consistent with the terminology used by others.[27,28] The 5-second interval represents a very conservative time to assess shock success, as cardiac mapping studies have demonstrated defibrillation actually occurs within the first 100 to 500 msec after the shock is delivered.[29,30] Assessment at 5 seconds also allows the postshock voltage offset to stabilize. A VF episode was defined as the interval from the onset to termination of VF and may include multiple shocks prior to successful termination.

Following defibrillation, ECG rhythms continue to evolve. This evolution is influenced by the effects of the underlying cardiac substrate or effects of other interventions, including CPR or drugs. Accordingly, ECGs were continuously analyzed to examine subsequent transitions to other rhythm categories. ECGs that were classified as organized or asystole at 5 seconds, and later classified as VF, were defined as a new VF episode. The entire ECG recording was evaluated until the AED was turned off or removed from the patient. Rhythms at the time the AED was deactivated, an overall measure of AED success, were classified as organized, asystole, or persistent VF.

AED User Interface

To assess the efficiency of the interaction between the AED and the responder (clarity and value of voice prompts, pad icons, screen instructions, color coding, 1-2-3 shock sequencing), time intervals were measured from AED power-on to attachment of the defibrillation pads, to first shock delivered, and to first defibrillation. Time intervals were measured from automated AED annotations on the ECG recordings.

Sample Size and Statistical Analysis

The study size was preselected to be the first 100 consecutive documented out-of-hospital AED uses. A use was defined as any event in which the AED was attached to a patient regardless of whether or not a defibrillation shock was delivered. One hundred postmarket surveillance uses was predetermined based upon recommendations by the Food and Drug Administration at the AHA's first conference on Public Access Defibrillation (December 10, 1994, Washington, DC, USA).

To place the results of this study in context, we compared our findings with similar, earlier studies. For studies of this kind, one would expect that approximately 40% of AED uses are VF cases requiring defibrillation shocks.[31,32] Assuming six shocks per VF patient (including shocks delivered as a consequence of refibrillation), 240 total shocks would be expected to be delivered to 40 patients.[31,32] The published experience to date suggests that the first-shock defibrillation rate would be approximately 65% (95% confidence interval [CI] of first-shock defibrillation success would range from 50% to 80%); with the all-shock defibrillation rate being approximately 60% (95% CI would range from 55% to 65%).[5,27,28,31-34]

Results are presented as mean ± SD [range] with 95% CIs where appropriate. Shock characteristics were analyzed on a per shock and on a per patient basis. Comparison of proportions were made using two-sided Chi-square significance tests with $P \leq 0.05$ defined as statistically significant.

Results

Study Enrollment

Twelve sites provided data on 100 consecutive victims of SCA from December 15, 1996 to August 14, 1997 (Table 1). AEDs were applied to SCA victims by flight attendants (3), police officers (37), emergency medical technicians (44), non-EMT emergency responders (6), paramedics (3), and ambulance physicians (in Europe) (7). Thirty-one SCAs took place in the home, 11 in a public place, 8 during transportation (airplane 3, roadway 2, train 2, boat 1), 5 in a health care facility, 3 in the workplace, 3 in a hotel room, 1 in a jail, and 37 where the location of cardiac arrest was not noted.

TABLE 1
Summary of Data Collection

SCA patients enrolled	100
Number of study sites	12
Patients presenting with VF	44
Gender	11 female, 28 male, 5 unknown
Age (years)	68 ± 14 [36–89]
SCA witnessed	25/37 (68%), 7 unknown
Bystander CPR	17/38 (45%), 6 unknown
Presenting VF amplitude (mV)	0.5 ± 0.5 [0.1–3.0]
Presenting VF rate (beats/min)	256 ± 85 [74–462]
Preshock VF amplitude (mV)	0.4 ± 0.3 [0.1–3.1]
Preshock VF rate (beats/min)	259 ± 77 [111–429]
911 call to first shock interval (min)	8.1 ± 3.0 [4.3–16.5]

SCA = sudden cardiac arrest; VF = ventricular fibrillation.

Of the 100 SCA victims, 44 had VF as their initial rhythm upon attachment of the AED. Of the 44 SCA victims presenting with VF (11 females and 28 males, 5 unknown; 68 ± 14 [36–89] years), 25 were known to have been witnessed and 17 were known to have received bystander CPR. For the 44 patients presenting in VF, the presenting (initial 4.5-sec ECG segment) VF amplitude (median peak-to-peak amplitude) and rate were 0.5 ± 0.5 [0.1–3.0] mV and 256 ± 85 [74–462] beats/min, respectively. (The low rates for some VFs, as low as 74 beats/min, reflect the long cardiac arrest time and long duration of VF prior to AED application. The VF in these patients had a low amplitude, a low slew rate, and a slowly undulating near-sinusoidal characteristic deemed to require a shock.)

VF amplitude and rate immediately prior to each shock were 0.4 ± 0.3 [0.1–3.1] mV and 259 ± 77 [111–429] beats/min respectively. Time from 911 call to first shock delivery was available in 29 of the presenting VF victims and was 8.1 ± 3.0 [4.3–16.5] minutes. No device failures were encountered. The AED correctly identified all 44 VF patients (100% sensitivity), and correctly identified and did not shock all 56 patients presenting with non-VF rhythms (100% specificity) (Table 2). Because no shocks were delivered unless VF was detected, there were no instances where a shock converted asystole or a nonfibrillating rhythm into VF.

Defibrillation Efficacy

Initial VF episode

Defibrillation was accomplished with a single 150-J biphasic shock in 39 of 44 (89%) *initial* VF episodes (95% CI: 75%–97%), and 41 of 44 (93%) with two shocks or fewer (95% CI: 81%–99%). In one patient, resuscitation efforts were transferred to advanced life support (ALS) after two unsuccessful AED shocks were delivered to the initial VF episodes. All 43 (100%) of the remaining VF patients were defibrillated with three shocks or fewer (Fig. 2, Table 3). A total of 249 shocks were delivered to 202 episodes of VF in 44 patients (Tables 2 and 3). These VF episodes were terminated by 199 (80%) of the 249 shocks (95% CI: 74%–85%). The average number of shocks delivered per initial VF episode was 1.2 ± 0.5 (Table 2).

All VF episodes

In the total 202 VF episodes in the 44 patients presenting with VF, 175 (87%) were terminated with a single biphasic shock (95% CI: 81%–92%) and 195 (95%) with two shocks or fewer (95% CI: 91%–98%). Because resuscitation efforts were ceased in one patient after two shocks had been delivered, 201 VF episodes remained that could have received shocks. Of the 201 VF episodes that received up to three shocks, 199 (99%) were terminated with 3 shocks or fewer (95% CI: 96%–100%) (Fig. 2, Table 3). The average number of shocks delivered per VF episode was 1.2 ± 0.9. Patients received 5.7 ± 6.0 (1–26) shocks during the use of the AED, which included ALS care in some cases. The total use time for the AED was 13.3 ± 8.8 minutes (0.9–33.0) and was measured from power-on to either power-off or pads off.

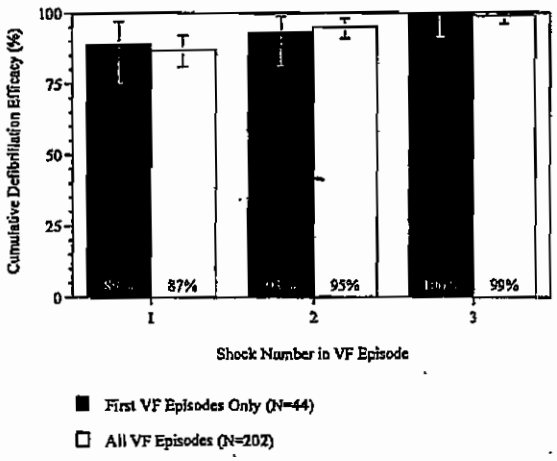


Figure 2. *Cumulative defibrillation shock success for initial ventricular fibrillation (VF) episodes and for all VF episodes.*

TABLE 2
Summary of AED Use

AED sensitivity to VF patients	44/44 (100%), CI not definable
AED specificity to non-VF patients	56/56 (100%), CI not definable
Number of VF episodes	202
Number of shocks delivered	249
Shocks per initial VF episodes only (N = 44)	1.2 ± 0.5
Shocks per all VF episodes (N = 202)	1.2 ± 0.9
Shocks per patient (N = 44)	5.7 ± 6.0
Total AED use time (min)	13.3 ± 8.8 [0.9–33.0]

AED = automatic external defibrillator; CI = confidence interval; VF = ventricular fibrillation.

TABLE 3
Low-Energy Impedance-Compensating Biphasic Waveform Defibrillation Efficacy

Initial VF episodes only		
1 shock	39/44 (89%)	CI: 75%–97%
≤ 2 shocks	41/44 (93%)	CI: 81%–99%
≤ 3 shocks	43/43 (100%)	CI not definable
All VF episodes		
1 shock	175/202 (87%)	CI: 81%–92%
≤ 2 shocks	195/202 (95%)	CI: 91%–98%
≤ 3 shocks	199/201 (99%)	CI: 96%–100%
All shocks pooled	199/249 (80%)	CI: 74%–85%

CI = 95% confidence interval; VF = ventricular fibrillation.

Defibrillation Shock Characteristics

Per shock basis

Delivered biphasic waveform energy (152 ± 3 [141–158] J) and peak voltage (1753 ± 5 [1739–1771] V) were tightly controlled over a wide range of shock resistances (71 ± 28 [36–171] Ω) for the total number of shocks delivered (Table 4). Consistent with the ability of this biphasic waveform to adapt to patient impedance, peak current (28.4 ± 10.8 [10.2–49.5] A) and total waveform duration (11.6 ± 3.6 [7.7–20.4] msec) varied proportionally with patient resistance. High shock resistance (≥ 100 Ω) was not an independent predictor of defibrillation efficacy. High-resistance shocks (122 ± 26 Ω) were effective in 23 of 26 (88%) attempts compared to shocks with resistances < 100 Ω that were effective in 176 of 223 (79%) attempts (P = 0.3).

Per patient basis

When averaged over each patient, delivered biphasic waveform energy was 151 ± 2 [142–157] J and peak voltage was 1752 ± 5 [1739–1768] V with patient resistances of 81 ± 29 [37–170] Ω (Table 4 and Fig. 1). Peak current was 24.7 ± 9.8 [10.3–47.3] A, and total biphasic waveform duration was 12.9 ± 3.8 [7.7–20.4] msec.

Analysis of Rhythm at AED Transfer

Of the 44 patients presenting in VF, 37 (84%) developed an organized rhythm at least once at some point during the resuscitation attempt (95% CI: 69%–94%). On average, the first appearance of an organized rhythm occurred after 2.1 ± 1.7 shocks. For all episodes of VF that were restored to an organized rhythm, 1.6 ± 1.2 shocks were required. The last rhythm recorded by the AED prior to transfer to ALS or emergency department (ED) personnel, or when the AED was powered-off by the on-site physician, was organized in 34 (77%), asystole in 7 (16%), and VF in 3 (7%). Two of the three patients transferred in VF to ALS/ED personnel were previously defibrillated by the AED, but were in mid-rhythm analysis at the time of AED disconnection by ALS/ED personnel. The third patient received only two shocks prior to transfer and disconnection of the AED. Data regarding return of spontaneous circulation (ROSC) for patients presenting with VF, whether having witnessed or unwitnessed collapse, was available in 34 patients and was achieved in 19 (56%) patients.

AED User Interface

User interface time interval measurements were as follows. The time from AED power-on *and* pad attachment to the first shock delivered was 21 ± 10 [15 –77] seconds and to first successful shock

TABLE 4
Delivered 150-J Impedance-Compensating Biphasic Waveform Parameters

Analysis on a Per Shock Basis	**Mean ± SD [Range]**
Delivered energy (J)	152 ± 3 [141–158]
Peak delivered voltage (V)	1753 ± 5 [1739–1771]
Resistance (Ω)	71 ± 28 [36–171]
Peak delivered current (A)	28.4 ± 10.8 [10.2–49.5]
Total waveform duration (msec)	11.6 ± 3.6 [7.7–20.4]
Analysis on a Per Patient Basis	**Mean ± SD [Range]**
Delivered energy (J)	151 ± 2 [142–157]
Peak delivered voltage (V)	1752 ± 5 [1739–1768]
Resistance (Ω)	81 ± 29 [37–170]
Peak delivered current (A)	24.7 ± 9.8 [10.3–47.3]
Total waveform duration (msec)	12.9 ± 3.8 [7.7–20.4]

(defibrillation) was 25 ± 17 [15–81] seconds. Time from AED power-on only to first shock was 39 ± 26 [18–142] seconds and to first successful shock (defibrillation) was 43 ± 30 [18–142] seconds. These times include delays for events such as repositioning the patient.

Discussion

The results of this study focus on effective out-of-hospital defibrillation as a key link in the "chain of survival." The data demonstrate that the low-energy impedance-compensating BTE waveform used in the AED under study consistently terminates long-duration VF as encountered in OHCA. The AED incorporating this therapy was used efficiently and with good outcome by a wide variety of early responders, ranging from experienced EMS personnel to first time non-EMS, nonmedical users.

Defibrillation Efficacy and Resulting Rhythms

Low-energy impedance-compensating biphasic waveforms were very effective at terminating VF. A single shock defibrillated 89% of initial VF episodes and 87% of all VF episodes despite a very wide range of patient resistances (36 to 171 Ω). This confirms that automated impedance compensation maintains high efficacy without the need to either step-up energy levels or use high-energy shocks with their attendant negative consequences on cardiac mechanics and electrophysiology. Moreover, crucial to the thesis of rapid defibrillation, all VF patients were defibrillated and the patients' initial VF episode was defibrillated with only 1 to 3 shocks (with the exception of the one patient who was disconnected from the AED prematurely). Recurring VF was terminated in a similar, rapid manner, as cumulative defibrillation success per episode was 99% with ≤ 3 shocks.

During the use of an AED on a VF patient, it is expected that the patient's underlying acute disease state, the effects of defibrillation, and the effects of other interventions will affect outcome. In the course of resuscitation, rhythms change in a complex manner following defibrillation, including transitions into organized rhythms, asystole, and VF. As a consequence, it is important to measure the ability of the AED, in conjunction with ALS care, to restore an organized rhythm. In this study, most patients (84%) achieved an organized rhythm at some time during their resuscitation attempt with only 1.6 ± 1.2 shocks. When the AED was turned off or removed (usually at hand-off to the next care provider), 77% of patients were in an organized rhythm.

ROSC data for all patients presenting with VF, whether having witnessed or unwitnessed collapse, was available in 34 patients and was achieved in 19 (56%) patients having an average 911 call to shock time of 8.1 minutes and index VF amplitudes of only 0.5 mV. Previous reports on ROSC originate only from experienced EMS systems and average 58% (48%–61%).[5,27,31-33] Our ROSC results are similar to the previously reported ROSC results, most likely because of comparable response times (Table 5). One might have expected a diverse group of users, treating patients with low-amplitude VF and long response times, to have an even lower ROSC rate than that reported from single, well-experienced sites. It may be that the ease of use of the AED under study and its ability to defibrillate at a high rate resulted in relatively good ROSC rates in a population of cardiac arrest victims who were treated by more nontraditional users,

TABLE 5
Published Literature on Monophasic Damped Sine (MDS) and Monophasic Truncated Exponential (MTE) Waveform Defibrillation Efficacy

Reference	Waveform	VF Patients	Witnessed Arrests	Time Interval (min)	First-Shock Efficacy	All-Shock Efficacy
Weaver[5]	175–320 J MDS	457	285 (62%)	11.0 ± 3.9*	273/457 (60%)	Not reported
Weaver[27]	175–320 J MDS	249	Not reported	10.6 ± 5.5*	152/249 (61%)	Not reported
Behr[28]	200–360 J MDS	42	42 (100%)	8.4 ± 0.4*	27/41 (66%)	63/108 (58%)
Behr[28]	200–360 J MTE	44	44 (100%)	8.0 ± 0.4*	19/43 (44%)	45/130 (35%)
Cummins[31]	200 J MDS	63	Not reported	9.0*	Not reported	87/144 (60%)
Weaver[32]	200 J MDS	205	158 (77%)	3.8 ± 2.0†	157/205 (77%)	245/392 (63%)
Cummins[33]	200–360 J MDS	29	15 (46%)	11.6 ± 2.9*	Not reported	37/47 (79%)
Pooled					628/995 (63%) CI: 60%–67%	477/821 (58%) CI: 54%–62%
Best[32,33]					157/205 (77%) CI: 70%–83%	37/47 (79%) CI: 64%–90%

*From collapse to first shock; †from 911 call to defibrillator arrival. CI = 95% confidence interval.

46% of whom were not EMT, paramedic, or physician responders.

User Interface

The ability of a responder to quickly and properly deploy an AED is a critically important, often untested characteristic of new AEDs. Given the critical relationship between early defibrillation and the likelihood of survival from SCA, an AED with a well-designed user interface may have a dramatic contribution to patient outcome. Attention to ergonomic design can improve pad placement and reduce time of AED deployment.

The AED under study meets these criteria as demonstrated by the brief time to attach pads, deliver the first shock, and defibrillate. The time from pad placement to first shock of 21 ± 10 seconds in this study of a wide range of users is much less than the 38 ± 27 seconds previously reported by Weaver et al.,[32] when AEDs were used in an experienced EMS system. The overall time from AED power-on to first shock delivery of 39 ± 26 seconds is also much less than the 1.1 minutes reported in another AED study of experienced users by Cummins et al.[31] Using the model that the likelihood of survival from SCA decreases by 10% for every minute that passes,[35] this well-designed AED user interface may itself significantly contribute to improved survival.

Study Limitations

One limitation of this study is that a concurrent comparison with a high-energy waveform AED was not made. However, the objective of this study was to monitor the performance of a low-energy impedance-compensating biphasic waveform AED in conditions best resembling typical use. The study conditions of a randomized, concurrent control protocol may introduce factors specific to the study protocol, which could potentially alter our observations. By performing a postmarket surveillance type of study (as recommended by the AHA Task Force on Automatic External Defibrillation),[25] device performance was assessed according to intended use across a broad spectrum of both new and experienced AED users.

Comparison with Published High-Energy Defibrillation Studies

Although concurrent controls were not obtained, a comparison with published high-energy monophasic waveform data can be made. Publications were selected if they met all of the following criteria: (1) peer-reviewed publication of EMS response to out-of-hospital SCAs; (2) either first shock or all defibrillation efficacy was reported; (3) the defibrillation waveform and energies were reported; and (4) defibrillation was attempted on a minimum of 20 patients. Publications were excluded if waveforms were mixed and performance for each waveform could not be distinguished, or in-hospital and out-of-hospital data were mixed and unseparable. Even though the data summarized in Table 5 were taken from different sources with many uncontrolled factors that may potentially influence results, it gives a practical representation of the performance of high-energy monophasic waveform defibrillation across a variety of EMS systems (as in our study).

The pooled defibrillation efficacy for high-energy waveforms was 628 of 995 (63%) for first shocks and 477 of 821 (58%) for all shocks.[5,27,28,31-33] Prior to this report, the *best* reported OHCA first-shock defibrillation efficacy rate was from Weaver and colleagues,[32] 157 of 205 (77%) first-shock and 245 of 392 (63%) all-shock defibrillation rate success rates, in a patient population treated on average in 3.8 minutes from 911 call to arrival of the defibrillator. Cummins et al.[33] reported the highest all-shock efficacy rate of 79% prior to our report; they did not report first-shock efficacy in their study. Figure 3 compares these published monophasic waveform data to our biphasic waveform results.

The defibrillation rate in our study for all VF episodes of 87% cannot be compared to published

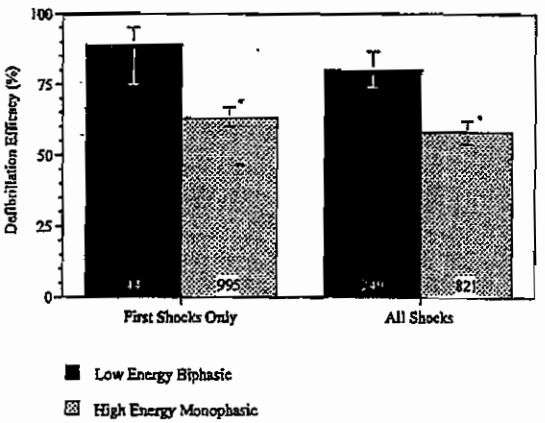


Figure 3. *Comparison of defibrillation efficacy with the 150-J impedance-compensating biphasic waveform with the average published results for high energy shocks. *P < 0.0001 by Chi-square analysis.*

studies on other waveforms, as this measure of device efficacy has not been previously reported. However, first-shock defibrillation rates for the initial VF episode and all-shock defibrillation rates have been reported. In our study, the first-shock defibrillation rate for initial VF episodes was 89% and the all-shock defibrillation rate was 80%. These values are consistent with an early publication of patients defibrillated with this waveform in the out-of-hospital setting.[36] Although concurrent controls were not used in our study, comparisons to earlier results can be made as long as these limitations are understood. The defibrillation efficacy rates were significantly higher than those reported for high-energy monophasic waveforms having, on average, a first-shock defibrillation rate of 63% ($P < 0.0001$; 95% CI of the difference between low- and high-energy defibrillation rates: 15%–36%) and an all-shock defibrillation rate, on average, of 58% ($P < 0.0001$; 95% CI of the difference: 15%–28%). Even when compared with the best previously reported high-energy results, achieved with response times of 3.8 minutes from 911 call to defibrillator arrival, the 150-J impedance-compensating biphasic waveform exhibited higher first-shock defibrillation rate than the high-energy waveform first-shock efficacy of 77% ($P = 0.08$, 95% CI of the difference: 1%–24%).[32] Thus, this biphasic waveform terminates VF at a higher rate, using several measures, than those reported with high-energy monophasic waveform shocks.

In reviewing the literature on previous waveform experience, it is worthwhile to note that one type of waveform currently in broad use, monophasic truncated exponential (Table 5), has no data in the peer-reviewed literature to support it as being reasonably effective. Nevertheless, this waveform is widely implemented in both manual and automatic external defibrillators. The only publication examining the relative performance of this type of waveform by Behr et al.[28] shows defibrillation efficacy rates below any other report, even though the cardiac arrest population under study had witnessed arrests 100% of the time. This leaves open the possibility that cardiac resuscitation rates may be low in significant part because of the use of waveforms that are not only suboptimal but below reasonable relative performance standards.

The Value of Lower Shock Strength and Biphasic Waveform: Why is Less More?

The superior defibrillation results with less energy begs the question: "Why is less more?" There are at least two possible explanations for the improved defibrillation efficacy: (1) a more appropriate dose of energy; and (2) an impedance-compensating biphasic waveform. The rationale for the traditional high-energy shock sequences of 200, 200, and 360 J is not founded on the results of randomized clinical trials. Neither is the value of step-up energy delivery. There are no prospective studies available in the literature to support the use of high energy. The only randomized clinical trial data on the subject argue that more moderate shock strength is superior. In 1982, Weaver et al.[27] demonstrated in an out-of-hospital study that a 175-J monophasic damped sine (MDS) waveform shock defibrillated as well as a 320-J MDS shock but without the negative side effects of an increased postshock incidence of AV block. In 1996, Bardy et al.[37] showed in an in-hospital electrophysiology study that a 200-J MDS shock defibrillated as well as a 360-J MDS shock but with less ECG evidence of myocardial injury from the shock. In 1988, Kerber et al.[38] in an in-hospital study showed defibrillation success rates to fall progressively with MDS shocks after peak currents increased over 41 A. In 1979, Gold et al.[39] showed in an animal study that defibrillation success fell progressively as current increased beyond about 50 A.

These empirical clinical and animal findings are reasonably explained by two electrophysiologic effects that arise in the myocardium in the vicinity of high electric field strength: electroporation with its attendant electrophysiologic sequelae of prolonged inexcitability, and a propensity to ectopic impulse formation.[40-42] Electroporation, the development of holes in the cell membrane that allow for calcium and potassium influx into the cell, results in spontaneous electrical activity as a consequence of the generation of early afterdepolarizations. Excessive prolongation of refractoriness can result in areas of delayed conduction that serve as a substrate for reentry. Either or both of these mechanisms can cause failed defibrillation or refibrillation. Thus, given the growing body of experimental and clinical data that suggest that high field strengths (i.e., high-energy shocks) have an upper limit of safety and efficacy, it is time to reconsider the standard recommendations for defibrillation.

The Value of Impedance Compensation

Superior defibrillation results with less energy may also be a consequence of the use of an impedance-compensating biphasic waveform. The literature is replete with evidence that biphasic

waveforms provide defibrillation results superior to those with monophasic waveforms.[16-22,26,37,43] An early report on the 150-J impedance-compensating biphasic waveform indicated that a high defibrillation efficacy (88%) was maintained for patients with high shock impedances.[36] In addition to the obvious value of a well-designed BTE waveform is the added value of patient-specific impedance compensation. To date, no high-energy external defibrillator has optimized the waveshape to patient impedance.[19] Previous studies by Kerber et al.,[38,44] using damped sine monophasic waveforms, report that higher patient impedances adversely affect monophasic waveform defibrillation success rates. The hypothesis to explain this finding at the time was that current delivery was inadequate in high-impedance patients. Although this explanation may still be pertinent to monophasic damped sine or high-energy waveforms, the high efficacy of the BTE waveform used in our study, unaffected by patient impedance variation, either argues against a dominant role of current in defibrillation in general or indicates that the role of current in defibrillation is waveform specific. In fact, the impedance-compensating BTE maintains efficacy despite a fall in peak current (Table 4). This finding serves as yet another reminder of the multiple factors affecting defibrillation success and the importance of waveform shape.

Impedance compensation can also be used to limit waveform duration in a favorable manner. In high-impedance patients, damped sine waveforms or monophasic truncated pulses without impedance optimization can result in physiologically active currents for up to 40 msec. Such small persistent currents are well beyond the chronaxie for defibrillation[45] and for decades have been suspected of refibrillation phenomena.[46-48] We believe that one of the reasons defibrillation success rates were as high as they were in this study, and were not diminished by the high-impedance patients, was because impedance compensation limited waveform duration to 20 msec.

Physiologic Effects of the Shock

In experimental preparations, biphasic waveforms, compared with monophasic waveforms, have been shown to reduce cell membrane damage postshock.[20,49] It is also known that the higher the shock energy, the more postshock cardiac dysfunction as a result of a direct membrane depressant effect and cell wall electroporation.[20-22,49] Free ascorbyl radical formation following shock delivery has also been shown to occur.[23] In addition, there is evidence to implicate mitochondrial dysfunction early following high-energy transthoracic defibrillation.[50] Each or all of these membrane and cellular effects may explain why high-energy shocks can result in a higher incidence of myocardial depression and bradyarrhythmias.[27,37,51-57]

Xie et al.[23] have shown, in an animal model of cardiac arrest from VF persisting for 10 minutes, a broad array of negative hemodynamic consequences following defibrillation with unnecessarily high energies. Despite using shocks of equivalent defibrillation efficacy (all 100% effective at terminating VF with one shock), Xie et al. showed that the higher the shock strength, the more the impairment in left ventricular contractility and relaxation, the greater the rise in left ventricular end-diastolic pressure, the worse the fall in cardiac index, and the greater the rise in systemic lactate levels. Moreover, the greater the energy, the longer these abnormalities persisted. Most importantly, energy strength, despite success at defibrillation, had an inverse effect on survival.

Previous clinical trials have also shown ECG ST segment depression postshock to be significantly less with low-energy BTE shocks compared to high-energy shocks.[37,51] Such abnormalities are likely to be magnified in patients receiving multiple shocks.[24]

Truncated biphasic waveforms also interfere less with pharmacologic resuscitation efforts. In animals, lidocaine increased monophasic waveform ventricular defibrillation energy requirements by 92%, whereas a biphasic waveform decreased defibrillation energy requirements by 6%.[52] Amiodarone has similar effects.[53] These observations imply that patients requiring antiarrhythmic drugs might be managed better with biphasic defibrillation.

Osswald et al.[22] have shown in an animal study that BTE waveforms result in less injurious effects on myocardial oxidative metabolism and hemodynamic performance than monophasic waveforms. Finally, biphasic waveform transthoracic defibrillation may offer advantages for patients having antibradycardia pacemakers. Monophasic defibrillation has been shown to lead to postshock failure to capture, presumably due to a shock-related rise in pacing threshold that sometimes persists for as long as 10 minutes.[54,55] Low-energy biphasic waveform defibrillation, on the other hand, may not interfere with antibradycardia pacing and may be safer in pacemaker-dependent patients.[56]

Biphasic Waveforms and Long-Duration VF

The longer a patient is in VF, the more difficult defibrillation becomes, when monophasic waveforms are used.[57,58] In contrast to the progressive deterioration in performance of monophasic waveforms, animal studies have shown that biphasic waveforms increase in relative superiority to monophasic waveforms as the duration of VF increases.[59-61] This time-dependent advantage of truncated biphasic waveforms favors their use in cardiac arrest patients who are very likely to have been in VF for many minutes before help arrives. Our study confirms earlier findings in humans in OHCA.[62] The average high-energy monophasic waveform first-shock efficacy has been only 63%, whereas the 150-J impedance-compensating BTE waveform maintained a high first-shock defibrillation rate of 89% after 8.1 minutes of VF (Fig. 4).

Implications for the Chain of Survival

The chain of survival concept highlights how resuscitation from OHCA can be improved by linking the actions of the lay public with those of professional EMS systems. The progression of response—from bystander CPR to early defibrillation to more advanced emergency medical services—will only be facilitated by effective and easy-to-use AEDs.

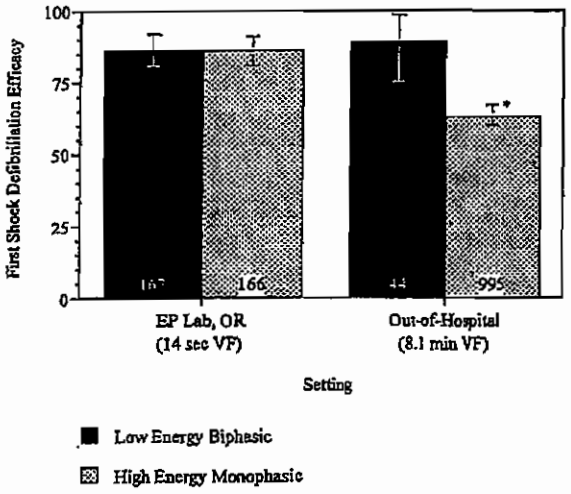


Figure 4. *Defibrillation efficacy comparison of the 150-J impedance-compensating biphasic waveform to high energy monophasic waveform shocks delivered to patients in the electrophysiology lab (14 sec of VF) and in the out-of-hospital setting (8.1 min of VF). Shown are first shock defibrillation efficacies and associated 95% confidence intervals. *P = 0.0001 compared with biphasic by Chi-square analysis.*

Previous-generation AEDs used high-energy (up to 360 J delivered, 435 J stored) monophasic waveforms for defibrillation. The high voltage (up to 5200 V stored) and energy requirements of these monophasic waveforms inhibit AED miniaturization and are not optimal for a device designed for early defibrillation, as stored voltage and energy are directly proportional to device size, weight, and ultimately cost. The fact that technology can be brought to bear to overcome the limitations of device size, weight, and cost carries with it the potential to improve national resuscitation rates from cardiac arrest. The link in the chain of survival that such AEDs provide is possible by virtue of all the features that improve AED dissemination: cost reduction, size reduction, weight reduction, and advanced ergonomic design concepts that allow modestly trained, and even first time, lay users the ability to defibrillate successfully. Many of these advances are the direct result of using low-energy impedance-compensating biphasic waveforms. The power of such technology might also relieve EMS systems of the near impossible burden of responding in a time-sensitive manner to a broadly dispersed population. Prospective clinical trials offer the opportunity to confirm the value of these types of AEDs on public access defibrillation programs and demonstrate their affect on survival.

Easy-to-use AEDs may modify the response of the lay public to OHCA. CPR, although relatively easy to teach, often is ineffectively implemented by nonprofessionals. The concern over communicable diseases and the disagreeable aspects of mouth-to-mouth resuscitation can inhibit all but the most resolute bystander from performing effective CPR.[63] As a consequence, with easy-to-use AEDs, it may be better to defibrillate first, saving precious moments that might otherwise be wasted by poorly administered CPR.

There is one more implication of easy-to-use, low-cost AEDs for the chain of survival: true public access defibrillation. What is the obstacle to personal AED acquisition? SCA is a broadly recognized public health problem and the leading cause of death in the United States. Moreover, at least two thirds of cardiac arrests occur in the home.[64] The obstacle to implementing a fire-extinguisher analogy for AEDs has been a concern for the safety of the lay user and the nonfibrillating unconscious patient. There is ample evidence, however, both in this report and in the experience of others, that the risk to the user and the non-VF patient is near nil, whereas the true risk to the public is a delay in defibrillation. It is time to consider that AEDs be readily accessible to those

interested in their own personal safety or the safety of their family or employees. AED access should parallel the public's ability to protect themselves from a host of other well-acknowledged risks as is done with fire extinguishers, smoke detectors, and security alarms. It is ironic that the risk of death from cardiac arrest, which far exceeds that from fire and burglary, should be so high when the means to reduce this risk is so readily available.

Conclusion

The low-energy impedance-compensating BTE waveform used in this study's AED consistently terminated long-duration VF as encountered in OHCA. The observed defibrillation rate exceeds that of published studies on higher energy monophasic waveforms. Higher energy is not clinically warranted with this BTE waveform. The efficient user interface and high defibrillation efficacy of this low-energy biphasic waveform allows the AED to have device characteristics consistent with widespread deployment and early defibrillation. These findings suggest that the role of higher energy waveforms, with their potential to adversely affect early defibrillation efforts as well as cardiac mechanics, requires further study.

The LIFE Investigators (*Low Energy Impedance Compensating Waveform Field Experience*) and Participating Institutions (Presented in Order of Number of Contributing Patients)

(1) Roger D. White, M.D.
Professor of Anesthesiology, Mayo Medical School
Co-Medical Director, Mayo Clinic Gold Cross Ambulance Services
200 First Street SW
Rochester, MN 55905

(2) Karl-Georg Kanz, M.D.
Friederike Hengstenberg, M.D.
Taimerhofstrasse 50, D-81927
Munich, Germany

(3) Hatzoloh Ambulance Service of New York
1371 East 8th Street
Brooklyn, NY 11230

(4) G. Truett Jarrard, M.D.
PAPP Clinic
Newnan, GA 30263

(5) Jack C. Robinson, Deputy Chief
Peter McFall, EMT-P
Joann Clifton, EMS Office Coordinator
Everett Fire Department
2811 Oakes
Everett, WA 98201

(6) Valerie Santana, R.N., EMT-D Program Coordinator
Robert Hansen, M.D., EMT-D Program Director
Jim Kilner, Training Officer
Kings County Fire Department
Hanford Community Medical Center
450 North Greenfield
Hanford, CA 93230

(7) James Stubblefield, M.D.
Peggy Toft
Monterey County Emergency Medical Services Agency
19065 Portola, Suite I
Salinas, CA 93908

(8) David K. McKenas, M.D.
Director, Corporate Medical Department
American Airlines
PO Box 619615, Mail Drop 5187
Dallas/Fort Worth Airport, TX 75261-9816

(9) Nathan Rich, M.D., Medical Director
Steven Rosas, M.D., Quality Assurance Director
Jack Ganzemiller, County Coordinator
Dunn County Medical Emergency First Responders Program
Dunn County Sheriff's Dept.
714 17th Street
Menomonie, WI 54751

(10) Sally Merritt, EMT
Chenango Forks Medical Team
117 Oak Grove Drive
Chenango Forks, NY 13746

(11) Luke Magnotto, M.D.
Medical Program Director
Kitsap County EMS
Sherrie Shafer, R.N., Q/I Coordinator
Harrison Memorial Hospital
2520 Cherry Avenue
Bremerton, WA 98310-4270

(12) John V. Gallagher III, M.D.
City of Phoenix Fire Department
Emergency Medical Services
150 South 12th Street
Phoenix, AZ 85034

References

1. Ryan TJ, Anderson JL, Antman EM, et al: ACC/AHA guidelines for the management of patients with acute myocardial infarction: Executive summary. Circulation 1996;94:2341-2350.
2. Gillum RF: Sudden coronary death in the United States. Circulation 1989;79:756-765.

3. Bayes de Luna A, Coumel P, Leclercq JF: Ambulatory sudden cardiac death: Mechanisms of production of fatal arrhythmia on the basis of data from 157 cases. Am Heart J 1989;117:151-159.
4. Emergency Cardiac Care Committee and Subcommittees, American Heart Association: Guidelines for cardiopulmonary resuscitation and emergency cardiac care, IX: Ensuring effectiveness of community-wide emergency cardiac care. JAMA 1992;268:2289-2295.
5. Weaver WD, Copass MK, Bufi D, et al: Improved neurologic recovery and survival after early defibrillation. Circulation 1984;69:943-948.
6. Spaite DW, Hanlon T, Criss EA, et al: Prehospital cardiac arrest: The impact of witnessed collapse and bystander CPR in a metropolitan EMS system with short response times. Ann Emerg Med 1990;19:1264-1269.
7. Larsen MP, Eisenberg MS, Cummins RO, et al: Predicting survival from out-of-hospital cardiac arrest: A graphic model. Ann Emerg Med 1993;22:1652-1658.
8. Weaver WD, Cobb LA, Hallstrom AP, et al: Factors influencing survival after out-of-hospital cardiac arrest. J Am Coll Cardiol 1986;7:752-757.
9. Herlitz J, Ekström L, Wennerblom B, et al: Survival in patients found to have ventricular fibrillation after cardiac arrest witnessed outside hospital. Eur Heart J 1994;15:1628-1633.
10. Becker LB, Ostrander MP, Barrett J, et al: Outcome of CPR in a large metropolitan area—Where are the survivors? Ann Emerg Med 1991;20:355-361.
11. Lombardi G, Gallagher EJ, Gennis P: Outcome of out-of-hospital cardiac arrest in New York City: The Pre-Hospital Arrest Survival Evaluation (PHASE) Study. JAMA 1994;271:678-683.
12. Eisenberg MS, Horwood BT, Cummins RO, et al: Cardiac arrest and resuscitation: A tale of 29 cities. Ann Emerg Med 1990;19:170-186.
13. White RD, Vukov LF, Bugliosi TF: Early defibrillation by police: Initial experience with measurement of critical time intervals and patient outcome. Ann Emerg Med 1994;23:1099-1113.
14. White RD, Asplin BR, Bugliosi TF, et al: High discharge survival rate after out-of-hospital ventricular fibrillation with rapid defibrillation by police and paramedics. Ann Emerg Med 1996;28:480-485.
15. Weisfeldt ML, Kerber RE, McGoldrick RP, et al: American Heart Association Report on the Public Access Defibrillation Conference, December 8–10, 1994: Automatic External Defibrillation Task Force. Circulation 1995;92:2740-2747.
16. Winkle RA, Mead RH, Ruder MA, et al: Improved low energy defibrillation efficacy in man with the use of a biphasic truncated exponential waveform. Am Heart J 1989;117:122-127.
17. Bardy GH, Ivey TD, Allen MD, et al: A prospective, randomized evaluation of biphasic vs monophasic waveform pulses on defibrillation efficacy in humans. J Am Coll Cardiol 1989;14:728-733.
18. Swartz JF, Fletcher RD, Karasik PE: Optimization of bipbasic waveforms for human nonthoracotomy defibrillation. Circulation 1993;33:2646-2654.
19. Charbonnier FM: External defibrillators and emergency external pacemakers. Proc IEEE 1996;84:487-499.
20. Jones JL, Jones RE: Decreased defibrillator-induced dysfunction with biphasic rectangular waveforms. Am J Physiol 1984;247:H792-H796.
21. Jones JL, Jones RE, Balasky G: Improved defibrillator waveform safety factor with biphasic waveforms. Am J Physiol 1983;245:H60-H65.
22. Osswald S, Trouton TG, O'Nunain SS, et al: Relation between shock-related myocardial injury and defibrillation efficacy of monophasic and biphasic shocks in a canine model. Circulation 1994;90:2501-2509.
23. Xie J, Weil MH, Sun S, et al: High-energy defibrillation increases the severity of postresuscitation myocardial dysfunction. Circulation 1997;96:683-688.
24. Crampton R: Accepted, controversial, and speculative aspects of ventricular defibrillation. Prog Cardiovasc Dis 1980;23:167-186.
25. Kerber RE, Becker LB, Bourland JD, et al: Automatic external defibrillators for public access defibrillation. Recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety: A statement for health care professionals from the American Heart Association Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. Circulation 1997;95:1677-1682.
26. Gliner BE, Lyster TE, Dillon SM, et al: Transthoracic defibrillation of swine with monophasic and biphasic waveforms. Circulation 1995;92:1634-1643.
27. Weaver WD, Cobb LA, Copass MK, et al: Ventricular defibrillation—A comparative trial using 175-J and 320-J shocks. N Engl J Med 1982;307:1101-1106.
28. Behr JC, Hartley LL, York DK, et al: Truncated exponential versus damped sinusoidal waveform shocks for transthoracic defibrillation. Am J Cardiol 1996;78:1242-1245.
29. Chen PS, Shibata N, Dixon EG, et al: Activation during ventricular defibrillation in open-chest dogs. J Clin Invest 1986;77:810-823.
30. Usui M, Callihan RL, Walker RG, et al: Epicardial sock mapping following monophasic and biphasic shock of equal voltage and an endocardial lead system. J Cardiovasc Electrophysiol 1996;7:322-334.
31. Cummins RO, Eisenberg MS, Litwin PE, et al: Automatic external defibrillators used by emergency medical technicians: A controlled clinical trial. JAMA 1987;257:1605-1610.
32. Weaver WD, Martin JS, Wirkus MJ, et al: Influence of external defibrillator electrode polarity on cardiac resuscitation. PACE 1993;16:285-290.
33. Cummins RO, Eisenberg MS, Hallstrom AP, et al: What is a "save"?: Outcome measures in clinical evaluations of automatic external defibrillators. Am Heart J 1985;110:1133-1138.
34. Kerber RE, Martins JB, Kelly KJ, et al: Self-adhesive preapplied electrode pads for defibrillation and car-

dioversion. J Am Coll Cardiol 1984;3:815-821.
35. Eisenberg MS, Horwood BT, Cummins RO, et al: Cardiac arrest and resuscitation: A tale of 29 cities. Ann Emerg Med 1990;19:179-186.
36. White RD: Early out-of-hospital experience with an impedanee-compensating low-energy biphasic waveform automatic external defibrillator. J Interven Card Electrophysiol 1997; (In press).
37. Bardy GH, Marchlinski FE, Sharma AD, et al: Multicenter comparison of truncated biphasic shocks and standard damped sine wave monophasic shocks for transthoracic ventricular defibrillation. Circulation 1996;94:2507-2514.
38. Kerber RE, Martins JB, Kienzle MG, et al: Energy, current, and success in defibrillation and cardioversion: clinical studies using an automated impedance-based method of energy adjustment. Circulation 1988;77: 1038-1046.
39. Gold JH, Schuder JC, Stoeckle H: Contour graph for relating per cent success in aehieving ventricular defibrillation to duration, current, and energy content of shock. Am Heart J 1979;98:207-212.
40. Wharton JM, Wolf PD, Smith WM, et al: Cardiac potential and potential gradient fields generated by single, combined, and sequential shocks during ventricular defibrillation. Circulation 1992;85:1510-1523.
41. Yabe S, Smith WM, Daubert JP, et al: Conduction disturbances caused by high current density electric fields. Circ Res 1990;66:1190-1203.
42. Tovar OH, Jones JL: Cellular basis of type B defibrillation occurring at high shock intensity. (Abstract) Circulation 1996;94:I-131.
43. Bardy GH, Gliner BE, Kudenchuk PJ, et al: Truncated biphasic pulses for transthoracic defibrillation. Circulation 1995;91:1768-1774.
44. Kerber RE, Kouba CK, Martins J, et al: Advance prediction of transthoracic impedance in human defibrillation and cardioversion: Importance of impedance in determining the success of low-energy shocks. Circulation 1984;70:303-308.
45. Kroll MW: A minimal model of the monophasic defibrillation pulse. PACE 1993;16:769-777.
46. Geddes LA, Tacker WA, McFarlane J, et al: Strength-duration curves for ventricular defibrillation in dogs. Circ Res 1970;27:551-560.
47. Schuder JC, Stoeckle H, West JA, et al: Transthoracic ventricular defibrillation in dogs with truncated and untruncated exponential stimuli. IEEE Trans Biomed Eng 1971;18:410-415.
48. Schuder JC, Rahmoeller GA, Stoekle H: Transthoracic ventricular defibrillation with triangular and trapezoidal waveforms. Circ Res 1966;19:689-694.
49. Jones JL, Jones, RE, Balasky G: Microlesion formation in myocardial cells by high-intensity electric field stimulation. Am J Physiol 1987;253:H480-H486.
50. Trouton TG, Allen JD, Yong LK, et al: Metabolic changes and mitochondrial dysfunetion early following transthoracic countershock in dogs. PACE 1989;12: 1827-1834.
51. Reddy RK, Gleva MJ, Gliner BE, et al: Biphasic transthoracic defibrillation causes fewer ECG ST-segment changes after sbock. Ann Emerg Med 1997;30: 127-134.
52. Ujhelyi MR, Schur M, Frede T, et al: Differential effects of lidocaine on defibrillation threshold with monophasic versus biphasic shock waveforms. Circulation 1995;92:1644-1650.
53. Kopp D, Kall J, Kinder C, et al: Effect of amiodarone and left ventricular mass on defibrillation energy requirements: Monophasic vs. biphasic shocks. (Abstract) PACE 1995;18:872.
54. Yee R, Jones DL, Jarvis E, et al: Changes in pacing threshold and R-wave amplitude after transvenous catheter countershock. J Am Coll Cardiol 1984;4:543-549.
55. Altamura G, Bianconi L, Bianco F, et al: Transthoracic DC shock may represent a serious hazard in pacemaker dependent patients. PACE 1995;18:194-198.
56. Kudenchuk PJ, Poole JE, Dolack GL, et al: Prospective evaluation of the effect of biphasic waveform defibrillation on ventricular pacing thresholds. J Cardiovasc Electrophysiol 1997;8:485-495.
57. Kerber RE, Sarnat W: Factors influencing the success of ventricular defibrillation in man. Circulation 1979; 60:226-230.
58. Weaver WD, Cobb LA, Dennis D, et al: Amplitude of ventricular fibrillation waveform and outcome after cardiac arrest. Ann Intern Med 1985;102:53-55.
59. Echt DS, Barbey JT, Black JN: Influence of ventricular defibrillation duration on defibrillation energy in dogs using bidirectional pulse discharges. PACE 1988;11: 1315-1323.
60. Jones JL, Swartz JF, Jones RE, et al: Increasing fibrillation duration enhances relative asymmetrical biphasic versus monophasic defibrillator waveform efficacy. Circ Res 1990;67:376-384.
61. Walcott GP, Melnick SB, Chapman FW, et al: Comparison of monophasic and biphasic waveforms for external defibrillation in an animal model of cardiac arrest and resuscitation. (Abstract) J Am Coll Cardiol 1995;405A.
62. Bardy GH, Gliner BE, White RD: Comparison of human defibrillation efficacy rates in short-duration and long-duration ventricular fibrillation using monophasic and biphasic transthoracic shocks. (Abstract) Circulation 1997; (In press).
63. McCormack AP, Damon SK, Eisenberg MS: Disagreeable physical characteristics affecting bystander CPR. Ann Emerg Med 1989;18:283-285.
64. Ritter G, Wolfe RA, Goldstein S, et al: The effect of bystander CPR on survival of out-of-hospital cardiac arrest victims. Am Heart J 1985;110:932-937.

Reprinted from BIOMEDICAL INSTRUMENTATION & TECHNOLOGY
Published by HANLEY & BELFUS, INC., Philadelphia, PA © 1998

Treatment of Out-of-Hospital Cardiac Arrest with a Low-Energy Impedance-Compensating Biphasic Waveform Automatic External Defibrillator

BRADFORD E. GLINER, DAWN B. JORGENSON, PHD, JEANNE E. POOLE, MD, ROGER D. WHITE, MD, KARL-GEORG KANZ, MD, THOMAS D. LYSTER, KENT W. LEYDE, DANIEL J. POWERS, CARLTON B. MORGAN, RICHARD A. KRONMAL, PHD, GUST H. BARDY, MD, FOR THE LIFE INVESTIGATORS

Few victims of sudden cardiac arrest survive. A new generation of automatic external defibrillators (AEDs), smaller, lighter, easier to use, and less costly, makes the goal of widespread AED deployment and early defibrillation feasible. A low-energy impedance-compensating biphasic waveform allows AED device characteristics more suitable to the goal of early defibrillation than high-energy waveforms. This study observed the performance of such a biphasic waveform in the out-of-hospital setting on 100 consecutive victims of sudden cardiac arrest treated by a wide range of first-responders. AEDs incorporating 150-J impedance-compensating biphasic waveforms were placed into service of 34 EMS systems. Data were obtained from the AED PC data card-recording system. The first endpoint was to determine the effectiveness of this waveform in terminating ventricular fibrillation (VF). The second endpoint was to determine whether or not the use of such an AED culminated in an organized rhythm at the time of patient transfer to an advanced life support (ALS) team or emergency department (ED). The third endpoint was to assess the efficiency of the human-factors design of the AED by measuring user time intervals. The 34 sites provided data from 286 consecutive AED uses, 100 from SCA victims with VF as their initial rhythm upon attachment of the AED. All 286 patients were correctly identified by the AED as requiring a shock (100% sensitivity for the 100 VF patients) or not (100% specificity to the 186 patients not presenting in VF). Times from emergency call to first shock delivery averaged 9.1 ± 7.3 minutes. A single 150-J biphasic shock defibrillated the initial VF episode in 86% of patients. For all 450 episodes of VF in these 100 patients, an average of 86% ± 24% of VF episodes were terminated with a single biphasic shock. Of the 449 VF episodes that received up to three shocks, 97% ± 11% were terminated with three shocks or fewer. The average number of shocks per VF episode was 1.3 ± 0.7. The average time from AED power-on and pads attached to first defibrillation was 25 ± 23 sec. At the time of patient transfer, an organized rhythm was present in 65% of the VF patients; asystole was the result in 25%, and VF was in progress in 10%. It is concluded that low-energy impedance-compensating biphasic waveforms terminate long-duration VF at high rates in out-of-hospital cardiac arrest and provide defibrillation rates exceeding those previously achieved with high-energy shocks. Use of this waveform allows AED device characteristics consistent with widespread AED deployment and early defibrillation. (BIOMEDICAL INSTRUMENTATION & TECHNOLOGY 1998;32:631-644)

PEER-REVIEWED ORIGINAL RESEARCH

Received from Heartstream, Inc., Seattle, Washington (BEG, DBJ, TDL, KWL, DJP, CBM); the University of Washington, Seattle, Washington (JEP, RAK, GHB); the Mayo Clinic, Rochester, Minnesota (RDW); and Universität München, Munich, Germany (K-GK).

Address correspondence and reprint requests to Mr. Gliner: Director of Research, Heartstream, Inc., 2401 Fourth Avenue, Suite 300, Seattle, WA 98121; phone: (206) 664-5134; Fax: (206) 664-9694; e-mail: <GlinerB@heartstream.com>.

Each year in the United States, over one million deaths are attributed to cardiovascular disease, making it the single leading cause of death.[1,2] Approximately one fourth of these deaths occur suddenly outside the hospital (sudden cardiac arrest, SCA) with few victims surviving.[3,4] The majority of SCA deaths are caused by irregular heart activity known as ventricular fibrillation (VF).[5] During VF, the heart's electrical system is chaotic and ceases to elicit coordinated mechanical movement. The heart stops pumping blood, and victims

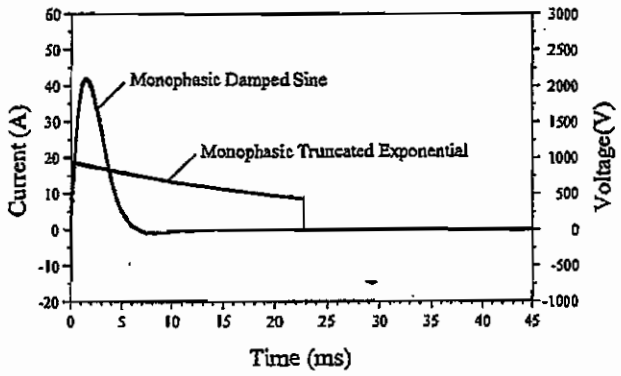


Figure 1. Traditional 200-J monophasic defibrillation waveforms as delivered to a 50-Ω load, the industry standard. The monophasic damped sine waveform was generated with a Hewlett-Packard Codemaster XL defibrillator. The monophasic truncated exponential waveform was generated with a Laerdal Heartstart 3000 defibrillator.

lose consciousness within seconds, often without prior warning.[6] Unless an organized rhythm and circulation are restored within a few minutes, death results.

The only known definitive treatment of VF is electrical defibrillation, the application of an electrical shock to the heart. Defibrillation therapy halts the heart's chaotic electrical activity, allowing propagation of the cardiac impulse through normal conduction pathways. An organized heart rhythm and coordinated pumping action may then resume.

The time from collapse to defibrillation is the critical determinant of survival of SCA.[7,8] With every minute that passes, the likelihood of survival decreases by approximately 10%.[9] Other factors affecting survival include bystanders witnessing the arrest, prompt access to emergency medical services (EMS), and bystander cardiopulmonary resuscitation (CPR).[10–13] Reported survival rates from SCA caused by VF average less than 5% nationwide, but vary widely, from 2% to 49%, with lower survival rates primarily a result of delays in defibrillation.[9,14–17] Large metropolitan areas such as Chicago[14] and New York City[15] have reported survival rates near 2%, largely due to extensive delays in the availability of defibrillators. In contrast, cities with mature early defibrillation programs, such as Seattle, WA,[9] and Rochester, MN,[16,17] have survival rates in the range of 25% to 45%. Thus, early-defibrillation programs with widespread deployment of automatic external defibrillators (AEDs) have been shown to be an effective response to this problem. The establishment of early-defibrillation programs as part of the standard care for SCA is encouraged by the American Heart Association (AHA),[18,19] the European Resuscitation Council (ERC), and the International Liaison Committee on Resuscitation (ILCOR).[20]

Automatic External Defibrillators (AEDs)

The development of the AED in the 1980s was a major advancement over manual defibrillators. Manual defibrillators require the user to interpret a patient's electrocardiogram (ECG) and determine the appropriateness of a defibrillation shock, thus limiting use to highly trained individuals such as physicians and paramedics. In contrast, AEDs sense and analyze a patient's ECG automatically. When the AEDs' rhythm-recognition algorithm determines that a patient may benefit from a shock, the AED automatically charges the energy-storage capacitor and alerts the user that a shock is advised. By automating the task of rhythm recognition, AEDs allow defibrillation to be performed by a much more diverse group of responders, including flight attendants, security guards, police officers, firefighters, and other designated individuals.

Although AEDs have significantly increased survival in some cities,[11,17,21,22] their dissemination has been limited. This is largely the result of limitations in AED technology associated with high-energy defibrillation waveforms that affect size, weight, cost, and ease of use. The high energy (360 J delivered, 435 J stored) and voltage (5,200 V stored) requirements of monophasic waveforms have made traditional external defibrillators relatively large (1,200 to 3,000 cm^3), heavy (4 to 10 kg), and expensive ($7,000 to $10,000). Traditional external defibrillators use rechargeable batteries (nickel cadmium or lead acid), which have demonstrated reliability problems and require frequent maintenance, thus making an AED burdensome to own.[23] Some of these limitations have been reduced in newer-generation monophasic-waveform AEDs. For example, cost has been reduced and the option of disposable lithium batteries may replace the less reliable rechargeable technologies. However, size and weight are still limited by the high voltage and energy requirements of monophasic waveforms. Because an essential element to increasing resuscitation rates for victims of SCA is the institution of a

TABLE 1. Typical Monophasic Waveform Circuit Parameters

Waveform	C_s* (μF)	L† (mH)	R_i‡ (Ω)
Monophasic damped sine	30–50	20–40	10–12
Monophasic truncated exponential	200–600	—	5–10

*Energy-storage capacitor.
†Waveshaping inductor.
‡Internal resistance of the output circuit.

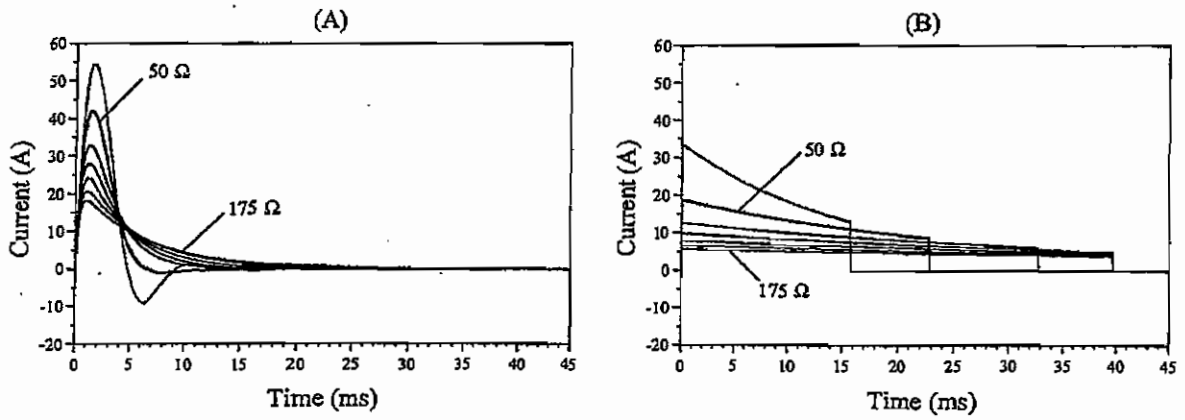


Figure 2. Representative current plots of traditional (A) monophasic damped sine waveforms and (B) monophasic truncated exponential waveforms as a function of load impedance from 25 to 175 Ω in 25-Ω increments.

wider network of defibrillator-equipped emergency responders, miniaturization and cost reduction of AEDs are critical to realizing the goal of early defibrillation.

Defibrillation Waveforms

The electrical therapy provided by defibrillators is delivered to the patient's chest through a pair of hand-held paddles or through a set of adhesive electrode pads. A defibrillation shock is traditionally quantified by an energy setting that represents the amount of energy delivered to a 50-Ω load, the industry standard.[24] However, the time course of the delivered current or voltage pulse, the defibrillator waveform, is a more meaningful description of the delivered shock. The defibrillator waveform directly affects the efficacy of a defibrillation attempt.[25] It also affects essential defibrillator components, such as batteries, the energy-storage capacitor, and the output-circuit switches and topology.

Two types of monophasic waveforms have traditionally been used in clinical defibrillators: monophasic damped sine (MDS) and monophasic truncated exponential (MTE). Figure 1 demonstrates MDS and MTE current and voltage waveforms as delivered to a 50-Ω load. Typical circuit parameters for monophasic waveforms are given in Table 1. Although the industry standard for energy calibration is 50 Ω, the average patient impedance is actually about 80 Ω, with a clinical range of about 35 to 170 Ω.[26–32] This wide range of patient impedances affects the defibrillation waveform, and thus is a critical factor in defibrillation effectiveness.

MONOPHASIC DAMPED SINE (MDS) WAVEFORMS

Monophasic damped sine waveforms have remained essentially unchanged since they were first used clinically in the 1960s.[33,34] Today's monophasic-waveform defibrillators have a maximum energy setting of 360 J, as recommended by the Association for the Advancement of Medical Instrumentation (AAMI)[24] and the American Heart Association (AHA).[7] To deliver a 360-J MDS waveform to a 50-Ω load, approximately 435 J and 5,200 V need to be stored, due to losses in the output circuit. In addition, the relatively large wave-shaping inductor accounts for approximately 150 cc of volume and 300 g in mass, thus hindering device miniaturization.

Although MDS waveforms defibrillate reasonably well, they do not respond well to the wide range of patient impedances encountered clinically. The shape of MDS waveforms changes passively as a function of load (i.e., patient) impedance, as represented in Figure 2A. Specifically, the duration of physiologically active currents increases for high patient impedances. Clinical studies indicate that the efficacy of the MDS waveform decreases at higher impedances.[30–32] Animal studies demonstrate that low-level voltage and current lasting tens of milliseconds (a characteristic of high-impedance MDS shocks) decreases the defibrillation efficacy, presumably by inducing refibrillation.[35–37] Approximately 20% of the population has impedances greater than 100 Ω[26–32] and may receive less effective MDS waveforms.

MONOPHASIC TRUNCATED EXPONENTIAL (MTE) WAVEFORMS

Monophasic truncated exponential waveforms are designed to deliver the selected energy to all load impedances by extending the waveform duration until the desired energy is delivered (Figure 2B). For high impedances, the MTE waveform is low in current and may be excessively long in duration, up to 40 msec. Animal studies show that the effectiveness of an MTE waveform decreases for waveform durations greater than 20 msec.[35,38,39]

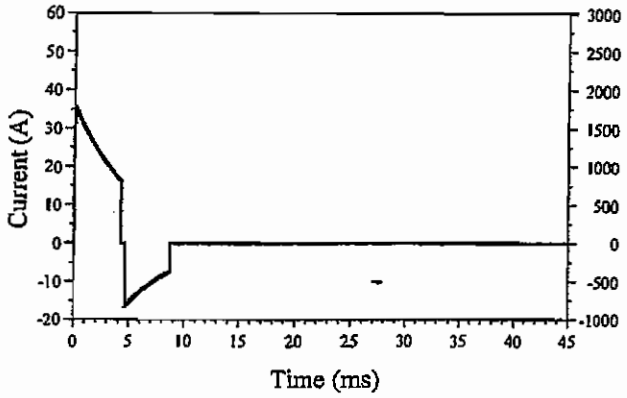


Figure 3. Representative biphasic truncated exponential defibrillation waveform employed in the automatic external defibrillator under study as delivered to a 50-Ω load.

Although MTE waveforms have been utilized since the 1970s, the effectiveness of the MTE waveform as incorporated in many of today's defibrillators has not been sufficiently proven. A 1976 observational study often cited as justification for the MTE waveform did not report defibrillation efficacy on a per-shock basis, but did report that 31 of the 108 (29%) VF patients were not defibrillated, even with multiple MTE shocks.[40] More recently, in a 1996 study of 44 VF patients, only 19 (43%) were defibrillated with the first MTE shock, and only 45 of 130 (35%) MTE shocks successfully defibrillated.[29] A 1997 abstract on an MTE AED also did not report defibrillation efficacy for first shocks or all shocks.[41] This leaves open the possibility that resuscitation rates may be low in part because of the use of waveforms with poor defibrillation performance.

In light of the clinical limitations of past MTE waveforms for external defibrillation, new variations of MTE defibrillators are being introduced. However, the clinical effectiveness of these new MTE waveforms has not been reported.

BIPHASIC TRUNCATED EXPONENTIAL (BTE) WAVEFORMS

Biphasic truncated exponential waveforms (Figure 3) offset many of the technologic constraints of previous-generation AEDs and so permit smaller, lighter, easier to use, and less costly devices. BTE waveforms have been shown unequivocally to be superior to monophasic waveforms for internal defibrillation by reducing voltage and energy requirements.[42–44] BTE waveforms are now standard in implantable cardioverter–defibrillators (ICDs), and monophasic waveforms are no longer used in these devices. Similarly, low-energy BTE waveforms seem poised to displace high-energy monophasic waveforms in external defibrillators. BTE waveforms, specifically those designed to compensate for individual patient variation in transthoracic shock impedance, are thought to be best suited to this purpose.[45] Lower energies have the added benefit of reducing post-shock cardiac dysfunction.[46–50]

DESIGN OF A BTE WAVEFORM FOR EXTERNAL DEFIBRILLATION

Designing a BTE waveform for external defibrillation was not merely a matter of scaling an ICD waveform to a higher energy. Because each ICD is dedicated to a single patient, its waveform parameters may be effectively adjusted for each patient during the implant procedure to optimize the defibrillator's performance. Even though the implanting physician may have the ability to change the ICD operating parameters to compensate for changes in the impedance of the defibrillator leads and/or the patient's heart (e.g., waveform duration, voltage, and energy), the range of internal defibrillation impedances is relatively small.

In contrast, because external defibrillators are used on a variety of patients under numerous circumstances, external defibrillators must operate effectively across a wide range of patient impedances. Variations in the anatomy of the thorax and skin properties influence the current pathway and impedance, thereby varying the waveform intensity and shape of the pulse actually delivered to the patient's heart. Pulse amplitudes and durations effective for low-impedance patients are not necessarily as effective and energy-efficient for high-impedance patients.

Also, external defibrillators may be subjected to extreme load conditions that could potentially damage the waveform generator circuits. For example, improperly applied defibrillator electrodes may create a very-low-impedance path, which could result in excessively high current within the output circuit. Thus, an external defibrillator has an additional design requirement to limit the peak current to safe levels in the waveform circuit. One must also limit circuit voltages in order to reliably use solid state switches, thus enabling device miniaturization.

Study Objective

Low-energy impedance-compensating BTE waveforms enable AEDs to be smaller, lighter, easier to use, and less costly, compared with previous generation AEDs, thus enabling the goal of widespread AED deployment and early defibrillation. The safety and efficacy of the impedance-compensating BTE waveform used in the AED under study has been demonstrated in the electrophysiology laboratory using the methods outlined by AAMI[24] and the AHA (Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy).[51] Out-of-

hospital results have also been reported, demonstrating high algorithm accuracy and defibrillation effectiveness.[26,27] The objective of this study was to validate this AED in the out-of-hospital setting on the first 100 consecutive SCA patients presenting in VF.

Methods

THE BIPHASIC WAVEFORM

The 150-J impedance-compensating BTE waveform used in the AEDs under study (Figure 3) was generated by discharging 1,790 V from a 100-μF capacitor through an H-bridge composed of semiconductor controlled rectifiers (SCRs) and insulated gate bipolar transistors (IGBTs). Measurement of the current through a 10-Ω sense resistor in series with the patient for the first 100 μsec of the waveform was used to ensure that the load impedance was within an acceptable range, and for short-circuit protection and leads off detection. If a short circuit or open circuit was detected, the waveform was immediately terminated. If an acceptable impedance was detected, the series resistor was removed from the output circuit and waveform delivery continued.

The amount of charge delivered from the capacitor was continuously monitored during the discharge. The time to reach a predetermined charge threshold, t(Qt), is directly proportional to the load impedance. Charge control is a cumulative measure and provides better noise immunity than instantaneous measures such as voltage or current monitoring. Once t(Qt) was determined, the durations of the first and second phases of the BTE waveform were set as shown in Table 2. The waveform properties of impedance compensation were determined from an extensive series of animal studies.[38] The total waveform duration could vary from 5 to 20 msec, without compromising defibrillation efficacy across a broad range of transthoracic shock resistances (25 to 180 Ω, Figure 4). Phasic duration, i.e., first phase percentage of the total duration, was 50% for shorter-duration waveforms delivered to lower impedances, and 60% for longer-duration waveform delivered to higher impedances. Total tilt, i.e., fraction of the initial voltage delivered, was not allowed to be excessively high, thus eliminating low-voltage tails attributed to refibrillation. The animal studies demonstrated that defibrillation voltage and energy requirements increased significantly when total tilt exceeded 80–90%, depending on total waveform duration.[38] Therefore, for each shock delivered to each patient, an optimal biphasic waveform was delivered.

TABLE 2. Time to Charge Threshold, t(Qt), for Given Load Impedances and Corresponding Biphasic Truncated Exponential (BTE) Phase Durations

Impedance (Ω)	t(Qt) (msec)	Phase 1 Duration (msec)	Phase 2 Duration (msec)
25	1.13	2.83	2.83
31	1.38	3.13	3.13
40	1.77	3.63	3.63
50	2.22	4.09	4.09
64	2.86	5.75	3.83
79	3.57	7.17	4.78
100	4.62	8.95	5.97
≥125	≥5.93	12.00	8.00

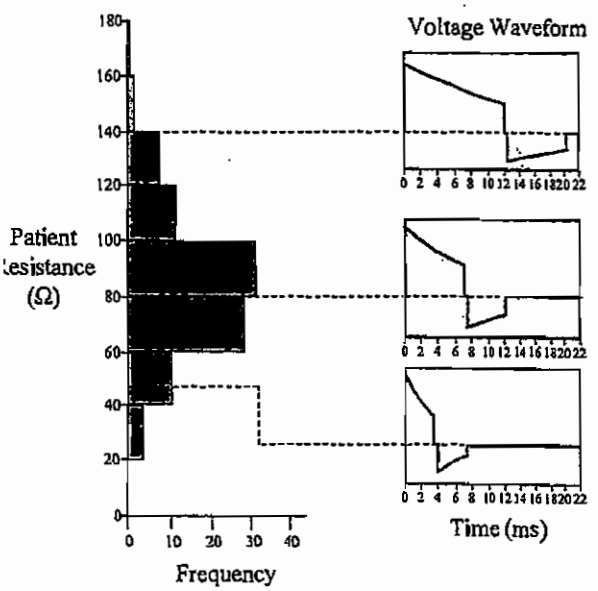


Figure 4. Distribution of shock resistances for the 100 patients presenting in ventricular fibrillation and representative low-energy impedance-compensating biphasic-voltage waveforms.

THE AUTOMATIC EXTERNAL DEFIBRILLATOR (AED)

An AED incorporating the 150-J impedance-compensating BTE shock waveform under study (ForeRunner® AED, SMART Biphasic™, Hewlett Packard Heartstream, Seattle, WA) is shown in Figure 5. Each adhesive defibrillation pad had a surface area of 100 cm² (HP Heartstream) and was applied in the standard anterior–anterior position. Consecutive AED uses were enrolled to obtain 100 consecutive SCA victims presenting in VF. The AED rhythm-detection algorithm analyzed 4.5-second ECG segments and quantified rate, conduc-

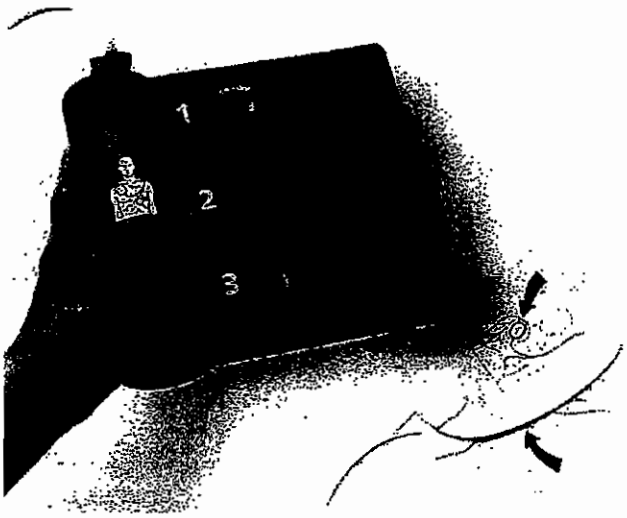


Figure 5. The HP Heartstream ForeRunner automatic external defibrillator employing SMART Biphasic technology.

tion, and stability. A shock decision was then made based on a three-dimensional decision surface. For safety reasons, the median peak-to-peak amplitude of the ECG signal must have been ≥0.08 mV to be considered shockable by the rhythm detection algorithm.

DATA COLLECTION

Data were obtained from the PC data-card-recording system within the AEDs. The PC data cards recorded continuous digitized ECG data (0.1–80 Hz) in all cases and were reviewed on a PC Windows application (CodeRunner®, HP Heartstream). Similarly, shock data, including patient impedance, delivered energy, peak voltage, peak current, and waveform duration, were obtained from the PC data cards, along with ancillary event timing data for calculation of critical time intervals. Near area voice was also recorded as a device option.

RHYTHM ANALYSIS

In examining ECG recordings, defibrillation success was defined as termination of VF into an organized rhythm or asystole for 5 seconds post-shock, while the presence of VF at that time was considered a failed attempt.[26] Including resulting organized rhythms or asystole as successful defibrillation attempts is consistent with terminology used by others.[29,52] The 5-second interval represents a very conservative time to assess shock success, as cardiac mapping studies have demonstrated defibrillation actually occurs within the first 100–500 milliseconds after the shock is delivered.[53,54] Assessment at 5 seconds also allows the post-shock voltage offset to stabilize, and is long enough to allow a clinical interpretation without excessive delays in time-critical treatment. A VF episode was defined as the interval from the onset to termination of VF and could include multiple shocks prior to successful termination.

Following defibrillation, ECG rhythms continue to evolve in a complex and dynamic manner. The effects of the underlying cardiac substrate and effects of other interventions, including CPR or drugs, influence this evolution. Accordingly, ECGs were continuously analyzed to examine subsequent transitions to other rhythm categories. The entire ECG recording was evaluated until the AED was turned off or removed from the patient. Rhythms at the time the AED was deactivated, an overall measure of success, were classified as organized, asystole, or VF.

AED USER INTERFACE

Human-factors design was evaluated by assessing the efficiency of the interaction between the AED and the responder (clarity and value of voice prompts, pad icons, screen instructions, color coding, 1–2–3 shock sequencing). Specifically, time intervals were measured from AED power-on and attachment of the defibrillation pads to first shock delivered and to first defibrillation. The time intervals between subsequent shocks were also examined for patients requiring more than one shock to terminate VF. Time intervals were measured from automated AED annotations on the ECG recordings.

SAMPLE SIZE, STATISTICAL ANALYSIS

The study size was preselected to be the first 100 consecutive documented out-of-hospital SCAs where the first ECG rhythm recorded by the AED was VF. A use was defined as any event in which the AED was attached to a patient regardless of whether or not a defibrillation shock was delivered. Assuming 40% of SCA patients present in VF,[21,55] it was estimated that 250 patients would be enrolled. Results are presented as means ± standard deviations (ranges), with 95% confidence intervals (CIs) where appropriate. $p \leq 0.05$ was considered statistically significant.

Results

The results of this study are an extension of data previously reported on 100 consecutive AED uses, including 44 SCA patients presenting in VF.[26] They are reproduced with permission from Futura Publishing Co., Inc., from Journal of Cardiovascular Electrophysiology, Volume 8, December 1997, pages 1373–1385.

STUDY ENROLLMENT

Thirty-four sites provided data on 286 consecutive AED uses from December 15, 1996, to February 9, 1998 (Table

TABLE 3. Summary of Automatic External Defibrillator (AED) Use

Number of study sites	34
Consecutive patients	286
Patients presenting with ventricular fibrillation (VF) Gender Age Sudden cardiac arrest (SCA) witnessed Bystander CPR	100 25 female, 65 male, 10 not reported 69 ± 15 (years) (36–89), 13 not reported 60 yes, 22 no, 18 not reported 27 yes, 49 no, 24 not reported
AED sensitivity to VF patients	100/100 (100%)
AED specificity to non-VF patients	186/186 (100%)
Presenting VF amplitude	0.48 ± 0.25 (mV) (0.10–1.35)
Presenting VF rate	259 ± 84 (bpm) (111–586)
Pre-shock VF amplitude	0.43 ± 0.31 (mV) (0.08–3.1)
Pre-shock VF rate	249 ± 79 (bpm) (97–514)
Call to shock interval	9.1 ± 7.3 (minutes) (2.5–50.2), 43 not reported
Number of VF episodes	450
Number of shocks delivered	590
Shocks per initial VF episode only	1.3 ± 0.8
Shocks per all VF episodes	1.3 ± 0.7
Shocks per patient	6.0 ± 6.3
Total AED use time	12.7 ± 8.5 (minutes) (0.9–34.5)

3). Sites contributing data to this study are listed in Appendix A. AEDs were applied by flight attendants (24), police officers (76), emergency medical technicians (126), non-EMT emergency responders (26), nurses (2), paramedics (8), ambulance physicians (in Europe) (18), and personnel not noted (6) (Figure 6A). There were 123 AED uses in the home, 31 during transportation (airplane 22, car 6, train 1, boat 1, ambulance 1), 21 in a health care facility (long-term

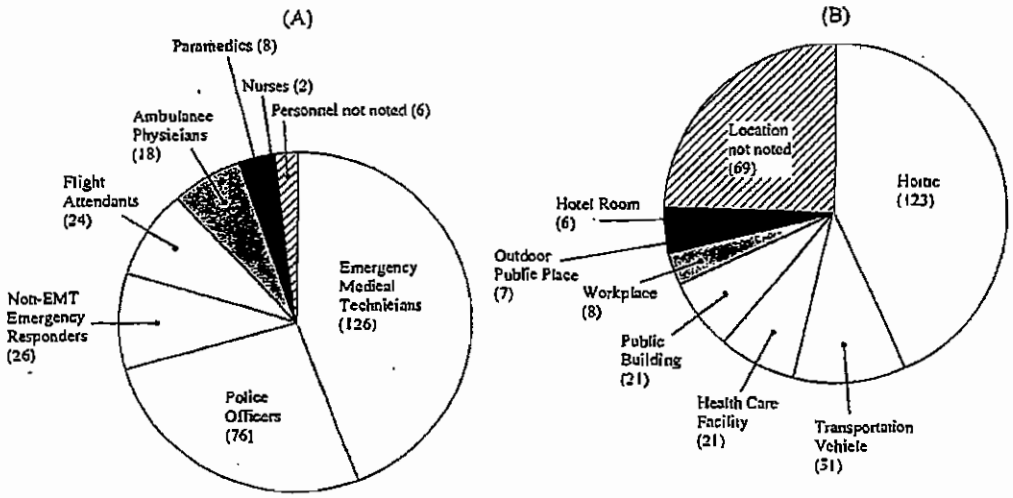


Figure 6. Distributions of (A) automatic external defibrillator users and (B) locations of use.

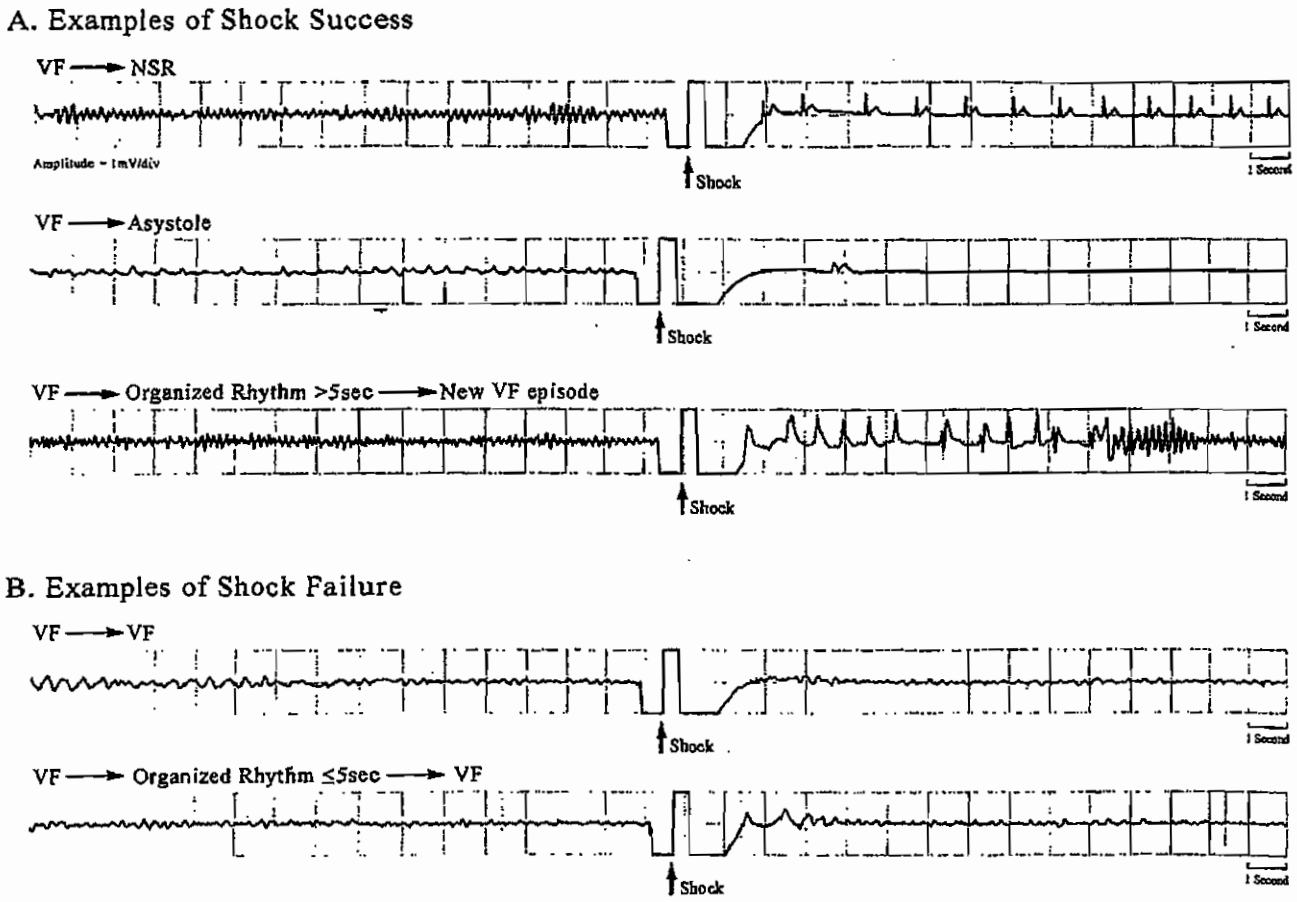


Figure 7. Representative ECGs and determination of defibrillation success 5 seconds post-shock.

care facility 11, outpatient clinic 9, physician's office 1), 21 in a public building (including 3 church/synagogue, 3 transportation hub, 1 concert hall, 1 restaurant, and 1 jail), 8 in the workplace, 7 at an outdoor public place, 6 in a hotel room, and 69 where the location was not noted (Figure 6B).

Of the 286 AED uses, 100 SCA victims had VF as their initial rhythm upon attachment of the AED. Of the 100 SCA victims presenting with VF [25 female, 65 male, 10 not reported; aged 69 ± 15 (36–89) years], 60 were known to have witnessed arrests and 27 were known to have received bystander CPR. Presenting (initial 4.5-second ECG segment) VF amplitude (median peak-to-peak) and rate were 0.48 ± 0.25 (0.10–1.35) mV and 259 ± 84 (111–586) bpm, respectively. (The low rates for some VFs reflect the long duration of VF prior to AED application. The VF in these patients had a low amplitude, low slew rate, and a slowly undulating near-sinusoidal characteristic deemed to require a shock.)

Amplitude of VF and rate immediately prior to each

TABLE 4. Low-Energy, Impedance-Compensating Biphasic-Waveform Defibrillation Efficacy

	Defibrillation Efficacy	95% Confidence Interval
Initial VF* episodes only		
1 shock	86/100 (86%)	78–92%
≤ 2 shocks	94/100 (94%)	87–98%
≤ 3 shocks	96/99 (97%)	91–99%
All VF* episodes†		
1 shock	86% ± 24%	81–91%
≤ 2 shocks	95% ± 14%	92–98%
≤ 3 shocks	97% ± 11%	95–100%

*Ventricular fibrillation.

†The independent variable in this analysis is patients, not shocks. Therefore, to reduce bias in the analysis, all VF episodes were analyzed as average defibrillation efficacy per patient.

shock were 0.43 ± 0.31 (0.08–3.1) mV and 249 ± 79 (97–514) bpm, respectively. Time from emergency call to first shock delivery, available for 52 of the presenting VF victims, was 9.1 ± 7.3 (2.5–50.2) minutes. The AED correctly identified all 100 VF patients (100% sensitivity), and correctly identified and did not shock all 186 patients presenting with non-VF rhythms (100% specificity). No device failure was encountered.

Figure 7 demonstrates the determination of defibrillation success at 5 seconds post-shock for representative ECGs.

DEFIBRILLATION EFFICACY—INITIAL VF EPISODE

Defibrillation was accomplished with a single 150 J biphasic shock in 86 of 100 *initial* VF episodes (86%) (Table 4, Figure 8). Two shocks or fewer defibrillated 94 of 100 initial VF episodes (94%). In one patient, resuscitation efforts were transferred to advanced life support (ALS) after two unsuccessful AED shocks were delivered to the initial VF episode. Of the remaining 99 VF patients, 96 (97%) were defibrillated with three shocks or fewer. The remaining three VF patients were defibrillated, requiring four, five, and seven shocks, respectively. The average number of shocks delivered per initial VF episode was 1.3 ± 0.8 (range 1–7).

The patients who required four, five, and seven shocks to terminate VF presented with VF amplitudes of 0.51, 0.30, and 0.18 mV, and VF rates of 162, 375, and 240 bpm, respectively. The call-to-shock times were 6.9 and 16.0 minutes for the four- and five-shock patients, respectively, and not reported for the seven-shock patient. Return of Spontaneous Circulation (ROSC) was achieved in

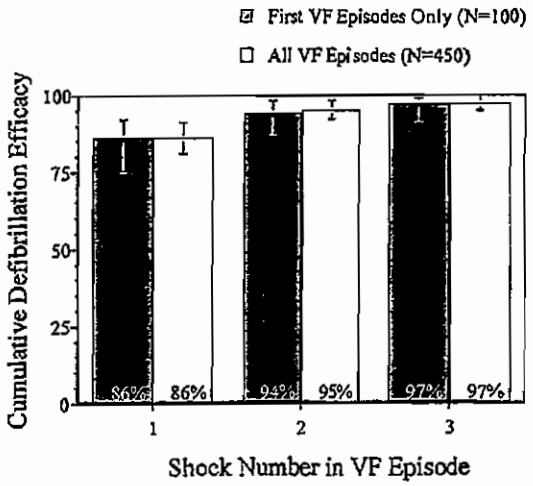


Figure 8. Cumulative 150-J impedance-compensating biphasic waveform defibrillation efficacies for initial episodes of ventricular fibrillation (VF) and for all VF episodes.

TABLE 5. Delivered 150-J Impedance-Compensating Biphasic-Waveform Parameters

Delivered energy	151 ± 2 (Joules) (142–157)
Peak delivered voltage	1,751 ± 6 (volts) (1,730–1,768)
Resistance	86 ± 26 (Ω) (36–170)
Peak delivered current	22.7 ± 8.0 (Amps) (10.3–48.6)
Total waveform duration	13.5 ± 3.8 msec (7.7–20.4)

the five-shock patient only. These measures were not significantly different from those of the VF patients requiring three shocks or fewer to terminate VF.

DEFIBRILLATION EFFICACY—ALL VF EPISODES

A total of 590 shocks were delivered to 450 episodes of VF in the 100 patients. An average of 86% ± 24% of VF episodes were terminated with a single biphasic shock, 95% ± 14% with two shocks or fewer, and 97% ± 11% with three shocks or fewer (Table 4, Figure 8). Only 11 of the 450 VF episodes (2%) required more than three shocks. The average number of shocks delivered per VF episode was 1.3 ± 0.7. Patients received 6.0 ± 6.3 (range 1–36) shocks during the use of the AED, which included ALS care in many cases. The high numbers of shocks for some patients reflect aggressive ALS treatment of patients presenting in low-amplitude, low-frequency VF associated with long arrest times. Due to the unstable nature of the extended arrest, VF tends to recur after successful defibrillation in these patients. The total use time for the AED was 12.7 ± 8.5 (0.9–34.5) minutes as measured from power-on to either power-off or pads off.

DEFIBRILLATION SHOCK CHARACTERISTICS

When averaged over each patient, delivered biphasic waveform energy was 151 ± 2 (142–157) J, peak voltage was 1,751 ± 6 (1,730–1,768) V, and peak current was 22.7 ± 8.0 (10.3–48.6) Amps with patient resistances of 86 ± 26 (36–170) Ω (Table 5, Figure 4). Consistent with the ability of this biphasic waveform to adapt to patient impedance, total biphasic waveform duration, 13.5 ± 3.8 (7.7–20.4) msec, varied proportionally with patient resistance. Patients with high average shock resistances ≥100 Ω (n = 23, r = 121 ± 18 Ω) were defibrillated in 93% ± 15% of attempts, compared with those with resistances <100 Ω (n = 77, r = 75 ± 18 Ω), who were defibrillated in 83% ± 25% attempts, p = 0.1.

ANALYSIS OF RHYTHM AT AED TRANSFER

Of the 100 patients presenting in VF, 85 developed an organized rhythm at least once at some point during the

resuscitation attempt (95% CI: 76–91%). The last rhythm recorded by the AED prior to transfer to ALS or emergency department (ED) personnel, or when the AED was powered off by the on-site physician, was available for 97 of the 100 VF patients. Either the defibrillation pads were removed or the AED was powered off immediately after shock delivery in three patients, not allowing the last rhythm to be assessed. The last rhythm recorded by the AED was organized in 63 patients (65%) and asystole in 24 patients (25%); VF was in progress in 10 patients (10%). Nine of the ten patients transferred in VF to ALS/ED personnel had previously been defibrillated by the AED, but were in mid-rhythm analysis at the time of AED disconnection by ALS/ED personnel. The tenth patient had received only two shocks prior to transfer and disconnection of the AED. Data regarding return of spontaneous circulation (ROSC) for patients presenting with VF, whether having witnessed or unwitnessed collapse, was available for 73 patients, and ROSC was achieved in 39 patients (53%).

AED USER INTERFACE

The time from AED power-on *and* pad attachment to the first shock delivered was 20 ± 9 (15–77) seconds and the time to first successful shock (defibrillation) was 25 ± 23 (15–167) seconds. The time from AED power-on only to first shock was 44 ± 29 (18–166) seconds, and the corresponding time to first successful shock (defibrillation) was 49 ± 34 (18–182) seconds. These times include delays for events such as defibrillation pad placement and repositioning the patient.

For patients who required more than one shock to terminate VF, the interval between the first and second shocks was 18.6 ± 3.1 (15.4–25.4) seconds. The interval between the second and third shocks was 18.7 ± 2.7 (16.8–20.6) seconds.

Discussion

The results of this study demonstrate that the low-energy impedance-compensating BTE waveform consistently terminates long-duration VF as encountered in out-of-hospital cardiac arrest. This study also confirms that automated impedance compensation maintains high defibrillation efficacy without the need to either step up energy levels or use high-energy shocks, with their attendant negative consequences on cardiac mechanics and electrophysiology. The AED incorporating this therapy was used efficiently and with good outcomes by a wide variety of responders, ranging from experienced EMS personnel to first time non-EMS, non-medical users.

RESULTING RHYTHM

During the use of an AED, it is expected that the patient's underlying acute disease state, the effects of defibrillation, and the effects of other interventions will affect outcome. In the course of resuscitation, rhythms change in a complex manner following defibrillation, including transitions into organized rhythms, asystole, and VF. As a consequence, it is important to measure the ability of the AED in conjunction with ALS care, such as epinephrine and other drug therapies, to restore an organized rhythm. In this study, most patients (85%) achieved an organized rhythm at some time during the resuscitation attempt. When the AED was turned off or removed (usually at hand-off to the next care provider), 65% of the patients were in an organized rhythm.

RETURN OF SPONTANEOUS CIRCULATION (ROSC)

Return of spontaneous circulation was achieved in 53% of the VF patients, including those who had both witnessed and unwitnessed arrests. With an emergency call-to-shock time of 9.4 ± 8.1 minutes for this subgroup, the presenting VF amplitude of only 0.44 mV and a rate of 256 bpm typify the long duration of arrest. Previous reports on ROSC originate only from experienced EMS systems and average 58% (ranging from 48% to 61%).[8,21,52,55,56] Our ROSC results are similar to the previously reported ROSC results, most likely because of comparable response times. One might have expected a diverse group of users, treating patients with low-amplitude VF and long response times, to have an even lower ROSC rate than that reported from single, well-experienced sites. It may be that the ease of use of the AED under study and its ability to defibrillate at a high rate resulted in relatively good ROSC rates in a population of cardiac arrest victims who were treated by more nontraditional users, 46% of whom were not EMT, paramedic, or physician responders.

It should be emphasized that survival from SCA to hospital discharge depends on many factors beyond the realm of the AED. The most significant factor is the duration of arrest. Even an ideal defibrillation waveform, one that is highly effective and produces minimal post-shock myocardial dysfunction, cannot completely compensate for long delays to defibrillation. Meaningful comparisons of ROSCs and patient survivals could be made only if it were possible to tightly control these variables in a prospective randomized trial. Given the nature of out-of-hospital research, the barriers to this type of study may be formidable. For these reasons, the measure of AED effectiveness should be defibrillation efficacy and not patient mortality. Secondarily, algorithm accuracy and human-factors design should be assessed. Post-shock myocardial dysfunction as a direct consequence of

defibrillation shocks delivered to ischemic tissue may also contribute to patient mortality.[49]

To have a significant impact on the 5% nationwide SCA survival rate, individuals, EMS systems, and communities must strive to reduce delays to defibrillation. Delays may include the interval from collapse to emergency call, and EMS activation and response times. Making AEDs available to minimally trained users on a widespread basis will dramatically reduce the delay to defibrillation and increase survival from SCA.

AED USER INTERFACE

The ability of a responder to deploy an AED quickly and properly is a critically important, often untested, characteristic of new AEDs. Given the critical relationship between early defibrillation and the likelihood of survival from SCA, an AED with a well-designed user interface may make a dramatic contribution to patient outcome.

The AED under study meets these criteria, as demonstrated by the brief time to attach pads, to deliver the first shock, and to defibrillate. The time from pad placement to first shock of 21 ± 10 seconds in this study of a wide range of users is much less than the 38 ± 27 seconds previously found by Weaver et al. when AEDs were used in an experienced EMS system.[55] The overall time from AED power-on to first shock delivery of 39 ± 26 seconds is also much less than 1.1 minutes reported in another AED study of experienced users by Cummins et al.[21] Using the model that the likelihood of survival from sudden cardiac arrest decreases by 10% for every minute that passes,[9] this well-designed AED user interface may itself significantly contribute to improved survival.

STUDY LIMITATIONS

One limitation of this study is that a concurrent comparison with a high-energy-waveform AED was not made. However, the objective of this study was to monitor the performance of the low-energy impedance-compensating biphasic-waveform AED in conditions best resembling typical use. The study conditions of a randomized, concurrent control protocol may introduce factors specific to the study protocol, which could potentially alter our observations. By performing a post-market-surveillance type of study (as recommended by the AHA Task Force on Automatic External Defibrillation),[51] device performance was assessed according to intended use across a broad spectrum of both new and experienced AED users.

Although concurrent controls were not obtained, a comparison with published high-energy monophasic-waveform data can be made. Publications were selected if they met all of the following criteria: 1) peer-reviewed publication of out-of-hospital sudden cardiac arrests, 2) either first shock or all shock defibrillation efficacy was reported, 3) the defibrillation waveform and energies were reported, and 4) defibrillation was attempted on a minimum of 20 patients. Publications were excluded if waveforms were mixed and performances for individual waveforms could not be distinguished, or in-hospital and out-of-hospital data were mixed and inseparable. Even though this meta-analysis was taken from different sources with many uncontrolled factors that might potentially influence results, it gives a practical representation of the performance of high-energy monophasic-waveform defibrillation across a variety of EMS systems (as in our study).

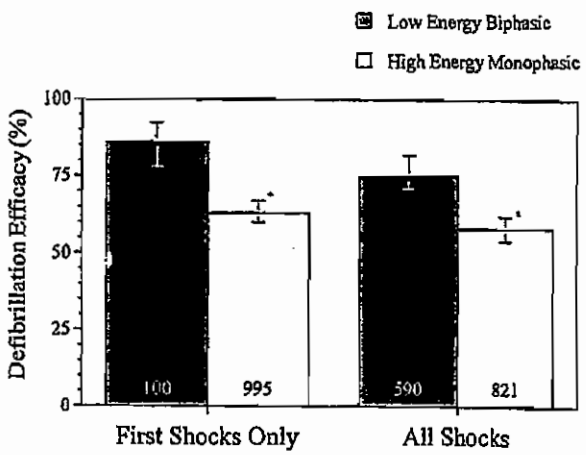


Figure 9. Comparison of the defibrillation effectiveness of the 150-J impedance-compensating biphasic waveform with the average published results for high-energy shocks. *$p < 0.0001$ by chi-square analysis.

In our study, the first-shock defibrillation rate for the 150-J biphasic waveform of *initial* VF episodes was 86%, significantly higher than the pooled defibrillation efficacy for high-energy monophasic waveforms of 628/995 (63%) for first shocks ($p < 0.0001$) (Figure 9). The single-shock defibrillation rate in our study for *all* VF episodes of 86% cannot be compared with rates in published studies of other waveforms, as this measure of device efficacy has not been previously reported. The 150-J biphasic-waveform defibrillation rate for all shocks combined was 75%, compared with 477/821 (58%) for all high-energy monophasic shocks ($p < 0.0001$).[8,21,29,52,55,56] Thus, this biphasic waveform terminates VF at a higher rate than those reported with high-energy monophasic waveform shocks. Statistical comparisons should be made with caution, acknowledging the inherent limitations previously described.

Conclusion

The impedance-compensating low-energy BTE waveform employed in this study's AED consistently terminated

long-duration VF as encountered in out-of-hospital SCA. The observed defibrillation rates exceed those of published studies of higher-energy monophasic waveforms. Higher energy is *not* clinically warranted with this BTE waveform. The efficient user interface and high defibrillation efficacy of this low energy biphasic waveform allow the AED to have device characteristics consistent with widespread deployment and early defibrillation. These findings suggest that the role of higher-energy waveforms, with their potential to adversely affect early defibrillation efforts as well as cardiac mechanics, requires further study.

REFERENCES

1. Emergency Cardiac Care Committee and Subcommittees, American Heart Association. Guidelines for cardiopulmonary resuscitation and emergency cardiac care. I. Introduction. JAMA. 1992;268:2172–83.
2. Myerburg RJ, Kessler KM, Castellanos A. Sudden cardiac death: structure, function, and time-dependence of risk. Circulation. 1992;85:I2–I10.
3. Ryan TJ, Anderson JL, Antman EM, et al. ACC/AHA guidelines for the management of patients with acute myocardial infarction: executive summary. Circulation. 1996;94: 2341–50.
4. Gillum RF. Sudden coronary death in the United States. Circulation. 1989;79:756–65.
5. Bayes de Luna A, Coumel P, Leclercq JF. Ambulatory sudden cardiac death: mechanisms of production of fatal arrhythmia on the basis of data from 157 cases. Am Heart J. 1989;117: 151–9.
6. Hearne TR, Cummins RO. Improved survival from cardiac arrest in the community. Pacing Clin Electrophysiol. 1988; 11:1968–73.
7. Emergency Cardiac Care Committee and Subcommittees, American Heart Association. Guidelines for cardiopulmonary resuscitation and emergency cardiac care. IX. Ensuring effectiveness of community-wide emergency cardiac care. JAMA. 1992;268:2289–95.
8. Weaver WD, Copass MK, Bufi D, Ray R, Hallstrom AP, Cobb LA. Improved neurologic recovery and survival after early defibrillation. Circulation. 1984;69:943–8.
9. Eisenberg MSEC, Horwood BT, Cummins RO, Reynolds-Haertle R, Hearne TR. Cardiac arrest and resuscitation: a tale of 29 cities. Ann Emerg Med. 1990;19:179–186.
10. Spaite DW, Hanlon T, Criss EA, et al. Prehospital cardiac arrest: the impact of witnessed collapse and bystander CPR in a metropolitan EMS system with short response times. Ann Emerg Med. 1990;19:1264–9.
11. Larsen MP, Eisenberg MSEC, Cummins RO, Hallstrom AP. Predicting survival from out-of-hospital cardiac arrest: a graphic model. Ann Emerg Med. 1993;22:1652–8.
12. Weaver WD, Cobb LA, Hallstrom AP, Fahrenbruch CE, Copass MK, Ray R. Factors influencing survival after out-of-hospital cardiac arrest. J Am Coll Cardiol. 1986; 7:752–7.
13. Herlitz J, Ekström L, Wennerblom B, Axelsson Å, Bång A, Holmberg S. Survival in patients found to have ventricular fibrillation after cardiac arrest witnessed outside hospital. Eur Heart J. 1994;15:1628–33.
14. Becker LB, Ostrander MP, Barrett J, Kondos GT. Outcome of CPR in a large metropolitan area—where are the survivors? Ann Emerg Med. 1991;20:355–61.
15. Lombardi G, Gallagher EJ, Gennis P. Outcome of out-of-hospital cardiac arrest in New York City: the Pre-Hospital Arrest Survival Evaluation (PHASE) Study. JAMA. 1994; 271:678–83.
16. White RD, Vukov LF, Bugliosi TF. Early defibrillation by police: initial experience with measurement of critical time intervals and patient outcome. Ann Emerg Med. 1994;23: 1099–1113.
17. White RD, Asplin BR, Bugliosi TF, Hankins DG. High discharge survival rate after out-of-hospital ventricular fibrillation with rapid defibrillation by police and paramedics. Ann Emerg Med. 1996;28:480–5.
18. Weisfeldt ML, Kerber RE, McGoldrick RP, et al. American Heart Association Report on the Public Access Defibrillation Conference, December 8–10, 1994: Automatic External Defibrillation Task Force. Circulation. 1995;92:2740–7.
19. Emergency Cardiac Care Committee and Subcommittees, American Heart Association. Guidelines for cardiopulmonary resuscitation and emergency cardiac care. III. Adult JAMA. 1992;2199:2172–2241.
20. Kloeck W, Cummins RO, Chamberlain D, et al. Early defibrillation. An advisory statement by the Advanced Life Support Working Group of the International Liaison Committee on Resuscitation. Circulation. 1997:15;95:2183–4.
21. Cummins RO, Eisenberg MSEC, Litwin PE, Graves JR, Hearne TR, Hallstrom AP. Automatic external defibrillators used by emergency medical technicians: a controlled clinical trial. JAMA. 1987;257:1605–10.
22. Weaver WD, Hill D, Fahrenbruch CE, et al. Use of the automatic external defibrillator in the management of out-of-hospital cardiac arrest. N Engl J Med. 1988;319:661–6.
23. Cummins RO, Chesemore K, White RD. Defibrillator failures: causes of problems and recommendations for improvement. JAMA. 1990;264:1019–25.
24. Association for the Advancement of Medical Instrumentation. ANSI/AAMI DF2: 1996, Cardiac defibrillator devices.
25. Alferness C, Ideker RE. The influence of shock waveforms on defibrillation efficacy. IEEE Eng Med Biol. 1990;12:25–7.
26. Poole JE, White RD, Kanz KG, et al. Low-energy impedance-compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out-of-hospital cardiac arrest. J Cardiovasc Electrophysiol. 1997;8:1373–85.
27. White RD. Early out-of-hospital experience with an imped-

ance-compensating low-energy biphasic waveform automatic external defibrillator. J Interventional Cardiac Electrophysiology. 1997;1:203–8.
28. Bardy GH, Marchlinski FE, Sharma AD, et al. Multicenter comparison of truncated biphasic shocks and standard damped sine wave monophasic shocks for transthoracic ventricular defibrillation. Circulation. 1996;94:2507–14.
29. Behr JC, Hartley LL, York DK, Brown DD, Kerber RE. Truncated exponential versus damped sinusoidal waveform shocks for transthoracic defibrillation. Am J Cardiol. 1996; 78:1242–5.
30. Dalzell GWN, Cunningham SR, Anderson J, Adgey AAJ. Electrode pads size, transthoracic impedance and success of external ventricular defibrillation. Am J Cardiol. 1989; 64:741–4.
31. Kerber RE, Kouba CK, Martins J, et al. Advance prediction of transthoracic impedance in human defibrillation and cardioversion: importance of impedance in determining the success of low-energy shocks. Circulation. 1984;70:303–8.
32. Kerber RE, Martins JB, Kienzle MG, et al. Energy, current, and success in defibrillation and cardioversion: clinical studies using an automated impedance-based method of energy adjustment. Circulation. 1988;77:1038–46.
33. Lown W, Neuman J, Amarasingham R, Berkovitz BV. Comparison of alternating currents with direct countershock. Am J Cardiol. 1962:10:223–33.
34. Edmark KW. Simultaneous voltage and current waveforms generated during internal and external direct current defibrillation. Surg Forum. 1963:51;326–33.
35. Geddes LA, Tacker WA, McFarlane J, Bourland J. Strength-duration curves for ventricular defibrillation in dogs. Circ Res. 1970;27:551–60.
36. Schuder JC, Stoeckle H, West JA, Keskar PY. Transthoracic ventricular defibrillation in dogs with truncated and untruncated exponential stimuli. IEEE Trans Biomed Eng. 1971;18:410–5.
37. Schuder JC, Rahmoeller GA, Stoekle H. Transthoracic ventricular defibrillation with trangular and trapezoidal waveforms. Circ Res. 1966;19:690–4.
38. Gliner BE, Lyster TE, Dillon SM, Bardy GH. Transthoracic defibrillation of swine with monophasic and biphasic waveforms. Circulation. 1995;92:1634–43.
39. Gold JH, Schuder JC, Stoeckle H. Contour graph for relating per cent success in achieving ventricular defibrillation to duration, current, and energy content of shock. Am Heart J. 1979;98:207–12.
40. Anderson GJ, Suelzer J. The efficacy of trapezoidal wave forms for ventricular defibrillation. Chest. 1976;70:298–300.
41. Brewer JE, Lilja GP, Tay SW, Mason J. Automated external defibrillators using truncated exponential waveforms have good field performance. Prehosp Emerg Care. 1997;1:190.
42. Winkle RA, Mead RH, Ruder MA, et al. Improved low energy defibrillation efficacy in man with the use of a biphasic truncated exponential waveform. Am Heart J. 1989;117:122–7.
43. Bardy GH, Ivey TD, Allen MD, Johnson G, Mehra R, Greene HL. A prospective, randomized evaluation of biphasic vs monophasic waveform pulses on defibrillation efficacy in humans. J Am Coll Cardiol. 1989;14:728–33.
44. Swartz JF, Fletcher RD, Karasik PE. Optimization of biphasic waveforms for human nonthoracotomy defibrillation. Circulation. 1993;33:2646–54.
45. Charbonnier FM. External defibrillators and emergency exernal pacemakers. Proc IEEE. 1996;84:487–99.
46. Jones JL, Jones RE. Decreased defibrillator-induced dysfunction with biphasic rectangular waveforms. Am J Physiol. 1984;247:H792–H796.
47. Jones JL, Jones RE, Balasky G. Improved defibrillator waveform safety factor with biphasic waveforms. Am J Physiol. 1983;245:H60–H65.
48. Osswald S, Trouton TG, O'Nunain SS, Holden HB, Ruskin JN, Garan H. Relation between shock-related myocardial injury and defibrillation efficacy of monophasic and biphasic shocks in a canine model. Circulation. 1994;90:2501–9.
49. Xie J, Weil MH, Sun S, et al. High-energy defibrillation increases the severity of postresuscitation myocardial dysfunction. Circulation. 1997:96;683–8.
50. Crampton R. Accepted, controversial, and speculative aspects of ventricular defibrillation. Progr Cardiovasc Dis. 1980;23:167–86.
51. Kerber RE, Becker LB, Bourland JD, et al. Automatic external defibrillators for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety. A statement for health care professionals from the American Heart Association Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. Circulation. 1997;95:1677–82.
52. Weaver WD, Cobb LA, Copass MK, Hallstrom AP. Ventricular defibrillation—a comparative trial using 175-J and 320-J shocks. N Engl J Med. 1982;307:1101–6.
53. Chen PS, Shibata N, Dixon EG, et al. Activation during ventricular defibrillation in open-chest dogs. J Clin Invest. 1986; 77:810–23.
54. Usui M, Callihan RL, Walker RG, et al. Epicardial sock mapping following monophasic and biphasic shock of equal voltage and an endocardial lead system. J Cardiovasc Electrophysiol. 1996;7:322–34.
55. Weaver WD, Martin JS, Wirkus MJ, et al. Influence of external defibrillator electrode polarity on cardiac resuscitation. Pacing Clin Electrophysiol. 1993;16:285–90.
56. Cummins RO, Eisenberg MSEC, Hallstrom AP, et al. What is a "save"?: outcome measures in clinical evaluations of automatic external defibrillators. Am Heart J. 1985;110: 1133–8.

APPENDIX A

The LIFE (*L*ow-Energy *I*mpedance-Compensating Biphasic Waveform *F*ield *E*xperience) Investigators listed according to the numbers of patients contributed.

Gold Cross Ambulance Service and City of Rochester Police Department
Roger D. White, MD, Professor of Anesthesiology, Mayo Medical School; Co-Medical Director, Gold Cross Ambulance Service; Medical Director, City of Rochester Police Department Defibrillation Program
Rochester, MN

Hatzolah Volunteer Ambulance
New York, NY

American Airlines
David K. McKenas, MD, Director, Corporate Medical Department
Dallas, Texas

Everett Fire Department
Jack C. Robinson, Deputy Chief
Everett, WA

Monterey County Emergency Medical Services Agency
James Stubblefield, MD
Monterey, CA

Universität München
Karl-Georg Kanz, MD
Munich, Germany

Glendora Police Department
Captain Leonard J. Pihlak
Glendora, CA

Kalamazoo County Medical Control Authority
William D. Fales, MD, Director of Prehospital Care, Department of Emergency Medicine
Kalamazoo, MI

Kings County Fire Department
Valerie Santana, RN, EMT-D Program Coordinator
Hanford, CA

PAPP Clinic
G. Truett Jarrard, MD
Newnan, GA

Kitsap County EMS
Luke Magnotto, MD, Medical Program Director
Bremerton, WA

Lewis County Fire District Number Five
Patrick O'Neill, MD, Medical Director
Centralia, WA

Orem Fire Department
Ralph C. Derico, Fire Captain
Orem, UT

Yakima County Department of EMS
Michael W. Campbell, Director
Yakima, WA

Aiken County Emergency Services
Aiken, SC

Chenango Forks Medical Team
Sally Merritt, EMT
Chenango Forks, NY

Holden EMS
Terri Smith, Director
Holden, MO

Mirage Resorts Inc.
Alan W. Feld, MD, Medical Director for AED Program Mirage Resorts Inc.
Las Vegas, NV

Fabio D'Este, MD
Mestre Emergenza
Venice, Italy

Sanilac Medical Control Authority
John R. Turner, Executive Director
Sandusky, MI

Sharkey-Issaquena Community Hospital Ambulance Service
Andrew George, MD, Medical Director
Rolling Forks, MSEC

City of Springfield Department of Fire and Life Safety
Frederick E. Lundgren, EMS Program Officer
Springfield, OR

Cheltenham General Hospital
Katherine Bassey, Resuscitation Training Officer
Cheltenham, Gloucestershire, UK

China Grove Fire and Rescue
Gene Ripps, EMT-B, Fire Chief
San Antonio, TX

Dunn County Medical Emergency First Responders Program
Nathan Rich, MD, Medical Director
Menomonie, WI

Event Medical Services, Inc.
Dean Grose, EMT, Medical Coordinator
Los Alamitos, CA

Knob Noster Fire Department
Rick Johnson, Chief
Knob Noster, MO

Law Hospital N.H.S. Trust
Ian McConnell, Resuscitation Training Officer
Cerluke, Lanertshire, Scotland

Minneapolis Fire Department
Charlotte Holt, EMS Coordinator
Minneapolis, MN

New York University Downtown Hospital
Patricia A. Strizak, Director, Emergency Care Institute
New York, NY

The Institute of Critical Care Medicine
Max Harry Weil, MD, Ph.D.
Palm Springs, CA

City of Phoenix Fire Department
John V. Gallagher III, M.D.
Phoenix, AZ

Staffordshire Ambulance Service N.H.S. Trust
Simon Davies, Clinical Services Manager
Stafford, UK

Westcountry Ambulance Service
Graham G. Kemp, A.A.S.I. Training Officer
Derriford, Plymouth, Devon, UK

USE OF AUTOMATED EXTERNAL DEFIBRILLATORS BY A U.S. AIRLINE

RICHARD L. PAGE, M.D., JOSÉ A. JOGLAR, M.D., ROBERT C. KOWAL, M.D., PH.D., JASON D. ZAGRODZKY, M.D., LAUREN L. NELSON, B.S.N., KARTHIK RAMASWAMY, M.D., SAVERIO J. BARBERA, M.D., MOHAMED H. HAMDAN, M.D., AND DAVID K. MCKENAS, M.D., M.P.H.

ABSTRACT

Background Passengers who have ventricular fibrillation aboard commercial aircraft rarely survive, owing to the delay in obtaining emergency care and defibrillation.

Methods In 1997, a major U.S. airline began equipping its aircraft with automated external defibrillators. Flight attendants were trained in the use of the defibrillator and applied the device when passengers had a lack of consciousness, pulse, or respiration. The automated external defibrillator was also used as a monitor for other medical emergencies, generally at the direction of a passenger who was a physician. The electrocardiogram that was obtained during each use of the device was analyzed by two arrhythmia specialists for appropriateness of use. We analyzed data on all 200 instances in which the defibrillators were used between June 1, 1997, and July 15, 1999.

Results Automated external defibrillators were used for 200 patients (191 on the aircraft and 9 in the terminal), including 99 with documented loss of consciousness. Electrocardiographic data were available for 185 patients. The administration of shock was advised in all 14 patients who had electrocardiographically documented ventricular fibrillation, and no shock was advised in the remaining patients (sensitivity and specificity of the defibrillator in identifying ventricular fibrillation, 100 percent). The first shock successfully defibrillated the heart in 13 patients (defibrillation was withheld in 1 case at the family's request). The rate of survival to discharge from the hospital after shock with the automated external defibrillator was 40 percent. A total of 36 patients either died or were resuscitated after cardiac arrest. No complications arose from use of the automated external defibrillator as a monitor in conscious passengers.

Conclusions The use of the automated external defibrillator aboard commercial aircraft is effective, with an excellent rate of survival to discharge from the hospital after conversion of ventricular fibrillation. There are not likely to be complications when the device is used as a monitor in the absence of ventricular fibrillation. (N Engl J Med 2000;343:1210-6.)

SUDDEN cardiac arrest remains a leading cause of death in the United States.[1] Defibrillation performed soon after the onset of cardiac arrest is the most important determinant of survival. As a result, efforts have been undertaken by the American Heart Association to implement programs to ensure public access to defibrillation.[2,3] Recent advances in the design of the automated external defibrillator have made it small, simple to use, and easy to maintain. As discussed at the 31st Bethesda Conference on emergency cardiac care, the use of automated external defibrillators has generally been successful when the devices have been made available to persons other than traditional emergency-response personnel.[4]

Commercial aircraft create a unique environment for the use of the automated external defibrillator. Before the development of the device, emergency response was not available until diversion and landing of the airplane, creating a delay that eliminated all but the most remote chance of survival. Although use of the automated external defibrillator as a monitor is not one of the labeled indications, the device can be used to assist volunteer medical personnel in emergencies in which cardiac arrest is not present. When the automated external defibrillator is on board an aircraft parked at a terminal gate, it can also be used in the emergency care of passengers nearby in the terminal (an environment in which levels of stress and the potential for cardiac arrest are high).[5] The likely benefit of access to defibrillators on aircraft has been weighed against the potential risk to passengers.[6]

In March 1997, American Airlines, a large commercial airline, began to place automated external defibrillators aboard selected aircraft. The program has grown to include the placement of the device on all flights and the training of all 24,000 flight attendants. Training consists of four hours of instruction (one hour in the classroom and three hours in a workshop), followed annually by a one-and-a-half-hour refresher workshop and an examination. Previously, we reported the first successful resuscitation of a passenger with the use of an automated external defibrillator aboard one of the aircraft.[7] We subsequently analyzed the experience of the program, including data on the use of the device in 200 patients.

METHODS

Equipment and Protocol

The automated external defibrillator (Hewlett–Packard Heartstream ForeRunner, model E, Hewlett–Packard [Agilent Technol-

From the Section of Clinical Cardiac Electrophysiology, Division of Cardiology, Department of Internal Medicine, University of Texas Southwestern Medical Center, Dallas (R.L.P., J.A.J., R.C.K., J.D.Z., L.L.N., K.R., S.J.B., M.H.H.); and American Airlines, Fort Worth, Tex. (D.K.M.). Address reprint requests to Dr. Page at the Division of Cardiology, Department of Internal Medicine, University of Texas Southwestern Medical Center, Rm. CS7.102, 5323 Harry Hines Blvd., Dallas, TX 75390-9047, or at rpage@parknet.pmh.org.

ogies], Seattle) delivers a nonprogressive sequence of three 150-J shocks with a biphasic, truncated exponential wave form and adjusts automatically to the impedance across the chest. The device measures 6 by 22 by 20 cm and weighs 2 kg. The electrode pads are 100 cm^2 in size, and illustrations for placement on the right infraclavicular region and the left lateral wall of the chest are printed on the backs of the electrode pads. A single electrocardiographic tracing is displayed, recorded from the electrode pads. The device is semiautomatic: through a recorded voice, it provides audible analysis and instructions to initiate a shock if criteria for defibrillation are met. A shock is delivered only if the operator presses the button after recommendation by the device.

In response to symptoms that may indicate sudden cardiac arrest (unconsciousness, absence of breathing, and absence of detectable pulse), the flight crew follows a specific protocol for use of the defibrillator. The passenger is moved to the aisle, galley, or bulkhead; clothing covering the chest is removed; and the electrode pads are placed on the chest, which, if necessary, has been cleaned, dried, and shaved. The assistance of medical personnel is solicited, although the flight attendants follow the protocol independently of such advice. The automated external defibrillator may also be used for other medical problems, generally at the request of passengers who are physicians.

Review of the Event and Analysis of the Data

After each use of the defibrillator, two specialists in arrhythmia review the data, which consist of the electrocardiogram and files from the medical department of American Airlines. The current analysis includes data from all devices installed on aircraft that were used to evaluate or treat passengers in a medical emergency, both those used aboard the aircraft and those used in the adjoining terminal (when they were the closest defibrillators available).

The study was approved by the institutional review board of the University of Texas Southwestern Medical Center, Dallas. The board permitted waiver of informed consent because the study involved anonymous data collected for nonresearch purposes.

RESULTS

Characteristics of the Patients

From June 1, 1997, to July 15, 1999, automated external defibrillators were used on 200 persons (66 percent male; mean age, 58 years), 191 of whom were aboard the aircraft and 9 of whom were in the terminal. Transient or persistent loss of consciousness was documented in 99 persons (49.5 percent). In the remaining persons, the device was placed after a primary diagnosis of chest pain (62 patients), dyspnea (19), nausea or malaise (8), light-headedness (3), palpitations (3), or stroke (1) or for unclear reasons (5). In 139 patients (69.5 percent), a physician assisted.

Electrocardiographic Data

Among the 200 persons on whom the automated external defibrillator was placed, the device functioned appropriately in all but 1 case, in which a 73-year-old woman reported chest pain and remained conscious. In 14 of the remaining 199 cases, the solid-state memory card of the device failed or was erased inadvertently, leaving a total of 185 electrocardiograms available for review. Sample electrocardiograms are shown in Figures 1 and 2.

In 145 patients, the initial rhythm recorded was a

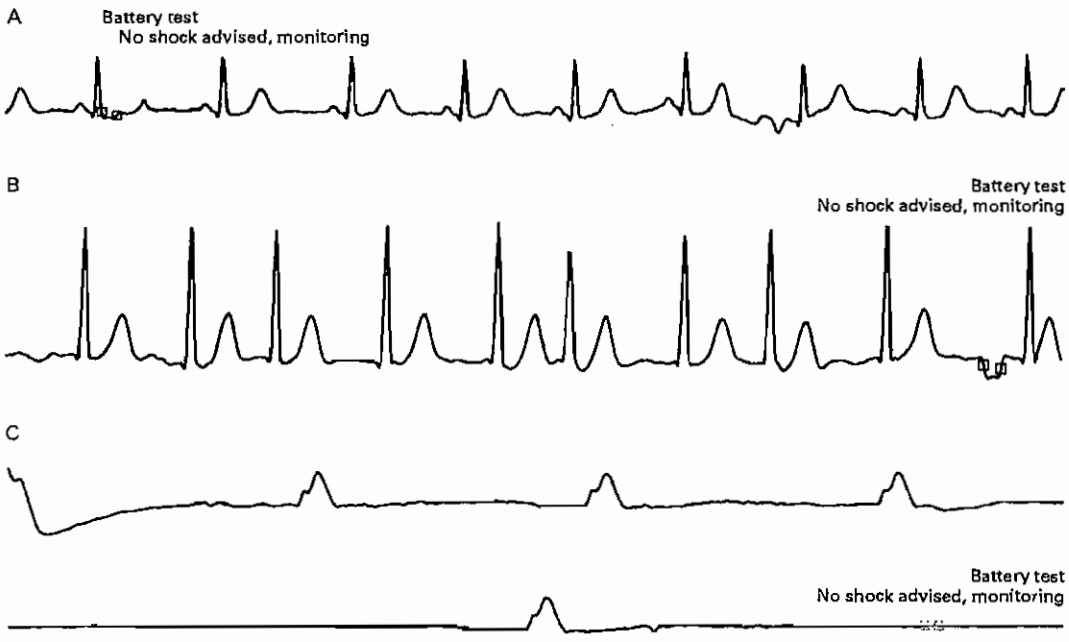


Figure 1. Electrocardiograms from the Automated External Defibrillator for Passengers in Whom Shock Was Not Recommended. Panel A shows sinus rhythm, Panel B shows atrial fibrillation, and Panel C shows agonal rhythm. The patients whose electrocardiograms are shown in Panels A and B survived, but the patient whose electrocardiogram is shown in Panel C did not. The labels shown in each panel depict the activity of the device, including testing of the battery, as displayed on the electrocardiographic tracing.

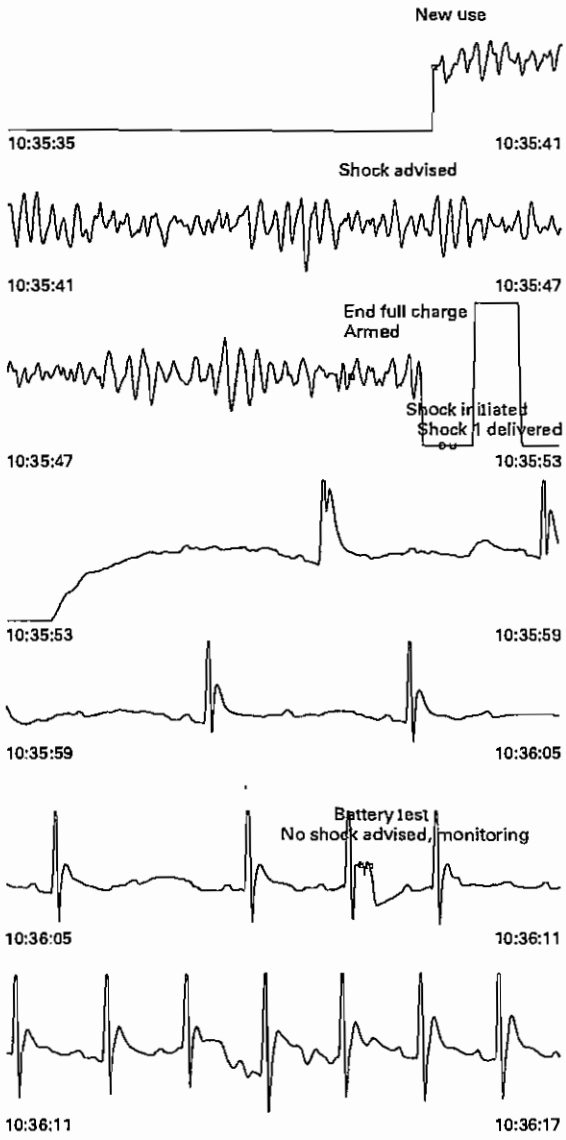


Figure 2. Ventricular Fibrillation as Recorded on an Aircraft.

Ventricular fibrillation was successfully converted in this passenger after a total recording of 12 seconds, resulting in a pause followed by sinus rhythm with 2:1 atrioventricular conduction and then normal conduction to the ventricle. The passenger survived to be discharged from the hospital. The labels shown depict the activity of the device, including testing of the battery, as displayed on the electrocardiographic tracing.

sinus rhythm. Bradycardia was present in 14 of these patients, and tachycardia in 21. Atrial fibrillation was found in eight patients, junctional rhythm in three, and supraventricular tachycardia and multifocal atrial tachycardia in one patient each. An agonal rhythm (defined as an idioventricular rhythm at fewer than 30 beats per minute) was seen initially in 13 patients, and ventricular fibrillation was documented in 14 (Fig. 1 and 2).

Defibrillator Shocks and Survival

In each of the 14 patients with documented ventricular fibrillation, the arrhythmia was recognized and cardioversion was recommended. Shock was withheld at the family's request in one man who was terminally ill. In the remaining 13 patients, the presenting episode of ventricular fibrillation was terminated with the first shock. Thus, for the documented episodes of ventricular fibrillation, the sensitivity of the device was 100 percent (14 of 14) and success in terminating the first episode was 100 percent (13 of 13). An example is shown in Figure 2. Recurrent fibrillation (for a total of up to eight episodes) occurred in eight patients; each episode was successfully terminated, except in one patient, who had cardiac arrest at the gate before his flight. In this patient, conversion was initially achieved with a single shock. For 20 minutes he received further care from a volunteer physician who was at the scene; during this period the arrhythmia recurred seven times. Each shock was successful until the eighth occurrence of arrhythmia, when fibrillation persisted despite three shocks. The patient was subsequently transferred to a hospital by emergency medical personnel and died.

Two other patients died after shocks were delivered (after three shocks in one patient and after two shocks in another patient), but the electrocardiographic data were lost. Both patients were unconscious, apneic, and without a pulse. The appropriateness of these shocks cannot be assessed, but for statistical purposes these cases have been considered to represent ventricular fibrillation and failed resuscitation.

Of the 15 patients who received shocks (13 for documented and 2 for presumed ventricular fibrillation), 6 (40 percent) were subsequently discharged home with full neurologic and functional recovery. Four of the 15 patients who received shocks had cardiac arrest in the terminal; none of these patients survived. Eleven of the 15 patients had documented or presumed ventricular fibrillation and received shocks aboard the aircraft, with 6 (55 percent) surviving to discharge from the hospital. Electrocardiographic data and outcomes are shown in Table 1.

All Deaths and Cardiac Arrests

A total of 36 patients either died or were resuscitated after cardiac arrest (29 on the aircraft and 7 in the terminal). In addition to the 16 with documented

TABLE 1. RESULTS OF USE OF THE AUTOMATED EXTERNAL DEFIBRILLATOR IN 200 PASSENGERS ON BOARD AN AIRCRAFT OR AT THE AIRLINE TERMINAL, ACCORDING TO THE INITIAL FINDINGS.*

VARIABLE	LOSS OF CONSCIOUSNESS (N=99)					NO LOSS OF CONSCIOUSNESS (N=101)		
	SINUS RHYTHM (N=61)	SVA (N=5)	AGONAL RHYTHM (N=13)	VF (N=14)	NO DATA AVAILABLE (N=6)	SINUS RHYTHM (N=84)	SVA (N=8)	NO DATA AVAILABLE (N=9)
Shock recommended — no.	0	0	0	14	2	0	0	0
Shock delivered — no.	0	0	0	13†	2	0	0	0
Survived to hospital discharge after shock — no. (%)				6 (40)				

*SVA denotes supraventricular arrhythmia including atrial fibrillation, and VF ventricular fibrillation. One patient for whom no data were available had the defibrillator put in place, but no electrocardiogram was recorded at the scene. In the other cases in which data were not available, the electrocardiogram recorded at the scene was inadvertently erased before it could be reviewed.

†In the case of one passenger, no shock was delivered, at the request of the family.

or presumed ventricular fibrillation, 20 patients died at the scene or after transfer from the airport; none required or received a shock. Thirteen patients initially had agonal rhythms. One patient, who was assessed as having died an hour or more before being discovered, had no cardiac electrical activity and very high transthoracic impedance. Six patients showed initially stable rhythms that deteriorated either while they were being monitored by the defibrillator or after transfer to emergency personnel.

Use of the Defibrillator as a Monitor

The automated external defibrillator was placed and recorded an electrocardiogram in 171 patients who did not have ventricular fibrillation and in whom shock from the defibrillator would therefore not have been appropriate. In 101 of 200 cases (50.5 percent), the device was placed without documented loss of consciousness, generally on the recommendation of a passenger who was a physician. In these persons, shock was not recommended by the device and was not administered. Thus, the specificity of the algorithm for the delivery of shock was 100 percent. In 12 patients who survived and did not receive shock, data were recorded but lost; the favorable outcome of these patients suggests that the algorithm appropriately did not recommend defibrillation.

Frequency of Placement of the Defibrillator

In the current series, automated external defibrillators were present on 627,956 flights (or for 1442 million km [896 million miles]) carrying 70,801,874 passengers. The number of flights represents less than one full year of travel on American Airlines, which had a total of 792,168 flights in 1998. A defibrillator was used once for every 3288 flights, and a death or resuscitation after cardiac arrest occurred once in every 21,654 flights.

On the basis of these data and industry estimates that American Airlines represents 18 percent of the domestic market and that U.S. air traffic accounts for 45 percent of commercial flights worldwide, we calculated the potential use of automated external de- fibrillators globally if all commercial planes were so equipped. Our estimates suggest that the device would be used 2975 times for 452 patients with cardiac arrest while on board an aircraft, saving the lives of 93 persons with ventricular fibrillation each year.

DISCUSSION

In the first two years after installation, during which the device was used 200 times aboard a U.S. aircraft, the automated external defibrillator performed satisfactorily. The device recognized ventricular fibrillation in 14 patients with 100 percent sensitivity and specificity and terminated every initial episode with the first shock. The rate of survival after defibrillation to discharge from the hospital, 40 percent, compares favorably with the rate of survival to discharge among patients who received a defibrillator shock in other out-of-hospital settings. In addition, the device was safe when used as a monitor; in no case was an inappropriate shock recommended or delivered.

In the past, the number of deaths per year on commercial airlines has not been well defined. The International Air Transport Association reported only 72 deaths per year (the majority of them sudden) between 1977 and 1984, an estimate that is likely to be low[8] since others have suggested that there may be up to 1000 such deaths per year on commercial flights.[9] By an act of Congress,[10] data on emergencies on aircraft were collected for the period from July 1, 1998, through June 30, 1999; the results showed a total of 108 deaths on the 15 major U.S. carriers. Unfortunately, the accuracy of these data is highly variable and the scope of the problem is likely to be un-

derreported.[11] Our data confirm that the number of deaths on aircraft has been underestimated.

The aircraft is a unique setting for cardiac arrest, and air travel may expose or exacerbate medical conditions. Contributing factors include the stress associated with flying, exertion in reaching the gate, disruption of circadian rhythms, and reduced oxygen tension in the cabin (equivalent to that found at an elevation of 1844 to 2576 m [6050 to 8450 ft] above sea level).[12] In addition, the aircraft is poorly designed for the recognition and treatment of cardiac arrest. An unconscious passenger may be assumed to be asleep, so that the cardiac arrest is not noticed in spite of a crowded environment. After the cardiac arrest is recognized, treatment is complicated by difficulty in reaching the patient, noise, vibration, and a lack of privacy.[13]

The most important limitation in delivering treatment to patients with cardiac arrest on board an aircraft has been the lack of availability of advanced-life-support devices. Under the best of circumstances, approximately 20 minutes is required for diversion and emergency landing of an aircraft. Even when the airplane is already on the runway, it may take 10 to 15 minutes to return to the terminal.[14] Such delay in defibrillation translates into a very poor prognosis.[15]

In spite of the potential benefits associated with placing automated external defibrillators aboard aircraft, there has been concern about the associated risks. Issues of passenger or crew safety have been raised, along with the issue of potential injury to the patient. Our experience suggests that there is no basis for such concern.

In 1990 and 1991, respectively, Virgin Atlantic Airways and Qantas Airways began equipping their aircraft with automated external defibrillators. On Qantas, during the first 65 months, 27 passengers had cardiac arrest on board the aircraft; the cardiac arrest was noticed in only 16 of these passengers (59 percent). In 21 passengers (78 percent), the initial rhythm was asystole or pulseless idioventricular rhythm. Six passengers were in ventricular fibrillation; initial conversion was successful in five, of whom two survived for two years or more.[14] In addition to placing the devices on board its aircraft, Qantas placed the devices near its terminal gates. Episodes of cardiac arrest were noticed in 19 passengers in the terminal, and 17 of these patients (89 percent) had ventricular fibrillation as the initial rhythm. Four of these patients (24 percent) survived to discharge from the hospital.

Varig Airlines recently installed automated external defibrillators aboard its aircraft; in the first year (May 1998 to May 1999) the device was used three times for cardiopulmonary arrest. One patient had atrial flutter with high-degree atrioventricular block; two patients with ventricular fibrillation had initial conversion but did not survive. Varig has also placed a separate cardiac monitor without the capacity for defibrillation aboard its aircraft, to be used when the strict definition of cardiac arrest has not been met (Magalhães P: personal communication).

Our study has two important findings regarding the use of automated external defibrillators by an airline. First, the device can be used effectively to recognize and treat ventricular fibrillation; shock was recommended for each documented episode, and in each patient in whom defibrillation was delivered, the first shock was effective. The survival rate was excellent; 40 percent of the patients survived to discharge from the hospital with intact neurologic function. This rate compares favorably with that obtained by the best emergency medical systems. For example, in Seattle, when firefighters provided initial defibrillation, 30 percent of the patients survived to discharge from the hospital, as compared with 19 percent when defibrillation was provided by paramedics.[16] In other cities, survival rates are much lower, such as 1.8 percent in Chicago.[17]

The survival rate of passengers with cardiac arrest on board an aircraft or at the gate of American Airlines was higher than for Qantas Airways, probably because fewer passengers on American Airlines flights had bradycardia. The difference may relate to the fact that Qantas has longer flights and therefore passengers are more likely to be sleeping or assumed to be asleep (thus delaying emergency care). The experience of American Airlines refutes a possible conclusion from the data on Qantas that cardiac arrest aboard an aircraft, as compared with that occurring on the ground, is more likely to be due to bradycardia.

The second important finding of our study is that the device was safe for use as a monitor. Although it is labeled for use only in cases of apparent cardiac arrest, in more than half of the passengers in our study the automated external defibrillator was used to monitor symptoms other than loss of consciousness. The additional data provided by the device allowed further assessment of the status of the passenger and of the need for diversion or use of the emergency medical kit on the aircraft (which now includes many emergency medications).

There has been concern that the use of the automated external defibrillator as a monitor could result in inappropriate and potentially dangerous electrical discharge, with precipitation of ventricular fibrillation in a previously stable patient. Inappropriate shocks are unlikely to occur, however. We have never documented the inappropriate recommendation of shock, much less its delivery. The semiautomatic feature, which ensures that the shock is delivered only after confirmation of cardiac arrest by the operator, is one safety feature. A further protection against the induction of a lethal arrhythmia by an errant shock is the high success rate of defibrillation. It is well recognized that nonsynchronized shocks can result in ventricular fibrillation (by chance occurrence on the

T wave). However, the theory of an upper limit of vulnerability suggests that ventricular fibrillation will not be induced unless the shock is below the threshold for defibrillation.[18] In view of the high success rate in the current study and in others of defibrillation with the biphasic 150-J shock, even a nonsynchronized shock occurring on the T wave would be unlikely to induce ventricular fibrillation.[19-21]

With the placement of automated external defibrillators on aircraft, new issues of liability have been raised. In response, the Aviation Medical Assistance Act of 1998 was passed, providing immunity for both the airline, for the acts of a medically qualified passenger rendering medical assistance, and the medically qualified passenger, in the absence of gross negligence or willful misconduct.[10] In a definitive treatise on this subject, Ruckman states that "the medically qualified passenger, called upon to assist in an in-flight emergency, should not today be concerned about [his or her] personal liability."[22]

We can expect automated external defibrillators to be on all U.S. commercial flights soon. The Federal Aviation Administration recently proposed that all aircraft capable of carrying 3410 kg (7500 lb) of payload and with a flight attendant be equipped with an automated external defibrillator and an enhanced medical kit.[11] This proposed rule would not be mandatory for 36 months, although major domestic carriers are already placing automated external defibrillators on their aircraft. Recently, Lufthansa was found liable for not providing adequate care to a passenger who had cardiac arrest.[23]

Our findings confirm that a large-scale program by an airline to include automated external defibrillators on commercial aircraft is both safe and effective. We believe that these devices should become standard equipment for all commercial aircraft. Flight attendants must be trained in the use of the defibrillator and instructed to deliver care without delay or interference from medical personnel who volunteer assistance. The use of the automated external defibrillator as a monitor, when requested by qualified medical personnel, appears to be safe; therefore, it is unnecessary to equip the aircraft with a separate monitor (without the capability to provide defibrillation).

The current study has implications for other programs designed to ensure public access to defibrillation. The survival rate in this study compares favorably with that in any other series for which data are available and was achieved in an isolated environment in which nonmedical personnel, most of whom received just one course of instruction, used the device. Another study in this issue of the *Journal* reports on the use of automated external defibrillators by security guards employed in casinos.[24] A recent study showed that untrained sixth-grade students performed almost as quickly as trained paramedics in a trial of automated external defibrillators in mock cardiac arrest.[25] These findings, along with our data and the data of others, are evidence of the safety and efficacy of widespread placement of these devices as part of a program to enhance public access to defibrillation.

Dr. Page has been a consultant to Hewlett–Packard (Agilent Technologies), the manufacturer of the automated external defibrillator used in this study. The University of Texas Southwestern Medical Center, Dallas, has a consulting relationship with American Airlines for Dr. Page's consultation on the defibrillator program. Dr. McKenas is the Corporate Medical Director of American Airlines.

We are indebted to Robert F. Ruckman, J.D., for his advice regarding legal issues associated with the use of automated external defibrillators.

REFERENCES

1. Anderson RN, Kochanek KD, Murphy SL. Report of final mortality statistics, 1995. Mon Vital Stat Rep 1997;45(11):Suppl 2.
2. Weisfeldt ML, Kerber RE, McGoldrick RP, et al. American Heart Association report on the Public Access Defibrillation Conference December 8-10, 1994. Circulation 1995;92:2740-7.
3. *Idem.* Public access defibrillation: a statement for healthcare professionals from the American Heart Association Task Force on Automatic External Defibrillation. Circulation 1995;92:2763.
4. 31st Bethesda Conference: emergency cardiac care. J Am Coll Cardiol 2000;35:825-80.
5. Becker L, Eisenberg M, Fahrenbruch C, Cobb L. Public locations of cardiac arrest: implications for public access defibrillation. Circulation 1998;97:2106-9.
6. Wade B. Airlines adding defibrillators. New York Times. July 6, 1999: XX4.
7. Page RL, Hamdan MH, McKenas DK. Defibrillation aboard a commercial aircraft. Circulation 1998;98:1429-30.
8. Cummins RO, Chapman PJ, Chamberlain DA, Schubach JA, Litwin PE. In-flight deaths during commercial air travel: how big is the problem? JAMA 1988;259:1983-8.
9. O'Rourke RA. Saving lives in the sky. Circulation 1997;96:2775-7.
10. Aviation Medical Assistance Act of 1998, Pub. L. No. 105-170, H.R. 2843, 105th Cong. (1998).
11. Emergency Medical Equipment, 65 Fed. Reg. 33,702 (2000) (to be codified at 14 C.F.R. pt. 121, 135) (proposed May 24, 2000).
12. Aldrette JA, Aldrette LE. Oxygen concentrations in commercial aircraft flights. South Med J 1983;76:12-4.
13. Donaldson E, Pearn J. First aid in the air. Aust N Z J Surg 1996;66: 431-4.
14. O'Rourke MF, Donaldson E, Geddes JS. An airline cardiac arrest program. Circulation 1997;96:2849-53.
15. Cummins RO, Ornato JP, Thies WH, Pepe PE. Improving survival from sudden cardiac arrest: the "chain of survival" concept: a statement for health professionals from the Advanced Cardiac Life Support Subcommittee and the Emergency Cardiac Care Committee, American Heart Association. Circulation 1991;83:1832-47.
16. Weaver WD, Hill D, Fahrenbruch CE, et al. Use of the automatic external defibrillator in the management of out-of-hospital cardiac arrest. N Engl J Med 1988;319:661-6.
17. Becker LB, Han BH, Meyer PM, et al. Racial differences in the incidence of cardiac arrest and subsequent survival. N Engl J Med 1993;329: 600-6.
18. Chen PS, Shibata N, Dixon EG, Martin RO, Ideker RE. Comparison of the defibrillation threshold and the upper limit of ventricular vulnerability. Circulation 1986;73:1022-8.
19. Bardy GH, Marchlinski FE, Sharma AD, et al. Multicenter comparison of truncated biphasic shocks and standard damped sine wave monophasic shocks for transthoracic ventricular defibrillation. Circulation 1996;94:2507-14.
20. Cummins RO, Hazinski MF, Kerber RE, et al. Low-energy biphasic waveform defibrillation: evidence-based review applied to emergency cardiovascular care guidelines: a statement for healthcare professionals from the American Heart Association Committee on Emergency Cardiovascular Care and the Subcommittees on Basic Life Support, Advanced Cardiac Life Support, and Pediatric Resuscitation. Circulation 1998;97:1654-67.
21. Mittal S, Ayati S, Stein KM, et al. Comparison of a novel rectilinear biphasic waveform with a damped sine wave monophasic waveform for

transthoracic ventricular defibrillation. J Am Coll Cardiol 1999;34:1595-601.
22. Ruckman RF. ER in the skies: in-flight medical emergencies. J Air Law Commerce 1999;65:77-123.
23. Smith SC Jr, Hamburg RS. Automated external defibrillators: time for federal and state advocacy and broader utilization. Circulation 1998;97:1321-4.
24. Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. N Engl J Med 2000;343:1206-9.
25. Grimdy JW, Conoss KA, DeRook FA, Jogensoo D, Brady GH. Comparison of naive sixth-grade children with trained professionals in the use of an automated external defibrillator. Circulation 2000;100:1703-7.

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association.
Learn and Live.

Is Arrhythmia Detection by Automatic External Defibrillator Accurate for Children? : Sensitivity and Specificity of an Automatic External Defibrillator Algorithm in 696 Pediatric Arrhythmias

Frank Cecchin, Dawn B. Jorgenson, Charles I. Berul, James C. Perry, A. Andrew Zimmerman, Brian W. Duncan, Flavian M. Lupinetti, David Snyder, Thomas D. Lyster, Geoffrey L. Rosenthal, Brett Cross and Dianne L. Atkins

Circulation 2001;103;2483-2488
Circulation is published by the American Heart Association. 7272 Greenville Avenue, Dallas, TX 72514
 Print ISSN: 0009-7322. Online ISSN: 1524-4539

Is Arrhythmia Detection by Automatic External Defibrillator Accurate for Children?

Sensitivity and Specificity of an Automatic External Defibrillator Algorithm in 696 Pediatric Arrhythmias

Frank Cecchin, MD; Dawn B. Jorgenson, PhD; Charles I. Berul, MD; James C. Perry, MD; A. Andrew Zimmerman, MD; Brian W. Duncan, MD; Flavian M. Lupinetti, MD; David Snyder, MS; Thomas D. Lyster, MS; Geoffrey L. Rosenthal, MD, PhD; Brett Cross, BS; Dianne L. Atkins, MD

Background—Use of automatic external defibrillators (AEDs) in children aged <8 years is not recommended. The purpose of this study was to develop an ECG database of shockable and nonshockable rhythms from a broad age range of pediatric patients and to test the accuracy of the Agilent Heartstream FR2 Patient Analysis System for sensitivity and specificity.

Methods and Results—Children aged ≤12 years who either developed arrhythmias or were at risk for developing arrhythmias were studied. Two sources were used for the database: children whose rhythms were recorded prospectively via a modified AED and children who had arrhythmias captured on paper and digitized for subsequent analysis. The rhythms were divided into 5-second strips, classified by 3 reviewers, and then assessed by the AED analysis algorithm. A total of 696 five-second rhythm strips from 191 children (81 female and 110 male) aged 1 day to 12 years (median 3.0 years) were analyzed. There was 100% specificity for nonshockable rhythms. Sensitivity for ventricular fibrillation was 96%.

Conclusions—There was excellent AED rhythm analysis sensitivity and specificity in all age groups for ventricular fibrillation and nonshockable rhythms. The high specificity and sensitivity indicate that there is a very low risk of an inappropriate shock and that the AED correctly identifies shockable rhythms, making the algorithm both safe and effective for children. (***Circulation.*** **2001;103:2483-2488.)**

Key Words: defibrillation ■ pediatrics ■ arrhythmia

Automatic external defibrillators (AEDs) have been available to the adult population for >20 years.[1] Recent technology has allowed AEDs to be widely disseminated, improving treatment and decreasing the time to defibrillation. Currently AED use is not recommended for children aged <8 years.[2] Restriction of the use of AEDs means that pediatric patients do not receive a level of care equivalent to that of adults. After a cardiac arrest, a child must wait for the arrival of advanced life support and treatment with a manual defibrillator. This increases the crucial time to shock delivery, which has been shown to be the major determinant of resuscitation.[3–5] Although ventricular fibrillation (VF) has been reported to occur in only 19% of pediatric cardiac arrests, the percent survival and neurological outcome is better in survivors of VF arrest compared with victims of asystolic arrest.[3]

The algorithms in use with current AEDs were derived by using rhythm databases recorded from adults. Children differ from adults as to the types and characteristics of shockable and nonshockable rhythms. The lower incidence of VF indicates that they are more likely to have nonshockable rhythms than are adults. The characteristics of these nonshockable rhythms will be different because children have faster sinus and supraventricular tachycardia rates than do adults. Theoretical concerns about the capacity of the AED to detect VF in pediatric patients exist because of the smaller cardiac mass in children. Although AEDs have not been fully tested in children, the available data suggest excellent specificity.[6,7]

The purpose of the present study was to create a database of recordings of shockable and nonshockable rhythms from children. This database was used to test an AED patient analysis system for accuracy in determining a shock decision for pediatric rhythms.

Methods

Study Design

Two sources of ECG recordings were used to create the database for children aged ≤12 years. First, we performed a prospective clinical

Received November 8, 2000; revision received February 28, 2001; accepted March 8, 2001.

From the University of Washington (F.C., B.W.D., F.M.L., G.L.R.) and Agilent Technologies (D.B.J., D.S., T.D.L., B.C.), Seattle, Wash; Harvard Medical School (C.I.B.), Boston, Mass; Children's Hospital and Health Center (J.C.P., A.A.Z.), San Diego, Calif; and the University of Iowa (D.L.A.), Iowa City.

Dr Cecchin serves as a consultant to Agilent Technologies; Drs Jorgenson, Snyder, Lyster, and Cross are employees of Agilent Technologies.

Correspondence to Frank Cecchin, MD, Children's Hospital and Medical Center, 4800 Sandpoint Way, NE, Seattle, WA 98105. E-mail fcecch@chmc.org

Circulation is available at http://www.circulationaha.org

TABLE 1. Patient Characteristics

Age Group	Median Age, y	Median Weight (Range), kg	Sex (Male/Female), n/n
≤1 y (74 patients)	0.3	5.2 (2.1–10.1)	47/27
>1 to <8 y (62 patients)	3.5	16.0 (7.6–38.0)	30/32
≥8 to ≤12 y (55 patients)	10.0	35.0 (22.0–70.7)	33/22
Total (191 patients)	3.0	13.9	110/81

study in which rhythms were recorded via a modified AED in children at risk of arrhythmias. Second, prerecorded ECG strips of infrequently observed shockable arrhythmias were digitized for subsequent analysis.

Recorded Rhythms

Children at risk for developing arrhythmias were enrolled prospectively at 4 pediatric care centers (Children's Hospital and Medical Center, Seattle, Wash; Children's Hospital of Iowa, Iowa City; Children's Hospital, Boston, Mass; and Children's Hospital and Health Center, San Diego, Calif). Institutional review board approval was obtained from each institution in addition to informed assent and consent from each study participant and parent. Rhythms were recorded in the following settings: electrophysiology laboratory, intensive care unit, and cardiac surgical operating room.

An AED (ForeRunner, Agilent Heartstream) was modified to function as a 30-minute loop recorder with a wide bandwidth (0.2 to 80 Hz) ECG recording system identical to a fully functioning AED and similar to a standard 12-lead ECG. The defibrillation capability of the device was disabled. Defibrillation pads were used to record the rhythms. Pad size depended on the child's chest size and clinical setting; either the standard 100-cm^2 adult size (DP1, Agilent Heartstream) or a smaller 43-cm^2 pediatric version (M3717A, modified to connect to a ForeRunner, Agilent Heartstream) was used. Pad position was determined by the clinical setting, with the preferred pad position being anterior-anterior. The other pad position was anterior-posterior, and some patients required a more side-to-side configuration. In some instances, monitoring electrodes were used if it was not possible to apply defibrillation pads. Some of the recorded supraventricular and ventricular tachycardia (VT) rhythms were paced rhythms, and the pacing artifact was filtered for the reviewers. Paced rhythms were 5% of the total, and 59% of these were in the unspecified VT group.

Digitized Rhythms

VF and VT paper recordings were acquired retrospectively from 11 centers via solicitation through letters mailed to a registry of pediatric electrophysiologists. Recordings came from both in-hospital and out-of-hospital sources and were converted into a digital format by scanning, image manipulation, and data processing.

Rhythm Strip Classification

AED algorithm performance was evaluated for both sensitivity and specificity. Sensitivity refers to the ability of the device to detect shockable rhythms. Specificity refers to the ability of the device to detect nonshockable rhythms.

The American Heart Association (AHA) 1997 recommendations for classification and performance goals were used.[3] This is intended for the assessment of AEDs developed for adults. No AED standards are available for children. Rhythm groups are organized in 3 broad categories that are based on the likely benefit of defibrillation for that rhythm group: (1) Shockable rhythms are lethal rhythms unless a shock is delivered very quickly. (2) Intermediate rhythms are those for which the benefits of immediate electric countershock are limited or uncertain. No performance goals have been established for this category. (3) The final category is nonshockable rhythms, which are benign (or normal) rhythms that must not be shocked, especially in children who have a pulse, because no benefit will follow and deterioration in rhythm may result. To maximize safety in the event of misapplication of the device/electrodes, asystole is included in this group. The following definitions refer to a 5-second ECG strip.

Shockable Rhythms

For VF, complexes show only ventricular origin and rapidly changing morphology. The amplitude is ≥200 μVpp for ≥5 of the complexes, and there are ≥12 complexes ≥100 μVpp (peak to peak).

Rapid VT involves polymorphic VT and ventricular flutter with rates ≥250 bpm.

Intermediate Rhythms

For intermediate VT, complexes show only ventricular origin but do not satisfy the criteria for rapid VT.

Low rate/amplitude VF includes low-rate or low-amplitude VF or electrical activity of unknown etiology. The rhythm does not satisfy criteria for asystole, VF, or idioventricular classes.

Nonshockable Rhythms

For sinus rhythm, complexes show an atrial origin and do not qualify for supraventricular arrhythmia (SVA) class.

For SVA, complexes show a supraventricular origin with or without atrioventricular block and bundle-branch block. This includes atrial flutter and AF, sinus arrhythmia with or without premature atrial contractions, junctional rhythms, and supraventricular tachycardia.

Ventricular ectopic beats are defined as single or multiple ventricular ectopic beats mixed with or without supraventricular ectopic beats.

For idioventricular rhythms, complexes are only of ventricular origin, with or without uniform morphology. The rate is <100 bpm, with at least 1 complex of ≥100 μVpp.

Asystole is defined as a maximum of 1 complex >100 μVpp and all complexes <200 μVpp.

Classification Process

The recordings were divided into 5-second segments, classified by 3 pediatric electrophysiologists (F.C., J.C.P., D.L.A.) and by the AED analysis algorithm. The reviewers used the following assumptions: (1) The patient is "unresponsive." (2) The age of the patient is unknown. (3) The patient may or may not have a pulse. (4) The AED

TABLE 2. Recorded and Digitized Data Sensitivity of Shockable Rhythms

	VF				Rapid VT			
	Recorded		Digitized		Recorded		Digitized	
Age Group	Rhythms, n	Sensitivity, %	Rhythms, n	Sensitivity, %	Rhythms, n	Sensitivity, %	Rhythms, n	Sensitivity, %
≤1 y (19 patients)	30	93	8	100	2	100	4	50
>1 to <8 y (28 patients)	5	100	10	90	9	33	15	93
≥8 to ≤12 y (25 patients)	11	100	9	100	21	62	7	100
Total (72 patients)	46	96	27	96	32	56	26	88

n indicates number of rhythms recorded.

TABLE 3. Recorded Data Specificity of Nonshockable Rhythms

	Sinus Rhythm		SVA		VEB		Idioventricular		Asystole	
Age Group	Rhythms, n	Specificity, %	Rhythms, n	Specificity, %	Rhythms, n	Specifitcity, %	Rhythms, n	Specificity, %	Rhythms, n	Specificity, %
≤1 y (59 patients)	83	100	50	100	34	100	17	100	24	100
>1 to <8 y (40 patients)	52	100	43	100	27	100	9	100	8	100
≥8 to ≤12 y (47 patients)	38	100	23	100	34	100	14	100	7	100
Total (146 patients)	173	100	116	100	95	100	40	100	39	100

VEB indicates ventricular ectopic beats.

cannot deliver a synchronized shock. Each reviewer independently reviewed the segments, identified the rhythm class, and made a shock or no-shock recommendation. The recommendations of the 3 reviewers were compiled, and disagreements were resolved for rhythms that were not unanimously placed into a defined category. The results reported in the present study reflect the final consensus of the reviewers after discussion of the merit of each potential recommendation.

The AED patient analysis system characterizes the ECG in terms of 4 rhythmic characteristics: the rate of ECG complex occurrence, morphological stability of the ECG complexes, evidence of rapidly conducted electrical signals, and signal amplitude. These characteristics are respectively referred to as rate, stability, conduction, and amplitude. Stability and conduction are measured on a scale of 0 to 1. Higher conduction and stability scores indicate more rapid conduction and less variability in the morphology of the ECG complexes. To optimize the robustness of the analytical system, redundant assessments of the ECG measurements are performed with the use of both temporal and transform-based analyses. Amplitude measurement is used only for identifying asystole. Rate, stability, and conduction measures are assessed concurrently to make a shock/no-shock determination. Each measure exerts an influence over the decision, but none is independently capable of triggering a shock recommendation. This synergistic use of the rhythm characteristics ensures that a high rate rhythm will not cause a shock recommendation if evidence of supraventricular origin is present and that a lower VF rate will receive a shock recommendation if it demonstrates poor stability and conduction properties.

Statistical Analysis

Data are expressed as median (range) or mean±SD. With consensus from a panel of 3 electrophysiologists as the gold standard, the sensitivity and specificity of the algorithm for detecting shockable rhythms were calculated. Comparisons were made by the Student t test and χ^2 test. A value of $P<0.05$ was considered significant.

Results

Patient Characteristics

Recorded Rhythms

One hundred thirty-eight children were studied at 4 centers over 11 months; 4 children were excluded because of incorrectly recorded data with irretrievable ECG recordings. The largest group (44%) were those aged <1 year. The reviewers classified a total of 614 rhythm strips. Heart disease was present in 73% of the children, of whom 63% had congenital heart disease and 10% had cardiomyopathy.

Digitized Rhythms

Data were digitized from 57 children, and reviewers classified a total of 82 rhythm strips.

All Rhythms

The children were divided into 3 groups according to age: ≤1 year, >1 year to <8 years, and ≥8 years to ≤12 years. The characteristics for the children are displayed in Table 1. A total of 696 rhythms were classified by the reviewers and were subjected to algorithm analysis. There were 463 nonshockable, 131 shockable, and 102 intermediate rhythms. Nonsbockable rhythms constituted 67% of the total. Table 2 summarizes the shockable rhythms, and Table 3 summarizes the nonshockable rhythms. Sinus rhythm was the most frequent nonshockable rhythm, at 37%. VF (n=73) was the most common shockable rhythm, at 56%. The largest percentage of VF, 52%, was recorded in those aged <1 year. The low-amplitude VF and shockable unspecified VT had the lowest percentages, 5% and <1%, respectively.

TABLE 4. Pooled Rhythm Sensitivity and Specificity and LCL

	Sensitivity and Specificity				
Rhythm	Sensitivity, %	Specificity, %	AHA Goal, %	90% 1-Sided LCL, %	AHA LCL Goal, %
VF (38 patients)	96	...	>90	91	87
Rapid VT (49 patients)	71	...	>75	62	67
Sinus rhythm (103 patients)	...	100	>99	99	97
SVA (69 patients)	...	100	>95	98	88
VEB (52 patients)	...	100	>95	98	88
idioventricular (27 patients)	...	100	>95	94	88
Asystole (28 patients)	...	100	>95	94	92

LCL indicates lower confidence limits.

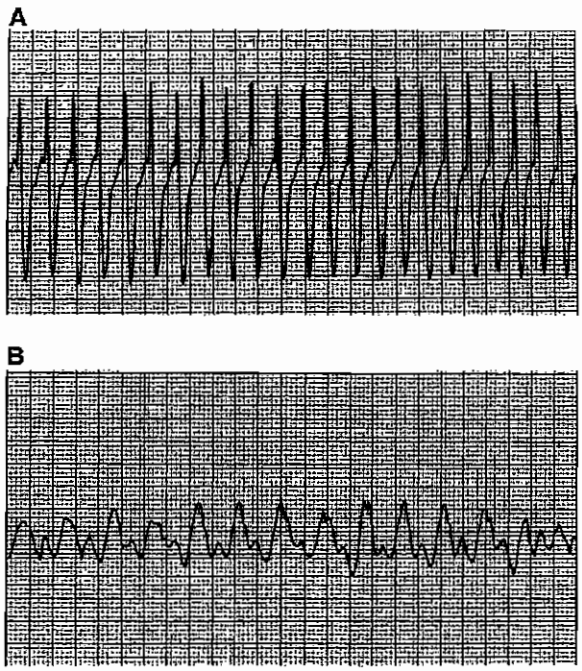


Figure 1. ECG examples of 2 reviewer-designated shockable rhythms recorded at 10 mm/mV and 25 mm/s. A, Wide QRS tachycardia had high conduction and stability scores and was assigned no-shock designation by AED algorithm, given concern about possibility of being supraventricular tachycardia. B, Rhythm had much lower conduction and stability scores and was given shock designation.

Sensitivity and Specificity of Rhythms

The sensitivity and specificity of the AED analysis algorithm for the 3 age groups are shown in Tables 2 and 3. The overall sensitivity, specificity, 90% one-sided lower confidence limits, and AHA performance goals for each rhythm classification are displayed in Table 4. Specificity for nonshockable rhythms was 100%. Sensitivity for the shockable rhythms was highest for VF, at 96%. The overall accuracy was 97%. The AED analysis algorithm exceeded the AHA performance goals for each rhythm classification except for rapid VT. Intermediate rhythms (for which the benefits of defibrillation are limited or uncertain and there are no performance goals) had a sensitivity of 45% and specificity of 97%. There was no significant difference in sensitivity or specificity between the 3 age groups.

The sensitivity results for the rapid VT group were further explored by examining the AED algorithm classification parameters: stability, conduction, and rate. The mean conduction scores for the 41 shock and 17 no-shock designations were 0.55 ± 0.12 and 0.91 ± 0.06, respectively ($P<0.001$). The stability scores were 0.48 ± 0.28 and 0.94 ± 0.03, respectively ($P<0.001$). The rates were 288 ± 74 and 261 ± 28, respectively ($P=0.16$). Figure 1 illustrates 2 rhythms that were classified as rapid VT by the reviewers. Figure 1A shows a high conduction and stability score (0.94 and 0.96, respectively) and was given a no-shock designation by the analysis algorithm. Figure 1B shows a low conduction and stability score (0.52 and 0.18, respectively) and was given a shock designation.

Adult Versus Pediatric Rhythm Characteristics

The pediatric ECG database was compared with a previously collected database of adult rhythms.[9] The rhythm characteristics (rate, stability, and conduction), as determined by the algorithm, were compared between the databases. Figure 2 demonstrates the rhythm characteristics for the shockable rhythm groups, VF and rapid VT. The pediatric VF (n=73) had a mean rate of 323 ± 95 bpm. This was significantly higher than the adult VF (n=300) rate of 289 ± 71 bpm ($P<0.001$). Similarly, VT rates were significantly higher for pediatric subjects (n=58, 281 ± 65 bpm) than for adult subjects (n=100, 221 ± 59 bpm) ($P<0.001$). Conduction scores were higher ($P<0.001$) for the pediatric database in both shockable rhythm groups. Stability scores were not statistically different between the 2 databases.

The pediatric nonshockable rhythm groups, ie, sinus rhythm, SVA, and ventricular ectopic beats, were also compared with the adult database. These groups had the following overall mean rates for the pediatric (n=384) and adult (n=500) databases: 129 ± 57 and 87 ± 46 bpm, respectively ($P<0.001$). The average rate for these rhythm groups in the

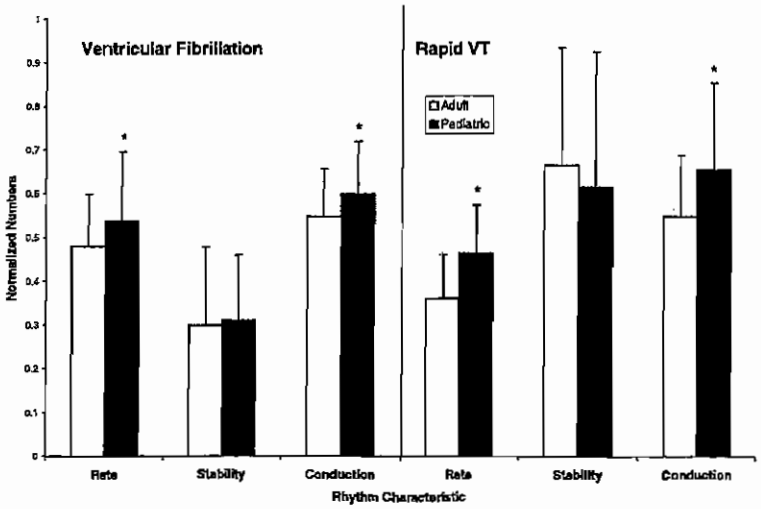


Figure 2. Comparison of shockable rhythm characteristics between adult and pediatric databases. *$P<0.001$

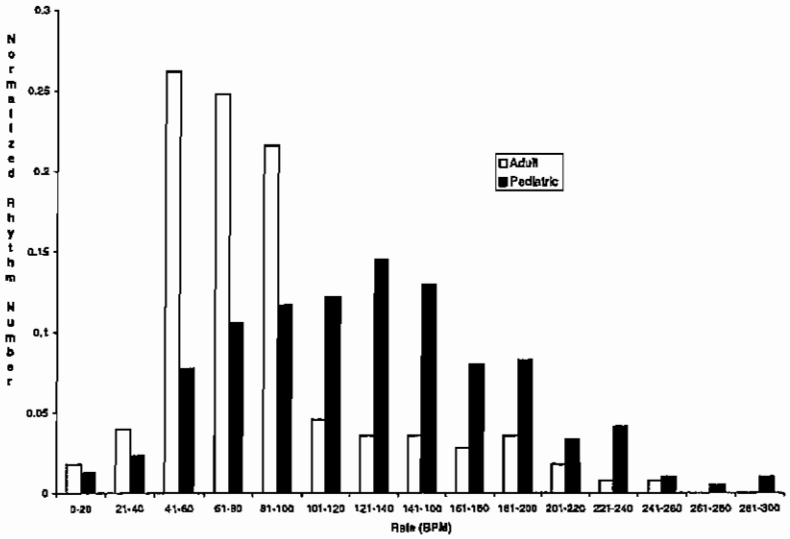


Figure 3. Rate comparison for nonshockable rhythms in adult and pediatric databases. Rhythm number was normalized because the 2 databases were different in size.

pediatric database was fastest in the youngest age group, at 136 bpm, and slowest for the oldest age group, at 107 bpm. Of these 384 nonshockable rhythms, the rate was >180 bpm in 70 (18.2%) rhythms, with a maximum of 300 bpm. In the comparable adult database, there were 500 rhythms. The maximal rate was 250 bpm, and 7% were >180 bpm. Figure 3 shows the distribution of the rates of the nonshockable rhythms in these groups.

Discussion

This is the first published study to record and analyze shockable and nonshockable rhythms from a pediatric population. We have successfully created a large rhythm database from a broad age range of children to test an AED detection algorithm. The largest group was aged <1 year, and from this group, we analyzed 38 recordings of VF. The AED analysis algorithm exceeded the AHA performance goals for each rhythm classification except for rapid VT. Sensitivity for VF was excellent at 96%. Specificity for all nonshockable rhythms was excellent at 100%. Although the performance goal for rapid VT was not achieved, a conservative approach for this rhythm category for pediatric patients is appropriate because of the higher uncertainty of association of wide QRS supraventricular tachycardias with pediatric cardiac arrest. Furthermore, nonperfusing rapid VT is likely to rapidly degenerate into VF, for which there is a higher sensitivity. In regard to the intermediate rhythm group, for which the benefits of defibrillation are limited or uncertain, the AED algorithm was appropriately conservative. The 90% one-sided lower confidence limit goals set by the AHA were also satisfied in every category, with the exception of the rapid VT group. This indicates that the pooled sample sizes and sensitivity and specificity values were within acceptable goals of the AHA.

Prior Studies

There are minimal data evaluating arrhythmia analysis or AED use in pediatric patients. Hazinski et al[6] presented data demonstrating high sensitivity and specificity in 21 hospitalized infants and children aged <8 years. Atkins et al[7] reported a sensitivity of 88% and specificity of 100% when AEDs were used in older children during out-of-hospital cardiac arrest and resuscitation. Atkins et al further reported that there were 3 of 25 instances in which VF was initially not recognized, but the second analysis was correct, and shocks were delivered. In addition, 43% survival was observed in patients who received an electric countershock as opposed to 11% survival in those who had a nonshockable life-threatening rhythm, such as asystole. This emphasizes the importance of early recognition of VF followed by defibrillation in the young.

In adults, studies using prerecorded and field-tested databases[9–16] have reported sensitivity for VF (81% to 100%) similar to that obtained in the present study. Most studies have not separated VT into a separate category, but in the study that did, there was sensitivity of 65% for sustained VT recorded in the electrophysiology laboratory.[16] To set standards for specifying and reporting the performance of the arrhythmia analysis algorithm, the AHA published recommendations in 1995.[8] The present study is the first to incorporate those recommendations regarding the performance of the arrhythmia analysis algorithm into AED testing for pediatric patients.

Pediatric Database Creation and Algoritbm Development

Development of a pediatric database for algorithm testing is essential to ensure adequate safety and efficacy of AEDs in a pediatric population. Our rhythm database collected from children was clearly different from the adult database. Children had higher heart rates for shockable VF and rapid VT. Importantly, the nonshockable rhythm group contained rhythms with faster maximal and overall rates. The maximal rate in the pediatric supraventricular tachycardia group was 300 versus 250 bpm in the adult database. Garson et al[17] reported that the overall mean rate of pediatric supraventricular tachycardia was 240 bpm, and for infants aged <4 months, it was 268 bpm.

The pediatric population had higher conduction scores for the VF and rapid VT group than did the adult population. This is consistent with large 12-lead ECG recording studies in

normal children.[18] Heart rate decreases and QRS duration increases during childhood. The lower sensitivity found in the rapid VT group can potentially be explained by these differences between adults and children. The AED algorithm assigned no-shock designations to the most stable and well-conducting episodes of rapid VT, as seen in Figure 1. These rhythms are rare in children and may not be clinically relevant in pediatric victims of cardiac arrest.[19]

The present data illustrate the importance of using multiple parameters in a rhythm-detection algorithm for shock designation in children. The analysis algorithm of the Agilent Heartstream FR2 AED uses the 4 rhythm characteristics (rate, conduction, stability, and amplitude) as covariables in determining whether a particular rhythm is shockable. The large number of nonshockable pediatric rhythms with rates >180 bpm indicates that simplistic algorithms with shock criteria merely based on rate would be unsafe if used in children. The ability of the algorithm to evaluate conduction and stability in addition to rate reduces the potential for inappropriate shock recommendations for rhythms that are simply faster. This emphasizes the importance of testing each AED manufacturer's algorithm in a distinct pediatric database. That database should contain multiple age groups, especially infants aged <1 year. Shockable and nonshockable rhythms should be represented in each age group. Those nonshockable rhythms should include rhythms with rates >250 bpm, with at least 10% having rates >180 bpm.

Study Limitations

The major limitation of the present study is the lack of wide-bandwidth recordings of spontaneous or out-of hospital VF. However, obtaining wide-bandwidth recordings of spontaneous shockable ventricular arrhythmias from children is extremely difficult. These events occur so infrequently that thousands of hours of recording are required to capture a single event. Each of the surgical patients, a high-risk group for ventricular arrhythmias, had recording continued for 12 hours after surgery. However, no shockable rhythms were recorded in the postoperative period.

Field testing is essential ultimately for assessing performance of the AED arrhythmia algorithm. Weaver et al[20] demonstrated that an algorithm derived from a prerecorded rhythm database performed poorly in field testing. Despite the fact that the algorithm used in the present study has been field-tested in adults and did very well,[14] a postmarket surveillance study is required to assess its performance in children. The present study examined the performance of the arrhythmia analysis system and did not address the issue of appropriate energy dosage for children.

Conclusions

A pediatric database of shockable and nonshockable rhythms that was significantly different from an adult database was created. This pediatric database was used to test the Agilent Heartstream FR2 AED analysis algorithm. Excellent sensitivity and specificity in all age groups for VF and nonshockable rhythms were demonstrated. The high sensitivity to VF and the high specificity to nonshockable rhythms indicate that the analysis algorithm is both safe and effective for pediatric rhythms. Importantly, the analysis algorithm is unlikely to inappropriately shock a pediatric rhythm. These results indicate that the use of 1 algorithm for both adults and children is feasible.

Acknowledgments

This study was supported by Agilent Technologies, Seattle, Wash. We would like to thank the physicians who contributed paper recordings to the study.

References

1. Diack AW, Welborn WS, Rullman RG, et al. An automatic cardiac resuscitator for emergeocy treatment of cardiac arrest. *Med Instrum.* 1979;13:78–83.
2. Guidelines 2000 for Cardiopulmooary Resuscitation and Emergency Cardiovasenlar Care, 10: pediatric advanced life support: the American Heart Association in collaboration with the International Liaison Committee on Resuscitation. *Circulation.* 2000;102(suppl I):I-291–I-342.
3. Mogayzel C, Quan L, Graves JR, et al. Out-of-hospital ventricular fibrillation in children and adolescents: causes and outcome. *Ann Emerg Med.* 1995;25:484–491.
4. Losek JD, Hennes H, Glaeser P, et al. Prehospital care of the pulseless, nonbreathing pediatric patient. *Am J Emerg Med.* 1987;5:370–374.
5. Hickey RW, Cohen DM, Strausbaugh S, et al. Pediatric patients requiring CPR in the prehospital setting. *Ann Emerg Med.* 1995;25:495–501.
6. Hazinski MF, Walker C, Smith J, et al. Specificity of automatic external defibrillator (AED) rhythm analysis in pediatric tachyarrhythmias. *Circulation.* 1997;96(suppl I):I-561. Abstract.
7. Atkins DL, Hartley LL, York DK. Accurate recognition and effective treatment of ventricular fibrillation by automated external defibrillators in adolescents. *Pediatrics.* 1998;101:393–397.
8. Kerber RE, Becker LB, Bourland JD, et al. Automatic external defibrillators for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety: a statement for health professionals from the AHA Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. *Circulation.* 1997;95:1677–1682.
9. Poole JE, Weaver WD, White RD, et al. Development, testing, and use of a highly sensitive and highly specific cardiac rhythm detection algorithm for automatic external defibrillators. *Circulation.* 1997;96(suppl I):I-560. Abstract.
10. Jack CM, Hunter EK, Pringle TH, et al. An external automatic device to detect ventricular fibrillation. *Eur Heart J.* 1986;7:404–411.
11. Dickey W, Dalzell GWN, Anderson JM, et al. The accuracy of decision-making of a semi-automatic defibrillator during cardiac arrest. *Eur Heart J.* 1992;13:608–615.
12. Murray A, Clayton RH, Campbell RWF. Comparative assessment of the ventricular fibrillation algorithms in five semi-automatic or advisory defibrillators. *Resuscitation.* 1993;26:163–172.
13. Cummins RO, Stults KR, Haggar B, et al. A new rhythm library for testing automatic external defibrillators: performance of three devices. *J Am Coll Cardiol.* 1988;3:597–602.
14. Poole JE, White RD, Kanz K, et al. Low-energy impedance-compensating biphasic waveforms terminate ventricular fibrillatioo at high rates in victims of out-of-hospital cardiac arrest. *J Cardiovasc Electrophysiol.* 1997;8:1373–1385.
15. Stults KR, Brown DD, Kerber RE. Efficacy of an automated external defibrillator in the management of out-of-hospital cardiac arrest: validation of the diagnostic algorithm and initial clinical experience in a rural environment. *Circulation.* 1986;4:701–709.
16. Carlson MD, Freeman CS, Garan H, et al. Sensitivity of an automatic external defibrillator for ventricular tachyarrhythmias in-patients undergoing electrophysiologic studies. *Am J Cardial.* 1988;61:787–790.
17. Garson A Jr, Gillette PC, McNamara DG. Supraventricular tachycardia in children: clinical features, response to treatment, and long-term follow-up in 217 patients. *J Pediatr.* 1981;6:875–882.
18. McCammon RW. A longitudinal study of electrocardiographic intervals in healthy children. *Acta Paediatr.* 1961;50:2–52.
19. Walsh CK, Krongard E. Terminal cardiac electrical activity in pediatric patients. *Am J Cardiol.* 1983;51:559–561.
20. Weaver WD, Hill DL, Fahrenbruch C, et al. Automatic external defibrillators: importance of field testing to evaluate performance. *J Am Coll Cardiol.* 1987;6:1259–1264.

PUBLIC USE OF AUTOMATED EXTERNAL DEFIBRILLATORS

SHERRY L. CAFFREY, E.M.T.-P., PAULA J. WILLOUGHBY, D.O., M.H.P.E., PAUL E. PEPE, M.D., M.P.H., AND LANCE B. BECKER, M.D.

ABSTRACT

Background Automated external defibrillators save lives when they are used by designated personnel in certain public settings. We performed a two-year prospective study at three Chicago airports to assess whether random bystanders witnessing out-of-hospital cardiac arrests would retrieve and successfully use automated external defibrillators.

Methods Defibrillators were installed a brisk 60-to-90-second walk apart throughout passenger terminals at O'Hare, Midway, and Meigs Field airports, which together serve more than 100 million passengers per year. The use of defibrillators was promoted by public-service videos in waiting areas, pamphlets, and reports in the media. We assessed the time from notification of the dispatchers to defibrillation, survival rate at 72 hours and at one year among persons with cardiac arrest, their neurologic status, and the characteristics of rescuers.

Results Over a two-year period, 21 persons had nontraumatic cardiac arrest, 18 of whom had ventricular fibrillation. With two exceptions, defibrillator operators were good Samaritans, acting voluntarily. In the case of four patients with ventricular fibrillation, defibrillators were neither nearby nor used within five minutes, and none of these patients survived. Three others remained in fibrillation and eventually died, despite the rapid use of a defibrillator (within five minutes). Eleven patients with ventricular fibrillation were successfully resuscitated, including eight who regained consciousness before hospital admission. No shock was delivered in four cases of suspected cardiac arrest, and the device correctly indicated that the problem was not due to ventricular fibrillation. The rescuers of 6 of the 11 successfully resuscitated patients had no training or experience in the use of automated defibrillators, although 3 had medical degrees. Ten of the 18 patients with ventricular fibrillation were alive and neurologically intact at one year.

Conclusions Automated external defibrillators deployed in readily accessible, well-marked public areas in Chicago airports were used effectively to assist patients with cardiac arrest. In the cases of survivors, most of the users had no duty to act and no prior training in the use of these devices. (N Engl J Med 2002; 347:1242-7.)

CARDIOVASCULAR disease remains the most common cause of death in the United States and most other Western nations.[1-4] Among these deaths, sudden, out-of-hospital cardiac arrest claims approximately 1000 lives each day in the United States alone.[3] Most of these cardiac arrests are due to ventricular fibrillation.[4-7] Though highly reversible with the rapid application of a defibrillator, ventricular fibrillation is otherwise fatal within minutes, even when cardiopulmonary resuscitation is provided immediately.[7-11] The overall survival rate in the United States is estimated to be less than 5 percent.[4,5,7,12-14]

Recent developments in automated-external-defibrillator technology have provided a means of increasing the rate of prompt defibrillation after out-of-hospital cardiac arrest.[15] After minimal training, nonmedical personnel (e.g., flight attendants and casino workers) are able to use defibrillators in the workplace, with life-saving effects.[16-20] Nonetheless, such programs have involved designated personnel whose job description includes assisting persons who have had sudden cardiac arrest. Data are still lacking on the success of programs in which automated external defibrillators have been installed in public places to be used by persons who have no specific training or duty to act.

Beginning in June 1999, the City of Chicago placed highly visible, readily accessible automated external defibrillators for public use at its municipal airports under the auspices of the Chicago HeartSave Program.[21] We evaluated the success of the program.

METHODS

Study Design

This two-year, prospective, observational study evaluated how often bystanders used automated defibrillators placed in high-traffic locations — airports — and determined the resulting survival rates. The study sites were the three Chicago airports: O'Hare (1,735,561 ft² of terminal space [161,240 m²] and 80 million passengers annually), Midway (259,408 ft² [24,100 m²] and 20 million passengers annually), and Meigs Field (7000 ft² (650 m²] and 77,000 passengers annually). The percentage of people with training in cardiopulmonary resuscitation who pass through these airports is not known. Since 1999, basic training in cardiopulmonary resus-

From the City of Chicago Department of Aviation, Chicago (S.L.C.); the Chicago Fire Department, Chicago (P.J.W.); the Departments of Surgery and Medicine and the School of Public Health, University of Texas Southwestern Medical Center, Dallas (P.E.P.); and the Division of Emergency Medicine, University of Chicago, Chicago (L.B.B.). Address reprint requests to Ms. Caffrey at the Department of Aviation, O'Hare International Airport, P.O. Box 66142, Chicago, IL 60666, or at sherord@aol.com.

citation and the use of automated external defibrillators has been provided to a total of 450 airport police, security personnel, and public-safety dispatchers. Similar training has been made available, on a voluntary basis, to other airport-based employees (i.e., personnel without a specific duty to act in a medical emergency) from both the public sector (e.g., customs and immigration agents and members of the airport commissioner's staff) and the private sector (e.g., restaurant vendors and custodial workers). During the study, approximately 3000 of 44,000 airport workers were trained. Other potential users of the defibrillators are flight attendants, who have been trained in the in-flight use of defibrillators.[17,20]

Defibrillators

On June 1, 1999, 33 publicly accessible automated defibrillators were installed throughout the O'Hare terminals. By February 1, 2001, 9 more had been placed in publit areas and 17 had been placed in areas that were not accessible to the public (e.g., maintenance and secured baggage areas). Initially, 7 defibrillators were installed at Midway (10 as of March 13, 2001) and 1 at Meigs.

Defibrillators were housed in glass-faced cabinets a brisk 60-to-90-second walk apart (Fig. 1). Indicator signs similar to those for toilets and telephones were placed in highly visible positions, usually above concourse walkways, adjacent to the defibrillators. Warning signs cautioned against tampering with or inappropriate use of defibrillators. Cabinets were equipped with audible alarms, strobe lights, and dispatcher alerts (to indicate the site) that were activated when the cabinet door was unsealed. Police, security personnel, and emergency-medical-services personnel were then dispatched to the indicated location unless follow-up callers provided more exact information.

Three-minute public-service announcements were played every half hour on television monitors in waiting areas, indicating the availability of the automated defibrillators, explaining their purpose, and encouraging their use. Printed materials were made available to the public and distributed to the airlines in bulk. Three public training sessions on the use of automated external defibrillators and cardiopulmonary resuscitation were held at various locations in Chicago, and numerous local and national media reports promoted the program.

The Chicago HeartSave Program was approved by the Chicago municipal government as an adjunct to its emergency-medical-services system. The study was considered part of a routine evaluation of the initiative. Participation by the bystanders was entirely voluntary, and informed consent was neither sought nor obtained. The State of Illinois has good-Samaritan laws that protect those who voluntarily provide cardiopulmonary resuscitation to others against litigation.

The defibrillator used (Model E, ForeRunner, Heartstream) delivers a biphasic, truncated exponential defibrillatory wave form and about 150 joules with each shock.[12] A single-channel, liquid-crystal electrocardiographic tracing is displayed across the surface of the defibrillator.

Collection of Data

When activated, digital data cards within the defibrillator record electrocardiographic data, rescuers' voices, machine prompts, thoracic-impedance values, the amount of energy delivered, and the time of all events; data from the cards are downloaded for analysis. Security officers also complete incident reports, which include contact information for the patients and those who assisted them, information on whether bystanders performed cardiopulmonary resuscitation, and information obtained from interviews with the

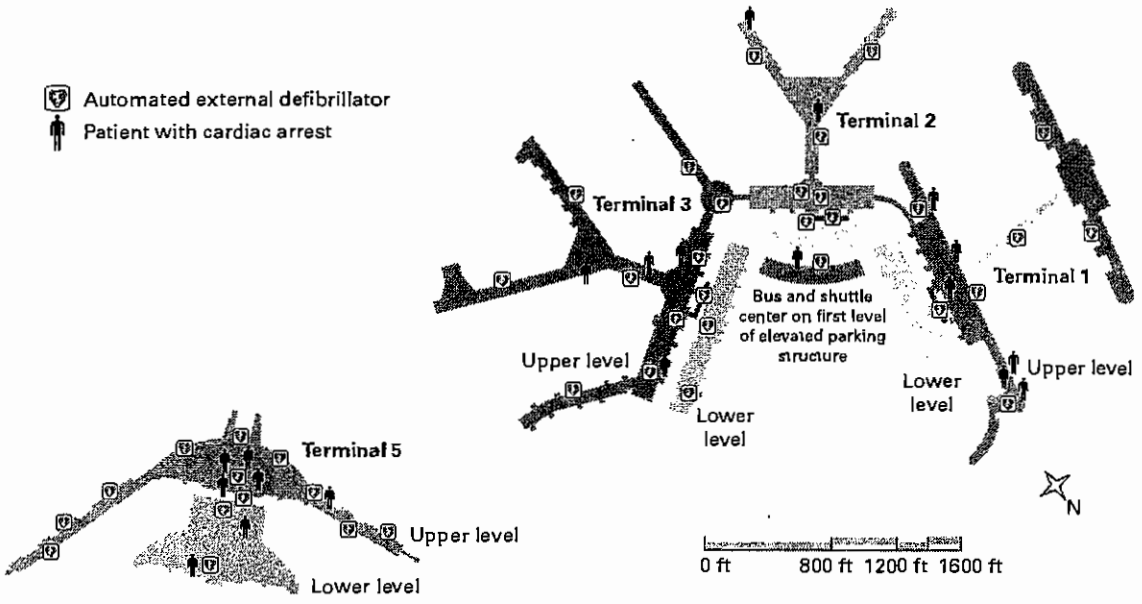


Figure 1. Map of O'Hare International Airport, Showing the Locations of Automated External Defibrillators in Public Areas and the Locations of 20 Patients with Witnessed Cardiac Arrest.

To convert distances to meters, multiply by 0.3.

persons who provided assistance. We abstracted data from the paramedics' records on patients' condition at the time of the arrival and departure of emergency-medical-services personnel and at the time they arrived at the hospital.

Although the actual time of the collapse could not be determined definitively, the time from the notification of dispatchers (e.g., as a result of opening the defibrillator-cabinet door or a telephone call) to the delivery of the first shock was documented with the use of automated clocks at dispatch centers and data cards from the defibrillators. Dispatch and data-card–computer clocks were synchronized prospectively and checked regularly to ensure accuracy.

A patient's neurologic status, assessed at the scene and at the hospital and reassessed one year later over the telephone by one of the investigators, was defined as good if the patient had a cerebral performance category score of 1 (normal) or 2 (minimal disability).[23,24] The time from the delivery of the first shock to the patient's initial return to consciousness, defined by a purposeful response to spoken commands, was documented, as was the number of shocks required for initial conversion or restoration of spontaneous pulses.

Complications were defined as defibrillator tampering, inappropriate delivery of shocks by the automated defibrillator, failure of the defibrillator to deliver a shock in response to ventricular fibrillation, malfunction of the audible and visual alarms or prompts of the defibrillator, inappropriate use of the defibrillator by rescuers, or injury of rescuers or other bystanders as a result of use of the defibrillator.

RESULTS

Characteristics of the Patients

Between June 1, 1999, and May 31, 2001, an automated defibrillator installed as part of the HeartSave Program was used for 21 persons at O'Hare, 5 at Midway, and none at Meigs. Among these 26 patients, 4 did not have cardiac arrest: 2 persons had seizures, 1 had shortness of breath (the defibrillator was used as a diagnostic tool by an off-duty paramedic), and 1 person, in the custody of immigration officials, feigned a syncopal episode. The defibrillators functioned appropriately — no shock was administered — in the cases of all four patients. Four additional persons with ventricular fibrillation were defibrillated with equipment that was not supplied by the HeartSave Program: three collapsed near gate areas and were defibrillated by nearby flight attendants using defibrillators from airplanes, and a fourth initially underwent defibrillation by paramedics with their own equipment.

Of the 22 patients with cardiac arrest for whom an airport-terminal defibrillator was obtained, a 33-year-old man had an arrest after a long fall and a 60-year-old man was found dead on a transit-system train. Of the 21 patients with nontraumatic cardiac arrest, 2 were women (age, 78 and 81 years) and 19 were men (median age, 58 years; range, 44 to 86). Nineteen were travelers, one was an airport employee, and one was a visitor.

Excluding the patient with trauma and the man who was found dead on the train, there were 20 patients with witnessed cardiac arrest. Although pulseless, two patients presented with some organized electrocardiographic activity. The remaining 18 (90 percent) presented with ventricular fibrillation; this group comprised both women and 16 men. The characteristics of these 18 patients are provided in Table 1.

Outcome of Defibrillation

The automated defibrillator functioned correctly in all 18 patients with ventricular fibrillation, immediately determining the need for and delivering shocks. In all 18 patients, the defibrillators were retrieved and operated by travelers or airport employees before the arrival of the emergency-medical-services crews. In the cases of four of the seven patients who died, the defibrillator was not immediately accessible (e.g., two patients on airplanes) or was not accessed within five minutes after collapse. Three others remained in persistent ventricular fibrillation and eventually died despite rapid use of the defibrillators (within five minutes). Two of these patients received seven and nine defibrillator shocks, respectively, before the paramedics arrived.

Eleven of the patients with ventricular fibrillation regained spontaneous circulation and eventually regained consciousness. Four returned to consciousness before the paramedics arrived, two during transport, two in the emergency department, and another three after hospitalization. For 9 of these 11 patients, defibrillators were retrieved and used by bystanders within five minutes. The other two did not receive a shock for seven minutes, but they received immediate cardiopulmonary resuscitation. All 11 had good neurologic outcomes before discharge (with a cerebral performance category of 1), and 10 were alive at one year. One patient died of other sequelae weeks after cardiac arrest. The long-term survival rate with a good neurologic outcome among all 18 patients with ventricular fibrillation was 56 percent (regardless of the location of cardiac arrest), and it was 67 percent among the 12 patients who underwent defibrillation within five minutes.

Characteristics of the Rescuers and Complications of Defibrillation

With two exceptions, the operators of the defibrillators were good Samaritans (airline passengers or airport employees) who had no duty to act, and all used the defibrillators voluntarily and correctly (Table 1). In 6 of the 11 cases in which patients were successfully resuscitated and regained consciousness, the defibrillator users had neither operated an automated external defibrillator previously nor been trained in its use, although three were physicians. No complications occurred. One of the 53 defibrillators was stolen during the two-year period.

TABLE 1. CHARACTERISTICS OF 18 PATIENTS WITH VENTRICULAR FIBRILLATION WHO RECEIVED DEFIBRILLATOR SHOCKS FROM AUTOMATED EXTERNAL DEFIBRILLATORS (AED) INSTALLED AT CHICAGO AIRPORT TERMINALS BETWEEN JUNE 1, 1999, AND MAY 31, 2001.*

CHARACTERISTIC	RESUSCITATED AND REGAINED FULL CONSCIOUSNESS (N=11)	NOT RESUSCITATED (N=7)
Mean (±SD) age — yr	67.7±8.4	67.9±12.1
Male sex — no. (%)	10 (91)	6 (86)
Purpose at airport — no. of patients (%)		
Travel	11 (100)	6 (86)
Dropping off or picking up traveler	0	1 (14)
Basic cardiopulmonary resuscitation performed before AED used — no. of patients (%)	11 (100)	6 (86)
Time from notification of dispatcher to delivery of first shock — no. of patients (%)		
≤5 Min	9 (82)	3 (43)
>5 Min	2 (18)	4 (57)
No. of shocks required for conversion to organized rhythm — no. of patients (%)		
1 Shock	7 (64)	2 (29)
2 or 3 Shocks	4 (36)	2 (29)
>3 Shocks	0	3 (43)
Witnessed arrest — no. of patients (%)	11 (100)	7 (100)
Outcome — no. of patients (%)		
Regained consciousness before arrival of EMS personnel	4 (36)	—
Regained consciousness before hospitalization	8 (73)	—
Neurologically intact (CPC score=1) before discharge†	11 (100)	—
Alive at 1 yr	10 (91)	—
Defibrillation performed by good Samaritan — no. of patients (%)	10 (91)	6 (86)
Defibrillation performed by person with no prior use of AED or training — no. of patients (%)	6 (55)	1 (14)

*EMS denotes emergency medical services.

†Cerebral performance category (CPC) scores range from 1 through 5, with higher scores indicating more severe disability.

DISCUSSION

The results of this study demonstrate the lifesaving potential of public access to defibrillation.[15] Most of the patients with ventricular fibrillation in the study were resuscitated within minutes by good Samaritans who had immediate access to an automated defibrillator. The overall one-year survival rate with a good neurologic outcome regardless of location was 56 percent. In contrast, survival rates are estimated to be less than 5 percent with the use of conventional, "rapid-response" emergency medical services.[12] Traditionally, most resuscitated patients are still comatose on hospital admission, and typically, more than half never regain consciousness.[25,26] Our results reflect a substantial change in that traditional clinical course.

Given the expected lifetime of the defibrillators installed by the HeartSave Program (a minimum of about 10 years), the cost of the program at the three Chicago airports, including the devices, cabinets, alarm systems, and quality-assurance measures, averages about $35,000 a year. On the basis of our results, this figure translates to a cost of about $3,000 per patient and about $7,000 per life saved. Our finding that the majority of patients who underwent successful defibrillation were conscious before reaching the hospital also has implications for the immediate use of medical resources (such as the need for mechanical ventilation and treatment in the intensive care unit) and for long-term cost effectiveness.[27] Nevertheless, further economic analyses are needed to confirm these potential cost savings.

Despite the central role of the automated defibrillator, the performance of cardiopulmonary resuscitation by bystanders may also have contributed to the good outcomes in this study.[7,9,10,28,29] All survivors received cardiopulmonary resuscitation, and one received cardiopulmonary resuscitation for 10 minutes between episodes of ventricular fibrillation before eventually being resuscitated. Even under optimal conditions, some time elapses before the first shock can be delivered. In one case, two HeartSave personnel who were standing next to an automated defibrillator

witnessed the collapse. Still, it took at least two minutes for these experts to ready the patient and the equipment. These considerations and the role of basic cardiopulmonary resuscitation must be kept in mind when program designers are calculating predicted response intervals.[15]

In the cases of four of the seven patients for whom defibrillation was unsuccessful, the arrest occurred far from the main terminal and ticket-counter areas, and the response was thus delayed. Previous work has made clear the inverse association between the time needed to respond and survival. Of the patients who collapsed in a terminal for whom a defibrillator was retrieved and used within five minutes, 75 percent were resuscitated and rapidly regained consciousness.

Three patients remained in fibrillation despite a rapid response. All three had diabetes and were described as obese in medical records. Other data have suggested that obesity and diabetes may decrease the success of external defibrillation.[30,31] We did not systematically collect data on these clinical features, and thus we cannot address their frequency among patients who underwent successful defibrillation.

The program we studied has some unique advantages.[32] Although most cardiac arrests occur at home (70 to 80 percent),[7,32] airports may be the public places with the highest concentration of cardiac arrests.[21] O'Hare is used by many thousands of persons daily, including many health professionals and other persons who are likely to know how to perform cardiopulmonary resuscitation and who thus may feel more comfortable acting in such situations. Three of the seven rescuers without training or experience in the use of an automated external defibrillator had medical degrees. Thus, it is not known whether these results can be generalized to other public places that may be less frequented by health professionals.

Previous studies have demonstrated that targeted nonmedical personnel can be trained as part of their job descriptions to use automated external defibrillators in public venues, including casinos[16] and airplanes.[17] Our findings showed that bystanders will voluntarily aid persons with cardiac arrest and can do so successfully, even without prior training in the use of defibrillators. The survival rates were similar to (or exceeded) those in prior studies.[16,17] Although many rescuers were airport employees (i.e., custodians, customs or immigration officials, or wheelchair assistants), the majority had taken cardiopulmonary-resuscitation courses voluntarily and had no specific duty to act.

Studies demonstrate that even sixth-grade children can use automated external defibrillators without prior instruction.[33] In our study, 6 of the 11 successfully resuscitated patients were resuscitated by persons who had neither previously operated an automated defibrillator nor been specifically trained in its use. Although three had medical degrees and another was a health professional, this attribute does not imply that such persons have a duty to act or are comfortable using an unfamiliar device.

Although training in cardiopulmonary resuscitation and the use of automated external defibrillators is strongly encouraged for everyone, our findings suggest that the lack of such training should not constrain attempts to use a defibrillator in emergencies. Given the safety of these devices and our results, reasonable public health strategies would be to promulgate good-Samaritan laws; encourage the development of less expensive, more user-friendly automated defibrillators for public deployment in appropriate locations; and undertake aggressive public-education campaigns that promote the idea that anyone is capable of immediate action in such situations.[15,33-37]

Ms. Caffrey reports having received consulting and lecture fees from Phillips Medical System. Dr. Becker reports having received honorariums and research support from Phillips Medical Systems and research support from Laerdal.

Presented in part at the annual meeting of the American Heart Association, New Orleans, November 15, 2000.

We are indebted to Chicago Mayor Richard M. Daley, Maggie Daley, and the City Council of Chicago, to the Department of Aviation and its commissioner, Thomas Walker, and to the Chicago Fire Department and its commissioner, James Joyce, for their support; to Mark Linse, E.M.T.-P., Lourdes Rodrigues, E.M.T.-B., Ellen Demertzidis, E.M.T.-B., Robert Gundlach, E.M.T.-P., former commissioner of aviation Mary Rose Lony, and former first deputy fire commissioner Cortez Trotter for their assistance with the development and implementation of the project and quality assurance; to Sandy Kowerko for assistance with the figures; and to Carol W. Smith for assistance in the preparation of the manuscript.

REFERENCES

1. Rosamond WD, Chambless LE, Folsom AR, et al. Trends in the incidence of myocardial infarction and in mortality due to coronary heart disease, 1987 to 1994. N Engl J Med 1998;339:861-7.
2. Zheng ZJ, Croft JB, Giles WH, Mensah GA. Sudden cardiac death in the United States, 1989 to 1998. Circulation 2001;104:2158-63.
3. State-specific mortality from sudden cardiac death — United States, 1999. MMWR Morb Mortal Wkly Rep 2002;51:123-6.
4. 2002 Heart and stroke statistical update. Dallas: American Heart Association, 2002.
5. Becker LB. The epidemiology of sudden death. In: Paradis NA, Halperin HR, Nowak RM, eds. Cardiac arrest: the science and practice of resuscitation medicine. Baltimore: Williams & Wilkins, 1996:28-47.
6. Huikuri HV, Castellanos A, Myerburg RJ. Sudden death due to cardiac arrhythmias. N Engl J Med 2001;345:1473-82.
7. Cummins RO, Ornato JP, Thies WH, Pepe PE. Improving survival from sudden cardiac arrest: the "chain of survival" concept: a statement for health professionals from the Advanced Cardiac Care Committee, American Heart Association. Circulation 1991;83:832-47.
8. Hossack KF, Hartwig R. Cardiac arrest associated with supervised cardiac rehabilitation. J Card Rehabil 1982;2:402-8.
9. White RD, Hankins DG, Bugliosi TF. Seven years' experience with early defibrillation by police and paramedics in an emergency medical services system. Resuscitation 1998;39:145-51.
10. Cummins RO, Eisenberg MS, Hallstrom AP, Litwin PE. Survival of out-of-hospital cardiac arrest with early initiation of cardiopulmonary resuscitation. Am J Emerg Med 1985;3:114-9.
11. Larsen MP, Eisenberg MS, Cummins RO, Hallstrom AP. Predicting survival from out-of-hospital cardiac arrest: a graphic model. Ann Emerg Med 1993;22:1652-8.
12. Becker LB, Ostrander MP, Barrett J, Kondos GT. Outcome of CPR in

a large metropolitan area — where are the survivors? Ann Emerg Med 1991;20:355-61.
13. Lombardi G, Gallagher J, Gennis P. Outcome of out-of-hospital cardiac arrest in New York City: the Pre-Hospital Arrest Survival Evaluation (PHASE) Study. JAMA 1994;271:678-83.
14. Becker LB, Pepe PE. Ensuring the effectiveness of community-wide emergency cardiac care. Ann Emerg Med 1993;22:354-65.
15. Guidelines 2000 for cardiopulmonary resuscitation and emergency cardiovascular care. 4. The automated external defibrillator: key link in the chain of survival. Circulation 2000;102:Suppl I:I-60–I-76.
16. Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. N Engl J Med 2000;343:1206-9.
17. Page RL, Joglar JA, Kowal RC, et al. Use of automated external defibrillators by a U.S. airline. N Engl J Med 2000;343:1210-6.
18. Wassertheil J, Keane G, Fisher N, Leditschke JF. Cardiac arrest outcomes at the Melbourne Cricket Ground and Shrine of Remembrance using a tiered response strategy — a forerunner to public access defibrillation. Resuscitation 2000;44:97-104.
19. MacDonald RD, Mottley JL, Weinstein C. Impact of prompt defibrillation on cardiac arrest at a major international airport. Prehosp Emerg Care 2002;6:1-5.
20. O'Rourke MF, Donaldson EE, Geddes JS. An airline cardiac arrest program. Circulation 1997;96:2849-53.
21. Becker L, Eisenberg M, Fahrenbruch C, Cobb LA. Public locations of cardiac arrest: implications for public access defibrillation. Circulation 1998;97:2106-9.
22. White RD, Hankins DG, Atkinson EJ. Patient outcomes following defibrillation with a low energy biphasic truncated exponential waveform in out-of-hospital cardiac arrest. Resuscitation 2001;49:9-14.
23. Cummins RO, Chamberlain D, Hazinski MF, et al. Recommended guidelines for reviewing, reporting, and conducting research on in-hospital resuscitation: the in-hospital "Utstein-style." Acad Emerg Med 1997;4:603-27.
24. Safar P. Cerebral resuscitation after cardiac arrest: summaries and suggestions. Am J Emerg Med 1983;1:198-214.
25. Greene HL. Sudden arrhythmic cardiac death — mechanisms, resuscitation and classification: the Seattle perspective. Am J Cardiol 1990;65:4B-12B.
26. Bonnin MJ, Pepe PE, Kimball KT, Clark PS Jr. Distinct criteria for termination of resuscitation in the out-of-hospital setting. JAMA 1993;270:1457-62.
27. Nichol G, Hallstrom AP, Ornato JP, et al. Potential cost-effectiveness of public access defibrillation in the United States. Circulation 1998;97:1315-20.
28. Gallagher EJ, Lombardi G, Gennis P. Effectiveness of bystander cardiopulmonary resuscitation and survival following out-of-hospital cardiac arrest. JAMA 1995;274:1922-5.
29. Cobb LA, Fahrenbruch CE, Walsh TR, et al. Influence of cardiopulmonary resuscitation prior to defibrillation in patients with out-of-hospital ventricular fibrillation. JAMA 1999;281:1182-8.
30. Kerber RE, Grayzel J, Hoyt R, Marcus M, Kennedy J. Transthoracic resistance in human defibrillation: influence of body weight, chest size, serial shocks, paddle size and paddle contact pressure. Circulation 1981;63:676-82.
31. Hallstrom AP, Cobb LA, Yu BH. Influence of comorbidity on the outcome of patients treated for out-of-hospital ventricular fibrillation. Circulation 1996;93:2019-22.
32. Litwin PE, Eisenberg MS, Hallstrom AP, Cummins RO. The location of collapse and its effect on survival from cardiac arrest. Ann Emerg Med 1987;16:787-91.
33. Gundry JW, Comess KA, DeRonk FA, Jorgenson D, Bardy GH. Comparison of naive sixth-grade children with trained professionals in the use of an automated external defibrillator. Circulation 1999;100:1703-7.
34. Domanovits H, Meron G, Sterz F, et al. Successful automatic external defibrillator operation by people trained only in basic life support in a simulated cardiac arrest situation. Resuscitation 1998;39:47-50.
35. Eisenberg MS. Is it time for over-the-counter defibrillators? JAMA 2000;284:1435-8.
36. SoRelle R. States set to pass laws limiting liability for lay users of automated external defibrillators. Circulation 1999;99:2606-7.
37. Good Samaritan Civil Immunity for Use of Automated External Defibrillator, tit. 42, §8331.2, Pa. consolidated statutes (1998).

Performance and Error Analysis of Automated External Defibrillator Use in the Out-of-Hospital Setting

Russell D. MacDonald, MD, MPH*‡
John M. Swanson, MD*
J. Lawrence Mottley, MD, MHSA*‡
Carl Weinstein, EMT-P‡

Department of Emergency Medicine, Boston Medical Center and Boston University School of Medicine, and Boston Emergency Medical Services,‡ Boston, MA.*

Author contributions are provided at the end of this article.

Received for publication October 18, 2000. Revision received May 1, 2001. Accepted for publication June 13, 2001.

Presented in part at the American College of Emergency Physicians Scientific Assembly, Las Vegas, NV, October 1999, and the Society for Academic Emergency Medicine annual meeting, San Francisco, CA, May 2000.

Address for reprints: Russell D. MacDonald, MD, MPH, Provincial Medical Director, Land Ambulance Program, Emergency Services Branch, Manitoba Health, 1680 Ellice Avenue, Unit #7, Winnipeg, Manitoba, Canada R3H 0Z2; 204-945-1665, fax 204-948-2531; E-mail rmacdonald@gov.mb.ca.

0196-0644/2001/$35.00 + 0
47/1/117953
doi:10.1067/mem.2001.117953

Study objective: We determined whether automated external defibrillators (AEDs) can meet the American Heart Association performance criteria to detect and shock unstable cardiac rhythms (ventricular fibrillation [VF], ventricular tachycardia [VT]) in the setting of an out-of-hospital cardiac arrest.

Methods: AED performance was reviewed for cardiac arrests occurring between January 1, 1995, and December 31, 1997. After every cardiac arrest, data regarding each rhythm analyzed and subsequent response (shock or no shock) were downloaded from the AED memory module. The study paramedic and study physician independently reviewed each case and interpreted cardiac rhythms from downloaded AED data. The emergency medical services medical director resolved all discrepancies in a blinded manner. All cases of out-of-hospital cardiac arrest in which an AED was turned on and a rhythm analyzed were included. The primary objective was the correct identification and defibrillation of VF or VT. Sensitivity, specificity, and predictive values with 95% confidence intervals (CIs) were calculated. Sources of error in AED rhythm management are also described.

Results: A total of 3,448 AED rhythms were available for interpretation. Sensitivity and specificity for appropriate AED management of a shockable (VF or VT) rhythm were 81.0% (95% CI 77.9% to 83.8%) and 99.9% (95% CI 99.7% to 100%), respectively. Positive and negative predictive values were 99.6% (95% CI 98.7% to 99.9%) and 95.5% (95% CI 94.7% to 96.2%), respectively. There were 132 errors associated with AED management. Two errors resulted in delivery of an inappropriate shock. In the remaining 130 errors, a shockable rhythm was not shocked. Fifty-five (42.3%) errors were AED dependent, 70 (53.9%) were operator dependent, and 5 (3.9%) were unclassified.

Conclusion: The AED had high specificity and moderately high sensitivity in detecting and shocking unstable cardiac rhythms in the out-of-hospital setting. Few cardiac rhythms

were mismanaged by the AED. Elimination of operator-dependent errors could increase AED sensitivity.

[MacDonald RD, Swanson JM, Mottley JL, Weinstein C. Performance and error analysis of automated external defibrillator use in the out-of-hospital setting. *Ann Emerg Med.* September 2001;38:262-267.]

INTRODUCTION

One of the major determinants of survival in persons who suffer an out-of-hospital cardiac arrest is the speed with which a defibrillatory countershock can be delivered.[1-6] The introduction of automated external defibrillators (AEDs) allows properly trained first responders or emergency medical technicians to deliver countershocks in cases of out-of-hospital ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT). Delivery of this countershock is often minutes before the arrival of paramedic personnel who are trained in advanced life support (ALS).

Public access defibrillation (PAD) programs using targeted first responders aim to make defibrillation available in a short period of time.[7] Locations such as office towers, sporting venues, mass transit facilities, and casinos can be targeted for PAD programs using AEDs.

AED effectiveness is dependent on the device's ability to detect an unstable cardiac rhythm and on the operator's ability to use the device correctly. There are no large-scale studies reviewing AED use in detecting and managing unstable cardiac rhythms under actual field conditions. In addition, the sources of error associated with AED use in this setting have not been reported. This study's primary objective is to determine AED performance in detection and delivery of a countershock to unstable cardiac rhythms (VF or VT) in the setting of an out-of-hospital cardiac arrest. This study also describes the sources of error in AED rhythm management in this setting.

MATERIALS AND METHODS

The city of Boston encompasses an urban area of 46 square miles (119 km^2). Its resident population is 575,000, with a weekday population of approximately 1.5 million. Boston Emergency Medical Services (BEMS) responds to all 911 requests for medical assistance in the city of Boston. Its annual call volume is approximately 90,000, with approximately 63,000 transports. Although a number of private ambulance services operate within the city of Boston, they are not accessed through the 911 system and rarely handle cases of cardiac arrest.

BEMS began equipping its basic life support (BLS) ambulance units with AEDs in 1988. By 1994, all BLS units were equipped with FirstMedic-510 AEDs (PhysioControl; Redmond, WA). In July 1994, fire department and airport fire rescue personnel were trained in the use of AEDs and began providing first response for suspected cardiac arrests. By December 1994, all fire department and airport fire rescue vehicles were equipped with AEDs.

BEMS has maintained a prospective cardiac arrest quality assurance (QA) database since July 1993. Fire fighters, airport rescue, and EMS personnel are required to complete and submit a cardiac arrest report form for all cases of cardiac arrest. The form is submitted to the QA division on a daily basis. A QA paramedic is permanently assigned to collect cardiac arrest data and maintain the database. This paramedic reviews the 911 dispatch records and patient care reports ("run sheets") on a daily basis to ensure that all cases of cardiac arrest are captured.

Each rhythm and code summary is stored on a memory module within the AED. The module is downloaded after each cardiac arrest to a computer database maintained by the QA division. The QA paramedic and a study physician independently review all cardiac arrest reports and code summaries to ensure accuracy and data integrity. The EMS medical director independently reviewed the first AED analyses and also resolved discrepancies in rhythm interpretations or code summaries in a blinded manner.

A review was undertaken to determine AED performance in detecting and defibrillating VF and VT in the out-of-hospital setting. The review included the identification and source of errors in detection and defibrillation of VF and VT. AED data were reviewed from January 1, 1995, to December 31, 1997.

During the study period, all BEMS, airport fire rescue, and fire department vehicles were equipped with FirstMedic-510 AEDs. The Utstein survival was 22.3% during the study period.

All confirmed cases of out-of-hospital cardiac arrest in which an AED was turned on and a rhythm analyzed were included in this study. Cases were excluded if EMS personnel attempted no resuscitation or if no rhythm analysis was carried out with the AED. To ensure the completeness of the case finding, a review of all ambulance patient care reports was performed to ensure that no cases of cardiac arrest were omitted. No additional cases of cardiac arrest were found.

The primary end point of the study was the correct identification of and delivery of a shock to VF or VT by the AED. This end point was chosen because it is the most reliable indicator of the AED's ability to properly manage

an unstable cardiac rhythm. AED performance was determined with the American Heart Association (AHA) recommendations for specifying and reporting AED arrhythmia analysis algorithm performance.[8] These criteria are outlined in Table 1.

Errors associated with AED use were identified and categorized as machine dependent or operator dependent in a predetermined manner. The categorization algorithm is depicted in the Figure. This categorization was chosen because it permits differentiation between errors that were intrinsic to the AED from errors that were extrinsic and related to the AED operator.

This review was approved by the Institutional Review Board of Boston Medical Center, the base hospital providing medical control for BEMS.

The QA paramedic (using Q&A, Version 4.0; Symantec Corporation, Eugene, OR) and the study physician (using Microsoft Access, version 97; Microsoft Corporation, Redmond, WA) independently entered all data into commercially available database software. The study personnel resolved discrepancies in data entry. The final results were exported to SPSS (version 8.0 for Windows; Chicago, IL) for statistical analysis.

Rhythms were categorized as discrete, unordered variables. AED performance was assessed calculating sensitivity and specificity in correctly identifying and delivering a shock to VF or VT. Interobserver rhythm interpretation measure of agreement for the first rhythm analyzed by the AED was computed using the κ statistic. Sources of error were reported using descriptive statistics.

RESULTS

A total of 3,045 cardiac arrests took place during the study period. Of those, 1,079 met the inclusion criteria and were included in the interpretation of AED performance. The remaining 1,966 cardiac arrests were excluded from analysis. Table 2 outlines the reasons these cases did not meet inclusion criteria.

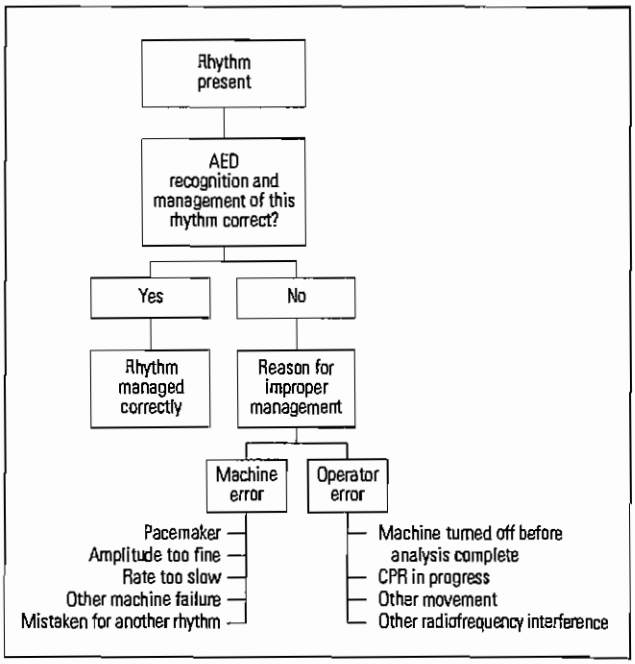
Inclusion criteria were met in 1,079 cases, with a total of 3,576 rhythm analyses performed by the AEDs. Of these, 3,448 analyses were available for review. Of the remaining analyses, 107 (3.0%) could not be retrieved because of AED memory module failure. An additional 21 (0.6%) analyses were excluded as a result of AED memory module artifact. The latter were excluded because the underlying cardiac rhythm could not be interpreted and could not be used in determination of AED performance, which was the study's primary objective. Rhythm analyses that were unavailable for interpretation were not associated with the delivery of an AED shock.

Tables 3, 4, and 5 summarize the AED performance data. The sensitivity and specificity for all shockable rhythms (VF or VT) were 81.0% (95% CI 77.9% to 83.8%) and 99.9% (95% CI 99.7% to 100%), respectively. The positive and negative predictive values were 99.6% (95% CI 98.7% to 99.9%) and 95.5% (95% CI 94.7% to 96.2%), respectively.

Table 1.
Performance goals for arrhythmia analysis algorithms.[8]

Rhythm	Minimum Sample Size	Performance Goal
Coarse VF	200	>90% sensitivity
Rapid VT	50	>75% sensitivity
Fine VF	25	Report only
Other VT	25	Report only
Sinus rhythm	100	>99% specificity
Asystole	100	>95% specificity
Other nonshockable rhythms	30	>95% specificity

Figure.
Categorization algorithm for AED errors.



The AHA performance criteria[8] distinguish VF as either coarse (>200 mV in amplitude) or fine (≤200 mV in amplitude). When coarse VF was present, the AED sensitivity was 91.9% (95% CI 88.7% to 94.2%). The sensitivity for fine VF was 67.3% (95% CI 61.5% to 72.6%).

Agreement between the QA paramedic and the study physician for shockable versus nonshockable rhythms on the first AED analysis was reached in 1,014 of 1,079 analyses (94.0%; κ=0.88). Agreement was reached between the QA paramedic and final consensus interpretation in 1,014 of 1,079 analyses (94.0%; κ=0.88) and between the study physician and final consensus interpretation in 1,073 of 1,079 analyses (99.4%; κ=0.99).

A total of 132 errors occurred in the AED's management of 3,448 (3.83%) cardiac rhythms. Two AED rhythm interpretations resulted in the delivery of a defibrillatory shock when none was required. The first was a case of a ventricular-paced rhythm with pronounced interventricular conduction delay, simulating VT at a rate of approximately 220 beats/min. The second was atrial tachycardia at a rate of 180 beats/min, with ventricular asystole.

The remaining 130 cardiac rhythms were considered unstable and required delivery of a shock, but the AED did not deliver the required shock. The QA paramedic and study physician were in agreement regarding the source of error associated with AED use in all cases. Table 6 summarizes the machine-dependent and operator-dependent sources of error as to why a shock was not delivered.

DISCUSSION

This study describes a 3-year experience with AEDs in the out-of-hospital setting. The results demonstrate that an AED analysis algorithm met or exceeded the AHA performance standards for coarse VF and nonshockable rhythms in the setting of out-of-hospital cardiac arrest.

Table 2.
Reasons cardiac arrest did not meet inclusion criteria (N=1,966).

Variable	No. of Cases
No resuscitation attempted	1,328
Obvious mortal injury	
Rigor mortis	
Extensive dependent lividity	
Tissue decomposition	
ALS crew first on scene	485
Traumatic arrest	145
Infant <1 y	4
Arrested in ED ambulance bay	1
BLS crew did not apply AED	1
Private BLS ambulance crew; no report available	1
Hypothermic or frozen patient	1

Table 3.
AED performance data summary.

Rhythm	Shockable*	Not Shockable†	Total
Shocked‡	555	2	557
Not shocked§	130	2,761	2,891
Total	685	2,763	3,448

*Rhythm is either VF or VT.
†Rhythm is not VF or VT.
‡Rhythm was shocked by AED.
§Rhythm was not shocked by AED.

Table 4.
AED performance data for shockable rhythms.

Rhythm	VF (Coarse*)	VF (Fine†)	VT (Rapid‡)	VT (Slow§)	Total
Shocked	360	181	9	5	555
Not shocked	32	88	3	7	130
Total	392	269	12	12	685
Sensitivity (95% CI)	91.8 (88.7–94.2)	67.3 (61.5–72.6)	75.0 (46.8–91.1)	41.7 (14.3–68.0)	81.0 (77.9–83.8)

*>200 mV in amplitude.
†≤200 mV in amplitude.
‡>180 beats/min.
§≤180 beats/min.

Table 5.
AED performance data for nonshockable rhythms.

Rhythm	Asystole	Sinus Rhythm	Other Rhythm	Total
Shocked	0	0	2	2
Not shocked	1,387	100	1,274	2,761
Total	1,387	100	1,276	2,763
Specificity (95% CI)	100 (99.7–100)	100 (96.3–100)	99.8 (99.4–100)	99.9 (99.7–100)

Further study is required in the setting of VT because the sample size was not sufficient.

The results also demonstrate that errors associated with AED use are low. Machine-related errors are infrequent, but they do occur. The AED model used in this study recognized VF when fibrillatory waves had amplitudes greater than 200 mV. The algorithm threshold for AED recognition of VT was a rate greater than 180 beats/min. Although VF or VT do occur below these recognition thresholds, the AED's analysis algorithm did not detect them. These thresholds have an inherently high specificity for unstable cardiac rhythms. This ensures AED safety and prevents inappropriate delivery of electrical countershocks. The need for such high specificity decreases sensitivity, but the overriding need for safety with these devices makes this a necessity.

Operator-dependent errors accounted for more than half of the errors in this study. Most were caused by patient movement during AED analysis of the cardiac rhythm. This movement was caused by the performance of cardiopulmonary resuscitation (CPR) or artificial ventilation. Refraining from performing CPR or artificial ventilation during the AED's analysis cycle can eliminate these movement-related errors.

A second type of operator-dependent error was inappropriate action taken by the AED operator. While the AED was analyzing a shockable rhythm, the operator caused the machine to abort the rhythm analysis prematurely (eg, AED power turned off, analysis button pushed again). These errors may be minimized by instructing operators to recognize when the AED is analyzing a cardiac rhythm, using a lockout mechanism to prevent premature rhythm reanalysis or powering off, or providing an audible or visual prompt during rhythm analysis.

Errors associated with AED use in the out-of-hospital setting can be minimized but not eliminated. Some sacrifice in sensitivity is necessary to ensure adequate specificity. A small number of machine-dependent errors will be unavoidable; however, operator-related errors may be avoided. Further study is required to determine which methods would be successful in decreasing errors associated with AED use.

The AHA's CPR training program currently includes AED use. The minimum time required to properly train a rescuer to use an AED has not been determined. Studies demonstrate that lay rescuers with minimal or no formal training can successfully operate an AED.[9,10] Studies also demonstrate that PAD is effective when used by targeted responders with formal training in locations such as casinos,[11] on board aircraft,[12] and in major airports (RDM and JLM, unpublished data, 2001).

This study has several limitations. The cardiac arrest QA database did not record situations in which an AED was used for rhythm analysis but it was determined in retrospect that a cardiac arrest had not occurred. AED performance and errors in this situation are not known. The initial study design excluded all patients for whom resuscitation was not attempted. Subsequent review revealed that first responders applied an AED in 16 such patients, resulting in 30 rhythm analyses. All 30 rhythms were nonshockable, no shocks were delivered, and there were no errors associated with AED use. These 30 rhythm analyses were not included in the study. Although this is a limitation, inclusion of these 30 rhythm analyses would only improve the AED performance measures in this setting.

A single AED model was used in this study. Use of a single model enabled assessment of its performance and of machine-related errors specific to that model. The results may not be applicable to other models from the same or different manufacturers.

Two reviewers independently interpreted all cardiac rhythm strips. The third reviewer interpreted only the first rhythm for each cardiac arrest and resolved discrepancies in the first and any subsequent rhythms independently. This differs from the AHA standard of 3 independent reviewers for analysis of all cardiac rhythms to determine AED algorithm performance.[8] The degree to which a lack of 3 independent reviewers for all cardiac

Table 6.
Sources of AED error for shock not delivered (N=130).

Type of Error	No.
Machine dependent (N=55; 42.3%)	
Fine ventricular fibrillation (amplitude <200 mV)	44
Pacemaker in place, unstable cardiac rhythm obscured	9
Coarse ventricular fibrillation (amplitude >200 mV)	2
Operator dependent (N=70; 53.85%)	
Interference as a result of movement (CPR in progress)	22
Interference as a result of movement (other source)	17
Operator turned AED off before completion of analysis cycle	22
Operator reanalyzed rhythm before completion of current analysis cycle	7
Operator failed to deliver shock after AED charged	1
Leads fell off during analysis	1
Unclassified errors (N=5; 3.85%)	
Missing data	3
External electrical interference*	2

*External electrical interference was "unclassified" because it was not possible to determine whether electrical interference was a result of a defibrillator problem (machine dependent) or placement of defibrillator close to source of electrical interference (operator dependent).

rhythms affected the study is not known. Two reviewers independently determined the source of AED error, but they were not blinded to the presence of an AED error. This was not possible within the existing QA program. The degree to which the lack of blinding regarding recognition of an AED error affected the study is not known.

Finally, no specific intervention, other than regular refresher courses in AED use, was used in an attempt to reduce operator errors. The effect of regular refresher courses on operator errors was not specifically assessed in this study.

The analysis of AED performance and the identification of sources of error associated with AED use in actual field conditions yield important information. PAD programs are increasingly popular. Their aim is to provide access to rapid, reliable defibrillation by lay rescuers before the arrival of trained medical personnel. This study describes AED performance and sources of error and demonstrates AED effectiveness in the out-of-hospital setting.

Author contributions: RDM, JMS, and JLM conceived the study and developed its design. RDM and CW acquired the data. RDM, JMS, JLM, and CW analyzed and interpreted the data. The article's initial draft was written by RDM and JMS. There was significant participation by RDM, JMS, JLM, and CW in subsequent revisions. The final version was approved by RDM, JMS, JLM, and CW. RDM and JLM take responsibility for the paper as a whole.

We thank the men and women of the Boston Emergency Medical Services, the Boston Fire Department, and Massport Fire Rescue for their dedication in treating victims of cardiac arrest and for their ongoing efforts to provide the necessary data to make the BEMS cardiac arrest project possible.

REFERENCES

1. Weston CFM, Wilson RJ, Jones SD. Predicting survival from out-of-hospital cardiac arrest: a multivariate analysis. *Resuscitation.* 1997;34:27-34.

2. Mols P, Beaucarne E, Bruyninx J, et al. Early defibrillation by EMTs: the Brussels experience. *Resuscitation.* 1994;27:129-136.

3. Weaver WD, Copass MK, Hill DK, et al. Cardiac arrest treated with e new automatic external defibrillator by out-of-hospital first responders. *Am J Cardiol.* 1986;57:1017-1021.

4. Weaver WD, Cobb LA, Hallstrom AP, et al. Factors influencing survival after out-of-hospital cardiac arrest. *J Am Coll Cardiol.* 1986;7:752-757.

5. Brison RJ, Davidson JR, Dreyer JF, et al. Cardiac arrest in Ontario: circumstances, community response, role of prehospital defibrillation and predictors of survival. *CMAJ.* 1992;147:191-199.

6. Eisenberg MS, Bergner L, Hallstrom A. Cardiac resuscitation in the community: importance of rapid provision and implications for program planning. *JAMA.* 1979;241:1905-1907.

7. Cummins RO, Orneto JP, Thies WH, et al. Improving survival from sudden cardiac arrest: the "chain of survival concept." A statement for health professionals from the Advanced Cardiac Life Support Subcommittee and the Emergency Cardiac Care Committee, American Heart Association. *Circulation.* 1991;83:1832-1847.

8. Kerber RE, Becker LB, Bourland JD, et al. Automated external defibrillator for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety. A statement for health professionals from the American Heart Association Task Force on Automated External Defibrillation, Subcommittee on AED Safety and Efficacy. *Circulation.* 1997;95:1677-1682.

9. Fromm RE, Varon J. Automated external versus blind manual defibrillation by untrained lay rescuers. *Resuscitation.* 1997;33:219-221.

10. Domanovits H, Meron G, Sterz F, et al. Successful automatic external defibrillator operation by people trained only in basic life support in a simulated cardiac arrest situation. *Resuscitation.* 1998;39:47-50.

11. Valenzuela TD, Roe DJ, Nichol C, et el. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. *N Engl J Med.* 2000;343:1206-1209.

12. Page RL, Joglar JA, Kowal RC, et al. Use of automated external defibrillators by a US airline. *N Engl J Med.* 2000;343:1210-1216.

Resuscitation (2008) 76, 168–174

available at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/resuscitation

CLINICAL PAPER

Sensitivity and specificity of an automated external defibrillator algorithm designed for pediatric patients☆

Dianne L. Atkins[a,*], William A. Scott[b], Andrew D. Blaufox[c,f], Ian H. Law[a], Macdonald Dick II[d], Frederick Geheb[e], Jamil Sobh[e], James E. Brewer[e]

[a] Division of Pediatric Cardiology, University of Iowa, 200 Hawkins Drive, University of Iowa Children's Hospital, Iowa City, IA 52242, United States
[b] Division of Cardiology, Department of Pediatrics, University of Texas Southwestern Medical Center at Dallas, Children's Medical Center, 5323 Harry Hines Boulevard, Dallas, TX 75390-9063, United States
[c] Medical University of South Carolina, Children's Hospital, Charleston, SC, United States
[d] Pediatric Cardiology, University of Michigan, C.S. Mott Children's Hospital, L1242 Box 0204 UMHS, Ann Arbor, MI 48109-2040, United States
[e] ZOLL Medical Corporation, 269 Mill Road, Chelmsford, MA 01824-4105, United States
[f] The Children's Heart Center, Schneider Children's Hospital, 269-01 76th Avenue, New Hyde Park, NY 11040, United States

Received 24 April 2007; received in revised form 13 June 2007; accepted 25 June 2007

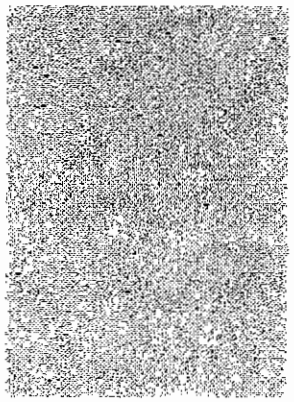
KEYWORDS
Automated external defibrillator (AED);
Arrhythmias;
Cardiac arrest;
Cardiac resuscitation;
Electric countershock/instrumentation

Summary
Objective: Electrocardiographic (ECG) rhythm analysis algorithms for cardiac rhythm analysis in automated external defibrillators (AEDs) have been tested against pediatric patient rhythms (patients ≤8 years old) using adult ECG algorithm criteria. However these adult algorithms may fail to detect non-shockable pediatric tachycardias because they do not account for the difference in the rates of normal sinus rhythm and typical tachyarrhythmias in childhood.
Methods: This study was designed to define shockable and non-shockable rhythm detection criteria specific to pediatric patients to create a pediatric rhythm database of annotated rhythms, to develop a pediatric-based AED rhythm analysis algorithm, and to test the algorithm's accuracy. Pediatric rhythm detection criteria were defined for coarse ventricular fibrillation, rapid ventricular tachycardia, and non-shockable rhythms, including pediatric supraventricular tachycardia. Pediatric rhythms were collected as sustained, classifiable, rhythms ≥9 s in length, and were annotated by pediatric electrophysiologists as clinically shockable or non-shockable based on pediatric criteria. Rhythms were placed into a pediatric rhythm database; each rhythm was converted to digitally accessible, public-domain, MIT rhythm data format. The database was used to evaluate a pediatric-based AED rhythm analysis algorithm.

☆ A Spanish translated version of the summary of this article appears as Appendix in the final online version at 10.1016/j.resuscitation.2007.06.032.

* Corresponding author. Tel.: +1 319 356 3540; fax: +1 319 356 4693.
E-mail address: dianne-atkins@uiowa.edu (D.L. Atkins).

doi:10.1016/j.resuscitation.2007.06.032



Results: Electrocardiographic rhythms from 198 children were recorded. There were 120 shockable rhythms from 49 patients (sensitivity; coarse ventricular fibrillation: 42 rhythms, 100%; rapid ventricular tachycardia: 78 rhythms, 94%), for combined sensitivity of 96.0% (115/120). There were 585 non-shockable rhythms from 155 patients (specificity normal sinus: 208 rhythms, 100%; asystole: 29 rhythms, 100%; supraventricular tachycardia: 161 rhythms, 99%; other arrhythmias: 187 rhythms, 100%), for combined specificity of 99.7% (583/585). Overall accuracy for shockable and non-shockable rhythms was 99.0% (702/709).

Conclusions: New pediatric rhythm detection criteria were defined and analysis based on these criteria demonstrated both high sensitivity (coarse ventricular fibrillation, rapid ventricular tachycardia) and high specificity (non-shockable rhythms, including supraventricular tachycardia). A pediatric-based AED can detect shockable rhythms correctly, making it safe and exceptionally effective for children.

Introduction

Automated external defibrillators (AEDs) are available in increasing numbers and are recommended for use by first responders, emergency medical personnel, hospital personnel and the trained lay public.[1,2] They are replacing manual defibrillators in some emergency medical settings such as hospitals and urgent care clinics.[3] The need to modify the equipment to permit safe use during pediatric cardiac arrest has been supported by an increased awareness of ventricular arrhythmias in children during both out-of-hospital and in-hospital arrest.[4–7] Safe use in children has required attenuation of the energy dose and validation that the rhythm algorithm has high sensitivity and specificity for pediatric rhythms.[8]

Electrocardiographic (ECG) rhythm analysis algorithms from two AEDs have been evaluated using pediatric patient rhythms (patients ≤8 years old).[9,10] The tested algorithms were originally designed using adult ECG detection criteria. The specificity and sensitivity for these two manufacturers was high for both non-shockable rhythms and ventricular fibrillation. However both were below the American Heart Association's recommendation for specificity for ventricular tachycardia.[11] Algorithms using adult thresholds for detection of shockable pediatric tachycardia have resulted in decreased accuracy. Adult algorithms may fail to identify non-shockable pediatric tachycardias correctly because they do not account for the difference in the wide spectrum of normal heart rates, QRS morphologies and tachyarrhythmias seen in children. Additionally, the rhythms were collected using the proprietary software of the individual manufacturers, limiting usefulness for testing other manufacturers' algorithms. A pediatric rhythm database that can be used to test future algorithms has not been developed.

The objectives of this study were to define shockable and non-shockable rhythm detection criteria specific for pediatric patients, to develop a pediatric-based AED rhythm algorithm for use in ZOLL AEDs, and determine the accuracy of this algorithm. This pediatric rhythm database of annotated rhythms could be used to test future device algorithms.

Methods

Definition of pediatric rhythms

Pediatric rhythm detection criteria were defined for coarse ventricular fibrillation, rapid ventricular tachycardia, and non-shockable rhythms, including pediatric supraventricular tachycardia. Definitions of rhythms were established by consensus five pediatric electrophysiologists (DA, WS, AB, IL, MD) and are presented in Table 1.

Rhythm collection and annotation

Pediatric rhythms were collected retrospectively from the electrophysiologic catheterization libraries at the participating institutions. Rhythms were obtained and recorded during intracardiac evaluation and testing of children <8 years with clinical arrhythmias. Rhythms were recorded with standard ECG electrodes. Acquisition software included the EP MEDSystem™, Prucka Cardiolab 400™ and Draeger™. Lead II was the preferred lead but if Lead II was not available, V5 was chosen. Electronically acquired and stored rhythms ≥9 s in length were converted to digitally accessible, public-domain, MIT rhythm data format with sampling rate of 250 samples/s and 12 bit resolution where the scaling was 4.9 μV/bit.

The rhythms were printed and distributed to three pediatric electrophysiologists (DA, WS, AB) who were blinded to institutional source and original interpretation of the rhythm. The cardiologists assumed that the patient was ≤8 years of age and was unresponsive. The rhythms were annotated by the cardiologists as clinically shockable, non-shockable, or intermediate based on the previously agreed pediatric criteria. Specific rhythm diagnoses were assigned to the strips based on interpretations from the three pediatric electrophysiologists. Disagreements were resolved by consensus.

Performance statistics for both the pediatric and adult algorithms were generated by running the ZOLL Advisory Algorithm against the rhythm strips, then comparing the results against the cardiologist assigned rhythm diagnosis. The sensitivity and specificity of the rhythms was calcu-

Table 1 Pediatric rhythm definitions

Shockable rhythm definitions	
Ventricular fibrillation	Uncoordinated ventricular depolarizations. Minimum of five complexes with an average >0.2 mVpp during a 3 s window
Rapid ventricular tachycardia	Absence of *P* waves. Rate >200 beats per minute (bpm) (R–R interval ≤300 ms). QRS complex width >160 ms. Includes monomorphic or polymorphic ventricular tachycardia, and ventricular flutter. Minimal (or no) isoelectric activity
Non shockable rhythm definitions	
Normal sinus rhythm	Complexes are sinus in origin. Does not satisfy the criteria of supraventricular arrhythmias
Supraventricular tachycardia (ABN)	Complexes show supraventricular origin. Rate >180 bpm. QRS duration ≤120 ms. R–R interval variability <20%
Supraventricular and ventricular rhythms (ABN)	Supraventricular arrhythmias that do not qualify as NSR or supraventricular tachycardia with or without AV block and bundle branch block. Includes atrial fibrillation, atrial flutter, junctional and sinus rhythm, arrhythmias with premature atrial, junctional, or ventricular complexes. Complex width ≤160 ms
Idioventricular rhythms (ABN)	Ventricular complexes only, no supraventricular complexes. Monomorphic or polymorphic. Rate <100 bpm. At least one complex >0.3 mVpp
Asystole	Absence of consistent electrical activity of at least 0.1 mVpp amplitude
Intermediate rhythm definitions	
Fine ventricular fibrillation	Uncoordinated ventricular depolarizations with a minimum of five complexes with an average >0.1 mVpp and <0.2 mVpp
Intermediate ventricular rhythms	QRS duration >160 ms. Absence of *P* waves, or AV dissociation if *P* waves present, ventricular complexes only. Rate <200 bpm and >100 bpm (the idioventricular rate). Includes monomorphic and polymorphic ventricular tachycardia

Abbreviations: mVpp, millivolts peak to peak; ABN, abnormal rhythms.

lated and compared to the recommendations developed by the American Heart Association for arrhythmia algorithm analysis.[11]

Results

Electrocardiographic rhythms from 198 children were recorded. Thirty-one subjects were ≤1 year of age. Non-shockable rhythms were recorded from 155 patients and shockable rhythms were recorded from 49 patients: some patients had both non-shockable and shockable rhythms. A total of 749 separate, 9 s rhythm strips were analyzed and classified. There were 585 non-shockable rhythms of which 208 were normal sinus rhythm (heart rate range 53–184 beats per minute, mean 110 bpm), 348 were abnormal rhythms and 29 were asystole. Abnormal rhythms included all supraventricular arrhythmias, premature ventricular complexes and idioventricular rhythms. Within the abnormal rhythms, there were 161 tracings of supraventricular tachycardia with heart rate range of 151–302 bpm. There were 44 tracings classified as intermediate rhythms, and are not classified as either shockable or non-shockable. These were ventricular tachycardias that did not satisfy the shockable criteria. One hundred and twenty rhythms were shockable ventricular tachycardia or fibrillation.

The sensitivity and specificity for each category of shockable or non-shockable rhythms are shown in Tables 2 and 3. There were 120 shockable rhythms from 49 patients for combined sensitivity of 96.7% (115/120); there were 585 non-shockable rhythms from 155 patients for combined specificity of 99.5% (583/585); overall accuracy for shockable and non-shockable rhythms was 99.0% (702/709). The 90% one-sided lower confidence limits of the pediatric algo-

Table 2 Sensitivity of pediatric and adult algorithms for shockable rhythms

Rhythm classification	*n*	Sensitivity		One-sided confidence intervals	AHA performance goal
Ventricular fibrillation	42	Pediatric	100%	93.1%	>90%
		Adult	97.6%	89.2%	
Rapid ventricular tachycardia	78	Pediatric	94.9%	88.7%	>75%
		Adult	98.7%	94.1%	

Table 3 Specificity of pediatric and adult algorithm for non-shockable rhythms

Rhythm classification	n	Specificity		One-sided confidence intervals	AHA performance goal
Normal sinus rhythm	208	Pediatric	100%	98.6%	>99%
		Adult	99.0%	97%	
Supraventricular rhythms	348	Pediatric	99.6%	99.14%	>95%
		Adult	87.1%	83.7%	
Asystole	29	Pediatric	100%	90.19%	100%
		Adult	100%	90.2%	
Fine ventricular fibrillation	0	NA		NA	Report only
Other ventricular tachycardia	44	Pediatric	84.1%	72.19%	Report only
		Adult	54.6%	41.1%	

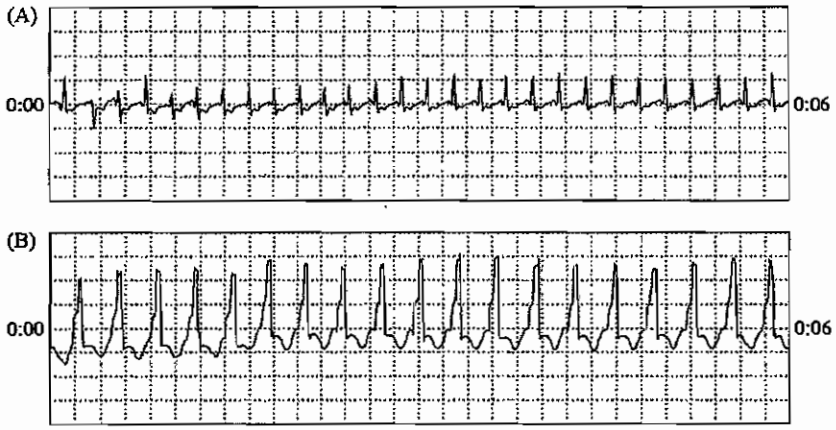


Figure 1 Non-shockable pediatric rhythms with significantly different rate characteristics compared to adult rhythms. Panel A shows supraventricular tachycardia with a heart rate of 300 bpm. Panel B shows ventricular tachycardia with a heart rate of 190 bpm.

rithm exceeded the goals recommended by the AHA in every category: the sample sizes, sensitivity, and specificity. The adult algorithm had high specificity and sensitivity but did not perform as well as the pediatric algorithm and was below the AHA standards for coarse ventricular fibrillation and asystole.

Figures 1 and 2 show representative tracings of rhythm disorders with characteristics different from comparable adult rhythms. Supraventricular tachycardia rates are frequently >250 bpm, however, they are non-shockable rhythms.

There were 14 tracings in which the physician diagnosis differed from the AED advisory. Four tracings were classi-

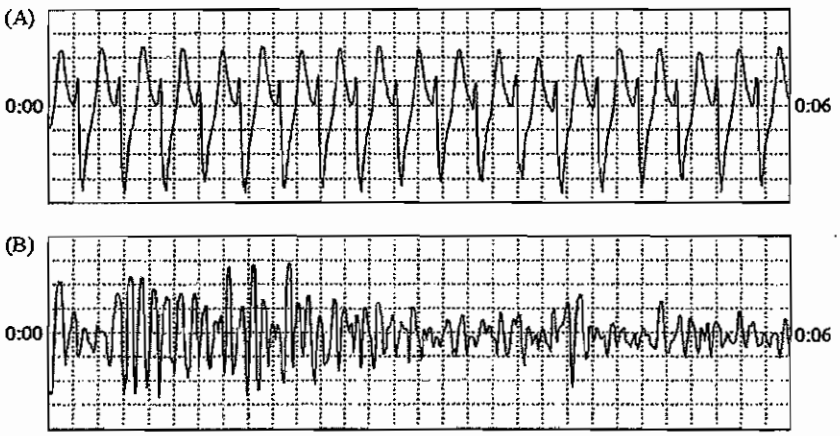


Figure 2 Typical shockable pediatric rhythms; shockable rates continue to remain higher than comparable adult rhythms. Panel A shows ventricular tachycardia and Panel B ventricular fibrillation.

fied by the electrophysiologists as ventricular tachycardia and shockable, but the QRS duration was just below the algorithm's criteria for a shockable rhythm. Three tracings were annotated as abnormal and non-shockable but were wide complex tachycardias with rates just inside the shockable criteria. The final seven tracings were classified as non-shockable ventricular tachycardia by the electrophysiologists due to the 200 beat per minute rate limitation. The AED algorithm determined the heart rate to lie on the 200 bpm rate boundary and therefore advised these seven tracings as shockable.

Discussion

Ventricular tachycardia and fibrillation are uncommon rhythms as a cause of pediatric cardiac arrest. However, their presence has been increasingly recognized in both in-hospital and out-of-hospital cardiac arrest.[4–6] The use of AEDs in children has increased since their original development. Equipment modifications have been developed to promote safe and accurate use.[9,10,12–14] AED use is now recommended for use in children <8 years.[8,15] Providers are strongly encouraged to use the pediatric modifications and to confirm that the algorithm accurately identifies pediatric rhythms.[8] To date, the algorithms from two other manufacturers have been demonstrated to have accurate sensitivity and specificity for pediatric rhythms.[9,10] Our study now provides the data for a specific pediatric algorithm which performs better than the adult algorithm.

Need for pediatric validation

The need for pediatric validation is based on the recognized higher heart rates, differing frequencies of rhythm abnormalities and differences of the QRS complexes with age. Children have higher heart rates compared to adults and this difference is greatest in the youngest children. Supraventricular tachycardia occurs commonly in children and the heart rates often exceed 250 bpm. Normal values for QRS duration are <0.09 ms in children <12 years of age.[16] Thus an algorithm based solely on rate could misidentify supraventricular tachycardia as a shockable rhythm and under identify ventricular tachycardia in which the QRS width is less than the adult values. Differences in both rate and conduction of ventricular fibrillation between children and adults have been identified.[9]

Our data demonstrate that an adult algorithm may not perform as well as one specifically designed to identify pediatric rhythms. Although the adult algorithm had both high sensitivity and specificity, the values were slightly below the AHA recommended values. In particular, the lower sensitivity of abnormal non-shockable rhythms might promote an inappropriate shock in a child with a supraventricular rhythm. This pediatric algorithm is present in all the ZOLL AEDs shipped by ZOLL since the April 2004. The earlier models can be upgraded to contain the pediatric algorithm. The pediatric algorithm is automatically used if the pediatric pads are attached. If the adult pads are used for a child, the device will operate in the adult mode with non-attenuated dosing. Even though the risk of an inappropriate shock is low, it is preferable to use the pediatric pads in a child <8 years, as recommended by the AHA.

Need for pediatric defibrillation

Although pediatric defibrillation is an uncommon event during pediatric cardiac arrest, accounting for 10–20% in both in hospital and out-of-hospital cardiac arrests,[4,6] survival and neurological outcome appears to be better if ventricular fibrillation is quickly recognized and treated. AEDs can identify and treat a shockable rhythm quickly. This may be particularly important in pediatric arrest for both experienced and inexperienced providers who frequently are unaware that ventricular fibrillation does indeed occur in young patients. If an AED is applied to all patients routinely in cardiac arrest, then identification of ventricular fibrillation is not dependent on a provider making a clinical judgment about the likelihood of ventricular fibrillation.

Recognition and detection of ventricular fibrillation may be associated with the frequency with which bystander CPR is performed,[4–6,17,18] in that locations which report high rates of bystander CPR also report higher frequencies of ventricular fibrillation and successful resuscitation. Even though most children suffer a cardiac arrest in the home and with family members in attendance, the frequency of CPR is no higher in children than in adults in public settings. As pediatric equipment is placed in locations where children are located, it is incumbent upon the healthcare providers to teach both CPR and use of the AED.

Differences between physician interpretation and shock advisory

The differences in interpretation between the physician diagnosis and the algorithm advisory were all at the decision boundaries of the algorithm. Skilled physician annotators can see that the waveform is ventricular tachycardia from subtle characteristics in the signal, e.g., lack of *P* waves and morphology shape. The algorithm typically cannot measure these characteristics and must make decisions based on the more obvious and/or quantitatively measurable characteristics. Also, the machine must make a shock decision in real-time. There were a number of records where the annotators had to discuss what would be the correct annotation based on repeated looks at the waveform. After much discussion and multiple views of the record, a consensus was achieved. The AED must make the same decision in 6–9 s. The current state of real-time signal processing cannot embed this level of knowledge into the system. During algorithm development, the thresholds are set based on clinical data to achieve a careful balance between the sensitivity and specificity of the system. Thus, it is expected that there will be an error rate. The error rate within the pediatric algorithm is well within accepted rates.

Limitations

Accuracy of the rhythm identification algorithm has been performed from in-hospital settings with patients in the intensive care units or the cardiac catheterization

laboratory.[9,10] Most arrest rhythms were obtained from patients with short duration ventricular fibrillation or from digitized tracings. We also used tracings recorded with standard ECG electrodes rather than defibrillation pads. Thus artifacts that may exist in out-of-hospital cardiac arrest related to the recording characteristics of the pads were not present. Although ECG electrode placement is standardized, which may not be the situation with emergency application of defibrillation pads, pad position does not appear to affect the algorithm accuracy.[10] Additionally, recordings from ECG electrodes has been used previously to validate pediatric arrest rhythms.[9]

Tracings with fine ventricular fibrillation were not present in the rhythm strips that were analyzed. Fine ventricular fibrillation typically results from prolonged ventricular fibrillation, which will not occur in the catheterization laboratory. This has been a shortcoming of the pediatric studies where the tracings are obtained from hospitalized patients.[9,10] No specificity/sensitivity standards were established by the AHA recommendations for evaluating algorithm accuracy.[11]

Field assessment of rhythm identification during out-of-hospital cardiac arrest has been verified only in a small case series.[12,13,19] Although a prospective trial would be ideal, the difficulties of obtaining these data are significant. A prospective trial to assess cardiac arrest rhythms in children <8 years during cardiac catheterization or electrophysiological study is not feasible as the estimate to acquire sufficient tracings is >10 years.[20]

Summary

New pediatric rhythm detection criteria were defined, and analysis based on these criteria demonstrated both high sensitivity (coarse ventricular fibrillation, rapid ventricular tachycardia) and high specificity (non-shockable rhythms, including supraventricular tachycardia). A pediatric-based AED can detect shockable rhythms correctly, making it safe and exceptionally effective for children.

Acknowledgements

This work was supported by ZOLL Medical Corporation, which provided salary support (DLA) and assistance and reimbursement for acquisition of the EKG tracings to the other investigators.

Dr. Dianne Atkins—current research support: ZOLL Medical Corporation (support for the work reported in this manuscript); previous (within last 5 years): Phillips Medical Systems Inc., research support, consulting fees, Medtronic Inc., consulting fees. Dr. William Scott—research support: ZOLL Medical Corporation (support for the work reported in this manuscript). Dr. Andrew Blaufox—research support: ZOLL Medical Corporation (support for the work reported in this manuscript). Dr. Ian Law—current research support: ZOLL Medical Corporation: educational grants: Boston Scientific Inc., Medtronic Inc.: previous proctoring support and speaker fees: Medtronic Inc. Dr. Macdonald Dick—research support: ZOLL Medical Corporation (Support for the work reported in this manuscript). Dr. Frederick Geheb—employee ZOLL Medical Corporation. Jamil Sobh—employee ZOLL Medical Corporation. James E. Brewer—employee ZOLL Medical Corporation.

References

1. Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Public use of automated external defibrillators. NEJM 2002;347: 1242–7.
2. White RD, Vukov LF, Bugliosi TF. Early defibrillation by police: initial experience with the measurement of critical time intervals and patient outcome. Ann Emerg Med 1994;23:1009–13.
3. Hanefeld C, Lichte C, Mentges-Schroter I, Sirtl C, Mugge A. Hospital-wide first-responder automated external defibrillator programme: 1 year experience. Resuscitation 2005;66(2):167–70.
4. Mogayzel C, Quan L, Graves JR, Tiedeman D, Fahrenbruch C, Herndon P. Out-of-hospital ventricular fibrillation in children and adolescents: causes and outcome. Ann Emerg Med 1995;25:484–91.
5. Hickey RW, Cohen DM, Strausbaugh S, Dietrich AM. Pediatric patients requiring CPR in the prehospital setting. Ann Emerg Med 1995;25:495–501.
6. Nadkarni VM, Larkin GL, Peberdy MA, et al. National registry of cardiopulmonary resuscitation. I First documented rhythm and clinical outcome from in-hospital cardiac arrest among children and adults. JAMA 2006;295(1):50–7.
7. Tibballs J, Kinney S. A prospective study of outcome of in-patient paediatric cardiopulmonary arrest. Resuscitation 2006;71(3):310–8.
8. Samson RA, Berg RA, Bingham R, et al. Use of automated external defibrillators for children—an update: an advisory statement from the pediatric advanced life support task force, international liaison committee on resuscitation. Circulation 2003;107:3250–5.
9. Cecchin FC, Perry JC, Berul CI, et al. Is AED arrhythmia detection accurate for children? sensitivity and specificity of an AED algorithm in 696 pediatric arrhythmias. Circulation 2001;103:2483–8.
10. Atkinson E, Mikysa B, Conway JA, et al. Specificity and sensitivity of automated external defibrillators rhythm analysis in infants and young children. Ann Emerg Med 2003;42:185–96.
11. Kerber RE, Becker LB, Bourland JD, et al. Automatic external defibrillators for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety. Circulation 1997;95:1677–82.
12. Atkins DL, Jorgenson DB. Attenuated pediatric electrode pads for automated external defibrillator use in children. Resuscitation 2005;66:31–7.
13. Gurnett CA, Atkins DL. Successful use of a biphasic waveform automated external defibrillator in a high-risk child. Am J Cardiol 2000;86:1051–3.
14. Jorgenson D, Morgan C, Snyder D, et al. Energy attenuator for pediatric application of an automated external defibrillator. Crit Care Med 2002;30(4 Suppl.):S145–7.
15. ECC Committee, Task Forces of the American Heart Association. 2005 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. Circulation 2005; 112 (24 Suppl):13.
16. Garson Jr A. The electrocardiogram in infants and children. A systematic approach. Philadelphia: Lea and Febiger; 1983.
17. Sirbaugh PE, Pepe PE, Shook JE, et al. A prospective, population-based study of the demographics, epidemiology, management, and outcome of out-of-hospital pediatric cardiopulmonary arrest. Ann Emerg Med 1999;33:174–84.

18. Donoghue AJ, Nadkarni V, Berg RA, et al. Out-of-hospital pediatric cardiac arrest: an epidemiologic review and assessment of current knowledge. Ann Emerg Med 2005;46(6):512–22.
19. Atkins DL, Hartley LL, York DK. Accurate recognition and effective treatment of ventricular fibrillation by automated external defibrillators in adolescents. Pediatrics 1998;101: 393–7.
20. Knilans TK, Atkins DL, Berg RA, Nadkarni V, Bean J. Feasibility of a study to assess efficacy of defibrillation in children. Circulation 2002;106:II-403.

Specificity and Sensitivity of Automated External Defibrillator Rhythm Analysis in Infants and Children

Elizabeth Atkinson, MD
Bridget Mikysa, MD
Jeffrey A. Conway, MD
Morgan Parker, MD
Karla Christian, MD
Jayant Deshpande, MD
Timothy Kevin Knilans, MD
Jacqueline Smith, RN
Carolyn Walker, MS
Ronald E. Stickney
David R. Hampton, PhD
Mary Fran Hazinski, RN, MSN

Author affiliations are provided at the end of this article.

Study objective: The rhythm detection algorithms of automated external defibrillators have been derived from adult rhythms, and their ability to discriminate between shockable and nonshockable rhythms in children is largely unknown. This study evaluates the performance of 1 automated external defibrillator algorithm in infants and children and evaluates algorithm performance with anterior-posterior versus sternal-apex lead placement.

Methods: We enrolled pediatric patients in a critical care unit, an electrophysiology laboratory, and a cardiac operating room. A monitor-defibrillator recorded ECGs by means of standard defibrillation-monitor pads. Selected 15-second rhythm samples were played into a LIFEPAK 500 automated external defibrillator, and the automated external defibrillator "shock/no shock" decision was documented. To determine sensitivity and specificity, the automated external defibrillator decision was compared with the "shockable" versus "nonshockable" rhythm classification provided by 3 expert clinicians who were blinded to the automated external defibrillator decision.

Results: We recorded 1,561 rhythm samples from 203 pediatric patients (median age 11 months; range, day of birth to 7 years). The automated external defibrillator recommended a shock for 72 of 73 rhythm samples classified as coarse ventricular fibrillation by expert review (sensitivity 99%; 95% confidence interval [CI] 93% to 100%); and correctly reached a "no shock advised" decision for 1,465 of 1,472 rhythm samples classified as nonshockable by experts (specificity 99.5%). Specificity was 99.1% (95% CI 97.8% to 99.8%) with the sternal-apex lead and 99.4% (95% CI 98.1% to 99.9%) with the anterior-posterior lead.

Conclusion: This automated external defibrillator algorithm has high specificity and sensitivity when used in infants and children with either sternal-apex or anterior-posterior lead placement.

[*Ann Emerg Med.* 2003;42:185-196.]

0196-0644/2003/$30.00 + 0
doi:10.1067/mem.2003.287

INTRODUCTION

In adults, use of automated external defibrillators in out-of-hospital settings can significantly reduce the time to defibrillation and improve survival for victims of sudden cardiac arrest. Multiple studies in adults with witnessed cardiac arrest and ventricular fibrillation have confirmed that a shorter time to defibrillation significantly improves survival to hospital discharge.[1-3] The lay rescuer defibrillation movement has stimulated widespread community dissemination of automated external defibrillators. Recently, clinicians, resuscitation experts, and emergency medical services managers have raised questions about extending the use of automated external defibrillators to pediatric patients in cardiac arrest. It is uncertain whether automated external defibrillators can convey the same benefits to pediatric patients in ventricular fibrillation that they have to adults.

An important concern has been how well the adult-derived diagnostic algorithms used in current-model automated external defibrillators will perform when used for infants (birth to <1 year of age) and children (1 to <8 years of age). It is unknown whether the position of the automated external defibrillator electrode pads on the child's chest influences the accuracy of rhythm evaluation. In 2000, there were no published studies regarding the sensitivity (ability to correctly identify shockable rhythms) and specificity (ability to recognize "nonshockable" rhythms) of automated external defibrillators in infants and children. As a result, the 2000 International Guidelines for Resuscitation and Emergency Cardiovascular Care did not recommend the use of automated external defibrillators for patients younger than 8 years.

The purpose of this study was to determine the sensitivity and specificity of the rhythm analysis algorithm of a widely available commercial automated external defibrillator in infants and in children younger than 8 years. In addition, we sought to determine whether automated external defibrillator accuracy was affected by electrode position (conventional sternal-apex position versus anterior-posterior position).

MATERIALS AND METHODS

To determine automated external defibrillator sensitivity and specificity we created a database of ECG recordings of both "shockable" and "nonshockable" pediatric rhythms, captured through defibrillator-monitor pads and recorded through a nontreating monitor-defibrillator. Fifteen-second samples were taken from the recordings and played through a commercially available automated external defibrillator. The automated external defibrillator "shock/no shock" decisions were recorded. Expert clinicians, blinded to the automated external defibrillator decision, classified the same rhythm segments as shockable or nonshockable. The sensitivity and specificity of the automated external defibrillator algorithm were calculated by comparing the automated external defibrillator decision to the rhythm classification by expert clinicians.

Patients were enrolled from 3 settings: the pediatric critical care unit, the electrophysiology laboratory, and the cardiovascular operating rooms of Vanderbilt University Medical Center. The Vanderbilt Pediatric Critical Care Unit admits approximately 1,400 pediatric patients annually with injuries, medical problems, or surgical problems. The pediatric electrophysiology laboratory staff perform approximately 165 diagnostic and therapeutic electrophysiology procedures annually. The cardiovascular operating rooms are used to treat approximately 400 pediatric cardiovascular surgery patients annually who require cardiopulmonary bypass during surgical intervention.

The pediatric critical care medical and nursing staff, the pediatric cardiologists, and the pediatric cardiovascular surgeons were asked to identify patients in the pediatric critical care unit and electrophysiology laboratory who met the inclusion criteria from March 10, 1997, through July 29, 1999. The major inclusion criteria were age younger than 8 years and rhythm. Patients with perfusing rhythms and arrest rhythms were enrolled. Emphasis was placed on children with tachyarrhythmias likely to challenge an automated external defibrillator algorithm.

Children who were younger than 8 years and undergoing open-heart surgery in the cardiac operating

rooms during the summer of 1999 were enrolled to obtain samples of ventricular fibrillation of sufficient duration for automated external defibrillator analysis. Some of these children experienced ventricular fibrillation when cardioplegia solution was administered at initiation of cardiopulmonary bypass, and many also demonstrated postbypass arrhythmias.

Therapy or other intervention was not delayed to collect ECG samples. The Vanderbilt University Medical Center institutional review board approved the study. We obtained informed consent from the parent or legal guardian of every patient enrolled in the pediatric critical care unit and electrophysiology laboratory. For the patients enrolled in the cardiac operating rooms, we obtained a waiver for informed consent from the institutional review board. Waiver of informed consent was granted because data collection for this study duplicated routine procedures used in the cardiac operating rooms.

All ECGs were captured through Pediatric QUIK-COMBO adhesive pacing-defibrillation-ECG electrode pads (Medtronic Physio-Control Corporation, Redmond, WA). All ECG recordings were collected with a First Medic 710 monitor-defibrillator (Medtronic Physio-Control Corporation) with the shock delivery function disabled. The 3-lead ECG module of the monitor-defibrillator allowed rhythm recordings of 0.5- to 40-Hz bandwidth (monitor bandwidth) for later expert analysis. This bandwidth is wider than the narrow (1 to 21 Hz) recording bandwidth typically used by automated external defibrillators.

The recorded ECGs were stored on 2-MB removable memory cards at a sample rate of 224 Hz. ECGs were extracted from the memory cards by using a Microsoft Windows (Microsoft Corporation, Redmond, WA) personal computer running First Medic Data Manager software (Medtronic Physio-Control Corporation).

When possible in the pediatric critical care unit, 2 sequential recordings were made for each patient. One recording was made with the adhesive electrodes in the conventional sternal-apex position; a second recording was made with the adhesive electrodes in an anterior-posterior position. Dual recordings were impossible for patients in the cardiac operating rooms or the electrophysiology laboratory because the electrodes were placed before sterile drapes were applied, and they were left in place throughout the procedure. Dual recordings were impossible for patients with chest incisions or chest tubes that restricted electrode pad placement.

In the pediatric critical care unit, each patient's ECG was recorded for approximately 5 minutes for each electrode position. In the electrophysiology laboratory, ECGs were recorded during programmed stimulation procedures. In the cardiac operating rooms, the recording commenced with the procedure and continued until the surgical drapes were removed. If any patient demonstrated intraoperative supraventricular tachycardia, ventricular fibrillation, or ventricular tachycardia, the recording was continued postoperatively as long as arrhythmias were detected, provided it did not interfere with medical treatment.

Where possible, for each patient we selected three 15-second samples per lead for each unique rhythm from different times during the recordings. We considered pulse rate changes of at least 20 beats/min, samples with new premature atrial or ventricular complexes, samples with different rhythm origin (eg, sinus rhythm versus junctional or ventricular rhythm), and samples with new heart block as unique rhythms.

Each wide-bandwidth rhythm sample was played into a LIFEPAK 500 automated external defibrillator (Medtronic Physio-Control Corporation) long enough to allow algorithm analysis and a shock/no shock automated external defibrillator decision. These automated external defibrillator treatment recommendations (shock versus no shock) were recorded and were later cross-tabulated against the reviewers' shockable versus nonshockable rhythm classifications.

Three clinical experts (2 authors [MFH and TKK], plus a third reviewer, Sue Anne Purdy, RN) independently classified the digitized, wide-bandwidth ECG samples into a category specified below. Because resting pulse rate changes with age, the rate criteria for tachycardia, normal rates, and bradycardia were based on the child's age (Table 1).[4] When disagreement occurred, the 2 author-reviewers discussed the classification until consensus was reached.

ECG rhythms were classified into 1 of the following categories:

1. Ventricular fibrillation: disorganized ventricular activity with a peak-to-trough amplitude of at least 0.08 mV. Ventricular fibrillation samples were subclassified by amplitude:
   a. Coarse ventricular fibrillation: amplitude at least 0.2 mV.
   b. Fine ventricular fibrillation: amplitude 0.08 to 0.19 mV.
2. Ventricular tachycardia: QRS duration at least 0.16 seconds, absence of P waves, or atrioventricular dissociation if P waves present. Included were monomorphic and polymorphic ventricular tachycardia. By expert reviewer consensus, ventricular tachycardia segments were further classified as shockable ventricular tachycardia versus other (nonshockable) ventricular tachycardia:
   a. Shockable ventricular tachycardia: presence or absence of a palpable pulse unknown and pulse rate more than 20 beats/min above the age-matched normal rate.
   b. Other ventricular tachycardia: palpable pulse known to be present or pulse rate is no more than 20 beats/min above the age-matched normal rate. These ventricular tachycardia samples were classified as intermediate nonshockable.
3. Supraventricular tachycardia: narrow-complex QRS, or P waves followed by QRS; rate above age-matched normal rate.
4. Normal sinus rhythm: discernible P waves; QRS after every P wave; rate within reported normal range for age.
5. Other normal-rate rhythm: normal rate for age, but not sinus rhythm.
6. Bradycardia: rate below normal for age.
7. Asystole: absence of any electrical activity of at least 0.08-mV peak amplitude.

The reviewers, blinded to how the automated external defibrillator interpreted the rhythms, classified all ventricular fibrillation as shockable. Classifying ventricular tachycardia as shockable versus nonshockable posed a problem for the expert reviewers. In the clinical setting, the health care provider decision to shock ventricular tachycardia is based on whether the patient has a pulse. Because the presence or absence of a pulse was not known for patients on cardiopulmonary bypass or for patients in the electrophysiology laboratory, the reviewers initially proposed to classify ventricular tachycardia samples assuming that the patient had no pulse. However, this classification was inappropriate for the recordings made in the pediatric critical care unit because all of the recordings were obtained from patients who had a documented pulse and measurable blood pressure. During analysis of the results (post hoc), the experts agreed to classify ventricular tachycardia with pulse unknown and a pulse rate faster than 20 beats/min above the age-matched normal rate as shockable. Ventricular tachycardia was classified as "other" (nonshockable; intermediate category) if the rhythm was recorded in the pediatric critical care unit when the patient was known to have a palpable pulse or if the rate was no more than 20 beats/min above the age-matched normal rate in a patient with unknown pulse. This classification of ventricular tachycardia is consis-

Table 1.
Patient characteristics by age group.[4]

Age Group (No. of Patients)	Median Age	Median Weight, kg (Range)	Median Height, cm (Range)	Sex	Normal Pulse Rate, Beats/Min
0 to 28 d (33)	8 d	3.3 (2.2–4.5)	50 (44–56)	14 male, 19 female	90–160
29 d to <1 y (72)	132 d	5.5 (2.5–9.6)	57 (43–76)	43 male, 29 female	90–160
1 to <8 y (98)	3.3 y	14 (6.3–40)	95 (60–133)	54 male, 44 female	70–130
Total (203)	11 mo	7.7	73	111 male, 92 female	

tent with the design intent of the automated external defibrillator algorithm being tested. The algorithm was designed to reach a no-shock decision for pulsatile ventricular tachycardia or for ventricular tachycardia within 20 beats/min of the normal pulse rate range for adults.[5] All remaining rhythms were classified as nonshockable.

Automated external defibrillator sensitivity for shockable rhythms was calculated as the number of "shock advised" decisions by the automated external defibrillator, divided by the expert reviewers' matching classification as shockable rhythms.[6] Automated external defibrillator specificity was calculated as the number of "no shock advised" decisions by the automated external defibrillator, divided by the expert reviewers' matching classification as nonshockable. Exact 95% confidence intervals (CIs) were calculated for sensitivity and specificity by using StatXact 5 software (Cytel Software, Cambridge, MA).

We adopted the sensitivity and specificity goals as called out in the DF39-1993 Standard for automated external defibrillators (from the Association for the Advancement of Medical Instrumentation) and supplemented by the American Heart Association AED Task Force in 1997[6,7]:

1. Shockable rhythms
   a. Coarse ventricular fibrillation: observed sensitivity more than 90%
   b. Shockable ventricular tachycardia: observed sensitivity more than 75%
2. Nonshockable rhythms
   a. Normal sinus rhythm: observed specificity more than 99%
   b. Overall: observed specificity more than 95%
3. Intermediate rhythms
   a. Fine ventricular fibrillation: no requirement
   b. Other ventricular tachycardia: no requirement

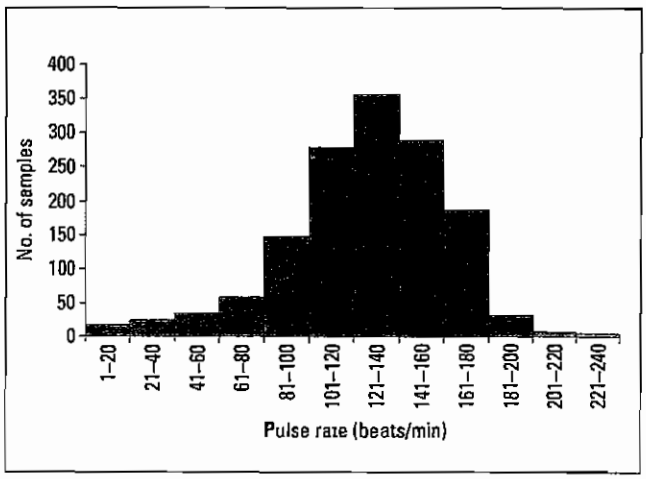
RESULTS

A total of 203 patients were enrolled in the study, with an age range from 1 day (day of birth) to 7 years of age and a weight range of 2.2 to 40 kg. Table 1 presents the patient characteristics with the range for normal pulse rate by age. Median recording duration for each patient was 20 minutes (range 22 seconds to 18 hours). These 203 patients supplied a total of 1,561 rhythm samples suitable for annotation and analysis.

The patients had an assortment of medical conditions, including congenital heart defects, asthma, motor vehicle–related injuries, firearm injuries, and toxic ingestions. Because this study intentionally enrolled a large number of infants and young children with rapid pulse rates, our data reflect a higher pulse rate range than is typical for adults, which was done to challenge the automated external defibrillator rhythm analysis algorithm. A total of 324 samples (21%) with a pulse rate of at least 160 beats/min were included. The distribution of pulse rate ranges by number of samples analyzed is shown in Figure 1.

Table 2 presents the results of the classification of rhythm segments by the expert reviewers, cross-tabulated by the results of the automated external defibrillator rhythm analysis. Total results for all patients are shown in Table 2A, while Tables 2B through 2D show results separately for each of the 3 age groups: neonate (birth to 28 days), infant (29 days to <1 year), and child (1 to <8 years).

Figure 1.
Distribution of pulse rates among ECG samples.



Rhythm classification by the expert clinicians was done in 3 rounds. After the first round, the experts disagreed on the rhythm for 385 of 1,561 (25%) of the ECG samples, with 79% of the disagreements being whether the rhythm was sinus or other supraventricular in origin. After a second round of reconsidering samples with

Table 2A.
Classification of rhythm samples by expert reviewers and by automated external defibrillator shock advisory analysis: all patients.

Rhythms	Patients	ECG Samples	AED Advised Shock	AED Advised No Shock
Total database	203	1,561		
Shockable by expert reviewers				
Coarse ventricular fibrillation	25	73	72	1
Shockable ventricular tachycardia	3	3	3	0
Total shockable		76	75	1
Nonshockable by expert reviewers				
Supraventricular tachycardia	102	378	1	377
Normal sinus rhythm	168	798	6	792
Other normal-rate rhythm	52	120	0	120
Bradycardia	36	97	0	97
Asystole	38	79	0	79
Total nonshockable		1,472	7	1,465
Intermediate by expert reviewers				
Fine ventricular fibrillation	0	1	0	1
Other ventricular tachycardia	3	12	1	11

AED, Automated external defibrillator.

Table 2B.
Classification of rhythm samples by expert reviewers and by automated external defibrillator shock advisory analysis: neonatal patients aged birth to 28 days.

Rhythms	Patients	ECG Samples	AED Advised Shock	AED Advised No Shock
Total database	33	228		
Shockable by expert reviewers				
Coarse ventricular fibrillation	2	3	3	0
Shockable ventricular tachycardia	2	2	2	0
Total shockable		5	5	0
Nonshockable by expert reviewers				
Supraventricular tachycardia	12	31	1	30
Normal sinus rhythm	30	131	5	126
Other normal-rate rhythm	10	19	0	19
Bradycardia	9	23	0	23
Asystole	9	17	0	17
Total nonshockable		221	6	215
Intermediate by expert reviewers				
Fine ventricular fibrillation	0	0	0	0
Other ventricular tachycardia	1	2	0	2

Table 2C.
Classification of rhythm samples by expert reviewers and by automated external defibrillator shock advisory analysis: infant patients aged 29 days to <1 year.

Rhythms	Patients	ECG Samples	AED Advised Shock	AED Advised No Shock
Total database	72	636		
Shockable by expert reviewers				
Coarse ventricular fibrillation	10	36	36	0
Shockable ventricular tachycardia	0	0	0	0
Total shockable		36	36	0
Nonshockable by expert reviewers				
Supraventricular tachycardia	33	101	0	101
Normal sinus rhythm	64	348	1	347
Other normal-rate rhythm	23	67	0	67
Bradycardia	14	45	0	45
Asystole	12	28	0	28
Total nonshockable		589	1	588
Intermediate by expert reviewers				
Fine ventricular fibrillation	0	1	0	1
Other ventricular tachycardia	2	10	1	9

Table 2D.
Classification of rhythm samples by expert reviewers and by automated external defibrillator shock advisory analysis: child patients aged 1 to <8 years.

Rhythms	Patients	ECG Samples	AED Advised Shock	AED Advised No Shock
Total database	98	697		
Shockable by expert reviewers				
Coarse ventricular fibrillation	13	34	33	1
Shockable ventricular tachycardia	1	1	1	0
Total shockable		35	34	1
Nonshockable by expert reviewers				
Supraventricular tachycardia	57	246	0	246
Normal sinus rhythm	74	319	0	319
Other normal-rate rhythm	19	34	0	34
Bradycardia	13	29	0	29
Asystole	17	34	0	34
Total nonshockable		662	0	662
Intermediate by expert reviewers				
Fine ventricular fibrillation	0	0	0	0
Other ventricular tachycardia	0	0	0	0

disagreement, the disagreement dropped to 6.1%. The author-reviewers met for the third round and reached a consensus for all samples.

Of primary importance for an automated external defibrillator are sensitivity for coarse ventricular fibrillation and overall specificity for nonshockable rhythms, and of secondary importance is sensitivity for shockable ventricular tachycardia. The American Heart Association recommendations consider an automated external defibrillator's interpretation of fine ventricular fibrillation and other ventricular tachycardia to be of lower importance. Our study yielded just 1 sample of fine ventricular fibrillation, which normally occurs only when the myocardium has been without perfusion for at least 10 minutes.

Table 3 demonstrates that the automated external defibrillator sensitivity for coarse ventricular fibrillation (ie, the rate at which the automated external defibrillator advised a shock for coarse ventricular fibrillation) was 99% (95% CI 93% to 100%), exceeding the Association for the Advancement of Medical Instrumentation and American Heart Association recommendations of more than 90%. Table 4 shows that the overall specificity for nonshockable rhythms (ie, the rate at which the automated external defibrillator indicated "no shock advised" for nonshockable rhythms) was 99.5% (95% CI 99.0% to 99.8%), exceeding the Association for the Advancement of Medical Instrumentation and American Heart Association recommendations of more than 95%. Specificity for normal sinus rhythm was 792 of 798 (99.2%; 95% CI 98.4% to 94.7%], exceeding the American Heart Association recommendation of more than 99% observed specificity. Tables 3 and 4 show sensitivity for coarse ventricular fibrillation and overall specificity by age group.

The automated external defibrillator advised a shock for only 7 (0.5%) of the 1,472 samples that the expert reviewers considered nonshockable. Six of these 7 samples came from the same infant (aged 10 days), who had undergone correction of pulmonary atresia with ventricular septal defect. This child had a sinus rhythm at 160 to 170 beats/min and low QRS amplitude with T and P waves (refer to Figure 2 for a sample ECG from this patient). Examination of the algorithm's measurements for these 6 samples showed that there was not enough isoelectric content to cause the automated external defibrillator algorithm to reach a no-shock decision, and the QRS complexes did not have enough amplitude to be recognized as having the steep slope normally identified with supraventricular impulse origin.

The study yielded only 15 samples of ventricular tachycardia, 1 of them polymorphic ventricular tachycardia. Three samples met the requirements for shockable ventricular tachycardia (pulse unknown and pulse rate >20 beats/min above normal for age). A shock was advised for all 3 samples, giving a sensitivity for shockable ventricular tachycardia of 100% (95% CI 29% to 100%). The other 12 ventricular tachycardia samples were classified as other (nonshockable) ventricular tachycardia by the expert reviewers because they included 10 samples from the pediatric critical care unit where the patients were known to have a pulse plus 2 samples during cardiopulmonary bypass (pulse unknown) with a pulse rate within 20 beats/min of the

Table 3.
Sensitivity of automated external defibrillator for coarse ventricular fibrillation.

Age Group	Shock Advised	No Shock Advised	Sensitivity, % (95% CI)
Birth to 28 d	3	0	100 (29–100)
29 d to <1 y	36	0	100 (90–100)
1 to <8 y	33	1	97 (85–100)
Total	72	1	99 (93–100)

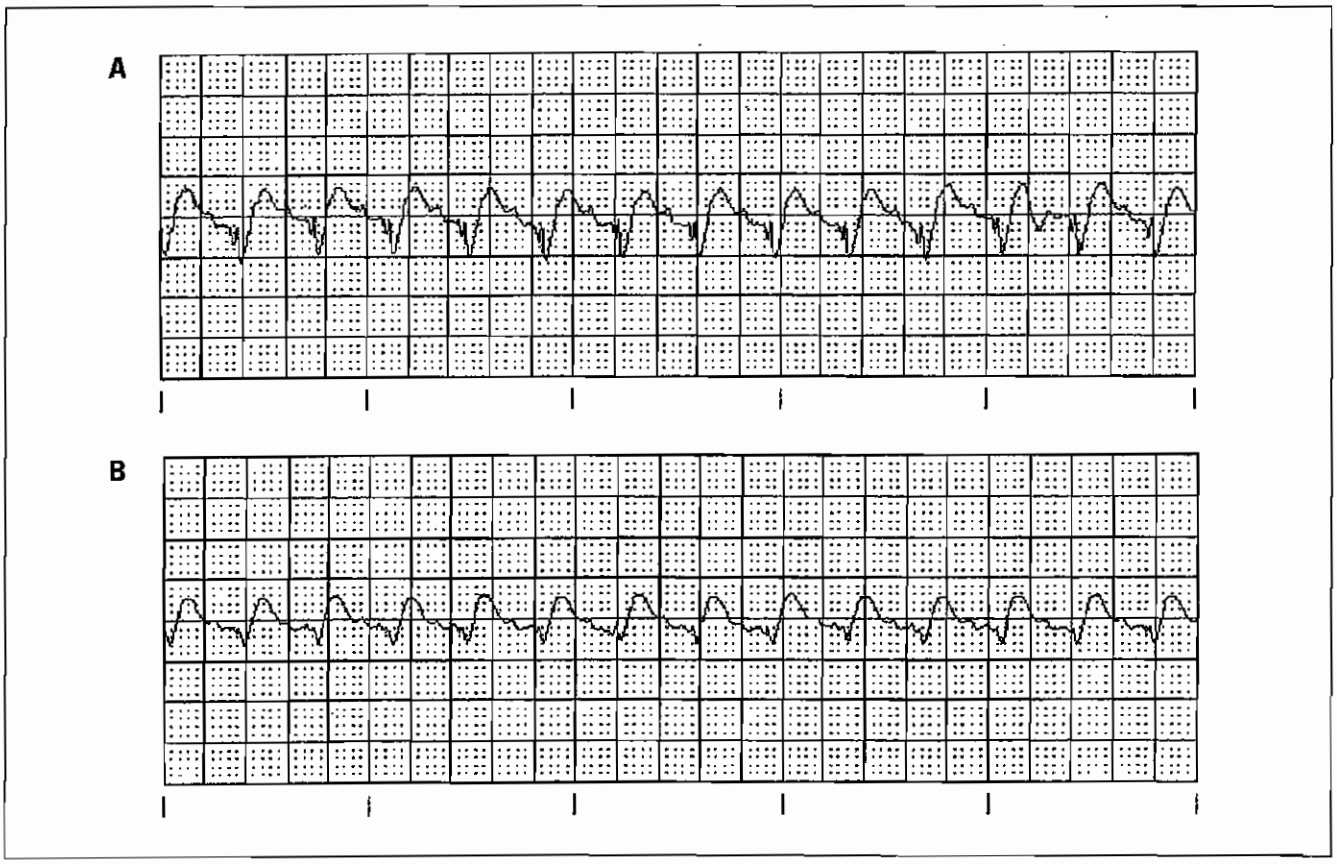
Table 4.
Specificity of automated external defibrillator for nonshockable rhythms.

Age Group	Shock Advised	No Shock Advised	Specificity, % (95% CI)
Birth to 28 d	6	215	97.3 (94.2–99.0)
29 d to <1 y	1	588	99.8 (99.1–100.0)
1 to <8 y	0	662	100.0 (99.4–100.0)
Total	7	1,465	99.5 (99.0–99.8)

normal range for age. By definition, these rhythms were classified as nonshockable other ventricular tachycardia and placed in the intermediate category. One of the 12 samples of other ventricular tachycardia (from a pediatric critical care unit patient) generated a "shock advised" decision, giving a specificity of 92% (95% CI 62% to 100%).

Automated external defibrillators, including the LIFEPAK 500 automated external defibrillator, use an ECG analysis bandwidth that is more narrow (1 to 21 Hz is typical) than the bandwidth used for conventional 3-lead ECG monitoring (0.5 to 40 Hz). Automated external defibrillators use this narrow bandwidth for rhythm analysis to filter out various types of artifacts. The narrow bandwidth can, however, reduce peak amplitudes and modify diagnostic features of the ECG. Some rhythm samples that are not ventricular fibrillation or ventricular tachycardia may resemble ventricular fibrillation or ventricular tachycardia after passing through the narrow-bandwidth filters. We observed that the appearance of several of the ECG samples that resulted in an inappropriate "shock advised" decision were consistent with a shockable rhythm when viewed with the automated external defibrillator's narrow

Figure 2.
A, An ECG sample recorded with a monitor bandwidth (0.5–40 Hz). P waves and discrete Q, R, and S waves are easily identified. B, ECG sample from the same patient, recorded with an automated external defibrillator bandwidth (1–21 Hz). The automated external defibrillator advised a shock for this sample. P, Q, R, and S waves are much less discrete. The rhythm more closely resembles ventricular tachycardia. If expert reviewers had reviewed only this bandwidth, they may have erroneously labeled this rhythm shockable.



bandwidth but could be identified as "nonshockable" when viewed with a wider bandwidth ECG. Figure 2 provides an example of how the narrow-bandwidth automated external defibrillator recording can result in an incorrect "shock advised" recommendation, which demonstrates how important it is to validate automated external defibrillator rhythm analysis under study conditions by using wide-bandwidth recordings. The typical postmarket surveillance of algorithm accuracy by using only automated external defibrillator (narrow bandwidth) recordings may not detect these errors.

In 139 patients with perfusing nonshockable rhythms, we were able to obtain ECG recordings from 2 electrode pad positions: the sternal-apex position (468 samples) and the anterior-posterior position (465 samples). These dual recordings constituted a convenience sample and were not limited by age or size; dual recordings were made on patients as small as 2.2 kg. The specificity of the automated external defibrillator was calculated for rhythm samples recorded from the sternal-apex position and from the anterior-posterior position. The following results were obtained:

- Sternal-apex position (specificity 464/468 [99.1%; 95% CI 97.8% to 99.8%])
- Anterior-posterior position (specificity 462/465 [99.4%; 95% CI 98.1% to 99.9%])

DISCUSSION

We achieved our goal of creating a large, diverse, and challenging database of infant and child rhythms gathered under clinical conditions and captured through adhesive defibrillation electrodes. A total of 105 (52%) patients were infants younger than 1 year. By recording through the 3-lead ECG module of the monitor-defibrillator, we obtained moderately wide bandwidth (0.5 to 40 Hz) samples that allowed more accurate rhythm interpretation by our expert reviewers than would be possible by using only the narrow-bandwidth automated external defibrillator recording. We also obtained a large number of samples (969/1561) with rapid rhythms within or above the range of 120 to 180 beats/min, where many automated external defibrillators set a threshold for a possibly shockable rhythm. The median pulse rate of all database rhythms (excluding ventricular fibrillation and asystole) was 130 beats/min, and 21% (324/1,561) of the analyzed samples had pulse rates of at least 160 beats/min. The large number of samples with high pulse rates provided a rigorous test of the automated external defibrillator algorithm.

Sensitivity for coarse ventricular fibrillation (99%) and overall specificity (99.5%) exceeded the Association for the Advancement of Medical Instrumentation requirements and American Heart Association recommendations.[6,7] High specificity was observed even for supraventricular rhythms at high pulse rates, even though the automated external defibrillator is designed to recommend a shock for pulseless ventricular tachycardia at similar pulse rates.

The LIFEPAK shock advisory algorithm analyzes 5 characteristics for each ECG sample: isoelectric (flat) content, amplitude, frequency, rate, and QRS slope. Of those 5 tests, a substantial isoelectric segment and a "steep" QRS slope contribute to the high specificity for rapid nonshockable rhythms. Even with pediatric supraventricular tachycardia, the isoelectric content between QRS complexes is usually sufficient to cause the algorithm to reach a no-shock decision. Steep slopes in QRS complexes are associated with either a supraventricular rhythm or pulsatile ventricular tachycardia, whereas pulseless ventricular tachycardia usually lacks such steep slopes. Testing with adult patients in the electrophysiology laboratory has shown that the LIFEPAK shock advisory algorithm is accurate at differentiating pulseless ventricular tachycardia from supraventricular tachycardia and pulsatile ventricular tachycardia.[5]

There was no difference in specificity when the electrode pads were placed in an anterior-posterior position versus the conventional sternal-apex position, which is an important finding because the anterior-posterior position may be used for small infants and may be necessary for some pediatric trauma victims.

The high specificity of the automated external defibrillator algorithm means that few nonshockable ECG

samples generated an erroneous "shock advised" decision. These uncommon errors could be difficult to appreciate through evaluation of only the typical narrow-bandwidth (eg, 1 to 21 Hz) recording made by most commercially available automated external defibrillators. The errors were clearly identified when the experts examined a wider bandwidth recording (0.5 to 40 Hz) and compared this analysis with the conclusion reached by the automated external defibrillator.

The database included a small number of ventricular tachycardia samples (15 of 1,561), so it was difficult to determine how well this automated external defibrillator would do when challenged by ventricular tachycardia rhythms in clinical use. However, rapid ventricular tachycardia is infrequently analyzed by automated external defibrillators during actual clinical use. For example, MacDonald et al[8] found that only 12 (0.35%) of 3,448 rhythms analyzed by automated external defibrillators in the Boston Emergency Medical Services system were rapid ventricular tachycardia. Furthermore, pulseless rapid ventricular tachycardia will quickly deteriorate into ventricular fibrillation. For these reasons, performance of an automated external defibrillator's shock advisory algorithm for rapid ventricular tachycardia will have little effect on patient outcome.

Because this study evaluated the diagnostic algorithm of a single model automated external defibrillator developed by a single manufacturer, these results cannot be generalized to other brands of automated external defibrillators that use other algorithms. The results can, however, be generalized to all other automated external defibrillators from the same manufacturer that incorporate this same algorithm.

This study attempted to challenge the adult-derived diagnostic algorithm of an automated external defibrillator by using rhythms gathered in difficult clinical situations, through standard dual-function monitor–shock pads. Pad application in the pediatric critical care unit and the electrophysiology laboratory was performed carefully and precisely by the authors and did not duplicate the potentially hurried and less precise application that may occur with lay responders in out-of-hospital emergencies. Pad application in the cardiac operating rooms was less precise because the pads could not be placed near the planned surgical incision. This less precise placement more closely mimics pad placement by lay rescuers in the out-of-hospital setting.

A limitation of this study is that the sample is not representative of patients on whom use of an automated external defibrillator is intended. Many of the patients were not in cardiac arrest. However, in the out-of-hospital setting, lay rescuers may use automated external defibrillators for patients who are not in cardiac arrest, so it is important to validate the specificity of the automated external defibrillator algorithm. Patients and ECG samples were selected with a bias toward collecting rhythms that we presumed would challenge the automated external defibrillator and rhythms recommended by the American Heart Association Automated External Defibrillator Task Force for testing automated external defibrillators.[6,7] A recommended next step would be a test of the automated external defibrillator in clinical use on pediatric patients in presumed cardiac arrest. However, because pediatric cardiac arrest is much less common than adult cardiac arrest, such a study may be difficult to complete in a timely manner.

In the 2000 International Guidelines for Resuscitation, use of the automated external defibrillator for neonates (birth to 28 days of age), infants (29 days to <1 year of age) and children (1 to <8 years of age) was not recommended. At that time, there were insufficient data regarding the accuracy (sensitivity and specificity) of automated external defibrillators in children, and all automated external defibrillators available in 2000 delivered a shock dose that was too high for small children.[9] This study addresses only the accuracy issue in the potential use of "adult" automated external defibrillators for pediatric patients. The shock dose remains an issue. Most commercially available automated external defibrillators deliver initial defibrillation doses of 150 to 200 J and subsequent doses of 150 to 360 J. Resuscitation experts have expressed concern that these doses may to be too high for infants and small children.[10,11] If these devices are to be safe for use in young victims of cardiac arrest, there must be a method for reducing

delivered shock dose to a level that is safe and effective for pediatric patients.

The American Heart Association recommends use of an automated external defibrillator for victims 8 years of age and older if the victim has signs of cardiac arrest: unresponsiveness, no normal breathing, and no signs of circulation.[10] It has been shown that lay rescuers cannot reliably determine the presence or absence of a pulse.[12] In infants and young children, respiratory arrest frequently precedes cardiac arrest.[9,13,14] An unresponsive, apneic infant may meet the criteria for automated external defibrillator placement, even when cardiac arrest is not present. For this reason, it is important to ensure that automated external defibrillators have high specificity.

There is little published information about the use of automated external defibrillators in infants and children. The only other study to prospectively evaluate the sensitivity and specificity of an automated external defibrillator algorithm included rhythms captured through automated external defibrillator pads from 99 patients younger than 8 years and 82 ECG samples digitized from paper recordings.[15]

In a retrospective cohort report of automated external defibrillator rhythm evaluation in 18 patients, with 1 patient younger than 8 years, Atkins et al[16] reported 100% specificity and 88% sensitivity when the automated external defibrillator decisions were reviewed by one investigator. Most of the cases were from use of earlier models of LIFEPAK automated external defibrillators, which used the same shock advisory algorithm as the automated external defibrillator in the study at hand. However, in this retrospective study, rhythm verification was based only on interpretation of the recorded narrow-bandwidth automated external defibrillator ECG, and there was no verification of ECG interpretation by using a wide-bandwidth recording.

Although ventricular fibrillation is uncommon in infant and child victims of cardiac arrest, it is associated with relatively high survival in many studies.[17-19] Survival among pediatric victims with ventricular fibrillation or pulseless ventricular tachycardia averaged 30% in one recent review.[18] Use of automated external defibrillators can facilitate rapid identification and treatment of pediatric victims of ventricular fibrillation or pulseless ventricular tachycardia and can potentially improve survival from cardiac arrest in these victims.

Automated external defibrillator use is becoming widespread in the treatment of adult out-of-hospital sudden cardiac arrest. It is important that automated external defibrillators be proven safe and accurate for the widest age group possible. These results document accurate analysis of rhythm in infants and children by the same LIFEPAK 500 automated external defibrillator shock advisory algorithm used for adults. High specificity was demonstrated for the anterior-posterior and sternal-apex leads. If these devices are to be safe for use in young victims of cardiac arrest, there must be a method for reducing delivered shock dose to a level that is safe and effective for pediatric patients.

From the Department of Emergency Medicine, Indiana University, Indianapolis, IN (Atkinson); the Department of Radiology, University of Washington, Seattle, WA (Mikysa); the Departments of Anesthesia and Critical Care, University of Chicago, Chicago, IL (Conway); the Department of Ophthalmology, University of Michigan School of Medicine, Ann Arbor, MI (Parker); the Department of Cardiovascular Surgery, Vanderbilt University, Nashville, TN (Christian); the Departments of Pediatrics and Anesthesiology, Vanderbilt University, Nashville, TN (Deshpande); Cincinnati Children's Hospital Medical Center, Cincinnati, OH (Knilans); Department of Nursing, Vanderbilt University Children's Hospital, Nashville, TN (Smith); Medtronic Physio-Control Corporation, Redmond, WA (Walker, Stickney, Hampton); and the Departments of Surgery and Pediatrics, Vanderbilt University, Nashville, TN (Hazinski).

We thank Sue Anne Purdy, RN, from Millsboro, DE, for her help in rhythm classification. At the time of her participation in the study, she was employed by Medtronic Physio-Control Corporation.

Author contributions: MFH, CW, RES, and DRH conceived of the study, designed the study, and reviewed all results. RES and DRH obtained funding. EA, BM, JAC, MP, KC, JD, and JS identified suitable study patients and enrolled the patients and collected all of the ECG samples. MFH, KC, and JD supervised the data collection and provided quality control. TKK and MFH provided the clinical ECG analysis and classification with a third reviewer. CW created the sample segments, and CW, RES, and DRH performed the automated external defibrillator analysis. CW, RES, and DRH performed data analysis and statistical support. MFH developed the first draft. All of the authors reviewed the draft manuscript and made substantive

comments that contributed to the final revision. MFH takes responsibility for the paper as a whole.

Received for publication October 2, 2002. Revisions received December 19, 2002, and March 4, 2003. Accepted for publication March 24, 2003.

Supported by a Developmental Grant from the Medtronic Physio-Control Corporation.

Medtronic Physio-Control Corporation provided the equipment and provided grant funds for Dr. Atkinson, Dr. Mikysa, Dr. Conway, and Dr. Parker. The funds provided were matched by Vanderbilt University School of Medicine to enable these authors to perform the data collection for a summer semester during their medical school education. Each of these authors received a total of 10 weeks of grant support with matched funds.

Address for reprints: Mary F. Hazinski, RN, Surgery and Pediatrics, Vanderbilt University School of Medicine, 2100 Pierce Avenue #243, Nashville, TN 37215; 615-936-0185, fax 615-322-5000; E-mail Mary.f.hazinski@vanderbilt.edu.

REFERENCES

1. White R, Aspelin B, Bugliosi T, et al. High discharge survival rate after out-of-hospital ventricular fibrillation with rapid defibrillation by police and paramedics. *Ann Emerg Med.* 1996;28:480-465.

2. White RD, Hankins DG, Bugliosi TF. Seven years' experience with early defibrillation by police and paramedics in an emergency medical services system. *Resuscitation.* 1998;39:145-151.

3. Valenzuela TD, Roe DJ, Nichol G, et al. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. *N Engl J Med.* 2000;343:1206-1209.

4. Garson A Jr, Bricker JT, Fisher DJ, et al. *The Science and Practice of Pediatric Cardiology.* 2nd ed. Baltimore, MD: Williams and Wilkins; 1996.

5. Carlson MD, Freeman CS, Garan H, et al. Sensitivity of an automatic external defibrillator for ventricular tachyarrhythmias in patients undergoing electrophysiologic studies. *Am J Cardiol.* 1966;61:787-790.

6. Kerber RE, Becker LB, Bourland JB, et al. Automatic external defibrillators for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety: a statement for health professionals from the American Haart Association Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. *Circulation.* 1997;95:1677-1682.

7. Charbonnier F, Crampton RS. *ANSI/AAMI DF39-1993 Standard for Automatic External Defibrillators and Remote-Control Defibrillators.* Arlington, VA: Association for the Advancement of Medical Instrumentation; 1993.

8. MacDonald RD, Swanson JM, Mottley JL, et al. Performance and error analysis of automated external defibrillator use in the out-of-hospital setting. *Ann Emerg Med.* 2001;138:262-267.

9. American Heart Association and the International Liaison Committee on Resuscitation. Guidelines 2000 for cardiopulmonary resuscitation and emergency cardiovascular care, part 9: pediatric basic life support. *Circulation.* 2000;102:253-290.

10. American Heart Association and the International Liaison Committee on Resuscitation. Guidelines 2000 for cardiopulmonary resuscitation and emergency cardiovascular care, part 4: the automated external defibrillator: key link in the chain of survival. *Circulation.* 2000;102:60-76.

11. Hazinski MF, Zaritsky AL, Hickey RW, et al. Rhythm disturbances. In: Hazinski MF, ed. *PALS Provider Manual.* Dallas, TX: American Heart Association; 2002:185-226.

12. Eberle B, Dick WF, Schneider T, et al. Checking the carotid pulse: diagnostic accuracy of first responders in patients with and without a pulse. *Resuscitation.* 1996;33:107-116.

13. Losek JD, Hennes H, Glaeser PW, et al. Prehospital countershock treatment of pediatric asystole. *Am J Emerg Med.* 1989;7:571-575.

14. Zaritsky A, Nadkarni V, Getson P, et al. CPR in children. *Ann Emerg Med.* 1987;16:1107-1111.

15. Cecchin F, Jorgenson DB, Berul CI, et al. Is arrhythmia detection by autometic external defibrillator accurate for children? sensitivity and specificity of an automatic external defibrillator algorithm in 696 pediatric arrhythmias. *Circulation.* 2001;103:2483-2488.

16. Atkins DL, Hartley LL, York DK. Accurate recognition and effective treatment of ventricular fibrillation by automated external defibrillators in adolescents. *Pediatrics.* 1998;101:393-397.

17. Sirbaugh PE, Pepe PE, Shook JE, et al. A prospective, population-based study of the demographics, epidemiology, management, and outcome of out-of-hospital pediatric cardiopulmonary arrest. *Ann Emerg Med.* 1999;33:174-184.

18. Young KD, Seidel JS. Pediatric cardiopulmonary resuscitation: a collective review. *Ann Emerg Med.* 1999;33:195-205.

19. Mogayzel C, Quan L, Graves JR, et al. Out-of-hospital ventricular fibrillation in children and adolescents: causes and outcomes. *Ann Emerg Med.* 1995;25:484-491.

Circulation. 2000;102:I-371-I-376 « Previous Article | Table of Contents | Next Article »

(*Circulation.* 2000;102:I-371.)

Editorials

The Most Important Changes in the International ECC and CPR Guidelines 2000

Richard O. Cummins, MD; Mary Fran Hazinski, RN, MSN[1]

Background

The release of new resuscitation guidelines has a profound effect on clinical practice and on resuscitation teaching. New guidelines produce changes in the marketing and sales of resuscitation products. New guidelines stimulate discussions and debates surrounding the evidence and the rationale. We recognize the strong possibility that many people will concentrate on just a small number of specific details and will overlook the major conceptual changes in how we developed the guidelines and in the basic principles that provide the foundation for these new guidelines. In the following sections we summarize what we consider significant revisions and innovations in resuscitation concepts and principles.

1. Resuscitation Guidelines Now Internationally Developed, Science-Based, and Evidence-Based

The Guidelines 2000 Conference was a fulfillment of important changes that have been under way since 1992.[1,2,3] The most important changes are expressed in the subtitle of the conference name: "an international consensus on science." The conference was part of an international process, culminating in an international scientific collaboration, fulfilling a mission to produce international guidelines. In addition, for the conference to succeed as a consensus on science, participants had to be strongly committed to the principles of evidence-based guideline development.

At the 1992 guidelines conference, an international panel of experts on resuscitation set a goal to make international resuscitation guidelines as consistent as possible by the year 2000.[1,2,3] If all scientists review the same science and evaluate it using the same criteria, they reasoned, we should come to the same conclusions and recommendations about how to resuscitate patients. This goal of a single international version of evidence-based, scientific resuscitation guidelines is now a reality with the publication of this document. These international guidelines have grown from several years of planning and review of evidence, reaching a pinnacle at the Guidelines 2000 Conference, the forum for the final presentation and discussion of the draft recommendations.

The 1999 Evidence Evaluation Conference and the Guidelines 2000 Conference were not just new versions of the ECC and CPR conference of the American Heart Association with some invited guests from non-AHA organizations. The participating international leaders ignored parochial issues of meeting venue, financing, and numbers of participants. Instead, the international leadership took the only step that could give us truly international guidelines: both AHA and non-AHA experts and consultants occupied every decision-making position that could influence the final conclusions. These positions included panel chairs, expert presenters, expert reviewers, first draft authors, discussion group leaders, peer reviewers, and editorial board members. Regional and national differences seemed to vanish as participants concentrated on review of evidence, critical appraisal, and debate about conclusions.

We can develop valid resuscitation guidelines only by review of *all* the science and *all* the evidence published internationally, including non–English-language sources. Because good research is being performed and published around the world, guideline developers must have a mechanism to capture this international evidence. The need to capture the world's scientific conclusions created a daunting task that required international planning and consultation. The emphasis on international participation came not from a sense of hospitality but from a sense of quality improvement.

Because of concern that some participants and experts would be unfamiliar with the principles of critical appraisal and evidence-based guideline development, a Research Task Force, with international liaisons, was appointed by ILCOR and the ECC Committee/Subcommittees. The objectives of the Task Force were to specify how to perform critical appraisal of scientific literature and, in particular, how to develop evidence-based scientific guidelines. The Task Force produced a consensus document to explain evidence-based guideline processes to all participants. This document was pilot-tested multiple times with appropriate revisions and modifications after each of 3 evaluation meetings: the Mini

Evidence Evaluation Conference, March 1999; the Evidence Evaluation Conference, September 1999; and the Guidelines 2000 Conference, February 2000. This statement, titled "How to Develop Evidence-Based Resuscitation Guidelines," supplied the rationale and template for ECC guideline development.[4] An appendix provided a fill-in-the-blanks worksheet that paralleled the steps recommended in the statement. To gain experience and further develop this evidence-based approach, we applied the recommendations to a proposed guideline for an automated external defibrillator (AED) that used an impedance-compensated biphasic waveform.[5]

The template worksheet was then made available on diskette and online. All topic experts for the Evidence Evaluation Conference completed or contributed to a worksheet. Anyone, whether a participant in the conference or not, could propose a new guideline. We asked only that proposers share with us the evidence they had identified and on which they based their proposals. Anyone who wanted to propose a new guideline could obtain a file from the AHA with directions and a template worksheet. (This worksheet can be downloaded from http://www.americanheart.org/ECC/index.html. Interested persons can also download the statement "How to Develop Evidence-Based Resuscitation Guidelines" from this web site.)

2. Expanded Scope of ECC: From Before the Heart Stops Beating to After the Pulse Returns

During the 1990s resuscitation leaders and experts realized that the range of topics discussed in the ECC and CPR guidelines needed to expand. ILCOR, along with the AHA, recognized that there were dangers associated with limiting the guidelines to patients who have lost their pulse and are in full cardiac arrest. Frequently rescuers and clinicians encounter patients "on their way to a cardiac arrest." Proper interventions at this point may stabilize a patient and keep him or her from further deterioration.

In the United States the AHA ECC programs have added a new course called ACLS for Experienced Providers. This course was designed to address a growing list of prearrest conditions that if treated effectively before the heart stopped would not deteriorate to the point of needing resuscitation. Furthermore, these prearrest conditions would still affect the therapeutic approach if the victim continued to deteriorate despite the prearrest treatments. Life-threatening hyperkalemia provides an example of such a prearrest-to-arrest continuum, as does a lethal overdose of a tricyclic antidepressant. Obviously knowledge of the problem of high potassium or a tricyclic antidepressant overdose will drive the therapeutic approach used after the arrest. The well-trained provider would not simply look at the display of a PEA arrhythmia on the monitor and follow the PEA algorithm.

Included in this expanded list of arrest etiologies are a number of conditions that require specific guidelines but until now have not had precise recommendations, eg, asthma, anaphylaxis, electrolyte disturbances, and toxin-induced disturbances in rhythm and blood pressure. Although these were evidence-based and reviewed in a consensus fashion by many international participants, these special resuscitation conditions did not receive full, face-to-face, international, evidence-based review.

Complete international, evidence-based review and consensus for these topics is planned for the near future and will be provided in supplemental materials.

3. First Aid, CPR, and Defibrillation in the Workplace

The International Guidelines 2000 present a new section on first aid in the workplace. In the United States and most other countries involved in resuscitation research, workplace injuries are a leading cause of death and disability. Deaths from fatal injuries, however, are still only about one third of all workplace deaths. The remaining two thirds are due to sudden cardiac arrest from ventricular fibrillation or other urgent cardiovascular emergencies. In US workplaces, subject to specific federal regulations, trained lay rescuers are expected to respond to all emergencies. Workplace responders need evidence-based guidelines for the response to these emergencies. Because the ECC and CPR guidelines already provide protocols to manage more than two thirds of life-threatening worksite events, it was natural to add evidence-based first aid guidelines to the existing CPR and early defibrillation protocols.[6] The published research for most first aid topics, however, is insufficient to support higher-level classes of recommendations for all actions. Most first aid guidelines merited only a IIb or an Indeterminate class (classes of recommendation are discussed in Part 1). However, we expect the need for evidence-based first aid recommendations to foster additional research on these topics.

4. Elimination of Pulse Check by Lay Rescuers

Since 1992 many published studies have documented the inability of lay rescuers (and usually healthcare professionals as well) to determine accurately the presence or absence of a carotid pulse.[7] [8] [9] [10] [11] [12] [13] [14] [15] [16]

When laypersons assess for a pulse, they take too long and are often wrong in their assessment. The large number of errors made in assessing the pulse in simulations is alarming. In actual witnessed arrests, responders may fail to provide chest compressions and fail to apply an AED to people who they mistakenly think have a pulse. This result is called a false-negative (or type II) error—an error that denies a victim an opportunity to be resuscitated. [This topic is discussed in more detail in the editorial titled "Guidelines Based on Fear of Type II (False-Negative) Errors."] By extrapolation from existing data we estimate that this false-negative error will occur in approximately 10% of all of witnessed cardiac arrest victims.

To increase the number of victims who receive appropriate resuscitation, these guidelines recommend elimination of the pulse check for lay rescuers. The training will substitute a simple step: *evaluate for signs of circulation* (normal breathing, coughing, or movement in response to rescue breaths).

5. Revision and Simplification of Adult BLS Compression Rate and Compression-Ventilation Ratio

The compression rate for adult victims (≥8 years of age) has been changed to a specific target

(approximately 100 compressions per minute) rather than a broad range (80 to 100 compressions per minute). This change should simplify training and retention by making the compression rate for adults and children (1 to 8 years of age) the same. This recommendation is based on the observation that every time compressions are stopped, multiple compressions are required to reestablish adequate blood flow. In addition, many rescuers compress at a rate much lower than the recommended rate. A recommendation to aim for a 25% higher rate should help bring the average rate into an acceptable range.

The adult compression-ventilation ratio has been simplified to a 15:2 ratio for both 1- and 2-rescuer CPR until the airway is secure (then a 5:1 compression-ventilation ratio can be used for 2-rescuer CPR). Again, this recommendation was prompted by the observation that multiple compressions are required before adequate blood flow resumes after each time the rescuer interrupts compressions to deliver a rescue breath. This change will reduce the number of times per minute that chest compressions are interrupted and will increase the number of chest compressions per minute.

6. Changes in the Foundations of Education, Training, and Evaluation: Skills-Based, Video-Mediated Instruction for Lay Rescuers

For several years educators have criticized the lecture-based approach to teaching and learning CPR. Education experts have rightly criticized loosely scheduled courses packed with information about diverse topics and focused on lectures rather than on acquisition of a small number of critical skills.[17] [18] [19] To acquire CPR skills, participants need hands-on practice; excessive lecture time reduces skills practice time. Principles of adult education and evidence documenting the success of video-based learning have led to endorsement and acceptance of video-based teaching techniques.[20] [21] [22] [23] These "practice-as-you-watch" and "watch-then-practice" techniques promote acquisition of skills in skills-based educational programs for lay rescuers.

All innovative educational programs should be pilot-tested and evaluated on objective criteria. The program's success at teaching is measured by the percentage of participants who can demonstrate satisfactory critical skills.[24] The AHA has adopted a "watch-then-practice" video-based medium, having documented that as the most effective didactic method for skills acquisition.[25] This focus on skills acquisition represents a dramatic shift in the approach to teaching CPR. By the next iteration of these guidelines research should be able to document whether this shift in teaching techniques makes lay rescuers more likely to learn and perform CPR. The more important outcome should be whether this approach increases the frequency of bystander CPR for out-of-hospital cardiac arrest.

7. Outcome-Driven Education and Evaluation

CPR educators should be able to identify the core learning objectives of any CPR course for any participant.[26] CPR education should emphasize these core objectives and should evaluate whether the participants meet these objectives. Regardless of whether a CPR course teaches a lay rescuer or a

healthcare provider, the course should be structured to eliminate extraneous material and focus the participant on acquisition of core information and skills. A course that uses skills or written evaluations should also focus on the core objectives. If the participant then fails to achieve the core objectives, the course (including the instructor) may be at fault.[19] This represents a dramatic departure from the old "pass-fail" philosophy that failure was the fault of the participant. It is now clear that when participants fail to learn it may be that instructors fail to teach.

8. Teaching ACLS: The Primary and Secondary ABCD Surveys as a Unifying Approach to Assessment and Management

ACLS training since 1994 has reformulated cardiac arrest treatment away from a rhythm-based treatment approach to a unifying approach based on reviewing the Primary and Secondary ABCD Surveys.[27] [28] [29] All ACLS algorithms in 2000 are oriented around this system, taking the same generic approach to all problems (the primary and secondary ABCD approach), with specific modifications introduced at the second D (differential diagnosis).

The new ACLS for Experienced Providers Course became available in the United States in 1999.[30] The topics addressed in the course were developed to appeal to experienced people who have already taken an ACLS Provider Course. Nevertheless, the ACLS Course for Experienced Providers adopted the primary and secondary ABCD model, noting it to be a logical, uniform, and easily memorized approach.

9. Acute Coronary Syndromes and Acute Ischemic Stroke: Increased Efforts to Achieve Rapid Identification, Rapid Transport, Prearrival Treatment, and Prearrival Notification of the Emergency Department

With the availability and reported success of fibrinolytic therapy for acute coronary syndromes and ischemic stroke, more emphasis must be placed on what appears to be the major obstacle to early fibrinolytic therapy: patient delay.[31] Patients who may be eligible for fibrinolytic treatment must reach a treatment center and be evaluated within the narrow therapeutic window for administration of these drugs. Although patient delays are addressed in other programs, prehospital providers and Emergency Departments must be organized so that they occupy as little of the therapeutic window as possible. To achieve this goal, prehospital care providers must be able to do the following:

- Screen for patients with a high likelihood of an acute coronary syndrome or a potential stroke; immediately transport these patients to appropriate treatment centers.
- Contact and alert emergency facilities that a candidate for fibrinolytic therapy is en route (prearrival notification).
- Initiate diagnostic (eg, 12-lead ECGs or stroke screening exams) and therapeutic actions when indicated. (Where locally appropriate and authorized, this can include field fibrinolytic protocols and antihypertensive protocols.)

To achieve the goal of treatment within the therapeutic window, Emergency Departments and specialists

in emergency medicine must be able to do the following:

- Meet the recommended stroke evaluation targets for patients who are potential fibrinolytic candidates. These targets include multiple steps from arrival to disposition, including door-to-physician evaluation, to CT scan obtained, to CT scan interpreted and fibrinolytic decision made.
- Meet the recommended acute coronary syndrome evaluation targets for patients who are potential candidates for fibrinolytic therapy or percutaneous coronary interventions.

10. Devices for Secondary Confirmation of Proper Tracheal Tube Placement: Techniques to Prevent Dislodgment of Tracheal Tubes

For the first time, the ECC guidelines for PALS and ACLS include 2 new recommendations to use devices and techniques for secondary confirmation of tracheal tube placement and to prevent tracheal tube dislodgment after it has been placed:

- Use a validated secondary confirmation technique to confirm tracheal tube placement, in addition to primary confirmation through physical examination.
- Use a specific, validated technique or device to prevent tracheal tube dislodgment, especially in the prehospital setting or whenever transport of the patient is necessary.

The rationale for these important new recommendations is presented in a companion editorial, "Guidelines Based on the Principle 'First, Do No Harm.'" The rationale for this step is based less on hard, definitive evidence and more on a *philosophy of care* (ie, do no harm). These recommendations were driven by an imperative to prevent harm rather than to initiate an intervention because of support from powerful and compelling evidence.

11. Comparable Effectiveness: Competent Ventilation Using Bag-Mask Device May Be as Effective as Compromised Ventilation Using Tracheal Tube

The recent publication of a prospective, randomized trial compared the effectiveness of out-of-hospital ventilations via tracheal tube placement versus ventilations via bag-mask for pediatric emergencies.[32] The results, which confirmed the 2 interventions as equivalent, challenged the concept that ventilation via a properly placed tracheal tube was resuscitation's "gold standard." The choice of ventilatory support (bag-mask ventilation or tracheal intubation) should be based on the clinical condition of the patient, transport time to Emergency Department care, and the experience, training, and expertise of the rescuers. Proficiency in bag-mask ventilation is mandatory for anyone providing BLS or ACLS in the prehospital setting and is of higher priority than skill in tracheal intubation. In locations where prehospital intubation is preferred, quality assurance monitoring must be in place to document rates of successful intubation and rates and severity of complications. Secondary confirmation of tracheal tube placement (see point 10) should be performed immediately after intubation, during transport, and during any movement of the patient.

12. Pharmacological Therapy for Adult and Pediatric Cardiac Arrest and for Pediatric Arrhythmias With Poor Perfusion

Whenever possible, the pediatric guidelines for drug therapy for cardiac arrest and significant arrhythmias have been made consistent with the pharmacological guidelines for adult resuscitation. The adult evidence-based recommendations, however, may not be the best model on which to base pediatric recommendations. On review of the evidence supporting the effectiveness of antiarrhythmics for adult VF or pulseless VT, only amiodarone received an acceptable, effective classification (IIb).[33] Other traditional agents such as lidocaine, bretylium, and procainamide received an indeterminate rating because valid, prospective, randomized trials confirming effectiveness were absent. Similarly, there is insufficient data in the pediatric population to support any agent beyond a Class IIb recommendation. Most PALS recommendations are classed Indeterminate. A major objective of the Subcommittee on Pediatric Resuscitation is to obtain definitive evidence to answer these clinical questions in time for the next iteration of the guidelines.

13. Support for Family Presence at Resuscitation Attempts

When questioned, most family members state that they would like to be present during the attempted resuscitation of a loved one, especially when the resuscitation attempt involves a child. A number of studies have confirmed the desire of family members to be present either at the last minutes of a loved one's life or at the recovery of an effective heartbeat.[5 34 35 36] Whenever possible, family members should be given this option, but they will require support and specific attention during the resuscitation. Furthermore, such initiatives require advance planning, discussions among all the staff, and general commitment to work through initial problems. If at all possible, a member of the resuscitation team should remain with the family members while they are in the resuscitation suite. This team member can answer their questions, provide support, and recognize when the family members might need to leave.

14. Honoring Out-of-Hospital No-CPR Advance Directives

In the United States, since 1992 more and more states have instituted regulations that permit EMS personnel to honor advance directives or no-CPR documents/bracelets when they arrive on the scene. For many years the principle followed was *"if called, EMS personnel institute all clinically indicated emergency procedures."* On arrival of EMS personnel at the location of a pulseless person, the protocols required initiation of resuscitative efforts regardless of futility or the prearrest wishes of the victim. The International Guidelines 2000 strongly encourage all US EMS systems to address this issue and follow the lead of our colleagues from Europe and other countries. Those systems place much emphasis on the important role of EMS responders to support the survivors.

15. Death Pronouncement in the Field, Survivor Support Plans, the Futility of Transport of Patients Needing Continued CPR

There has been little evidence that EMS systems and Medical Control Emergency Departments in the United States have reacted to the large and consistently negative experience with transporting pulseless patients from the field to the Emergency Department.[37] [38] [39] [40] [41] [42] [43] [44] The survival rate of patients who fail to respond to effective ALS care in the field has never been improved by high-speed, potentially dangerous transportation to an Emergency Department. Researchers in Europe report the same dismal outcomes.[45] [46] Unless patients are suffering from rare, specific pathological conditions (eg, hypothermia, drug overdose), there are no in-hospital interventions that will successfully resuscitate patients who fail out-of-hospital efforts.[47] High-speed transport of pulseless patients persists to a large extent because EMS personnel are uncomfortable with having to stop efforts in a victim's home and, in effect, making such a public acknowledgment of failure.[48] In addition, both family and personnel experience discomfort with leaving a body at the scene. The indignity, futility, and danger involved with these transports, however, must end, as it has in many countries.

The solution requires thoughtful planning for the steps to follow when resuscitative efforts stop in the field. Answers to the following questions require reflection, but the answers are available: what are the legal requirements for death certification? for disposition of the body? for post-event survivor support? This is not a new guideline in the United States. Mature EMS systems such as in Seattle–King County, Washington, USA, have implemented protocols for certification of death in the out-of-hospital setting for >20 years.[49] A recent statement from the National Association of EMS Physicians provides an excellent review of this topic, including a thorough list of recommendations almost identical to the guidelines included in the International Guidelines 2000.[48] These futile transports must stop; a little planning and work are all that is necessary.

Summary

Many people involved with resuscitation have specific interests and enthusiasm. They will review the new guidelines to see how their favorite interventions fared. This essay lists a number of the new guidelines that merit special attention: support for family presence at resuscitations, pronouncing death at the scene rather than after futile transport efforts, honoring advance directives, comparable effectiveness of bag-mask ventilation versus tracheal intubation, revision of compression rates and compression-ventilation ratios, and devices to confirm tracheal intubation and prevent tube dislodgment.

Even more important are the new principles and concepts that the International Guidelines 2000 endorse: international guideline science, international guideline development, evidence-based guidelines, training by objectives, expanded scope of ECC to first aid and periarrest conditions, avoidance of false-negative (type II) errors, video-mediated instruction, and a philosophy to "do no harm."

The number and magnitude of these new guidelines reflect the dynamic nature of resuscitation at the start of the 21st century. There is great optimism that these new and revised guidelines will help achieve our ultimate objective. This objective is to be ready when fate brings some lives to a premature end. If

we are, we can restore more of these people to a high-quality life, ready for many more years of living.

Footnotes

[1] With contributions from the representatives of the resuscitation councils of ILCOR, including the Resuscitation Council of Southern Africa, the New Zealand Resuscitation Council, the Heart and Stroke Foundation of Canada, the European Resuscitation Council, the Australian Resuscitation Council, and the American Heart Association; the Members of the Emergency Cardiovascular Care (ECC) Committee and ECC Subcommittees; and the Editors of the Science Product Development Panel, ECC Programs, American Heart Association. R.O. Cummins and M.F. Hazinski are Senior Science Editors, American Heart Association ECC Programs.

Circulation. 2000;102(suppl I):I-371–I-376.

References

1. Cummins RO, Chamberlain DA. Advisory statements of the International Liaison Committee on Resuscitation. *Circulation.* 1997;95:2172–2173.[Full Text]

2. Chamberlain D, Cummins RO. International emergency cardiac care: support, science, and universal guidelines. *Ann Emerg Med.* 1993;22(2 pt 2):508–511.

3. Cummins RO, Eisenberg MS. Cardiopulmonary resuscitation: American style. *BMJ.* 1985;291:1401–1403.[Medline]

4. Cummins RO, Hazinski MF, Billi J, Babbs C, Kerber R, Ornato J. How to develop evidence-based ECC and CPR guidelines. Syllabus for the International Guidelines Conference on CPR and ECC, February 6–8, 2000. Dallas, Tex: American Heart Association.

5. Cummins RO, Hazinski MF, Kerber RE, Kudenchuk P, Becker L, Nichol G, Malanga B, Aufderheide TP, Stapleton EM, Kern K, Ornato JP, Sanders A, Valenzuela T, Eisenberg M. Low-energy biphasic waveform defibrillation: evidence-based review applied to emergency cardiovascular care guidelines: a statement for healthcare professionals from the American Heart Association Committee on Emergency Cardiovascular Care and the Subcommittees on Basic Life Support, Advanced Cardiac Life Support, and Pediatric Resuscitation. *Circulation..* 1998;97:1654–1667.[Full Text]

6. Eisenburger P, Safar P. Life supporting first aid training of the public: review and recommendations. *Resuscitation.* 1999;41:3–18.[Medline]

7. Handley AJ, Becker LB, Allen M, van Drenth A, Kramer EB, Montgomery WH. Single rescuer adult basic life support: an advisory statement from the Basic Life Support Working Group of the International Liaison Committee on Resuscitation (ILCOR). *Resuscitation.* 1997;34:101–108.[Medline]

8. Handley AJ, Becker LB, Allen M, van Drenth A, Kramer EB, Montgomery WH. Single-rescuer adult basic life support: an advisory statement from the Basic Life Support Working Group of the International Liaison Committee on Resuscitation. *Circulation.* 1997;95:2174–2179.[Full Text]

9. Flesche CW, Breuer S, Mandel LP, Brevik H, Tarnow J. The ability of health professionals to check the carotid pulse. *Circulation.* 1994;90(suppl I):I-288. Abstract.

10. Flesche CW, Zucker TP, Lorenz C, Neruda B, Tarnow J. The carotid pulse check as a diagnostic tool to assess pulselessness during adult basic life support. *Euroanesthesia.*. 1995;95:72. Abstract.

11. Bahr J, Klingler H, Panzer W, Rode H, Kettler D. Skills of lay people in checking the carotid pulse. *Resuscitation.* 1997;35:23–26.[Medline]

12. Monsieurs KG, De Cauwer HG, Bossaert LL. Feeling for the carotid pulse: is five seconds enough? *Resuscitation.*. 1996;31:S3.

13. Cummins RO, Hazinski MF. Cardiopulmonary resuscitation techniques and instruction: when does evidence justify revision? [editorial; comment]. *Ann Emerg Med.* 1999;34:780–784.[Medline]

14. Ochoa FJ, Ramalle-Gomara E, Lisa V, Saralegui I. The effect of rescuer fatigue on the quality of chest compressions. *Resuscitation.* 1998;37:149–152.[Medline]

15. Flesche C, Neruda B, Breuer S, Tarnow J. Basic cardiopulmonary resuscitation skills: a comparison of ambulance staff and medical students in Germany. *Resuscitation.* 1994;28:S25. Abstract.

16. Flesche C, Neruda B, Noetages P, Tarnow J. Do cardiopulmonary skills among medical students meet current standards and patients' needs? *Resuscitation.* 1994;28:S25. Abstract.

17. Kaye W, Mancini ME. Teaching adult resuscitation in the United States: time for a rethink. *Resuscitation.*. 1998;37:177–187.[Medline]

18. Kaye W, Wynne G, Marteau T, et al. An advanced resuscitation training course for preregistration house officers. *J R Coll Physicians Lond.*. 1990;24:51–54.[Medline]

19. Kaye W, Rallis SF, Mancini ME, et al. The problem of poor retention of cardiopulmonary resuscitation skills may lie with the instructor, not the learner or the curriculum. *Resuscitation.*. 1991;21:67–87.[Medline]

20. Brennan RT, Braslow A. Skill mastery in cardiopulmonary resuscitation training classes. *Am J Emerg Med.*. 1995;13:505–508.[Medline]

21. Braslow A, Brennan RT, Newman MM, Bircher NG, Batcheller AM, Kaye W. CPR training without an instructor: development and evaluation of a video self-instructional system for effective performance of cardiopulmonary resuscitation. *Resuscitation.* 1997;34:207–220.[Medline]

22. Todd KH, Heron SL, Thompson M, Dennis R, O'Connor J, Kellermann AL. Simple CPR: a randomized, controlled trial of video self-instructional cardiopulmonary resuscitation training in an African American church congregation. *Ann Emerg Med.* 1999;34:730–737.[Medline]

23. Todd KH, Braslow A, Brennan RT, et al. A randomized, controlled trial of video self-instruction versus traditional CPR training. *Ann Emerg Med.* 1998;31:364–369.[Medline]

24. Aufderheide T, Stapleton E, Hazinski MF, Cummins RO. *Heartsaver AED for the Lay Rescuer and First Responder*. Dallas, Tex: American Heart Association; 1998.

25. Deleted in proof.

26. Deleted in proof.

27. Montgomery WH, Brown DD, Hazinski MF, Clawsen J, Newell LD, Flint L. Citizen response to cardiopulmonary emergencies. *Ann Emerg Med.* 1993;22(2 pt 2):428–434.

28. Billi JE, Membrino GE. Education in adult advanced cardiac life support training programs: changing the paradigm. *Ann Emerg Med.*. 1993;22:475–483.[Medline]

29. Billi JE. The educational direction of the ACLS training program. *Ann Emerg Med.* 1993;22:484–488.[Medline]

30. Cummins RO, Hazinski MF. *Instructor's Manual: Advanced Cardiac Life Support for Experienced Providers*. Dallas, Tex: American Heart Association; 1999.

31. Katzan IL, Furlan AJ, Lloyd LE, Frank JI, Harper DL, Hinchey JA. Use of tissue-type plasminogen activator for acute ischemic stroke: the Cleveland area experience. *JAMA.* 2000;283:1151–1158. [Medline]

32. Gausche M, Lewis RJ, Stratton SJ, Haynes BE, Gunter CS, Goodrich SM, Poore PD, McCollough MD, Henderson DP, Pratt FD, Seidel JS. Effect of out-of-hospital pediatric endotracheal intubation on survival and neurological outcome: a controlled clinical trial. *JAMA.* 2000;283:783–790.[Medline]

33. Kudenchuk PJ, Cobb LA, Copass MK, et al. Amiodarone for resuscitation after out-of-hospital cardiac arrest due to ventricular fibrillation *N Engl J Med.*. 1999;341:871–879.[Medline]

34. Boie ET, Moore GO, Brummett C, Nelson DR. Do parents want to be present during invasive procedures performed on their children in the emergency department? A survey of 400 parents. *Ann Emerg Med.* 1999;34:70–74.[Medline]

35. Boyd R. Witnessed resuscitation by relatives. *Resuscitation.* 2000;43:171–176.[Medline]

36. Adams S, Whitlock M, Bloomfield P, Baskett PJF. Should relatives be allowed to watch resuscitation? *BMJ.* 1994;308:1687–1689.[Full Text]

36. Robinson SM, Mackenzie Ross S, Campbell Hewson GL, et al. Psychological effect of witnessed resuscitation on bereaved relatives. *Lancet.*. 1998;352:614–617.[Medline]

37. Bonnin M, Swor R. Outcomes in unsuccessful field resuscitation attempts. *Ann Emerg Med.* 1989;18:507–512.[Medline]

38. Bonnin M, Pepe P, Kimball K, Clark P. Distinct criteria for termination of resuscitation in the out-of-hospital setting. *JAMA.* 1993;270:1457–1462.[Medline]

39. Gray W, Capone R, Most A. Unsuccessful emergency medical resuscitation: are continued efforts in the emergency department justified? *N Engl J Med.* 1991;325:1393–1398.[Medline]

40. Gray W. Prehospital resuscitation: the good the bad and the futile. *JAMA.* 1993;270:1471–1472. [Medline]

41. Kellerman A, Staves D, Hackman B. In-hospital resuscitation following unsuccessful prehospital advanced cardiac life support: "heroic efforts" or an exercise in futility? *Ann Emerg Med.* 1988;17:589–594.

42. Kellermann A, Hackman B. Terminating unsuccessful advanced cardiac life support in the field. *Am J Emerg Med.* 1987;5:548–549.[Medline]

43. Kellermann AL. Criteria for dead-on-arrivals, prehospital termination of CPR, and do-not-resuscitate orders [see comments]. *Ann Emerg Med.* 1993;22:47–51.[Medline]

44. Kellermann A, Hackman B, Somes G. Predicting the outcome of unsuccessful prehospital advanced cardiac life support. *JAMA.* 1993;270:1433–1436.[Medline]

45. Herlitz J, Ekstrom L, Axelson A, et al. Continuation of CPR on admission to Emergency Department after out-of-hospital cardiac arrest: occurrence, characteristics and outcome. *Resuscitation.* 1997;33:223–231.[Medline]

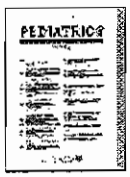
46. Naess A-C, Steen E, Steen PA. Ethics in treatment decisions during out-of-hospital resuscitation. *Resuscitation.* 1997;33:245–256.[Medline]

47. Eisenberg MS, Cummins RO. Termination of CPR in the prehospital arena [editorial]. *Ann Emerg Med.* 1985;14:1106–1107.[Medline]

48. Bailey ED, Wydro GC, Cone DC, and the National Association of EMS Physicians (NAEMSP) Standards and Clinical Practice Committee. Termination of resuscitation in the prehospital setting for adult patients suffering nontraumatic cardiac arrest: a position statement from the NAEMSP. *Prehosp Emerg Care.* 2000;4:190–195.[Medline]

49. Dull SM, Graves JR, Larsen MP, Cummins RO. Expected death and unwanted resuscitation in the prehospital setting. *Ann Emerg Med.* 1994;23:997–1002.[Medline]

This article has been cited by other articles:



ELSEVIER

Resuscitation 56 (2003) 237–239

RESUSCITATION

www.elsevier.com/locate/resuscitation

Erratum

Erratum to "Abstracts of Poster and Oral Presentations at Sixth Congress of the European Resuscitation Council, Firenze, October, 2002"☆

The Publisher regrets and apologises for the omission of the following Abstracts presented at the Sixth Congress of the European Resuscitation Congress, Firenze, October 2002, published in volume 55, issue no. 1.

EFFECTIVENESS OF A BPLS & APLS WORKSHOP

C. Katsanoulas, A. Heliades, A.M. Spanaki, M. Hantzara, E. Assimina, S. Sbyrakis. University Hospital of Heraklion, PICU Dept. 8, Europe str., 71202, Heraklion, Crete, Greece.

Purpose: The necessity of Continuous Medical Education (CME) in Resuscitation, is always important, especially in connection with children. We wished to evaluate the effectiveness of a satellite workshop on Basic and Advanced Paediatric Life Support (BPLS & APLS), organized by our PICU, during the Annual Paediatric Symposium of the Medical School of the University of Crete. *Materials and Methods:* Instructors were PICU's medical and nursing staff. All doctors were APLS Providers. Preparation needed 2 months. The course was addressed to doctors and nurses with a limit of 40 persons and a scheduled duration of 4 h. The workshop comprised five educational steps: (1) A 24 question PreCourse Multiple-Choice-Question (MCQ) Paper. Time available 10 min. (2) A step by step lecture presentation on current BPLS and APLS issues and algorithms, including emergency equipment. (45 min duration). (3) A case-scenario of an infant meningococcal septicaemia, following the APLS structured approach. (20 min duration). (4) Six different practical skills different stations (i) BPLS, (ii) airway management and intubation, (iii) airway and mechanical ventilation equipment, (iv) vascular access and emergency drugs, (v) intraosseous drug administration, (vi) foreign body airway obstruction management. (4 min/station). (5) An MCQ Paper, similar to the PreCourse examination. At the end of the workshop, candidates completed an evaluation form and received an APLS booklet. *Results:* Because of great demand, 60 persons were finally accepted. The total duration was 2 h more than the scheduled. Forty persons had experienced at least one a pediatric arrest, while 20 had never had this experience. Thirty seven persons had already followed relevant adult workshops, while 23 had not. Pretest MCQ success was 68%, final 80% (17.6% improvement). Candidates expectations were fulfilled, being especially motivated by the case-scenario and the practical skills stations. Lack of available time available was the main disadvantage. *Conclusions:* CME on BPLS and APLS is a ever present issue. Workshops should be focused on more practical ways of presentation, with more available time.

EDUCATIONAL ANALYSIS OF AVANCED LIFE SUPPORT TRAINING COURSES

F.J. Garcá Vega[1], J.A. Blanco González[2], J. Nogueira Dios[1], A. Pascual Hermida[1], A.M. Suarez Briones[1], F. del Busto Prado[2], E. Ruy-Diaz[3]. [1]Emergency Department, Complejo Hospitalario de Pontevedra; [2]Emergency Department, Hospital Central de Asturias; [3]Emergency Department, Complejo Hospitalario de Ferro, Spain.

Introduction: It is generally agreed that the techniques of Life Support (LS) should be universally known, as far as possible, to ensure that none of links in the chain of survival breaks. The Basic (BLS) and Advanced Life Support (ALS) training courses are indispensable in order to obtain this. Teaching of these courses should be improved and what is learned should be remembered for longer. Our group has been carrying out BLS and ALS courses for more than 12 years, for both physicians and nursing staff. All the instructors are recognised by the ERC. *Objective:* The aim of this study was to analyze different aspects of the courses t to identify possible improvements that can be made, in order to optimize the educational methodology in LS. *Methodology*: We analyzed the profiles of the students and the post-course satisfaction surveys in the last 10 years. A total of 18 courses involving 460 students was studied. A practical evaluation was carried out on 84 students, based on the capability to 'remember' aspects of BLS, 2 years after finishing the BLS courses taught by our group. *Results:* Of the total number of students (460), 353 (82%) were physicians and 77 (18%) nurses. 67% had never carried any LS course previously. The results of the surveys of satisfaction were: General appraisal of the course: 4.9 (max. 5); Appraisal of the educational capacity of the instructor: 4.8 (max. 5); Practicality of what was learned: 4.9 (max. 5). The worst thing about the course: the theoretical classes; the best thing about the course: the Megacodes (scenarios); the most repeated suggestion: that the course should be longer. From the 84 students who were re-evaluated 2 years after the course had been carried out, the following results were obtained: Seeking help: 30% correct; 70% did ask for help; Management of the airway: 21% correct and 79% incorrect; Circulatory Support: 80% incorrect in the rate and 50% incorrect in the technique; Operation of an AED: 70% did not know it and of the 30% that knew it, 92% used it badly; Following algorithm: 19% correct and 81% incorrect. *Conclusions:* It is necessary to spread the techniques of LS much more considering that there is a high proportion of health providers who have little knowledge of this discipline. The courses are highly valued by the students. The practical aspects of the ALS training courses should be highlighted more, the theoretical classes should be reduced and there should be an increase in teaching hours. Considerable loss both in knowledge and in practical ability in LS is verified. We train the students learning the practical aspects of LS in a didactic way and so enforcing our mission. It is necessary to carry out periodic refresher courses, at least once a year, in order to maintain the knowledge acquired.

OUT-OF-HOSPITAL IMMEDIATE THROMBOLYSIS AFTER CARDIAC ARREST

F. Prados Roa, E. Corral Torres, A. Gonzales Municio, R. Suarez Bustamante, C. Barra Elgueta, R. De Elias Hernandez, R. SAMUR-

☆ PII of original article: S0300-9572(02)00274-5

PII: S0300-9572(03)00018-2

Protección Civil, Ayuntamiento de Madrid. Pza. de Legazpi, 7. 28045 Madrid, Spain.

Purpose of the study: The Prehospital Emergency and Rescue System of Madrid (Samur P. Civil) has been running an operation called 'Fibrinolysis in the First Hour'. Its main objective is to provide efficient reperfusion for the patients who suffer from Acute Myocardial Infarction. In the course of this study, there were two patients who received fibrinolytic therapy after a cardiac arrest. *Methodology:* Two cases in which thrombolytic therapy with 'Tenecteplase' was administered after restoring circulation after a cardiac arrest are presented. *Results:* -Case 1: Male, 54 years old, heavy smoker with hypercholesterolaemia, who presented with typical chest pain, suggestive of ischaemia. He had arterial hypotension and bradycardia, and immediately developed cardiac arrest in Ventricular Fibrillation. After a return of spontaneous circulation, the ECG showed an anteroinferior myocardial infarction that was treated with thrombolytic therapy, 50 min after the initial onset. The patient recovered haemodynamically, the chest pain disappeared and ST descended to between 2–3 mm. He was discharged from hospital 5 days later. Case 2: Male, 59 years old, heavy smoker with essential hypertension who presented with typical chest pain that did not respond to conventional treatment. In the course treatment, the patient suffered from two episodes of cardiac arrests, due to ventricular fibrillation, on both occasions the rhythm reverted to sinus rhythm. Thrombolytic therapy was administered after 55 min from the initial onset. The chest pain disappeared after some reperfusion arrhythmias. Finally, he was admitted to hospital presenting with sinus rhythm and haemodynamically stable, the ST segment was descended. The patient was discharged from the Intensive Care Unit after few hours later and from hospital 7 days later. *Conclusions:* Nowadays, the benefits of reperfusion therapy for patients who suffer from Acute Myocardial Infarction are clearly established, even for those who previously had a cardiac arrest. Cardiac arrest is not a contraindication for thrombolytic therapy, and in some situations it should be considered an extra indication.

BYSTANDER ALERT: A TEACHING PROGRAMME AIMED AT THE GENERAL POPULATION

A. Gonzales Municio, G. Martinez Acicoya, F. Prados Roa, R. Suarez Bustamante, J.J. Gimenez Mediavilla, E. Corral Torres. SAMUR-Protección Civil, Ayuntamiento de Madrid. Pza. de Legazpi, 7. 28045 Madrid, Spain.

Purpose of the study: Early identification of the patient at risk, rapid notification of EMS response team and immediate CPR by lay rescuers are highly desirable. The probability of survival approximately doubles when a bystander initiates CPR before the arrival of EMS personnel. The Prehospital Emergency and Rescue System of Madrid (Samur P. Civil) has developed a teaching programme geared towards as many citizens of Madrid as possible The aim of this study is to present this programme, in which the main objectives were to teach bystanders the organisation of EMS, how to identify patient collapse, to notify the EMS rapidly and perform early CPR by themselves until the arrival of EMS personnel. *Methodology:* The implementation of the programme was reviewed over three academic years. (1) It is a community-wide programme, with special emphasis on schools (children under eleven and teachers), public service workers (transport), hotel services, and other company services. (2) Courses are designed in two steps—Bystander alert and bystander CPR, of 2 and 4 h, respectively; with 50% theory and 50% practice. (3) The courses are offered to the community. (4) The programme is continuously checked and analysed and modified to improve results. *Results:*

Academic year	Instructors	Citizens	Courses
1998/1999	109	2.800	112
1999/2000	113	13.638	310
2000/2001	90	7.117	249
Total	(*)	23.555	671

After analysis, several changes were implemented: Four hour courses were rejected, new and more specialised courses were designed instead, for example 'Children as bystanders', aimed at children between six and 11 years old. Didactic material were renewed, etc. *Conclusions:* It is necessary to make a continuous assessment of the programme to equate it with new expectations. The huge community-wide programme has many advantages, such as early and effective activation of the EMS, improved survival of cardiac arrest patients by reducing the interval between collapse to CPR and collapse to defibrillation. This is not an expensive programme, with very profitable social and economical results.

TIME TO SHOCK VS. VOICE PROMPT DURATION: OPTIMIZATION OF DEFIBRILLATORS FOR PUBLIC ACCESS AND HOME DEPLOYMENT

David E. Snyder. Philips Medical Systems, 2401 4th Avenue, Suite 500, Seattle, WA 98121, USA.

Purpose: The time interval from onset of ventricular fibrillation (VF) to delivery of defibrillation shock has been identified as a primary correlate to survival. Widespread deployment of automated external defibrillators (AEDs) for public access defibrillation (PAD) and home use offers the potential of reducing this interval by minutes. Unfortunately, studies have reported that a significant percentage (25–50%) of minimally trained responders may fail to adequately attach the defibrillation electrode pads when using current generation AEDs. Could survival be improved via additional AED voice-prompts which emphasize pad application, at the expense of somewhat delayed defibrillation? *Materials and methods:* A probability of survival is calculated from the widely accepted mortality rate of 10% per minute of untreated VF, in conjunction with the probability of successful pad application, P[A]. *Results:* The overall probability of survival is $P[S] = (1 - t/600)\ P[A]$, $t < 600$, where t is time to shock (seconds). In a hypothetical PAD system with 4.5 min time to shock and 75% $P[A]$, the expected survival rate is 41%. If the AED is enhanced with 15 seconds of additional voice prompts to accomplish 90% $P[A]$ (which must be verified by testing), the survival rate is improved to 47%. In this scenario, survival benefit can be realized with up to 54 s of added voice prompts in order to achieve 90% $P[A]$. *Conclusions:* Probability calculations may be used to optimize the trade-off between duration of AED voice prompts and time to defibrillation. AEDs for public access or home use should be designed, via improvement of human factors such as voice prompts, to enhance the successful placement of defibrillation pads, even at the expense of some increase in time to shock. An AED capable of adaptation to the faster pace of a skilled responder would yield further benefit.

EXTERNAL SERIES RESISTORS ACCURATELY MODEL WAVEFORM TIME COURSE, BUT NOT CARDIAC DOSE IN ANIMAL MODELS OF DEFIBRILLATION

David E. Snyder, C. Morgan. Philips Medical Systems, 2401 4th Avenue, Suite 500, Seattle WA 98121, USA.

Purpose: Transthoracic defibrillation researchers have modified laboratory animals with an external series resistance in an attempt to model variation in human transthoracic resistance (TTR). The failure of this surrogate to predict human clinical defibrillation experience consistently has not been explained. We propose that the use of an external series resistance, while accurately reproducing the time course (shape) of a defibrillation waveform, nevertheless does not act as a model for cardiac defibrillation dose. *Materials and Methods:* We surveyed human and animal transthoracic defibrillation research literature concerning intrathoracic current flow. We then performed an engineering examination of the ability of an external series resistor to reproduce cardiac defibrillation dose correctly. *Results:* Generally, animal TTR is lower and exhibits a smaller variation than human TTR (e.g. 40 ± 7 for 25–30 kg swine, vs. 86 ± 26 for adult humans). Detailed studies of intrathoracic current flow in dogs and humans have demonstrated that the thoracic cage resistance (TCR), which is in

parallel with the heart, dominates the TTR and cardiac defibrillation dose. An increase in TTR due to increased TCR results in a larger percentage of the transthoracic current and energy dose being delivered to the heart. In contrast, animal surrogates must incorporate an external series (not parallel) resistor approximately equal to the animal TTR in order to achieve total resistance similar to humans. This modification accurately reproduces waveforms of the proper time course (shape). However, by failing to act as an accurate model of intrathoracic current flow, the external series resistance forces an inappropriate reduction in cardiac current and energy dose of approximately 50%. *Conclusions:* An external series resistor may be used in animal defibrillation research to reproduce waveform time course effects accurately, but by failing to be an accurate model of intrathoracic current flow, substantially misrepresents the effect of transthoracic resistance on cardiac energy and current dose.

Biphasic Truncated Exponential Waveform Defibrillation

Roger D. White, MD, Donald M. Blanton, MD, MS

Abstract

This paper presents data from studies that have compared the efficacies of biphasic truncated exponential (BTE) and monophasic damped sine (MDS) waveform defibrillation in patients with out-of-hospital cardiac arrest and in in-hospital defibrillation. When a shock is delivered, rhythms evolve rap-idly in a variety of directions and take different courses, even over a short time. When defibrillation is defined as termination of ventricular fibrillation at 5 seconds postshock, whether to an organized rhythm or asystole, low-energy BTE shocks appear to be more effective than high-energy MDS shocks in out-of-hospital arrest. For future research, the terms associated with defibrillation should be standardized and used uniformly by all investi-gators. In particular, there should be an agreed-upon definition of shock efficacy. **Key words:** cardiac arrest; ventricular fibrillation; defibrillation; automated external defibrillators; biphasic waveform.

PREHOSPITAL EMERGENCY CARE
1999;3:283–289

Out-of-Hospital Cardiac Arrest

An ongoing study of early defibrillation in Rochester, Minnesota, provides comprehensive data on the outcome of biphasic truncated exponential (BTE) waveform defibrillation compared with monophasic damped sine (MDS) waveform defibrillation in out-of-hospital cardiac arrest. From November 1990 through December 1998, data have been gathered on the results of police- and paramedic-initiated MDS or BTE defibrillation attempts. Defibrillators with BTE waveforms (ForeRunner, HP/Heartstream, Seattle, WA) were placed into service in December 1996. A preliminary report has been published[1] and more recent data have been summarized in abstracts.[2,3] In addition, a complete report on this experience has been accepted for publication.[4] Also, a report on patient outcome for the first seven years in this study was published recently.[5]

The database includes 116 patients, 87 of whom received MDS shocks and 29 of whom received BTE shocks. The groups did not differ significantly in demographics, whether the arrest was witnessed or cardiopulmonary resuscitation (CPR) delivered, or in the call-to-shock interval (Table 1). Nor did they differ in rates of return of spontaneous circulation or survival to discharge (Table 2).

The monophasic automated external defibrillators (AEDs) delivered 455 MDS shocks to the 87 patients, 55% at 200 J and 40% at 360 J (Table 3). All of the biphasic shocks were delivered at 150 J. There were no differences in patient resistance or in the number of shocks delivered per patient.

The efficacy of defibrillation, defined as termination of ventricular fibrillation (VF) at 5 seconds postshock, was determined in the two groups of patients for the first episode of VF only and for all episodes (Table 4). The conversion rate for the first (presenting) episode of VF with three or fewer shocks was 100% in the BTE group (150 J) and 93% in the MDS group (200 J for first shocks), but the difference did not achieve statistical significance.

However, a significant differ-

Table 1. Baseline Data on Patients Receiving Out-of-hospital Defibrillation in Rochester, Minnesota, between November 1990 and December 1998

	Monophasic Waveform AED	Biphasic Waveform AED	p
Dates of study	November 1990–April 1997	December 1996–December 1998	
Number of patients	87	29	
Gender			
Female	16 (18%)	5 (17%)	0.89
Male	71 (82%)	24 (83%)	
Age—mean ± SD (range)	63 ± 14 (10–91) years	68 ± 11 (44–87) years	0.12
Cardiac arrest witnessed	73 (84%)	24 (83%)	0.88
Bystander CPR	42 (48%)	11 (38%)	0.33
Call-to-shock interval—mean ± SD (range)	6.5 ± 2.2 (1.0–17.7) min	6.3 ± 1.5 (3.3–9.1) min	0.58

Received May 18, 1999, from the Department of Anesthesiology, Mayo Clinic, and City of Rochester Early Defibrillation Program, Rochester, Minnesota (RDW); and the Nashville Fire Department EMS, Nashville, Tennessee (DMB). Revision received May 27, 1999; accepted for publication July 1, 1999.

Presented at the Turtle Creek Consensus Conference on Prehospital Care, Dallas, Texas, February 1999.

Supported by an unrestricted educational grant from Wyeth-Ayerst Laboratories.

Address correspondence and reprint requests to: Roger D. White, MD, Department of Anesthesiology, Mayo Clinic, Rochester, MN 55905. e-mail: <white.roger@mayo.edu>.

TABLE 2. Patient Outcome by Type of Shock

	Monophasic Waveform AED	Biphasic Waveform AED	p
Return of spontaneous circulation	58/87 (67%) [55%–76%]*	20/29 (69%) [49%–85%]	0.82
Survival to hospital discharge	36/87 (41%) [30%–52%]	9/29 (31%) [15%–51%]	0.32

*Brackets represent 95% confidence intervals.

TABLE 3. Automated External Defibrillator (AED) Use

	Monophasic Waveform AED (n = 87)	Biphasic Waveform AED (n = 29)	p
Number of shocks delivered	249 at 200 J 5 at 300 J 183 at 360 J 18 at unknown energy setting	152 at 150 J	
Patient resistance—mean ± SD (range)	101 ± 27 (56–177) ohms	95 ± 24 (39–143) ohms	0.32
No. shocks per patient—mean ± SD (range)	5.2 ± 4.8 (1–22)	5.2 ± 4.1 (1–15)	1.00

ence in efficacy between MDS and BTE shocks is seen in an examination of the data for all shocks. Eighty-five percent of all VF episodes were terminated with three or fewer shocks with MDS waveform AEDs, whereas 99% of all VF episodes were terminated with three or fewer shocks in the group treated with the BTE waveform AEDs ($p < 0.0001$).

Several conclusions can be drawn from these data. First, postshock rhythms evolve over time after both MDS and BTE shocks. For first VF episodes, both waveforms yielded statistically comparable rates of conversion, whereas for all VF episodes, 150-J BTE shocks resulted in a significantly higher frequency of conversion. A much larger number of shocks was available for analysis for all VF episodes compared with those for only the first episode, which may account for the highly significant difference between groups for all VF episodes. The rates of VF recurrence were similar for the two waveforms. In light of these differences with MDS and BTE waveform shocks and the emergence of new BTE waveforms, electrocardiographic definitions of defibrillation must be standardized and used uniformly in clinical investigations.

Results similar to the Rochester data have been obtained in other studies of BTE. In an investigation of the efficacy of low-energy, impedance-compensating biphasic defibrillation in 44 patients (including patients from the Rochester group), 99% of all VF episodes were terminated with three or fewer shocks (95% CI, 96%–100%).[6] In another study of 100 patients (again including our patients), 97% ± 11% of VF episodes were terminated with no more than three shocks (95% CI, 95%–100%).[7]

According to a preliminary report by Duncan et al. in 19 patients, 52 episodes of VF had first-shock conversion rates of 79% (BTE) and 73% (monophasic).[8] In this study, ten patients received 72 shocks from a BTE device and nine patients received 27 shocks from a monophasic device. Overall conversion rates were 56% (BTE) and 44% (monophasic) ($p = 0.32$). Because this abstract does not provide detailed technical information, including the type of monophasic waveform used (MDS or monophasic truncated exponential, MTE), it is not possible to draw definitive conclusions about the findings in the study. In another preliminary report of BTE defibrillation in 35 patients with out-of-hospital VF, the first-shock VF termination rate was 71%.[9] Seven patients (20%) survived to hospital discharge. No detailed data are available regarding definitions of defibrillation or postshock rhythms.

IN-HOSPITAL STUDIES

Several in-hospital studies have compared the efficacies of biphasic and monophasic shocks in VF conversion. The first was a multicenter, prospective, randomized, blinded investigation that compared the first-shock transthoracic defibrillation efficacy of a 130-J BTE waveform with that of a standard 200-J MDS waveform using anterior

TABLE 4. Comparative Efficacy of Defibrillation in Patients Receiving Monophasic or Biphasic Waveform Automated External Defibrillation

	Monophasic Waveform AED (n = 87)	Biphasic Waveform AED (n = 29)	p
First VF episode			
Single shock	38/55 (69%) [55%–81%]*	23/29 (79%) [60%–92%]	0.31
≤3 shocks	74/79 (93%) [85%–98%]	29/29 (100%) [88%–100%]	0.17
All VF episodes			
Single shock	138/210 (66%) [58%–72%]	110/129 (85%) [78%–91%]	<0.0001
≤3 shocks	179/210 (85%) [79%–90%]	128/129 (99%) [96%–100%]	<0.0001

*Brackets represent 95% confidence intervals.

thoracic pads during implantable cardioverter–defibrillator testing.[10] Results in 294 eligible patients indicated that both waveforms achieved first-shock efficacy rates of 86%.

Another study done during electrophysiologic testing provides additional data on the comparative efficacies of MDS and BTE shocks. This study compared the 200-J MDS waveform and the 130-J BTE waveform in 115 patients during evaluation of implantable cardioverter–defibrillator function and in 39 patients during evaluation of ventricular arrhythmias.[11] First-shock success rates were 90% (95% CI, 80%–96%) for 200-J MDS, 100% (95% CI, 91%–100%) for 200-J BTE, and 83% (95% CI, 69%–92%) for 130-J BTE. It should be noted that 130-J BTE shocks are not used in AEDs currently available.

Another recent study compared the defibrillation efficacies of 120-J biphasic shocks with 200-J MDS shocks in a prospective, randomized study of 186 patients undergoing transthoracic ventricular defibrillation.[12] The biphasic waveform incorporated a constant current first phase and truncated exponential second phase. First-shock efficacy was 99% for biphasic shocks and 92% for MDS shocks ($p = 0.03$). Defibrillation with this biphasic waveform was accomplished with 58% less current than that delivered with MDS shocks (14 ± 2 vs 33 ± 8 amp, $p < 0.0001$).

CONCLUSIONS

Available data indicate that the efficacy of biphasic defibrillation is at least comparable or possibly superior to that of MDS defibrillation. The only biphasic waveform evaluated rigorously in the out-of-hospital VF environment is the BTE version. Experience with out-of-hospital cardiac arrest in Rochester, Minnesota, has shown that, for first VF episodes, both waveforms yielded statistically comparable rates of conversion for first VF episodes (150-J BTE and 200-J MDS shocks), whereas for all VF episodes, 150-J BTE shocks resulted in a significantly higher frequency of conversion.

As we enter an era in which biphasic waveforms of various types are becoming available and being assessed, it is essential that concise, standardized definitions of shock outcomes and postshock rhythms be formulated, accepted, and universally used. For example, it is necessary to agree on a time interval during which successful defibrillation occurs. Strong arguments have been made for an interval of 5 seconds, both because defibrillation actually occurs well within this interval and because use of a longer postshock interval can lead to uncertainty regarding the influence of CPR and other interventions on postshock rhythms. The specific need is to define precisely the effect of the shock waveform on VF, isolated from the many other variables that determine postshock rhythms. Adoption of standardized terms will facilitate comparisons of shock outcomes among studies and among defibrillation modalities.[13]

CONSENSUS PRESENTATION

Abundant evidence shows that any form of early defibrillation is beneficial for patients with out-of-hospital cardiac arrest with VF as the presenting rhythm. Monophasic defibrillation has saved thousands of lives and has been the standard of care. It is not yet possible to determine whether biphasic defibrillation confers measurable clinical benefits different from monophasic defibrillation, because few comparative studies have addressed this issue, and the number of patients in these studies was small. Nonetheless, based on available evidence, it is likely that biphasic defibrillation will eventually replace monophasic defibrillation.

Acceptance of biphasic AEDs has been growing steadily because they are smaller, lighter, and less expensive to build than monophasic units. Although all implanted defibrillators are biphasic, comparisons with external units may be misleading because implanted units can assess and convert fibrillation immediately. In contrast to external units, implanted devices have no "downtime."

ECONOMIC CONSIDERATIONS

Inasmuch as biphasic units are less expensive to produce than monophasic AEDs, more biphasic devices can be bought for the same amount of money. If biphasic waveform AEDs prove to have comparable or better outcomes in terms of shock efficacy, there would be a strong incentive for favoring biphasic defibrillation. Other clinical variables more remote from the direct effect of the shock on VF, such as restoration of pulses with shocks and discharge survival, also should be evaluated and reported along with shock efficacy.

Funding additional studies comparing the benefits of biphasic and monophasic defibrillation will be difficult, in part because randomization to different treatment groups involves patient consent issues. This applies as well to attempted comparisons of different biphasic waveforms. Data analysis also would be difficult because of the small numbers of cardiac arrests that occur in any emergency medical services system. It would be necessary to establish a data registry to obtain large numbers. Moreover, even if one defibrillation

waveform is proved superior to the other, it is unlikely that existing equipment would be replaced; any impact probably would be on future purchases.

REGULATORY ISSUES RELATED TO COMPARATIVE STUDIES

Both monophasic AEDs (MDS and MTE) and biphasic AEDs have been approved by the U.S. Food and Drug Administration (FDA) on the basis of electrophysiologic studies of induced VF and its immediate defibrillation. Biphasic units were approved for use despite the fact that their clinical application in prehospital defibrillation is different in many respects from experience in electrophysiology studies. Although randomized, comparative trials would be ideal, the initiation of such trials would require institutional review board approval. Furthermore, even though both monophasic defibrillation and BTE defibrillation are approved techniques and the devices are marketed, the FDA would require that provision be made for a waiver of informed consent before a randomized trial could begin. Finally, the wide array of clinical variables that can affect response to defibrillation shocks would present imposing difficulties on trial design. These are many, including the underlying myocardial pathophysiologic substrate preceding the VF episode.

ESTABLISHMENT OF A STANDARD TERMINOLOGY

To make possible the accurate interpretation of research, it is essential that precise definitions related to defibrillation be developed as a means of establishing a common terminology. Some suggested definitions follow:

Biphasic and Monophasic Defibrillators

The *biphasic* waveform AED studied in out-of-hospital cardiac arrest delivers low-energy impedance-compensating shocks that defibrillate with apparent greater efficacy than do higher energy *monophasic* waveform shocks. Several versions of biphasic waveforms are becoming available. Most waveform designs are proprietary and vary among manufacturers. The clinical implications of these differences, if any, are not known. Rigorous evaluation in out-of-hospital cardiac arrest would be required to discern measurable differences in waveform efficacies.

Defibrillation

Defibrillation is the termination of VF. In many clinical trials, conversion of VF to a pulseless organized rhythm or asystole is considered successful defibrillation as well as restoration of a rhythm with pulses. It is essential that a standardized definition of defibrillation be agreed on before major studies assessing the comparative efficacy of various waveforms begin.

Defibrillation Efficacy

Defibrillation efficacy refers to the rate of success in terminating VF within a given time. There has been considerable discussion about the time postshock at which a determination about the success of a defibrillation attempt should be made. It has been argued persuasively that 5 seconds postshock is the ideal time to assess the effect that the shock itself has had on VF. After that, other interventions, such as chest compression, ventilation, and drug therapy, influence postshock rhythms, independent of the direct effect of the shock on terminating VF.

Besides measuring defibrillation efficacy by determining conversion at a set interval, some researchers feel that it would also be desirable to employ a secondary efficacy variable, such as restoration of spontaneous circulation after 60 seconds. This interest in establishing a secondary criterion is prompted by the possibility that the shock itself might be a measurable determinant of this outcome. An optimal defibrillation is one that produces restoration of pulses after the shock or that is followed by an interim rhythm that allows the other components of the resuscitation process to increase the likelihood of survival.

Some investigators believe that studies comparing the efficacy of different waveforms should include a surrogate endpoint for survival. This endpoint might be a rhythm at a specific time or some other marker that might identify patients who are likely to have a good clinical outcome. It is argued that use of such a marker is important in view of the limited number of patients available for studies of out-of-hospital cardiac arrest.

In assessing defibrillation efficacy, many researchers feel that consideration of baseline patient characteristics is important. These include the interval since the cardiac arrest and the patient's underlying myocardial pathophysiologic substrate from which VF emerged. Unless these, among other variables influencing survival, are considered, it is very difficult to relate the direct effect of the waveform shock to patient outcome. It is also important to keep in mind that interim success may not result in a favorable clinical outcome, including an acceptable level of neurologic function.

ENHANCING THE BENEFITS OF BIPHASIC DEFIBRILLATION

In addition to studies investigating the question of which biphasic waveforms are most efficacious, other research should focus on the optimal integration of defibrillation with other interventions. When should the shock be given with respect to oxygenation, CPR, and pharmacotherapy? What combination and timing of epinephrine, lidocaine, amiodarone, and investigational drugs, such as the lazaroids, would be most beneficial?

THE ENERGY LEVEL OF BIPHASIC DEFIBRILLATORS

The commercially available bipha-

sic device that has been evaluated in out-of-hospital arrest delivers shocks at 150 J. This level reflects the evidence from electrophysiologic laboratory studies that biphasic shocks require less energy than do monophasic shocks. Clinical experience with out-of-hospital VF also supports this in-hospital evidence. The 150-J device not only offers an acceptable level of efficacy but also was based on design considerations and the costs of different types of batteries and capacitors.

Electrical energy delivered during defibrillation shocks has been shown to result in ventricular dysfunction, and the magnitude of dysfunction is correlated with the amount of energy delivered. This has been observed with both internal and external defibrillation.[14–16] Consistent with this are results demonstrating less injurious effects on myocardial oxidative metabolism and hemodynamic performance after biphasic shocks compared with monophasic shocks in a canine model.[17]

Weaver and colleagues concluded in humans that low-energy (175-J) MDS shocks were as effective as high-energy (320-J) shocks for initial defibrillation. Also, shocks at the higher energy level resulted in a higher incidence of heart block after defibrillation compared with lower-energy shocks.[18] Low-energy BTE shocks (150-J) have been shown experimentally to be as effective as high-energy MDS shocks (200–360-J) after 7 minutes of untreated VF but with significantly less postresuscitation myocardial dysfunction.[19,20]

MANUFACTURING ISSUES

Manufacturers favor the use of biphasic AEDs because of the refinement in energy management and delivery and because they are less costly to manufacture. It is unlikely that this thrust toward the use of biphasic defibrillators will be reversed, nor is there any reason to believe that it should.

In their advertising, AED manufacturers often make aggressive claims about the superiority of their device to their competitors' products. In actuality, however, the basis for FDA approval of new devices is that they are at least functionally equivalent to previously evaluated AEDs. When refining their defibrillators, manufacturers are likely to focus on ease of use and maintenance, battery technology, overall size and weight, energy storage technology, and efficiency of the defibrillation pads. It seems unlikely that quantitative, measurable, and clinically relevant differences among variations in biphasic waveforms will be observed, though each variation in biphasic waveforms should be subjected to in-depth evaluation in out-of-hospital cardiac arrest. Purchasers will be offered biphasic waveform devices by all manufacturers and purchasing decisions will be made primarily based on the considerations listed above.

SUMMARY

In attempting to reduce the mortality and morbidity associated with out-of-hospital cardiac arrest, efforts to provide rapid defibrillation must be promoted. It is also essential that research on waveform efficacy and the overall resuscitation process be continued.

The superiority of newly developed biphasic waveforms will need to be defined in out-of-hospital cardiac arrest. However, owing to many other considerations, it is certain that biphasic defibrillation will replace monophasic defibrillation in the near future. Therefore, thorough prehospital evaluation of the efficacy of each type of biphasic waveform is essential, with clearly-defined and rigorously-applied definitions of defibrillation shock efficacy. To ensure proper interpretation and comparison of future studies of biphasic defibrillation, researchers must develop, agree on, and consistently use a standardized definition of defibrillation efficacy. There is persuasive evidence that the rhythm at 5 seconds postshock should be a primary determinant of shock efficacy. At this point in postshock time a definitive determination can be made regarding termination of VF, which is the "task" of the defibrillator waveform. It remains to be decided whether other variables should also be included in efficacy assessments.

References

1. White RD. Early out-of-hospital experience with an impedance-compensating low-energy biphasic waveform automatic external difibrillator. J Interv Card Electrophysiol. 1997;1:203–8.
2. Gliner BE, White RD. Post-shock ECG rhythm classification following out-of-hospital low-energy impedance-compensating biphasic and high-energy monophasic defibrillation shocks [abstract]. Circulation. 1998;98:I-173–I-174.
3. Gliner BE, White RD. Recurrence of out-of-hospital VF following low-energy biphasic and high-energy monophasic defibrillation shocks [abstract]. J Am Coll Cardiol. 1999;33:127A.
4. Gliner BE, White RD. Electrocardiographic evaluation of defibrillation shocks delivered to out-of-hospital sudden cardiac arrest patients. Resuscitation. 1999;41:129–40.
5. White RD, Hankins DG, Bugliosi TF. Seven years' experience with early defibrillation by police and paramedics in an emergency medical services system. Resuscitation. 1998;39:145–51.
6. Poole JE, White RD, Kanz K-G, et al. Low-energy inpedance-compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out-of-hospital cardiac arrest. J Cardiovasc Electrophysiol. 1997;8:1373–85.
7. Gliner BE, Jorgenson DB, Poole JE, et al. Treatment of out-of-hospital cardiac arrest with a low-energy impedance-compensating biphasic waveform automatic external defibrillator. Biomed Instrum Technol. 1998;32:631–44.
8. Duncan BR, Kavanagh PR, Smith DL, Fales WD. Comparison of biphasic and monophasic automated external defibrillators: preliminary results [abstract]. Prehosp Emerg Care. 1999;3:79.
9. Ossmann E, Sasser S, Blackwell T. Biphasic external defibrillation in an urban EMS system [abstract]. Prehosp Emerg Care. 1999;3:85–6.
10. Bardy GH, Marchlinski FE, Sharma AD, et al. Multicenter comparison of truncated biphasic shocks and standard damped sine wave monophasic shocks for transthoracic ventricular defibrilla-

tion. Circulation. 1996;94:2507–14.
11. Herre JM, Higgins SL, Epstein AE, et al. A comparison of biphasic and monophasic shocks for external defibrillation of humans [abstract]. Circulation. 1998; 98:I–173.
12. Mittal S, Ayati S, Stein KM, et al. Comparison of a novel biphasic waveform with a damped sine wave monophasic waveform for transthoracic ventricular defibrillation [abstract]. J Am Coll Cardiol. 1999;33:105A.
13. White RD. External defibrillation: the need for uniformity in analyzing and reporting results. Ann Emerg Med. 1998; 32:234–6.
14. Tokano T, Bach D, Chang J, et al. Effect of ventricular shock strength on cardiac hemodynamics. J Cardiovasc Electrophysiol. 1998;9:791–7.
15. Xie J, Weil MH, Sun S, et al. High-energy defibrillation increases the severity of postresuscitation myocardial dysfunction. Circulation. 1997;96:683–8.
16. Mattana J, Singhal PC. Determinants of elevated creatine kinase activity and creatine kinase MB-fraction following cardipulmonary resuscitation. Chest. 1992;101:1386–92.
17. Osswald S, Trouton TG, O'Nunain SS, Holden HB, Ruskin JN, Garan H. Relation between shock-related myocardial injury and defibrillation efficacy of monophasic and biphasic shocks in a canine model. Circulation. 1994;90:2501–9.
18. Weaver WD, Cobb LA, Copass MK, Hallstrom AP. Ventricular defibrillation—a comparative trial using 175-J and 320-J shocks. N Engl J Med. 1982;307:1101–6.
19. Tang W, Weil MH, Sun S, et al. Defibrillation with low-energy biphasic waveform reduces the severity of post-resuscitation myocardial dysfunction after prolonged cardiac arrest [abstract]. Crit Care Med. 1999;27:A43.
20. Tang W, Weil MH, Sun S, et al. The effects of biphasic and conventional monophasic defibrillation on post resuscitation myocardial function. J Am Coll Cardiol. (in press, 1999).

Suggested Reading

21. Nichol G, Hallstrom AP, Kerber R, et al. American Heart Association report on the Second Public Access Defibrillation Conference, April 17–19, 1997. Circulation. 1998;97:1309–14.
22. Cummins RO, Hazinski MF, Kerber RE, et al. Low-energy biphasic waveform defibrillation: evidence-based review applied to emergency cardiovascular care guidelines. Circulation. 1998;97: 1654–67.
23. White RD, Vukov LF, Bugliosi TF. Early defibrillation by police: initial experience with measurement of critical time intervals and patient outcome. Ann Emerg Med. 1994;23:1009–13.
24. White RD, Asplin BR, Bugliosi TF, Hankins DG. High discharge survival rate after out-of-hospital ventricular fibrillation with rapid defibrillation by police and paramedics. Ann Emerg Med. 1996; 28:480–5.
25. White RD, Hankins DG, Bugliosi TF. Seven years' experience with early defibrillation by police and paramedics in an emergency medical services system. Resuscitation. 1998;39:145–51.
26. White RD. External defibrillation: the need for uniformity in analyzing and reporting results. Ann Emerg Med. 1998; 32:234–6.
27. Poole JE, White RD, Kanz K-G, et al. Low-energy impedance-compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out-of-hospital cardiac arrest. J Cardiovasc Electrophysiol. 1997;8:1373–85.
28. White RD. Early out-of-hospital experience with an impedance-compensating low-energy biphasic waveform automatic external defibrillator. J Interv Card Electrophysiol. 1997;1:203–8.
29. Gliner BE, Jorgenson DB, Poole JE, et al. Treatment of out-of-hospital cardiac arrest with a low-energy impedance-compensating biphasic waveform automatic external defibrillator. Biomed Instrum Technol. 1998;32:631–44.
30. Caterine MR, Spencer KT, Pagan-Carlo LA, Smith RS, Buettner GR, Kerber RE. Direct current shocks to the heart generate free radicals: an electron paramagnetic resonance study. J Am Coll Cardiol. 1996;28:1598–609.
31. Lerman BB, Engelstein ED. Increased defibrillation threshold due to ventricular fibrillation duration. Potential mechanisms. J Electrocardiol. 1995;28:21–4.
32. Stewart AJ, Allen JD, Adgey AAJ. Frequency analysis of ventricular fibrillation and resuscitation success. QJM. 1992;85:761–9.
33. Tacker WA, Geddes LA. The laws of electrical stimulation of cardiac tissue. Proc IEEE. 1996;84:355–65.
34. Charbonnier FM. External defibrillators and emergency external pacemakers. Proc IEEE. 1996;84:487–99.
35. Jones JL, Jones RE, Balasky G. Microlesion formation in myocardial cells by high-intensity electric field stimulation. Am J Physiol. 1987;253(2 pt 2):H480–H486.
36. Bardy GH, Marchlinski FE, Sharma AD, et al. Multicenter comparison of truncated biphasic shocks and standard damped sine wave monophasic shocks for transthoracic ventricular defibrillation. Circulation. 1996;94:2507–14.
37. Gliner BE, Lyster TE, Dillon SM, Bardy GH. Transthoracic defibrillation of swine with monophasic and biphasic waveforms. Circulation. 1995;92:1634–43.
38. Reddy RK, Gleva MJ, Gliner BE, et al. Biphasic transthoracic defibrillation causes fewer ECG ST-segment changes after shock. Ann Emerg Med. 1997; 30:127–34.
39. Walcott GP, Knisley SB, Zhou X, Newton JC, Ideker RE. On the mechanism of ventricular defibrillation. Pacing Clin Electrophysiol. 1997;20:422–31.
40. Walcott GP, Melnick SB, Chapman FW, Jones JL, Smith VM, Ideker RE. Relative efficacy of monophasic and biphasic waveforms for transthoracic defibrillation after short and long durations of ventricular fibrillation. Circulation. 1998;98: 2210–5.
41. Kwaku KF, Dillon SM. Shock-induced depolarization of refractory myocardium prevents wave-front propagation in defibrillation. Circ Res. 1996;79:957–73.
42. Dillon SM. The electrophysiology of ventricular defibrillation: today and yesterday. In: Allessie MA, Fromer M (eds). Atrial and Ventricular Fibrillation: Mechanisms and Device Therapy. Armonk, NY: Futura Publishing Co., 1997.
43. Dillon SM, Kwaku KF. Progressive depolarization: a unified hypothesis for defibrillation and fibrillation induction by shocks. J Cardiovasc Electrophysiol. 1998;9:529–52.
44. Jones JL, Tovar OH. The mechanism of defibrillation and cardioversion. Proc IEEE. 1996;84:392–403.
45. Jones JL, Tovar OH. Threshold reduction with biphasic defibrillator waveforms. Role of charge balance. J Electrocardiol. 1995;28:25–30.
46. Tovar OH, Jones JL. Biphasic defibrillation waveforms reduce shock-induced response duration dispersion between low and high shock intensities. Circ Res. 1995;77:430–8.
47. Jones JL, Swatz JF, Jones RE, Fletcher R. Increasing fibrillation duration enhances relative asymmetrical biphasic versus monophasic defibrillator waveform efficacy. Circ Res. 1990;67:376–84.
48. Winkle RA, Mead RH, Ruder MA, et al. Improved low energy defibrillation efficacy in man with the use of a biphasic truncated exponential waveform. Am Heart J. 1989;117:122–7.
49. Sweeney RJ, Gill RM, Steinberg MI, Reid PR. Ventricular refractory period extension caused by defibrillation shocks. Circulation. 1990;82:965–72.
50. Behr JC, Hartley LL, York DK, Brown DD, Kerber RE. Truncated exponential versus damped sinusoidal waveform for transthoracic defibrillation. Am J Cardiol. 1996;78:1242–5.
51. Greene HL, DiMarco JP, Kudenchuk PJ, et al. Comparison of monophasic and biphasic defibrillating pulse waveforms for transthoracic cardioversion. Am J Cardiol. 1995;75:1135–9.
52. Windecker S, Kay GN, KenKnight BH,

Walcott GP, Smith WM, Ideker RE. The effects of ventricular fibrillation duration and a preceding unsuccessful shock on the probability of defibrillation success using biphasic waveforms in pigs. J Cardiovasc Electrophysiol. 1997;8:1386–95.
53. Walcott GP, Walcott KT, Knisley SB, Zhou X, Ideker RE. Mechanisms of defibrillation for monophasic and biphasic waveforms. Pacing Clin Electrophysiol. 1994;17:478–498.
54. Sweeney RJ, Gill RM, Reid PR. Refractory interval after transcardiac shocks during ventricular fibrillation. Circulation. 1996;94:2947–52.
55. Gliner BE, White RD. Electrocardiographic evaluation of defibrillation shocks delivered to out-of-hospital sudden cardiac arrest patients. Resuscitation. 1999;41:133–44.
56. Xie J, Weil MH, Sun S, et al. High-energy defibrillation increases the severity of postresuscitation myocardial dysfunction. Circulation. 1997;96:683–8.
57. Tokano T, Bach D, Chang J, et al. Effect of ventricular shock strength on cardiac hemodynamics. J Cardiovasc Electrophysiol. 1998;9:791–7.
58. Osswald S, Trouton TG, O'Nunain SS, Holden HB, Ruskin JN, Garan H. Relation between shock-related myocardial injury and defibrillation efficacy of monophasic and biphasic shocks in a canine model. Circulation. 1994;90:2501–9.
59. Kerber RE, Kouba CK, Martins J, et al. Advance prediction of transthoracic impedance in human defibrillation and cardioversion: importance of impedance in determining the success of low-energy shocks. Circulation. 1984;70:303–8.
60. Kerber RE, Martins JB, Kienzle MG, et al. Energy, current, and success in defibrillation and cardioversion: clinical studies using an automated impedance-based method of energy adjustment. Circulation. 1988;77:1038–46.
61. Kerber RE. Editorial comment concerning "Early out-of-hospital experience with an impedance-compensating low-energy biphasic waveform automatic external defibrillator." J Interv Card Electrophysiol. 1997;1:209–10.
62. Kerber RE, Becker LB, Bourland JD, et al. Automatic external defibrillators for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety: a statement for health professionals from the AHA Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. Circulation. 1997; 95:1677–82.
63. Cummins RO, Hazinski MF, Kerber RE, et al. Low-energy biphasic waveform defibrillation: evidence-based review applied to emergency cardiovascular care guidelines. Circulation. 1998;97:1654–67.
64. Weaver WD, Copass MK, Hill DL, Fahrenbruch C, Hallstrom AP, Cobb LA. Cardiac arrest treated with a new automatic external defibrillator by out-of-hospital first responders. Am J Cardiol. 1986;57:1017–21.
65. Weaver WD, Cobb LA, Copass MK, Hallstrom AP. Ventricular defibrillation—a comparative trial using 175-J and 320-J shocks. N Engl J Med. 1982; 307:1101–6.
66. Weaver WD, Hill DL, Fahrenbruch C, et al. Automatic external defibrillators: importance of field testing to evaluate performance. J Am Coll Cardiol. 1987;10: 1259–64.
67. Weaver WD, Hill D, Fahrenbruch CE, et al. Use of the automatic external defibrillator in the management of out-of-hospital cardiac arrest. N Engl J Med. 1988;319:661–6.

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association®
Learn and Live℠

Multicenter, Randomized, Controlled Trial of 150-J Biphasic Shocks Compared With 200- to 360-J Monophasic Shocks in the Resuscitation of Out-of-Hospital Cardiac Arrest Victims

Thomas Schneider, Patrick R. Martens, Hans Paschen, Markku Kuisma, Benno Wolcke, Bradford E. Gliner, James K. Russell, W. Douglas Weaver, Leo Bossaert and Douglas Chamberlain

Circulation 2000;102;1780-1787
Circulation is published by the Ameriean Heart Assoeiation. 7272 Greenville Avenue, Dallas, TX 72514
 Print ISSN: 0009-7322. Online ISSN: 1524-4539

Multicenter, Randomized, Controlled Trial of 150-J Biphasic Shocks Compared With 200- to 360-J Monophasic Shocks in the Resuscitation of Out-of-Hospital Cardiac Arrest Victims

Thomas Schneider, MD; Patrick R. Martens, MD; Hans Paschen, MD; Markku Kuisma, MD; Benno Wolcke, MD; Bradford E. Gliner, MS; James K. Russell, PhD; W. Douglas Weaver, MD; Leo Bossaert, MD; Douglas Chamberlain, MD; for the Optimized Response to Cardiac Arrest (ORCA) Investigators

Background—In the present study, we compared an automatic external defibrillator (AED) that delivers 150-J biphasic shocks with traditional high-energy (200- to 360-J) monophasic AEDs.

Methods and Results—AEDs were prospectively randomized according to defibrillation waveform on a daily basis in 4 emergency medical services systems. Defibrillation efficacy, survival to hospital admission and discharge, return of spontaneous circulation, and neurological status at discharge (cerebral performance category) were compared. Of 338 patients with out-of-hospital cardiac arrest, 115 had a cardiac etiology, presented with ventricular fibrillation, and were shocked with an AED. The time from the emergency call to the first shock was 8.9±3.0 (mean±SD) minutes.

Conclusions—The 150-J biphasic waveform defibrillated at higher rates, resulting in more patients who achieved a return of spontaneous circulation. Although survival rates to hospital admission and discharge did not differ, discharged patients who had been resuscitated with biphasic shocks were more likely to have good cerebral performance. (***Circulation.*** **2000;102:1780-1787.**)

Key Words: defibrillation ■ resuscitation ■ heart arrest ■ heart-arrest device

Sudden cardiac arrest associated with ventricular fibrillation (VF) remains a leading cause of unexpected death in the Western world.[1,2] Rapid-response programs[3,4] with automatic external defibrillators (AEDs) used as part of the "chain of survival"[5] have achieved marked improvements in survival rates in selected localities. The European Resuscitation Council, the American Heart Association, and the International Liaison Committee on Resuscitation have advocated the widespread dissemination of AEDs.[6–8]

The success of widespread AED lifesaving programs depends on the development of therapeutic technology suitable for mass deployment with infrequent individual use. This will require great strides in defibrillator cost, size, and unattended reliability.

Traditional monophasic defibrillators deliver high and escalating energies, from 200 to 360 J. These waveforms and energy levels place fundamental limitations on device cost, weight, and volume reduction.[9]

Biphasic waveforms have replaced monophasic waveforms for implantable defibrillators because of proved advantages in energy requirements, size, and weight.[10–12] The incorporation of low-energy impedance-compensating biphasic truncated exponential (ICBTE) waveforms into external defibrillators facilitates effective and automated application of the therapy to the general patient population. The safety and efficacy of these waveforms have been demonstrated under controlled laboratory and in-hospital conditions,[13–15] and evidence that the use of lower energies and biphasic waveforms offers further benefit by reducing postshock myocardial dysfunction is mounting.[16–23]

Prospective, clinical studies to date have been conducted under highly controlled in-hospital conditions. Out-of-hospital cardiac arrest victims have more varied and longer arrest times. Data from out-of-hospital studies are needed to investigate the new role of low-energy biphasic waveforms in sudden cardiac arrest.[24]

Observational studies on patients with out-of-hospital cardiac arrest have previously demonstrated that a 150-J ICBTE AED terminated long-duration VF at high rates.[25–27] We now present the results of the first prospective, randomized trial that compared a 150-J ICBTE AED with traditional, energy-escalating monophasic AEDs. The objective of this multicenter trial was to assess the effectiveness of the AEDs for victims of cardiac arrest in the out-of-hospital setting.

Received March 3, 2000; revision received May 15, 2000; accepted May 16, 2000.

From Johannes Gutenberg-Universitaet (T.S., B.W.), Mainz, Germany; St Jan Hospital (P.R.M.), Brugge, Belgium; Feuerwehr Hamburg (H.P.), Hamburg, Germany; Helsinki City EMS (M.K.), Helsinki, Finland; Agilent Technologies Heartstream Operation (B.E.G., J.K.R.), Seattle, Wash; Henry Ford Hospital (W.D.W.), Detroit, Mich; University Hospital (L.B.), Antwerp, Belgium; and University of Wales College of Medicine (D.C.), Cardiff, UK.

Correspondence to Benno Wolcke, MD, Clinic of Anaesthesiology, The Johannes Gutenberg-University Medical School, Langenheckstr 1, D-55131 Mainz, Germany. E-mail wolcke@mail.Uni-Mainz.de

Circulation is available at **http://www.circulationaha.org**

TABLE 1. Description of EMS Systems

	Mainz, Germany	Brugge, Belgium	Hamburg, Germany	Helsinki, Finland
Population served	190 000	250 000	1.7 million	550 000
Training level, 1st tier	Paramedic, 2000 h	EMT, 130 h	Paramedic, 2000 h	EMT, 1200 h
Training level, 2nd tier	Anesthesiology residents, ≥3 y clinical experience, 80 h emergency training	Emergency physicians, assisted by emergency department nurses	Physicians, mainly anesthesiologist, 80 h of specialized training	Paramedics, ≥2200 h of training
EMS 1st tier vehicles, participating/total	5/5 emergency ambulances	6/7 emergency ambulances	4/61 emergency ambulances	6/7 ambulances, 0/8 fire engines
EMS 2nd tier vehicles, participating/total	0/1 fast-response vehicle, 1/1 MICU	2/2 MICUs, 0/1 helicopter	0/4 fast-response vehicles, 3/6 MICUs, 0/2 helicopters	0/3 ALS units, 0/1 MICU

ALS indicates advanced life support; EMT, emergency medical technician; MICU, mobile intensive care unit (physician staffed).

Methods

Enrollment

On approval by each local ethics committee, all patients who weighed ≥36 kg, who had a known or suspected cardiac arrest, and who were attended by the emergency medical services (EMS) system during the study period were included. All devices used in the study were CE (European Community)–marked and commercially available in Europe, so informed consent was not required under the circumstances of this study. Arrests witnessed by EMS personnel were excluded because the response time from collapse was not representative of out-of-hospital arrest. Patients with do-not-resuscitate instructions, patients whose arrest resulted from a noncardiac cause such as trauma or drowning, and patients who were not treated with AEDs were also excluded.

Protocol

Patients were prospectively enrolled in 4 EMS systems (Table 1). First responders, whether first or second tier, used either 150-J ICBTE AEDs or 200- to 360-J monophasic AEDs on victims of sudden collapse when defibrillator application was indicated. All consecutive incidents were included in the study in each area until the study was completed. Shocks were delivered with self-adhesive defibrillation pads recommended by the respective equipment manufacturers. Physicians also carried manual defibrillators as backup and to address other electrotherapy and monitoring needs (eg, synchronized cardioversion, external pacing).

If the responder suspected that the patient was in cardiac arrest, then the randomly preselected AED was immediately turned on. The patient was then positioned for cardiopulmonary resuscitation (CPR) and AED use. CPR was typically performed while the defibrillation pads were being attached to the patient. A sequence (200, 200, and 360 J for monophasic or 150,150, and 150 J for biphasic) of up to 3 defibrillation shocks was then delivered. If 3 consecutive shocks failed to defibrillate or if the AED did not advise that a shock be delivered, the local protocols according to European Resuscitation Council guidelines were followed.[28,29]

Randomization

A daily schedule of randomly selected AED types was distributed on a quarterly basis. At the change of crew shifts in the morning, the carrying case of the selected AED type was tagged, clearly indicating which AED had to be used for the entire day. If the AED was being used in a mission at the designated time, then randomization was delayed until immediately after that mission was completed and the AED was returned.

AED Descriptions

The biphasic AEDs (ForeRunner AED; Agilent Technologies Heartstream Operation) delivered 150-J impedance-compensated biphasic waveforms from a 100-μF capacitor. This waveform adjusts the duration of each phase in response to patient impedance measured during each shock, providing the desired total waveform duration, tilt, and energy delivery.[10–15,25]

Monophasic waveforms were delivered by AEDs designed to conform to the defibrillation waveform requirements of AAMI/ANSI Standard DF-2.[30] The monophasic AEDs delivered either monophasic truncated exponential (MTE) or monophasic damped sine (MDS) defibrillation waveforms, depending on the device model in use at each investigational site. MTE AEDs included Heartstart 3000 and Heartstart 911 (Laerdal Medical Corporation). MDS AEDs included Heartstart 2000 (Laerdal Medical Corporation) and LifePak 200 (Physio-Control).

End Points

The primary end point of the study was the percentage of patients with VF as the initial monitored rhythm who were defibrillated in the first series of ≤3 shocks. Secondary end points included defibrillation with ≤2 shocks, first-shock defibrillation, and survival to hospital admission and discharge. Other predetermined observations included return of spontaneous circulation (ROSC), response times, and neurological status at discharge.

Sample Size

The sample size was based on historical data from the investigators, which suggested that 70% of monophasic-waveform patients would be defibrillated within 3 shocks. The detection of a 22% increase or a 28% decrease in the primary end point with 80% power and a significance level of 0.05 would therefore require 48 patients per arm. With the estimation that VF would be the initial monitored rhythm in 40% of the sudden cardiac arrest victims,[31] a total enrollment of 240 was anticipated.

Data Collection

ECG and shock data were obtained from the recording systems within the AEDs. Patient data were collected from the incident reports and follow-up reports. Neurological status was scored according to the Glasgow-Pittsburgh Cerebral Performance Category (CPC) and Overall Performance Category (OPC) by study investigators at each site at patient discharge from the hospital.[32]

Rhythm Definitions

Postshock ECGs were classified by the investigator at each site and reviewed by an independent Data and Safety Monitoring Board (DSMB). VF was defined as a disorganized rhythm with a median peak-to-peak amplitude of ≥100 μV. Any rhythm with an amplitude of <100 μV was defined as asystole. An episode of VF was required to persist ≥5 seconds before transition to a non-VF rhythm. The subsequent recurrence of VF was considered a new episode.

Defibrillation was defined as the termination of VF for ≥5 seconds, without regard to hemodynamic factors.[33] By definition, rhythms that occurred after successful shocks included supraventricular and paced rhythms, ventricular standstill (asystole), bradycardia, and idioventricular rhythms. Non-VF ventricular tachyarrhythmias

TABLE 2. Enrollment Data for Cardiac Arrest Patients Who Presented With VF and Were Treated With an AED

	Biphasic AED	Monophasic AED	*P*
Patients	54	61	...
Age, mean±SD y (range)	67±13 (30–87)	66±14 (37–94)	0.89
Sex, n (%)			0.83
Female	13 /54 (24)	13 /59 (22)	
Male	41 /54 (76)	46 /59 (78)	
Not reported	0	2	
Weight, mean±SD kg (range)	85±24 (55–150)	84±20 (45–150)	0.79
Primary structural heart disease,* n (%)			0.74
Coronary artery disease	36/41 (88)	37/39 (95)	
Primary electrical disease	3/41 (7)	3/39 (8)	
Idiopathic dilated cardiomyopathy	1/41 (2)	1/39 (3)	
Hypertrophic cardiomyopathy	0/41 (0)	0/39 (0)	
Other	1/41 (2)	1/39 (3)	
Not reported	13	22	
Cause of cardiac arrest, n (%)			0.97
Primary cardiac arrest	18/39 (46)	18/36 (50)	
Proved acute myocardial infarction	20/39 (51)	17/36 (47)	
Other	1/39 (3)	1/36 (3)	
Not reported	15	25	
Location, n (%)			0.08
Home	35 (65)	33 (54)	
Public place	19 (35)	23 (38)	
Workplace	0 (0)	5 (8)	
Cardiac arrest witnessed by bystander, n (%)	48 (89)	53 (87)	0.74
Lay person	45 (83)	48 (79)	
Medical professional	3 (6)	5 (8)	
Bystander CPR, n (%)	25 (46)	26 (43)	0.69
Lay person	17 (31)	15 (25)	
Medical professional	5 (9)	10 (16)	
Both lay and medical	3 (6)	1 (2)	
Duration of bystander CPR, median (25th, 75th percentile)			
All patients	0 (0, 6.1)	0 (0, 7.1)	0.99
Bystander CPR patients only	6.3 (5.3, 9.3)	8.2 (6.7, 10.8)	0.07
Responder, n (%)			0.59
Paramedic	45 (83)	53 (87)	
Physician	9 (17)	8 (13)	
AED used, n	ForeRunner, 54	Heartstart 3000, 47 LifePak 200, 7 Heartstart 2000, 6 Heartstart 911, 1	...

*The categories are not mutually exclusive.

were defined as successful defibrillation rhythms if they self-terminated within 30 seconds from shock delivery.

Data and Safety Monitoring

Each case report form was sent independently from the centers to the independent DSMB. Members of the DSMB (D.C., L.B., W.D.W.) reviewed all case reports to ensure patient safety and integrity of the data and selected source data (eg, original ECGs) as deemed necessary to resolve apparent discrepancies, by judgment of the chairman (D.C.). The DSMB conducted a separate analysis of the major study end points. The data were formally analyzed after the accumulation of the first 10% of the data and each successive 25% thereafter, based on the equivalent group sequential test for the primary hypothesis. The board reviewed each case at the conclusion of the study. Discrepancies were discussed until an agreement was reached on all cases.

TABLE 3. Resuscitation of VF Patients With AEDs

	On Treatment			Intention to Treat		
	Monophasic AED	Biphasic AED	*P* (95% CI)	Monophasic AED	Biphasic AED	*P* (95% CI)
Defibrillation efficacy, n (%)						
1 Shock	36/61 (59)	52/54 (96)	<0.0001 (24 to 51)	44/67 (66)	44/48 (92)	0.001 (12 to 40)
≤2 Shocks	39/61 (64)	52/54 (96)	<0.0001 (19 to 45)	47/67 (70)	44/48 (92)	0.005 (8 to 35)
≤3 Shocks	42/61 (69)	53/54 (96)	<0.0001 (17 to 41)	49/67 (73)	46/48 (96)	0.002 (11 to 35)
Patients defibrillated,* n (%)	49/58 (84)	54/54 (100)	0.003 (6 to 23)	57/65 (88)	46/47 (98)	0.05 (1 to 19)
ROSC, n (%)	33/61 (54)	41/54 (76)	0.01 (5 to 39)	35/67 (52)	39/48 (81)	0.001 (13 to 45)
Survival to hospital admission, n (%)	31/61 (51)	33/54 (61)	0.27 (−8 to 28)	31/67 (46)	33/48 (69)	0.02 (5 to 40)
Survival to hospital discharge, n (%)	19/61 (31)	15/54 (28)	0.69 (−20 to 13)	18/67 (27)	16/48 (33)	0.45 (−11 to 24)

*Final defibrillation status was not available for 3 patients treated with backup defibrillators.

Statistical Analysis

Continuous variables are expressed as mean±SD and compared with the use of *t* tests. Ordinal variables (discharge destination, CPC, OPC) were compared by the Kruskal-Wallis rank sums test. Discharge destination was assigned a rank of 1 for home, 2 for rehabilitation facility, and 3 for extended care facility. Proportions were compared by log-likelihood ratio χ^2 tests and include ≈95% CIs of differences. Tests were 2-tailed and were computed with the JMP software application developed by the SAS Institute. A *P* value of ≤0.05 was considered statistically significant.

Results

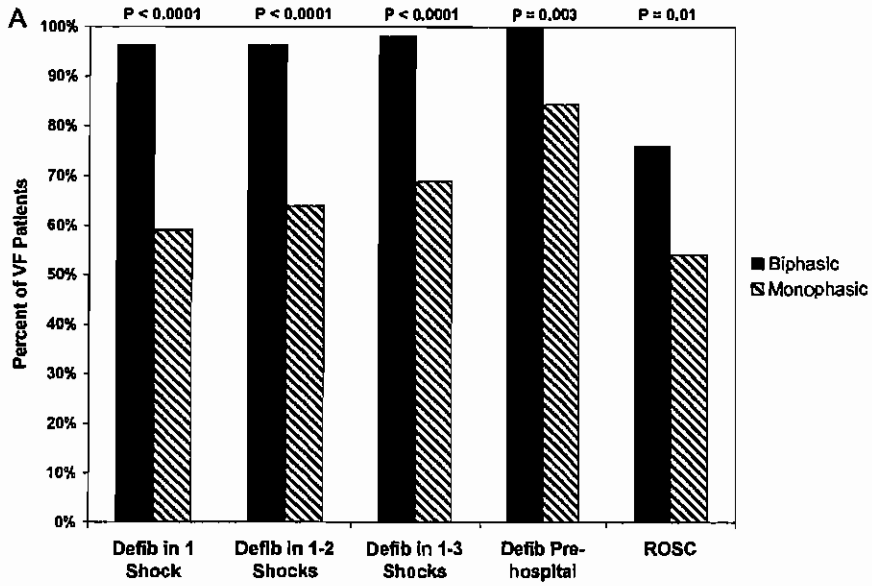
Enrollment

The site in Mainz, Germany, enrolled 197 patients starting from December 1996; the site in Brugge, Belgium, enrolled 69 patients starting from September 1997; the site at Hamburg, Germany, enrolled 37 patients starting from November 1997; and the site at Helsinki, Finland, enrolled 35 patients starting from July 1998. By the conclusion of the study in December 1998, a total of 338 patients had been enrolled.

Of the 338 patients, 246 had an arrest of cardiac etiology that was not witnessed by EMS personnel and were randomized to an AED. There were no statistical differences between the monophasic and biphasic AED patients in terms of age, sex, weight, primary structural heart diseases, cause or location of arrest, bystanders who witnessed the arrest or performed CPR, or the type of responder. Similarly, these factors were not statistically different when only the 115 patients who presented with VF as their initial monitored rhythm were considered (Table 2). The patients who presented with VF are the subjects of interest for this study of AED efficacy. All analyses and discussions from this point on focus exclusively on these patients.

TABLE 4. Outcomes of Patients Resuscitated With AEDs and Discharged From Hospital

	On Treatment			Intention to Treat		
	Monophasic AED	Biphasic AED	*P*	Monophasic AED	Biphasic AED	*P*
Destination of discharge, n (%)			0.21			0.33
Home or prearrest residence	9/19 (47)	10/15 (67)		9/18 (50)	10/16 (63)	
Rehabilitation facility	6/19 (32)	4/15 (27)		5/18 (28)	5/16 (31)	
Extended care facility	4/19 (21)	1/15 (7)		4/18 (22)	1/16 (6)	
Cerebral performance category at time of discharge, n (%)			0.03			0.02
Good	10/19 (53)	13/15 (87)		9/18 (50)	14/16 (88)	
Moderate	4/19 (21)	1/15 (7)		4/18 (22)	1/16 (6)	
Severe	1/19 (5)	1/15 (7)		1/18 (6)	1/16 (6)	
Coma	4/19 (21)	0/15 (0)		4/18 (22)	0/16 (0)	
Overall performance category at time of discharge, n (%)			0.11			0.13
Good	4/19 (21)	5/15 (33)		4/18 (22)	5/16 (31)	
Moderate	9/19 (47)	9/15 (60)		8/18 (44)	10/16 (63)	
Severe	2/19 (11)	1/15 (7)		2/18 (11)	1/16 (6)	
Coma	4/19 (21)	0/15 (0)		4/18 (22)	0/16 (0)	



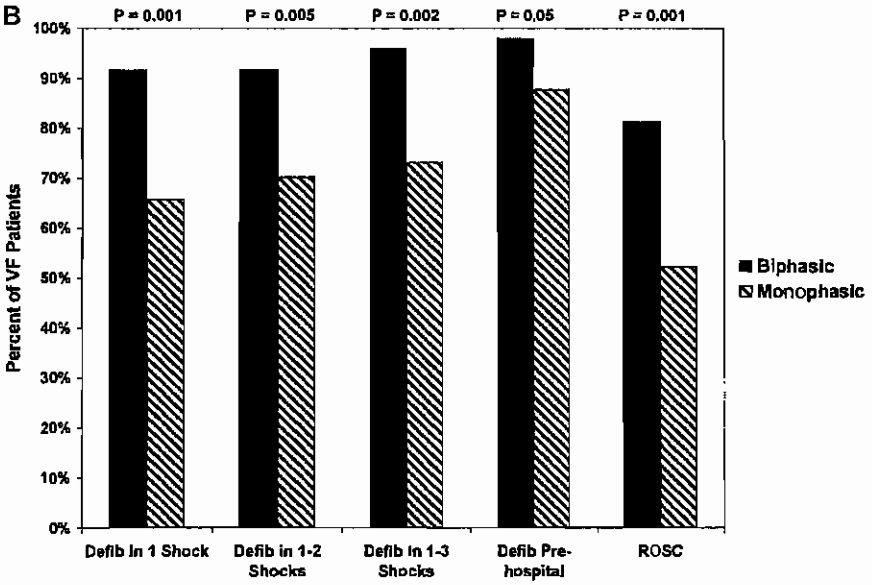


Figure 1. Prehospital defibrillation and resuscitation efficacy for 115 patients who presented with VF. (A) On-treatment analysis. (B) Intention-to-treat analysis.

Response Time

The time from the emergency call to the first shock was 8.9±3.0 minutes overall and did not differ between treatments: 8.7±3.2 for monophasic versus 9.2±2.9 for biphasic (P=0.51).

Resuscitation of VF Patients

The defibrillation efficacy of the 150-J biphasic waveform was superior to that of the 200- to 360-J monophasic waveforms (Table 3, Figure 1). Four patients in the monophasic group were not treated with the AED due to low-amplitude VF not being detected by the AED. For the primary end point of defibrillation within the first shock series, 53 of 54 (98%) VF patients were defibrillated with 150-J biphasic shocks compared with 42 of 61 (69%) patients defibrillated with 200- to 360-J monophasic shocks (P<0.0001).

More patients were defibrillated with the initial biphasic shock than with the initial monophasic shock (96% compared with 59%, P<0.0001), and ultimately all patients treated with biphasic AEDs were defibrillated while under EMS care, whereas this was not true for those treated with monophasic AEDs or a combination of monophasic AEDs and backup manual monophasic defibrillators (100% compared with 84%, P=0.003).

A higher percentage of patients (76%) achieved ROSC after 150-J biphasic-waveform defibrillation compared with higher-energy monophasic-waveform defibrillation (54%) (Figure 1, P=0.01). Rates of survival to hospital admission and to hospital discharge did not differ between the treatments.

Outcomes of Discharged Patients

Destination of discharge did not differ between the treatments (Figure 2). CPC at hospital discharge favored patients treated with 150-J biphasic shocks (Figure 2). Among survivors to hospital discharge, 87% of patients resuscitated with 150-J

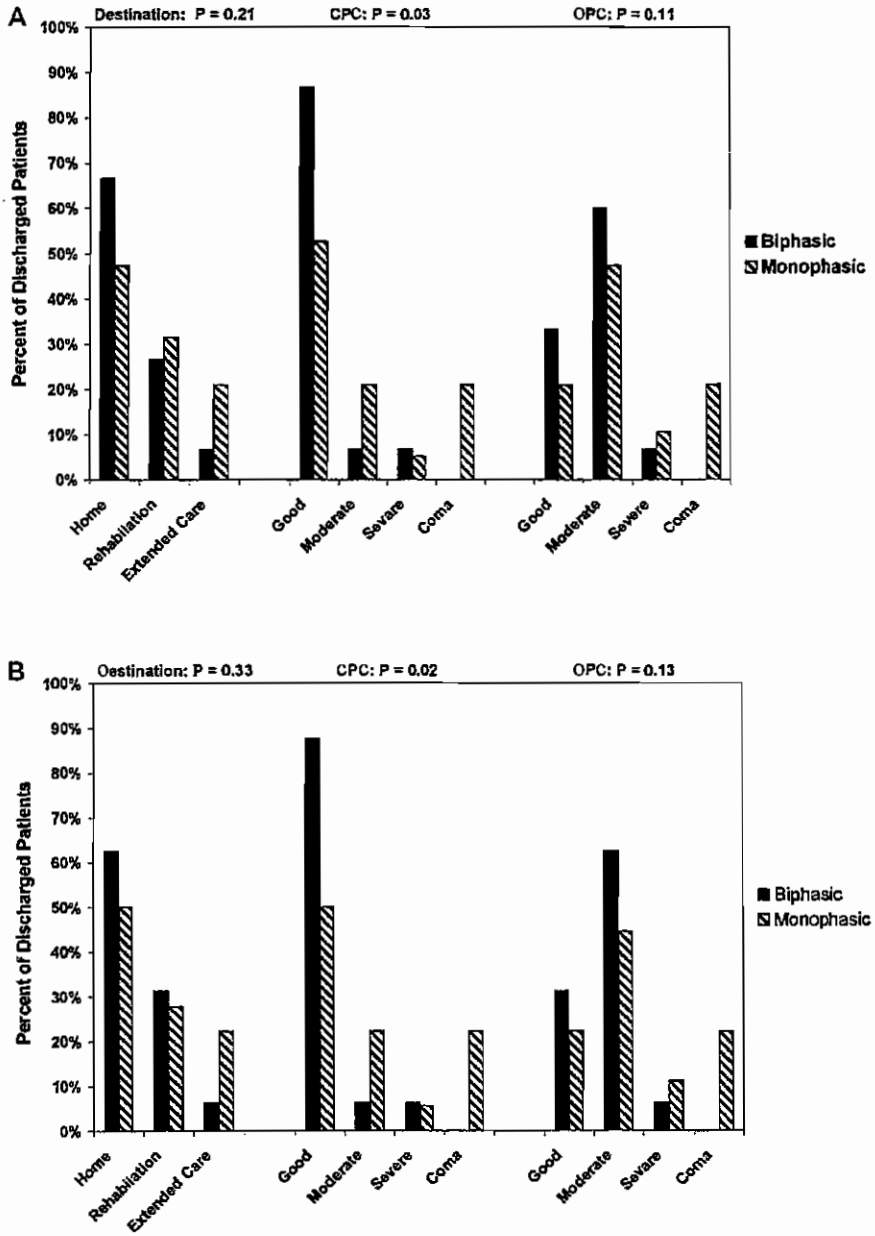


Figure 2. Destination and neurological and functional status at hospital discharge for 34 patients with VF who were discharged alive. (A) On-treatment analysis. (B) Intention-to-treat analysis.

biphasic shocks had good cerebral status compared with only 53% after resuscitation with higher-energy monophasic shocks (P=0.04, 95% CI 6% to 62%). OPC did not differ between the treatments (Figure 2).

Discussion

Improved Defibrillation Efficacy

The high defibrillation efficacy of the particular 150-J impedance-compensating biphasic waveform observed in the present study is consistent with previous reports but strengthens the finding by providing randomized data from out-of-hospital emergency care.[26,27] The concurrent controls substantiate the magnitude of the improvement in defibrillation efficacy obtained with this biphasic waveform compared with conventional escalating-energy monophasic-waveform methods. In addition to the improved defibrillation rates of individual biphasic shocks or shock sequences, it is noted that all patients who received treatment with 150-J biphasic shocks were eventually defibrillated during the resuscitation attempt and without resort to backup manual defibrillators, which was not true for the higher-energy monophasic waveforms. Dynamic control of waveform parameters via impedance compensation with a 150-J biphasic shock provides consistently high defibrillation rates without the need for escalating energies. This finding is key to encouraging the further evolution of small, low cost, and widely available AED technology with dynamic waveform control techniques.

Impact on Patient Survival

Despite a statistically significant increase in ROSC after defibrillation with 150-J biphasic shocks, no differences in survival to admission to or discharge from hospital were

established. The present study was statistically powered to show differences in defibrillation efficacy, not in patient survival. Our objective was to assess the relative performances of the AEDs. The determination of statistical differences in short- or long-term patient survival would require a prohibitively large study to mitigate the uncontrolled variables associated with EMS system influences and postresuscitation treatment.

Impact on Patient Outcome

Although the rate of survival to discharge from hospital did not differ between treatments, among patients who survived to be discharged, those treated with the biphasic waveform were more likely to be in good condition (eg, to have a CPC of "good") than were those treated with monophasic waveforms. Discharge destinations and OPCs were consistent with these findings in favoring biphasic patients, although the differences were not statistically significant. Improved neurological status has previously been associated with shorter overall resuscitation times in the treatment of sudden cardiac arrest victims[34] but not with defibrillation energy or waveform. It is our hypothesis that the superior neurological status observed at hospital discharge after resuscitation with 150-J biphasic defibrillation shocks is associated with shorter time to ROSC and resultant better postresuscitation cardiac output during the critical interval immediately after severe ischemic compromise. This hypothesis is supported by the significantly higher rate of ROSC obtained with the biphasic waveform. Furthermore, studies in animals have demonstrated that both defibrillation waveform and energy dose affect postresuscitation myocardial function.[18–23] In these studies, both stroke volume and ejection fraction were significantly depressed for many hours after high-energy monophasic shocks to a much greater degree than after 150-J biphasic shocks. Increasing the number of neurologically intact survivors from out-of-hospital sudden cardiac arrest may directly depend on reducing the compromise of cardiac output associated with high-energy defibrillation.

Study Limitations

Randomization of treatment was conducted on the basis of date rather than on the basis of patient and responders were not blinded to the AED type. The AEDs were all commercially available devices, with each of the 5 models differing in its user interface, analysis algorithm, and therapy waveform. The EMS personnel were familiar with the monophasic devices at the outset of the study, whereas the biphasic devices were newly introduced. These choices were made due to practical and ethical considerations. The urgency of immediate intervention precluded concealment. Training, budget, and regulatory constraints precluded the development and use of novel devices solely for the purposes of the study. Our method is, however, superior to the alternative day technique used in other recent resuscitation trials.[35,36]

In designing our nonblinded study, we considered that unintended randomization errors might favor one mode of defibrillation or the other. Bias in selection of the type of defibrillator used would then be difficult to disprove. It was for this reason that an intention-to-treat analysis was included in the protocol and in this report.

The control AEDs used in the present study deployed either MTE (79%) or MDS (21%) shocks, reflecting the distribution of AED types in service at the time of the study. There is some evidence that MTE waveforms have lower defibrillation rates than MDS waveforms.[37] Thus, the observed defibrillation efficacy of the control group may depend in part on the distribution of monophasic AED types. However, a subset analysis that compared the efficacy of each waveform substantiates the benefits of the biphasic waveform over each of the monophasic waveforms (P. Martens, MD, unpublished data, 2000), as does a comparison of this biphasic AED with only MDS AEDs in a similar smaller study (K.-G. Kanz, unpublished data, 1999).

In summary, the results of the present study show that an appropriately dosed low-energy impedance-compensating biphasic-waveform strategy results in superior defibrillation performance in comparison with escalating, high-energy monophasic shocks in out-of hospital cardiac arrest. Moreover, the 150-J biphasic-waveform AED results in a higher rate of ROSC and better neurological status at the time of hospital discharge.

Acknowledgments

This work was supported by a grant from Agilent Technologies Heartstream Operation. B. Gliner and Dr Russell were employees of and Dr Weaver was an advisor to Heartstream during the study. Prof Chamberlain's Honorary Chair in Cardiff is supported (expenses only) by a grant from the Laerdal Foundation.

Appendix

Investigators and participating institutions are given in the order of the number of patients enrolled:

Thomas Sehneider, MD; Benno Wolcke, MD; Gerhard Tauscher, Study Coordinator; Heinke Teichmann, Clinic of Anaesthesiology, The Johannes Gutenberg-University Medical School, Mainz, Germany; Patrick R. Martens, MD; Francis Cooman, MD; Martin De Meyer, RN, Emergency Medical Department, St Jan Hospital, Brugge, Belgium; Luc Charles, Project Coordinator, Fire Brigade, Brugge, Belgium; Hans-Richard Paschen, MD, EMS Medical Director, Hamburg Fire Brigade, Hamburg, Germany; and Markku Kuisma, MD, Janne Aaltonen, MD, Jouni Pousi, RN, Helsinki City EMS, Helsinki, Finland.

References

1. Emergency Cardiac Care Committee and Subcommittees, American Heart Association. Guidelines for cardiopulmonary resuscitation and emergency cardiac care, part I: introduction. *JAMA*. 1992;268:2172–2183.
2. Myerburg RJ, Kessler KM, Castellanos A. Sudden cardiac death: structure, function, and time-dependence of risk. Circulation 1992; 85(suppl I):I-2–I-10.
3. White RD. External defibrillation: the need for uniformity in analyzing and reporting results. *Ann Emerg Med*. 1998;32:234–236.
4. Eisenberg MS, Horwood BT, Cummins RO, et al. Cardiac arrest and resuscitation: a tale of 29 cities. *Ann Emerg Med*. 1990;19:179–186.
5. Cummins RO, Ornato JP, Thies WH, et al. Improving survival from sudden cardiac arrest: the "chain of survival" concept: a statement for health professionals from the Advanced Cardiac Life Support Subcommittee and the Emergency Cardiac Care Committee, American Heart Association. *Circulation*. 1991;83:1832–1847.
6. Weisfeldt ML, Kerber RE, McGoldrick RP, et al. American Heart Association Report on the Public Access Defibrillation Conference, December 8–10, 1994: Automatic External Defibrillation Task Force. *Circulation*. 1995;92:2740–2747.

7. Emergency Cardiac Care Committee and Subcommittees, American Heart Association. Guidelines for cardiopulmonary resuscitation and emergency cardiac care, part III: adult advanced cardiac life support. *JAMA*. 1992;2199:2172–2241.
8. Kloeck W, Cummins RO, Chamberlain D, et al. Early defibrillation. An advisory statement by the Advanced Life Support Working Group of the International Liaison Committee on Resuscitation. *Circulation*. 1997;95: 2183–2184.
9. Gliner BE, Jorgenson DB, Poole JE, et al. Treatment of out-of-hospital cardiac arrest with a low-energy impedance-compensating biphasic waveform automatic external defibrillator. *Biomed Instrum Technol*. 1998;32:631–644.
10. Winkle RA, Mead RH, Ruder MA, et al. Improved low energy defibrillation efficacy in man with the use of a biphasic truncated exponential waveform. *Am Heart J*. 1989;117:122–127.
11. Bardy GH, Ivey TD, Allen MD, et al. A prospective, randomized evaluation of biphasic vs monophasic waveform pulses on defibrillation efficacy in humans. *J Am Coll Cardiol*. 1989;14:728–733.
12. Swartz JF, Fletcher RD, Karasik PE. Optimization of biphasic waveforms for human nonthoracotomy defibrillation. *Circulation*. 1993;33: 2646–2654.
13. Gliner BE, Lyster TE, Dillon SM, et al. Transthoracic defibrillation of swine with monophasic and biphasic waveforms. *Circulation*. 1995;92: 1634–1643.
14. Bardy GH, Gliner BE, Kudenchuk PJ, et al. Truncated biphasic pulses for transthoracic defibrillation. *Circulation*. 1995;91:1768–1774.
15. Bardy GH, Marchlinski FE, Sharma AD, et al. Multicenter comparison of truncated biphasic shocks and standard damped sine wave monophasic shocks for transthoracic ventricular defibrillation. *Circulation*. 1996;94: 2507–2514.
16. Crampton R. Accepted, controversial, and speculative aspects of ventricular defibrillation. *Prog Cardiovasc Dis*. 1980;23:167–186.
17. Weaver WD, Cobb LA, Copass MK, et al. Ventricular defibrillation—a comparative trial using 175-J and 320-J shocks. *N Engl J Med*. 1982; 307:1101–1106.
18. Tokano T, Bach D, Chang J, et al. Effect of ventricular shock strength on cardiac hemodynamics. *J Cardiovasc Electrophysiol*. 1998;9:791–797.
19. Tang W, Weil MH, Sun S, et al. Defibrillation with low-energy biphasic waveform reduces the severity of post-resuscitation myocardial dysfunction after prolonged cardiac arrest. *J Am Coll Cardiol*. 1999;34: 815–822.
20. Xie J, Weil MH, Sun S, et al. High-energy defibrillation increases the severity of postresuscitation myocardial dysfunction. *Circulation*. 1997;96:683–688.
21. Osswald S, Trouton TG, O'Nunain SS, et al. Relation between shock-related myocardial injury and defibrillation efficacy of monophasic and biphasic shocks in a canine model. *Circulation*. 1994;90:2501–2509.
22. Jones JL, Jones RE. Decreased defibrillator-induced dysfunction with biphasic rectangular waveforms. *Am J Physiol*. 1984;247:H792–H796.
23. Jones JL, Jones RE, Balasky G. Improved defibrillator waveform safety factor with biphasic waveforms. *Am J Physiol*. 1983;245:H60–H65.
24. Kerber RE, Becker LB, Bourland JD, et al. Automatic external defibrillators for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety. A statement for health care professionals from the American Heart Association Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. *Circulation*. 1997;95:1677–1682.
25. Gliner BE, Jorgenson DB, Poole JE, et al. Treatment of out-of-hospital cardiac arrest with a low-energy impedance-compensating biphasic waveform automatic external defibrillator. *Biomed Instrum Technol*. 1998;32:631–644.
26. Poole JE, White RD, Kanz K-G, et al. Low-energy impedance-compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out-of-hospital cardiac arrest. *J Cardiovasc Electrophysiol*. 1997;8:1373–1385.
27. White RD. Early out-of-hospital experience with an impedance-compensating low-energy biphasic waveform automatic external defibrillator. *J Intervent Cardiol Electrophysiol*. 1997;1:203–208.
28. Handley AJ, Bahr J, Baskett P, et al. The 1998 European Resuscitation Council guidelines for adult single rescuer basic life support: a statement from the Working Group on Basic Life Support, and approved by the Executive Committee. *Resuscitation*. 1998;37:67–80.
29. Robertson C, Steen P, Adgey J, et al. The 1998 European Resuscitation Council guidelines for adult advanced life support: a statement from the Working Group on Advanced Life Support, and approved by the Executive Committee. *Resuscitation*. 1998;37:81–90.
30. Association for the Advancement of Medical Instrumentation. *Cardiac Defibrillator Devices: ANSI/AAMI DF2-1996*. Arlington, Va: Association for the Advancement of Medical Instrumentation; 1996.
31. Schneider T, Mauer D, Diehl P, et al. Early defibrillation by emergency physicians or emergency medical technicians? A controlled, prospective multi-centre study. *Resuscitation*. 1994;27:197–206.
32. Cummins RO, Chamberlain DA, Abramson NS, et al. Recommended guidelines for uniform reporting of data from out-of-hospital cardiac arrest: the Utstein style: a statement for health professionals from a Task Force of the American Heart Association, the European Resuscitation Council, the Heart and Stroke Foundation of Canada, and the Australian Resuscitation Council. *Circulation*. 1991;84:960–975.
33. Gliner BE, White RD. Electrocardiographic evaluation of defibrillation shocks delivered to out-of-hospital sudden cardiac arrest patients. *Resuscitation*. 1999;41:133–144.
34. Weaver WD, Copass MK, Bufi D, et al. Improved neurologic recovery and survival after early defibrillation. *Circulation*. 1984;69:943–948.
35. Plaisance P, Lurie KG, Vicaut E, et al. A comparison of standard cardiopulmonary resuscitation and active compression-decompression resuscitation for out-of-hospital cardiac arrest: French Active Compression-Decompression Cardiopulmonary Resuscitation Study Group. *N Engl J Med*. 1999;341:569–575.
36. Gueugniaud PY, Mols P, Goldstein P, et al. A comparison of repeated high doses and repeated standard doses of epinephrine for cardiac arrest outside the hospital: European Epinephrine Study Group. *N Engl J Med*. 1998;339:1595–1601.
37. Behr JC, Hartley LL, York DK, et al. Truncated exponential versus damped sinusoidal waveform shocks for transthoracic defibrillation. *Am J Cardiol*. 1996;78:1242–1245.

ELSEVIER

Resuscitation 55 (2002) 17–23

RESUSCITATION

www.elsevier.com/locate/resuscitation

Refibrillation, resuscitation and survival in out-of-hospital sudden cardiac arrest victims treated with biphasic automated external defibrillators

Roger D. White [a,b,c,*], James K. Russell [d]

[a] *Department of Anesthesiology, Mayo Clinic, 200 First Street SW, Rochester, MN 55905, USA*
[b] *Mayo Clinic Gold Cross Ambulance Service, Rochester, MN 55905, USA*
[c] *City of Rochester Early Defibrillation Program, Rochester, MN 55905, USA*
[d] *Philips Medical Systems, 2301 Fifth Avenue, Suite 200, Seattle, WA 98121, USA*

Received 14 April 2002; received in revised form 29 May 2002; accepted 29 May 2002

Abstract

Primary objective: Defibrillation is essential for victims of sudden cardiac arrest (SCA) with ventricular fibrillation (VF), yet it does not terminate the underlying causes of VF. Prior to more definitive interventions, these same causes may result in recurrence of VF following defibrillation (refibrillation). The incidence and course of refibrillation, and its relation to patient outcomes, has not been previously described in the context of treatment of out-of-hospital SCA with biphasic waveform automated external defibrillators (AEDs). *Materials and methods:* ECGs were recovered from all shocks delivered with biphasic AEDs by Basic Life Support (BLS) first responders, primarily police, in witnessed cardiac arrests occurring from December 1996 to December 2001 in the Rochester, MN public service area. Only events prior to administration of cardio-active medications were considered. Frequency and time to occurrence of refibrillation were compared in patients in relation to the progress of their resuscitation and survival. *Results and conclusions:* One hundred and sixteen of 128 shocks delivered under BLS care to 49 patients with witnessed cardiac arrests presenting with VF terminated VF. Most patients (61%) refibrillated while under BLS care, many (35%) more than once. Occurrence of and time to refibrillation were unrelated to achievement of return of spontaneous circulation (ROSC) under BLS care (BLS ROSC), to survival to hospital discharge and to neurologically intact survival.

Keywords: Automated external defibrillator (AED); Outcome; Return of spontaneous circulation; Sudden cardiac death; Ventricular fibrillation

Resumo

Objectivo primário: A desfibrilhação é essencial para vítimas de paragem cardíaca súbita (PCS) com fibrilhação ventricular, no entanto a desfibrilação não determina as causas subjacente da fibrilhação. Enquanto não for feita intervenção mais definitivas, as causas de PCS podem provoar recorrência da fibrilhação ventricular após desfibrilhação (ou refibrilhação). A incidência e curso da refibrilhação, bem como a sua relação com o prognóstico dos doentes, nao foi ainda descrita no contexto de tratamento de paragem cardíaca súbita extra-hospitalar com desfibrilhadores automáticos externos (DAE) de onda bifásica. *Materiais e métodos:* Foram recuperados os ECGs de todos os choques dados com DAEs bifásicos por socorristas que primeiro realizaram suporte básico de vida (SBV), principalmente polícias, em paragens cardíacas testemunhadas, ocorridas entre Dezembro 1996 a Dezembro 2001 na área de serviço público de Rochester, MN. Só foram considerados episódios anteriores á administração de medicamentos cardioactivos. A frequência e o tempo até à refibrilhação foram comparados com o curso da reanimação e com a sobrevida. *Resultados e conclusões:* 116 de 128 choques administrados enquanto decorria SBV pararam a fibrilação em 49 doentes com paragem cardíaca testemunhada. A maioria dos doentes (61%) refibrilhou enquanto decorria SBV, muitos (35%) mais que uma vez.

* Corresponding author. Tel.: +1-507-255-2435; fax: +1-507-255-6463
E-mail address: white.roger@mayo.edu (R.D. White).

0300-9572/02/$ - see front matter
PII: S0300-9572(02)00194-6

A ocorrência e o tempo para refibrilhação não se relacionaram com o retorno da circulação espontânea durante o SBV, com a sobrevida á alta hospitalar e á sobrevivência sem sequelas neurológicas © 2002 Elsevier Science Ireland Ltd. All rights reserved.

Palavras chave: Desfibrilador automático externo (DAE); Prógnóstico; Retorno de circulação espontânea; Paragem cardíaca súbita; Fibrilação ventricular

Resumen

Objetivo primario: La desfibrilación es escencial para las víctimas paro cardíaco súbito (SCA) con fibrilación ventricular(VF), aunque no termine con las causas subyacentes de la VF. Antes de realizar intervenciones más definitivas, estas mismas causas pueden resultar en la recurrencia de la VF después de la desfibrilación (o refibrilación). La incidencia y curso de la refibrilación, y su relación con los resultados de los pacientes, no ha sido descrita previamente en el contexto de tratamiento del SCA extrahospitalario con desfibriladores automáticos externos (AEDs) con ondas bifásicas. *Materiales y métodos*: Se recuperaron los electrocardiogramas de todas las descargas entregadas con AEDs bifásicos en paros cardíacos presenciados, ocurridos entre Diciembre 1996 y Diciembre 2001, atendidos por reanimadores del área se servicio de salud pública MN en Rochester, entrenados en Soporte Vital Básico (BLS), primariamente policías. Solamente se consideraron los eventos previos a la administración de medicamentos vasoactivos. La frecuencia y tiempo de ocurrencia de la refibrilación fueron comparadas en los pacientes en relación con el progreso de su resucitación y sobrevida. *Resultados y conclusiones*: ciento dieciséis de 128 descargas entregadas con BLS a 49 pacientes con paro cardíaco presenciado que presentaban VF terminaron con la VF. La mayoría de los pacientes (61%) refibriló mieutras se encontraba bajo cuidados de BLS, muchos (35%) refibrilaron mas de una vez. La ocurrencia de refibrilación y el tiempo a ella, no se relacionaron con el logro de retorno a circulación espontánea (ROSC) mientras están bajo cuidados de BLS (BLS ROSC), a la sobrevida al alta hospitalaria ni con la sobrevida neurológicamente intacto. © 2002 Elsevier Science Ireland Ltd. All rights reserved.

Palabras clave: Desfibrilador automático externo (DEA); Resultado; Retorno a circulación espontánea; Muerte súbita de origen cardíaco; Fibrilación ventricular

1. Introduction

Sudden cardiac arrest (SCA) victims in ventricular fibrillation (VF) must be defibrillated early to increase the likelihood of survival. While defibrillation may enable return of spontaneous circulation (ROSC), it does not remove the underlying cause of the VF episode, and until more definitive therapy can be applied, patients are at risk of recurrent VF (refibrillation). Refibrillation has been found to be frequent during out-of-hospital resuscitation with monophasic defibrillators [1,2]. The present study examines the incidence and course of refibrillation of SCA patients while under the care of Basic Life Support (BLS) first responders using fixed-energy impedance-compensating biphasic automated external defibrillators (AEDs) in relation to patient outcomes.

2. Materials and methods

The Rochester, MN early defibrillation program has been described in detail [3–6]. Beginning in December 1996 ForeRunner AEDs (Philips Medical Systems, Seattle, WA), which use an impedance-compensated biphasic truncated exponential waveform with a fixed 150 J energy protocol, have been deployed primarily in police vehicles, with additional devices deployed originally in ambulances and later in fire vehicles.

All adult atraumatic witnessed VF cardiac arrests of known or presumed cardiac etiology occurring from December 1996 to December 2001 in Rochester, MN and the surrounding public service area were analyzed. ECGs were recovered from the AEDs. Data cards were synchronized to the Public Safety Communications dispatch clock on download to the CodeRunner application (Philips Medical Systems), which was used for rhythm review and annotation of times from the voice and dispatch records.

Data were collected during an on-going study of patient outcome following out-of-hospital cardiac arrest, under approval of the Institutional Review Board.

The rhythm at 5 s following each shock was characterized as VF (disorganized, median peak-to-peak amplitude > 100 uV), asystole (amplitude < 100 uV) or organized. Organized rhythms were defined by the presence of one or more QRS complexes (regardless of width or morphology) in the 5-s post-shock period (Fig. 1). The rhythm preceding each shock was classified as VF or not, by the same criteria, to assure consistency with our analysis. The time from each shock to the first occurrence of a rhythm satisfying this definition of VF was measured. Classification of post-shock rhythms was by consensus following independent review by the authors.

Neurological status at hospital discharge utilized Overall Performance Category (OPC) [7].

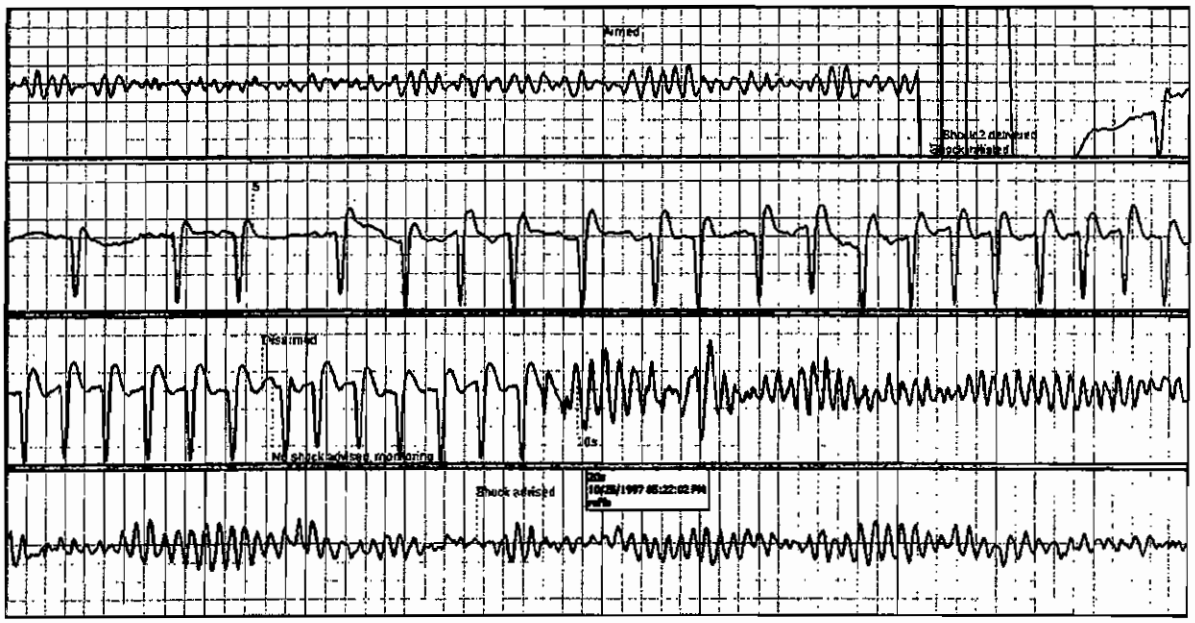


Fig. 1. Refibrillation following restoration of an organized rhythm (atrial fibrillation) by a preceding shock. The recurrent episode began 20 s after the preceding shock, and it was terminated by another shock.

2.1. Statistical analysis

Binomial outcomes were analyzed with the Fisher-Freeman-Halton exact test, Gaussian continuous data (checked with the Shapiro–Wilks W test) with Analysis of Variance (ANOVA), ordinal data and non-Gaussian continuous data with non-parametric Kruskal–Wallis ANOVA. Durations of post-shock rhythms were censored data because of hand-off of patients to ALS care, and underwent Kaplan–Meier analysis, assessed with the Cox–Mantel test. Dependence of binomial outcomes on continuous predictors was assessed with logistic regression. All tests were two-tailed. Tests on continuous data were performed with STATISTICA, version 6.0 (StatSoft, Tulsa, OK). Tests on binomial data were analyzed with STATXACT, version 5.0 (Cytel, Cambridge, MA), which was also used to calculate exact binomial confidence limits using the Blyth–Still–Casella method.

3. Results

Forty-nine patients experienced witnessed cardiac arrest and had a presenting rhythm of VF on attachment of the AED (Table 1). Age (mean ± S.D.) was 64 ± 14 years, and 40 (80%) were males. Twenty-two patients (44%) received bystander cardiopulmonary resuscitation. Call-to-first shock time averaged 6.1 ± 2.0 min. For survivors this time interval was 5.5 min, and for non-survivors it was 6.5 min. First shock efficacy was high: (92%) with the first shock. Most patients (63%) received > one shock, either due to a failed conversion or more often due to refibrillation. All patients were defibrillated at least once.

Of 128 total shocks delivered by BLS first responders, 116 (91%) converted the patient to a non-VF rhythm. After ALS arrival and administration of a cardio-active drug (epinephrine (adrenaline) or lidocaine), an additional 80 shocks were administered. Continued use of the AED or transfer to an ALS defibrillator was at the discretion of ALS personnel. Excluded from this analysis are shocks which interacted with ALS interventions, including drug administration, and the 12 failed shocks, since by definition refibrillation could not occur in this setting. The most common rhythm at 5 s following successful shocks was asystole (first shocks: 32/49 (65%), all BLS shocks: 61/116 (53%). Most (29/49 61%) patients refibrillated at some point while still under BLS care, and many (35%) refibrillated more than once (median 1 refibrillation, range 0–9).

Nineteen patients (39%) achieved ROSC with a combination of cardio-pulmonary resuscitation (CPR) and AED shocks, prior to any ALS interventions (BLS ROSC). An additional 18 patients (37%) first achieved ROSC after ALS interventions (ALS ROSC). Thus, 37 patients (76%) achieved sustained on-scene ROSC. Thirty-two patients (65%) survived to hospital admission, 22 (45%) to hospital discharge, and 20 (41%) were discharged neurologically intact (OPC 1) (Table 1).

BLS ROSC patients were very likely to survive to hospital discharge (95%), while patients who achieved ROSC only later in the resuscitation attempt fared more poorly (22% survival) (Table 1). BLS ROSC predicted

Table 1
Characteristics of response and resuscitation

Resuscitation parameter	All patients	BLS ROSC patients	ALS ROSC patients	No ROSC patients	P-value (BLS vs. ALS vs. no ROSC)
n	49	19	18	12	–
Call-to-shock time (min)[a]	6.1±2.0	5.3±1.5	7.2±1.7	5.7±2.3	0.007
First shock efficacy[b]	45/49 92[81–97]%	19/19 100[84–100]%	15/18 83[59–95]%	10/12 83[55–97]%	0.13
Multiple BLS shocks[b]	31/49 63[48–76]%	11/19 58[34–78]%	11/18 61[37–83]%	9/12 75[55–94]%	0.70
Total BLS shocks	128	46	48	34	–
Successful conversions[b]	116/128 91[84–95]%	46/46 100[93–100]%	40/48 83[71–92]%	30/34 88[73–96]%	0.008
Post-conversion rhythm organized: initial shock[b]	17/49 35[22–48]%	8/19 42[22–66]%	5/18 28[12–53]%	4/12 33[12–65]%	0.14
Post-conversion rhythm organized: all BLS shocks[b]	55/116 47[38–57]%	32/46 70[55–82]%	11/40 28[16–43]%	12/30 40[24–59]%	0.0003
Any BLS refibrillation[b]	29/49 59[44–73]%	11/19 58[34–78]%	10/18 56[33–76]%	8/12 67[35–88]%	0.87
Multiple BLS refibrillattions[b]	17/49 35[22–48]%	7/19 37[16–62]%	6/18 33[16–59]%	4/12 33[12–65]%	1.00
Number of BLS refibrillations[c]	1 [0–2]	1 [0–2]	1 [0–2]	1 [0–2]	0.98
Hospital admission[b]	32/49 65[52–78]%	19/19 100[84–100]%	16/18 89[68–98]%	0/12 0[0–24]%	<0.0001
Hospital discharge[b]	22/49 45[31–60]%	18/19 95[76–100]%	4/18 22[8–47]%	0/12 0[0–24]%	<0.0001
Neurologically intact survival (OPC = 1)[b]	20/49 41[27–56]%	17/19 89[68–98]%	3/18 17[5–41]%	0/12 0[0–24]%	<0.0001

[a] Times are given as mean±S.D.
[b] Percentages are given with [95% confidence limits].
[c] Numbers are given as median [interquartile range].

outcome, and as well predicted a better outcome (Table 2). No patient who failed to achieve on-scene ROSC survived. Shorter call-to-1st shock times were characteristic of patients who achieved BLS ROSC (5.3±1.5 vs. 6.6±2.1 min for BLS ROSC and non-BLS ROSC patients, respectively; logistic regression $P = 0.02$). The 19 BLS ROSC patients received a total of 46 shocks from BLS providers, all of which terminated VF. Rates of successful conversion were high also for ALS ROSC patients (83%) and patients with no ROSC (88%), though lower than for BLS ROSC patients (Table 1).

3.1. Post-shock rhythms

At 5 s following initial successful shocks, rhythms were similar for BLS ROSC, ALS ROSC and non-ROSC patients; 42% of the BLS ROSC patients were in an organized rhythm, compared with 28% for ALS ROSC and 33% for non-ROSC patients. However, considering all successful shocks, substantially more shocks to BLS ROSC patients resulted in organized rhythms (70%) than did shocks for ALS ROSC (28%) or non-ROSC patients (40%, $P = 0.0003$, Table 1).

3.2. Refibrillation, BLS ROSC and survival

Refibrillation was no more or less likely to occur among patients who did or did not achieve BLS ROSC (Fig. 2). Refibrillation was not a good predictor of BLS ROSC, survival to hospital discharge, or neurologically intact survival (Table 3). Furthermore, the number of times a patient refibrillated while in BLS care was similar regardless of their outcome (median 1, interquartile range 0–2 for BLS ROSC, ALS ROSC, and non-ROSC patients, as well as for patients who survived to discharge or not, and who survived neurologically intact or not). Logistic regression of BLS ROSC, survival to hospital discharge, and neurologically intact survival on number of refibrillations confirmed no relationship ($P = 0.85$, 0.57, 0.79, respectively). Although the median time interval between shock delivery and refibrillation was slightly longer for

Table 2
Utility of BLS ROSC and ALS ROSC for predicting outcomes

	Survival to hospital discharge		Neurologically intact survival	
	BLS ROSC	ALS ROSC	BLS ROSC	ALS ROSC
Percent surviving	18/19 (95%)	4/18 (22%)	17/19 (89%)	3/18 (17%)
Sensitivity (%)	82	18	85	15
Specificity (%)	96	48	93	48
Positive predictive accuracy (%)	95	22	89	17
Negative predictive accuracy (%)	87	42	90	45

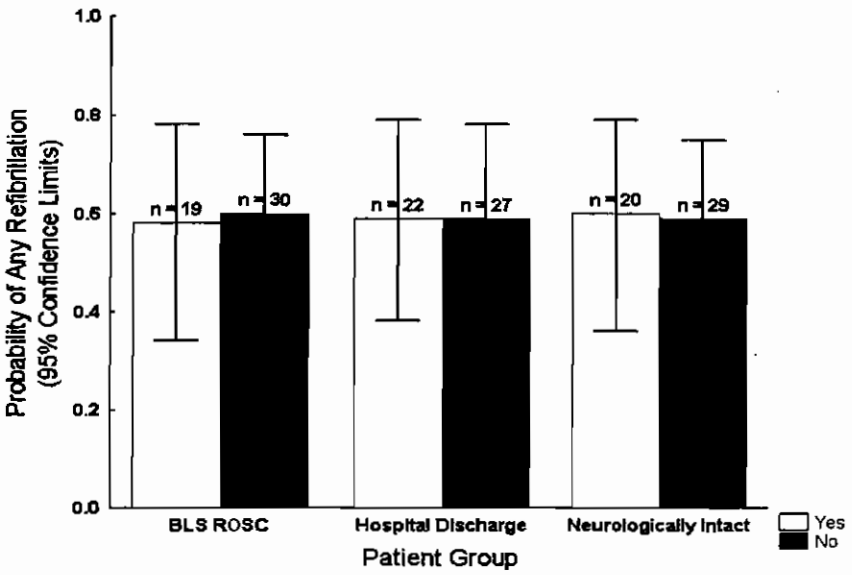


Fig. 2. Probability of refibrillation while patients were attended by BLS personnel, (n = number of patients in each group).

patients who achieved BLS ROSC, for survivors and for neurologically intact survivors (Fig. 3), the differences were not statistically significant when data truncation due to hand-off to ALS providers was taken into account (Kaplan–Meier analysis: Cox–Mantel test statistic = 1.31, $P = 0.19$, 1.73; 0.08, 1.47; 0.14, respectively). Time to refibrillation (or duration of non-fibrillating rhythm) did not differ depending on whether the post-shock rhythm at 5 s was organized (median 27 s, seconds) or asystolic (29 s, Cox–Mantel test statistic = 0.32, $P = 0.75$). Time to refibrillation exhibited a wide range when analyzed by shock parity, with no overall pattern (Kruskal–Wallis ANOVA, $P = 1.0$.

BLS ROSC (100%) and ALS ROSC (89%) were strongly associated with survival to hospital admission, but only BLS ROSC was strongly associated with survival to hospital discharge (95%) and neurologically intact survival (89%) (Table 1).

4. Discussion

Defibrillation is essential therapy for SCA victims in VF. It interrupts the fibrillatory rhythm, giving the heart the opportunity to establish a perfusing rhythm (ROSC) and ultimately survival of the arrest. Yet, defibrillation alone cannot assure survival; outcome ultimately depends on an array of variables, among them the underlying cardiac disorders that provoked the VF cardiac arrest. The most frequent cause is ischemic heart disease; since this underlying myocardial substrate is still present after defibrillation, refibrillation is an ever-present possibility. This risk prevails for most other causes of VF arrest as well.

In this study, no relation was found between occurrence of refibrillation, frequency of refibrillation or time to refibrillation and patient outcome. Asystole is the prevailing initial post-shock rhythm for all patients at 5 s post-shock. A tendency for post-shock asystole to progress to organized rhythms has been noted for the biphasic AEDs in this program when compared with monophasic AEDs used earlier in the program [8].

There is limited comparative data available on refibrillation in out-of-hospital cardiac arrest because many studies [9,10] report only total numbers of shocks, and do not distinguish between shocks following failures to convert (refractory fibrillation) and shocks following recurrence of fibrillation (refibrillation). This presents difficulties when comparing the efficacy of different defibrillation waveforms. It is necessary to define what is

Table 3
Utility of refibrillation for predicting outcomes

	BLS ROSC	Survival to hospital discharge	Neurologically intact survival
Sensitivity (%)	58	59	41
Specificity (%)	38	38	60
Positive predictive accuracy (%)	38	45	60
Negative predictive accuracy (%)	58	53	41

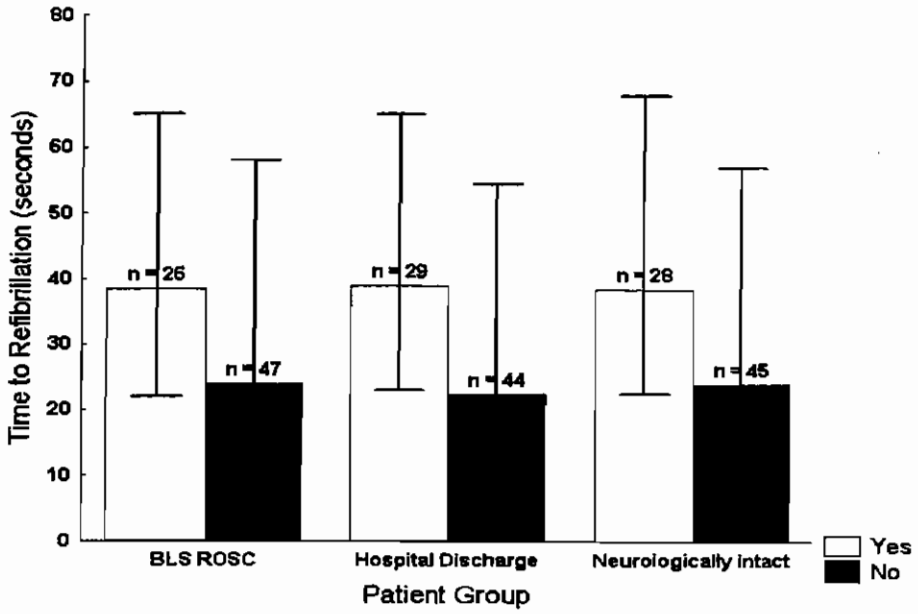


Fig. 3. Time to refibrillation. The bars depict the median time and the vertical lines represent the interquartile range (n = sample size in each group).

meant by a successful shock and to differentiate persistent from recurrent VF. We have described the electrophysiologic rationale for observing the 5-s post-shock and others also have used this definition in characterizing shock success [1,8,11–14]. Refibrillation is common in out-of-hospital VF cardiac arrest, as has been established in studies using monophasic defibrillation [1,2], and as observed here in a program using biphasic waveform defibrillators. Weaver et al. [1] noted refibrillation in 68% of their patients and Callaham et al. [2] in 54%, rates consistent with the 61% observed here. Page et al. [15] observed refibrillation in 62% of the 13 patients defibrillated in an airline AED program, using the same biphasic waveform defibrillators used in this study. Weaver et al. noted an inverse relation between either resuscitation (ROSC) or survival to discharge and number of shocks. However, they do not distinguish between refractory and recurrent fibrillation and also include shocks delivered during ALS interventions. ALS inteventions are capable of sustaining cardiac arrest victims in a shockable condition (i.e. supporting a fibrillating rhythm of a sufficient amplitude) and even of supporting ROSC in patients who nonetheless have poor prospects for recovery, as reflected in the relatively poor outcomes of patients who first achieved ROSC with ALS interventions when compared with those who achieved ROSC under BLS care in our study, and as observed by Callaham et al. [16]. Thus, the relation between numbers of shocks and refibrillation, and between either of these and survival, are not likely the same in the Weaver study as in our study.

Patients who achieve ROSC with BLS interventions have a good likelihood of survival, as has been observed by others [16,17], The specificity (Sp) and negative predictive value (NPV) of BLS ROSC as a predictor of hospital discharge were similar to those found by Callaham and Madsen [16] (Sp 96%, NPV 87% here compared with Sp 98%, NPV 97% for Callaham and Madsen). The sensitivity (Se) was similar but the positive predictive value (PPV) was considerably higher in the present study (Se 82%, PPV 95% here compared with Se 39%, PPV 55% for Callaham and Madsen), perhaps reflecting the higher proportion of patients who had ROSC at handoff to ALS (39% here compared with 10% for Callaham and Madsen). This may reflect a higher proportion of patients with shorter call-to-first shock intervals. Callaham and Madsen report a mean call-to-first shock interval of 5 min for survivors, versus 7.5 min for non-survivors, remarkably similar to the difference in the present study (5.5 min for survivors, 6.5 min for non-survivors). BLS ROSC is highly predictive of favorable outcome. It is of particular interest in the context of more widespread deployment of AEDs and their utilization by non-medical first responders. The observation that a modest difference in time to first shock (1.3 min) distinguished BLS ROSC patients from others reemphasizes the importance of implementing programs that reduce time to defibrillation.

4.1. Limitations

This study was retrospective and observational, and limited to a single center and with a relatively small

sample size. A large difference would have been required to establish statistical significance of contributors to survival. However, for the principal points of observation there is no evidence of systematic differences.

5. Conclusions

Refibrillation is frequent during resuscitation from sudden VF cardiac arrest, even in the early minutes of care provided by first responders. Refibrillation had no evident adverse effect on outcome for patients with witnessed VF arrest in this study. Defibrillation of recurrent VF by first responders is frequently followed by sustained ROSC without need for ALS interventions. Using a standardized, electrophysiologically defensible definition of shock success, and distinguishing between persistent and recurrent VF (refibrillation) will enhance comparisons of shock efficacy and also our understanding of the role of refibrillation in ultimate patient outcome. This will be particularly relevant to the expanding application of defibrillation by non-traditional AED users prior to arrival of ALS personnel.

References

[1] Weaver WD, Cobb LA, Copass MK, Hallstrom AP. Ventricular defibrillation-a comparative trial using 175-J and 320-J shocks. New Engl J Med 1982;307:1101–6.

[2] Callaham M, Braun O, Balentine W, Clark DM, Zegans C. Prehospital cardiac arrest treated by urban first-responders: profile of patient response and prediction of outcome by ventricular fibrillation waveform. Ann Emerg Med 1993;22:1664–77.

[3] White RD, Vukov LF, Bugliosi TF. Early defibrillation by police: initial experience with measurement of critical time intervals and patient outcome. Ann Emerg Med 1994;23:1009–23.

[4] White RD, Asplin BR, Bugliosi TH, Hankins DG. High discharge survival rate after out-of-hospital ventricular fibrillation with rapid defibrillation by police and paramedics. Ann Emerg Med 1996;28:480–5.

[5] White RD, Hankins DG, Bugliosi TF. Seven years' experience with early defibrillation by police and paramedics in an emergency medical services system. Resuscitation 1998;39:145–51.

[6] White RD, Hankins DG, Atkinson EJ. Patient outcomes following defibrillation with a low energy biphasic truncated exponential waveform in out-of-hospital cardiac arrest. Resuscitation 2001;49:9–14.

[7] Cummins RO, Chamberlain DA, Abramson NS, Allen M, Baskett PJ, Becker L, Bossaert L, Delooz HH, Dick WF, Eisenberg MS. Recommended guidelines for uniform reporting of data from out-of-hospital cardiac arrest: the Utstein Style. A statement for health professionals from a task force of the American Heart Association, the European Resuscitation Council, the Heart and Stroke Foundation of Canada, and the Australian Resuscitation Council. Circulation 1991;84:960–75.

[8] Gliner BE, White RD. Electrocardiographic evaluation of defibrillation shocks delivered to out-of-hospital sudden cardiac arrest patients. Resuscitation 1999;41:133–44.

[9] Tanigawa K, Tanak K, Shigematsu A. Outcomes of out-of-hospital ventricular fibrillation: their association with time to defibrillation and related issues in the defibrillation program in Japan. Resuscitation 2000;45:83–90.

[10] Holmberg M, Holmberg S, Herlitz J. Incidence, duration and survival of ventricular fibrillation in out-of-hospital cardiac arrest patients in Sweden. Resuscitation 2000;44:7–17.

[11] The LIFE Investigators, Poole JE, White RD, Kanz K-G, Hengstenberg F, Jarrard GT, Robinson JC, Santana V, McKenas DK, Rich N, Rosas S, Merritt S, Magnotto L, Gallagher JV, Gliner BE, Jorgenson DB, Morgan CB, Dillon SM, Kronmal RA, Bardy GH. Low-energy impedance-compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out-of-hospital cardiac arrest. J Cardiovasc Electrophysiol 1997;8:1373–85.

[12] American Heart Association. Guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. Part 4: the automated external defibrillator. Circulation 2000;102:I60–76.

[13] Calle PA, Monsieurs KG, Buylaert WA. Equivalence of the standard monophasic waveform shocks delivered by automated external defibrilations? Resuscitation 2002;53:41–6.

[14] Zhang Y, Clark CB, Davies LR, Karlsson G, Zimmerman MB, Kerber. Body weight is a predictor of biphasic shock success for low energy transthoracic defibrillation. Resuscitation 2002;54:281–7.

[15] Page RL, Joglar JA, Kowal RC, Zagrodzky JD, Nelson LL, Ramaswamy K, Barbera SJ, Hamdan MH, McKenas DK. Use of automated external defibrillators by a US airline. New Engl J Med 2000;343:1210–6.

[16] Callaham M, Madsen CD. Relationship of timeliness of paramedic advanced life support interventions to outcome in out-of-hospital cardiac arrest treated by first responders with defibrillators. Ann Emerg Med 1996;27:638–64.

[17] MacDonald RD, Mottley JL, Weinstein C. Impact of prompt defibrillation on cardiac arrest at a major international airport. Prehospital Emerg Care 2002;6:1–5.

The New England Journal of Medicine

VOLUME 343 OCTOBER 26, 2000 NUMBER 17

OUTCOMES OF RAPID DEFIBRILLATION BY SECURITY OFFICERS AFTER CARDIAC ARREST IN CASINOS

TERENCE D. VALENZUELA, M.D., M.P.H., DENISE J. ROE, DR.P.H., GRAHAM NICHOL, M.D., M.P.H., LANI L. CLARK, B.S., DANIEL W. SPAITE, M.D., AND RICHARD G. HARDMAN, B.S.

ABSTRACT

Background The use of automated external defibrillators by persons other than paramedics and emergency medical technicians is advocated by the American Heart Association and other organizations. However, there are few data on the outcomes when the devices are used by nonmedical personnel for out-of-hospital cardiac arrest.

Methods We studied a prospective series of cases of sudden cardiac arrest in casinos. Casino security officers were instructed in the use of automated external defibrillators. The locations where the defibrillators were stored in the casinos were chosen to make possible a target interval of three minutes or less from collapse to the first defibrillation. Our protocol called for a defibrillation first (if feasible), followed by manual cardiopulmonary resuscitation. The primary outcome was survival to discharge from the hospital.

Results Automated external defibrillators were used in 105 patients whose initial cardiac rhythm was ventricular fibrillation. Fifty-six of the patients (53 percent) survived to discharge from the hospital. Among the 90 patients whose collapse was witnessed (86 percent), the clinically relevant time intervals were a mean (±SD) of 3.5±2.9 minutes from collapse to attachment of the defibrillator, 4.4±2.9 minutes from collapse to the delivery of the first defibrillation shock, and 9.8±4.3 minutes from collapse to the arrival of the paramedics. The survival rate was 74 percent for those who received their first defibrillation no later than three minutes after a witnessed collapse and 49 percent for those who received their first defibrillation after more than three minutes.

Conclusions Rapid defibrillation by nonmedical personnel using an automated external defibrillator can improve survival after out-of-hospital cardiac arrest due to ventricular fibrillation. Intervals of no more than three minutes from collapse to defibrillation are necessary to achieve the highest survival rates. (N Engl J Med 2000;343:1206-9.)

OUT-OF-HOSPITAL cardiac arrest is a major cause of death in the United States.[1,2] Studies of cardiac arrest in the nation's largest cities have shown dismal rates of survival to hospital discharge (less than 5 percent for cases of ventricular fibrillation in which the collapse is witnessed).[3,4] By contrast, some mid-sized urban areas with excellent emergency medical systems have achieved survival rates of 15 to 35 percent.[5,6] The majority of cases of out-of-hospital cardiac arrest arise from ventricular fibrillation.[7,8] Survival after out-of-hospital cardiac arrest due to ventricular fibrillation is determined primarily by the length of time from the onset of ventricular fibrillation to electrical defibrillation.[9] Therefore, early in the 1990s, the American Heart Association initiated a program to ensure public access to defibrillation and reduce the delay between collapse and electrical defibrillation.[10] The keys to reducing the interval from collapse to defibrillation are increasing the availability of automated external defibrillators and increasing the number of people trained to use them. We conducted a prospective, observational study of cardiac arrest in casinos to determine whether training casino security officers in electrical defibrillation and manual cardiopulmonary resuscitation would increase the rate of survival to discharge from the hospital after cardiac arrest.

METHODS

Subjects

We identified persons who had had cardiac arrest in casinos in Clark County, Nevada (in which Las Vegas, Henderson, and Laughlin are located); Lake Tahoe, Nevada; Philadelphia, Mississippi; and

From the Department of Emergency Medicine, College of Medicine (T.D.V., L.L.C., D.W.S.), and the Division of Epidemiology and Biostatistics, College of Public Health (D.J.R.), University of Arizona, Tucson; the Clinical Epidemiology Unit, Ottawa Civic Hospital, University of Ontario, Ottawa, Ont., Canada (G.N.); and the Clark County Fire Department, Las Vegas (R.G.H.). Address reprint requests to Dr. Valenzuela at the Department of Emergency Medicine, 1501 N. Campbell Ave., P.O.B. 245057, Tucson, AZ 85724-5057, or at terry.aemrc.arizona.edu.

Tunica, Mississippi. The subjects had cardiac arrest within the property of the casinos, including the common areas where gambling occurred and the hotel rooms. Subjects who met the inclusion criteria had been unconscious and unresponsive, had no palpable carotid pulse, and had no spontaneous respiration. Subjects less than nine years of age or weighing 36 kg or less were excluded, according to the specifications of the defibrillator manufacturers. Age and weight were estimated visually by security officers. Data on cases of cardiac arrest were collected consecutively from participating casinos.

Training and Equipment of Responders

The security officers were required to have current American Heart Association basic-cardiopulmonary-resuscitation certification before training. Training was conducted by two of the investigators and lasted five to six hours. The curriculum consisted of the following: introduction to cardiac arrest and objectives of defibrillation training, basic anatomy and physiology of cardiac arrest, assessment of the patient, orientation to the automated external defibrillator, protocol for automated external defibrillation, small-group practice with the defibrillator, skills testing, written examination, and review. Two to three hours of the course consisted of hands-on practice and scenarios. The passing score for the written test was set at 75 percent.

An initial group of approximately 1350 security officers from 10 casinos was trained and equipped by March 1, 1997. Thereafter, security officers at casinos that requested participation in the program were trained as the time of the investigators allowed. All officers received the same course and testing. A prospectively set threshold for data analysis (100 cases of ventricular fibrillation) was reached on October 12, 1999. Data were collected from a total of 32 casinos over approximately 32 months.

The casinos were encouraged to place a sufficient number of defibrillators on their premises to meet a goal of no more than three minutes of elapsed time from collapse to defibrillation. Implementation of these recommendations was left to the management of the individual casinos. Casino security officers staged mock cardiac arrests at various locations to determine the length of time required to bring defibrillators to those locations from their storage places. The casinos were free to purchase any current-generation automated external defibrillator; several brands were in use by the end of the study.

Protocol

Security officers remain in designated areas of the casinos at all times. An officer is always visible from any point in the public area of the casino. In addition, security cameras mounted in the ceiling randomly scan the public areas, and security personnel can focus on unusual events. In our study, when the officers were notified by radio of the presence of a "sick person," the nearest officer proceeded to the patient and assessed him or her for responsiveness, spontaneous respiration, and palpable carotid pulse. This officer initiated manual cardiopulmonary resuscitation if indicated. A second officer, who had also been informed by radio of the patient's location and who had prior knowledge of where the defibrillators were stored, brought the nearest defibrillator to the patient. The defibrillator was immediately attached and activated, and audible prompts (by a recorded voice) from the various devices were followed. Resuscitative efforts by the security officers continued until the patient regained pulse and spontaneous respiration or until the paramedics arrived.

Collection of Data

Data from the participating casinos were provided to the study investigators by the Clark County Fire Department. The casinos outside Nevada are owned by corporations with headquarters in Las Vegas and also reported through the Clark County Fire Department. The following data were collected: the subject's name, address, Social Security number (for collection of follow-up data from survivors), and date of birth; the location of the arrest in the casino; whether the subject was receiving cardiopulmonary resuscitation from either the first-responding security officer or from a bystander when the security officer equipped with a defibrillator arrived; and the presence or absence of a pulse, the subject's respiratory effort, and any change in level of consciousness at the time the subject left the casino with the paramedics. In addition, the security officers completed a one-page data form and an incident report specific to the casino.

The time of collapse and the time of initiation of manual cardiopulmonary resuscitation for witnessed arrests were obtained from security videos if the subject collapsed in a common area. If the cardiac arrest was witnessed in a hotel room, the security officer asked the witness or witnesses about the interval between the collapse and the call for help. The time of the call for help was documented on the officer's incident report.

The defibrillation times were recorded automatically by the defibrillator devices. Two types of devices were used. In the case of one type, each device's internal clock is synchronized when contact with the main computer is made to transmit data after an event or each month if the automated electrical defibrillator is not used. The computer's clock is synchronized daily with an atomic clock in Boulder, Colorado. For the other type of device, whose internal clock could not be synchronized remotely, the machine was reset every day to match the casino's security-center clock.

The defibrillators recorded a detailed sequence of events during resuscitation that provided tracings of the cardiac wave form with real clock times and, if the device had audio recording, an audio recording of the resuscitation effort. The time of arrival of the paramedics at the arrest scene was obtained from audio recordings, dispatch records, reports from the emergency medical service, and security videotapes. Data on the subjects' outcomes and their hospital course were obtained by the paramedics of the Clark County Fire Department from the hospitals to which the subjects were transported. Study data forms and electronic data from the defibrillators were collected from all participating casinos by the Clark County Fire Department and forwarded to investigators at the University of Arizona for review and analysis.

Outcome Variables

The time of collapse, time of initiation of manual cardiopulmonary resuscitation, and time of first electrical defibrillation were used to calculate the predictor intervals from collapse to cardiopulmonary resuscitation and from collapse to defibrillation. The primary outcome variable was survival to discharge from the hospital. Consent for review of hospital records was obtained from surviving subjects and from family members of those who did not survive. The study was approved by the institutional review board of the University of Arizona.

Statistical Analysis

Descriptive statistics such as proportions, means, and standard deviations were used to summarize the results. A sample size of 100 subjects with cardiac arrest due to ventricular fibrillation was prospectively established to ensure that the accuracy of the model of survival after cardiac arrest could be estimated with a standard error of no more than 5 percent. The rate of survival among subjects undergoing defibrillation no more than three minutes after collapse was compared with that among subjects undergoing defibrillation more than three minutes after collapse by a chi-square test, and the 95 percent confidence interval was computed for the difference between the rates of survival. Differences between the results for the subjects in our study and previously reported results for patients in Tucson, Arizona, and King County, Washington,[9] were examined with use of chi-square tests for categorical variables and Kruskal–Wallis tests for continuous variables. All P values are two-sided.

RESULTS

The demographic characteristics of the subjects and the intervals from collapse to various interventions are shown in Table 1. The sample contained 148 subjects

TABLE 1. CHARACTERISTICS OF SUBJECTS WITH CARDIAC ARREST IN CASINOS.*

CHARACTERISTIC	ALL CARDIAC ARRESTS (N=148)	WITNESSED ARRESTS WITH AN INITIAL RHYTHM OF VENTRICULAR FIBRILLATION (N=90)
Age — yr	64±12	65±11
Male sex — %	80	84
CPR administered before arrival of defibrillator — no. (%)	63 (43)	49 (54)
Interval from collapse to CPR — min	—†	2.9±2.8
Initial rhythm of ventricular fibrillation — no. (%)	105 (71)	90 (100)
Interval from collapse to attachment of defibrillator — min	—†	3.5±2.9
Interval from collapse to first defibrillation — min	—†	4.4±2.9
Interval from collapse to arrival of paramedics — min	—†	9.8±4.3
Survival to discharge from hospital — no. (%)	56 (38)	53 (59)

*Plus–minus values are means ±SD. CPR denotes cardiopulmonary resuscitation.

†Intervals from collapse to intervention could not be calculated for unwitnessed arrests.

with confirmed cardiac arrest. None of them were children, and therefore no cases were excluded because of the age and weight criteria. One hundred five subjects had an initial cardiac rhythm of ventricular fibrillation, 17 had pulseless electrical activity, and 26 had asystole. No subjects whose initial cardiac rhythm was not ventricular fibrillation survived to discharge from the hospital. Of the 148 subjects in the total group, 17 (11 percent) were pronounced dead at the scene, 60 (41 percent) were pronounced dead in the hospital emergency department, 15 (10 percent) were admitted to the hospital and died before discharge, and 56 (38 percent) survived to discharge from the hospital.

Ventricular fibrillation accounted for 105 of the 148 cases (71 percent). Fifteen subjects who had ventricular fibrillation collapsed unobserved; three of them survived to hospital discharge (20 percent). Of the 105 patients with ventricular fibrillation, 4 (4 percent) were pronounced dead at the scene, 35 (33 percent) were pronounced dead in the hospital emergency department, 10 (10 percent) were admitted to the hospital and died before discharge, and 56 (53 percent) survived to discharge from the hospital.

We performed subgroup analysis on data from the 90 subjects with witnessed cardiac arrest due to ventricular fibrillation. They were predominantly male (84 percent), with a mean (±SD) age of 65±11 years. The demographic characteristics of this subgroup did not differ significantly from those of the entire group of subjects. Fifty-four percent of the subjects with witnessed arrests received cardiopulmonary resuscitation before the arrival of the guard with the defibrillator: 61 percent of them from security officers, 16 percent from strangers, 14 percent from family members, and 8 percent from friends or coworkers. The mean intervals from collapse to various interventions were 2.9±2.8 minutes for cardiopulmonary resuscitation, 3.5±2.9 minutes for attachment of the defibrillator, 4.4±2.9 minutes for the first defibrillation shock, and 9.8±4.3 minutes for arrival of the paramedics. Fifty-three of those with witnessed cardiac arrest due to ventricular fibrillation (59 percent) survived to discharge from the hospital; those who did not survive died at the casino (2 percent), in the emergency department of the hospital (29 percent), or after hospital admission (10 percent). Among subjects whose collapse was witnessed, the survival rate was 74 percent (26 of 35) for those who received their first defibrillation no later than three minutes after collapse and 49 percent (27 of 55) for those who received their first defibrillation more than three minutes after collapse. This difference (25 percentage points) was statistically significant ($P=0.02$), with a 95 percent confidence interval of 5.6 to 44.8 percentage points.

DISCUSSION

The work of White and others demonstrated that people without other medical training could successfully resuscitate victims of out-of-hospital cardiac arrest due to ventricular fibrillation.[11,12] Investigators subsequently advocated strategies to shorten the delay from collapse to electrical defibrillation by training and equipping for defibrillation new classes of responders with a variety of backgrounds.[13] Device manufacturers responded to the American Heart Association's public-access defibrillation initiative by producing automated external defibrillators that are simpler and less expensive and that require less maintenance than previous portable defibrillators.

The challenge for the future is to decide where defibrillators should be available, place them there, and train appropriate groups of people to use them. Some airlines have already placed defibrillators on their aircraft and trained their attendants to use them.[14-16]

On the basis of their experience with cardiac arrests in casinos, officers of the Clark County Fire Department reasoned that casino security officers, whose job involves rapid response to emergencies but who have not previously received medical training other than basic cardiopulmonary resuscitation, would be ideal candidates for training in a rapid-defibrillation program. Our objective was to determine whether these officers could successfully resuscitate victims of cardiac arrest due to ventricular fibrillation through the use of automated external defibrillators. The survival rates achieved in this project were very high for persons with out-of-hospital cardiac arrest due to ventricular fibrillation.

What accounts for the apparent success of this project, and what are the implications for so-called public-access defibrillation? First, the majority of all arrests in this study occurred in the public areas of the casinos, not in the guests' rooms, and therefore were visible to security officers and video cameras. Studies of traditional emergency-medical-services systems indicate that less than 20 percent of cardiac arrests occur in public places.[17] The arrests in the casinos were therefore more frequently witnessed and recognized than those in other studies, and treatment was initiated sooner. Cardiac arrests are not likely to be detected as quickly in sites such as apartment buildings or gated communities, where residents do not spend extended periods in public areas. Second, the response intervals in the casinos were shorter than those reported with traditional emergency-response systems. The intervals from collapse to cardiopulmonary resuscitation were significantly shorter for the arrests that occurred in casinos (2.9 minutes) than for those that occurred in Tucson, Arizona (4.7 minutes), and King County, Washington (3.4 minutes), as were the intervals from collapse to defibrillation (4.4 minutes in the casinos, 5.1 minutes in King County, and 9.5 minutes in Tucson).[9]

These results have implications for the Public Access Defibrillation Study funded by the National Heart, Lung, and Blood Institute, a prospective, randomized study of rapid defibrillation by nonmedical providers. Survival rates in study sites where collapse-to-defibrillation intervals are not consistently in the range of three to four minutes may not be much higher than those with the best traditional emergency-medical-services systems; still, the results from these sites may be an improvement over those of emergency-medical-services systems with prolonged response times. Casinos also have an unusually high density of cardiac arrests in their public areas, in comparison with other types of public places.[18]

The limitations of this study include the lack of access to data on cardiac arrests that occurred in casinos other than the participating casinos during the study period. At the time the study was undertaken, uncertainty about potential legal liability limited the group of casinos willing to risk participation. A rolling implementation strategy, such as we used, was the only feasible option. In addition, there was no formal neurologic testing in survivors. However, the disposition of the subjects sheds light on their neurologic function at discharge. At the end of the study, no survivor was dependent on others for daily support. Therefore, it is unlikely that any survivor could be classified in cerebral-performance categories higher than 1 (good cerebral performance) or 2 (moderate cerebral disability) on the widely used Cerebral Performance scale.[19]

Our study has shown that rapid defibrillation by casino security officers is both feasible and effective; it also demonstrates that, to increase the survival rates over those obtained with standard emergency-services systems, the interval between collapse and the first defibrillation must be short.

We are indebted to the Clark County Fire Department, whose officers conceived the project; to the participating casinos, which had the courage to implement this program when their potential liability was unclear; to the medical directors of the casinos who, without financial compensation, provided the local medical oversight necessary for the project; and to Medtronic-PhysioControl for supplying the study computers.

REFERENCES

1. Engelstein ED, Zipes DP. Sudden cardiac death. In: Alexander RW, Schlant RC, Fuster V, eds. Hurst's the heart, arteries and veins. 9th ed. Vol. 1. New York: McGraw-Hill, 1998:1081-112.
2. Myerburg RJ, Castellanos A. Cardiac arrest and sudden cardiac death. In: Braunwald E, ed. Heart disease: a textbook of cardiovascular medicine. 5th ed. Philadelphia: W.B. Saunders, 1997:742-79.
3. Becker LB, Ostrander MP, Barrett J, Kondos GT. Outcome of CPR in a large metropolitan area — where are the survivors? Ann Emerg Med 1991;20:355-61.
4. Gallagher EJ, Lombardi G, Gennis P. Effectiveness of bystander cardiopulmonary resuscitation and survival following out-of-hospital cardiac arrest. JAMA 1995;274:1922-5.
5. Eisenberg MS, Horwood BT, Cummins RO, Reynolds-Haertle R, Hearne TR. Cardiac arrest and resuscitation: a tale of 29 cities. Ann Emerg Med 1990;19:179-86.
6. Valenzuela TD, Spaite DW, Meislin HW, Clark LL, Wright AL, Envy GA. Case and survival definitions in out-of-hospital cardiac arrest: effect on survival rate calculation. JAMA 1992;267:272-4.
7. Eisenberg MS. The problem of sudden cardiac death. In: Eisenberg MS, Bergner L, Hallstrom AP, eds. Sudden cardiac death in the community. New York: Praeger, 1995:1-16.
8. Becker LB. The epidemiology of sudden death. In: Paradis NA, Halperin HR, Nowak RM, eds. Cardiac arrest: the science and practice of resuscitation medicine. Baltimore: Williams & Wilkins, 1996:28-47.
9. Valenzuela TD, Roe DJ, Cretin S, Spaite DW, Larsen MP. Estimating effectiveness of cardiac arrest interventions: a logistic regression survival model. Circulation 1997;96:3308-13.
10. Weisfeldt ML, Kerber RE, McGoldrick RP, et al. American Heart Association report on the Public Access Defibrillation Conference December 8-10, 1994. Circulation 1995;92:2740-7.
11. White RD, Hankins DG, Bugliosi TF. Seven years' experience with early defibrillation by police and paramedics in an emergency medical services system. Resuscitation 1998;39:145-51.
12. Mosesso VN Jr, Davis EA, Auble TE, Paris PM, Yealy DM. Use of automated external defibrillators by police officers for treatment of out-of-hospital cardiac arrest. Ann Emerg Med 1998;32:200-7.
13. Nichol G, Hallstrom AP, Kerber R, et al. American Heart Association report on the Second Public Access Defibrillation Conference, April 17-19, 1997. Circulation 1998;97:1309-14.
14. O'Rourke MF, Donaldson E, Geddes JS. An airline cardiac arrest program. Circulation 1997;96:2849-53.
15. Page RL, Hamdan MH, McKenas DK. Defibrillation aboard a commercial aircraft. Circulation 1998;97:1429-30.
16. Page RL, Joglar JA, Kowal RC, et al. Use of automated external defibrillators by a U.S. airline. N Engl J Med 2000;343:1210-6.
17. Becker L, Eisenberg M, Fahrenbruch C, Cobb L. Public locations of cardiac arrest: implications for public access defibrillation. Circulation 1998;97:2106-9.
18. Gratton M, Lindholm DJ, Campbell JP. Public-access defibrillation: where do we place the AEDs? Prehosp Emerg Care 1999;3:303-5.
19. Safar P, Bircher NG. Cardiopulmonary cerebral resuscitation: basic and advanced cardiac and trauma life support: an introduction to resuscitation medicine. 3rd ed. London: W.B. Saunders, 1988.

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association®
Learn and Live℠

Public Access Defibrillation in Out-of-Hospital Cardiac Arrest: A Community-Based Study

Linda L. Culley, Thomas D. Rea, John A. Murray, Barbara Welles, Carol E. Fahrenbruch, Michele Olsufka, Mickey S. Eisenberg and Michael K. Copass

Circulation 2004;109;1859-1863; originally published online Mar 15, 2004;
DOI: 10.1161/01.CIR.0000124721.83385.B2
Circulation is published by the American Heart Association. 7272 Greenville Avenue, Dallas, TX 72514
 Print ISSN: 0009-7322. Online ISSN: 1524-4539

Public Access Defibrillation in Out-of-Hospital Cardiac Arrest

A Community-Based Study

Linda L. Culley, BA; Thomas D. Rea, MD, MPH; John A. Murray, MD; Barbara Welles, RN; Carol E. Fahrenbruch, BS, MSPH; Michele Olsufka, RN; Mickey S. Eisenberg, MD, PhD; Michael K. Copass, MD

Background—The dissemination and use of automated external defibrillators (AEDs) beyond traditional emergency medical services (EMS) into the community has not been fully evaluated. We evaluated the frequency and outcome of non-EMS AED use in a community experience.

Methods and Results—The investigation was a cohort study of out-of-hospital cardiac arrest cases due to underlying heart disease treated by public access defibrillation (PAD) between January 1, 1999, and December 31, 2002, in Seattle and surrounding King County, Washington. Public access defibrillation was defined as out-of-hospital cardiac arrest treated with AED application by persons outside traditional emergency medical services. The EMS of Seattle and King County developed a voluntary Community Responder AED Program and registry of PAD AEDs. During the 4 years, 475 AEDs were placed in a variety of settings, and more than 4000 persons were trained in cardiopulmonary resuscitation and AED operation. A total of 50 cases of out-of-hospital cardiac arrest were treated by PAD before EMS arrival, which represented 1.33% (50/3754) of all EMS-treated cardiac arrests. The proportion treated by PAD AED increased each year, from 0.82% in 1999 to 1.12% in 2000, 1.41% in 2001, and 2.05% in 2002 ($P=0.019$, test for trend). Half of the 50 persons treated with PAD survived to hospital discharge, with similar survival for nonmedical settings (45% [14/31]) and out-of-hospital medical settings (58% [11/19]).

Conclusions—PAD was involved in only a small but increasing proportion of out-of-hospital cardiac arrests. (***Circulation.* 2004;109:1859-1863.**)

Key Words: heart arrest ■ defibrillation ■ automated external defibrillator ■ cardiopulmonary resuscitation

Out-of-hospital cardiac arrest accounts for hundreds of thousands of deaths annually in the United States.[1,2] Estimates are that 5% or less of all persons suffering cardiac arrest are resuscitated successfully and subsequently discharged alive from the hospital.[3,4] The "chain of survival" outlines opportunities to improve outcome through prompt activation of 9-1-1, early cardiopulmonary resuscitation (CPR), rapid defibrillation, and timely advanced life support.[5] Although all the links in the chain of survival are important, rapid defibrillation appears to be the most critical, with survival declining by ≈5% to 10% with each minute of delay.[6,7]

The automated external defibrillator (AED) provides the possibility to decrease the interval from collapse to attempted defibrillation by enabling persons outside the traditional emergency medical services (EMS) response system who are typically not trained in rhythm recognition to deliver life-saving therapy. Various approaches have incorporated the AED in an effort to improve survival from out-of-hospital cardiac arrest. In the Public Access Defibrillation trial, a rigorous program of trained citizen first responders equipped with AEDs in specific high-risk sites improved survival by ≈2-fold.[8] In other specific settings, such as gaming establishments, airports, or airplanes, the placement of AEDs and training of personnel appear to offer survival advantages.[9–12] Police-responder programs may also increase survival.[13–15] Finally, specialized community-responder programs in select European communities have demonstrated potential survival improvements.[16]

However, the optimal strategy of community-wide AED distribution is not yet certain. High-risk sites have been identified.[17,18] Some groups have mandated AED placement,

Received September 3, 2003; de novo received November 18, 2003; accepted January 27, 2004.

From Public Health–Seattle and King County, Emergency Medical Services Division (L.L.C., T.D.R., B.W., J.A.M., M.S.E.); Seattle Medic One (C.E.F., M.O., M.K.C.); and the Department of Medicine, University of Washington (T.D.R., J.A.M., M.S.E., C.E.F., M.O., M.K.C.), Seattle, Wash.

Presented in part at the 76th Scientific Sessions of the American Heart Association, Orlando, Fla, November 9–12, 2003, and published in abstract form (*Circulation*. 2003;108[suppl IV):IV-1045).

Correspondence to Linda Culley, Public Health Seattle and King County, Emergency Medical Services Division, 999 Third Ave, Suite 700, Seattle, WA 98104-4039. E-mail Linda.Culley@metrokc.gov

Circulation is available at http://www.circulationaha.org

DOI: 10.1161/01.CIR.0000124721.83385.B2

whereas others have voluntarily instituted an AED program.[19,20] In some instances, AEDs have been prescribed for patients with heart disease.[21] The reasons and motivations for instituting an AED program may differ across groups or persons. Similarly, the actual dissemination of AEDs beyond EMS use into the community is likely to be heterogeneous. We investigated a community experience with AED dissemination and use in a US metropolitan community to evaluate the frequency and outcome of PAD AED use.

Methods

Study Design, Population, and Setting

This investigation was a cohort study of out-of-hospital cardiac arrest cases due to underlying heart disease that were treated by "public access defibrillation" between January 1, 1999, and December 31, 2002, in Seattle and surrounding King County, Washington. Public access defibrillation was defined as out-of-hospital cardiac arrest treated with AED application by persons outside the traditional first-responder EMS. Thus, cases treated by non-EMS AEDs, regardless of location or AED operator, were considered PAD AEDs. The study was approved by the investigators' Institutional Review Board.

King County including Seattle has a population of ≈1.75 million persons and comprises urban, suburban, and rural areas. Seventy-six percent of inhabitants are white, 11% Asian, 6% Hispanic or Latino, and 5% black.[22]

Community-Responder AED Program

In 1996, a community conference was held to discuss issues surrounding the dissemination of AEDs beyond EMS. Participants identified the existing EMS system as an integral part of any AED program. Liability concerns were cited as a potential obstacle preventing AED dissemination and EMS participation and leadership. The passage of Washington state law in 1999 outlined the necessary steps for AED program liability protection. The law addressed requirements for training, maintenance, medical supervision, and EMS notification (available at www.leg.wa.gov/RCW/index.cfm?fuseaction=section&section =70.54.310).[19]

After passage of the law, the Seattle Fire Department Medic One and the Emergency Medical Services Division of Public Health–Seattle and King County developed a voluntary Community Responder AED Program in Seattle and King County. The Community Responder AED Program was designed to facilitate a coordinated effort that would comply with Washington State law and ensure an optimal response during a cardiac arrest. A program manager was designated (B.W.) to coordinate the Community Responder AED Program. The manager is a health professional (nurse) certified as a CPR and AED instructor.

The manager's responsibilities include program announcement and publicity, enrollment, and follow-up. Announcement and publicity is achieved through a variety of methods. To make potential AED owners aware of the Community Responder AED Program, printed informational packets were developed and distributed to local hospitals, clinics, institutions such as libraries, and public meeting sites, as well as to EMS agencies and AED manufacturers. The program maintains a telephone contact number.

Enrollment in the Community Responder Program requires that potential PAD AED entities fulfill AED and CPR training requirements, notify local EMS and emergency 9-1-1 dispatch, acquire medical direction, and develop a plan for ongoing training, AED maintenance, and program notification should AED use occur. The program manager either provides CPR and AED training or directs entities to certified training organizations. The initial training includes recommendations for retraining and AED maintenance. The AED site information is registered with local EMS and dispatch. As a result, in case of a 9-1-1 call for cardiac arrest, dispatch is automatically alerted that an AED is available on site and can relay this information to the caller and responding EMS. The entity is directed to notify the program in the event of an AED use. Medical supervision is provided by agreement with the King County EMS Medical Program Director or the Medical Director of Seattle Fire Department Medic One (at no cost). Medical supervision is responsible for approving medical authorization for device placement and use, reviewing events within the context of ongoing EMS surveillance for out-of-hospital cardiac arrest, and addressing other issues that may arise as part of the program. In addition, the program conducts periodic follow-up via a written survey that inquires about ongoing training and maintenance and any AED use. For those who do not respond to the mailed survey, a phone contact is attempted. Taken together, response is ≈75%.

EMS System

Citizens in Seattle and King County access EMS by calling 9-1-1. Seattle and surrounding King County are served by a 2-tiered EMS response system.[23] First and second tiers of EMS complete standard medical incident reports for every EMS-treated cardiac arrest case that includes information regarding demographic, clinical, and event characteristics. Death certificates or hospital records for each patient are reviewed to determine survival to hospital discharge. In this investigation, Seattle EMS classified the cause of the cardiac arrest on the basis of the information provided by the EMS incident report, whereas surrounding King County used a combination of incident reports, death certificate information, and the hospital discharge diagnosis. This approach to classification was consistent for the 4 years of the study.

Data Collection

For each participating entity in the Community Responder AED Program, information was collected during registration that included site name and address, site coordinator, medical supervisor, device location, number of persons trained, and type of training, as well as plans for maintenance and ongoing training. Information about cardiac arrest involving PAD AEDs was collected from 3 possible sources: the EMS report, a direct contact between the EMS agency and Community Responder program manager, and/or a direct contact between the PAD AED entity and the program manager. For all events, EMS attempted to review the AED electronic record.

Statistical Analysis

Descriptive statistics were used to assess the duration of exposure and use of PAD AEDs according to location type, the proportion of cardiac arrests that were treated by a PAD AED, and characteristics of the PAD AED cases. A χ^2 analysis with test for trend was used to determine whether the proportion of arrests treated by PAD AEDs increased over the 4 years of the study.

Results

A total of 475 AEDs were registered in the Community Responder AED program, 102 in the year 1999, 136 in 2000, 155 in 2001, and 82 in 2002. The AEDs were located in a variety of settings (Table 1). A total of 4004 persons underwent initial training in CPR and AED skills with a median of 5 trained per site.[1,14] All sites were registered with emergency dispatch centers.

In the years 1999 through 2002, a total of 2124 treated cardiac arrests cases were screened in Seattle, with 1767 (83.2%) considered to be due to heart disease, whereas in surrounding King County, a total of 3037 treated cases were screened, with 1987 (65.4%) considered to be due to heart disease, which resulted in a total of 3754 treated cardiac arrest cases due to underlying heart disease. During the 4 years from 1999 through 2002, 50 cases of out-of-hospital cardiac arrest due to heart disease were treated by PAD AEDs before EMS arrival, for an overall incidence of 4.9 PAD AED treated arrests per 100 AED-years (Table 1). The proportion of all

TABLE 1. Percent Distribution of AEDs in the Community Responder AED Program by Setting in Seattle and King County 1999–2002

Location Type	AEDs, % (n)	AED-Years	Events	Incidence*
Business	36.8 (175)	392	18	4.6
Police	12.0 (57)	169	4	2.4
Medical	11.0 (52)	136	15	11.0
Private	10.7 (51)	77	0	0
Recreational	9.9 (47)	89	6	6.7
Government	9.3 (44)	90	2	2.2
School	7.4 (35)	43	1	2.3
Senior center/nursing home	2.9 (14)	26	4	15.4
Total	475	1022	50	4.9

*Incidence is No. of events per 100 AED-years.

EMS-treated cardiac arrests that were treated by PAD AEDs increased each year from 0.82% (8/974) in 1999 to 1.12% (11/980) in 2000, 1.41% (13/923) in 2001, and 2.05% (18/877) in 2002. Comparable figures were 1.56% (3/192) in 1999, 3.03%, (5/165) in 2000, 5.88% (11/187) in 2001, and 5.23% (8/153) in 2002 for nonmedical public setting arrests and 2.42% (4/165) in 1999, 2.83% (6/212) in 2000, 1.30% (2/154) in 2001, and 4.23% (7/166) in 2002 for out-of-hospital medical setting (ie, nursing home, doctor's office, dialysis center, non-EMS medical transport) arrests. Twenty-two percent (11/50) of the PAD AED-treated cases were not registered in the Community Responder AED Program. Nine of these events occurred in medical clinics. On the basis of a follow-up survey of a sample of sites during 2000 and 2001, a PAD AED was applied for an event other than cardiac arrest in a similar number of cases: 15 nonarrest events compared with 13 actual cardiac arrest events among the sampled sites during the time period. No adverse outcomes were reported from the AED application in these nonarrest events.

Characteristics of the 50 cardiac arrest cases treated initially by PAD AED are presented in Table 2. Overall, 76% (38/50) were admitted to the hospital and 50% (25/50) were discharged alive from the hospital, with most discharged to home. Among persons presenting with presumed ventricular fibrillation (PAD shock advised), 81% (34/42) were admitted to the hospital and 55% (23/42) were discharged alive. Eleven persons regained a pulse before EMS arrival (all after an AED shock). Of these 11, 10 were discharged alive from the hospital. When stratified by location, 48% (13/27) who experienced the arrest in a public nonmedical location, 58% (11/19) in an out-of-hospital medical setting, and 25% (1/4) in a private residential setting were discharged alive. Survival was similar across the AED operator groups: 54% (14/26) for medically trained operators, 50% (9/18) for lay operators, and 50% (2/4) for police (the operator was unknown in 2 cases).

Survival for all cases of out-of-hospital cardiac arrest due to heart disease in Seattle and King County from 1999 through 2002 was 14.6% (548/3754), whereas survival was 24.3% (419/1722) for all witnessed arrests, 29.0% (202/697) for public-setting arrests, and 17.5% (245/1399) in public plus out-of-hospital medical settings. EMS first-tier response

TABLE 2. Characteristics of Cases Treated by PAD AEDs (n=50)

Characteristic	Value
Age, y, median (25th %, 75th %)	64 (54,75)
Male, n (%)	38 (76)
Location, n (%)	
Public nonmedical	27 (54)
Out-of-hospital medical	19 (38)
Home/private residence	4 (8)
Witnessed, n (%)	46 (92)
Bystander CPR, n (%)	50 (100)
Person who applied and operated AED, n (%)	
Nurse/physician/other medical	26 (52)
Lay responder	18 (36)
Police	4 (8)
Unknown	2 (4)
Presumed VF rhythm, n (%)	42 (84)
No. of PAD shocks before EMS arrival, median (25th %, 75th %)*	1 (1, 3)
Interval from 9-1-1 call received to EMS dispatch, min, median (25th %, 75th %)†	1 (1, 2)
Interval from EMS dispatch to scene arrival, min, median (25th %, 75th %)†	4 (3, 6)
Combined interval from call received to scene arrival, min, median (25th %, 75th %)†	5 (5, 7)
Admitted to hospital, n (%)	38 (76)
Survival to hospital discharge, n (%)	25 (50)
Discharge location, n (%)‡	
Home	22 (88)
Nursing home/rehabilitation center	3 (12)

VF indicates ventricular fibrillation.

*Among those persons who received a PAD shock (n=42).

†Interval information available for 40 cases (interval from 9-1-1 call received to EMS dispatch), 46 cases (interval from EMS dispatch to scene arrival), and 38 cases (combined interval from call received to scene arrival).

‡Among those discharged alive after hospitalization (n=25).

interval from time of dispatch to scene arrival was 5.7±2.5 minutes in King County and 3.7±1.6 minutes in Seattle.

Discussion

During the 4 years of study, a variety of groups and individuals undertook an AED program. A small but increasing proportion of out-of-hospital cardiac arrests were treated by PAD AEDs. Survival was 50% in cases treated by PAD AED, a figure considerably better than most EMS systems and similar to other out-of-hospital PAD AED programs in specialized settings.[3,9,10]

In this community, the surveillance of PAD AED use required a coordinated effort that was guided by EMS. The undertaking initially required legislation that in part outlined legal requirements for AED ownership and consequently provided liability protection to involved parties. In response, EMS developed a Community Responder AED Program and registry that provided important services aimed at ensuring proper response in case of a cardiac arrest. Surveillance was

also aided by an advanced EMS system with an established practice for reporting and reviewing cardiac arrest. Finally, surveillance required participation by other potential stakeholders, most notably the entities that adopted AED programs and AED manufacturers, local agencies involved in layperson education for heart emergencies, and community leaders.

A heterogeneous collection of medical, government, police, and business groups and individuals undertook an AED program according to the Community Responder registry. Although the registry was voluntary, most events treated by PAD AEDs, especially those outside physicians' clinics, were registered with the program, which suggests that the registry may have been representative of AED dissemination into the community. Importantly, some sites have been identified as high risk, such as dialysis centers or nursing homes.[17] Other sites presumably possess lower risk. In this regard, the overall incidence of PAD AED use in this experience was 5 per 100 AED-years of exposure, a figure less than the projected rate used to design the PAD Trial. The variety of sites likely reflects different factors that may influence the decision to undertake an AED program, including scientific reports, an entity's past experience or knowledge of cardiac arrest, personal preferences, economic considerations, and legal requirements.[17–21,24–27]

As might be expected during the initial years of community-wide AED dissemination, PAD AEDs were used in only a small proportion of arrests. The proportion, however, increased each year and to some extent may reflect the increase in the cumulative total of PAD AEDs in the community. Whether this temporal trend of increasing PAD AED use will continue is uncertain. Importantly, the community-wide dissemination of PAD AEDs is not necessarily constrained to public location sites that might ultimately limit the public health implications of PAD AEDs.[28] In the present cohort, some AEDs were situated in private locations, and actual cardiac arrests that occurred in the home were treated by PAD AEDs. Ultimately, a multifaceted strategy of AED dissemination that uses a variety of responders and locations may enable the greatest involvement of PAD AEDs.[13,16,29,30]

Half of the 50 persons treated with PAD AEDs survived to hospital discharge, with similar survival for nonmedical and out-of-hospital medical settings and when the AED was operated by a nonmedical or medical provider. The high level of survival appears to be the consequence of both the predominance of ventricular fibrillation as the presenting rhythm and the high rate of conversion of ventricular fibrillation to a perfusing rhythm. In contrast to most EMS systems that report less than 50% of cardiac arrest cases in ventricular fibrillation, 84% of cardiac arrest victims presented in ventricular fibrillation in the present investigation, a proportion similar to the EMS circumstance with extremely short response intervals or PAD responder programs in gaming establishments and airports.[9,10] The difference is likely in part the result of the time-dependent deterioration of ventricular fibrillation to asystole.[31] In addition, survival among those presenting in ventricular fibrillation was ≈50%, consistent with prior experience that ventricular fibrillation can be corrected more readily soon after collapse and subsequently becomes more difficult to treat.[6] Taken together, the findings suggest that many cardiac arrests could be treated with defibrillation if an AED could be applied within minutes of the collapse and that survival might be better than traditional experience.

This investigation has limitations. Although the study community comprised a heterogeneous population that may be representative of other communities, AED dissemination and the EMS system may differ from other communities, factors that may influence the generalizability of the findings. We did not have complete information on every case and in some instances had to rely on surrogate measures. For example, the AED electronic recording was not available in some instances, so that the presence of ventricular fibrillation was determined on the basis of whether the AED provided a shock. Prior reports have demonstrated that AEDs have a high level of accuracy for identifying ventricular fibrillation.[32] In addition, although we are unaware of any cases of out-of-hospital cardiac arrest that occurred where a PAD AED was present but not accessed or applied, these situations may have occurred. The investigation had minimal power to evaluate for differences in patient, event, or therapy characteristics between survivors and nonsurvivors treated with PAD AEDs. Neurological outcome was not collected routinely for the survivors outside of Seattle, although the location of discharge (most to home) suggests that neurological function was satisfactory in most cases.

Given the considerable challenge of improving survival from out-of-hospital cardiac arrest, no particular strategy is likely to constitute a single best approach. Rather, efforts to strengthen each link in the chain of survival may incrementally improve outcomes. Careful surveillance and review will be an important part of assessing the potential community impact of technological, research, and programmatic advances in resuscitation. Studies to date support the use of AEDs and CPR by nontraditional responders as an approach that may improve survival from cardiac arrest. The results of this investigation suggest that the dissemination of PAD AEDs has had a small impact in out-of-hospital cardiac arrest. The impact of this strategy may ultimately depend on economic, scientific, public preference, and health policy considerations that will influence the extent and location of AED distribution, as well as the infrastructure to support and coordinate such programs.

Acknowledgments

The authors acknowledge Leah Doctorello, Dan Anderson, Anthony Cagle, and Linda Becker of Public Health–Seattle and King County, who assisted in the registry database. Thomas Hearne, manager of the Emergency Medical Services Division of Public Health, provided administrative support. The EMS agencies of Seattle and King County provided site review and training, dispatch centers documented device site information, and both provided care for patients with cardiac arrest. Cardiac Science, Medtronic Physio-Control, Philips Medical Systems, and Zoll Medical Corporation provided potential AED purchasers with information regarding the Community Responder Program. No external funding was used in conducting the investigation.

References

1. Zheng ZJ, Croft JB, Giles WH, et al. Sudden cardiac death in the United States, 1989 to 1998. *Circulation*. 2001;104:2158–2163.

2. Cobb LA, Fahrenbruch CE, Olsufka M, et al. Changing incidence of out-of-hospital ventricular fibrillation, 1980–2000. *JAMA*. 2002;288: 3008–3013.
3. Nichol G, Stiell IG, Laupacis A, et al. A cumulative meta-analysis of the effectiveness of defibrillator-capable emergency medical services for victims of out-of-hospital cardiac arrest. *Ann Emerg Med*. 1999;34: 517–525.
4. *2002 Heart and Stroke Statistical Update*. Dallas, Tex: American Heart Association; 2002.
5. Jacobs I, Callanan V, Nichol G, et al. The chain of survival. *Ann Emerg Med*. 2001;37:S5–S1.
6. Valenzuela T, Roe DJ, Cretin S, et al. Estimating effectiveness of cardiac arrest interventions: a logistic regression survival model. *Circulation*. 1997;96:3308–3313.
7. Larsen MP, Eisenberg MS, Cummins RO, et al. Predicting survival from out-of-hospital cardiac arrest: a graphic model. *Ann Emerg Med*. 1993; 22:1652–1658.
8. National Institutes of Health News. Available at: http://www.nih.gov/news/pr/nov2003/nhlbi-11.htm. Accessed November 14, 2003.
9. Valenzuela TD, Roe DJ, Nichol G, et al. Outcomes of rapid defibrillation by security officers after arrest in casinos. *N Engl J Med*. 2000;343: 1206–1209.
10. Caffrey SL, Willoughby PJ, Pepe PE, et al. Public use of automated external defibrillators. *N Engl J Med*. 2002;347:1242–1247.
11. MacDonald RD, Mottley JL, Weinstein C. Impact of prompt defibrillation on cardiac arrest at a major international airport. *Prehosp Emerg Care*. 2002;6:1–5.
12. Page RL, Joglar JA, Koval RC, et al. Use of automated external defibrillators by a U. S. airline *N Engl J Med*. 2000;343;1210–1216.
13. Myerburg RJ, Fenster J, Velez M, et al. Impact of community-wide police car deployment of automated external defibrillators on survival from out-of-hospital cardiac arrest. *Circulation*. 2002;106:1058–1064.
14. Mosesso VN Jr, Davis EA, Auble TE. Use of automated external defibrillators by police officers for treatment of out-of-hospital cardiac arrest. *Ann Emerg Med*. 1998;32:200–207.
15. White RD, Asplin BR, Bugliosi TF, et al. High discharge survival rate after out-of-hospital ventricular fibrillation with rapid defibrillation by police and paramedics. *Ann Emerg Med*. 1996;28:480–485.
16. Capucci A, Aschieri D, Piepoli MF, et al. Tripling survival from sudden cardiac arrest without traditional education in cardiopulmonary resuscitation. *Circulation*. 2002;106;1065–1070.
17. Becker L, Eisenberg M, Fahrenbruch C, et al. Public locations of cardiac arrest: implications for public access defibrillation. *Circulation*. 1998;97: 2106–2109.
18. Frank RL, Rausch MA, Menegazzi JJ, et al. The locations of non-residential out-of-hospital cardiac arrests in the city of Pittsburgh over a three-year period: implications for automated external defibrillator placement. *Prehosp Emerg Care*. 2001;5:247–251.
19. Wash Rev Cod §70.54.310. Semi-automatic external defibrillator, duty of acquirer–immunity from liability.
20. Mosesso VN, Newman MM, Ornato JP, et al. Law enforcement agency defibrillation: proceedings of the National Center for Early Defibrillation Police AED Issues Forum. *Prehosp Emerg Care*. 2002;6:273–282.
21. Sandison T, Meischke HW, Schaeffer SM, et al. Barriers and facilitators to the prescription of automated external defibrillators for home use in patients with heart disease: a survey of cardiologists. *Heart Lung*. 2001; 30:210–215.
22. United States Census 2000: Race and Hispanic or Latino by state and county. Available at: http://www.census.gov. Accessed April 15, 2003.
23. Rea TD, Eisenberg MS, Becker LJ, et al. Emergency medical services and community mortality from heart disease. *Ann Emerg Med*. 2003;41: 494–499.
24. Meischke HW, Rea TD, Eisenberg MS, et al. Intentions to use an automated defibrillator in a cardiac emergency among a group of seniors. *Heart Lung*. 2002;31:25–29.
25. Groh WJ, Lowe MR, Overgaard AD, et al. Attitudes of law enforcement officers regarding automated external defibrillators. *Acad Emerg Med*. 2002;9:751–753.
26. Nichol G, Valenzuela T, Wells GA, et al. Potential cost-effectiveness of early defibrillation by nontraditional responders for treatment of out of hospital sudden cardiac arrest. *Circulation*. 1999;100(suppl):I-868. Abstract.
27. Foutz RA, Sayre MR. Automated external defibrillators are cost effective. *Prehosp Emerg Care*. 2000;4:314–317.
28. Pell JP, Sirel JM, Marsden AK, et al. Potential impact of public access defibrillators on survival after out-of-hospital cardiopulmonary arrest: retrospective cohort study. *BMJ*. 2002;325:515–519.
29. Zipes DP. Saving time saves lives. *Circulation*. 2001;104:2506–2508.
30. Eisenberg MS. Is it time for over-the-counter defibrillators? *JAMA*. 2000; 284:1435–1441.
31. Holmberg M, Holmberg S, Herlitz J. Incidence, duration and survival of ventricular fibrillation in out-of-hospital cardiac arrest patients in Sweden. *Resuscitation*. 2000;44:7–17.
32. Macdonald RD, Swanson JM, Mottley JL, et al. Performance and error analysis of automated external defibrillator use in the out-of-hospital setting. *Ann Emerg Med*. 2001;38:262–267.

Human factors impact successful lay person automated external defibrillator use during simulated cardiac arrest

Sonia Callejas, MD; Anne Barry, RN, MBA; Ellen Demertsidis, EMT-B; Dawn Jorgenson, PhD; Lance B. Becker, MD

Objective: **With the dissemination of automated external defibrillators in the community, there is increasing lay person use, along with less formal automated external defibrillator training and retraining. Therefore, the "ease of use" factors related to the human-device interface may be vital for successful use. We sought to determine whether human factor differences would result in differences in parameters of successful or safe use by lay persons in the setting of simulated cardiac arrest.**

Methods: **We measured parameters of successful and safe use with two automated external defibrillator devices among two groups of volunteers, those trained with a brief video tape and those without any training (completely naive). Both devices (the Philips FR2 or the HS1) are used in public access defibrillator settings. Volunteers entered a mock cardiac arrest scenario after randomization to either the naive (untrained) group or to a video-trained group.**

Results: **Both the FR2 and HS1 were found to be completely safe when used by video-trained and by naive groups of participants, with no adverse events observed (total, n = 256). For both devices, video-trained participants demonstrated high rates of successful defibrillation in the simulated testing (86% for FR2 and 89% for HS1). With the FR2, video-trained participants were significantly more successful compared with naive, untrained participants (86% vs. 48% successful use; $p < .001$). However, for the HS1, there was no significant difference in success rates for the video-trained vs. naive, untrained groups (89% vs. 87%; $p = .79$).**

Conclusions: **Both devices are safe with either video-trained or naive users. The successful use of each device is high when participants view the training videotape designed for the device. An important difference in successful use was observed for naive users where the HS1 showed improved successful use compared with the FR2. Because defibrillation in the community may increasingly be attempted by lay persons whose training is remote or who have not been trained at all, the "naive" scenario may be increasingly relevant to automated external defibrillator use. Collectively, these data support the notion that human factors associated with ease of use may play a critical factor in survival rates achieved by specific devices. (Crit Care Med 2004; 32[Suppl.]:S406–S413)**

It is a paradox of modern society that while sudden cardiac arrest kills >1,000 persons each day in the United States and remains a leading cause of death worldwide, the majority of these deaths are potentially avoidable dependent only on extremely rapid intervention (1–4). The primary therapies for sudden cardiac arrest are cardiopulmonary resuscitation and defibrillation, and a broad literature supports their lifesaving effectiveness (5–12). The majority of sudden cardiac arrests are due to ventricular fibrillation, which becomes lethal unless defibrillation of the heart is rapidly provided (3, 13). With each passing minute that defibrillation is delayed, the chances of restoration of pulse decrease by 5% to 7% (14–16). Because rapid defibrillation is the single best chance for a victim of sudden cardiac arrest, a new generation of defibrillators was developed in the 1990s. The new defibrillators were designed for non-healthcare rescuers and could automatically detect ventricular fibrillation and provide rapid defibrillation in community settings. These automated external defibrillators (AEDs) have been cleared for use and have been proven to save lives from sudden cardiac arrest in multiple settings (7–10, 17–25).

AEDs have made it possible to move rapid defibrillation into the communities where the majority of sudden cardiac arrests occur. An important realization has been the observation that emergency medical systems in most communities simply cannot afford to support the rapid response interval of <5 mins that is required for high levels of survival from cardiac arrest. Because the only currently feasible option available is to disseminate AEDs more broadly to the community where arrests occur, the public access defibrillation strategy was developed to promote the responsible dissemination of AEDs into the community (8–10, 12). With the development of AEDs and public access defibrillation systems for rapid defibrillation, more lay persons are becoming involved in defibrillation and the formal training of these increasing numbers of responders is becoming less traditional. Although training is strongly recommended for all rescuers, it is not certain that all people who attempt use of an AED will undergo training. Moreover, even with initial training, there is no assurance that skills will be retained to the time of actual use. An optimal interval for retraining may be between 6 months and 1 yr (26), but it is highly unlikely that all lay rescuers will retrain on such a schedule. Thus, it is very likely that many rescuers will not use the AED for many years

From the University of Chicago, Section of Emergency Medicine, Chicago, IL (SC, AB, ED, LBB); and Philips Medical Systems, Seattle, WA (DJ).

Supported, in part, by a grant from Philips Medical Systems.

Address requests for reprints to: Lance B. Becker, MD, 5841 S. Maryland Avenue, MC 5068, Chicago, IL 60637. E-mail: lbecker@medicine.bsd.uchicago.edu

DOI: 10.1097/01.CCM.0000139948.46663.3A

and their degree of training proficiency is uncertain. With less formal training, the intrinsic ease of use for a specific device logically becomes more and more important. Little is currently published on AED ease of use or the factors relating to the human-device interface, although such human factors have been reported to play an important role with other medical and non-medical devices.

The objective of our study was to determine whether there were differences in successful and safe use of two closely related AED devices, the Philips' FR2 and HS1, under simulated conditions of cardiac arrest. We further sought to test the two devices for two levels of trained users: (1) video-trained users—those who were trained only by watching the provided video instructions on device use; and (2) completely naive users—those who had never seen the device or watched the video instructions. Specifically, we sought to determine for the two devices under two different training levels if:

- the devices would be used in a manner that was safe to both rescuer and victim
- the device would be used in a manner that would be effective at delivery of a potentially lifesaving shock

METHODS AND DESIGN

Selection of a Simulation (Mock Arrest with Manikin) Scenario for Testing

After discussion with national experts and local Institutional Review Board experts, a mock arrest with a manikin was determined to be the most appropriate venue for the study. The consensus of experts was that allowing untrained personnel to act as rescuers in an actual cardiac arrest was ethically problematic, as would be use of AEDs on newly dead patients. In addition, a review of the human testing literature revealed that a simulated cardiac arrest in a manikin (mock arrest) was standard within the literature for AED use testing. Therefore, we designed a simulated mock arrest scenario with the use of a fully clothed adult manikin.

Study Design

Arrest Scenario. In the test scenario, all participants were told that they were about to encounter a cardiac arrest victim (a manikin) and that there was an AED available that might be used to help such a person. This scenario allowed participants to act in a manner consistent with how they would "most likely" act if such a situation occurred. In the room, each study participant found a clothed adult manikin lying on the floor, with an AED next to the manikin. The AED was set up such that it could not deliver an actual shock; rather, it simulated a patient in ventricular fibrillation and advised a shock after analysis.

When the study participant turned the device on, voice and text prompts began instructing the participant. After electrodes were applied to the manikin, the AED started rhythm analysis. After analysis, the test was ended if the participant pushed the orange button to administer the advised shock. In the event that a participant did not make progress for a period of 5 mins or if the participant wanted to quit, the test was ended. All participants had the choice to not attempt use of the AED at all.

Testing. After informed consent was obtained, participants were then read the following script:

This is a study of your response in a simulated emergency to a victim of sudden cardiac arrest. Sudden cardiac arrest is a condition that occurs unexpectedly when the heart stops pumping effectively. Defibrillation with an AED is the delivery of an electrical shock to a patient's heart. Defibrillation is intended to allow the heart to re-start itself and begin pumping again. Unless a shock is successfully delivered, the patient will die in minutes.

When you are asked, please enter the room. You will find a simulated cardiac arrest victim (a manikin). Assume that 911 has already been called. An AED will be in the room. You may use the AED to administer first aid if you wish. People may be in the room observing; you may not ask them questions or ask for help until after the test is finished. We do encourage you to voice your thoughts out loud as you help the victim. During the test we will be timing you. Keep in mind that we would like you to act in the same manner as you might during an actual emergency where timing is important and every second counts.

This is a simulation; this AED will not actually deliver a shock. The AED will be in training mode (you will see the words "training" on the screen). You cannot pass or fail this test. Anything you do will be helpful to us. A picture of the manikin will be taken after you are done. Thank you for participating.

After the test was completed participants completed a short demographic questionnaire (APPENDIX A).

Human Subjects, Inclusion, Exclusion Considerations

This study was approved by the University of Chicago Hospital's Institutional Review Board. All participants signed an informed consent form to participate and to be videotaped. Subjects were informed that the AED would not cause them harm. Subjects were given a $20 gift certificate to a local grocery store upon completion of the test.

For inclusion, participants met these criteria, by self-report:

1. no prior AED training or experience
2. minimum of 18 yrs of age

Participants may or may not have ever received cardiopulmonary resuscitation instruction at any point in their lifetime. Subjects were excluded if they:

1. were medical personnel (physicians, nurses, emergency medical technicians, etc.)
2. if they could not physically participate in study
3. if they accompanied a patient in the acute care section of the emergency department (one of the enrollment sites).

Subject Recruitment, Randomization, and AED Training

A convenience sample of study participants was recruited from two primary sites: the University of Chicago Hospital and Christ the King Catholic Church located on Chicago's south side. Participants were recruited from adult family members waiting in the emergency department waiting room, non-medical hospital employees (custodial, clerical staff, etc.), and spectators at children's athletic league games. Each device (FR2 or HS1) was tested separately. For each device, subjects were randomized (1:1) into one of the two training levels of video-training or naive groups of participants. Participants in the video-trained group were taken into a room and allowed to watch a brief video. For the FR2, the video was 8 mins in length; for the HS1, the video required 3 mins. Before video training, subjects were informed that they would be asked to demonstrate use of the AED after watching the video. If participants asked to watch the video more than once, they were allowed to do so. While watching the video, an AED was available for participants to handle and examine. By contrast, those participants randomized into the naive group were not shown the video and they were not allowed to inspect or handle the device before the test; rather, they went directly to the testing scenario. Questions from participants in either arm regarding AED operation were not addressed until after the testing was completed. The standard Quick Reference card (which contains very simple instructions) was located inside the AED case and was present during the mock test scenario.

Study Design: Devices Tested

The two devices under study were the HeartStart FR2 AED model M3861A (FR2) and the HeartStart Home Defibrillator model M5068A (HS1). For the purposes of this study, the devices were each altered such that they were incapable of delivering an actual shock. The alterations allowed the devices to respond as if the patient (manikin) required one shock for defibrillation. The instructional videos used for the trained arm of the study are excerpts from the videos currently available for FR2 (8 mins in length) and HS1 (3 mins in length) users.

Measurements, Data Collection, and Outcome Variables

In preparation for the study, a video recorder was placed on a tripod in the testing room, focused on the manikin, wired for remote control, and connected to a recording device (either video tape or digital recorder). The entire scenario was recorded for each participant. At the conclusion of each test, a Polaroid picture of the manikin's chest was also obtained. Scoring of actions and measurements occurred both during the scenario and later off-line with an independent review of each videotape and examination of each Polaroid picture of the chest (for pad placement).

A series of measurements was obtained, including if AED pads were placed successfully on the manikin's bare chest, the length of time it took to do so from entrance into the room, the length of time it took to push the shock button from entrance into the room, if the subject would have interfered with proper use of the AED and its ability to deliver a shock, and if the subject interfered with the AED, would it have resulted in an incorrect shock or no shock decision (APPENDIX B).

To determine the safety of AED use, subjects were observed for any touching of the manikin during the shock delivery; and if contact was made during delivery of the shock, would it have caused injury to the subject by causing any current exposure to the rescuer's chest. "Successful AED use" was defined as ALL of the following being completed within 5 mins after entering the room during the test scenario: 1) opening the AED case; 2) turning on the AED; 3) opening the envelope containing the pads; 4) placing the pads onto the bare chest in an acceptable position and with adequate contact; 5) plugging the pads into the AED (required for FR2); and 6) delivering the shock when instructed to by the AED. The test scenario was terminated if (a) the subject was not able to place the pads or deliver shock within 5 mins of entering room; (b) if the subject wished to terminate the event before the 5-min limit; or (c) when a shock was delivered.

After subjects left the room, the same researcher noted pad placement and scored it as acceptable, marginal, or unacceptable (see criteria below). This placement was photographed and the entire event videotaped. Videotapes were later reviewed for completion of actions, measurements of time intervals, and for possible adverse effects (i.e., touching the manikin during the delivery of a shock). An immediate oversampling of 10% of subjects videotaped was also reviewed for the accuracy of times recorded by the onsite researchers.

A second phase of measurements and scoring was performed off-line by a separate researcher (LBB) who was completely blinded to the subject's training randomization. Each photograph and videotape was again reviewed, pad placement was again scored, and all time intervals were remeasured. If the score given by the initial onsite researchers and the blinded researcher were not in agreement, then all researchers convened a third time to reach a consensus on parameters.

Pad Placement Criteria

The criteria for pads placement is based on achieving an adequate defibrillation vector. Pad position was judged by observers to be acceptable, marginal, or unacceptable. In determining placement, some placements were clearly unacceptable and these included placement of the pads on clothes or with the liner positioned between a pad and the manikin skin. Thus, minimum acceptance criteria included at least 50% of each pad in contact with the skin. Furthermore, for this study, we also require that the pad placement resemble that shown on the pad icon for adults, i.e., an anterior/anterior configuration (as opposed to anterior/posterior). Any pad positioning that failed to meet these minimal criteria was considered unacceptable.

If the above criteria were met, the following describes acceptable pad placement boundaries on the manikin. Note that the AHA defines "standard placement" as: one electrode just to the right of the upper sternal border below the clavicle and the second electrode to the left of the nipple with the center of the electrode in the midaxillary line (12). We have based our acceptable boundaries on this standard. These boundaries were also used to define the acceptable pad placement in a study by Eames et al. (27) The outline on the manikin photo below shows the areas that must contain at least one third of each pad.

Right Pad. At least one third of the pad need to be placed in the area defined by the clavicle superiorly, nipple line inferiorly, right sternal margin medially, and anterior axillary (armpit) line laterally (Fig. 1).

Left Pad. At least one third of the pad needed to be placed in the area defined by the nipple line superiorly, costal margin (bottom edge of rib cage) inferiorly, mid-clavicular line medially, and mid-axillary line laterally (Fig. 1).

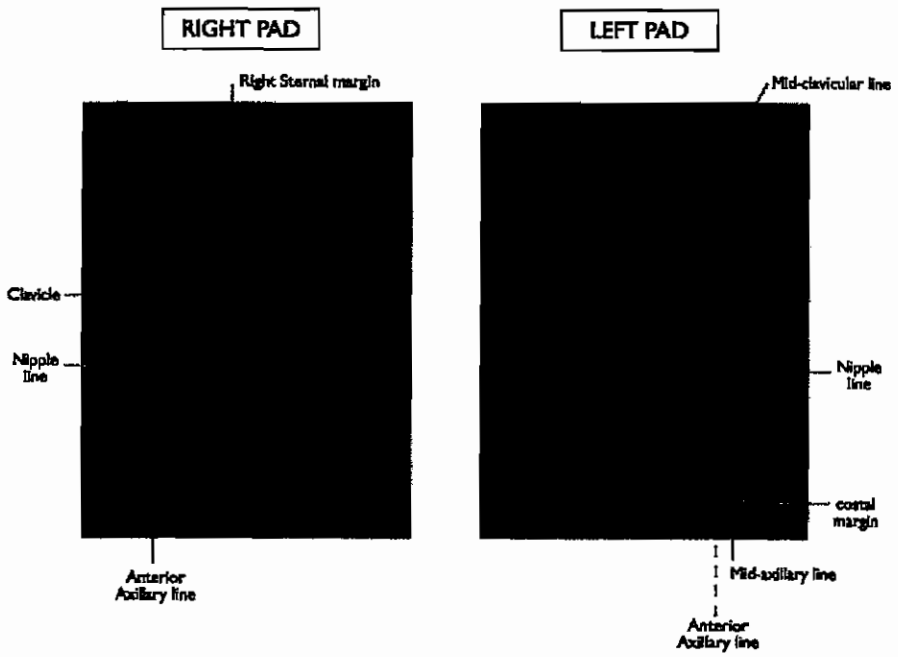


Figure 1. *Left*, at least one third of the pad need to be placed in the area defined by the clavicle superiorly, nipple line inferiorly, right sternal margin medially, and anterior axillary (armpit) line laterally; *right*, at least one third of the pad needed to be placed in the area defined by the nipple line superiorly, costal margin (bottom edge of rib cage) inferiorly, mid-clavicular line medially, and mid-axillary line laterally.

Thus, pad positions were judged as Acceptable if the placement of both right and left pads met the above criteria. Marginal was a variation of this when the strict placement criteria were not met but when the defibrillation vector of current would have likely traveled through the long axis of the heart. Unacceptable was defined as pads that overlapped, touched, were placed side by side, were too close, were placed in an anteroposterior position, had <50% of the pad in contact with bare skin, and/or had a vector that did not go across the long axis of the heart or did not go across the heart at all. Note that for overall successful use, only "acceptable" placement met the criteria; both marginal and unacceptable failed to qualify for successful use.

Data Analysis

Binomial outcome variables were compared with Fisher's exact test. Comparisons of continuous data were performed using the log-rank test with censored observations. Time intervals that were unavailable because of subjects choosing to stop without performing the relevant task (e.g., pads application) were treated as censored at the time at which the subject chose to stop. For cases in which the task was not accomplished within the 5-min time limit, the relevant interval was censored at 5 mins. Intervals between two unaccomplished events (e.g., the interval between pads application and shock) were treated as missing data. Single-sided 95% confidence limits for binomial observations were calculated according to the method of Blyth-Still-Casella. Blyth-Still-Casella limits and calculations of odds ratios were performed with StatXact, version 5.0 (Cytel Software, Cambridge, MA). Log-rank tests and calculations of medians and interquartile ranges of censored continuous data were performed with Statistica, version 6.0, StatSoft, Tulsa, OK.

Table 1. FR2 full sample (n = 132)

	Mean	n Missing Data
Age, yrs	41.3 ± 9.7	0
Male, %	27.2	0
Education, % college grad	43.9	2
Previous CPR training, %	46.2	0
Special training, %[a]	10.2	4

CPR, cardiopulmonary resuscitation.

[a]Special training indicates subjects with some self-reported allied health or rescue training, for example, those with dental hygienist and first-aid training. Nurses, emergency medical technicians, and those who had previously operated an automated external defibrillator were completely excluded from the study.

Table 2. Baseline subject characteristics by group for FR2

	Naive	Video-Trained
Age, yrs	40.7	41.5
Male, %	30.4	23.8
Education, % college grad	47.1	40.3
Previous CPR training, %	40.6	52.4
Special training, %	10.4	9.8
n	69	63

CPR, cardiopulmonary resuscitation.

RESULTS

Subjects & Recruitment

A total of 256 volunteers were studied; 132 volunteers were studied using the FR2, and of these 67 were enrolled at the University of Chicago and 65 at Christ the King. A total of 124 volunteers were studied using the HS1, with 78 of these enrolled at University of Chicago and 46 from Christ the King. The demographic makeup for the FR2 and HS1 groups is shown in the tables below. There were three cases (1 FR2 and 2 HS1) in which the study personnel stopped the participants early: each case was considered "unsuccessful," and for time intervals analysis, each case was treated as missing data. One volunteer placed the unopened AED on the chest and attempted compressions, one removed the pads cartridge, and one turned the device off.

FR2 Analysis

FR2 Sample Descriptions. The test subjects who participated in the tests of the FR2 are shown in Table 1. The subjects were randomly assigned to either using the FR2 without training (the naive condition, 52.3%) or receiving video-based training (the "video-trained" condition, 47.7%). After randomization, there were no significant differences between the two groups on any demographic or background variables, as shown in Table 2.

FR2 Use in the Naive Population. The comparison of naive with video-trained groups provides useful information about the usability of this AED in the general population (Table 3). Overall, with no training, there were no serious adverse events and slightly less than half were able to successfully deliver a shock. For the purposes of this analysis, success is

Table 3. Effect of video training on FR2 outcomes

	Naive (n)	Video-Trained (n)	Odds Ratio	p
Adequate positioning, %[a]	49.3 [38.8%] (69)	85.7 [76.5%] (63)	OR6.2	<.001
Adequate contact, %[a]	84.1 [75.9%] (69)	100 [95.8%] (63)	OR ∞	<.001
Time to any shock, secs[b]	104 [93, 123](62)	91 [79, 107](63)	N/A	<.001
Time to electrode placement, secs[b]	79 [68, 105](62)	65 [55, 77] (63)	N/A	<.001
Time from placement to shock, secs[b]	21 [19, 25] (62)	25 [23, 28] (63)	N/A	<.001
Success, %[a]	47.8 [37.4%] (69)	85.7 [76.5%] (63)	↑ OR by6.5	<.001
Test ended without shock, %[c]	10.1 [17.6%] (69)	0.0 [4.2%] (63)	↓ OR by ∞	.014
Interfere with device operation, %[c]	0.0 [3.9%] (69)	0.0 [4.2%] (63)	No Δ	NA
Adverse event, %[c]	0.0 [3.9%] (69)	0.0 [4.2%] (63)	No Δ	NA

[a]Reported as proportion [95% single-sided exact lower confidence limit] (n); [b]reported as median [inter-quartile range] (n), with data censoring; [c]reported as proportion [95% single-sided exact upper confidence limit] (n).

defined as delivering a shock before the test was stopped (5 mins), with acceptable electrode positioning and with the electrodes in good contact with the skin.

FR2 Video Effects. The video was very effective in improving the successful use of the FR2, as demonstrated in Table 3. It increased the proportion of subjects who successfully delivered a shock from 47.8% to 85.7% ($p < .001$). Video training reduced the median time to deliver a shock by 13% or 13 secs, although this is of unclear clinical significance. Intriguingly, the video seems primarily to have helped with electrode placement, significantly cutting almost 14 secs from this step. The video eliminated all pad contact problems and nearly eliminated positioning problems. One volunteer in the video-trained group and two in the naive group were noted to lightly touch the side of the mannequin at the time of the shock with a knee or clothing; this difference is not statistically significant between groups and it would not have resulted in a serious adverse effect.

HS1 Analysis

HS1 Sample Descriptions. Test subjects who participated in the tests of the HS1 are shown in Table 4.

The subjects were randomly assigned to either using the HS1 without training (naive group, 49.2%) or receiving a 3-min video-based training (the video-trained group, 50.8%). After randomization, there were no significant differences between the two groups on any demographic or background variable, as shown in Table 5.

HS1 Use in the Naive Population. The HS1 was used well by the study participants. No serious adverse events were observed, and 86.9% of untrained participants were able to successfully deliver a shock (95% one-sided lower confidence limit of 78.6%) and 88.9% of video-trained participants able to successfully deliver a shock (95% one-sided lower confidence limit of 80.7%).

Video Effects. The ability of the video to improve performance with the HS1 was limited by the HS1's ease of use among the naive (untrained) group (Table 6) for the effects of video training on HS1 outcomes. As such, there were no qualitative, statistically significant differences between the trained and the untrained populations in the adequacy of positioning and contact, and overall success was statistically indistinguishable. With the video training, there was a small but significant improvement in time to shock; the clinical significance of this 20-sec difference is uncertain but likely to be modest.

Table 4. HS1 full sample (n = 124)

	Mean	n Missing Data
Age, yrs	38.5 ± 11.8	0
Male, %	34.7	0
Education, % college grad	39.5	0
Previous CPR training, %	61.0	1
Special training, %	7.6	5

CPR, cardiopulmonary resuscitation.

Table 5. Baseline characteristics by group for HS1

	Naive	Video-Trained
Age, yrs	39.4	37.7
Male, %	39.3	30.2
Education, % college grad	42.6	36.5
Previous CPR training, %	62.3	59.7
Special training, %	5.2	9.8
n	61	63

CPR, cardiopulmonary resuscitation.

DISCUSSION

Both the FR2 and HS1 were safe when used by video-trained and naive groups of participants. This is a particularly important finding for the naive user groups because the safety of AEDs with naive users could represent a serious public health issue if inappropriate use could result in harm to a victim or rescuer. No serious adverse events, including electrical current exposure during the shock, would have affected the rescuers during these simulations. There were a few light touches of clothing or the lateral knee at the side of the manikin, but none of these would have resulted in injury. Both devices were completely safe with the two groups of users.

For both the FR2 and HS1, video-trained participants (i.e., those who viewed the instructional videotape provided with the defibrillator) demonstrate very high rates of successful AED use in the simulated testing. With the FR2 and HS1, 86% (95% exact single-sided lower confidence limit, 77%) and 89% (95% exact single-sided lower confidence limit, 81%) of participants, respectively, were able to deliver a successful defibrillation shock within 5 mins in the test scenario. To deliver a successful shock, the participant was required to attempt rescue,

Table 6. Effect of video training on HS1 outcomes

	Naive	Video-Trained	Odds Ratio	p
Adequate positioning, %[a]	88.5 [80.0%] (61)	92.1 [84.7%] (63)	↑ ORby1.5	.556
Adequate contact, %[a]	95.1 [88.2%] (61)	98.4 [93.5%] (63)	↑ ORby3.2	.361
Time to shock, secs[b]	110 [96, 125](57)	90 [75, 101](62)	NA	<.001
Time to electrode placement, secs[b]	88 [76, 106](58)	70]55, 82] (63)	NA	<.001
Time from placement to shock, secs[b]	21 [20, 21] (57)	21 [19, 22] (62)	NA	.629
Success, %[a]	86.9 [78.6%] (61)	88.9 [80.7%] (63)	↑ ORby1.2	.788
Test ended without shock, %[c]	6.6 [14.3%] (61)	1.6 [6.5%] (63)	↓ ORby4.4	.203
Interfere with device operation, %[c]	0.0 [4.4%] (61)	1.6[d] [6.5%] (63)	↑ ORby ∞	1.000
Adverse event, %[c]	0.0 [4.4%] (61)	0.0 [4.2%] (63)	No Δ	NA

[a]Reported as proportion [95% single-sided lower confidence limit] (n); [b]reported as median [inter-quartile range] (n), with data censoring; [c]reported as proportion [95% single-sided upper confidence limit] (n); [d]pad cartridge ejected; preventing analysis.

These data support the notion that human factors associated with ease of use may play a critical factor in survival rates achieved by specific [automated external defibrillator] devices.

open the device, turn on the device, plug in pads if needed, expose the chest, peel pads from backing, place the pads in an acceptable position, ensure proper contact of the pads on the skin, not interfere with analysis, and press the defibrillation button after the device had charged and indicated the need for a shock. The high rate of usability of these devices, with the very minimal training provided (8- or 3-min video tape) is an excellent result. In addition, the times to defibrillation compare favorably with those reported by emergency medical services.

The HS1 demonstrated a very high rate of successful use without any training whatsoever. Although the video-trained participants were significantly more successful in their use of the FR2 compared with naive untrained participants (86% vs. 48% successful use; $p < .001$), there was no significant difference in success rates for the video-trained vs. the naive untrained HS1 groups (89% vs. 87%; $p = .79$). With 124 subjects, the power to detect an absolute difference of 20% in this range is approximately 0.80.

This finding has important considerations for successful AED use in the community. Although we strongly support formal training for all rescuers, the practical reality is that rescuers in the future may be untrained, poorly trained, or have trained so long before actual use that they will be much closer to the naive setting than trained. The differences in successful use between devices is an important difference (48% vs. 87%) and would translate into a large clinical difference in survival. For example, the 39% difference in initial successful use would be much larger than reported differences between biphasic and monophasic waveforms, the subject of much intense scientific controversy. The human factors associated with AED use seem particularly important because many devices will only be required for actual use many months or years after purchase. It is uncertain what the skill or knowledge retention of video training will be after a long interval of time without retraining. However, it is unlikely to be worse than the rates achieved here in totally naive untrained individuals. The high rates of success observed in the HS1 without any training clearly suggest it is better suited in such settings. Collectively, these data highlight a specific need for additional human factor studies on AEDs designed to be used by minimally trained lay persons.

We express our gratitude for the assistance of Jack Iwashyna, Ping-Yu Liu, James Russell, David Snyder, and Teresa Skarr who helped provide statistical support and/or editing suggestions in the preparation of this manuscript.

REFERENCES

1. Zheng ZJ, Croft JB, Giles WH, et al: Sudden cardiac death in the United States, 1989 to 1998. *Circulation* 2001; 104:2158–2163
2. Becker LB: The epidemiology of sudden death. *In:* Cardiac arrest: The science and practice of resuscitation medicine. Paradis NA, Halperin HR, Nowak RM (Eds). Baltimore, Williams & Wilkins, 1996, pp 28–47
3. Myerburg RJ, Spooner PM: Opportunities for sudden death prevention: Directions for new clinical and basic research. *Cardiovasc Res* 2001; 50:177–185
4. Weil MH, Tang W: Cardiopulmonary resuscitation: A promise as yet largely unfulfilled. *Dis Mon* 1997; 43:429–501
5. White RD, Hankins DG, Bugliosi TF: Seven years' experience with early defibrillation by police and paramedics in an emergency medical services system. *Resuscitation* 1998; 39:145–151
6. Weaver WD, Copass MK, Bufi D, et al: Improved neurologic recovery and survival after early defibrillation. *Circulation* 1984; 69:943–948
7. Marenco JP, Wang PJ, Link MS, et al: Improving survival from sudden cardiac arrest: The role of the automated external defibrillator. *JAMA* 2001; 285:1193–200
8. MacDonald RD, Mottley JL, Weinstein C: Impact of prompt defibrillation on cardiac arrest at a major international airport. *Prehosp Emerg Care* 2002; 6:1–5
9. Cummins RO: From concept to standard-of-care? Review of the clinical experience with automated external defibrillators. *Ann Emerg Med* 1989; 18:1269–1275
10. Capucci A, Aschieri D, Piepoli MF, et al: Tripling survival from sudden cardiac arrest via early defibrillation without traditional education in cardiopulmonary resuscitation. *Circulation* 2002; 106:1065–1070
11. Caffrey SL, Willoughby PJ, Pepe PE, et al: Public use of automated external defibrillators. *N Engl J Med* 2002; 347:1242–1247
12. Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care: International consensus on science. *Circulation* 2000; 102(Suppl):I-1–I-403
13. Myerberg R, Castellanos A: Cardiac arrest and sudden death. *In:* Heart Disease. Braunwald E (Ed). Philadelphia, Saunders, 1997, pp 742–779
14. Cummins RO, Ornato JP, Thies WH, et al: Improving survival from sudden cardiac arrest: The "chain of survival" concept. A statement for health professionals from the Advanced Cardiac Life Support Subcommittee and the Emergency Cardiac Care Committee, American Heart Association. *Circulation* 1991; 83:1832–1847
15. Valenzuela T, Roe D, Cretin S, et al: Estimating effectiveness of cardiac arrest interventions: A logistic regression survival model. *Circulation* 1997; 96:3308–3313
16. Eisenberg M, Hallstrom A, Bergner L: The ACLS score: Predicting survival from out-of-hospital cardiac arrest. *JAMA* 1981; 246:50–52
17. Caffrey S: Feasibility of public access to defibrillation. *Curr Opin Crit Care* 2002; 8:195–198
18. Forrer CS, Swor RA, Jackson RE, et al: Estimated cost effectiveness of a police automated external defibrillator program in a suburban community: 7 years experience. *Resuscitation* 2002; 52:23–29
19. Groeneveld PW, Kwong JL, Liu Y, et al: Cost-effectiveness of automated external defibrillators on airlines. *JAMA* 2001; 286:1482–1489
20. Mosesso VN Jr, Davis EA, Auble TE, et al: Use of automated external defibrillators by police officers for treatment of out-of-hospital cardiac arrest. *Ann Emerg Med* 1998; 32:200–207
21. Myerburg RJ, Fenster J, Velez M, et al: Impact of community-wide police car deployment of automated external defibrillators on survival from out-of-hospital cardiac arrest. *Circulation* 2002; 106:1058–1064
22. O'Rourke MF, Donaldson E, Geddes JS: An airline cardiac arrest program. *Circulation* 1997; 96:2849–2853
23. Ornato JP, Hankins DG: Public-access defibrillation. *Prehosp Emerg Care* 1999; 3:297–302
24. White RD, Hankins DG, Atkinson EJ: Patient outcomes following defibrillation with a low energy biphasic truncated exponential waveform in out-of-hospital cardiac arrest. *Resuscitation* 2001; 49:9–14
25. Valenzuela T, Roe D, Nichol G, et al: Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. *N Engl J Med* 2000; 343:1206–1209
26. Woollard M, Whitfeild R, Smith A, et al: Skill acquisition and retention in automated external defibrillator (AED) use and CPR by lay responders: A prospective study. *Resuscitation* 2004; 60:17–28
27. Eames P, Larsen PD, Galletly DC: Comparison of ease of use of three automated external defibrillators by untrained lay people. *Resuscitation* 2003; 58:25–30

APPENDIX A

Post-Test Questionnaire

Post-test Questionnaire Participant Number_____

Thank you for participating in our simulation. Please answer the following questions:

1) age _____ years male/female

2) highest level of education completed:

Less than High school or High School/GED degree

Some College or Vocational school

College degree/post college

3) Have you ever been trained in CPR? (yes/no)

If yes, date of last training:_____

4) Do you have any special training or experiences pertinent to this test (e.g., nursing, EMT)?_____

5) Do you think that in a real emergency you would use the AED if it was available to you?

Yes___No_____Why?_____

APPENDIX B

Data Collection Form

Participant number_____

Randomization arm: trained or untrained

If trained, comments or observation regarding training_____

1) Was the manikin touched during the shock? _____

If yes, describe_____

Would the touch result in a shock across the caregiver's heart? _____

2) Did the participant harm themselves? _____

If yes, describe_____

3) Did the participant interfere with the operation of the AED?_____

If yes, describe_____

Could the interference have resulted in an incorrect shock/no shock decision?_____

4) Time from entry into the room to both electrodes positioned_____

5) Time from entry into the room to shock delivery_____

6) Were the electrode positions acceptable/marginal/unacceptable?_____

Attach Polaroid of electrode positions.

Was each electrode at least 50% in contact with the skin?_____

Describe contact_____

7) Was the test ended prior to or without electrodes attached or shock delivered? _____

If yes, describe_____

Automated External Defibrillator Use by Untrained Bystanders:

Can the Public-use Model Work?

Anthony D. Andre, PhD, Dawn B. Jorgenson, PhD, Jamie A. Froman, MBA, David E. Snyder, MS, Jeanne E. Poole, MD

Abstract

Objective. For automated external defibrillators (AEDs) to be practical for broad public use, responders must be able to use them safely and effectively. This study's objective was to determine whether untrained laypersons could accurately follow the visual and voice prompt instructions of an AED. **Methods.** Each of four different AED models (AED1, AED2, AED3, and AED4) was randomly assigned to a different group of 16 untrained volunteers in a simulated cardiac arrest. Four usability indicators were observed: 1) number of volunteers able to apply the pads to the manikin skin, 2) appropriate pad positioning, 3) time from room entry to shock delivery, and 4) safety in terms of touching the patient during shock delivery. **Results.** Some of the 64 volunteers who participated in the study failed to open the pad packaging or remove the lining, or placed the pads on top of clothing. Fifty-percent of AED2 pads and 44% of AED3 pads were not placed directly on the manikin skin compared with 100% of AED1 and AED4 pads. Adjacent pad displacements that potentially could affect defibrillation efficacy were observed in 6% of AED1, 11% of AED2, 0% of AED3, and 56% of AED4 usages. Time to deliver a shock was within 3.5 minutes for all AEDs, although the median times for AED1 and AED4 were the shortest at 1.6 and 1.7 minutes, respectively. No significant volunteer contact with the manikin occurred during shock delivery. **Conclusions.** This study demonstrated that the AED user interface significantly influences the ability of untrained caregivers to appropriately place pads and quickly deliver a shock. Avoiding grossly inappropriate pad placement and failure to place AED pads directly on skin may be correctable with improvements in the AED instruction user interface. **Key words:** automated external defibrillators; cardiac arrest; resuscitation; emergency medical services.

PREHOSPITAL EMERGENCY CARE 2004;8:284–291

Received October 17, 2003, from Interface Analysis Associates, Morgan Hill, California (ADA); Philips Medical Systems, Seattle, Washington (DBJ, JAF, DES); and Arrhythmia Service and Electrophysiology Laboratory, University of Washington Medical Center, Seattle, Washington (JEP). Revision received February 20, 2004; accepted for publication February 27, 2004.

Portions published as an abstract for the American Heart Association meeting, November 2003, Orlando, Florida.

Supported by Philips Medical Systems, Seattle, WA. Three of the authors are employees of Philips (DBJ, JAF, DES). Philips manufactures one of the AEDs studied.

Address correspondence and reprint requests to: Anthony D. Andre, PhD, Interface Analysis Associates, 16275 Monterey Street, Suite S, Morgan Hill, CA 95037. e-mail: <andre@interface-analysis.com>.

doi:10.1016/j.prehos.2004.02.004

Sudden cardiac arrest (SCA) is a leading cause of death in the United States, resulting in 250,000 to 450,000 deaths per year.[1,2] Unlike many other life-threatening illnesses and conditions, sudden cardiac arrest due to ventricular fibrillation (VF) often occurs outside of a medical setting. The estimated national survival rate is less than 5%.[3] Survival from SCA has been well correlated with the rapidity of delivering a successful defibrillatory shock. In most instances, survival is limited by the arrival time of an emergency medical service with the capacity to provide rapid defibrillation. If no bystander CPR is provided, survival decreases dramatically for every minute that transpires between collapse and successful defibrillation.[3]

Recently, access to automated external defibrillators (AEDs) has increased in public and corporate environments. For example, AEDs have been placed in airports, airplanes, shopping malls, government buildings, and various other public places.[4] In most of these environments, selected individuals (e.g., flight attendants) are trained to use the devices. However, it is clear that, to make an impact on the SCA mortality rate, these devices must be made accessible to and usable by bystanders, who may not have received prior AED training. Moreover, for these devices to be practical for broad public use, they must be designed in a way that allows people to use them quickly, easily, and effectively in the context of an unexpected and dramatic emergency medical situation. This premise represents an important challenge to AED manufacturers, many of whom have historically designed devices to be used by trained medical professionals (e.g., nurses or emergency medical technicians (EMTs]) and, more recently, by selected and trained lay individuals (e.g., flight attendants, lifeguards, or security personnel). Current-generation AEDs all have voice prompts and graphical instructions to guide the user. But it is not known whether these interfaces are sufficient in supporting a public-use model for untrained bystanders.

Given that success with lay users is a critical goal for the broad public deployment of AEDs, it is important to determine whether AEDs can be used effectively, and without undue difficulty, by the average layperson.[5,6] Our objectives were, first, to determine whether laypersons with no prior exposure or training with AEDs could accurately follow the voice and graphical prompts in a simulated cardiac arrest, and, second, to

determine if there were observable differences between four AEDs in terms of usability. The primary goal of this study was to gain insight into AED usage with untrained volunteers. This information could then be incorporated into the design improvements of AEDs. The four usability factors evaluated were: 1) number of volunteers able to remove pads from packaging, remove the liner, and apply the pads to the manikin skin, 2) appropriate pad placement as guided by the manufacturer's pad icon, 3) time from room entry to shock, and 4) safety in terms of touching the patient during shock delivery.

Methods

Volunteer Selection and Randomization

The study was conducted in April 2003 at the Usability Testing Research Facility of Interface Analysis Associates, a human factors, ergonomics, and usability consulting firm. Adult participants between the ages of 35 and 55 years were recruited via public advertisement and direct-mail letters to local businesses. Participants were prescreened via phone interview and excluded if they worked in medical or related fields, or had any exposure to, prior training, or familiarity with AEDs. Participants were also excluded if they self-disclosed any of the following: poor English comprehension, cardiopulmonary resuscitation (CPR) training within the last 24 months, sight or hearing impairment (that was not corrected), or injuries or disabilities that would prevent the participant from bending down, kneeling on the ground, or holding a package. All participants granted written permission and received $50 for participation. The study was exempted from institutional review board approval because it did not meet the criteria of an investigational study and was determined to have nonsignificant risk.

Volunteers were assigned to one of the four AED groups using a stratified random sampling technique, where gender and age were equally distributed across the four groups. Within the block randomization strata, volunteers were sequentially assigned to an AED in the order they presented for testing. Each of the four AEDs was used by a different group of 16 participants.

AEDs Used

To examine our assumption that AEDs differ in the quality of voice and graphical prompts, thus affecting usability, four different AEDs were studied: AED1 was the Philips HeartStart OnSite (Seattle, WA), AED2 was the Zoll AED Plus (Chelmsford, MA), AED3 was the Cardiac Science Powerheart (Irvine, CA), and AED4 was the Medtronic CRPlus (Minneapolis, MN). To make the simulation more realistic, clinical AEDs were used as opposed to AED trainers. The AEDs were modified so that, when the shock button was pressed, no actual shock was delivered. No other modifications were made to the AEDs. Fully charged batteries and clinical pads were used throughout the study.

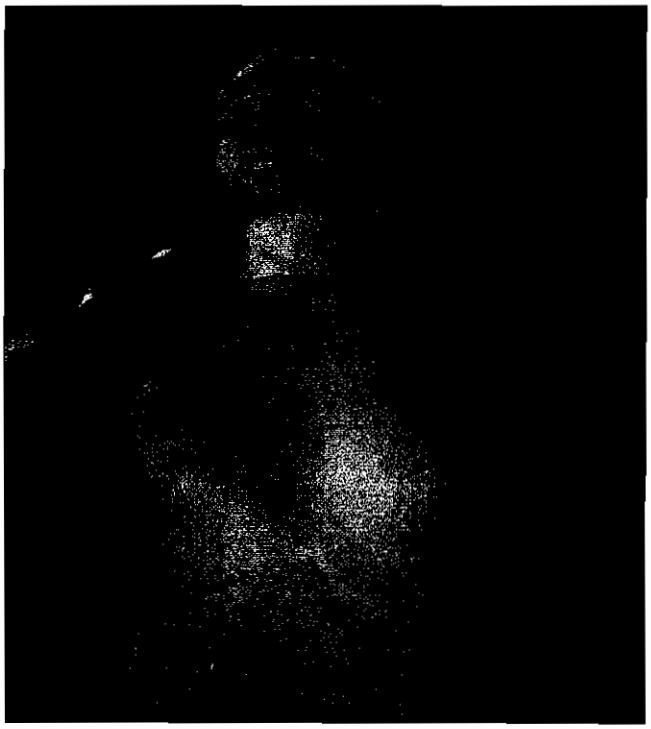


FIGURE 1. The manikin with wires stitched into the skin covering the right and left sides from the upper chest through the abdomen. The wires were attached inside the manikin to a rhythm simulator to provide the electrocardiographic (ECG) ventricular fibrillation (VF) signal. The wires allowed transmission of impedance and ECG signals to the electrode pads simulating a patient in VF.

Resuscitation Simulation Setup

The volunteers were asked to rush into a room and attempt to use an AED to resuscitate a victim of sudden cardiac arrest. Volunteers were provided with only basic information about the main functions of an AED (Appendix A) before they entered the room where they found a fully clothed, full-sized adult manikin (Resusci Anne; Laerdal Medical, Wappingers Falls, NY) on the floor and one of the four AEDs nearby. The volunteers were guided only by the instructions (the AED voice and graphical prompts) specific to that AED. The manikin was dressed in pants, a button-front shirt, and zippered jacket. Wires were stitched into the plastic skin covering the right and left sides of the manikin from the upper chest through the abdomen and attached to a rhythm simulator (Symbio AED Simulator; Symbio Corporation, Beaverton, OR) to provide the electrocardiograph (ECG) VF signal (Figure 1). The wires allowed transmission of impedance and ECG signals to the electrode pads simulating a patient in VF. The AEDs were able to detect that the

pads had been placed and analyze the signal when one pad was placed on the right side of the chest, and the other pad placed on the left side of the chest. Note that the wires intentionally covered a large area of the manikin so that the volunteers would not deduce correct pad position. The AED would then analyze the signal and advise a shock. Note that a limitation of the test setup was that if both pads were placed on the same side of the chest, only an asystolic signal was transmitted to the AED (so no shock was advised). In addition, any pad placed in the middle of the chest (where no wires were present) or with only a small portion making contact with the wire, resulted in an inability of the AED to recognize that the pads had been placed on the manikin. Two remote-controlled video cameras were used to record the AED use; three observers were located in a control room behind a one-way mirror.

Assessment of Usability Factors

The number of volunteers who were able to remove pads from packaging, remove the liner, and apply the pads to the manikin skin was recorded for each AED and volunteer. The "ideal" pad position was determined before the study began based on each manufacturer's recommended location, as depicted on the pad icon for each AED. The position was agreed on by three observers (ADA, DBJ, JEP) and then a template defining the "ideal" pad location for each AED was created from a plastic sheet laid over the manikin thorax. This was then used to measure pad displacement from the ideal by placing the sheet over the pads after each trial and measuring the discrepancy between actual pad placement and the template-indicated ideal pad location. Measurements were made from the ideal center of the template pad to the actual center of the pad placed by the volunteer on the manikin. Electrode pad placement measures were collected immediately after each trial. Digital photos were also taken of pad positions after each trial, and these were later reviewed to further record and verify pad displacement, contact with manikin skin, and removal of pad liners.

The number of volunteers who were able to proceed through the trial to the point of pushing the shock button was recorded for each of the AEDs tested. The time from entry into the room until the AED was turned on, pads were positioned, a shock was advised, and the shock was delivered was recorded. Timing was accomplished via video recording and stopwatch. Safety was defined in terms of instances of users' touching the manikin during shock delivery. The trial ended after the volunteer had successfully delivered a shock, 5 minutes had elapsed from entry into the room, the device did not advise a shock or entered the CPR pause mode, or the volunteer expressed a desire to stop.

TABLE 1. Demographics of Study Participants

Device	AED1	AED2	AED3	AED4
Age in years (mean ± SD, n = 16)	44 ± 7	43 ± 7	45 ± 6	43 ± 5
High school/vocational	3	3	5	5
Post–high school	13	13	11	11

AED = automated external defibrillator; SD = standard deviation.

Statistical Analysis

The statistical analysis was performed with StatXact, version 5 (Cytel Software, Cambridge, MA) and Statistica, version 6 (StatSoft, Tulsa, OK). Outcome variables were tested for statistical significance of overall effect using exact nonparametric methods. The Fisher-Freeman-Halton test was employed for categorical data, and the Kruskal-Wallis analysis of variance was used for continuous variables. If a statistically significant overall effect was identified, between-group comparisons were performed using Fisher's exact test for categorical data and exact Mann-Whitney tests for continuous data.

RESULTS

Volunteer Demographics

There were 64 volunteers who participated in the study. The occupations of the volunteers spanned a wide range of industries and activities, including teachers, security guards, sales representatives, software developers, office administrators, waitresses, and truck drivers. Each AED group comprised eight male and eight female participants. Table 1 summarizes the demographic characteristics of the four volunteer groups. The median age of the volunteers was 44 years; the distributions of ages were not statistically significantly different between the groups ($p = 0.70$). The educational levels of volunteers were not statistically significantly different between the groups ($p = 0.77$).

Simulation Setup and Data Collection

In several instances, pads were placed on the manikin in areas where no wires were present. One volunteer (using AED4) placed the right sternal pad over the sternum where there were no wires; we included the pad-placement data from this case, but time-to-shock data were not available. In two other cases (one AED1 and one AED4), both pads were placed on the same side of the chest, so again pad-placement data were included but there were no time-to-shock data. In a final case (AED1), pads were properly placed on the

Table 2. Shock Delivery and Pad Placement Measures

Device	AED1	AED2	AED3	AED4
Pads applied to skin	*100% (16/16)	50% (8/16)	56% (9/16)	*100% (16/16)
Pad displacement error (cm)	†S 4.8 [3.0–5.9] A 4.5 [2.3–7.0]	†S 3.5 [2.8–5.5] A 3.5 [2.4–5.5]	S 6.5 [3.8–8.4] A 6.5 [4.4–10.0]	S 7.5 [4.6–16.3] A 12.3 [2.8–17.4]
Separation of pads (cm)	‡16.0 [12.0–17.9]	‡15.0 [13.0–15.3]	11.0 [7.3–12.8]	5.5 [3.8–13.8]
% Pads placed adjacent	†6% (1/16)	†11% (1/9)	†0% (0/13)	56% (9/16)
% Successful shock delivery	*100% (14/14)	§44% (7/16)	75% (12/16)	*100% (14/14)
Time to shock (sec)	*99 [84–109] $n = 14$	§210 [170–287] $n = 7$	132 [96–196] $n = 12$	*93 [78–115] $n = 14$

S = right upper parasternal pad; A = left apex pad, median [interquartile].
*$p < 0.05$ vs AED2 and AED3.
†$p < 0.05$ vs. AED4.
‡$p < 0.05$ vs. AED3 and AED4.
§$p < 0.05$ vs. AED3.

manikin chest, but the AED did not recommend a shock; this was subsequently identified as caused by an ECG artifact originating within the test setup, so only pad-placement data were included.

In terms of the number of volunteers able to remove pads from packaging, remove the liner, and apply the pads to the manikin skin, Table 2 contains a summary of the pad-placement results. Significant proportions of volunteers were unable to attach pads directly to the manikin skin (50% AED2 and 44% AED3). Many volunteers did not remove the pads from the packaging, placed the pads on top of clothing, or left liners on the pads. Two of the AED2 users and three of the AED3 users never managed to open the pad package. Another two AED2 users and four AED3 users failed to remove the liner from one or both electrode pads. Five AED2 users placed the pads directly over the victim's clothes (see Figure 2). Further, we observed that, in 31% of AED4 uses, participants inadvertently pulled the pad connector plug out of its socket while attempting to open the pad package.

In terms of appropriate pad location placement as guided by the manufacturer's pad icon, Table 2 summarizes the average displacement from ideal center for apical and right sternal pads for all four AEDs tested. The greatest displacement error (12.3 cm) was noted with AED4. More important was the observation that, in some instances, pads were placed in positions that were *adjacent* to each other, meaning locations 1) side by side, 2) on the same side of the chest, 3) at the same vertical level, or 4) touching each other. Our results demonstrated inappropriate pad adjacency in 56% of uses of AED4 (Figure 3) uses versus a range of 0% to 11% with the other devices. Table 2 also contains the measured separation between the pads. Median separation was as low as 5.5 cm (AED4). The close proximity of the pads resulted primarily from placement of the apical pad medially and cranially.

For the time from room entry to shock delivery, nine of the 16 users of AED2 (56%) and four of the 16 users of AED3 (25%) failed to administer a shock to the simulated victim (Table 2). Three of the four AED3 users who failed to remove the liner from one of the pads still received a shock command, because the AED3 liner has small holes that allow a fraction of the pad to contact the skin even with the liner left on. These were counted as successful shock deliveries, though appropriate energy delivery for defibrillation would likely be severely compromised.

In contrast, AED1 and AED4 users were successful in delivering a shock in all valid trials. In the time it took users to deliver a shock, AED1 and AED4 were mathematically similar (Figure 5, Table 2). The median times were well under 2 minutes, at 99 and 93 seconds, respectively. The other two devices were significantly slower, with users of AED3 taking 132 seconds (just over 2.0 minutes), and users of AED2 taking 210 seconds (or 3.5 minutes). We also looked at time per AED task for each of the four AEDs, broken down into

Figure 2. An example of electrode pads placed over the victim's clothes.

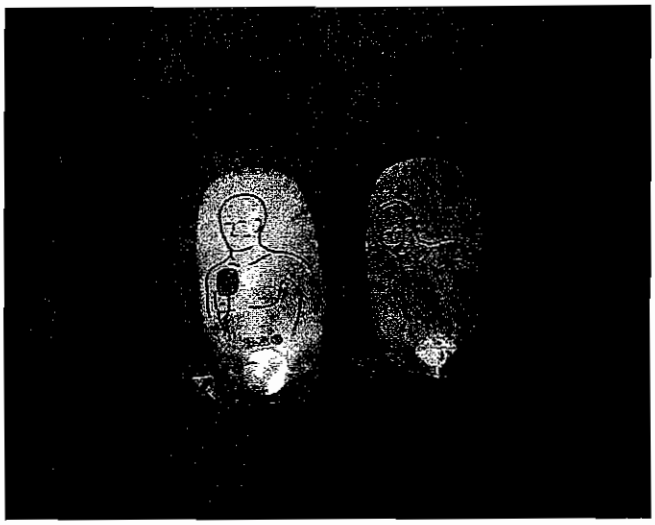


FIGURE 3. An example of electrode pads placed adjacent to each other.

five time segments: AED power on, first pad on (attached), second pad on, shock command given, and shock delivered. As shown in Figure 5, the "lost" time for AED2 and AED3 compared with AED1 and AED4 was primarily in achieving pad placement.

For safety in terms of touching the patient during shock delivery, in three cases the volunteer was in contact with the manikin during shock delivery. In two cases (AED4), the contact was clothing to clothing, with the participant's right knee touching the manikin's right arm and the participant's right knee touching the manikin's right knee. In one case (AED2), the participant's right knee touched the manikin's right hand (clothing-to-skin contact).

DISCUSSION

Success with untrained users is a critical goal for the broad public deployment of AEDs. We investigated the ability of untrained volunteers to use an AED without prior exposure or training with an AED. Specifically, we wanted to observe how well a layperson could initiate usage of the AED and follow through with the given directions to the point of delivering a shock. Previous studies have suggested that this is possible with some AEDs.[7–11] For example, the majority of patients who survived a sudden cardiac arrest in Chicago airports over a two-year period were saved by persons who had no duty to act and no prior training in the use of AEDs.[7] Another study showed that naive 6th graders could successfully employ an AED.[8] A recent study by Eames et al. compared ease of use of three AEDs by untrained laypeople.[9] They found statistically significant differences among AEDs, including time to shock and pad position. The Eames study differs from this study in that they used AED training devices (Larsen P, personal communication, 2003), they scored all pad positions against the same criteria regardless of manufacturer's instructions, and volunteers randomly used all devices, thus introducing learning effects.

In this study of simulated cardiac arrest, we observed several important mistakes made by untrained volunteers when attempting to follow the voice and visual AED prompts. A specific focus of this study was the ability of participants to correctly position pads on the manikin. Obvious errors that would affect defibrillation success included failure to remove the pads from the packages or to remove the pad backings, or placing the pads on top of the clothes. Pad location was evaluated and compared with the manufacturer ideal location as directed by the pad icons. "Correct" or "ideal" position varies between the four AEDs, but they share the similarity of a right upper sternal and a left apical pad position. Displacement from ideal center may not have a clinical significance as long as an appropriate vector for defibrillation can be maintained. We therefore highlighted pad displacement that might raise concerns in a true clinical setting. Those were the instances when pads were placed adjacent to each other, often at the same level on the chest or on the same side of the chest. One of the AEDs (AED2) has a fixed connection between the apical and sternal pads that prevented the two pads from being placed in adjacent positions. Whether a fixed pad position would be adequate for a variety of different thorax sizes is unknown.

Another observation was the tendency to displace the left apical pad medially and cranially, which if anything would be more likely to decrease defibrillation efficacy as the two pads come into proximity of each other and the apical pad moves *away from* overlying the left ventricular myocardium, particularly in patients with dilated hearts. One wonders if this tendency, as well as the instances of pad adjacency, is derived from television scenarios of defibrillation where handheld paddles are usually placed in right upper and left upper parasternal positions. The risk of current shunt between the pads is a function of distance and the resulting vector defined by the specific pad placement. Caterine et al. found that, when one electrode was placed in the right parasternal position and the other within 2 cm in the left parasternal position, the theoretical percentage of current traversing the heart was significantly reduced.[12]

Pad placement has been well documented as the Achilles' heel for lay responders and those with advanced training alike.[13–15] Heames et al. tested the ability of doctors to position paddles correctly on a manikin and found 35% of the sternal and 78% of the apical paddle placements to be incorrect.[13] Meischke et al. reported that the most difficult task in a simulation study with seniors was correct pad placement.[14]

Approximately 17% following initial training and 48% at the retesting three months later did not correctly place the pads on the manikin. Mattei et al. tested untrained nurses and physiotherapists and reported that 53% failed to initially position the pads correctly, although all participants were able to place the pads appropriately following training.[15] This study is consistent with these previous findings and extends them to the realm of public use. We found that the least pad placement error occurred with AED1 both in terms of displacement from ideal center and in no instances of pad adjacency error. This probably is because of the very specific voice prompt "Look carefully at the pictures on the white adhesive pads ... place pads exactly as shown in the picture" and the fact that both pad placement icons are shown on each pad, giving users a good sense of the relative placement of the two pads (Figure 4). This was also true of AED2 and AED3, which had a low instance of pads' being placed in adjacent positions. In addition, AED1 includes sensor technology that detects the current action of the user and adjusts the voice instructions to match that action. We observed many instances with the other three devices where the audio instruction and the user's current action were incongruent.

An important issue in AED usage is how quickly a shock can be delivered. Brillhart et al. used AED recordings and emergency medical services (EMS) reports to study the time elapsed for EMTs to arrive on scene and recognize cardiac arrest to shock delivery.[16] They found the median time for the EMTs was 51 seconds. The investigators suggested a 1-minute goal and a 90-second minimum standard for time to first shock by EMTs using AEDs in the field. Although most of the users of the AEDs in this study were able to deliver a shock in less than 2.0 minutes, the users of AED2 took 3.5 minutes. One difference is that users of this AED found it difficult even to turn on the device (Figure 5). Nevertheless, the time to shock for all the devices tested, if used in an actual SCA, would likely result in a significant time reduction compared with that which can be achieved by awaiting the arrival of most EMS responders.[17]

One concern that has been raised regarding layperson usage of an AED is whether the rescuer might inadvertently receive a shock by touching the victim. We observed only three instances of participants' contacting the manikin during the simulated shock; none of these instances would likely cause serious harm. In each case, the volunteer's knee or hand made a single point of contact with the victim's clothes during shock delivery.

Resuscitating a victim of cardiac arrest involves much more than operation of an AED. Recognizing the cardiac arrest, calling EMS, and performing CPR as a bystander are all important steps; however, timely defibrillation is a critical factor for those patients in VF. Defibrillators that are to be used by lay responders should be designed from a human-centered perspective. That is, they should provide useful, timely guidance, include effective and salient graphics, and induce acceptable levels of workload and stress. This study demonstrated that all AEDs share a common set of functionality and, if used correctly, result in the delivery of a shock to the victim, but the objective experiences of the users are likely to vary greatly based on the presence or absence of critical usability design attributes.

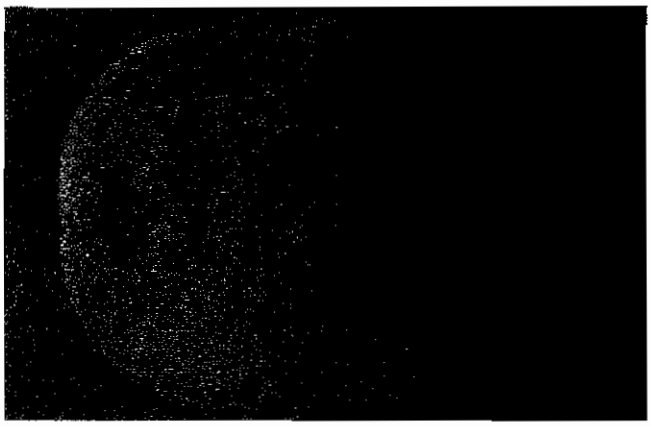


FIGURE 4. Icon for AED1 (one of the four automated external defibrillators studied) depicting the relative locations for both pads.

To be effectively used by untrained laypersons, AEDs targeted for use by the lay public must be tested to determine whether they are intuitive enough. In the present study, we found that performance suffered for AEDs that 1) had to be manually turned on, 2) provided a minimal and implicit set of instructions, 3) incorporated components that easily became loose or detached, 4) did not provide an image of both pads on the pad placement graphic, and 5) failed to guide the user explicitly through the pad-placement process. These five critical usability design attributes accounted for nearly all performance and behavioral deficiencies observed in this study.

LIMITATIONS

This study is limited in that it was a simulation of a cardiac arrest. However, an actual emergency situation would likely increase the stress and confusion of the rescuer and amplify some of the results found here. A limited number of volunteers participated in this observational study, which was not powered to test any specific hypothesis. Training would likely increase the ability of users to place pads appropriately and deliver a shock and is recommended in all AED manufacturers' labeling. However, in the context of public access, defibrillation users may very well be

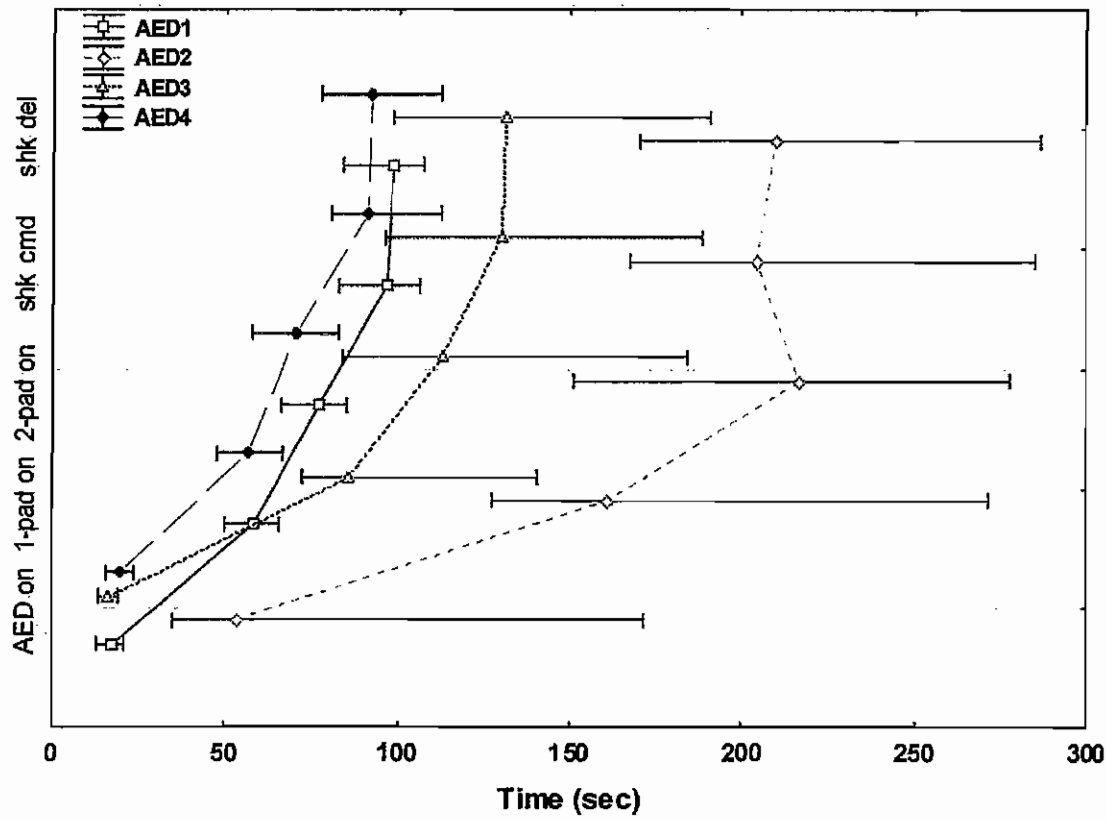


FIGURE 5. Breakdown of automated external defibrillator (AED) tasks and timing for each device, median [interquartile range]. Note that pad application times are inclusive of all uses with pads placed on clothes and liners left in place, even if shocks were not delivered.

untrained.[7] Further, issues with training retention may limit the ability of a previously trained caregiver to use an AED.

CONCLUSIONS

Because laypersons and innocent bystanders with no prior exposure to, training with, or understanding of AEDs may use them in public settings during an unexpected emergency, the devices must be intuitive to use. We found observable differences among the AEDs we studied and have identified a number of AED pad-placement errors that could theoretically lead to ineffective defibrillation. Untrained laypersons require a categorically different level of guidance and design support than do traditional medical professionals or trained laypersons. Pad icon graphics, voice prompts, and industrial design significantly influence the ability of caregivers to deliver a shock appropriately and quickly. Although the majority of our study's rescuer volunteers were able to deploy the AED to the point of shock delivery, not all AEDs were able to guide the rescuer through AED use in a manner that would ensure the highest likelihood of successful defibrillation. We conclude that untrained laypersons can safely and effectively use an AED in the public-use context simulated in this study only when a clear, comprehensive, and explicit instruction scheme is employed.

References

1. Zheng Z, Croft JB, Giles WH, Mensah GA. Sudden cardiac death in the United States, 1989 to 1998. Circulation. 2001;104:2158–63.
2. Myerburg RJ. Sudden cardiac death: exploring the limits of our knowledge. J Cardiovasc Electrophysiol. 2001;12:369–81.
3. American Heart Association. Heart Disease and Stroke Statistics—2003 Update. Dallas, TX: American Heart Association, 2002.
4. Jorgenson DB, Skarr T, Russell JK, Snyder DE, Uhrbrock K. AED use in businesses, public facilities and homes by minimally trained first responders. Resuscitation. 2003;59:225–33.
5. Caffery S. Feasibility of public access to defibrillation. Curr Opin Crit Care. 2002;8:195–8.
6. Marenco JP, Wang PJ, Link MS, Homoud MK, Estes NA 3rd. Improving survival from sudden cardiac arrest, the role of the automated external defibrillator. JAMA. 2001;285:1193–200.
7. Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Public use of automated external defibrillators. N Engl J Med. 2002; 347:1242–7.
8. Gundry JW, Comess KA, DeRook FA, Jorgenson D, Bardy GH. Comparison of naive sixth-grade children with trained professionals in the use of an automated external defibrillator. Circulation. 1999;100:1703–7.
9. Eames P, Larsen PD, Galletly DC. Comparison of ease of use of three automated external defibrillators by untrained lay people. Resuscitation. 2003;58:25–30.

10. Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. N Engl J Med. 2000; 343:1206–9.
11. Lawson L, March J. Automated external defibrillation by very young, untrained children. Prehosp Emerg Care. 2002;6:295–8.
12. Caterine MR, Yoerger DM, Spencer KT, Miller SG, Kerber RE. Effect of electrode position and gel-application technique on predicted transcardiac current during transthoracic defibrillation. Ann Emerg Med. 1997;29:588–95.
13. Heames RM, Sado D, Deakin CD. Do doctors position defibrillation paddles correctly? Observational study. BMJ. 2001; 322:1393–4.
14. Meischke HW, Rea T, Eisenberg MS, Schaffer S, Kudenchuk P. Training seniors in the operation of an automated external defibrillator: a randomized trial comparing two training methods. Ann Emerg Med. 2001;38:216–22.
15. Mattei LC, McKay U, Lepper MW, Soar J. Do nurses and physiotherapists require training to use an automated external defibrillator? Resuscitation. 2002;53:277–80.
16. Brillhart AM, Rea TD, Becker L, Eisenberg MS, Murray JA. Time to first shock by emergency medical technicians with automated external defibrillators. Prehosp Emerg Care. 2002;6:373–7.
17. Becker LB, Ostrander MP, Barrett J, Kondos GT. Outcome of CPR in a large metropolitan area—where are the survivors? Ann Emerg Med. 1991;20:355–61.

Appendix A

Participant Instructions

This is a study of your response in a simulated emergency to a victim of sudden cardiac arrest. Sudden cardiac arrest is a condition that occurs unexpectedly when the heart stops pumping effectively. Soon you will be asked to enter a room across the hall where you will find a simulated cardiac arrest victim (a mannequin). I hope this is never the case, but let's assume it is a friend of yours who suffered a cardiac arrest while you were out shopping together. You should assume the following:

- 9-1-1 has already been called.
- The victim is not breathing and does not have a pulse.

In the room you will also find an Automatic External Defibrillator, or AED device. Defibrillation with an AED is the delivery of an electrical shock to a patient's heart. Defibrillation is intended to allow the heart to restart itself and begin pumping again. Unless a shock is successfully delivered, your friend will die in minutes. I want you to use this AED to attempt to save your friend's life.

People will be observing and videotaping your actions; but you may not ask them questions or ask for help until after you have saved your friend. During the test we will be timing you. Keep in mind that we would like you to act in the same manner as you might during an actual emergency where timing is important and every second counts.

Note that this is a simulation; you will not actually deliver a shock, but the product will work in all other aspects. You cannot pass or fail this test. I only ask that you act with the same sense of urgency, determination, and care that you would bring to a real emergency situation of this kind.

Some final things to note:

- When you enter the room, the victim will be lying on the floor in the center of the room.
- The AED device will be located on a chair to your left.
- You already know that the victim is not breathing and has no pulse and therefore you should immediately use the AED rather than initiate any form of CPR. 9-1-1 has already been called.
- Remember, when I open the door for you across the hall, you are about to attempt to save a life. Your goal should be to deliver a shock to your friend's heart as quickly as possible. Every second counts.

ELSEVIER

Resuscitation 63 (2004) 43–48

RESUSCITATION

www.elsevier.com/locate/resuscitation

Automated external defibrillation by untrained deaf lay rescuers

Claudio Sandroni [a,*], Peter Fenici [b], Maria Luisa Franchi [c], Fabio Cavallaro [a], Claudio Menchinelli [d], Massimo Antonelli [a]

[a] *Department of Anaesthesiology and Intensive Care, Catholic University School of Medicine, Rome, Italy*
[b] *Department of Emergency Medicine, Catholic University School of Medicine, Rome, Italy*
[c] *Italian Sign Language Interpreter, SILIS Centre, Rome, Italy*
[d] *Occupational Medicine Department, Italian National Olympic Committee (CONI), Rome, Italy*

Received 2 June 2003; received in revised form 24 February 2004; accepted 12 March 2004

Abstract

Introduction: The use of automated external defibrillators (AEDs) by lay rescuers can reduce the time to defibrillation, improving survival after out-of-hospital cardiac arrest. However, some people have hearing defects that can prevent them from understanding the AED verbal prompts. Moreover, even rescuers with normal hearing function may not easily understand the AED verbal prompts when operating in a noisy environment. This study was designed to assess the capability of rescuers to defibrillate effectively using an AED which included visual prompts. *Methods and results:* Nine deaf employees with no previous experience in basic life support (BLS) or defibrillation were asked to defibrillate a manikin following the text prompts of a Heartstart FR2+ AED. Subjects were tested before and after a 6 h BLS–AED course carried out with the help of a sign language interpreter. Before training, seven out of nine deaf subjects (78%) were able to defibrillate, eight out of nine subjects (89%) placed the pads correctly, and the mean time to defibrillation was 101.6 ± 28.4 s. After the course, all subjects were able to complete the defibrillation sequence and place the pads correctly. The mean post-course time to defibrillation was 47.8 ± 5.4 s ($P < 0.001$). None of the nine subjects touched the manikin during charging of the defibrillator and shock delivery before or after the course. *Conclusions:* This study demonstrates that untrained deaf rescuers can use AEDs appropriately providing that the defibrillator has visual instructions. Training improves defibrillator use and reduces time to defibrillation.

Keywords: Automated external defibrillator (AED); Cardiopulmonary resuscitation; Defibrillation; Training

Resumo

Introdução: A utilização de desfibrilhadores automáticos externos (DAE) por leigos pode apressar a desfibrilhação, permitindo a recuperação de um maior número de vítimas de paragem cardiorespiratória (PCR) em contexto pré-hospitalar. Os leigos com limitações auditivas estão impedidos de aceder ás orientações sonoras emitidas pelo DAE. Aliás, mesmo os reanimadores sem limitações auditivas podem ter dificuldade em seguir as indicações do aparelho, sobretudo em ambientes com elevados níveis de ruído. Este estudo foi desenhado para a avaliar a eficiêneia na desfibrilhação, usando DAEs com orientações visuais. *Métodos e resultados*: Nove leigos com limitações auditivas e sem treino prévio em suporte básico de vida (SBV) ou desfibrilhação foram solicitados a desfibrilhar um manequim seguindo orientações escritas de um DAE Heartstart FR2. Estes operadores foram avaliados antes e após uma formação de 6 horas em SBV e DAE, com o apoio de um interprete de linguagem gestual. Antes do treino, sete dos nove (78%) avaliados conseguiram desfibrilhar; oito dos nove (89%) colocaram as pás de forma adequada e o tempo médio até à desfibrilhação foi de 101.6 ± 28.4 segundos. Depois da formação, todos os avaliados colocaram as pás correctamente e completaram a desfibrilhação de forma adequada. O tempo médio para a desfibrilhação foi, nesta fase de 47.8 ± 5.4 s ($P <$ 0.001). Nenhum dos sujeitos tocou no manequim durante a fase de carga do DAE ou na fase de choque, quer antes quer depois da formação. *Conclusão*: este estudo demonstra que reanimadores com limitações auditivas e sem treino prévio, podem manusear DAEs de forma adequada, seguindo orientações visuais. O treino melhora a capacidade de desfibrilhar e reduz o tempo de desfibrilhação.

* Corresponding author. Present address: Department of Anesthesiology and Intensive Care, Catholic University School of Medicine, Largo Gemelli 8, 00168 Rome, Italy. Tel.: +39-06-30154490; fax: +39-06-3013450.
E-mail address: sandroni@rm.unicatt.it (C. Sandroni).

0300-9572/$ – see front matter © 2004 Elsevier Ireland Ltd. All rights reserved.
doi:10.1016/j.resuscitation.2004.03.010

Resumen

Introducción: El uso de desfibriladores automáticos externos (AEDs) por reanimadores legos pueden reducir el tiempo a desfibrilación, mejorando la sobrevida después del paro cardíaco súbito extrahospitalario. Sin embargo, algunas personas tienen defectos de audición que puedan evitar que entiendan las indicaciones verbales. Es mas, aun los reanimadores con función auditiva normal pueden tener dificultad para entender las indicaciones verbales del AED cuando lo operan en un ambiente ruidoso. Este estudio fue diseñado para evaluar la capacidad de los reanimadores para desfibrilar efectivamente usando un AED que incluye indicaciones visuales. *Métodos y resultados*: Se solicitó a 9 empleados sordos, sin experiencia previa en soporte vital básico (BLS) o en desfibrilación, que desfibrilarán a un maniquí siguiendo las instrucciones de texto de un Heartstart FR2+ AED. Los sujetos fueron probados antes y después de un curso de 6 hrs de BLS AED llevado a cabo con la ayuda de un interprete de lenguaje de señales. Antes del entrenamiento, 7 de 9 sujetos sordos (78%) fueron capaces de desfibrilar, 8 de 9 sujetos (89%) colocaron adecuadamente los electrodos, y el tiempo promedio a la desfibrilación fue 47.8 ± 5.4s ($P < 0.001$). Ninguno de los 9 sujetos tocaron el maniquí mientras se cargaba el desfibrilador y la entrega de la descarga antes y después de el curso. *Conclusiones*: Este estudio demuestra que reanimadores sordos no entrenados pueden usar un AED apropiadamente si se hace que el desfibrilador tenga instrucciones visuales. El entrenamiento mejora el uso del desfibrilador y reduce el tiempo a la desfibrilación.

Palabras clave: Desfibrilador automático externo (AED); Reanimación cardiopulmonar; Desfibrilación; Entrenamiento.

1. Introdnction

Cardiovascular disease is the leading cause of death in most Western countries [1,2]. In the United States, sudden out-of-hospital cardiac arrest accounts for more than 350,000 cases of death annually [3]. The majority of these cardiac arrests are due to ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT) [4–6]. The time interval between the onset of VF/VT and the delivery of the first shock is the main determinant of survival. Unfortunately, due to long response times of emergency medical systems, the overall survival rate from out-of-hospital cardiac arrest rarely exceeds 5% [7–9]. To reduce the collapse-to-defibrillation interval, automated external defibrillators (AEDs), which provide antomated rhythm analysis, have been developed. AED use is guided by visual and vocal prompts and requires minimal training.

Recent studies have demonstrated that AEDs can be used successfully in public places, not only by trained non-medical personnel, sueh as flight attendants [10], easino

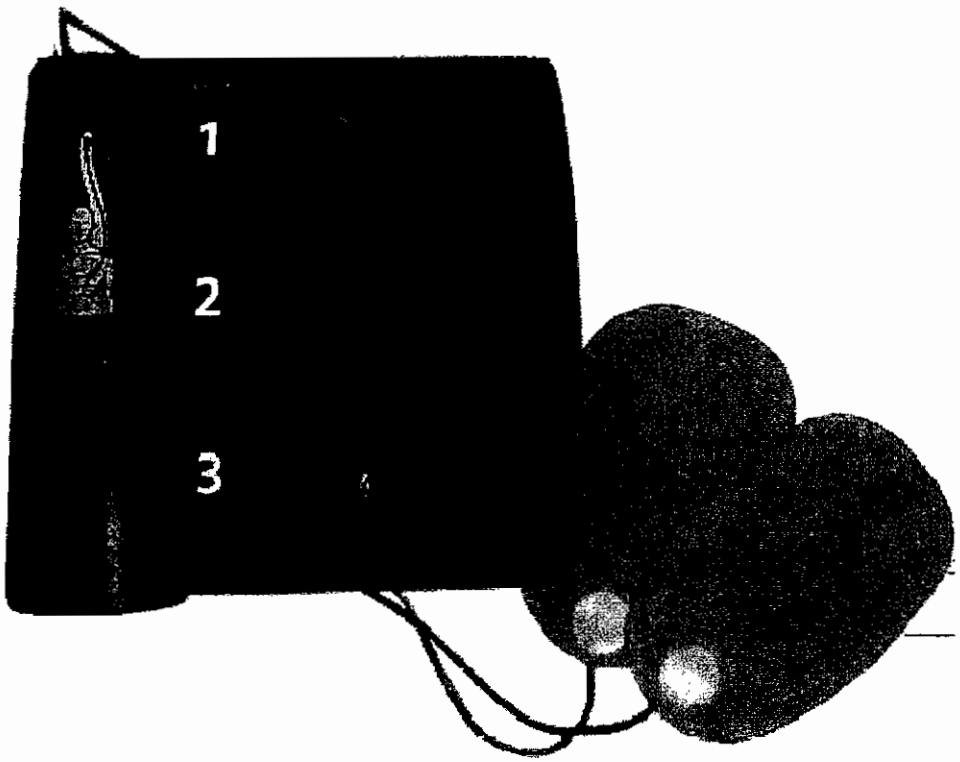


Fig. 1.

workers [11] and police officers [12], but also by untrained bystanders [13]. Moreover, effective AED use by untrained healthcare professionals [14] and sixth-grade children [15] has been demonstrated in simulated cardiac arrest scenarios (Fig. 1).

Success of projects for public access defibrillation (PAD) requires that every citizen can perform defibrillation using an AED. However, many people have physical limitations, such as visual or hearing defects, that can prevent them from understanding the AED prompts. If trained appropriately, deaf people are capable of learning and performing basic life support (BLS) effectively [16] but their ability to perform automated external defibrillation has not been evaluated before. Besides the common audio prompts, some AEDs also have visual and text prompts that can be understood by deaf users and these can be also very useful for normal hearing users operating in a noisy environment.

The aim of our study was to assess the capability of deaf rescuers to use an AED with visual/text prompts in a simulated cardiac arrest scenario before and after a BLS–AED course.

2. Material and methods

2.1. Subject recruitment

Informed consent was obtained by the subjects before the test and comprehension was verified by an Italian Sign Language (LIS) interpreter.

Ten deaf employees of the Italian National Olympic Committee (CONI) in Rome were recruited. They were required to have at least a secondary school degree and no previous experience in BLS or AED use. Nine of them gave consent to participate. None of the subjects had visual handicaps. Two used a hearing aid and were asked to remove this before taking part in the study. Subjects were informed that the performance would be evaluated in a simulated cardiac arrest scenario, and that they would be videotaped.

2.2. Manikin

The Skill Reporter Laerdal Resusci Anne manikin was used for all scenarios. The manikin includes an ECG simulator that can reproduce the ECG signal on two areas of the chest corresponding to the two anterior–lateral sites for defibrillator paddle placement. The manikin also includes a display which measures the amplitude of chest compressions and ventilations given by the trainee, allowing self-correction of BLS performance. During the test, the manikin was placed on the floor and fully dressed.

2.3. Defibrillator

The Heartstart FR2+ AED (Fig. 1) (manufactured by Philips Electronics North America Corp. and distributed in Italy by Laerdal Italia s.r.l.) was used to defibrillate the manikin. This AED delivers a 150 J truncated exponential waveform shock adjusted according to chest impedance. The device measures 6.6 cm × 21.8 cm × 21.8 cm and weighs 2.1 kg. ECG recording and defibrillation is performed using two disposable self-adhesive defibrillation pads with an integrated cable and connector. The pads are put in an envelope that has to be peeled off before use, and their adhesive side is covered by a protective paper. The other side of the pads has pictures indicating the correct pad placement on the chest. This model of AED has not only voice prompts, that are delivered by a loudspeaker, but also visual prompts, which consist of brief text messages displayed on a liquid-crystal screen on the front of the device (Table 1). The volume of the voice prompts was set to zero. Other visual messages consist in a flashing light indicating the plug for the pad connector and another flashing light built in the "shock" button that lightens when it is time to deliver the shock. The ECG recorded by the paddles is displayed on the front LCD screen.

2.4. Video recording

A Canon MVX1i digital video camera was used to record the performance of all subjects. The camera has a time code which allows exact measurement for all the time intervals of the recorded sequences, and can also take digital pictures (maximum resolution 1280 × 960 pixels).

2.5. Initial test

Subjects were told that in the adjoining room there was a patient (simulated by the manikin) whose heart had stopped

Table 1
Sequence of AED voice prompts and abbreviated text prompts on the screen

Step	Voice prompt	Text prompt
1	Apply pads to patient's bare chest	Apply pads
2	Plug in pads connector next to flashing light	Plug in connector
3	Analyzing heart rhythm. Do not touch the patient	Analyzing. Do not touch the patient
4	Shock advised. Charging. Stay clear of patient	Shock advised. Charging. Stay clear
5	Deliver shock now. Press the orange button now	Deliver shock. Press orange button
6	Shock delivered. Analyzing heart rhythm. Do not touch the patient	Shock delivered. Analyzing. Do not touch the patient
7	Analyzing heart rhythm	Analyzing
8	No shock advised. It is safe to touch the patient. Check airway, check breathing, check pulse. If needed begin CPR	No shock advised. Monitoring. Check patient

after a heart attack and that they could save its life using a defibrillator. Subjects were tested individually and they were not allowed to communicate with each other during the testing protocol.

When the subjects entered the testing room, they were given the defibrillator bag, which included the AED and the adhesive paddles in their envelope. The manikin was lying supine and no resuscitation attempt was in progress.

A BLS–AED instructor was present during the procedure to evaluate the performance of the subject and assess safety.

For all subjects the standard scenario included VF as the cardiac arrest rhythm. Since the subjects had no previous experience in BLS, they were not requested to perform it, and the scenario was stopped (i.e., defibrillation was successful) after delivery of the first shock.

The steps for the defibrillation attempt included: (1) opening the soft case of the defibrillator; (2) turning on the AED by pressing the "on/off" button; (3) opening the envelope and applying the electrode pads to the patient; (4) inserting the electrode pad connector to the AED; (5) staying clear of the patient during the ECG analysis; (6) safely staying clear of the patient while charging; (7) safely administering the shock with a press of the "shock" button.

The duration of steps 1–4 represented the "time to analysis", i.e. the time interval between the defibrillator was switched on and the pads were put on the patient's chest; the duration of the steps 5–7 represented the "time to shock delivery", i.e., the time interval between the analysis was started and the shock button was pressed. The sum of these two time intervals resulted in the total AED on to first shock interval.

The pad placement was evaluated on the basis of the International Guidelines 2000 for CPR and Emergency Cardiac Care [17]. For the anterior-apical position the right infraclavicular pad should be on the upper-right sternal border (directly below the clavicle), while the left apical pad should be lateral to the left nipple, with the top margin of the pad approximately 7 cm below the axilla. The correct pad placement was evaluated by three experienced BLS–AED instructors who independently reviewed the videotapes.

2.6. BLS-AED course

After initial testing, the subjects received the standard BLS–AED training course for lay rescuers developed by the Italian Resuscitation Council (IRC) and based on the ERC Guidelines for Adult Basic Life Support and Automated External Defibrillation [18,19]. The course included a 1 h lecture, 3 h and 30 min of practical training, and 1 h for testing (see Table 2).

The lecture was given by an IRC instructor and translated into LIS by an interpreter. The subsequent training was not translated and the instructors used gestures and hip reading to instruct the candidates.

Table 2
Standard course schedule of the Italian Resuscitation Council (IRC) Basic Life Support and Automated External Defibrillation (BLS–AED) course for lay rescuers

	Registration – timing to be decided locally	
Lecture	Epidemiology of sudden cardiac death The chain of survival Basic life support Automated external defibrillation Safety during defibrillation Adult BLS–AED algorithm	60 min
Skill station	Basic airway management Expired air ventilation External chest compression Recovery position	60 min
Demo/skill station	How to use an AED	30 min
Skill station	Cardiac arrest scenarios using an AED	120 min
Evaluation	Testing scenarios Course closure	60 min

2.7. Final test

At the end of the course, the subjects were tested again using the same setting and equipment but this time the scenario included a refractory VF. Candidates had to perform three shocks, one minute of CPR and a fourth shock before obtaining a pulse.

Evaluation of candidate performance included the same variables assessed for the initial test, plus the adequacy of CPR. The CPR sequence was evaluated using the BLS testing sheet of the ERC Advanced Life Support Course. Cardiopulmonary resuscitation was considered adequate if more than 75% of chest compressions and ventilations were performed correctly.

2.8. Data analysis

The paired two-tailed t-test was used to compare the time intervals before and after the BLS–AED course and the Mc-Nemar test was used to compare the categorical variables (defibrillation and safety).

3. Results

3.1. Time intervals to defibrillation

Seven out of nine deaf subjects (78%) were able to defibrillate the manikin before training, following the visual instructions provided with the equipment. Two of them placed the pads on the chest but did not press the shock button.

The mean "time to analysis" was 80.0 ± 23.5 s (range: 50–106 s) and 28.9 ± 5.6 s after the course (range: 21–36 s), while the mean "time to shock delivery" was 24.7 ± 4.7 s (range: 19–35 s) before the course and 18.6 ± 1.3 s after the

Table 3
Time intervals and performance of the nine subjects studied

	Before training	After training	*P*-value
Time to analysis	80 ± 23.5	28.9 ± 5.6	<0.001
Time to shock delivery	24.7 ± 4.7[a]	18.6 ± 1.3	0.007
Total AED on/first shock interval	101.6 ± 28.4[a]	47.8 ± 5.4	0.001
First shock delivered	7/9 (78%)	9/9 (100%)	NS
Pad placed correctly	8/9 (89%)	9/9 (100%)	NS
Safety	0/9 (0%)	9/9 (100%)	<0.001

[a] Two subjects did not deliver a shock before training, therefore the data refer to seven subjects.

course (range: 17–21 s). The sum of these two time intervals resulted in a total AED on to first shock interval of 101.6 ± 28.4 s (range: 69–135 s) before the course and 47.8 ± 5.4 s after the course (range: 39–53 s). All of the time intervals were significantly shorter than their respective pre-course values (Table 3). After the course, all subjects were able to complete the defibrillation sequence.

3.2. Pad placing

Eight out of nine subjects (89%) placed the pads correctly on the manikin chest prior to training. After training all subjects placed the pads correctly (P = NS).

3.3. Safety

None of the subjects touched the patient during charging of the defibrillator and shock delivery before or after the course.

3.4. BLS adequacy

After the course the CPR performance was adequate and all the interventions included in the BLS–AED algorithm were performed in the correct order.

4. Discussion

In USA there are about 1,968,000 deaf people [20] and more than 30 million citizens have some degree of hearing impairment [21]. For a significant part of the population, following the voice prompts of an AED could therefore be difficult or impossible, and this would prevent them performing defibrillation in a cardiac arrest scenario or might lead to inappropriate interventions.

Our study shows how the majority of deaf lay rescuers can perform effective defibrillation in a simulated scenario, even without formal BLS–AED training, providing that the AED delivers not only audible, but also visual, messages. This simulated situation demonstrates that a deaf occasional lay responder is able to use an AED without having even seen it. After training, all of the deaf subjects were able to defibrillate and improved their performance. Pre- and post-course timing differed significantly.

The "time to analysis" interval reflects the capability to use the pads. The mean "time to analysis" interval in untrained rescuers was over one minute. This relatively long interval was due to an only apparently small detail: the adhesive side of the defibrillator pads was covered by a protective paper that had to be removed before using the pads. Paper removal was displayed in a picture on the pad envelope, but the majority of the rescuers did not see the message because they opened the envelope very quickly and threw it away. Therefore the pads initially did not stick on the chest. This phenomenon disappeared after training. Similar problems were reported by Gundry et al., who evaluated the capability of naive sixth-grade children to use the same defibrillator model [15]. Since in preliminary tests many lay rescuers faced difficulties in peeling off the cover, the investigators should give the children some verbal instructions about pad use before starting the test. Purposely, we did not give any instructions to our subjects, in order to simulate as closely as possible the condition of an untrained bystander. On the basis of our results, we think that some improvements to the pads could be useful, e.g. graphic and written instructions could be printed on the protective paper to remind the inexperienced users to remove it before using the pads.

All but one untrained lay subjects (89%) placed the pads correctly on the chest, on the basis of the visual instructions printed on the pad surface. It should be noted that, in a population of non-deaf healthcare providers using the same equipment, the percentage of correct placement before training was only 47% [14]. This probably reflects a superior ability of deaf performers to understand visual instructions. It is also likely that for non-deaf performers operating in a noisy environment the visual messages of the defibrillator could be less helpful.

The "time to shock delivery" interval reflects the capability to understand the message "shock indicated" and to deliver the shock. The mean "time to shock delivery" interval was less affected by problems with the equipment and was much shorter than the "time to analysis" interval. However, two subjects did not deliver the shock during the initial test. The reason was because they expected the defibrillator to deliver it automatically. After the message "stay clear" was displayed, they stood so far from both the manikin and the defibrillator that they could not read the message "press the orange button". The flashing light in the shock button was interpreted as a warning message. In a real situation, this problem would have prevented these rescuers from defibrillating a cardiac arrest patient. Changing the text message (e.g. "do not touch the patient" instead of "stay clear") or providing other types of messages (e.g. flashing arrows directed through the shock button) could represent possible solutions. A "fully automated defibrillation" option, which automatically delivers a shock if the shock button is not pressed after a certain time interval, would also be an al-

ternative, but its implications for rescuer safety should be carefully considered.

All subjects were able to perform adequate CPR after the course. Although the evaluation of CPR teaching was not an endpoint of the present study, the results indicate how, using appropriate techniques, both CPR and AED use can be learnt effectively by deaf candidates, in the same amount of time allocated for a standard IRC BLS–AED course.

In our deaf population, the 1 h lesson was delivered using sign language translation. Similarly, some American Red Cross chapters organise special interpreter-staffed classes for hearing impaired candidates. However, since professional sign language interpreters are expensive and not available everywhere, video lectures would represent a possible alternative for some training centres. Captioned videos have been successfully used in deaf candidates for BLS training [16] but their use for AED training has not yet been documented.

Our study has been performed using the Heartstart FR2+. However, other defibrillator models equipped with video messages (e.g. Access Cardiosystems AED, Heart Sine Technologies Samaritan AED, Philips Heart Start FR2+, Physio Control LP 500, Zoll AED Plus) would probably have been suitable as well. Comparative studies are needed to evaluate which of them would be the most effective when used by hearing impaired rescuers or in noisy environments.

5. Conclusions

This study demonstrates how even untrained deaf rescuers can use AEDs appropriately by following the visual instructions on the defibrillator display. Considering the relatively high number of deaf and hearing-impaired subjects in the adult population, this appears to be very important to achieve the most widespread use of AEDs in all situations. Some improvement of the user interface could eliminate minor difficulties and shorten the time to shock delivery. As for non-deaf providers, training has a key role to reduce time to defibrillation and to ensure safety. In the small group of deaf candidates that we studied, BLS–AED training did not require special techniques or longer times, providing that sign language translation was available during teaching. BLS–AED teaching and training in the deaf deserve further investigation with a larger candidate population.

Acknowledgements

We really thank the group of deaf employers of the Italian National Olympic Committee (CONI) in Rome for the great enthusiasm showed in participating in this trial. We also thank the CONI Medical Staff for giving us hospitality and support. Finally, we thank Anne Cathrine Eklund and Patrizia Fenici for the English revision of the manuscript.

References

[1] Zheng ZJ, Croft JB, Giles WH, Mensah GA. Sudden cardiac death in the United States, 1989 to 1998. Circulation 2001;104:2158–63.
[2] Becker LB. Epidemiology: etiology, incidence and survival rates. In: Weil MH, Tang W, editors. CPR: resuscitation of the arrested heart. Philadelphia: Saunders; 1999. p. 13–27.
[3] Gillum RF. Sudden coronary death in the United Stated. Circulation 1989;79:756–65.
[4] Bayes De Luna A, Coumle P, Leclercq JF. Ambulatory sudden cardiac death: mechanisms of production of fatal arrhythmias on the basis of data from 157 cases. Am Heart J 1989;17:151–9.
[5] 2002 Heart and stroke statistical update. Dallas: American Heart Association; 2002.
[6] Cummins RO. From concept to standard-of-care? Reviews of the clinical experience with automated external defibrillators. Ann Emerg Med 1993;22:1652–8.
[7] Lombardi G, Gallagher J, Gennis P. Outcome of out-of-hospital cardiac arrest in New York City: the Pre-hospital Arrest Survival Evaluation (PHASE) study. JAMA 1994;271:678–83.
[8] Becker LB, Ostrander MP, Barrett J, Kondos GT. Outcome of CPR in a large metropolitan area—where are the survivors? Ann Emerg Med 1991;20:355–61.
[9] Eisenberg MS, Horwood BT, Cummins RO, Reynolds-Haertle R, Hearne TR. Cardiac arrest and resuscitation: a tale of 29 cities. Ann Emerg Med 1990;19:179–86.
[10] Page RL, Joglar JA, Kowal RC, et al. Use of automated external defibrillators by a US airline. N Engl J Med 2000;343:1210–6.
[11] Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes after rapid defibrillation by security officers after cardiac arrest in casinos. N Engl J Med 2000;343:1206–9.
[12] White RD, Hankins DG, Bugliosi TF. High discharge survival rate after out-of-hospital ventricular fibrillation with rapid defibrillation by police and paramedics. Resuscitation 1998;39:145–51.
[13] Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Public use of automated external defibrillators. N Engl J Med 2002;347:1242–7.
[14] Mattei LC, McKay U, Lepper MW, Soar J. Do nurses and physiotherapists require training to use and automated external defibrillator? Resuscitation 2002;53:277–80.
[15] Gundry JW, Comess KA, DeRook FA, Jorgenson D, Bardy GH. Comparison of Naive Sixth-Grade children with trained professionals in the use of automated external defibrillator. Circulation 1999;100:1703–7.
[16] Tomasetti JA, Beck KH, Clearwater ED. An analysis of selected instructional methods on cardiopulmonary resuscitation retention competency of deaf and non-deaf college students. Am Ann Deaf 1983;128:474–8.
[17] International Guidelines 2000 for CPR and ECC. A consensus on science. Part 4. The automated external defibrillator: key link in the chain of survival. Resuscitation 2000;46:73–91.
[18] Handley AJ, Monsieurs KG, Bossaert LL. European Resuscitation Council Guidelines 2000 for Basic Life Support: a statement from the Basic Life Support and Automated External Defibrillation Working Group and approved by the Executive Committee of the European Resuscitation Council. Resuscitation 2001;48:199–205.
[19] Monsieurs KG, Handley AJ, Bossaert LL. European Resuscitation Council Guidelines 2000 for Automated External Defibrillation: a statement from the Basic Life Support and Automated External Defibrillation Working Group and approved by the Executive Committee of the European Resuscitation Council. Resuscitation 2001;48:207–9.
[20] Beck KH, Tomasetti JA. A national survey of cardiopulmonary resuscitation training for the deaf. Am Ann Deaf 1983;128:909–12.
[21] Vital and Human Statistics. US Department of Health and Human Services; 1994.

Research

Open Access

Minimal instructions improve the performance of laypersons in the use of semiautomatic and automatic external defibrillators

Stefan Beckers[1], Michael Fries[1], Johannes Bickenbach[1], Matthias Derwall[2], Ralf Kuhlen[3] and Rolf Rossaint[4]

[1]Resident, Department of Anaesthesiology, University Hospital Aachen, Aachen, Germany
[2]Medical Student, Department of Anaesthesiology, University Hospital Aachen, Aachen, Germany
[3]Professor, Department of Anaesthesiology, University Hospital Aachen, Aachen, Germany
[4]Professor and Chairman, Department of Anaesthesiology, University Hospital Aachen, Aachen, Germany

Corresponding author: Stefan Beckers, sbeckers@ukaachen.de

Received: 14 September 2004

Revisions requested: 13 October 2004

Revisions received: 1 November 2004

Accepted: 30 November 2004

Published: 31 January 2005

Critical Care 2005, 9:R110-R116 (DOI 10.1186/cc3033)

This article is online at: http://ccforum.com/content/9/2/R110

Abstract

Introduction There is evidence that use of automated external defibrillators (AEDs) by laypersons improves rates of survival from cardiac arrest, but there is no consensus on the optimal content and duration of training for this purpose. In this study we examined the use of semiautomatic or automatic AEDs by laypersons who had received no training (intuitive use) and the effects of minimal general theoretical instructions on their performance.

Methods In a mock cardiac arrest scenario, 236 first year medical students who had not previously attended any preclinical courses were evaluated in their first study week, before and after receiving prespecified instructions (15 min) once. The primary end-point was the time to first shock for each time point; secondary end-points were correct electrode pad positioning, safety of the procedure and the subjective feelings of the students.

Results The mean time to shock for both AED types was 81.2 ± 19.2 s (range 45–178 s). Correct pad placement was observed in 85.6% and adequate safety in 94.1%. The time to shock after instruction decreased significantly to 56.8 ± 9.9 s (range 35–95 s; $P \leq 0.01$), with correct electrode placement in 92.8% and adequate safety in 97%. The students were significantly quicker at both evaluations using the semiautomatic device than with the automatic AED (first evaluation: 77.5 ± 20.5 s versus 85.2 ± 17 s, $P \leq 0.01$; second evaluation: 55 ± 10.3 s versus 59.6 ± 9.6 s, $P \leq 0.01$).

Conclusion Untrained laypersons can use semiautomatic and automatic AEDs sufficiently quickly and without instruction. After one use and minimal instructions, improvements in practical performance were significant. All tested laypersons were able to deliver the first shock in under 1 min.

Keywords: automated external defibrillator, cardiopulmonary resuscitation, defibrillation, layperson, intuitive

Introduction

Mortality from sudden cardiac death is up to 375,000 patients per year in Europe [1] and in the vast majority of cases it is caused by ventricular fibrillation [2]. To increase survival rates, the period between developing ventricular fibrillation and the first defibrillation must be as short as possible. Early defibrillation, done during the first minute of the event, is successful in 85% of cases. Each additional minute without treatment reduces the survival rate by a further 10% [3]. Therefore, early defibrillation must be implemented into the chain of survival [4], and to this end the development of programmes for non-medical lay responders is recommended and supported by many international societies. For years, the American Heart Association has postulated inclusion of AED use in basic life

AED = automated external defibrillator; BLS = basic life support; PAD = public access defibrillation.

support (BLS) training [4,5]. Furthermore, first responders may operate an AED without having any background knowledge about the instrument. Previous studies have shown that even children can handle an AED confidently and effectively [6].

There is no consensus as yet regarding time frames for specific training programmes, but for organizational reasons and for further implementation of public access defibrillation (PAD) programmes in the future, it is necessary that this period be defined. It remains unclear how lay users should be instructed to perform safe and effective defibrillation. The aim of the present study was to evaluate the intuitive use (i.e. without training) of AEDs, both in fully automatic and in semiautomatic modes, and to study the effect of brief and well directed theoretical instruction.

Methods

Participants

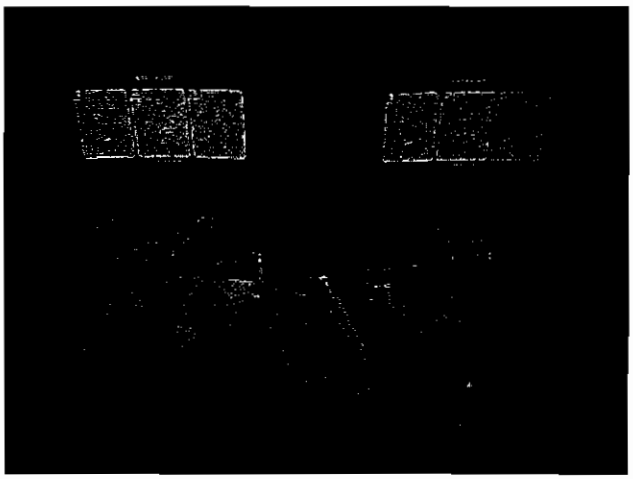
A total of 236 first year medical students were tested during their first 2 weeks at the medical school of the University of Aachen. All students were informed that their performance would be evaluated and used for scientific study. No personal data were collected. Furthermore, no damage to anyone's health was anticipated because the AED uses no current. Therefore, the institutional ethical committee waived the need to obtain informed consent from each participant. None of the students were prompted or prepared in any way before the study.

Equipment

The Medtronic Physio-Control LifePak™ CR-T AED trainer (Medtronic Physio-Control LifePak™; Medtronic, Düsseldorf, Germany) provides the necessary interface for demonstrating practical skills during a simulated cardiac arrest, and was used rather than the original Medtronic Physio-Control LifePak™ CR Plus. No current is applied by the training device.

After opening the lid a red handle must be pulled, which then releases self-adhesive electrode pads with integrated cables connected to the device (Fig. 1). Voice prompts (Table 1) and an illustrated reference card inside the opened lid guides users in a step-by-step manner. No text prompts are displayed on the screen. After turning the device on and positioning the electrodes properly, the analyzing process of the AED starts automatically and is finished after 10 s in both types of AED. In the semiautomatic mode it takes 18 s from the beginning of the analyzing process until the device is charged, and an alarm tone sounds until the shock button is pressed. In the automatic mode the shock is delivered automatically after 21 s and the charge is calculated from the analysis of heart rhythm over this period [7].

Figure 1



Evaluated automated external defibrillator: (left) automatic mode and (right) semiautomatic mode. Weight: 2.1 kg; physical dimensions: 10 × 20 × 24 cm.

Study protocol

In a mock cardiac arrest scenario, the students were evaluated on a manikin (ResusciAnne®; Laerdal, Stavanger, Norway). After randomization, 118 students were tested on an AED in automatic mode, and 118 were tested on a semiautomatic AED. The device was kept in its usual standby mode. The manikin was positioned supine and dressed in a zippered jacket. Three physicians skilled in providing and teaching advanced life support (certified instructors of the European Resuscitation Council) were present and recorded data while each student operated the AED. Each student was tested individually and was unable to observe the performance of other participants. They were read the following text: 'This patient is unconscious, not breathing and has no signs of circulation. The device in front of you may help to restore spontaneous circulation.'

The procedure ended when the first shock was delivered or no shock could be given in 240 s. Placement of the electrode pads was accepted as correct if the left pad covered at least 50% of an area circumscribed by the nipple line superiorly, costal margin inferiorly, mid-clavicular line medially and mid-axillary line laterally. The right pad was required to cover at least 50% of an area circumscribed by the clavicle superiorly, nipple line inferiorly, anterior axillary line laterally and right sternal margin medially. Application of the AED was considered to be safe if the student remained clear of the manikin during delivery of the shock. If a technical problem occurred, the student damaged the AED, started with conventional cardiopulmonary resuscitation, or had language difficulties, then this was classified as 'any other problem'.

After having completed the tests, each student completed a standardized questionnaire to evaluate whether they had any

Table 1

Voice prompts of the automated external defibrillator during the simulated cardiac arrest scenario

Automatic	Semiautomatic	Tones
	Call for help now	After the AED lid opens, two beeping tones sound. The voice prompts will sound following the beeping tones
	Remove clothing from chest	
	Pull red handle to open bag	
	Peel each pad off blue plastic	
	Apply pads to exposed chest	
	Do not touch patient – evaluating heart rhythm	Two beeping tones sound to simulate heart rhythm analysis
	Stand by – preparing to shock	
	Everyone clear	
	Press flashing button	Semiautomatic model only; an alarm tone sounds until the shock button is pressed
Do not touch patient – delivering shock		Automatic model only; an alarm tone sounds until shock is delivered automatically
	Shock delivered	
	Voice prompts that are not used	
	No shock advised	
	Shock not delivered	
	Check for pulse; if no pulse start CPR	
	Check for breathing; if not breathing start CPR	
	Check for signs of circulation; if no signs of circulation start CPR	
	Continue care	
	Check pads for good contact	
	Motion detected	
	Stop motion	

AED, automated external defibrillator; CPR, cardiopulmonary resuscitation. Data from Medtronic [7].

experience with an AED before the study or whether they had any medical education (e.g. nurse, paramedic etc.). After a period of 1 week all test candidates were assigned the same type of device they had used in their first test and were re-evaluated in the same scenario. During this week they attended a short lecture (15 min) emphasizing the following core objectives: importance of sudden cardiac death and of defibrillation in this context; importance of 'time to shock' to return of spontaneous circulation and success of resuscitation over time; importance of correct electrode pad positioning; safety aspects when using an AED; general procedure for defibrillation devices (e.g. analysis, voice prompts); general AED algorithm following guidelines; and special instructions for slim and overweight victims.

There were no practical training sessions available between the two evaluations and no specific information on the tested AED devices was given.

Data analysis

Data are expressed as means ± standard deviation. $P \leq 0.05$ was considered statistically significant. Statistical software SPSS version 11.0 (SPSS Inc., Chicago, IL, USA) was used.

Primary end-points

The primary end-point was to determine the time from the beginning of the scenario to first shock. Using a t-test, differences in time to shock between the first and second evaluations were calculated, as well as between the semiautomatic and the automatic devices for each time point.

Secondary end-points

The secondary end-points were chosen to assess correct electrode pad positioning and the safety of the procedure, as well as previous medical knowledge. Data were compared in a proportional manner and tested for significant differences using the McNemar test.

Table 2

Time to first shock, correct electrode pad positioning and safety aspects before and after brief general instruction in defibrillation

	Device	
	Semiautomatic	Automatic
n	118	118
Age (mean ± SD)	21.1 ± 3.3	20.4 ± 2.3
Male (*n* [%])	45 (38.1%)	38 (32.2%)
First evaluation		
Time to shock (s; mean ± SD)	77 ± 20.4*†	85 ± 17.2†
Not able to deliver shock (*n* [%])	6 (5.1%)‡	4 (3.4%)
Incorrect pad positioning (*n* [%])	15 (12.7%)	19 (16.1%)*
Safe shock (*n* [%])	109 (92.4%)	113 (95.8%)
Any other problems[a] (*n* [%])	18 (15.3%)	12 (10.2%)
Second evaluation		
Time to shock (s; mean ± SD)	55 ± 10.3*	59 ± 9.1
Not able to deliver shock (*n* [%])	0 (0%)	3 (2.5%)
Incorrect pad positioning (*n* [%])	11 (9.3%)	3 (2.5%)
Safe shock (*n* [%])	113 (95.8%)	115 (97.5%)
Any other problems[a] (*n* [%])	3 (2.5%)	2 (1.7%)

Comparison of subjects using semiautomatic and automatic devices at different evaluations. [a]Any other problems as described in the study protocol. *$P < 0.05$, versus automatic device (t-test). †$P < 0.05$, versus second evaluation (t-test). ‡$P < 0.05$, versus second evaluation (McNemar test). SD, standard deviation.

Results

The mean age of the study population was 20.7 ± 2.9 years (range 18–42 years). Of the 236 students included, 28 (11.9%) had a history of medical education (16 emergency medicine technicians and paramedics, and 12 nurses).

Time to defibrillation, electrode pad positioning and safety

In the first evaluation the time to shock for both devices was 81.2 ± 19.2 s (range 45–178 s). The pads were positioned correctly by 85.6% of the students. Shock was administered safely by 94.1%. In the second evaluation the time to first defibrillation decreased significantly to 56.8 ± 9.9 s (range 35–95 s; $P \leq 0.01$). The electrodes were correctly placed in 92.8% of cases, and shock was administered safely in 97% of cases.

Table 2 summarizes these variables by type of AED. When comparing time to first shock between semiautomatic and automatic AEDs, the students were significantly faster in both evaluations using the semiautomatic device (first evaluation: 77.5 ± 20.5 s versus 85.2 ± 17 s, $P \leq 0.01$; second evaluation: 55 ± 10.3 s versus 59.6 ± 9.6 s, $P \leq 0.01$).

In the second evaluation 113 out of 118 (95.8%) students were able to deliver a shock safely and none failed in the semiautomatic group. In the automatic group 115 of 118 (97.5%) were able to deliver a shock, but three students failed.

Students with pre-existing medical education were significant faster at both times (first evaluation: 73.0 ± 17.1 s versus 83.0 ± 19.1 s, $P \leq 0.01$; second evaluation: 51.8 ± 9.2 s versus 58.3 ± 10.1 s, $P \leq 0.01$). All other findings are summarized in Table 2.

Discussion

This study represents the first comparison in laypersons of the use of fully automatic devices with that of semiautomatic devices, including the largest study group yet reported. The improvements with both devices, in terms of time to first shock, between initial use without instruction and use following the described 15-min theoretical instruction were significant.

Since the first clinical use of AEDs in the early 1980s [8], developments in technology have led to initiatives by health and governmental organizations to develop PAD programmes [9]. Various studies [10-13] have shown improvements in rates of survival from out-of-hospital cardiac arrest where non-medical personnel were trained in PAD programmes. However, only a few studies described the performance of laypersons, but even these individuals were initially instructed before evaluation [6,14]. In a cross-over design, Eames and

coworkers [15] compared the use of three different AEDs by nearly untrained laypersons ($n = 24$), but information had been given concerning the application of a shock, following instructions for the device and the impact that time to defibrillation has on outcome. To our knowledge, the present study is the first to describe the use of AEDs without any instructions before first use. It is noteworthy that, even without instruction, 226 out of 236 participants (95.8%) were able to deliver a shock.

Safety aspects associated with automatic mode have been considered and critically discussed, but the question of whether it is better not to administer an advised shock in the case of proven ventricular fibrillation or to have a shock delivered automatically with a delay is rhetorical. Surveying safety aspects of the tested AED, we found that 92.4% of students were able to deliver a shock safely in semiautomatic mode and 95.8% in automatic mode during testing without prior instruction. After theoretical instruction, these rates increased to 95.8% and 97.5%, respectively. Eames and coworkers [15] found that all individuals stood clear while delivering the shock but, as mentioned above, only 24 subjects were tested; it follows that possible reluctance to adhere to safety procedures might not have been detected in that investigation. Fromm and Varon [16] found that still 10 months after initial training, the 'simplicity of use of the particular AED' was the core issue determining safety. The important benefit of devices programmed in automatic mode is that they relieve the layperson of decision making in an unfamiliar and stressful situation.

Contrary to expectations were our findings regarding electrode pad placement. There was an anticipated and significant improvement in the automatic group, but only a trend was observed in the semiautomatic group. It is inexplicable why, after instruction, 9.3% (11 students) still could not achieve correct pad positioning. This is in contrast to the study by Gundry and coworkers [6], in which all children were able to position the pad in the required area, whereas Eames and coworkers [15] observed 20.9% incorrect electrode placement with the LifePak CR Plus. With the Philips/Laerdal Heartstart1 the result was only 4.2%, and the Zoll AEDPlus had the worst result, with 41.6% incorrect pad positioning. In some cases, confusing descriptions or drawings might have caused the incorrect positioning of the adhesive pad electrodes in the present study. Overall, this supports the conclusion of Eames and coworkers that simple devices should be developed with clear visual instructions, and it reiterates that design, construction and visual aids have an impact on user performance. This statement was confirmed by our observation that even in the second evaluation, in the automatic group three students were unable to deliver a shock. In these three cases the students were confused by the voice prompts of the automatic device, and while trying to push the shock button they turned the device off. Other detected problems in both testing sessions occurred mainly as a result of language problems, but they were reduced after instruction. In general, none of the participants appeared to be apprehensive about operating the AED because none of them refused to participate in the study or to apply the device to the manikin.

The significant difference in time to shock before and after instruction between semiautomatic AED and the automatic device is a possible effect of the software version used. However, the programmed delay of 3 s to delivery of shock in the automatic device does not adequately explain this finding. Changing the timing of voice prompts and development of clearer instructions may lead to different results. In general, however, the voice prompts that lead to the best results remains a matter for discussion.

The studies published thus far led to the statement from the American Heart Association and the Resuscitation Council UK 'not to specify the nature of content or duration of BLS plus AED programs due to the lack of current evidence on which to base any such guidance' [17]. As yet there is no consensus regarding the optimal duration of specific training programmes. It will be difficult to achieve that perfect performance of certain skills that indicates successful training of laypersons. Especially for organizational reasons, it is fundamental to define time frames of course concepts. We endorse the assertion by Gundry and coworkers [6] and Moule and Albarran [17] that simplified training programmes should be developed, exploiting the potential of multimedia technology, along with adequate teaching and learning materials.

Various concepts have been described [10,11,17-21], but no data exist regarding how best to train and what the optimal duration of training is to achieve the best outcomes. Moule and Albarran [17] recently stated that the duration and most effective methods for teaching professionals and laypersons remain undefined. For this reason, no recommendation can yet be given. The implementation of PAD programmes in the future will depend mainly on the willingness of the public to participate in AED or cardiopulmonary resuscitation courses. The more time required to achieve the necessary skills, the less people will feel able to participate voluntarily. Furthermore, training sessions must be as precise and short as possible for organizational reasons; ideally, it should be possible for even a small number of instructors to reach a large group of trainees in minimal time.

Limitations of the study

The groups evaluated here are not representative of the general population with respect to sex (male 35% [$n = 83$], female 65% [$n = 153$]) and age, but the two groups are comparable (Table 2). In addition, the students were not chosen by random; nevertheless, they do represent young and inexperienced laypersons with respect to medical issues because, in Germany, students begin medical school directly after graduation from secondary school, without any specific preparation.

As considered by other studies [16,22], the participants might not have been free from external or internal motivations because of the fact that they were going into medicine. However, at this stage they are at best minimally trained and are not representative of the health care professional community. Furthermore, this internal motivation could have influenced their knowledge of theoretical issues concerning defibrillation within the evaluation period, but it is unlikely that there would have been a significant improvement in practical performance after, for instance, a web search.

Finally, no manikin used to represent an unconscious, breathless and pulseless victim can simulate a human perfectly. Because of this limitation, it is debatable whether benefits obtained in a simulated representation of a complex situation can be realized in clinical practice.

Conclusions

Untrained laypersons are able to use AEDs quickly and safely. The observation that measures of practical performance (i.e. time to first shock, accuracy of electrode pad placement and safety) were significantly improved after minimal theoretical instruction and one use, but without technical instructions in the use of the specific device, is supportive of widespread implementation of PAD programmes wherever possible. Moreover, enhanced acceptance of AEDs and the increased likelihood that AEDs will be used following directed 'public information' (e.g. television campaigns or other extensive publicly available media) is of great importance. Core issues (e.g. the significance of sudden cardiac death and the importance of defibrillation in this context) should be at the forefront of new educational changes; some suggestions in this regard were made in the present study.

Taken together, our findings support previous recommendations to develop features that can be made available in all AEDs. Sophisticated devices with simple instructions – visual or vocal – should be implemented in PAD programmes. Further developments should aim at simplifying the application of electrodes and achieving consistency in the instructions given by the different manufacturers. Value must be attached to giving general instructions and information about features that are common to all devices; describing the specific details of a device does not appear to be essential, as was assumed.

In our opinion, one of the most remarkable findings is that all tested laypersons were able to deliver a shock in less than 1 min after minimal instructions had been given, regardless of whether automatic or semiautomatic mode was used. Despite the limitations of the study, we conclude that only minimal background knowledge is needed for laypersons to use an AED safely and quickly, and that further implementation of AEDs for use by minimally trained persons without any medical training is possible. We believe that keeping instructions for laypersons as simple as possible will lead to greater acceptance and motivation, and will further facilitate PAD programmes. Time spent training to acquire necessary cardiopulmonary resuscitation skills within the BLS algorithm can be saved by focusing AED instructions in this way. Further studies are warranted to determine whether skills are retained over the long term.

Key messages

- This first observation in 'fully' automatic devices confirms that this type of AED can be used safely and effectively by lay responders.
- All tested laypersons were able to deliver a shock in less than 1 min after minimal instructions, regardless of whether automatic or semiautomatic mode was used.
- In future value must be attached to general instruction and similarities; describing specific details of available devices is not essential.
- Previous recommendations to develop features that can be made available in all AEDs are supported by our findings.

Competing interests

The author(s) declare that they have no competing interests.

Authors' contributions

SB had conceived the study. SB, MF, JB, RK and RR designed the study protocol. Testing was performed by SB, MF, JB and MD. Statistical analysis was done by MF and MD. SB, MF, JB, RK and RR wrote and reviewed the manuscript before submission. All authors read and approved the final manuscript.

Acknowledgements

We thank all first year students of the medical faculty, University Aachen, Germany, for participating in this study and Medtronic Physio-Control Germany Corp for loaning the AED trainer and electrode pads to the investigators of the study.

Part of this work was presented at the 24th International Symposium on Intensive Care and Emergency Medicine (ISICEM), Brussel, Belgium; 30 March 30 2004 [23].

References

1. The Hypothermia After Cardiac Arrest Study Group: **Mild therapeutic hypothermia to improve the neurological outcome after cardiac arrest.** *N Engl J Med* 2002, **346**:549-556.
2. Weaver DW: **Considerations for improving survival from out-of-hospital cardiac arrest.** *Ann Emerg Med* 1986, **15**:1181-1186.
3. Advanced Life Support Working Party of the ERC: **Guidelines for adult advanced cardiac life support.** *Resuscitation* 1992, **24**:111-121.
4. The American Heart Association in collaboration with the International Liaison Committee on Resuscitation: **Part 4: the automated external defibrillator: key link in the chain of survival. European Resuscitation Council.** *Resuscitation* 2000, **46**:73-91.
5. The American Heart Association in collaboration with the International Liaison Committee on Resuscitation: **Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascu-**

lar Care. An international consensus on science. *Circulation* 2000, 102:1-384.
6. Gundry JW, Comess KA, DeRook FA, Jorgenson D, Bardy GH: **Comparison of naive sixth-grade children with trained professionals in the use of an automated external defibrillator.** *Circulation* 1999, **100:**1703-1707.
7. Medtronic Physio-Control LifePak Corp: . In *RU. LifePak CR-T AED-Trainer Operating Instructions* Minneapolis, MN: Medtronic Physio-Control LifePak Corp; 2002.
8. Weaver DW, Copass MK, Hill DL, Fahrenbruch C, Hallstrom AP, Cobb LA: **Cardiac arrest treated with a new automatic external defibrillator by out-of-hospital first responders.** *Am J Cardiol* 1986, **57:**1017-1021.
9. Davies CS, Colquhoun M, Graham S, Evans T, Chamberlain D: **Defibrillators in public places: introduction of a national scheme for public access defibrillation in England.** *Resuscitation* 2002, **52:**13-21.
10. Page RL, Joglar JA, Kowal RC, Zagrodzky JD, Nelson LL, Ramaswamy K, Barbera SJ, Hamdan MH, McKenas DK: **Use of automated external defibrillators by a U.S. airline.** *N Engl J Med* 2000, 343:1210-1216.
11. Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG: **Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos.** *N Engl J Med* 2000, **343:**1206-1209.
12. White RD, Asplin BR, Bugliosi TF, Hankins DG: **High discharge survival rate after out-of-hospital ventricular fibrillation with rapid defibrillation by police and paramedics.** *Ann Emerg Med* 1996, 28:480-485.
13. Ross P, Nolan J, Hill E, Dawson J, Whimster F, Skinner D: **The use of AEDs by police officers in the City of London. Automated external defibrillators.** *Resuscitation* 2001, 50:141-146.
14. Moore JE, Eisenberg MS, Cummins RO, Hallstrom A, Litwin P, Carter W: **Lay person use of automatic external defibrillation.** *Ann Emerg Med* 1987, **16:**669-672.
15. Eames P, Larsen PD, Galletly DC: **Comparison of ease of use of three automated external defibrillators by untrained lay people.** *Resuscitation* 2003, 58:25-30.
16. Fromm RE Jr, Varon J: **Automated external versus blind manual defibrillation by untrained lay rescuers.** *Resuscitation* 1997, 33:219-221.
17. Moule P, Albarran JW: **Automated external defibrillation as part BLS: implications for education and practice.** *Resuscitation* 2002, **54:**223-230.
18. White RD, Vukow L, Buglosi T: **Early defibrillation by police: initial experience with measurement with time intervals and patient outcome.** *Ann Emerg Med* 1994, 23:1009-1013.
19. Stults KR, Brown D, Schug V, Bean JA: **Prehospital defibrillation performed by emergency medical technicians in rural communities.** *N Engl J Med* 1984, **310:**219-223.
20. Stults KR, Brown DD, Kerber RE: **Efficacy of an automated external defibrillator in the management of out-of-hospital cardiac arrest: validation of the diagnostic algorithm and initial clinical experience in a rural environment.** *Circulation* 1986, 73:701-709.
21. Mols P, Beaucarne E, Bruyninx J, Labruyere JP, De Myttenaere L, Naeije N, Watteeuw G, Verset D, Flamand JP: **Early defibrillation by EMTs: the Brussels experience.** *Resuscitation* 1994, 27:129-136.
22. Domanovits H, Meron G, Sterz F, Kofler J, Oschatz E, Holzer M, Mullner M, Laggner AN: **Successful automatic external operation by people trained only in basic life support in a simulated cardiac arrest situation.** *Resuscitation* 1998, 38:47-50.
23. Beckers S, Fries M, Bickenbach J, Derwall M, Kuhlen R, Rossaint R: **Comparison of automatic vs semiautomatic automated external defibrillators used by laypersons [abstract].** *Critical Care* 2004:P293.

ELSEVIER

Resuscitation 58 (2003) 25–30

RESUSCITATION

www.elsevier.com/locate/resuscitation

Comparison of ease of use of three automated external defibrillators by untrained lay people

P. Eames, P.D. Larsen *, D.C. Galletly

Section of Anaesthesia and Resuscitation, Wellington School of Medicine, Mein St., PO Box 7343, Wellington, New Zealand

Received 15 October 2002; received in revised form 17 December 2002; accepted 20 February 2003

Abstract

The use of automated external defibrillators (AED) by lay people has the potential to markedly increase survival from community cardiac arrest. Wider public use of AEDs requires units that can be operated safely and effectively by people with minimal or no training. This study compares the use of three AEDs by untrained lay people regarding ease-of-use, safety, pad positioning and time to defibrillation. 24 subjects with no prior exposure to the use of AEDs were asked to perform simulated defibrillation on a manikin using three defibrillators: Zoll AEDPlus, Medtronic Physio-Control LifePak CR Plus and Philips/Laerdal HeartStart OnSite Defibrillator. Subjects' performance were videotaped and reviewed for time to defibrillate, pad positioning and safety. Subjects were asked to rate the three units in terms of ease-of-use. Average times to first shock were 74.8 s for the Physio-Control, 83.0 s for the Laerdal and 153.4 s for the Zoll defibrillator. Pad positioning was scored as correct in 23/24 Laerdal trials, 19/24 Physio-Control trials and 14/24 Zoll trials. 23 out of the 24 subjects rated the Zoll most difficult to use. All subjects safely stayed clear of the unit when required. The majority of subjects safely and effectively delivered defibrillating shocks without any prior training and within quite acceptable times. Untrained subjects find the Physio-Control and Laerdal Defibrillator easier to use than the Zoll device. Features of AED design that improved ease of use are discussed.

Keywords: Automated external defibrillator; Resuscitation; Sudden cardiac death

Resumo

A utilização de Desfibrilhadores Automáticos Externos (AED) por leigos tem o potencial de aumentar, de forma marcada, a probabilidade de sobrevivência pós paragem cardíaca na comunidade. para que esta utilização dos AEDs pelo público seja alargada são necessários aparelhos que possam ser manipulados com segurança e eficácia por pessoas com treino mínimo ou mesmo sem treino nenhum. Este estudo estuda a utilização de três AEDs por leigos não treinados, comparando a: facilidade de utilização, segnrança, colocação das pás e tempo para desfibrilhar. Pediu-se a 24 indivíduos sem qualquer experiência prévia na utilização dos AEDs para realizarem desfibrilhação simulada num manequim utilizando três desfibrilhadores: Zoll AEDPlus, Medtronic Physio-Control LifePack CR Plus and Philips/Laredal HeartStart OnSite Defibrillator. O desempenho destes indivíduos foi filmado e avaliado relativamente ao tempo para desfibrilhar, posição das pás e segurança. Foi-lhes pedido que classificassem as três unidades relativamente à facilidade de utilização. O tempo médio para o primeiro choque foi 74.8 s para o desfibrilhador Physio-Control, 83.0 s para o Laerdal e 153.4 s para o Zoll. A posição das pás foi classificada como correcta em 23/24 ensaios Laerdal, 19/24 Physio-Control e 14/24 Zoll. 23 dos 24 indivíduos referiu que o Zoll era o mais difícil de utilizar. Todos os sujeitos permaneceram em segurança, afastados da unidade, quando foi necessário. A maioria dos indivíduos sem qualquer treino prévio, administrou a desfibrilhação em segurança e com eficácia e dentro de um tempo bastante aceitável. Indivíduos não treinados consideraram o desfibrilhador Physio-Control e o Laerdal mais fáceis de utilizar que o Zoll. São examinadas as características do desenho do AED que melhoram a facilidade da sua utilização.

* Corresponding author. Tel.: +64-4-385-5999; fax: +64-4-389-5318.
E-mail address: peter.larsen@wnmeds.ac.nz (P.D. Larsen).

0300-9572/03/$ - see front matter © 2003 Elsevier Ireland Ltd. All rights reserved.
doi:10.1016/S0300-9572(03)00103-5

Palavras chave: Desfibrilhação Automática Externa; Reanimação; Morte cardíaca Súbita

Resumen

El uso de desfibriladores automáticos externos (AED) por personal no entrenado tiene el potencial de aumentar marcadamente la sobrevida del paro cardíaco en la comunidad. El uso público mas amplio de AEDs requiere unidades que puedan ser operados con seguridad y efectivamente por personas sin entrenamiento o con entrenamiento mínimo. Este estudio compara el uso de tres AEDs por personas sin entrenamiento con respecto a facilidad de uso, seguridad, posicionamiento ,de electrodos y tiempo hasta la desfibrilación. Se solicitó a 24 sujetos sin previa exposición al uso de AEDs que realizaran una desfibrilación simulada en un maniquí usando tres distintos desfibriladores: ZollAEDPlus, Medtronic Physio-Control LifePak CR Plus y el Philips/Laerdal HeartStart Onsite Desfibrillator. El desempeño de los sujetos fue filmado en video y se revisó el tiempo a desfibrilación, posición de electrodos y seguridad. Se solicito a los sujetos que catalogaran las tres unidades en términos de facilidad de utilización. Los tiempos promedio a la primera descarga fueron 74.8s para el Physio-Control, 83.0s para el Laerdal, y 153.4 para el Zoll. Se consideró ubicación adecuada de electrodos en 23/24 intentos para el Laerdal, 19/24 para el Physio-Control y 14/24 para el Zoll. 23 de 24 sujetos tasaron el Zoll como el mas difícil de usar. Todos los sujetos se mantuvieron seguros sin contacto con la unidad cuando así se requería. La mayoría de los sujetos entregaron descargas en forma efectiva y segura dentro de tiempos aceptables y sin entrenamiento previo. Sujetos sin entrenamiento encuentran mas fáciles de usar las unidades de Laerdal y de Physio-Control que la de Zoll. Se discuten aspectos del diseño de los AED que mejoran la facilidad de utilización.

Palabras clave: Desfibrilador automático externo (DAE); Resucitación; Reanimación; Muerte súbita de origen cardíaco

1. Introduction

Recent studies have demonstrated significant increases in survival rates achieved by deployment of automated external defibrillators (AEDs) in a range of settings including casinos [1] aeroplanes [2] and in the hands of groups such as police officers [3].

While these studies support moves to increase the availability of AEDs to the general public, their wider use would only be possible if they can be shown to be very easy and safe to use by subjects with minimal or no training. A recent study of sixth-grade school children, completely unpracticed in AED use, demonstrated that AEDs can be used safely even in naïve users, with times-to-shock that would still be quite acceptable for first responders [4].

To overcome possible problems with safety and effective operation by the lay public, AED use must be intuitive. This requires a simple design, with clear, unambiguous instruction. The AED must be easy to activate and allow for rapid delivery of a shock.

With the lay public in mind, a number of manufacturers have developed AEDs designed to be very simple to use. There are, however, no studies comparing the use of different models of AEDs or looking at those features that improve ease of use. The current study aims to compare three newly developed AEDs; the Zoll AED-Plus, Medtronics Physio-control Lifepak CR Plus and Philips/Laerdal HeartStart Onsite Defibrillator in terms of their ease of use, safety, pad positioning and time to defibrillation by lay people who are completely untrained (Figs. 1–3).

2. Methods

We studied 24 subjects: seven men and 17 women with an age range of 18–46 years. None of the subjects had any prior experience with defibrillators and had not

Fig. 1. Medtronic Physio-Control LifePak CRPlus defibrillator with lid open showing electrode pads.

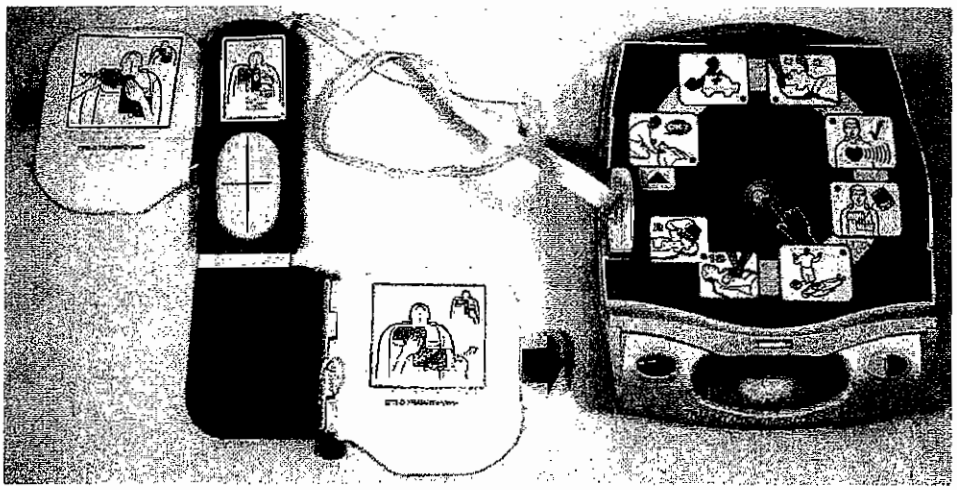


Fig. 2. Zoll AEDPlus defibrillator with lid removed and CPR-D padz.

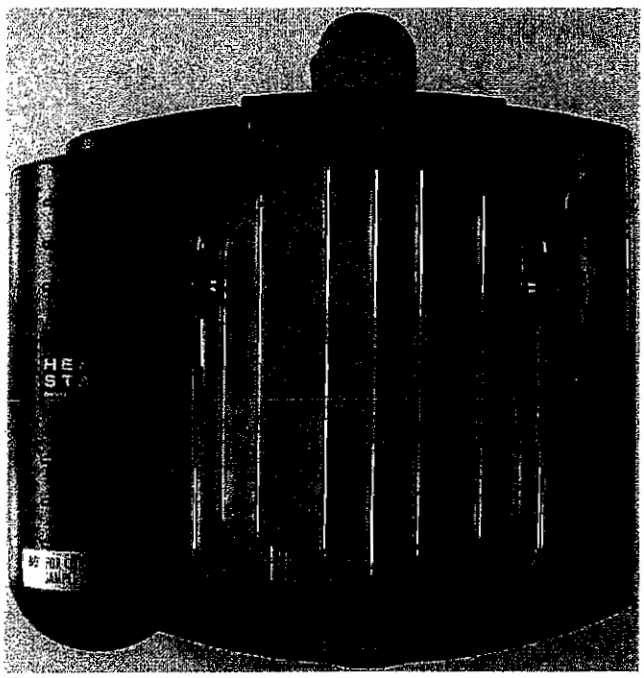


Fig. 3. Philips/Laerdal HeartStart OnSite defibrillator.

received basic life support training within the previous 5 years. The 24 subjects were randomly allocated to receive the devices using a Latin-square design, such that four subjects received each of the possible six orders.

3. Equipment

Automated external defibrillators:

1) Medtronic Physio-control Lifepak CR plus (Fig. 1);
2) Zoll AEDPlus with Zoll CPR-D pads (Fig. 2);
3) Philips/Laerdal HeartStart Onsite Defibrillator (Fig. 3).

4. Protocol

The subjects were instructed that they would be required to pretend to perform life saving first aid on a manikin. They were shown the AED and told that it was a device that could give an electric shock to a person's chest and that they would need to follow its instruction (Table 1) in order to restart the manikin's heart, and to do so as quickly as possible.

The manikin (Laerdal Resusci-Anne) was placed supine in the middle of the room dressed in a zippered jacket. The AED was placed along side the mannequin and left in the stand-by mode. A video camera and operator were positioned to one side of the room and the examiner read the subject their instructions at the door of the room and was then able to use the remote control of the AED when necessary. The trial was stopped when a shock had been delivered, or at 4 min, whichever came first.

All attempts were videotaped and from the videotapes we determined time required to defibrillate the manikin, correct pad placement and safety. In addition, the subjects were asked to rate the three units from best to worst in terms of ease of use.

The right sided pad was scored as correctly placed if at least one third of the pad was applied to an area circumscribed by the clavicle superiorly, nipple line inferiorly, anterior axillary line laterally and right sternal margin medially. The left pad was scored as correctly placed if at least one third of the pad was applied to an area circumscribe by the nipple line superiorly, costal margin inferiorly, mid-clavicular line medially and mid-axillary line laterally.

Table 1
AED voice prompts

	Physio-Control LifePak CR Plus	Philips/Laerdal HeartStart 1	Zoll AED Plus
AED self check	–	–	Unit OK
			Stay calm
Initial assessment	–	–	Check responsiveness
Help	Call for help now	–	Call for help Stay calm Check responsiveness
Repeat help	–	–	Call for help
Airway	–	–	Open airway
Breathing	–	–	Check for breathing. Give two breaths
Circulation	–	–	Check circulation
Expose chest	Remove clothing from chest	Begin by removing all clothing from the patients chest—cut clothing if needed	–
Access electrodes	Pull red handle to open bag	When patients chest is bare remove protective cover and take out white adhesive pads	–
Attach electrodes	Peel each pad off blue plastic and apply pads to exposed chest	Look carefully at the pictures on the white adhesive pads. Peel one pad from the yellow plastic liner Place pad exactly as shown in the picture. Press firmly to patient's bare skin When the first pad is in place, look carefully at the picture on the second pad. Peel the second pad from the yellow plastic liner. Place pad exactly as shown in the picture. Press firmly to patients bare skin	Attach electrode pads
Safety	Do not touch patient	No one should touch the patient. Analyzing	Do not touch patient, analyzing
	Evaluating heart rhythm	No one should touch the patient. Analyzing	
Shock advised	Stand by preparing to shock	Shock advised	Treatment advised
Additional safety	Everyone clear	–	Do not touch patient
Deliver shock	Press flashing button	Press the flashing orange button now	Press treatment button

The procedure was recorded as safe if the subject remained clear of the manikin (i.e. was not in contact with the manikin) during delivery of the defibrillating shock.

5. Results

24 lay people performed simulated defibrillation on the manikin using the three AEDs. These results are summarized in Table 2. The mean time to first shock for the Physio-Control was 74.8 s (range 61–90 s), the Laerdal had an average of 83.0 s (range 54–111 s) and the Zoll had an average time to first shock of 153.4 s (range 92–240 s). The differences in times between the three units were statistically significant (P-value < 0.05).

There was no statistically significant difference between the Laerdal and the Physio-Control in terms of subject preference, but a significant preference for either of these units over the Zoll was expressed. The Zoll was rated the most difficult to use by 23 out of the 24 participants.

Electrode pad placement was scored as incorrect in one out of 24 Laerdal trials, five out of 24 Physio-

Table 2
Summary of results

	Physio-Control LifePak CR Plus	Philips/Laerdal HeartStart 1	Zoll AEDPlus
Time to defibrillate	75 (8)	83 (15)	153 (56)
Incorrect electrode placement	5	1	10
Failed to deliver shock	0	0	6
Preference	1.5	1.4	3.0

Mean (S.D.) time to defibrillate in seconds, the number of subjects who placed the electrode pads incompletely, the number who failed to deliver any type of shock, and the mean rating of the device, from first to third are given for each of the three AEDs.

Table 3
Summary of order effect

	Laerdal	Zoll	Physio-Control
Time to defibrillate	97	170	75
Incorrect electrode placement	0/4	1/4	0/4
	Laerdal	Physio-Control	Zoll
Time to defibrillate	82	73	111
Incorrect electrode placement	0/4	0/4	0/4
	Physio-Control	Zoll	Laerdal
Time to defibrillate	80	114	74
Incorrect electrode placement	2/4	2/4	1/4
	Physio-Control	Laerdal	Zoll
Time to defibrillate	81	71	140
Incorrect Electrode Placement	2/4	0/4	1/4
	Zoll	Laerdal	Physio-Control
Time to defibrillate	207	100	78
Incorrect electrode placement	4/4	0/4	0/4
	Zoll	Physio-Control	Laerdal
Time to defibrillate	178	65	73
Incorrect electrode placement	2/4	1/4	0/4

Mean time to defibrillate in seconds, and the number of subjects who placed the electrode pads incompletely are given for each type of defibrillator for each of the six possible orders in which subjects received the three devices.

Control trials, and ten out of 24 Zoll trials. In all cases the pad placement errors for the Laerdal and the Physio-Control involved the placement of the pads side by side on the anterior chest without reference to the diagrams on the pads. A variety of errors were seen with the Zoll where ten of the 24 subjects were unable to attach the pads correctly. Electrode pad orientation and positioning were at fault in seven of these ten with several bunching up the two pads and placing them side-by-side on the chest. Several subjects failed to remove the adherent backing of the pads or realize that they were adhesive. In addition to these positioning problems, three subjects placed the Zoll pads over the clothing, four failed to remove the adherent backing and one placed the pad upside-down.

There was an order effect in the study in terms of both electrode positioning and time to defibrillation, which is summarized in Table 3. Those subjects that received the Zoll first made significantly more errors in pad placement (six error out of eight) and these errors were of a more profound nature (three subjects placed pads over the clothing and one subject placed the pads upside-down) than those who had previously used one of the other two models. A similar finding was encountered with the Physio-Control defibrillator where all five electrode placement errors occurred in the 12 subjects who received the unit prior to use of the Laerdal defibrillator.

Defibrillation times were significantly slower on the first attempt for the Physio-Control (8 s slower on first attempt, $P = 0.01$, ANOVA) and Zoll devices (59 s slower on first attempt, $P = 0.03$ ANOVA), but were not different between attempts for the Laerdal device.

All subjects moved clear of the manikin during the delivery of the defibrillating shock and did not touch the manikin during defibrillation or charging.

6. Discussion

Recent advances in AED technology have made the possibility of public access to defibrillators possible [5]; an initiative advocated by several major international health and government organizations [5–8]. Several studies have demonstrated impressive improvements in survival rates where trained non-medical personnel were given access to defibrillators [1–3,9], but few studies have looked at the use of AEDs by untrained, AED-naïve rescuers [4]. No studies have compared the use of different AEDs by untrained lay subjects and identified those features that may make lay rescuers capable of safely and quickly delivering a shock.

Although the manufacturers of AEDs advocate use by trained personnel, in the current study completely untrained lay people were chosen. The testing of these devices by completely untrained individuals has merit for a number of reasons. Firstly, it is inevitable that with widespread distribution of AEDs they will occasionally by used by untrained people. Secondly, these devices may be used by people who have little recall of their initial training or who have not received frequent retraining. Those features that ensure safe and effective use in untrained subjects are likely to be the same features that ensure safe and effective use in the stressful context of cardiac arrest in trained personnel.

While safe use was demonstrated with all three units in the current study, there were marked differences in

terms of speed, accuracy of pad placement and ease of use. The most difficulties were encountered with the Zoll AED plus unit, and some of these related to the use of the Zoll CPR-D electrode pads, which is a one-piece electrode. It is possible that had we used the traditional type of pads as used with the other two units that some of these difficulties may have been overcome. However, we chose to use the CPR-D pads because these are the default pads shipped with the device, and a significant portion of the difficulties users had with the Zoll unit cannot be attributed solely to this difference in the electrode pads. Some subject had difficulty opening the Zoll unit and activating the on/off switch, which requires 5 s of pressure. The Zoll AED gave no instruction to remove clothing from the victim's chest, and three subjects placed the electrode pads over the manikins clothing. Subjects appeared confused by the icons and indicator lights on the Zoll, often attempting to press these purely visual icons. They were also unsure which button was the "treatment button" on the Zoll AED, and four subjects responded to the prompt to push the treatment button by turning the machine off.

7. CPR prompts

Our study did not examine the effectiveness of the AEDs in instructing people to perform CPR. While the primary function of the AED is to deliver a defibrillating shock, both the Zoll AEDPlus and the Laerdal HeartStart also instruct people in the administration of CPR. Studies have demonstrated that with instruction from EMS dispatchers, untrained individuals can perform CPR adequately and that this may improve survival rates from cardiac arrest [10]. Therefore, instructions from the AED may be highly valuable in aiding the performance of CPR and this is an aspect of their function that needs further study.

8. Study implications

This study lends further support to the concept of lay-public access to defibrillation. The majority of subjects were able to effectively deliver a defibrillating shock and, despite having no training in defibrillation, all subjects moved clear of the manikin and observed the instruction not to touch the mannequin during defibrillation. The times to defibrillate were much faster than would be seen if an off-site defibrillator was required.

The features that improved use by untrained operators included clear, simple, method of activating the unit, and a clear method of delivering the shock. Explicit, clear and unambiguous voice prompts relating to pad placement, removal of adhesive plastic and a prompt to look at the diagrams on the pads also seems critical as the majority of difficulties within the current study related to pad placement. The study indicates that the HeartStart and LifePak CR are easier to use by untrained subjects than the AEDPlus, and are more suitable for use in public access defibrillation.

Acknowledgements

The Medtronic Physio-control Lifepak CR plus was supplied by PDI Medical, New Zealand, who are the New Zealand distributor for Medtronic Physio-Control. The Zoll AEDPlus was supplied by Zoll Medical, New Zealand, and the Philips/Laerdal HeartStart Onsite Defibrillator was supplied by Laerdal, Australia. We are grateful to these companies for the use of these devices to conduct this study.

References

[1] Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. New Engl J Med 2000;343:1210–6.
[2] Page RL, Joglar SA, Kowal RC, et al. Use of automated external defibrillators by a US airline. New Engl J Med 2000;343:1210–6.
[3] White RD, Asplin BR, Bugliosi TF, Hankins DG. High discharge survival rate after out-of-hospital ventricular fibrillation with rapid defibrillation by police and paramedics. Ann Emerg Med 1996;28:480–5.
[4] Gundry JW, Comess KA, DeRook FA, Jorgenson D, Brady GH. Comparison of naïve sixth-grade children with trained professionals in the use of an AED. Circulation 1999;100:1703–7.
[5] Davies CS, Colquhoun M, Graham S, Evans T, Chamberlain D. Defibrillators in public places: the introduction of a national scheme for public access defibrillation in England. Resuscitation 2002;52(1):13–21.
[6] Cummins RO, Thiers W, Paraskos J, et al. Encouraging early defibrillation: the AHA and AED. Ann Emerg Med 1990;19:1245–8.
[7] American Heart Association and International Liaison Committee on Resuscitation. Guidelines 2000 for cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Resuscitation 2000;46:73–91.
[8] Weisfeldt ML, Kerber RE, McGoldrick RP, Moss AJ, Nichol G, Ornato JP, Palmer DG, Riegel B, Smith SC. Public Access Defibrillation. A statement for healthcare professionals from the American Heart Association Task Force on automatic external defibrillation. Circulation 1995;92:2763.
[9] Ross P, Nolan J, Hill E, Dawson T, Whimster F, Skinner D. The use of AEDs by police officers in the city of London. Resuscitation 2001;50(2):141–6.
[10] Bang A, Biber B, Isaksson L, Lindqvist J, Herlitz J. Evaluation of dispatcher-assisted cardiopulmonary resuscitation. Eur J Emerg Med 1999;6:175–83.

Comparison of Naive Sixth-Grade Children With Trained Professionals in the Use of an Automated External Defibrillator

John W. Gundry, MD; Keith A. Comess, MD; Frances A. DeRook, MD; Dawn Jorgenson, PhD; Gust H. Bardy, MD

Background—Survival after out-of-hospital cardiac arrest (OHCA) is strongly influenced by time to defibrillation. Wider availability of automated external defibrillators (AEDs) may decrease response times but only with increased lay use. Consequently, this study endeavored to improve our understanding of AED use in naive users by measuring times to shock and appropriateness of pad location. We chose sixth-grade students to simulate an extreme circumstance of unfamiliarity with the problem of OHCA and defibrillation. The children's AED use was then compared with that of professionals.

Methods and Results—With the use of a mock cardiac arrest scenario, AED use by 15 children was compared with that of 22 emergency medical technicians (EMTs) or paramedics. The primary end point was time from entry onto the cardiac arrest scene to delivery of the shock into simulated ventricular fibrillation. The secondary end point was appropriateness of pad placement. All subject performances were videotaped to assess safety of use and compliance with AED prompts to remain clear of the mannequin during shock delivery. Mean time to defibrillation was 90±14 seconds (range, 69 to 111 seconds) for the children and 67±10 seconds (range, 50 to 87 seconds) for the EMTs/paramedics ($P<0.0001$). Electrode pad placement was appropriate for all subjects. All remained clear of the "patient" during shock delivery.

Conclusions—During mock cardiac arrest, the speed of AED use by untrained children is only modestly slower than that of professionals. The difference between the groups is surprisingly small, considering the naïveté of the children as untutored first-time users. These findings suggest that widespread use of AEDs will require only modest training. (***Circulation.*** **1999;100:1703-1707.)**

Key Words: defibrillation ■ fibrillation ■ death, sudden ■ cardiopulmonary resuscitation

Sudden cardiac death (SCD) is the leading cause of death in the United States, accounting for >350 000 cases annually.[1] The vast majority of SCD cases are due to ventricular fibrillation (VF).[2] Survival to hospital discharge after out-of-hospital cardiac arrest (OHCA) remains poor, generally only in the 5% to 20% range, from the best of emergency response centers.[3] The most effective intervention for VF is rapid defibrillation. This intervention is significantly more important to survival than cardiopulmonary resuscitation[4] and is the reason that American Heart Association guidelines were rewritten to support the use of defibrillatory shocks before basic life support in a cardiac arrest.[5] In certain environments, survival rates can approach 80% to 100% when defibrillation is achieved within the first few minutes of a cardiac arrest.[6,7] Despite efforts to bolster emergency medical care by broadening training in defibrillation to include, in addition to paramedics, emergency medical technicians, response times for OHCA remain unacceptably long.

The development of automated external defibrillators (AEDs) in the early 1980s made possible the use of defibrillation by individuals other than paramedics and hospital personnel.[8] Further technological developments in the 1990s have made these devices more portable and simpler to use. With these improvements and the recognition of time to defibrillation as 1 of the most critical, if not the most important, factors in clinical outcome, AED use by laypersons has developed widespread support.[9] More widespread use of AEDs may significantly affect response times for OHCA and therefore survival. In large measure, wider availability of AEDs means that lay users will increase in number. Consequently, this study endeavored to improve our understanding of how well lay users will use AEDs by measuring use times and appropriateness of pad location in a controlled fashion. Naive users, sixth-grade students, were chosen to simulate an extreme circumstance for purposes of comparison with trained professional users.

Received April 1, 1999; revision received June 27, 1999; accepted July 2, 1999.

From the Division of Cardiology, Department of Medicine, University of Washington, Seattle, Wash.

Correspondence to Gust H. Bardy, MD, Box 356422, University of Washington Medical Center, Seattle, WA 98195-6422. E-mail gbardy@u.washington.edu

Circulation is available at http://www.circulationaha.org

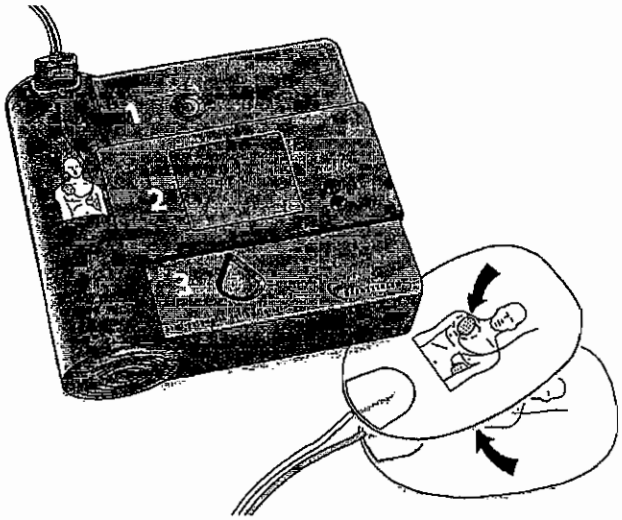


Figure 1. AED with electrode pads and connector.

Steps

1 "Apply pads to patient's bare chest."
2 "Plug in pads connector next to flashing light."
3 "Apply pads."
4 "Plug in connector."

Steps 3 and 4 repeat every 15 seconds until completed.

5 "Analyzing heart rhythm. Do not touch the patient."

5 second pause.

6 "Shock advised. Charging. Stay clear of patient."
7 "Deliver shock now. Press the orange button now."

Step 7 repeated every 6 seconds until completed.

8 "Shock delivered. Analyzing heart rhythm. Do not touch the patient."

5 second pause.

9 "Analyzing heart rhythm."

3 second pause.

10 "No shock advised. It is safe to touch the patient. Check airway, check breathing, check pulse. If needed begin CPR."

Figure 2. Sequence of AED voice prompts during mock cardiac arrest.

Methods

Subject Recruitment and Selection

The study was approved by the University of Washington Human Subjects Review Committee. Informed consent was obtained from each subject before the test was conducted (parental permission was obtained for the schoolchildren). Subjects were recruited by obtaining permission first from their respective training supervisors/teacher. They were required to have at least a sixth-grade reading level and no physical limitations (eg, visual or hearing handicaps or relative immobility) that would preclude the efficient use of an AED.

The 15 sixth-grade schoolchildren were selected from a single class at St Joseph Catholic School (Seattle, Wash). The entire class was recruited, but only 15 children received parental consent to participate. None of them had prior basic life support training or experience with an AED. None of the children was prompted or prepared in any way by the investigators before the study. The 22 emergency medical technicians (EMTs) or paramedics were chosen from the Kitsap County Fire Department (Bremerton, Wash). Each EMT or paramedic had extensive clinical training and experience managing a wide array of medical emergencies, including cardiac arrest. Every 6 months, each EMT or paramedic had been given a 2 1/2-hour formal workshop on AED use and its application to clinical scenarios.

Equipment

AED

The AED (Hewlett-Packard Heartstreant ForeRunner AED) delivers 150-J biphasic truncated exponential waveform shocks that adjust wave shape according to chest impedance. The device measures 6×22×20 cm and weighs 2 kg. Disposable, self-adhesive defibrillation pads with integrated cable and connector are supplied with the device. Diagrams on the pads illustrate placement in an anterior-anterior (lead II) position (Figure 1). Optional PC cards include the training card TC1, which places the AED in a scenario-based training mode and disables the energy delivery system. Each subject was assured of this safety feature before beginning the test. After the device was turned on and the pads were properly positioned and connected to the device, an internal protocol evaluated the patient's ECG and signal quality to determine whether a shock was appropriate. Connection impedance for proper defibrillation pad contact was also evaluated. Voice prompts guided the user through the necessary steps (Figure 2), and abbreviated text prompts were displayed on the screen.

Mannequin

The mannequin (Laerdal ResusciAnne) is widely used by the AHA for instructional purposes during advanced cardiac life support (ACLS) courses. The mannequin was fully dressed to better portray a cardiac arrest situation and to provide a natural barrier to the placement of electrode pads. Copper stripping was arranged in a grid on this mannequin to allow the AED to calculate patient impedance when electrode pads were placed during a training scenario. Voice prompts then told the subject if pads were making appropriate skin contact.

Video and Photography Materials

A Sony portable video recorder and videotape of sufficient quantity to record 5 minutes documented each subject's performance. A Polaroid instant camera photographed electrode pad applications and position.

Protocol

The subjects were informed that their performance would be evaluated in a mock cardiac arrest resuscitation on a mannequin. As part of this evaluation, the subjects were told they would be videotaped. Each subject was tested individually and could not view another's performance. The importance of speed was emphasized to each subject before the test. The only instruction given to the schoolchildren was verbal directions as to the identity of the electrode pads and the necessity of peeling them from their packaging and placing them on the mannequin's chest. (In earlier tests, lay users proved unfamiliar with the word "pads" and how to peel the cover off.) The EMTs/paramedics were not given any such instruction about the electrode pads.

The test began when the subject was handed the AED with instructions that in an adjoining room a mannequin was lying on the floor, representing an unresponsive, pulseless person. The AED was packaged in a soft case with the zipper shut. The device was kept in its usual standby mode at the beginning of the test, ie, battery inserted. Present in the testing room was a physician certified in ACLS and AED use. The physician's role was to observe the performance of the subject and give feedback after the resuscitation test was completed. A fully dressed mannequin lay supine on the floor. A video camera and operator stood at 1 corner of the room. The steps observed in performing resuscitation to first shock included (1) opening the soft case, (2) turning on the AED with a press of a single button, (3) attaching the electrode pad connector to AED, (4) applying the electrode pads to the patient, (5) safely staying clear of the mannequin while charging, and (6) administering the shock (press of a single button) when instructed by the AED.

Time From Start of Resuscitation Scenario to AED Shock

Subject	EMTs/Paramedics, s	Sixth Graders, s
1	72	93
2	70	69
3	59	111
4	52	88
5	69	81
6	59	69
7	74	85
8	74	105
9	65	82
10	50	109
11	56	77
12	72	98
13	63	98
14	77	103
15	56	75
16	58	
17	87	
18	77	
19	59	
20	65	
21	79	
22	80	
Mean±SD (range)	67±10 (50–87)	90±14 (69–111)
95% CI	62–71	82–97
P	<0.0001	
95% CI of difference	15–31	

The subjects were not permitted to ask questions during the test, and no guidance or clues were provided by the researchers. After each subject's completion of the test, the physician-observer took a photograph of the electrode pad positioning. This physician then reviewed the videotape material to determine the time from beginning the test to delivering a shock. (The AED is designed to give an audible sound when the shock is delivered during the cardiac arrest scenario.) A separate physician, also certified in ACLS and AED use, independently reviewed the videotape of each mock resuscitation. This physician was not present during the training or testing process. Proper completion of each step was verified and recorded by the reviewer.

Performance of the step involving the application of pads to the patient received particular attention. Evaluation of this step was based primarily on the application of pads that would achieve an effective current vector through the left ventricle.[10–13] For practical purposes, this involves placement in an anterior-apical position (right infraclavicular–left lateral chest wall) as diagrammed on the electrode pads provided in the AED package and shown in Figure 1. An accepted range for pad positioning was diagrammed on a custom-made plastic sheet designed to consistently fit the mannequin chest wall. Subject pad application (as determined from the photograph) was compared with this range as part of the performance evaluation. The relation between subject pad positioning and the accepted range was recorded by the physician-observer (see the Data Analysis section). The accepted range for the right infraclavicular pad involves the following: cephalad border, 3 cm above the clavicle; lateral border, midaxillary line; medial border, 3 cm left of the midsternum; and caudal border, costal margin. The accepted range for the apical pad involves the following: cephalad border, top of the axilla; lateral border, midaxillary line; medial border, 2 cm right of the midsternum; and caudal border, 4 cm below the costal margin. Admittedly, these border designations are somewhat arbitrary. They are created, however, in accordance with the idea of achieving an effective current vector. Subjects were graded in a pass/fail format for this step. Criteria for passing were for all the following to be met: (1) clothing separated from mannequin chest wall before pad placement, (2) each pad placed within the accepted range (as defined above), (3) pads separated by ≥2 cm from each other, and (4) each pad interfaced by ≥50% with the mannequin chest wall.

Data Analysis

Primary End Point

The primary end point in this study, time to first shock from entry into the room of the mock cardiac arrest scenario, was chosen to represent the most crucial factor in determining survival in a cardiac arrest victim. Previous studies have suggested that a large benefit in survival from OHCA is achieved with a reduction in time to defibrillation rates of >3 minutes. A much smaller survival benefit is seen when response times differ by just 1 minute.[14] Differences in time to defibrillation rates of ≤15 seconds have not been proven to result in significant differences in survival. By use of a *t* test and 95% CIs, the mean response time of the children was compared with that achieved by the EMT/paramedic group. The sample size was selected to show a 15-second difference in AED use times ($P=0.05$, power=0.80), assuming that the AED use time for the EMT/paramedic group would be 80±15 seconds (from preliminary tests). This design required ≥15 subjects for each group.

Secondary End Points

Secondary end points were chosen to assess the effectiveness of the resuscitation effort. Proper pad positioning (as outlined above) was determined in a pass/fail format and compared in a proportional manner between groups. Procedure safety was assessed by observing whether the subject stayed clear of the mannequin when instructed, ie, during device charging and shock delivery.

Results

Time to Defibrillation

Time from beginning the scenario to delivering the AED shock is summarized in the Table. Mean time to defibrillation was 90±14 seconds (range, 69 to 111 seconds) for the sixth-grade schoolchildren and 67±10 seconds (range, 50 to 87 seconds) for the EMT/paramedics ($P<0.0001$). The difference in mean values between the children and EMT/paramedics was 23 seconds, with a 95% CI of the difference from 15 to 31 seconds.

Electrode Pad Positioning and Safety

Electrode pad positioning was determined to be adequate for all schoolchildren and all EMT/paramedics. All subjects in each group stayed effectively clear of the mannequin during the process of device charging and shock delivery.

Discussion

Technological Developments in AEDs

AEDs were first developed in the late 1970s[8] and became available for clinical use in the early 1980s.[15] The AED identifies VF in cardiac arrest victims and provides the means to deliver defibrillation shocks. The operator is neither required to make judgments regarding the cardiac rhythm nor required to acknowledge the need for defibrillatory shocks. Recent advances have enhanced the ease of use of AEDs, including instructional verbal prompts, simplified displays, and icons to help in proper pad placement. An emphasis on

human-factors design has simplified the steps that the user must perform. In addition, application of more effective low-energy biphasic waveforms to these devices as a means of energy delivery has significantly reduced their size and enhanced their portable nature. The clinical utility of biphasic waveform use in victims of OHCA has been well demonstrated.[16–18] More efficient use of energy by biphasic waveform AEDs leads to smaller capacitors and batteries. This contributes to the significantly smaller overall size of the newest AEDs.

The impetus for support of the broader use of AEDs derives from observations that the single most important factor determining outcome from cardiac arrest is time to defibrillation. Providing defibrillation to a cardiac arrest victim improves survival by ≈10%/min during the first 10 minutes of the arrest.[14] Use of AEDs by trained EMTs has shown to improve survival from OHCA.[9] Likewise, use of AEDs in OHCA by police officers has significantly improved response times and yielded survival rates as high as 58%.[4] The successful use of AEDs by persons with minimal training or by nonprofessionals has now been applied also to the casino and airline industries.[7,16,17,19]

Undoubtedly, many public arenas exist in which response times by trained medical personnel may be unacceptably long. The AHA estimates that broader use of AEDs by first-line responders could avert 20 000 to 100 000 deaths per year.[20] Economic analysis has suggested that the cost per life saved from OHCA by emergency medical systems that provide EMTs with defibrillation training may be less than $5000, a value well below that addressing other major causes of death.[21]

Previous Studies Examining AED Use With Trained Laypersons

Unfortunately, few studies have addressed the training needs or requirements surrounding the use of these devices by lay individuals or non-EMT/paramedic personnel. One study examined the use of AEDs on mannequins by family members of cardiac arrest survivors.[22] All but 2 of 34 individuals were trained to deliver the first defibrillatory shock within 2 minutes in a mock cardiac arrest situation. Significant worsening of speed and quality of performance was observed on retesting after 6 weeks. The variable most highly correlated with skill decline was age. Decreases in performance may have related to the protocol used in the study, which preceded current guidelines for cardiopulmonary resuscitation (CPR); subjects were required to perform CPR before the first defibrillatory shock and between each successive shock. Furthermore, the device used for the study (Heart Aid, model 80, Cardiac Resuscitator Corp) was significantly larger than the most recent AEDs and lacks verbal prompts and simplified visual displays. In another study, volunteers were trained in a 2-hour class to operate an AED and perform CPR.[23] Retesting at 1 year showed that the volunteers were satisfactorily able to remember how to operate the device although the time required to deliver a shock was greater.

More recently, use of AEDs by student nurses trained in CPR was studied.[24] With a simplified and updated protocol (instructions initially for 3 successive defibrillatory shocks) and use of a somewhat newer-generation AED (Laerdal Heartstart 3000), these individuals were trained to deliver a first shock within 60 seconds. Subtle loss of speed and skill was seen after 1 week and 1 month, but training reinforcement led to a retention of the initial recorded speed and skill after 3 and 6 months. However, this AED did not include the more instructive verbal prompts and visual displays that many modern AEDs use. In another study, lay users were successfully trained to deliver shocks from an AED during an AHA HeartSaver course.[25] Time to first shock increased from 70 to 83 seconds when retention was tested 2 to 4 months later.

Study Implications

The studies referenced above involved laypersons who were given comprehensive instruction and training before AED use. From a public-access defibrillation standpoint, perhaps a more pertinent issue is whether individuals with minimal or no training can safely and effectively use these devices. No prior study has examined this question, nor has any prior study compared AED use by laypersons to a reference standard, in this case, EMTs and paramedics. This study demonstrated that the speed of AED use by essentially untrained sixth-grade schoolchildren was very good and only modestly slower than that of individuals whose job it is to resuscitate victims from cardiac arrest. Performance quality, specifically electrode pad application, was similar in both groups. All test subjects stayed effectively clear of the mannequin during device charging and shock delivery. In general, these findings suggest that training requirements will not significantly limit more widespread use of AEDs.

The principal obstacle to actual use of the AED appeared to be identifying and understanding the term "pads." Questionnaires distributed after the tests suggest that many laypersons do not have an initial intuitive understanding of electrode pad identity or function. Some children expected paddles as portrayed in movies or on television to be inside the case. This information may be helpful in the design of future equipment in which the identity of the electrode pads is clearly marked and the need to peel them from their packaging is clearly stated.

Despite some of these difficulties, most subjects responding to the posttest questionnaire found the AED to be relatively straightforward to use. Having completed the drill, all children but 1 agreed that they could teach use of this AED to someone else, and all believed that they would use the AED on a family member if the situation arose. For the EMTs/paramedics, 96% found AED use in this drill to be easier than performing CPR.

Finally, despite the very limited instruction, there were no safety concerns. None of the users touched the pads or the mannequin during mock shock delivery. Thus, given appropriate AED commands, modern AEDs can be used safely.

Study Limitations

The subjects chosen for this study were not selected at random. Therefore, this selection process may introduce some bias. Despite this limitation, they represent an extreme of the uninitiated lay user. Another limitation is subject

motivation. It is difficult to imagine the anxiety induced by a real cardiac arrest. A mock cardiac arrest scenario cannot simulate OHCA in all its variations. Nevertheless, the importance of speed was emphasized to each subject before the test. Considering the general premise of this study, it seems intuitive that the group performance would likely remain similar albeit somewhat longer for the children.

Conclusions

In conclusion, AEDs have developed concurrently with our understanding of time to defibrillation as a crucial factor determining outcome from cardiac arrest. Historically, the complexity and size of AEDs dictated that they could be used only by trained medical professionals. Recent technological developments and emphasis on human-factors design have made these devices much more portable and straightforward to use. These factors have supported the notion of a broader use of AEDs, including laypersons. In this study, statistically significant reductions in defibrillation times were seen with EMTs/paramedics versus untrained lay subjects. The absolute differences between groups, however, were small and may be of little clinical relevance. Furthermore, lay subjects demonstrated proficient electrode placement and safety precautions with the AED system used. These findings suggest that use of this AED by untrained laypersons may be feasible and that complex and time-consuming training programs may not be necessary. The utility of a simplified training program may be in helping a user perform under the pressure and anxiety of an actual emergency rather than learning a complex operational task. One might suggest that even a child can do it.

Acknowledgments

We thank the children and their parents of the sixth-grade class from St Joseph Catholic School, Seattle, Wash, for participating in this trial. We also thank the EMTs and paramedics from the Kitsap County Fire Department, Bremerton, Wash, for taking the time from their busy schedules to help advance our understanding of AED use. Finally, we thank Hewlett Packard, Inc, for loaning the resuscitation mannequin, AED, and electrode pads to the investigators of this study.

References

1. Gillum RF. Sudden coronary death in the United States. *Circulation*. 1989;79:756–765.
2. Weaver DW. Considerations for improving survival from out-of-hospital cardiac arrest. *Ann Emerg Med*. 1986;15:1181–1186.
3. Moss AJ. Sudden cardiac death and national health. *Pacing Clin Electrophysiol*. 1993;16:2190–2191.
4. White RD, Asplin BR, Bugliosi TF, Hankins DG. High discharge survival rate after out-of-hospital ventricular fibrillation with rapid defibrillation by police and paramedics. *Ann Emerg Med*. 1996;28:480–485.
5. Guidelines for cardiopulmonary resuscitation and emergency cardiac care. *JAMA*. 1992;268:2171–2298.
6. Hossack KF, Harwig R. Cardiac arrest associated with supervised cardiac rehabilitation. *J Cardiac Rehab*. 1982;2:402–408.
7. Valenzula TD, Bjerke HS, Clark LL, Hardman R, Spait DW, Nichol G. Rapid defibrillation by nontraditional responders: the casino project. *Soc Acad Emerg Med*. 1998;127:414. Abstract.
8. Diack AW, Welborn S, Rullman RG, Walter CW, Wayne MA. An automatic cardiac resuscitator for emergency treatment of cardiac arrest. *Med Instrument*. 1979;13:78–83.
9. Cummins RO, Thies W. Encouraging early defibrillation: the American Heart Association and automatic external defibrillators. *Ann Emerg Med*. 1990;19:1245–1248.
10. Ewy GA. Influence of paddle-electrode location and size on success of cardioversion. *N Engl J Med*. 1982;306:174–175.
11. Jorgenson DB, Haynor DR, Bardy GH, Kim Y. Computational studies of transthoracic and transvenous defibrillation in a detailed 3-D human thorax model. *IEEE Trans Biomed Eng*. 1995;42:172–184.
12. Jorgenson DB, Schimpf PH, Shen I, Johnson G, Bardy GH, Haynor DR, Kim Y. Predicting cardiothoracic voltages during high energy shocks: methodology and comparison of experimental to finite element model data. *IEEE Trans Biomed Eng*. 1995;42:359–371.
13. Murai T, Kagawa Y. Electrical impedance computed tomography based on a finite element model. *IEEE Trans Biomed Eng*. 1985;32:177–184.
14. Eisenberg MS, Horwood BT, Cummins RO, Reynolds-Haertle R, Hearne TR. Cardiac arrest and resuscitation: a tale of 29 cities. *Ann Emerg Med*. 1990;19:179–186.
15. Weaver DW, Copass MK, Hill DL, Fahrenbruch C, Hallstrom AP, Cobb LA. Cardiac arrest treated with a new automatic external defibrillator by out-of-hospital first responders. *Am J Cardiol*. 1986;57:1017–1021.
16. Poole JE, White RD, Kanz KG, Hengstenberg F, Jarrard GT, Robinson JC, Santana V, McKenas DK, Rich N, Rosas S, Merritt S, Magnotto L, Gallagher J, Gliner BE, Jorgensen DB, Morgan CB, Dillon SM, Kronmal RA, Bardy GH, for the LIFE Investigators. Low-energy impedance-compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out-of-hospital cardiac arrest. *J Cardiovasc Electrophysiol*. 1997;8:1373–1385.
17. Gliner BE, Jorgensen DB, Poole JE, White RD, Kanz KG, Lyster TD, Leyde KW, Powers DJ, Morgan CB, Kronmal RA, Bardy GH, for the LIFE Investigators. Treatment of out-of-hospital cardiac arrest with a low-energy impedance-compensating biphasic waveform automatic external defibrillator. *Biomed Instrum Technol*. 1998;32:631–644.
18. Cummins RO, Hazinski MF, Kerber RE, Kudenchuk PJ, Becker L, Nichol G, Malanga B, Aufderheide TP, Stapleton EM, Kern K, Ornato JP, Sanders A, Valenzuela T, Eisenberg M. Low-energy biphasic waveform defibrillation: evidence-based review applied to emergency cardiovascular care guidelines. *Circulation*. 1998;97:1654–1667.
19. Page RL, Hamden MH, McKenas DK. Defibrillation aboard a commercial aircraft. *Circulation*. 1998;97:1429–1430.
20. *Expanded Access to Defibrillation: Legislative Advocacy Guide*. Dallas, Tex: American Heart Association; 1996.
21. Ornato JP, Craren EJ, Gonzalez ER, Garnett AR, McClung BK, Newman MM. Cost-effectiveness of defibrillation by emergency medical technicians. *Am J Emerg Med*. 1988;6:108–112.
22. Moore JE, Eisenberg MS, Cumnins RO, Hallstrom A, Litwin P, Carter W. Layperson use of automatic external defibrillation. *Ann Emerg Med*. 1987;16:669–672.
23. Cummins RO, Schubach JA, Litwin PE, Hearne TR. Training laypersons to use automatic external defibrillators: success of initial training and one-year retention of skills. *Am J Emerg Med*. 1989;7:143–149.
24. McKee DR, Wynne G, Evans TR. Student nurses can defibrillate within 90 seconds: an evaluation of a training program for third year student nurses in the use of an automatic external defibrillator. *Resuscitation*. 1994;27:35–37.
25. Cummins RO, Doherty A, Hein K, Damon S, Doherty D, Jerin J, Stiehr D. Teaching citizens to use an AED during the AHA HeartSaver course: active vs passive learning and long-term retention of skills. *Circulation*. 1997;96(suppl I):I-365. Abstract.

ELSEVIER

Resuscitation 62 (2004) 167–174

RESUSCITATION

www.elsevier.com/locate/resuscitation

Differing operational outcomes with six commercially available automated external defibrillators

Roman Fleischhackl, Heidrun Losert, Moritz Haugk, Philip Eisenburger, Fritz Sterz, Anton N. Laggner, Harald Herkner*

Department of Emergency Medicine, General Hospital, Medical University of Vienna, Währinger Gürtel 18-20, 1090 Vienna, Austria

Received 30 December 2003; received in revised form 18 March 2004; accepted 24 March 2004

Abstract

Introduction: In general automated external defibrillators (AED) are handled easily, but some untrained lay rescuers may have major problems with the use of such products. This may result in delayed shock delivery and delay in basic life support (BLS) after use of the AED. To study the effect of voice prompts and design solutions we tested the time from the first shock to the initiation of BLS for six defibrillators available in Austria. *Methods:* Volunteers, who had no AED training, were evaluated to see when they delivered the first shock and how often BLS was started after the voice prompts were given by the defibrillators. *Results:* Time to first shock delivered ranged from 78 (95% CI: 68–89) to 128 (95% CI: 110–146) s. The defibrillator-type had a significant influence on the time to first shock delivered ($P < 0.0001$). The proportion of volunteers who started BLS after defibrillation ranged from 93 to 33% and differed significantly between the AEDs used ($P < 0.03$). *Conclusions:* We demonstrated that there are significant differences between AEDs, concerning important operational outcomes like time to first shock and the start of BLS. Further research and development is urgently required to optimise user-friendliness and operational outcomes.

Keywords: Automated external defibrillator; Basic Life support; Bystander CPR; Out-of-hospital CPR

Resumo

Introdução: Na generalidade, os desfibrilhadores automáticos externos (DAE) são facilmente manuseáveis, mas alguns socorristas leigos, sem treino podem ter problemas sérios na utilização de tais aparelhos. Isto pode resultar num atraso na administração do choque e atraso no suporte básico de vida (SBV) após a utilização do DAE. Para estudar o efeito das ordens vocais e desenvolver soluções testámos o tempo do primeiro choque ao início do SBV em seis dos desfibrilhadores disponíveis na Áustria. *Métodos:* Voluntários, sem treino em DAE, foram avaliados para verificar quando administravam o primeiro choque e com que frequência era iniciado o SBV depois de dadas as instruções pelo DAE. *Resultados:* O tempo até ao primeiro choque variou de 78 (95% CI: 68–69) a 128 (95% CI: 110–146) s. O tipo de desfibrilhador teve influência significativa no tempo para administração do primeiro choque ($P < 0.0001$). A proporção de voluntários que iniciou SBV após a desfibrilhação variou de 93 a 33% e diferiu significativamente entre os DAE utilizados. ($P < 0.03$). *Conclusões:* Demonstramos que há diferenças significativas entre DAE's, implicando diferenças operacionais importantes como o tempo até ao primeiro choque e início de SBV. É necessária investigação adicional para, com urgência, optimizar a facilidade de utilização e os resultados operacionais.

Palavras chave: Desfibrilhador automático externo (DAE); Suporte básico de Vida (SBV); RCP por leigo; RCP extra-hospitalar

Resumen

Introducción: En general los desfibriladores automáticos externos (AED) son fácilmente manipulables, pero algunos reanimadores legos no entrenados pueden tener mayores problemas con el uso de tales productos. Esto puede resultar en retraso en la entrega de las descargas desfibriladoras y retraso en el soporte vital básico (BLS) después de usar el AED. Para estudiar el efecto de las indicaciones audibles y soluciones de diseño, medimos el tiempo desde la primera descarga hasta el inicio del BLS en seis desfibriladores disponibles en Austria.

* Corresponding author. Tel.: +43-1-40400-1964; fax: +43-1-40400-1965.
E-mail address: harald.herkner@akh-wien.ac.at (H. Herkner).

0300-9572/$ – see front matter © 2004 Elsevier Ireland Ltd. All rights reserved.
doi:10.1016/j.resuscitation.2004.03.018

Métodos: Voluntarios, quienes no tenían entrenamiento en AED, fueron evaluados para ver cuando entregaban la primera descarga y con que frecuencia iniciaban el BLS después que de las indicaciones audibles de los desfibriladores. *Resultados:* El tiempo hasta la primera descarga varió en un rango de 78 (95% CI: 68–89) a 128 (95% CI: 110–146) segundos. El tipo de desfibrilador tuvo una influeneia significativa sobre el tiempo a la primera descarga ($P < 0.0001$). La proporción de voluntarios que iniciaron BLS después de desfibrilar varió en un rango de 93 a 33% y difirieron significativamente entre los AEDs usados ($P < 0.03$). *Conclusiones:* demostramos que hay diferencias significativas entre los AEDs, que conciernen resultados operacionales importantes como el tiempo a la primera descarga y el inicio del BLS. Se requiere urgentemente ulterior investigación y desarrollo para optimizarla facilidad de uso y los resultados operacionales.

Palabras clave: Desfibrilador automático externo (DAE); Soporte vital Básico (SVB); Reanimación por testigos; RCP extrahospitalaria

1. Introduction

Many out-of-hospital cardiac arrest victims suffer from mild to severe, very often irreversible, neurological damage [1,2]. Like mortality, also neurological impairment can be decreased by early effective resuscitation, whether by lay or professional rescuers [3]. The success of out-of-hospital cardio pulmonary resuscitation (CPR) attempts depends strongly on the period that has elapsed between the occurrence of a life threatening event and the initiation of bystander help [4]. The most important link in the chain of survival is the bystander who witnesses the collapse [5]. The chance of successful CPR nearly correlates linearly with the duration of the interval until basic life support (BLS) and early defibrillation are given [6]. Most citizens worry about making mistakes in bystander CPR, and therefore hesitate to provide immediate support [7]. Automated external defibrillators (AED) can potentially help to quell such anxieties and hesitation.

A tremendous amount of public resources have been focused on improving cardiac arrest survival in public places, yet most out-of-hospital cardiac arrest incidents occur in private residences [8]. Therefore, AEDs are becoming increasingly more available for lay responders in Austria, since the Austrian Red Cross initiated a nation-wide public access defibrillation (PAD) project in 2001 [9]. Further, there is a focused strategy initiative, where relatives of high risk patients, like cardiac arrest survivors, are supplied with AEDs [10].

Even though the devices are easily bandled in general [11], untrained lay reseuers may have major problems with the use of particular products [12]. Valuable time may be lost, impairing survival and good neurological outcome after cardiac arrest [13,14]. Unambiguous and intuitive understanding of instructions is crucial for time-saving action. Understanding of specific visual and linguistic instructions may depend on cultural particularities. Since most AEDs are produced by international companies for use in many countries, translations of instructions must allow for cultural differences. Not all technical solutions, guiding figures or voice prompts given by the different AEDs may be clear enough for everyone to provide proper BLS. Lay rescuers may become confused by AED prompts, whicb may result in delayed shock delivery and delay in BLS after the delivered shocks.

The current study aims to compare all six defibrillators available in Austria for time to the first shock given and the initiation of BLS by lay people who are completely untrained in the use of an AED.

2. Methods and study design

We included volunteers from a large company and one school in Vienna as lay rescuers, who had no experience with an AED beforehand and who consented to participate.

The study was carried out by members of the Department of Emergency Medicine at the University General Hospital of Vienna. We used all types of AEDs available in Austria at the time. These were training defibrillators with no electrical discharge, from the six companies represented in Austria. Standardised equipment consisted of the allocated AED, a face shield and latex gloves. At the beginning of the experiment dressed manikins (Recording Resusci Anne™ CPR Manikin, Laerdal Corporation, Norway) were put in supine position on the floor. We performed the experiment in an isolated area, so that volunteers were not aware of the action taken by their predecessors.

We cbose a parallel group design of six groups and randomly allocated the six types of AEDs. Randomisation was performed by using a random number generator from a spreadsheet programme. According to this random list we produced consecutively numbered sheets revealing the name of the AED allocated. To ensure allocation concealment tbe numbered sheets were folded and sealed with staples. Immediately after a volunteer gave informed consent, a folded sheet was opened, and the evaluation was started. After assignment to an AED, volunteers were instructed by investigators that they were going to be exposed to a simulated cardiac arrest situation and that they sbould attempt every action that they would consider to be helpful. After the introduction, no further interaction between the investigators and the volunteers was allowed.

The experiment was videotaped and the data were documented on a standardised evaluation form. The time elapsed from start to the first shock delivered ('time to first shock') was measured in seconds. Furthermore, we documented wbether BLS was started at all after delivery of the first shock. Malpositioning of the electrodes, misunderstanding of voice-prompts or other difficulties and events were recorded on the data-sbeets. The positioning of the pads

was scored as being correct when attached approximately in the axis of lead II [12]. The principle outcome variable being studied was time to first shock delivered. The secondary outcome was how often BLS was started according to the voice prompts from the defibrillators. Due to practical considerations and the largely objective nature of the outcome variables no formal blinding was performed. The trial was stopped after at least one shock was given and after BLS was started. The simulation was also terminated if volunteers indicated no further action, or after 5 min without any action, whichever came first. It is understood that feedback was given and retraining was offered to the lay helpers, but not until after the end of the experiment to avoid contamination of the data.

2.1. AEDs and AED training units studied (see Fig. 1)

2.1.1. LIFEPAK CRT™ (Medtronic, Minneapolis, USA)

Electrodes pre-connected, two adhesive pads in one plastic liner stored in the device, patient simulation through infrared remote control

2.1.2. Fred easy® (Schiller AG, Baar, Switzerland)

Electrodes not pre-connected, two adhesive pads in separate plastic liners stored in the bag of the device, patient simulation through infrared remote control.

2.1.3. AED+PLUS™ (Zoll Medical, Chelmsford, Massachusetts, USA)

Electrodes pre-connected, one large adhesive electrode, stored in the device, remote control via cable connection.

2.1.4. Access™ (Access Cardio Systems, Concord, Massachusetts, USA)

Electrodes not pre-connected, two adhesive pads in separate plastic liners, stored in the lid of the device, pre-selected simulation algorithm. After the last prompt (the one to start BLS) the device starts with a new simulation cycle and therefore it had to be turned off immediately after the last voice prompt, not to confuse volunteers.

2.1.5. Power Heart Training Unit™ (Cardiac Science Inc., Irvine, California, USA)

Electrodes pre-connected, two adhesive pads in one plastic liner, stored in the device, simulation through infrared remote control.

2.1.6. HS1™ (Philips Medical System, Andover, Seattle, USA)

Electrodes pre-connected, two adhesive pads in one plastic liner, stored in a cartridge included in the device, pre-selected scenarios for CPR simulation, device recognises attachment of the electrodes via an impedance simulating metal stripe.

2.2. Statistical analysis

Data are presented as a number and a percentage, the mean and 95% confidence intervals, or the mean and standard deviation if not otherwise stated. The groups allocated to the six defibrillators were regarded as independent. Baseline data including age, gender and time from last CPR training were tabulated. Baseline data were not compared using

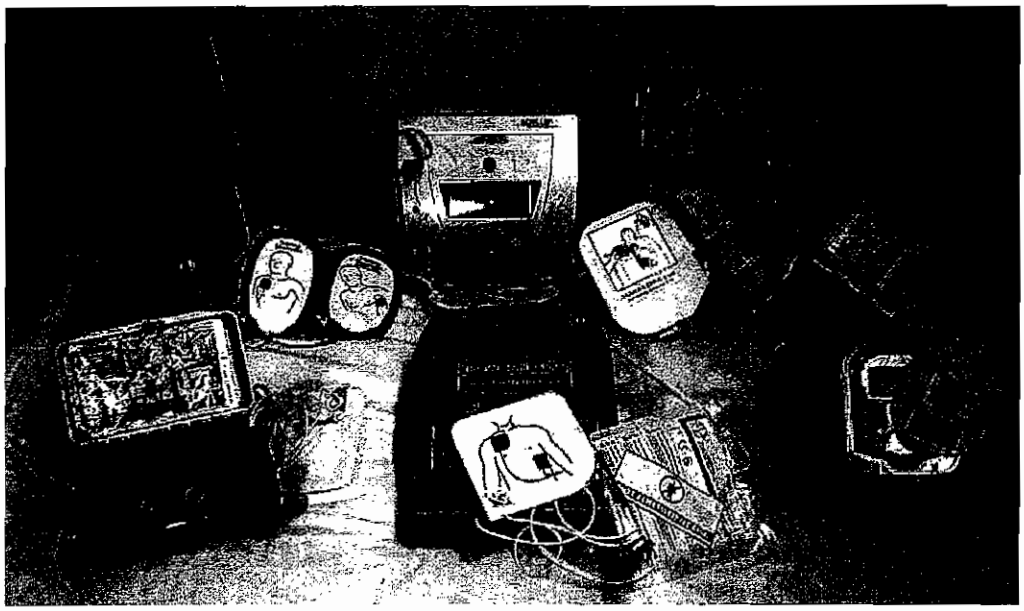


Fig. 1. The six automated external defibrillators (AED) currently commercially available in Austria, which were used in the experiment. Rear row (left–right): LIFEPAK CRT™ (Medtronic, Minneapolis, USA), Fred easy® (Schiller AG, Baar, Switzerland) AED+ PLUS™ (Zoll Medical, Chelmsford, Massachusetts USA); Front row (left–right): Access™ (Access Cardio Systems, Concord, Massachusetts, USA), Power Heart Training Unit™ (Cardiac Science Inc., Irvine, California, USA), HS1™ (Philips Medical System, Andover, Seattle, USA).

hypothesis testing. Upon inspection we did not find major baseline differences, indicating reasonably valid randomisation.

The principle outcome variable was time to first shock. Data were near the normal distribution in all groups as tested by the Kolomgorov Smirnov test and visual inspection of histograms. Hence, groups were compared by one-way ANOVA, testing the null hypothesis that there is no difference between the groups. The secondary outcome was how often BLS was started after the according voice prompt by the defibrillators. The proportions were compared between the defibrillator groups employing χ^2-statistics.

Two post-hoc analysis sets were performed to validate our findings. (1) To test whether the gender influenced the primary or secondary outcome, we used the Mann–Whitney U-test and a χ^2-test. (2) To test whether the time elapsed from the last CPR training influenced primary or secondary outcome we used linear correlation and a χ^2-test. SPSS for Windows 10.0.7 (SPSS Inc., Chicago, IL) was used for data management and processing. A two-sided P-value < 0.05 was considered statistically significant.

3. Results

Overall, 90 volunteers out of 120 consented to participate, and all of those who consented completed the experiment. Twenty-seven (30%) of the volunteers were female. Age ranged from 15 to 55 years with an average of 28 ± 16 years. Lay responders had attended their last CPR training 6.4 ± 6 years ago (range: 0.5–25), none had been trained to use an AED. Two volunteers had never attended CPR training before.

3.1. Main outcome

Time to first shock according to defibrillator type is presented in Fig. 2 and ranged from 78 (95% CI: 68–89) when the CR+^{TM} was used to 128 (95% CI: 110–146) s when AED+^{TM} was operated. As assessed by ANOVA, time to first shock was significantly different between the six AEDs ($P > 0.0001$).

Not all users reached the primary goal of delivering a shock. One device was turned off unintentionally (see "specific findings" of Fred easy®), on two occasions the shock was impaired by not removed clothing and/or plastic liner of the pads (AED+^{TM}). One volunteer was confused by the device and gave up without providing any further help (AED+^{TM}).

3.2. Secondary outcome

The proportion of volunteers who started BLS after defibrillation is presented in Fig. 3. This proportion ranged between AED groups from 93% (14 out of 15) to 33% (5 out of 15). The proportion of volunteers who started BLS after defibrillation in the AED groups, also differed significantly ($P < 0.03$).

The results of the defibrillator "Access^{TM}" are marked with an asterisk in Fig. 3 due to a procedural peculiarity of the training device. After completion of the first shock, the training simulation started again from the very beginning, shortly after its last prompt: "in absence of vital signs start cardio-pulmonary-resuscitation". Therefore, investigators had to turn off the device after this prompt and ask lay helpers what they would do next. Once the device was turned off, 13 out of 15 lay responders stated, that they would start

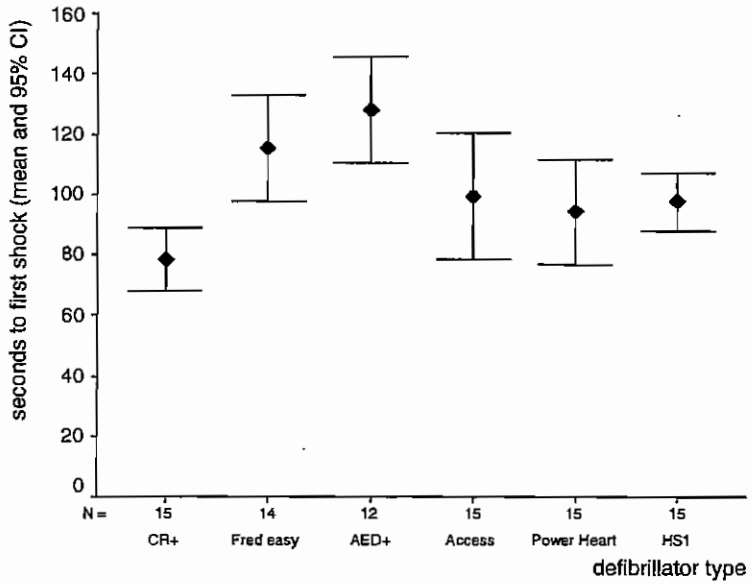


Fig. 2. Defibrillator type and the time to first shock (seconds, mean and 95% CI). In three occasions with AED+^{TM} and in one occasion with Fred easy® volunteers failed to deliver a shock.

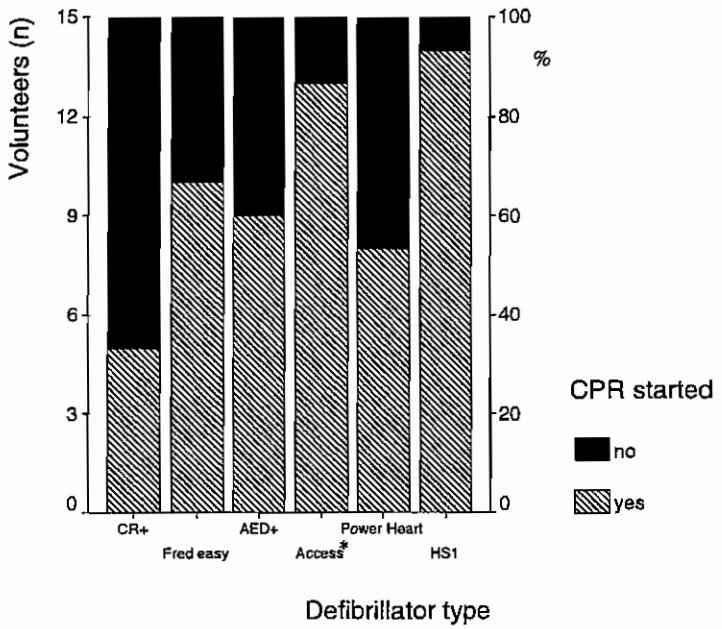


Fig. 3. The number of volunteers who started BLS after shock according to the defibrillator used in random order. *Access had limited comparability to other defibrillators, because the training-device had to be turned off after the last voice prompt.

BLS after the shocks. Hence, regarding the secondary end point, the "Access™" AED cannot be compared to the other AEDs directly.

3.3. Influence of gender, age and time since last CPR training on the use of an AED

There was no significant association between gender and time to first shock ($P < 0.7$) and the proportion of BLS started after the shocks ($P < 0.41$). There was also no significant association between the time since the last CPR training and time to first shock delivered ($P < 0.69$) or whether BLS was started after the shocks ($P < 0.96$).

3.4. Miscellaneous Findings

Electrodes were not attached correctly in nine cases (4 Power Heart™, 2 AED+™, 2 Access™, 1 CR+™). Volunteers stated that they were confused about the electrode positioning in 14 cases (5 Power Heart™, 3 Access™, 2 Fred easy®, 2 CR+™, 1 AED+™) but placed the pads correctly. In two cases the lay rescuers did not remove the plastic liner from the pads (1 Power Heart™, 1 AED+™). Two volunteers in the AED+ group did not remove clothing from the manikin's chest before attaching the electrodes. The information button provided by the HS1™ was pressed by all users (15 out of 15) to be guided through BLS.

4. Discussion

We could demonstrate clearly that there are significant differences between the AEDs tested, with regard to the time to first shock. These differences were not only statistically significant, but also of clinical significance. Looking at the time to first shock, the mean difference between the AEDs was as much as 50 s. This is of particular interest, because the time with the AED until the first shock is delivered is most likely time without chest compressions and therefore no-flow time [14]. Hence, this length of time could lead to increased mortality at the rate of almost 10% per minute [4]. Keeping this time to a minimum must be one of the major aims in developing AEDs. Recently, it was reported, that AEDs produced important delays in cardiac arrest situations [14,15]. It was beyond the scope of our study to identify prospectively the factors responsible for these important operational differences, but this heterogeneity should prompt further research. We also found significant heterogeneity in the proportion of BLS started after unsuccessful shocks. The maximum difference was as much as nine failures to start BLS in 15 trials. Theoretically, this could be translated into a relative risk reduction of 90%, when comparing the best and the worst AED, or a number needed to treat of two. Due to the importance of bystander BLS [6], a safe and easily understandable guide through the following steps after shock delivery is of utmost importance.

Most volunteers in our experiment had attended CPR training before. This might be due to the fact that first aid

education is mandatory when applying for a driving license in Austria.

Former studies showed quite similar periods before the first shock was provided by untrained lay responders [12]. The large number of successfully simulated defibrillations also strengthens former findings of the simple use of AEDs in general, even by school children [11]. According to current knowledge neither helpers nor patients were endangered through the first aid efforts including defibrillation during our experiment [16]. Therefore, even untrained helpers are able to provide early defibrillation safely.

We assumed that effects of the design had been extensively tested in advance for all AEDs by the respective companies. Given the simple aim of an AED to deliver appropriate shocks and guide BLS, it is indeed interesting that we could find differences in the operational outcome. It seems obvious, that the design of the device itself creates these differences. Most likely the key factors for failure were the content and volume of voice prompts and the arrangement of the buttons. We had the impression that some prompts were easier to understand for first time users, whereas others were not. In the absence of any correlation between the time since last first aid training and the initiation of BLS after shock, we conclude that volunteers placed a great deal of trust in the devices prompts. Once confused by a prompt, many of the volunteers stopped their BLS, despite former training.

We conld observe difficulties if voice prompts were given too quickly in a sequence. Our impression also was, that confusion could occur if the pictures were too numerous or too small.

The scenario of our experiment was a semi-public place comparable to the environment of a shopping mall. Though not extreme, the presence of voices and light conditions from a big window seemed to have an effect on the operation of the AEDs. Therefore, it should be assessed if the devices could be used in bright or low light conditions. Also, loud and disturbing surroundings should not detract from the application and operation of an AED.

4.1. Limitations

Even though AEDs and their user-friendliness turned out to vary in our experiment, the relevance for real cardiac arrest situations remains unclear. Volunteers knew about the simulated situation and in general showed very calm behaviour, which is unlikely to be the case in a real event. However, as AEDs have been used infrequently by lay-rescuers to date [17], it is currently not possible to gain necessary patient numbers to compare the effectiveness of different AEDs in clinical circumstances. Experimental work is probably the best we can have at the moment.

We did not investigate if BLS was performed in an effective way after defibrillation. Possible advantages caused by special interactive voice prompts, for example as given by the AED+™ are therefore not reported in this trial.

Because of the absent impedance in the manikins, investigators had to push a button, to simulate the attached electrodes. Even though being aware of this problem, this procedure may have caused a minor delay.

4.2. Specific findings in the AEDs

4.2.1. LIFEPAK CR™ (Medtronic, Minneapolis, USA)

Users of the CR+™ defibrillated very quickly. The narrow 95% CI indicates, that many users were guided through the defibrillation process well. The flashing shock button was visible without problems in all light conditions. Voice prompts are given loud and clearly. The two clearly marked electrodes guided users to the correct electrode position. The device prompts the user to start BLS by using the abbreviation "BLS", which is commonly unknown. This may be why only five out of 15 volunteer helpers started BLS after the initial defibrillation. Helpers reacted in a confused manner by pressing the shock button several times, turning the device off and on or by aborting their bystander support.

4.2.2. Fred easy® (Schiller AG, Baar, Switzerland)

Pictures on the electrodes show the users how to attach the pads in a correct position. Lay helpers liked the advice to start BLS or to bring the patient in recovery position depended on the presence of vital signs. Voice prompts that were not understood could be read on a display in addition. The device did not start the ECG analysis on its own. Therefore, users were prompted to press the on/off button after attaching the pads. One user pushed the button until the device was turned off and no shock could be delivered. This was the only device where users had to push an analyse button (= on/off button). In presence of a non shockable rhythm the device prompts users to start BLS by giving two breaths and compressing the chest 15 times if they were not able to detect vital signs. In the presence of vital signs the recovery position is recommended by the AED.

4.2.3. AED+™ (Zoll Medical, Chelmsford, Massachusetts, USA)

The single electrode of the AED+ PLUS™ seems to prevent users from attaching the pads in an incorrect position. If performing the chest massage too weakly the AED+ gives feedback to press deeper. Also the frequency of the chest compressions is advised by a metronome. These feedback features were not tested during our experiment with the training device, therefore maybe existing advantages are not highlighted here. One user failed to open the AED. Another volunteer needed a lot of time to find out how to open the device. Once opened, one participant tried to position the top of the AED under the manikins head unsuccessfully and lost valuable time. It seemed that the device prompted users too quickly and that optical signs were only understood after feedback and training. Two users did not undress the manikin to attach the electrodes. As the volume of the prompting voice of the training unit was quite low, some users had dif-

ficulties hearing the prompts clearly. The button to switch on the device was not visible enough for all users.

4.2.4. Access™ (Access Cardio Systems, Concord, Massachusetts, USA)

This device was the smallest of the devices tested. Electrode positioning is indicated on the electrode package clearly. Once the package is opened, the guiding pictures are not clearly visible any more. The device prompts users to plug in the electrodes by saying: "Connect electrodes". This prompt was not understood by all users, some thought that they had to attach the electrodes at that point and were unsure how to do this. The pictures shown on the pads are quite small and were not clearly visible for all volunteers. Some volunteers had problems with opening the lid, because the mechanism is not shown clearly. As already mentioned, the particular training programme of this device produced a peculiar situation for the interpretation of the further BLS guidance by restarting after the first shock instead of continuing the regular algorithm (see above).

4.2.5. Power Heart training unit™ (Cardiac Science Inc., Irvine, California, USA)

Opening the lid activates this AED. Because the voice prompts did not start immediately after activation, some users closed the lid again, to search for an activation button. The voice prompt to attach the electrodes was misunderstood by three users concerning the position. These volunteers attached the electrodes directly to the manikin's mamillae because the AED prompts: "Attach the electrodes to the patient's chest". Voice volume was low and the LEDs of the "flashing" button were too weak in daylight conditions. One volunteer did not remove packing material from the electrodes.

4.2.6. HS1™ (Philips medical system, Andover, Seattle, USA)

This device guides the user with slow and clear prompts. Users stated that the different signed electrodes of this device were useful. It also provides an information button to get further instruction as to how to start and provide BLS. All users pressed this button and did exactly what the device prompted. The recommended heart compression rate given by a metronome was appreciated by the volunteers. Mouth to mouth ventilation was explained precisely as well as chest compression.

5. Summary

We could demonstrate that there are significant differences between AEDs, concerning important operational outcomes such as the time to first shock and start of BLS.

It seems to be likely that the design of the device itself accounts mainly for these differences, but the proof for that was beyond the scope of this study. Factors for failure may have been related to the content and volume of voice prompts and arrangement of buttons. Further research and development is urgently required to optimise user-friendliness and operational outcomes.

Acknowledgements

We are indebted to the training centre of the Vienna Red Cross, for kindly supplying us with the manikins and other training material as well as to Medtronic Austria, Chemomedica Vienna, Zoll Medical, Schiller Austria, Marquette Hellige, and Philips Medical Systems for providing us with the AEDs and the training electrodes.

References

[1] Fertl E, Vass K, Sterz F, Gabriel H, Auff E. Neurological rehabilitation of severely disabled cardiac arrest survivors. Part I. Course of post-acute inpatient treatment. Resuscitation 2000;47:231–9.
[2] Pusswald G, Fertl E, Faltl M, Auff E. Neurological rehabilitation of severely disabled cardiac arrest survivors. Part II. Life situation of patients and families after treatment. Resuscitation 2000;47:241–8.
[3] Bur A, Kittler H, Sterz F, Holzer M, Eisenburger P, Oschatz E, et al. Effects of bystander first aid, defibrillation and advanced life support on neurologic outcome and hospital costs in patients after ventricular fibrillation cardiac arrest. Intensive Care Med 2001;27:1474–80.
[4] Larsen MP, Eisenberg MS, Cummins RO, Hallstrom AP. Predicting survival from out-of-hospital cardiac arrest: a graphic model. Ann Emerg Med 1993;22:1652–8.
[5] Cummins RO, Ornato JP, Thies WH, Pepe PE. Improving survival from sudden cardiac arrest: the "chain of survival" concept. A statement for health professionals from the Advanced cardiac life support subcommittee and the Emergency Cardiac care committee. American heart association. Circulation 1991;83:1832–47.
[6] Cummins RO, Eisenberg MS, Hallstrom AP, Litwin PE. Survival of out-of-hospital cardiac arrest with early initiation of cardiopulmonary resuscitation. Am J Emerg Med 1985;3:114–9.
[7] Johnston TC, Clark MJ, Dingle GA, FitzGerald G. Factors influencing Queenslanders' willingness to perform bystander cardiopulmonary resuscitation. Resuscitation 2003;56:67–75.
[8] Swor RA, Jackson RE, Compton S, Domeier R, Zalenski R, Honeycutt L, et al. Cardiac arrest in private locations: different strategies are needed to improve outcome. Resuscitation 2003;58:171–6.
[9] Foitik G, Fleischhackl R, Hoerauf K. Induction of a nationwide public access defibrillation programme - experiences from Austria. Abstract ERC Congress Marseille Nov 2003.
[10] Haugk M, Uray T, Sterz F, Kliegel A, Losert H, Bayegan K, et al. Preliminary experiences in providing cardiac arrest survivors with semiautomatic defibrillators (AED) at home. The Home Public Access Defibrillation Study (HPAD). Resuscitation 2002;55:154 [Abstract].
[11] Domanovits H, Meron G, Sterz F. Comparison of naive sixth-grade children with trained professionals in the use of an automated external defibrillator. Circulation 2000;102:E166.
[12] Eames P, Larsen PD, Galletly DC. Comparison of ease of use of three automated external defibrillators by untrained lay people. Resuscitation 2003;58:25–30.
[13] Berg RA, Hilwig RW, Kern KB, Sanders AB, Xavier LC, Ewy GA. Automated external defibrillation versus manual defibrillation for prolonged ventricular fibrillation: lethal delays of chest compressions before and after countershocks. Ann Emerg Med 2003;42:458–67.

[14] van Alem AP, Sanou BT, Koster RW. Interruption of cardiopulmonary resuscitation with the use of the automated external defibrillator in out-of-hospital cardiac arrest. Ann Emerg Med 2003;42:449–57.

[15] Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Public use of automated external defibrillators. N Engl J Med 2002;347: 1242–7.

[16] Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular, Care., Part, 4., The automated external defibrillator: key link in the chain of, survival., The American Heart Association in Collaboration with the International Liaison Committee on, Resuscitation. Circulation 2000; 102: I60–76.

[17] Gratton M, Lindholm DJ, Campbell JP. Public-access defibrillation. Where do we place the AEDs? Prehosp Emerg Care 1999;3:303–5.

Elsevier Business Intelligence

FOUNDED 1939
$565 A YEAR
www.TheSilverSheet.com

MEDICAL DEVICE QUALITY CONTROL

Vol. 13, No. 5 May 2009

THE NEWS THIS ISSUE

FDA Stresses Human Factors Design For Home-Use Devices

Usability Testing, Clear Instructions May Help Firms Avoid Product Problems

FDA is placing an even greater emphasis on human factors engineering and the development of user-friendly medical device interfaces as products continue to migrate from the clinical setting to the home.

"It's getting to the point where people want to be at home if they have chronic illnesses or other problems, so devices are starting to accommodate that and helping people stay as active as possible," says Mary Brady, associate director of CDRH's Office of Surveillance and Biometrics (OSB).

Home-use devices range from simple equipment like canes and wheelchairs, to sophisticated items such as glucose meters, ambulatory infusion pumps and laptop-sized ventilators.

Patients "can have their little portable oxygen cylinder, or a portable ventilator," Brady told "The Silver Sheet." These "are things that you can actually move around with and enjoy your activities of daily living without having to worry about being hooked up to a big machine somewhere."

To help ensure that patients use devices more safely and effectively at home, FDA is reminding firms to consider patients' specific needs via a strong usability program.

Human factors engineering aims to reduce the risk of user error, and is particularly critical in the interface of the device. An interface is any part of the device that the user interacts with, including not only the product itself, but training materials and instructions for use, as well.

"Conducting human factors for home-use devices is always important," says Ron Kaye, FDA's human factors and device-use safety team leader.

"When you have a medical device in the hands of professional medical personnel, they're more apt to know what is appropriate and what's not," and would likely be able to more easily manage a problem product, he says.

However, a poorly designed device "is frightening in the hands of a variety of different types of people who don't have expertise and are not adept with the use of devices or machines," he says.

"They're not sophisticated with respect to medicine and clinical issues, and they might not understand dosage issues, and what they should do in response to the device giving them an alarm or following instructions, and on and on," Kaye told "The Silver Sheet." "There are a lot of ways that naïve users in the home are different than health care professionals. So we really have to be concerned about that."

Pete Carstensen – a former CDRH senior systems and human factors engineer who spent 34 years working almost exclusively on matters of usability engineering – says FDA is very concerned about the usability of products that could find their way into the home.

"For whatever reason, the FDA management and on down is much more concerned about human factors issues with home-use devices than they are with professional devices. There's no question about that," says Carstensen, who retired last year from the agency to become a human factors consultant for Concord, Mass.-based Wiklund Research & Design.

"I could make the case that they're both equally important," he notes. "But there's always been an added emphasis by FDA on home use. I think it's a perception that FDA needs to be more protective of the average home user because they're not professionally trained."

Device Misuse, Unexpected Device Problems At Home Concern FDA

Misuse of home devices and other unexpected product problems can run the gamut from troubles with tubing and radiofrequencies, to improper maintenance and faulty power supplies.

"Hospitals and other clinical facilities are controlled environments, and a home environment is basically uncontrolled," FDA's Brady points out. "There are so many things that could happen."

Some of the more prominent misuses include problems with tubing, radiofrequencies and sterilization.

When it comes to tubing, "anything from a ventilator to an infusion pump to a home hemodialysis machine [could have problems if] you're hooking your tubing up incorrectly," Brady says.

"Also, with tubing there are factors such as children and pets and vermin, those things that can affect your tubing or play with your tubing, or chew into your tubing, or run over your tubing, or kink your tubing," she says. "Having been a home-care nurse, I did have a lot of problems with pets chewing through tubing. Those things happen quite frequently."

Some devices, such as motorized wheelchairs, also may encounter trouble if they come in contact with certain radiofrequencies.

"There is no real medical radiofrequency, so some of these devices can get hooked up to other radiofrequencies," Brady says.

For example, "we had a couple of power wheelchair incidents where they were on the same frequency as a police scanner," she says. "One person was fishing on a dock in their wheelchair and the Coast Guard went by, and it started his wheelchair spinning, and he fell into the water.

"The Silver Sheet"

FOUNDED 1997
www.TheSilverSheet.com
www.ElsevierBI.com

Elsevier Business Intelligence
Editorial office:
5635 Fishers Lane, Suite 6000
Rockville, MD 20852
Phone: 240-221-4500
Fax: 240-221-4400

Customer Care:
1-800-332-2181 or 1-908-547-2159 Fax 908-547-2165
E-mail: custcare@elsevier.com

Executive Editor:
Mary Houghton
240-221-4410 m.houghton@elsevier.com

Managing Editor:
Shawn M. Schmitt
240-221-4419 sm.schmitt@elsevier.com

Composition:
Ting Yang

Production:
Phil Simms

Corporate Sales:
Tom DePaul
Lynda Morrow
John Lucas

Commercial Sales Director:
Ken May

Director, Device Product Management:
Sean Smith

VP of Marketing & Customer Care:
Scott Breed

VP of Sales:
Deanna Flanick

VP of Operations & Product Development:
Julie Gordon

President:
Gerard J. Stola

"The Silver Sheet" (ISSN 1093-281X) is published monthly by Elsevier Business Intelligence, 685 Route 202/206, Bridgewater, NJ 08807. The annual subscription rate is (1) $665 or (2) $350 for additional copies mailed in the same envelope with $665 subscription. Periodicals Postage paid at Rockville, MD and additional mailing offices. POSTMASTER: Send address changes to Elsevier Business Intelligence, Attn: "The Silver Sheet", 685 Route 202/206, Bridgewater, NJ 08807. **In Japan, Elsevier Science KK** is the exclusive subscription representative for "The Silver Sheet." E-mail: jp.bkinfo@elsevier.com. URL: www.elsevierjapan.com. Telephone: 03-3589-6370. Fax: 03-3589-6371.

"There also was a person who was at a street intersection in his power wheelchair, and a police car went by, and the wheelchair started moving into the intersection accidentally," Brady continues. "So those are types of things that don't happen in the hospital environment that could happen in the home or other environments."

Battery and power-supply issues also can become a problem in the home or when a patient is traveling.

"A big issue has to do with power outages and what happens with devices when there's a power outage, and what kind of battery backup there is," Brady says.

"We also have to be thinking about how these things work in airplanes or on trains, because people are becoming ambulatory now; they're not sitting in a hospital bed," she adds. For example, "if you were to have a type of battery device, and you're traveling overseas, would you be able to find a replacement battery overseas? The issues are huge."

Further, some users of home devices tend to cut corners, which also can cause a device to fail or perform in an unintended way.

"They can get sloppy with respect to maintaining the device, recording their test information correctly, keeping things clean, keeping their accessory materials up to date and calibrating" the device, FDA's Kaye says.

"Familiarity brings bad habits. People may keep a pair of glasses in their case when they're not using them, but after a while they're putting them in their pocket or throwing them on their desk, and pretty soon they get scratched up," he says. "It's the same kind of thing with medical devices. There's an extent to which they need to be maintained and used correctly."

Some Devices Should Not Be Used At Home

Certain devices that were meant to be used only in a hospital or clinic have sometimes ended up in a home, which is especially dangerous if the patient does not know how to properly use the device.

"Sometimes IV pumps and more sophisticated equipment intended for hospital use are finding their way into the home, and that can cause problems," Kaye says. "You would expect those problems to happen because you have equipment designed for a certain type of user with a certain level of sophistication, and it ends up in the hands of others."

Although manufacturers need FDA approval to market a device over-the-counter directly to a patient or specifically for home use, there are few restrictions on whether a physician can send a patient home with a device that is not specifically labeled for use there.

Michael Wiklund, principal consultant for Wiklund Research & Design, says a device such as a dialysis machine is one that can be used in the home, but it's likely pushing the boundaries of what should be used outside of a clinical setting.

"Sometimes IV pumps and more sophisticated equipment intended for hospital use are finding their way into the home," FDA's Kaye says.

"The one machine I'm familiar with that is specifically designed for home use is the ***NxStage System One*** dialysis machine," which is manufactured by Lawrence, Mass.-based NxStage Medical, Wiklund told "The Silver Sheet."

That device "has become widely used by people who would rather perform dialysis at home as opposed to in a clinic," he says. "But patients have a lot to learn, and it can take them days – if not weeks – to master the device so they can operate it correctly and safely.

"For these more complicated devices, the key is to screen them properly to assess their cognitive abilities and their physical abilities," Wiklund adds.

A manufacturer doesn't always have to assume that its device will be used in the home, Kaye says.

"There are devices that just absolutely would never go in the home, such as a CT scanner or X-ray machines," he says, but he notes that there could be gray areas. "Respirators, IV pumps, feeding pumps, things like that – that's a tough call for the manufacturer," because those devices could possibly be placed in a home.

Consultant Carstensen says a firm would end up compromising the design of its device if it always had to be concerned that its clinical-use-only product would be used by patients at home.

"There are a lot of devices out there that are designed for a highly skilled user, and to redesign them so that a much less-skilled person at home could use it, well, you would end up with a useless device," he says. "It would be not usable for the professional for the intent it was really designed to do.

"A ventilator is a good example. We're seeing more and more of those in the home, but they're specialized ventilators that are very simple in terms of the user interface," Carstensen continues. "They're set up by a clinical person with parameters set in, and then they're locked in place. You can't change them. You need a

code to go in and make adjustments. That can be sent home with a person.

"But take a look at an ICU ventilator for professional use. They're very complex devices with lots of modes and features on them that aren't necessary for the home user, and in fact it would be dangerous to send that home with [the patient]. There are too many opportunities to screw things up."

Kaye says it wouldn't be right to impose a blanket requirement on manufacturers to make their devices useable in the home.

"I think that's a pretty tall order," he says. "For professional-use devices I would rather see the effort committed to making sure that the professionals can use the device and that [firms aren't] limiting necessary functionality or making some aspect of the interface less efficient for them."

After all, "there are simpler pumps and there are simpler versions of sophisticated devices," Kaye notes. "There are other alternatives than taking the IV pump off the floor in the hospital and sending it home with Grandma Jones."

FDA Guidance Will Focus On Human Factors, Instructions For Use, Interfaces

Because myriad problems could arise during the operation of home-use products, FDA launched a Home Health Care Committee in 2001 to keep an eye on devices as they move from hospital to home.

The group, which is headed by OSB's Mary Brady and includes 13 representatives from all of CDRH's various offices, meets once a month to discuss adverse events related to home devices, emerging technologies and labeling issues, among other topics.

The committee also is keeping tabs on home-use devices that use wireless technology, Brady says.

"You have all the emerging technology out there," she says. This includes "the interoperability devices, where you have your cell phone relaying all of your diagnostic information to your physician, or you can be online and share all of your diagnostic information in real time."

The agency also is concerned about "'smartphones,' which can measure your blood pressure, your respiration and your weight," Brady adds.

Because the home-health industry has greatly expanded in recent years, Brady now focuses exclusively on home device issues in her role at OSB. She acknowledges that her directive to work full time on issues related to home-use products is a signal that FDA is becoming more concerned about the subject.

The Home Health Care Committee currently "is trying to focus on what we can do within our regulatory purview to address home-use devices," Brady says.

That includes developing a guidance that will aid manufacturers as they develop new products that could be used in the home.

The guidance "is going to be mostly for pre-market at this point; we'll look at post-market issues later on," Brady says. "What we want to do is use our current FDA patient labeling guidance and fold home use into that." (The "Guidance on Medical Device Patient Labeling" can be found at www.fda.gov/cdrh/ohip/guidance/1128.html.)

"We would help [firms] through this guidance to say, 'OK, this is what we're looking for,'" Brady says. "We would be looking for the type of interface, how easy it is, and what that looks like for people who have visual problems. Can they operate the interface with limited physical capabilities?"

In addition, the proposed guidance – which could be finalized by the end of 2010 – will explain what FDA expects firms to consider when conducting usability activities.

"We're going to add to the guidance things about the home environment," Brady says. "What type of environmental situation are you going into? What do you do about power outages? What kind of a back-up power supply do you have? So there's quite a bit of human factors involved there."

The guidance also will address device labeling. Brady's committee wants to "make sure that the labeling is adequate for a non-health care professional in what we consider an uncontrolled environment," she says.

Human Factors Can Be More Challenging When Firms Make Home-Use Devices

While more manufacturers have been getting the message about the need for conducting usability engineering, some "act as if they have not heard of human factors," FDA's Kaye says.

"Or, they do it the way they want to, which often has a lot to do with talking to [subjects] and finding out what they like and what they would like to have," he says.

A company "may have read in the Quality System Regulation about addressing the needs of users, and they interpret 'user needs' to be whatever users say they want. We view 'user needs' as making a device that is designed so it won't allow likely errors and lead users to make errors when they use it."

Meanwhile, some firms carry out poor human factors programs either because they are misinformed about FDA's expectations or are trying to quickly push a new device out to market.

"Most often what you see is some hesitancy to do an evaluation that might expose a problem with the use of the device because the folks involved are on a schedule to try to get the device through the FDA and out the door," Kaye says.

"It appears that [some companies] are putting a lot more of their effort into doing that rather than making sure that the device, once it's out the door, is not going to cause subsequent problems with patterns of use error that are going to lead to a recall, or problems like that," he says.

These types of mistakes should not happen, consultant Carstensen says.

The overall human factors methodology is the same, whether the device is meant for the home or clinical setting, he says.

"The objective is the same. You identify the hazards and you use that information to inform how you're going to structure your usability study, because you want to make sure you cover those areas where those kinds of hazards you've identified are likely to occur."

Nevertheless, Carstensen concedes that performing human factors activities when developing home-use devices can be challenging.

"Remember, you have less-capable people using them," he says. "Half of the population has an IQ of less than 100, but you don't find too many professionals in the medical field that don't have an IQ quite a bit higher than 100. So it's more of a challenge in the sense that you have to take into account the capability of lay people. They can do some pretty stupid things."

Consultant Wiklund agrees that the general human factors methodology does not change when a company designs a device for use in the home as opposed to the hospital.

"However, the specific things that you do during the design process are going to be directed a little bit differently," he says. "Boiled down, the human factors engineering process involves conducting enough research to fully understand your users and their needs, and generate user requirements for the new product that is being developed.

"And then as you're designing the device, you would take into consideration the requirements you've identified, which address things such as cognitive skills, physical skills and the use environment," Wiklund adds.

"You have to take into account the capability of lay people. They can do some pretty stupid things," consultant Carstensen says.

Although the human factors process is fairly uniform no matter the type of device, "what is different are the people you're designing for and involving in the product development process," he says. "If I was designing a device for the home, I would make sure that I observed people in their homes using the devices. Or I would invite them to interviews to talk about their desires for future products. That's really the key."

While home-use device designs have to be more user-friendly, "I think you need to exercise the same level of care whether you're designing for a neurosurgeon or designing for a lay person with a cognitive impairment," Wiklund says. "There is potential in both cases for accidents and use errors that could lead to injuries, wasted materials and inefficiency."

Further, manufacturers should ensure that they are introducing usability engineering early on in the design process.

"The classic approach is to start early, right from the beginning," Wiklund says. Firms need to "understand the user's needs and their preferences, and the environment they're working in, or any special needs."

For example, "if you have a user population that might have some visual impairments or hearing impairments or dexterity limitations, you want to account for those early," he notes. "So the right time [to employ human factors] is right at the beginning so these requirements aren't addressed later as an afterthought, but rather addressed early as part of the creation of the product and its basic capabilities, and then is reflected as the product goes through concept development and a detailed design."

Murray Malin, a medical officer in CDRH's Office of Compliance, agrees.

Manufacturers "have to look at whether the user is a young child, for instance," he says. "They may not

have the cognitive capabilities to operate that device as intended, so that needs to be taken into account."

Malin's comments came during an April 22 FDA Office of In Vitro Diagnostics 510(k) Workshop hosted by the Association of Medical Diagnostics Manufacturers (AMDM) in Rockville, Md.

"Or, other times there may be patients who may not have the cognitive capabilities to use the device, and you have to consider that patient population" when using human factors engineering, Malin notes.

"For example, half of the little [non-medical device] gadgets I have at home are from my father, because he can't use these gadgets because the interface is just too difficult for him to use, so he'll give them to me," he says. "It's important, and it's no different in your medical devices. You have to be able to make these so that people using them at home understand how to use them."

When a device from a clinical setting is going into the home, the instructions for use need to be simplified, FDA's Brady says.

Understaffed FDA Human Factors Team May Not Check A Company's Usability Activities

Although some companies aren't employing usability engineering properly, they "think they're doing an adequate job," Carstensen says.

However, there is a good chance that the agency won't check to determine whether a firm properly conducted human factors activities, he points out.

"There are only three people [at FDA] to do these human factors pre-market reviews," Carstensen says. "They can't handle a human factors review of everything. They would be swamped. If FDA has any blame here, it's that, because it has not adequately resourced the program. I don't think that companies are knowledgeable about how thin FDA is in that area."

The agency's human factors group "needs a lot more people, and they know that," he says. "They've known that for a decade. But they would have to shift resources, so it would mean stealing some positions from another part of the program and building up the number of people who are dealing with human factors.

"That's a tough decision for management to make because everybody is screaming for more resources, and now you're going to take them away and give them to another group? I don't think so."

Usability Testing A Key To Success

Conducting usability testing is one of the more important tasks related to human factors, but it must be done right for the manufacturer to glean useful data. That includes using the proper number of subjects for the test and taking into consideration all of the problems that could occur in the home.

FDA's Kaye warns companies not to enroll subjects who wouldn't be representative of the types of patients who would use the product in the home.

"When you're talking about evaluating a device through simulated use, that simulated use should involve representative users and should approximate how – in this case – home users or lay users will use the device," he says.

"You wouldn't test a blood glucose meter or an insulin advisor piece of software just in the laboratory or an operating room, for instance," Kaye says. "And you wouldn't use physicians. And you wouldn't use all engineers."

Because home-use devices are used by "people with different backgrounds, you need to factor that in" when doing usability testing, consultant Carstensen says.

"In terms of home use, you take the typical 'Joe plumber,' and the clerk in the library, and the housewife, so they're your test subjects," he told "The Silver Sheet."

However, "if you're going to make a cardiovascular device that's used by interventional cardiovascular surgeons, then you would pick those people to do your usability study with," he says.

And sometimes it's important to use both clinicians and lay people in a study, FDA's Brady says.

"It depends on the type of device," she says. "If you have a prescription device that's going into the home where the health care professional is going to train the family to use the device, then I would suggest that there be usability testing for both the health care professional and the lay person."

The mental capability and age of the patient using the device at home also should be a consideration when a firm selects test subjects.

"For example, let's suppose the device is a blood glucose meter," Carstensen says. "What's the population there? Well, it's going to run the gamut, but it includes some pretty infirm people who may have some sight problems as a result of their advanced diabetes, and you have to take that into account.

"You have to say, 'What's the worst-case population we're dealing with here?'" he continues. "And you want a range, not just the worst case. But you want to make sure that you pick some of these marginal individuals."

Further, "you may have more than one population using a device," Carstensen says. "You may have kids and adults, and because of their disease they don't have all of the faculties that a normal healthy person does."

Minimum Of 15 Subjects For Usability Test

FDA expects that a manufacturer will enroll a minimum of 15 subjects in a usability study.

"There's not really a maximum number," FDA's Kaye says. "We've said 15 is a minimum, and we were kind of forced into making a call about that. The better answer is that [the number] should be what is determined by the tester to be appropriate."

Kaye says manufacturers sometimes call him to ask how many subjects they need to use.

"That question might be translated as, 'What's the least number of people we can get away with using in our study?'" he notes.

Further, some firms allow their own employees to participate in usability tests. "It has been a problem, and it continues to be to some degree," Kaye says. "It seems like it's happening less. The word is getting out on what we expect."

But Carstensen says a number "closer to 25" is more reasonable. "I'll absolutely guarantee you that if you come in with a list of 15 subjects that FDA is going to throw you out the door.

"They will accept as little as 15 under the right circumstances, depending on the specific circumstances of the device and the user population, and the kind of problems you're likely to encounter," he adds.

Once the subjects are selected, a firm should "step them through little bite-size tasks," Carstensen says. "You want to make observations. Did they hesitate? Did they go for the wrong thing and then correct themselves? You might ask them to think out loud so you can get some idea of what the users are thinking.

"These observations should be made by people who are knowledgeable in human factors," he adds. "It should be somebody who has a human factors engineering background and psychology background, or some knowledge of how usability tests are run, and what you're looking for."

Carstensen also recommends that companies videotape the study.

"From that, you can get some insight as to how people are reacting to the device," he says. "It can be enlightening."

In addition, firms should monitor how well the subjects are able to assemble the device.

"When I look through adverse event reports and complaints and I see 'user error' [listed as a root cause], to me that's a signal," FDA's Malin says.

"There seem to be always problems with people misassembling a device, but not only in the sense that they put something in backwards or they don't seat something correctly, and they just don't take care," Carstensen says.

Carstensen recounts a recent usability test that required subjects to fill a device with sterile water to specified level.

"We supplied them with a little cup just to make sure they didn't overfill" the device, he says. "Overfilling the device was a bad thing in this case. But while we observed the usability study, there were several of them who were pouring this stuff in and not using the cup that came along with it.

"All of this stuff was laid out for them," Carstensen continued. When the subjects first walked in the room, "all the parts of the device were laid out, and they were instructed by a nurse instructor. However, four hours later, it was found that the subjects forgot that one little step and poured in too much water.

"If that had been done in reality, it would've been a problem. When you look at it on paper, you may say, 'Oh, that's not a problem. We have this cup and you can't fill up the device so it will overflow. You fill the cup to the brim and you pour it in. How simple could it be?' And yet, in 15 subjects, three of them did it wrong."

Instructions Should Be Simple

FDA is reminding manufacturers to make instructions and labeling for home-use devices simple so patients will be able to understand them.

"A lot of times these devices are no different than something that has been used in a clinical environment, so [the instructions] remain very complicated, and [the patients] need a lot of training, and many times training is not provided," FDA's Brady says.

When a device from a clinical setting is "going into the home, the instructions for use need to be simplified,"

she says. "It needs to get down to that end user, and that's a much more simple type of thing.

"What you have is either a patient or a caregiver who is anxious to begin with going home with a medical device," Brady adds. There is "a lot of information that they're going home with, and then to try to train them on something that's quite complicated with complicated instructions for use is just not a good combination. What firms need to do is have something [that patients] can understand what it is that they're taking home with them."

FDA's Kaye agrees. "The general user has difficulty reading complex material, and often the use of the device is explained in complex ways by people with complex minds. So you have to watch out for that.

"Making things simple and making sure people can understand them is an ongoing challenge and is something that the FDA does look at," he notes.

Kaye suggests that it would be a good idea for companies to create two sets of instructions – one easier than the other – for a device that could be used either at home or in a hospital.

Consultant Wiklund says firms should create quick-reference cards to supplement instructions.

"A clinician might want to have a lot more detailed information and a lot more technical information about a device, and the home user, who may be using the whole device or maybe a component of the device, would definitely have to have different instructions," he says. "I know of firms that have made two sets of instructions for different components of the device."

If a device is likely never going to migrate to the home environment, providing easier instructions for use isn't necessary.

"Let's say, for example, you have a huge piece of equipment that couldn't show up in the home – an MRI machine, for instance – then there's no need for [easier instructions] because it won't be operated by a lay person," Brady says.

However, "if that device was to ever become very portable and it could go into a home for diagnostic purposes," then the company should take steps to modify its labeling, she says.

Another issue that firms must consider is that a lot of patients may not read the instructions.

"Patients don't always look at instructions for use," FDA's Malin says. "I was a physician and I never looked at instructions for use. I never looked at any of the information that came with the device, and I don't know of any clinician that has, either. We relied on people teaching us to do it. So don't assume that lay people are going to" read instructions.

Still, "my view of this is, if the user does not know how to use a product correctly, it's not the user's fault, that's really the manufacturer's fault," he says. "So it's really important to make a product that is very easy to use and you have instructions for use so people can understand how to use these products."

"Some people read some of the instructions some of the time," consultant Wiklund says. "Naturally people, especially lay people, are prone to want to just pick up a device and use it based on their intuition. Nurses and doctors also would rather just pick up a device and use it based on their established skills and experience rather than having to go through a user manual."

However, there are "certain kinds of tasks where the user interface is either not sufficiently intuitive or there's just a level of complexity that defeats any attempt to make something absolutely intuitive to use, then the user manual and those kinds of learning tools can become very effective," he says.

Wiklund suggests that manufacturers supply users of home devices with quick-reference cards to supplement the instructions for use.

"A lot of people get a lot of value out of quick-reference cards," he says. "They may not want to go through a 64-page booklet with lots of text and lots of information that may or may not be of interest to them, but they're fairly satisfied to pick up a quick-reference card and figure out the important details that way."

Further, more firms are turning to online learning tools.

"For example, somebody who is trying to use a glucose meter these days can go to a Web site and actually watch a video demonstration on how to use that device rather than necessarily having to read a manual," Wiklund says.

"The same thing is true of automated external defibrillators [AEDs]," he says. "Take, for example, the Philips ***HeartStart*** AED. If you go to the firm's Web site you'll see that they have an option to watch a demonstration, and it very quickly gives you a sense of how to use that device without having to actually have the device on hand or even read the manual. That's the way a lot of things are going these days."

Agency Plans Online Labeling Repository

FDA also plans to develop an online labeling repository for home-use devices.

"Let's say you get your device at home. What most of us do with the boxes and related things is just throw them all away," FDA's Brady says.

"So we want to have one repository where someone can say, 'I'm going to look up my device,' so then they can look it up on the FDA Web site," she says. "The Web site would also have the manufacturer's phone number, address and Web site information so the patient can go directly to the manufacturer, as well.

"We want get the PMA-labeled home-use devices onto the repository and eventually move to other devices that are labeled for home use as well so there's a place where somebody can go to and know that, yes, this device was indeed labeled for home use," Brady adds.

Consultant Wiklund believes this is a step in the right direction, although he questions whether patients will know that the resource is available.

"My guess is that a majority of the lay population probably hasn't visited an FDA Web site, so how will they know it's there?" he asks. "Keep in mind, too, that some of these [instruction] booklets are really long. I suppose people might download a PDF and read through it.

"That might be fine for the 42-year-old ***iPhone*** user, but maybe not so good for the 70-year-old person who is not quite connected with all these modern mediums," Wiklund notes.

FDA: Firms Underreporting Adverse Events

According to FDA, companies are underreporting adverse events that are connected to home-use devices.

"Even though adverse events are reportable, it's harder for firms to find out what's going on in the home environment, especially if they didn't intend for the device to be used in the home, and all of a sudden it's making its way there," FDA's Brady says.

However, "if I were a manufacturer, I would want to know if my device was failing in some way and find every which way that I could to get that information to better my product," she says.

"We rely on the manufacturer to look at post-market [data] and see if their device caused or contributed to an adverse event," Brady says. "I would expect them to figure out what happened in that particular environment, especially if it was labeled for home use, [and whether] what went wrong in that environment was something the company didn't think about when it was designing the device for the home."

Although it is difficult for firms to receive that type of information from home users, she says there are ways for manufacturers to obtain the data.

"They can start by making sure toll-free phone numbers are very prominent on the device or box," Brady says. "Tell patients to report these problems to the firm or call FDA with their problems."

Further, "if firms wanted to, there are different ways they could be tracking their devices," she says. "I know that's becoming a big thing, even in the hospital environment, to electronically track things. So it's another option they would have.

"A lot of it is up to the manufacturer," Brady adds. "How much do you want to know? How quickly do you want to know? Do you send out regular newsletters, especially if you have specific devices for specific purposes, like glucose meters? If so, you could advertise to professional organizations like the American Diabetes Association and say, 'If you're having problems, let us know.'"

FDA's Malin warns manufacturers against citing "user error" when reporting adverse events related to home-use devices.

"When I look through adverse event reports and complaints and I see 'user error' [listed as a root cause], to me that's a signal," he says. "I always will follow up on that, because too often firms blame problems on user error. Now we call it 'use error' [because] you can't really blame it on the user."

Brady believes it's also more difficult for firms – once they discover a problem with a home-use device – to establish the root cause.

Regardless, the firm "would have to determine [responsibility] for themselves – whether that was something that their device did or did not do," she says. "That's why we count on them to report to us to say this might have cause or contributed to an event, and then they have to follow up and give us the evaluation and the conclusion as to what actually happened out there."

In addition, a company may have trouble getting the home user to accurately recall the sequence of events that led to an incident.

"As far as an investigation is concerned, I think you can probably get some useful information by going into the home," consultant Wiklund says.

However, "it's pretty well established that when people witness an event or a group witnesses an event, you get varying stories about what happened, so I would imagine that's probably just a little bit more likely to be the case in the home than in the clinical environment where I'd get a more accurate, detailed accounting from a clinician," he says.

– Shawn M. Schmitt (sm.schmitt@elsevier.com)

In Brief

Obama budget calls for more FDA inspections: More device manufacturers would face the prospect of being selected for an FDA inspection under a fiscal year 2010 budget request from the Obama administration that would give CDRH a $35 million boost in funding. By the end of 2012, the agency plans to conduct 41 more inspections than it did in 2010, and it also plans to perform 41 more foreign inspections by the end of 2013 than it conducted in 2010. The agency hopes to conduct 2,049 domestic and 392 foreign device inspections during the current fiscal year, according to FDA's FY 2009 budget request. In FY 2008, FDA performed 1,977 domestic and 349 foreign device facility inspections ("The Silver Sheet" March 2009). The additional inspections called for under the Obama budget would not be completed until 2012 and 2013 because FDA plans to invest the next one to two years in hiring and training new field staff, budget documents explain. The budget proposal also calls for a new mandatory re-inspection user fee for firms that fail to come into compliance following an initial problematic inspection. These companies would have to "bear the full cost of re-inspection and associated follow-up work" by FDA, the budget documents note.

Post-market safety would be priority for Hamburg: FDA Commissioner-designate Margaret Hamburg's top priorities for the agency include fostering technological innovation and improving the safety of medical products through closer post-market monitoring. The commissioner nominee discussed her proposed goals for the agency during a May 7 Senate Health, Education, Labor and Pensions (HELP) Committee confirmation hearing. Close post-market monitoring of medical products "will be critical to identifying early safety signals and to acting quickly to protect the public," Hamburg, a former New York City health commissioner, said. Her efforts could build on FDA's ongoing major post-market safety initiative, which includes the year-old Sentinel safety surveillance project ("The Silver Sheet" June 2008). Fostering innovation also is a key component of FDA's future success, Hamburg said, noting that "there has never been a time when advances in science and technology have offered so many opportunities to bring new medical products to market."

FDA releases risk communication plan: FDA has released a new draft risk communication plan aimed at improving how the agency communicates product risks and how it oversees communications from manufacturers. The report acknowledges that FDA should strengthen the science behind risk communications, expand its capacity to generate and oversee communications, and optimize policies on conveying product risks and benefits. The agency identifies 14 specific strategies to achieve these goals, including recruiting more staff with expertise outside the medical and physical sciences realms. "FDA is not well staffed with the risk and decision analysts needed to identify the information that is necessary" to be relayed to device users, the draft plan states. "Nor is it well staffed with the behavioral scientists it needs to design and evaluate messages." The agency also wants to identify gaps in risk communication research, coordinate communication activities throughout its offices and centers, and create consistent criteria for when and how to communicate emerging product risks. FDA's Risk Communication Advisory Panel discussed the plan during an April 30-May 1 meeting in Rockville, Md. The agency will review feedback from the meeting and may deliver a revised report to Congress by the end of September.

Trial adverse event data must be posted to NIH database by September: Device and drug firms must begin posting serious and frequent adverse event data from certain clinical trials on the National Institutes of Health's ClinicalTrials.gov database by September, NIH said April 20. Because NIH failed to issue its own clinical trials adverse event reporting regulation by March 2009, a default provision in the 2007 FDA Amendments Act that outlines a general system for reporting adverse outcomes will now kick in ("The Silver Sheet" December 2007). By September, device and drug companies must add to the registry and results database a table of "serious" adverse events and a table of "frequent" adverse events not included in the first table that exceed a frequency of 5 percent within any arm of the trial. Some companies are currently reporting adverse outcomes voluntarily.

Device center on the move: CDRH plans to complete its move to FDA's new White Oak Campus in Silver Spring, Md., between May 15 and July 31, at which point all center staff will be located at a single site for the first time. The Office of In Vitro Diagnostics and the Office of Device Evaluation, specifically, will move in late June and July. Details on the move, including addresses for regulatory submissions, can be found at www.fda.gov/cdrh/whiteoakmove/.

Automated External Defibrillators Do Not Recommend False Positive Shocks Under the Influence of Electromagnetic Fields Present at Public Locations

Roman Fleischhackl, MD*†
Florian Singer, MD*
Bernhard Roessler, MD*‡
Jasmin Arrich, MD†
Sabine Fleischhackl, MD*
Heidrun Losert, MD†
Thomas Uray, MD†
Klemens Koehler, MD†
Fritz Sterz, MD†
Martina Mittlboeck, MSc, PhD§
Klaus Hoerauf, MD, PhD*‡

Electromagnetic fields (EMF) reduce the signal quality of electrocardiograms and may lead to the misinterpretation by automated external defibrillators (AED). We designed this investigation as a prospective study, with a randomized sequence of AED applications on healthy volunteers. We chose busy public places where public access defibrillation was possible as test locations. Strong EMF were sought and found at train stations next to accelerating and decelerating trains. The primary outcome variable was the absolute number of shocks advised in the presence of sinus rhythm by five commonly used AED in Austria. For data analysis, the statistician was blinded in regard to the AED models tested. Data analysis was based on a per protocol evaluation. Of 390 tests run, 0 cases of false positive results occurred (95% CI: 0–0.77). AED can be regarded as safe, even with the interference of EMF present at train stations.
(Anesth Analg 2006;103:1485-8)

Automated external defibrillators (AED) have been designed for use even by medically untrained bystanders in cases of cardiac arrest. Life-saving measures can be provided by either delivering electric shocks or by audible and/or visible prompts from the AED that help with the initiation of cardiopulmonary resuscitation. Once the patient has been connected to the device via self-adhesive gel electrodes, the AED analyzes the patient's heart rhythm. It decides whether shockable heart rhythms are present, and recommends for or against defibrillation. The sensitivity to detect shockable heart rhythms correctly varies from 95% to 100%. Nonshockable rhythms are determined with a specificity of 98%–100% (1–3).

From the *Research Institute, Vienna Red Cross; Departments of †Emergency Medicine and ‡Anaesthesia and Intensive Medicine; §Core Unit for Medical Statistics and Informatics, Medical University of Vienna, Vienna, Austria.

Accepted for publication August 17, 2006.

Address correspondence and reprint requests to Roman Fleischhackl, MD, Medical University of Vienna, Department of Emergency Medicine, Waehringer Guertel 18-20, A-1090 Vienna, Austria. Address e-mail to roman.fleischhackl@meduniwien.ac.at.

DOI: 10.1213/01.ane.0000244477.15072.16

The most important source for errors during the rhythm analysis is motion of the patient, but electromagnetic fields (EMF) have also been identified as weakening signal quality (4,5). However, findings in the literature are contradictory. Previous studies have reported no significant impairment of AED performance in the presence of strong magnetic fields (6) and high-frequency EMF (7), whereas a previous trial by our study group (8) reported that AED gave false positive decisions in the presence of strong EMF at locations such as transformer stations. Interference did not differ significantly in parallel or perpendicular positioning toward the source of EMF (8). However, these locations have no public access, and therefore, the practical consequences are limited. There are no further data obtained in a publicly accessible setting using a human experimental model. We therefore tested the hypothesis that EMF in publicly accessible settings, such as train stations, have an influence on the performance of AED. The results of this study will have a number of implications for Public Access Defibrillation (PAD) programs in general.

METHODS

This investigation was designed as a prospective study with a randomized sequence of AED applications

and was performed according to the Good Scientific Practice Guidelines.

Data collection and procedures were approved by the local ethics committee. Before enrollment, written informed consent was obtained from each of the subjects.

Study Sites

Studies have identified significant electromagnetic interference (EMI) with electrocardiogram (ECG) analysis of AED by static EMF at 16.7 Hz and alternating frequencies independent of the angle of the devices and the source of EMI (parallel or perpendicular) (4,5,9). EMI present at train stations both above and below ground were considered to be especially relevant for PAD. The characteristics in means and strengths of the electric and magnetic fields at the selected study sites were quantified by repetitive measurements using an EMF analyzer (EFA-300™, Narda, Long Island, NY; measurement uncertainty ±3%; data output: peak values).

Study sites and EMI characteristics are listed here:

1. Train Station "Westbahnhof," 15 kV AC, 16.7 Hz power supply;

   Test 1: Without train present (predominantly electrical field)

   Test 2: Accelerating loaded passenger train (electric locomotives 1016, 1116, 1047, and 1044; Siemens AG) (predominantly magnetic field)

2. Technical Support and Service Centre of the Vienna Transit Authority (Wiener Stadtwerke-Verkehrsbetriebe), 750 V DC power supply;

   Test 3: Accelerating unloaded underground train (low-floor underground motor car "T" (Bombardier Transportation), which was provided with a direct pulse inverter generating a three-phase current (range 20–300 Hz) (predominantly magnetic field)

   Test 4: Decelerating unloaded underground train (predominantly magnetic field).

Materials

To obtain a representative sample for Austria, we invited six AED manufacturers and distributors currently active in the Austrian market to support this postmarket study. Five manufacturers joined the study and provided AED, batteries, and electrodes. The AED tested are listed alphabetically:

1. AccessAED®, Access Cardio Systems, Concord, MA (after the study had been started Access Cardio Systems Inc. recalled AEDs of all models by November 3, 2004 and discontinued business)
2. CR+®, Medtronic, Minneapolis, MN
3. Fred Easy®, Schiller, Baar, Switzerland
4. HS1®, Philips Medical Systems, Amsterdam, Netherlands
5. Responder®, GE Healthcare, Chalfont St. Giles, United Kingdom

All AED tested were semiautomatic, CE (the "CE" mark certifies conformity with European Union standards; the sign has to be printed on the specific product for marketing) certified and licensed according to the medical product laws in Austria. Participating manufacturers were asked to provide routinely produced devices fully functioning, except without the ability to deliver an electrical shock or a plastic cover over the shock button. Details on safety have been presented elsewhere (8).

For simplicity, AED models will only be described with their numbers according to the list above. In compliance with good scientific practice, it is understood that the results of our investigation would be published whether positive or negative for individual companies. All source data remained with the principal investigator, and no permission of the sponsors had to be sought before manuscript submission.

Subject Selection

For participant recruitment, a notice was posted at the Medical University of Vienna inviting healthy people between 18 and 85 yr of age to take part in the study, and 25 subjects were invited to participate. The exclusion criterion for the subjects was a severe underlying illness and arrhythmic heart failure. All volunteers underwent a medical examination, including ECG analysis, before the investigation.

Randomization and Blinding

Every participant received a set of five opaque envelopes containing the names of the different devices. Before every test, randomization was performed by drawing one of the envelopes carried by each participant.

Because it was not possible to ensure correct blinding, participants and investigators were not blinded to the actual device tested, which seemed acceptable considering the aim of the study and the possible outcomes (shock advised/no shock advised). Statisticians only received AED model numbers and were blinded to the specific manufacturer and model.

Study Procedure

All investigators were trained to attach pads according to the current European Resuscitation Council's and the manufacturers' guidelines (10,11). Subjects were asked to lie down in a supine position, parallel to the railway tracks. All further actions, including analyzing the underlying heart rhythm, were performed as if in a real cardiac arrest situation. The study procedure was conducted as reported in our previous publication (12).

Data Management and Outcomes

The following data were documented on the case report form: number of test, model of AED, underlying ECG rhythm, difficulties with ECG interpretation

or abortion of analysis, and the final decision of the AED to deliver a shock or not. The principal investigator and one additional supervisor monitored correct data documentation on site.

The primary outcome variable was the absolute number of shocks advised in the presence of sinus rhythm. The secondary outcome was the number of impaired analyses caused by participants' movements or electrode failure.

Statistical Analysis

Continuous data are described with median and interquartile range (IQR) because of nonnormal distributions. Categorical data are described with absolute frequencies and percentages. Corresponding 95% confidence intervals (CI) are given under the assumption of independent measurements, either two-sided for percentages unequal to zero or one-sided for percentages equal to zero. Statistical calculations were performed using the statistical package SAS (SAS Version 9, SAS Institute, Cary, NC). P values ≤ 0.05 were considered statistically significant.

RESULTS

There were 20 participants for study site "A" and 19 participants for study site "B" on the 2 study days. There were no dropouts before or during the investigation.

The 20 participants included at Site A consisted of 9 men and 11 women. The participants' median age was 23.8 yr (IQR 21.8–25.1 yr), median height 175 cm (IQR 170–180 cm), median weight 67 kg (IQR 63–79 kg), and median body mass index was documented at 23 (IQR 21–25). Thoracic impedance measurements were all within the acceptable range provided by the AED manufacturers. Therefore, 100 tests could be performed at this location, resulting in 200 tests performed at Site A.

The 19 participants at Site B consisted of 8 men and 11 women. The participants' median age was 24.6 yr (IQR 22.2–25.6 yr), median height 174 cm (IQR 165–179 cm), median weight 66 kg (IQR 59–78 kg), and median body mass index was documented at 22 (IQR 20–24). Thoracic impedance measurements were all within the acceptable range provided by the AED manufacturers. All 19 participants were tested in a parallel position to the source of EMI situations with five different AED. Therefore, 95 tests could be performed at this location, resulting in 190 tests performed at Site B.

Measurements of electric and magnetic fields using the EMF analyzer at Site A are presented in Table 1, and measurements of Site B are presented in Table 2.

Our primary outcome variable was the absolute number of shocks advised in the presence of sinus rhythm. Of 390 tests run, 0 cases of false positive results occurred (95% CI: 0–0.77), versus 390 true negative results.

As a secondary outcome, we recorded the number of impaired analyses caused by participants' movements detected or electrode failure. Of 390 tests run, no electrode failure was detected, and motion was detected twice (0.51%; 95% CI: 0.06–1.84) by an AED in the presence of EMI. AED 1, AED 3, and AED 5 (n = 78 each) did not detect participant motion. AED 2 and AED 4 (n = 78 each) detected participant motion in one (1.28%) case each.

Table 1. Site A: Characteristics of Electric and Magnetic Fields

	Railway station	
	Acceleration (n = 10)	Power supply (n = 10)
Electric field strength (kV/m)	0.015 (0.015–0.015)	0.975 (0.950–1.120)
Magnetic flux density (μT)	29.0 (18.0–69.0)	0[a]

Data are presented as median; values given in parentheses are minimum and maximum. For all measurements an electromagnetic field analyzer EFA-300™ was used.

[a] Magnetic flux density was under the detection limit in the absence of an accelerating passenger train.

Table 2. Site B: Characteristics of Electric and Magnetic Fields

	Underground train station	
	Acceleration (n = 20)	Deceleration (n = 20)
Electric field strength (kV/m)	0.003 (0.003–0.003)	0[a]
Magnetic flux density (μT)	6.0 (5.0–15.0)	7.0 (6.0–17.0)

Data are presented as median; values given in parentheses are minimum and maximum. For all measurements an electromagnetic field analyzer EFA-300™ was used.

[a] Electric field strength was under the detection limit during deceleration of an underground train.

DISCUSSION

None of the five AED tested recommended shocks in the presence of EMI at our test locations. Furthermore, no electrode failures were reported. Mock participant movements, which could theoretically impair correct ECG analysis, were rarely reported. The available data were inconclusive. One study reported no negative interference inside a coal-burning or steam-generated electrical power plant (6) during the use of three AED models and an ECG-simulator. However, magnetic flux density was clearly lower, at a maximum of 1.558 μT, than during the underlying investigation. Kanz et al. (5) reported poor sensitivity and specificity of some AED models which showed higher magnetic flux densities varying from 0.7 to 3.7 μT. They concluded that most AED models are susceptible to EMI, especially in terminals with 15 kV 16 2/3 AC power supplies. A previous investigation published by our group (8) reported relevant impairment of proper ECG analysis at magnetic flux densities from 1.5 to 158 μT. Again, susceptibility of the device was mainly dependent on EMI frequency and the model itself.

Although Kanz et al. (5) reported minimization of interference in parallel positioning, we were not able to

confirm their finding, and found no significant difference between parallel and perpendicular positioning (8). This is why we chose not to test in both positions.

As frequent electrode errors or mock patient movement have been reported by Schlimp et al. (4), we also expected those errors to occur in our test locations. However, only a few such events occurred during our investigation.

All these differences may be explained by the absence of confirmation of data derived from ECG simulators. Schlimp et al. (4) found human ECGs differently receptive to EMI in contrast to simulated ECG signals. Our data, collected in volunteers and in a simulated cardiac arrest situation, seem to be in clear contrast to previous findings. Major differences in susceptibility to EMI are dependent on the source of signal. This may explain some of our findings.

We also estimate that artificially generated ECG rhythms, such as those provided by training dummies, may not be suitable for high-quality interference testing. Furthermore, previous studies (5) used much older AED models with significantly older hardware and software technology than in the current devices. Schlimp et al. (4) tested AED made for professionals that may also be of a significantly different design. Furthermore, investigators chose to lift the AED devices to hold them in the direction of the electrical source. We tried to simulate cardiac arrest situations as close to reality as possible.

We chose AED models that were commercially available in Austria. Our study locations were selected because our previous findings indicated that some of these AED models are susceptible to EMI, especially in the presence of 16.7 Hz fields (5,8). Furthermore, modern railways, including underground trains, use alternating frequencies to control acceleration and deceleration. Their generators produce strong magnetic fields and are also regarded as potentially harmful to ECG signal quality.

However, under the environmental conditions of our investigation, none of the tested AED was prompted to deliver a shock in the presence of sinus rhythm. We found that magnetic and electric interference at these publicly accessible sites much weaker when compared with our findings in a transformer station with restricted public access. As we used the same AED models as in our previous study without any modifications, it seems obvious that the nature of EMI, especially field strength, was the crucial factor of proper AED functioning (8).

This study has some limitations. Our investigation was designed in a human model, as no literature is available indicating the possibility of extrapolation of experimental data of ECG simulators. Therefore, we were not able to investigate anything other than false positive decisions of AED in the presence of sinus rhythm including possible electrode failure or participant movement. Blinding on the level of the active investigation was not possible, but investigators and participants were not able to influence the primary outcome.

We conclude that EMI at train stations does not interfere with proper ECG analysis of AED to simulate shockable heart rhythms. However, participant movements were reported at times, which may have caused a delay of shock admission and cardiopulmonary resuscitation initiation. In regard to the large potential benefit of PAD, these adverse events do not seem to be of clinical relevance. It remains unclear if false negative shock decisions could be a consequence of EMI.

ACKNOWLEDGMENTS

We are indebted to the Federal Institute of Technology and to the contributors Wolfgang Nitsche, PhD, MSc Engineering and Guenther Gamperl, MSc Engineering, who kindly supported us with technical expertise and measurements on electromagnetic field characteristics during data collection.

REFERENCES

1. DF 39–1993 standard for automatic external defibrillators and remote-control defibrillators. Association for the Advancement of Medical Instrumentation, Arlington, TX, 1993.
2. Ventricular arrhythmia detection algorithms: recommended practice for testing and reporting performance results of ventricular arrhythmia detection algorithms. Association for the Advancement of Medical Instrumentation, Arlington, TX, 1997. ECAR 1997.
3. Automatic external defibrillators for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety. A statement for health professionals from the American Heart Association Task Force on Automatic External Defibrillation, Subcommittee on AED and Efficacy. Biomed Instrum Technol 1997;31:238–44.
4. Schlimp CJ, Breiteneder M, Lederer W. Safety aspects for public access defibrillation using automated external defibrillators near high-voltage power lines. Acta Anaesthesiol Scand 2004;48: 595–600.
5. Kanz KG, Kay MV, Biberthaler P, et al. Susceptibility of automated external defibrillators to train overhead lines and metro third rails. Resuscitation 2004;62:189–98.
6. Stolzenberg BT, Kupas DF, Wieczorek BJ, Sole DP. Automated external defibrillators appropriately recognize ventricular fibrillation in electromagnetic fields. Prehosp Emerg Care 2002;6: 65–6.
7. Kanz KG, Kay MV, Biberthaler P, et al. Effect of digital cellular phones on tachyarrhythmia analysis of automated external defibrillators. Eur J Emerg Med 2004;11:75–80.
8. Fleischhackl R, Singer F, Nitsche W, et al. Influence of electromagnetic fields on function of automated external defibrillators. Acad Emerg Med 2006;13:1–6.
9. Davies CS, Colquhoun M, Graham S, et al. Defibrillators in public places: the introduction of a national scheme for public access defibrillation in Engl. Resuscitation 2002;52:13–21.
10. Handley AJ, Monsieurs KG, Bossaert LL. European Resuscitation Council Guidelines 2000 for Adult Basic Life Support. A statement from the Basic Life Support and Automated External Defibrillation Working Group (1) and approved by the Executive Committee of the European Resuscitation Council. Resuscitation 2001;48:199–205.
11. Mosesso VN Jr, Davis EA, Auble TE, et al. Use of automated external defibrillators by police officers for treatment of out-of-hospital cardiac arrest. Ann Emerg Med 1998;32:200–7.
12. Fleischhackl R, Foitik G, Czech G, et al. Reaching the public via a multi media campaign as a first step to nationwide public access defibrillation. Resuscitation 2006;69:269–75.

ELSEVIER

Resuscitation xxx (2004) xxx–xxx

RESUSCITATION

www.elsevier.com/locate/resuscitation

Susceptibility of automated external defibrillators to train overhead lines and metro third rails

Karl-Georg Kanz[a,b,*], Mike V. Kay[a], Peter Biberthaler[b], Walter Russ[b], Stefan Wessel[c], Christian K. Lackner[a], Wolf Mutschler[a,b]

[a] *Institute for Emergency Service and Management in Medicine (INM), Medical Center and School of Medicine of the University of Munich, Schillerstrasse 53, D-80336 München, Germany*

[b] *Department of Trauma Surgery, Medical Center and School of Medicine of the University of Munich, Nussbaumstrasse 20, D-80336 München, Germany*

[c] *Department of Electrical Engineering, Munich University of Applied Sciences, Lothstr. 34, D-80335 München, Germany*

Received 25 July 2003; received in revised form 17 February 2004; accepted 27 February 2004

Abstract

Introduction: Immediate accessibility to automated external defibrillators (AED) is recommended for highly frequented public areas. In train terminals and metro stations electromagnetic interference (EMI) is present. In preparation for a public access defibrillation (PAD) programme in this environment possible effects on AED safety and accuracy were studied. *Methods:* In typical public transportation settings 11 different AED models were bench tested for their sensitivity and specificity of ECG analysis with shockable and nonshockable rhythms provided by an ECG simulator. The devices were exposed to the electromagnetic interference of a rail system operating with 15 kV alternating current (ac) with a frequency of 16 2/3 Hz and a subway system powered with 750 V direct current (dc). AED cables were setup parallel and perpendicular to the tracks, the tests were carried ont at 3 m distance from the rails in an empty station and with incoming trains. *Results:* A total of 5280 tests were recorded, each device was tested a total of 480 times. Fifteen kilovolts 16 2/3 Hz ac interfered more than 750 V dc with the tachyarrhythmia detection systems ($P < 0.0001$). An AED setup with electrode cables perpendicular to track and power line redneed interference ($P < 0.0001$), while incoming trains had no significant effect on ECG analysis ($P = 0.19$). Depending on the AED model, sensitivity ranged from 60 to 100% and specificity from 54 to 100%, representing a positive likelihood-ratio from 1.3 to 241 and a negative likelihood-ratio from 0.7 to 0.0. In the public transportation setting tested, four AED models were unsuitable for automated defibrillation as these devices demonstrated an unacceptable performance in respect of accuracy and safety. In the train setting two devices performed with an accuracy of 57 and 65%. One AED recommended shocks for sinus rhythm at normal frequency. In the metro setting one AED did not advise shocks for ventricular tachycardia. *Conclusion:* Shock advisory systems of some AED models are susceptible to electromagnetic interference, especially in terminals with 15 kV 16 2/3 Hz ac power supplies. Interference is minimized, if patient position is parallel and electrode cables are perpendicular to overhead line. The choice of AED model for train or metro stations depends on its lack of susceptibility to typical electromagnetic interference.

Keywords: Automated external defibrillator (AED); Noise; Electromagnetic interference (EMI); Electromagnetic compatibility (EMC); Bench test

1. Introduction

The city of Munich has recently implemented a public access defibrillation (PAD) programme for the underground public transport system, which consists of subways and low level trains. The underground system was first built for the Olympic games in 1972, it covers 92.7 km of track with 92 stations and transports about 900,000 passengers per day. Access for emergency medical services (EMS) is difficult due to barriers. There is up to 250 m for EMS personnel to cover on foot and stations are up to a 34 m in depth underground. The collapse to first shock interval can therefore exceed 15 min, decreasing survival notably [3,15].

The American Heart Association (AHA) in collaboration with the International Liaison Committee on Resuscitation (ILCOR) has called for rapid defibrillation programmes [1].

* Corresponding author. Tel.: +49-89-99201330; fax: +49-89-99201332.
E-mail address: karl-georg.kanz@med.uni-muenchen.de (K.-G. Kanz).

0300-9572/$ – see front matter © 2004 Published by Elsevier Ireland Ltd.
doi:10.1016/j.resuscitation.2004.02.018

According to German law Good Samaritan immunity covers automated defibrillation, even by untrained laypersons. Furthermore, for bystanders non-assistance to endangered persons is liable to prosecution.

Consequently, the Mayor of Munich strongly supported an EMS initiative to install automated external defibrillators (AED) in the Munich underground rail system. Currently 18 AEDs in 16 subway stations are available for public responders. The devices are locked in cabinets and mounted beside emergency eall boxes. To eomplement their introduction, information on use and benefits are presented on video screens and wall posters. In the case of an emergeney, a bystander activating the SOS panel is connected via a call box with the traffic control eenter, while computer control systems automatically route video surveillance of that sector to monitor screens. The operator on duty is in contact with the caller via an intercom and is also able to convey instructions using the platform public annouueement system. The AED cabinet, which is locked to prevent theft, can be opened remotely by a simple mouse click. Emergency medieal services are activated simultaneously and security officers, when in the vieinity, are dispatehed.

In this environment there is strong electromagnetie interference (EMI), caused by overhead power lines with 15 kV 16 2/3 Hz alternating current (ac) and third rails with 750 V direct current (de). In preparation for this public access defibrillation project we investigated the possible effects of electromagnetic noise on the effieacy and safety of the tachyarrhythmia detection systems of automated external defibrillators.

2. Materials and methods

It was hypothesized, that two main AED malfunctions caused by eleetromagnetie interference could oceur. First, in the case of a shockable rhythm, inhibition of necessary shock advice/delivery might occur. Second, in the case of a nonshockable rhythm, inappropriate defibrillation might be advised.

The study was carried out on 11 different AEDs, 4 first responder and 7 EMS devices, with ECGs supplied from a simulator or two human subjects. The testing rhythms were generated by an ECG simulator (HeartSim 2000, Laerdal Medical, Norway), which was contained in a grounded box constructed from 2 mm sheet iron to create a Faraday cage. The ECG simulator received power from a 220 V source via an insulating transformer. A 5 mm PVC sheet was mounted on top of the box with protruding electrodes separated 30 cm apart. Inside the cage a 50 Ω manikin load box (Laerdal Medical, Norway) was connected between the simulator and the outer electrodes. The AEDs being tested were attaehed to the simulator with their original disposable defibrillation electrodes. Eight rhythms, five shockable and three nonshockable, were provided by the ECG simulator. Additionally the same procedure was carried out on two researehers

Table 1
Tested ECG rhythms

Shockable	Ventricular tachycardia 210 min^{-1} (simulator)
	Ventricular fibrillation coarse/amplitude 1.5 mV (simulator)
	Ventricular fibrillation normal/amplitude 1.0 mV (simulator)
	Ventricular fibrillation fine/amplitude 0.5 mV (simulator)
	Ventricular fibrillation very fine/amplitude 0.25 mV (simulator)
Nonshockable	Normal sinus rhythm 65–90 min^{-1} (human subject)
	Normal sinus rhythm 60–95 min^{-1} (human subject)
	Normal sinus rhythm 80 min^{-1} (simulator)
	Normal sinus rhythm with right bundle branch block 80 min^{-1} (simulator)
	Asystole (simulator)

with normal sinus rhythm (Table 1). This experimental setup was also used in another study of the effect of digital cellular phones on the same AEDs, whieh did not cause any malfunction of tachyarrhythmia detection systems in 8640 tests [6].

Two types of passenger stations with different power supplies were used; the low level train system (S-Bahn) operating with 15 kV ac and the subway system (U-Bahn) powered with 750 V dc. The tests were performed in two separate locations; a low level train platform and a subway platform. The different train lines are separated by depth and enclosed in tunnels, so that the EMI is isolated to the particular traek power usage. The experiment was setup 3 m from the rails (Fig. 1), representing a minimum safety distance for rescuers, when train services are operating. The AED was placed left of the simulator or the patient's head respectively, as this is the typieal position for use. Electrode cables were unpacked without any special coiling or straightening. For setup A the human subject or simulator was placed parallel to the tracks and with the eables perpendicular to the power line, while for setup B the setting was rotated 90°, so that the subject's feet aimed towards the rails and electrode eables were parallel to the power supply. The tests were also

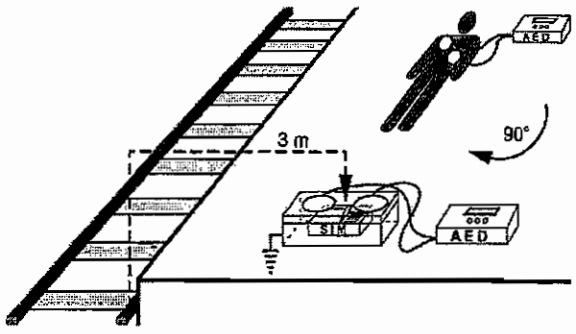


Fig. 1. Experiment setup with electrode cables perpendicular to the power line representing setup A. Ninety degree rotation with pivot axis between the electrodes results in setup B with the electrode cables parallel to the rails.

Table 2
Calculation of sensitivity, specificity and accuracy according to [8]

AED decision	Shockable	Nonsbockable
Shock	a: true positive	b: false positive
No shock	c: false negative	d: true negative

Sensitivity = a/(a + c); specificity = d/(b + d); accuracy = (a + d)/(a + b + c + d).

carried out in an empty station and with incoming trains.

Each AED was tested 480 times with 10 rhythms 6 times each in 8 different settings. The same investigation team performed all tests. All AEDs, disposable electrodes and pieces of equipment were tested using the recommended process by the manufacturer. Additionally we carried out one sequence of simulator rhythms tests per device in a setting without electromagnetic interference conditions.

The AED analysis was declared to be correct if, the AED recommended a shock by presence of ventrieular tachycardia or ventricular fibrillation, or no shock by all other tested rhythms. All other results were declared false. Calculation of sensitivity, specificity and accuracy were conducted according to AHA recommendations (Table 2) with 95% confidence intervals [8]. Unacceptable performance was defined for an accuracy of less than 90%, for inappropriate shock recommendation with QRS complexes at regular rate, and for no shock advised in the presence of ventricular tachycardia and ventricular fibrillation with amplitude ≥1.0 mV.

In addition sample measurements of electromagnetic fields existing in the 15 kV ac 16 2/3 Hz setting were taken using probes for electric field strength (E-Feld-Messgerät 68-280-38, ELV, Germany) and magnetic flux density (Teslameter, Elektror, Germany). Data was recorded online and stored in an Excel compatible database (Department of Electrical Engineering, Munich University of Applied Sciences). Probes were placed on the platform in the typical patient or simulator positions at a distance of 3 m from the rails. The electromagnetic fields were surveyed in parallel and perpendicular positions to the overhead line and with an empty station and incoming trains.

3. Results

Under our testing conditions with strong environmental electromagnetic interference, the 11 AEDs demonstrated a wide range of performance depending on the model, type of EMI and AED setup.

One AED was insusceptible in this setting, most of the devices fulfilled the requested performance goals [8], but showed minor problems in analyzing critical rhythms like very fine ventricular fibrillation or asystole, especially under 15 kV 16 2/3 Hz ac interference. This frequency range is equivalent to a rate of 1000 min^{-1}, which lies in range of arrhythmia analysis systems. However, certain AEDs demonstrated serious safety problems, failing overall in rhythm analysis and even charging during rhythms with QRS complexes at regular rate (Table 3).

High voltage alternating current with 16 2/3 Hz frequency interfered significantly more than low voltage direct current with the tachyarrhythmia detection systems (Table 4). AED setup, simulator and cable positions effected AED accuracy. Positioning the AED with cables perpendicular to the rails and power lines reduced interference significantly (Table 5). No significant effect on tachyarrhythmia analysis was observed by incoming trains (Table 6).

4. Discussion

Even though Europe is well advanced in its integration process, different rail electrification systems for long distance passenger trains still coexist (Table 7). The simplest method to deliver energy to an electrically powered train is by using a low voltage direct current traction motor, as used in metro systems since the end of the 19th century. This is however not practicable for locomotives with multiple wagons or travelling at higher speeds, as the relatively high power consumption at low voltage causes a very high current flow. In this case feeder stations must be distributed very closely together and the pantograph must be firmly pressed against a thick overhead line or third rail. At the turn of the 20th century engineers developed a method of delivering power with low current flow to long distance passenger trains using electrical motors available at that time by supplying them with a 15 kV high voltage alternating current at a low frequency of 16 2/3 Hz. This frequency was chosen, because it is exactly one third of 50 Hz and can be supplied from 50 to 16 2/3 Hz rotating converters. This reduced maintenance, as wear by sparking of electrical motor cummutators under high voltage is directly proportional to the supplied frequency. The first railway to have scheduled operation with low frequency high voltage ac power was the branch line from Murnau to Oberammergau in Bavaria, electrified by Siemens in 1904. In 1912, the German Railways adopted this 15 kV 16 2/3 Hz system as standard for low frequency high voltage electrification, and shortly afterwards Austria, Sweden, Norway and Switzerland build up separate 16 2/3 Hz power stations and networks for supplying railways with high voltage. Modern technologies using high power semiconductors now allow operation of trains supplied with 25 kV at 50 Hz obtained from the public network.

There is no doubt, that the use of AEDs in treating haemodynamically nonperfusing tachyarrhythmias is of utmost importance. As the interval to shock delivery has a direct relationship to patient outcome, the American Heart Association in collaboration with the International Liaison Committee on Resuscitation strongly recommend the use of AED by professional responders and lay persons [1]. It is of course only ethically and legally feasible to implement the use of AEDs, when the accuracy of their arrhythmia analysis is

Table 3
Results of rhythm analysis tests per AED model

15 kV 16 2/3 Hz ac	Corpuls 08/16	Dräger Cardiolog 2000S	Heartstream Forerunner	HP Codemaster 100	Laerdal Heartstart 911	Laerdal Heartstart QR 3000
Wrong shock decision	48/120	31/120	14/120	11/120	9/120	7/120
Wrong no-shock decision	55/120	48/120	0/120	9/120	0/120	1/120
Sensitivity (95% CI)	60% (51–68%)	74% (66–81%)	88% (81–93%)	91% (84–95%)	92% (86–96%)	94% (88–97%)
Specificity (95% CI)	54% (45–63%)	60% (51–68%)	100% (96–100%)	92% (86–96%)	100% (96–100%)	99% (95–100%)
Accuracy (95% CI)	57% (51–63%)	67% (61–72%)	94% (90–96%)	91% (87–94%)	96% (93–98%)	96% (93–98%)
Positive likelihood-ratio (95% CI)	1 (1–2)	2 (1–2)	213 (13–3388)	12 (6–22)	223 (14–3546)	113 (16–796)
Negative likelihood-ratio (95% CI)	0.73 (0.56–0.97)	0.43 (0.31–0.60)	0.12 (0.07–0.19)	0.10 (0.01–0.17)	0.08 (0.04–0.14)	0.06 (0.03–0.12)
Unacceptable performance	Yes	Yes	No	Yes	No	No
Comments	Reports cable malfunction, fails for sinus rhythm, ventricular fibrillation ≤0.5 mV, asystole	Charges for sinus rhythm with setup B, no shocks for ventricular fibrillation ≤0.25 mV, reports error for asystole	No shocks for ventricular fibrillation ≤0.5 mV with setup B	Shocks for sinus rhythm, no analysis possible for ventricular fibrillation ≤0.25 mV and asystole	No shocks for ventricular fibrillation ≤0.25 mV with setup B	1× shock for asystole with setup B
15 kV 16 2/3 Hz ac	Physio-Control FirstMedic 510	Physio-Control LifePak 300	Physio-Control LifePak 500	SurVivaLink FirstSave	Zoll 1600	
Wrong shock decision	1/120	7/120	12/120	0/120	0/120	
Wrong no-shock decision	0/120	6/120	0/120	12/120	0/120	
Sensitivity (95% CI)	99% (95–100%)	94% (88–97%)	90% (83–94%)	100% (96–100%)	100% (96–100%)	
Specificity (95% CI)	100% (96–100%)	95% (89–98%)	100% (96–100%)	90% (83–94%)	100% (96–100%)	
Accuracy (95% CI)	100%(97–100%)	94% (90–97%)	93% (89–96%)	93% (89–96%)	100% (98–100%)	
Positive likelihood-ratio (95% CI)	239 (15–3800)	18 (9–41)	217 (4–3451)	10 (6–16)	241 (15–3831)	
Negative likelihood-ratio (95% CI)	0.01 (0.00–0.06)	0.06 (0.03–0.13)	0.10 (0.06–0.17)	0.00 (0.00–0.07)	0.00 (0.00–0.07)	
Unacceptable performance	No	No	No	No	No	
Comments	1× no shock for ventricular fibrillation 0.25 mV with setup B	No shocks for ventricular fibrillation ≤0.25 mV. Shocks for asystole	No shocks for ventricular fibrillation ≤0.5 mV with setup B	Shocks for asystole with setup B		
750 V dc	Corpuls 08/16	Dräger Cardiolog 2000S	Heartstream Forerunner	HP Codemaster 100	Laerdal Heartstart 911	Laerdal Heartstart QR 3000
Wrong shock decision	0/120	0/120	0/120	0/120	7/120	0/120
Wrong no-shock decision	0/120	18/120	0/120	0/120	0/120	0/120
Sensitivity (95% CI)	100% (96–100%)	100% (96–100%)	100% (96–100%)	100% (96–100%)	100% (96–100%)	100% (96–100%)
Specificity (95% CI)	100% (96–100%)	85% (77–90%)	100% (96–100%)	100% (96–100%)	94% (88–97%)	100% (96–100%)
Accuracy (95% CI)	100% (98–100%)	92% (88–95%)	100% (98–100%)	100% (98–100%)	97% (94–98%)	100% (98–100%)

Table 3 (*Continued*)

15 kV 16 2/3 Hz ac	Corpuls 08/16	Dräger Cardiolog 2000S	Heartstream Forerunner	HP Codemaster 100	Laerdal Heartstart 911	Laerdal Heartstart QR 3000
Positive likelihood-ratio (95% CI)	241 (15–3831)	6 (4–10)	241 (15–3831)	241 (15–3831)	16 (8–32)	241 (15–3831)
Negative likelihood-ratio (95% CI)	0.00 (0.00–0.07)	0.00 (0.00–0.07)	0.00 (0.00–0.07)	0.00 (0.00–0.07)	0.00 (0.00–0.07)	0.00 (0.00–0.07)
Unacceptable performance	No	No	No	No	Yes	No
Comments		Reports error during asystole			3× no shock for ventricular tachycardia with setup B and incoming trains	
750 V dc	Physio-Control FirstMedic 510	Physio-Control LifePak 300	Physio-Control LifePak 500	SurVivaLink FirstSave	Zoll 1600	
Wrong shock decision	0/120	0/120	0/120	2/120	0/120	
Wrong no-shock decision	0/120	0/120	0/120	0/120	0/120	
Sensitivity (95% CI)	100% (96–100%)	100% (96–100%)	100% (96–100%)	100% (96–100%)	100% (96–100%)	
Specificity (95% CI)	100% (96–100%)	100% (96–100%)	100% (96–100%)	98% (94–99%)	100% (96–100%)	
Accuracy (95% CI)	100% (98–100%)	100% (98–100%)	100% (98–100%)		100% (98–100%)	
Positive likelihood-ratio (95% CI)	241 (15–3831)	241 (15–3831)	241 (15–3831)	48 (14–164)	241 (15–3831)	
Negative likelihood-ratio (95% CI)	0.00 (0.00–0.07)	0.00 (0.00–0.07)	0.00 (0.00–0.07)	0.00 (0.00–0.07)	0.00 (0.00–0.07)	
Unacceptable performance	No	No	No	No	No	
Comments				No shock for ventricular fibrillation ≤0.25 mV with setup B		

Table 4
Performance of tested AEDs under 15 kV 16 2/3 Hz ac vs. 750 V dc interference

	Wrong shock decision sensitivity	Wrong no-shock decision specificity	Wrong decision accuracy
15 kV 162/3 Hz ac	128/1320	140/1320	368/2640
Percentage	90.3	89.4	86.0
95% KI	88.6–91.8%	87.6–90.9%	84.7–87.3%
750 V dc	7/1320	18/1320	25/2640
Percentage	99.4	98.6	99.0
95% KI	98.9–99.7%	97.8–99.1%	98.6–99.3%
OR	20.1	8.5	16.9
95% KI	9.4–43.3	5.2–14.1	11.3–25.5
P-value	<0.0001	<0.0001	<0.0001

Table 5
Performance of tested AEDs with cables parallel (setup B) vs. perpendicular (setup A) to the rails

	Wrong shock decision sensitivity	Wrong no-shock decision specificity	Wrong decision accuracy
Cables parallel	102/1320	98/1320	200/2640
Percentage	92.2	92.6	92.4
95% KI	90.7–93.6%	91.0–93.8%	91.3–93.4%
Cables perpendicular	50/1320	15/1320	65/2640
Percentage	96.2%	98.8%	97.5%
95% KI	95.0–97.1%	98.1–99.3%	96.9–98.0%
OR	2.1	7.0	3.2
95% KI	1.5–3.0	4.0–12.1	2.4–4.3
P-value	<0.0001	<0.0001	<0.0001

extremely high. Immediate defibrillation must be advised and delivered to all patients with lethal tachyarrhythmias, but for all other patients an inappropriate shock could be harmful.

Automated external defibrillators are designed to allow shock delivery only to patients in rapid ventricular tachycardia or ventricular fibrillation. The incorporated algorithm analyzes the ECG waveform and verifies the rhythm as shockable or nonshockable by using a variety of criteria like frequency, amplitude, slope, order and regularity. The electrocardiographic signal passes through several filters and is then analyzed for rate, morphologic criteria and variability in the beat-to-beat interval. The AED assesses the ECG for arrhythmias by taking two–three segments of about 2–3 s in length and votes on these segments to make a shock decision [17]. An amplitude with voltage of less than 0.1 mV is generally defined as asystole. When a lethal tachyarrhythmia is identified, the AED charges and advises a shock. Two brands, Physio-Control and Heartstream, provide a supplementary analysis system, which detects respirations and chest movements via constant impedance measurement. Inappropriate defibrillation due to noise or interference is inhibited, if respirations or motions are present. However, availability of information concerning the functionality of shock advisory systems is limited, as the actual algorithms used in marketed AEDs are trade secrets [18].

Table 6
Performance of tested AEDs with in coming trains vs. empty station

	Wrong shock decision sensitivity	Wrong no-sbock decision specificity	Wrong decision accuracy
Incoming train	66/1320	86/1320	152/2640
Percentage	95.0	93.5	94.2
95% KI	93.7–96.0%	92.0–94.7%	93.3–95.1%
Empty station	77/1320	99/1320	176/2640
Percentage	94.1	92.5	93.3
95% KI	92.7–95.3%	90.9–93.8%	92.3–94.2%
OR	0.85	0.86	0.86
95% KI	0.60–1.2	0.64–1.2	0.68–1.1
P-value	0.390	0.360	0.190

Table 7
European train and metro voltage systems

dc or direct current	
750 V	Metro networks, South-England
1500 V	Southern part of France, Netherlands
3000 V	Belgium, Czech, Italy, Poland, Slovakia
ac or alternating current	
15 kV 16 2/3 Hz	Austria, Germany, Norway, Sweden, Switzerland
25 kV 50 Hz	Czech, Denmark, France, Finland, Portugal, United Kingdom, Slovakia, former Yugoslavia

In principal two different AED malfunctions are possible, especially under electromagnetic interference. First, in the case of shockable rhythms, no shock may be advised and second, in the case of nonshockable rhythms, an inappropriate defibrillation may occur. Less evidence is reported on safety and accuracy of modern AEDs and possible malfunctions in field [4,9,11,12,16]. The American Heart Association in collaboration with the American Association for the Advancement of Medical Instrumentation (AAMI) [2] calls for arrhythmia analysis algorithms with a sensitivity of >75% for ventricular tachycardia and >90% for ventricular fibrillation. For safety reasons a specificity of >99% for normal sinus rhythm and >95% for asystole is requested [8]. These performance goals apply however to artifact free ECGs, which had been recorded in field, and not for bench testing under strong EMI with specific rhythm libraries.

Our investigations were based on possible scenarios during sudden cardiac arrest (SCA) in train terminals or metro stations, when emergency medical services are responding with a defibrillator or first responders and laypersons are using an AED, prepositioned by the municipal transport services.

High voltage power lines, especially with a frequency of 16 2/3 Hz, can interfere severely with manual defibrillators and ECG monitors [13]. While filtering for diagnostic quality ECG is from 0.01 Hz at the low to 125 Hz at the high

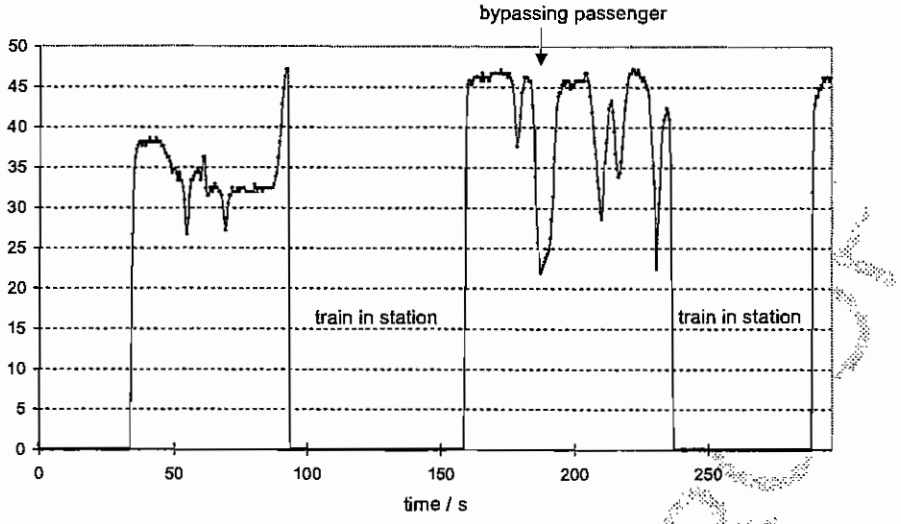


Fig. 2. Electric field strength in V/m under 15 kV ac 16 2/3 Hz at 3 m distance from the rails (vertical component).

end, typical filtering of an AED is from 0.5 to 25–35 Hz. This pass band eliminates 50 or 60 Hz interference, which is outside this range, and creates a solid baseline for rhythm analysis. However, in train terminals and railway stations with 15 kV ac 16 2/3 Hz overhead lines, noise of that frequency is not filtered out and drained by the AED. This explains why high voltage alternating current with 16 2/3 Hz frequency interfered significantly more with the shock advisory systems than low voltage direct current.

AED setup, patient position (or simulator) and cable course is another issue to consider, as positioning the AED with cables perpendicular to the rails and power lines reduces interference significantly. These results are consistent with measured electric and magnetic field in the high voltage setting at 3 m distance to the rails. Electric field strength ranged between 22 and 47 V/m and dropped to near zero, when the overhead lead was shielded either by a stationed train or passengers passing between probe and power line (Fig. 2). Relevant magnetic field variations, ranging from 0.7 to 3.7 μT, were recorded, due to the current caused by accelerating or decelerating trains on the common overhead power line (Fig. 3). No specific change of magnetic field was observed by an incoming train. The average magnetic flux density was 1.3 μT in parallel and 0.1 μT with the probe position perpendicular to overhead line.

We assume, that susceptible devices received electromagnetic interference mainly via electrode cables, especially if long, unshielded, or even separated lines run parallel to power lines.

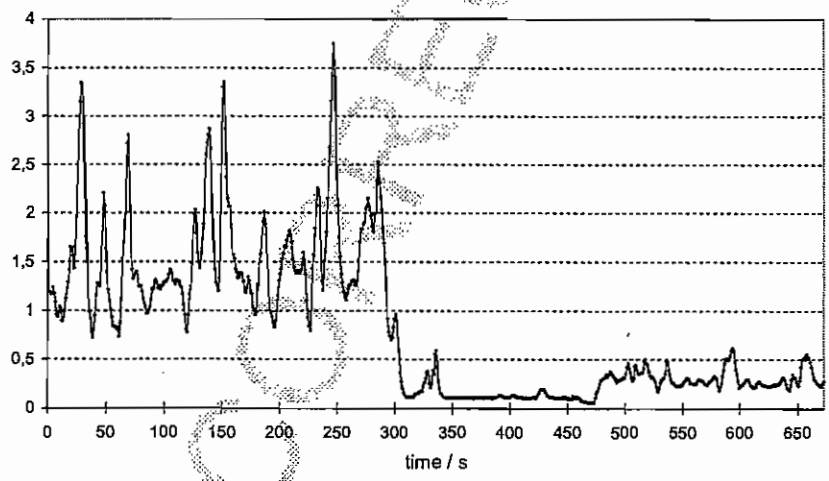


Fig. 3. Magnetic flux density in microTesla under 15 kV ac 16 2/3 Hz at 3 m distance from the rails (horizontal parallel, after 300 s horizontal perpendicular, after 480 s vertical component).

Another possible source of interference are the magnetic fields generated by electro motors and semiconductor regulators of incoming trains. In this study, no significant effect on tachyarrhythmia detection systems by incoming trains was observed, especially in the metro setting.

Seven AEDs performed well under interference, one model had a near total breakdown of the analysis system by constantly reporting cable malfunctions, two devices charged inappropriately for normal rate QRS complexes in the high voltage setting and one AED did not advise a shock for ventricular tachycardia in the metro setting with an incoming train. The typical 15 kV 16 2/3 Hz ac noise caused problems for most arrhythmia analysis systems in discriminating between very fine ventricular fibrillation, asystole and noise. With interference very fine ventricular fibrillation with 0.2 mV amplitude and even fine ventricular fibrillation with 0.5 mV amplitude was analyzed as a non shockable rhythm, while asystole was interpreted as a shockable rhythm. One AED always charged in the presence of asystole in the high voltage setting when electrode cables were in parallel position to the overhead line. It should be taken into consideration however, that these critical rhythms are associated with a small survival rate, the efficacy of defibrillation in very fine, prolonged ventricular fibrillation is low and the harm of shocking asystole is unclear. Possible effects of motion detection systems were not incorporated in the study design. With the exception of few devices, the majority of the AEDS tested demonstrated a safe and efficient performance, when presented with normal sinus rhythms, ventricular tachycardia and regular ventricular fibrillation.

There are few studies investigating the effect of environmental electromagnetic interference on the safety of modern AEDs. Two studies reported no interference of operating digital cellular phones on tachyarrhythmia analysis, but distorted voice prompts in some devices [6,7]. One study evaluated three commercially available AEDs with three types of generated ECG rhythms in the setting of a public utility coal-fired electrical generation plant. Under EMI ranging from 31 to 160 μT magnetic flux density, these AEDs correctly interpreted ventricular fibrillation, asystole and normal sinus rhythm [14]. In our experimental setup under high voltage with the critical frequency of 16 2/3 Hz, we observed severe malfunctions of some AED models despite a lower magnetic field from 0.7 to 3.7 μT.

Using our bench results to predict the expected field performance of AEDs under EMI in train terminals and metro stations, some aspects of study design and results have to be taken into consideration. In other studies on the accuracy of tachyarrhythmia detection algorithms, differences between bench and field results are reported [5,16]. Due to our limited resources we used a simple ECG simulator to generate our testing ECG patterns. Sophisticated ECG libraries for accuracy testing of tachyarrhythmia detection have also been used [10]. However, in the AHA recommendations mentioned above, it is stated, that there has been no standard database of ECG signals and noise for testing AED algorithms established. Manufacturers should determine, how to test their devices in the presence of noise and specify in detail, how the testing was done [8].

5. Conclusion

AEDs are not insusceptible to typical interference present in public transportation systems. Shock advisory systems of most AED models are susceptible to electromagnetic interference, especially in terminals with 15 kV 16 2/3 Hz ac power supplies. When presented with normal sinus rhythms, ventricular tachycardia and regular ventricular fibrillation, the majority of AEDs performed safely and accurately. However, discriminating between noise, very fine ventricular fibrillation and asystole caused problems for most arrhythmia analysis systems under conditions of high voltage interference. Some AED models cannot be recommended for use in public transport systems analogous to our test setting, as these devices demonstrated an unacceptable performance in respect of safety and accuracy.

Electromagnetic interference is minimized, if the position of the patient is parallel, and electrode cables are perpendicular, to the overhead line. Proper scene and AED setup can minimize magnetic flux density by a factor of 10. This issue needs to be incorporated in training programmes for emergency medical services.

Although EMS personnel can compensate for EMI by removing patient from the EMI source, a proper setup and positioning of defibrillator, or even by ordering a shut down of power supply, this is not feasible for laypersons using an AED. Therefore the choice of an AED for public access defibrillation in train or metro stations strongly depends on its performance and insusceptibility to the expected type of noise and interference.

References

[1] The American Heart Association in collaboration with the International Liaison Committee on Resuscitation (ILCOR). Guidelines 2000 for cardiopulmonary resuscitation and emergency cardiac care—an international consensus on science. Part 4. Automated external defibrillator. Resuscitation 2000;46:73–91.

[2] Association for the Advancement of Medical Instrumentation. DF39, Automatic External Defibrillators and Remote-Control Defibrillators. Arlington, VA: AAMI; 1993.

[3] Atkins JM. Emergency medical service systems in acute cardiac care: state of the art. Circulation 1986;74(Suppl IV):IV-4–IV-8.

[4] Herlitz J, Bang A, Axelsson A, Graves JR, Lindqvist J. Experience with the use of automated external defibrillators in out of hospital cardiac arrest. Resuscitation 1998;3:3–7.

[5] Jakobsson J, Rehnqvist N, Nyqvist O. Clinical experience with three different defibrillators for resuscitation of out of hospital cardiac arrest. Resuscitation 1990;19:167–73.

[6] Kanz KG, Kay M, Biberthaler P, Russ W, Lackner CK, Mutschler W. Effect of digital cellular phones on tachyarrhythmia analysis of automated external defibrillators. Eur J Emerg Med 2003, in press.

[7] Karczmarewicz S, Janusek D, Buczkowski T, Gutkowski R, Kulakowski P. Influence of mobile phones on accuracy of ECG interpretation algorithm in automated external defibrillator. Resuscitation 2001;51:173–7.

[8] Kerber RE, Becker LB, Bourland JD, et al. Automatic external defibrillators for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety. A statement for health professionals from the American Heart Association Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. Circulation 1997;95:1677–82.

[9] Macdonald RD, Swanson JM, Mottley JL, Weinstein C. Performance and error analysis of automated external defibrillator use in the out-of-hospital setting. Ann Emerg Med 2001;38:262–7.

[10] Murray A, Clayton RH, Campbell RW. Assessment of the ventricular fibrillation detection algorithm in the semi-automatic Cardio-Aid defibrillator. Resuscitation 1995;29:113–7.

[11] Ornato JP, Shipley J, Powell RG, Racht EM. Inappropriate electrical countershocks by an automated external defibrillator. Ann Emerg Med 1992;21:1278–82.

[12] Poole JE, White RD, Kanz KG, et al. Low-energy impedance-compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out-of-hospital cardiac arrest. LIFE Investigators. J Cardiovasc Electrophysiol 1997;8:1373–85.

[13] Schimansky J, Schwalbe H. Störungen der EKG-Diagnostik unter Hochspannungsleitungen. Notarzt 1997;13:155–6.

[14] Stolzenberg BT, Kupas DF, Wieczorek BJ, Sole DP. Automated external defibrillators appropriately recognize ventricular fibrillation in electromagnetic fields. Prehosp Emerg Care 2002;6:65–6.

[15] Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. N Engl J Med 2000;343:1206–12609.

[16] Weaver WD, Hill DL, Fahrenbruch C, et al. Automatic external defibrillators: importance of field testing to evaluate performance. J Am Coll Cardiol 1997;10:1259–64.

[17] Weigelt A, White RD. AED Algorithms. J Emerg Med Serv 1994;7:53–7.

[18] Weisfeldt ML, Kerber RE, McGoldrick RP, et al. American Heart Association Report on the Public Access Defibrillation Conference December 8–10, 1994. Automatic External Defibrillation Task Force. Circulation 1995;92:2740–7.

Influence of Electromagnetic Fields on Function of Automated External Defibrillators

Roman Fleischhackl, MD, Florian Singer, MD, Wolfgang Nitsche, PhD, MSc Eng, Guenther Gamperl, MSc Engineering, Bernhard Roessler, MD, Jasmin Arrich, MD, Sabine Fleischhackl, MD, Heidrun Losert, MD, Fritz Sterz, MD, Martina Mittlboeck, PhD, MSc, Klaus Hoerauf, PhD, MD

Abstract

Objectives: In this study, the authors tested whether electromagnetic interference (EMI) is able to impair correct electrocardiogram analysis and produce false-positive shock advice from automated external defibrillators (AEDs) when the true rhythm is sinus.

Methods: Nineteen healthy subjects were used to test five AEDs available on the Austrian market in a prospective, open, and sequence-randomized study. The primary outcome variable was the absolute number of shocks advised in the presence of EMI. The secondary outcome was the number of impaired analyses caused by incorrectly detected patient movements or electrode failure.

Results: Of 760 tests run, 18 (2.37%) cases of false-positive results occurred, and two of five AEDs recommended shocks in the presence of sinus rhythm. Of 760 tests run, no electrode failures occurred. There were 27 occurrences (3.55%) of motion detected by an AED in the presence of strong electromagnetic fields.

Conclusions: AED models differ in their response to EMI; it may be useful to consider specific safety requirements for areas with such fields present. Working personnel and emergency medical services staff should be informed about potential risks and the possible need for patient evacuation before AEDs are attached and shock recommendations are followed.

ACADEMIC EMERGENCY MEDICINE 2006; 13:1–6 © 2006 by the Society for Academic Emergency Medicine

Keywords: automated external defibrillator, electromagnetic interference, public access defibrillation

Sudden cardiac death is a major health problem in the industrialized world. In Austria, about 15,000 people die each year as a consequence of out-of-hospital cardiac arrests.[1] After out-of-hospital cardiac arrest, survival rates are low[2,3] and decline about 10% per minute if intervention is not given.[4] Basic life support and early defibrillation should be started as soon as possible after out-of-hospital cardiac arrest[5]; witnesses of cardiac arrest, even if not medically trained,[6] have been identified as the most important link in the chain of survival.[7]

Automated external defibrillators (AEDs) have been designed to provide lifesaving shocks for out-of-hospital cardiac arrests, regardless of whether or not bystanders have medical education and training.[8] The devices are easy to handle and instruct users by voice prompts and optical signals. Once the electrodes are connected to the patient's bare chest, the AED analyzes the underlying heart rhythm in regard to slope, amplitude, and waveform to identify shockable cardiac rhythms. The sensitivity of AEDs to correctly detect these shockable heart rhythms varies from 95% to 100%. Nonshockable rhythms are detected with a specificity of 98% to 100%.[9–11]

As electrocardiograms (ECGs) are obtained from the body surface, surrounding electromagnetic fields can weaken signal quality.[12] False-negative decisions based on AED analysis could prevent the delivery of a necessary shock.[13] Even worse, shocks could be advised in the presence of sinus rhythm and spontaneous circulation, which could be harmful, or at least very painful, for the patients. We therefore tested whether strong electric and magnetic fields are able to impair correct ECG analysis and

From the Department of Emergency Medicine (RF, JA, HL, FSt), Department of Anaesthesia and Intensive Medicine (BR, KH), and Core Unit for Medical Statistics and Informatics (MM), Medical University of Vienna, Vienna, Austria; Vienna Red Cross–Research Institute (RF, FSi, BR, SF, KH), Vienna, Austria; and Federal Institute of Technology–State Institute for Electrical and Electronic Engineering (WN, GG), Vienna, Austria.

Received April 15, 2005; revisions received June 13, 2005, and July 5, 2005; accepted July 13, 2005.

Address for correspondence and reprints: Roman Fleischhackl, MD, Department of Emergency Medicine, Medical University of Vienna, Waehringer Guertel 18-20, A-1090 Vienna, Austria. Fax: 43-1-40400-1965; e-mail: roman.fleischhackl@meduniwien.ac.at.

doi: 10.1197/j.aem.2005.07.036
ISSN 1069-6563
PII ISSN 1069-6563583

produce false-positive shock advice from AEDs in the presence of sinus rhythms.

METHODS

Study Design

The investigation was a prospective study with a randomized sequence of AED applications and was performed by the Research Institute of the Austrian Red Cross–Vienna Branch and the Medical University of Vienna, according to the good scientific practice guidelines of the Medical University of Vienna. The study was approved by the Ethics Committee of the Research Institute of the Austrian Red Cross–Vienna Branch. Before enrollment, written informed consent was obtained from each of the subjects. In compliance with good scientific practice, it was understood that the results of our investigation would be published whether positive or negative for individual companies that provided the AEDs we used. All source data remained with the principal investigator, and no permission from the sponsors was required before manuscript submission.

Study Setting and Population

For our investigation, we searched for a study site providing 50-Hz sources as used in the power supply network in Austria and 16⅔-Hz sources as used by the Austrian Railway Company. Both networks use transformer stations, overhead power lines, or other sources of electromagnetic interference (EMI) throughout the country that may impair correct ECG analysis if AEDs are used nearby. To test for a worst-case scenario, four study sites were identified and selected prospectively as locations with the strongest electromagnetic fields in the city area.[14]

The transformer substation Auhof in Vienna, Austria, proved to be particularly suitable, providing both 1) fields generated by transformers and high-voltage power lines, operating with a frequency of 50 Hz AC, and 2) generators and power lines for the Austrian Railway Company network, operating with a frequency of 16⅔ Hz AC. To identify sources generating the most intense electric and magnetic fields, respectively, measurements were conducted in the Auhof area using an electromagnetic field analyzer (EFA-300; Narda, Long Island, NY; measurement uncertainty, ±3%; data output, peak values).

The first location (Auhof 1) was 6 m below a power line at 110 kV and 50 Hz producing a predominantly electric field. Participants were positioned on the grass, lying on a woolen blanket. The second location (Auhof 2) was beside a generator of the railway company (10 kV; 16⅔ Hz) with a concrete floor. The third location (Auhof 3) was beside a generator providing electricity with 10.5 kV and 50 Hz. These two sites (Auhof 2 and 3) were regarded as contaminated by a predominantly magnetic field. The fourth location (Auhof 4) was affected by a predominantly electric field, 3.7 m below a power line for the railway network, operating with 110 kV and 16⅔ Hz. Again, subjects were positioned on the grass, lying on a woolen blanket.

The four sites had to be tested separately, because electric and magnetic fields require different measurements to determine strength of EMI noise. Furthermore, it is unknown which specifications of EMI might be more dangerous in contaminating ECG data for AED analysis. Therefore, to ensure transparency and to increase generalizability of our data to local particularities, our data reporting distinguishes between those two kinds of EMI.

To obtain a representative sample of AEDs available in Austria, we invited six companies of AED manufacturers and distributors currently active on the Austrian market to take part in this study. Five manufacturers joined the study and provided AEDs, batteries, and electrodes for free to support our investigation. The AEDs tested are listed alphabetically as follows: 1) AccessAED (Access Cardio Systems Inc., Concord, MA; after the study started, Access Cardio Systems Inc. recalled AEDs of all models and discontinued business), 2) CR+ (Medtronic, Minneapolis, MN), 3) Fred Easy (Schiller, Baar, Switzerland), 4) HS1 (Philips–Medical Systems, Amsterdam, The Netherlands), and 5) Responder (GE Healthcare, Chalfont St. Giles, England).

All AEDs tested were semiautomatic, CE certified (CE indicates conformity with mandatory European safety requirements), and licensed according to the medical product laws in Austria. No experimental products were tested. Participating manufacturers were asked to provide routinely produced devices that were fully functioning but without the ability to deliver an electric shock. If disarming was not feasible, or if software modifications would have been necessary to do so, shock buttons were protected by a plastic cover. In advance of each testing procedure, correct positioning of the safety cover was confirmed by the responsible investigator. This security check was documented on the case report forms (CRFs). All investigators received special training and were asked to disconnect the pads immediately in case of a false-positive shock decision. In this report, the AED models used are described using the numbers listed previously.

For participant recruitment, a notice was posted at the Medical University of Vienna inviting healthy people between 18 and 85 years to take part in the study; 25 subjects participated. We planned to include at least 20 participants in randomly allocated sequences of five different AEDs used in two positions (perpendicular and parallel to the electromagnetic field) at four different sites, resulting in 800 tests to be run. Exclusion criteria for the subjects were severe underlying illness and arrhythmic heart failure. Before participation, all volunteers underwent a medical examination, including ECG analysis, and written informed consent was obtained.

Study Protocol

Participants were randomly allocated to each of the five AEDs tested on every site; each participant was therefore tested with the five AEDs. Every participant received a set of five opaque envelopes containing the names of the five different AED devices. Before each test, one of the envelopes carried by each participant was randomly selected to indicate which of the AEDs would be tested next with that participant.

Because it was not possible to ensure blinding, participants and investigators were not blinded to the actual AED device tested. However, because of the nature of our hypothesis and the limited possibilities of responses (shock advised/no shock advised), investigators and participants were not able to influence the primary outcome.

Security advice was given to all participants and investigators according to the specific dangers of the study sites to avoid any hazardous accidents related to the presence of high-voltage power lines.

After arriving at the site of interest, the electrodes were attached by the participants to their bare chest. Volunteers had been instructed previously in written and verbal form how to attach the electrodes according to the current American Heart Association and manufacturers' guidelines.[8] If the pad wires were attached to each other, participants were asked not to pull them apart any further than necessary to affix the two pads in the correct position. Investigators were asked not to move the cables but to allow their positioning by random, as in real cardiac arrest situations.[13] At each site location, two different angles relative to the EMI were tested. The subjects were positioned parallel and perpendicular to the power line, according to recent findings suggesting potential impact of electrode cable orientation.[12]

To simulate a real cardiac arrest situation, volunteers were placed in a supine position. Clothes were opened but not removed completely. Female volunteers were allowed to wear swimsuits or t-shirts after attaching the pads to their bare chest.

The AED devices were located at the subject's right side, regardless of a potential source of electricity, and the electrodes were connected to the AED. Participants were moved as close to the magnetic field as possible. Once the devices were turned on, the voice prompts were followed as demanded until the decision of the device was obtained. During rhythm analysis, volunteers were asked to avoid any movement and to stop breathing in the resting expiratory position. Investigators who operated the AEDs near the participants were asked to ensure the absence of any patient movement during analysis and to report violations to the principal investigator on-site. This procedure was repeated until every device had been tested on every participant at every site.

Measurements

All sites tested received a site number (Auhof 1–4) that was documented on the CRF. The site investigator, volunteer's identification, and underlying ECG rhythm detected were recorded.

We documented the result of ECG analysis of the two AED positions at each site, the model of the AED, and if the AED had any difficulties with ECG interpretation. If analysis was aborted by the AED, the event and type of error reported were documented. The principal investigator was on-site as an additional supervisor to guarantee correct data entry on the CRFs according to the prompts of the different devices.

Once the data were collected, the CRFs were signed by the investigator and put into an opaque envelope. The investigators who performed data collection were unable to change the documentation afterward. They were not authorized to enter the data into the database or to perform data analysis.

Data were entered into the database of a statistics program (SAS version 9; SAS Institute Inc., Cary, NC) by research fellows of the research institute who were not involved in the study. Restricted access was granted to a senior scientific consultant and the statistician, who were not part of the data collection team. Statisticians only received AED model numbers and were blinded to the specific manufacturer and model.

The experiment aimed to verify if EMI occurring in locations where AEDs could eventually be used by lay personnel is able to simulate mock shockable rhythms in the presence of sinus rhythm or to hinder proper ECG analysis. Therefore, our primary outcome variable was the absolute number of shocks advised in the presence of sinus rhythm. The secondary outcome was the number of impaired analyses caused by incorrectly detected patient movements or electrode failure.

Data Analysis

Continuous data are described with median and interquartile range (IQR) because of non-normal distributions. Categorical data are described with absolute frequencies and percentages.

Dependencies between measured AED failures (first and secondary outcomes) and the investigated AED devices and environmental factors (angle, frequency, and type) are modeled with a generalized linear mixed model (PROC GLIMMIX in SAS) considering that each participant had repeated measurements (two angles, two frequencies, two types, and different AEDs). Because there were no malfunctions of AED 1, AED 2, and AED 4 with regard to the primary outcome, these devices were not included in the modeling procedure, and we did not include AED 2 and AED 3 with regard to the secondary outcome. These devices have an estimated false-positive response of zero. Corresponding one-sided 95% confidence intervals (CIs) are given under the assumption of independence of the 152 measurements for each AED.

In case of pairwise comparisons, the differences are described with odds ratios (ORs) and corresponding 95% CIs and p-values (both p-values and CIs are adjusted for multiple comparisons).

Statistical calculations were performed using the statistical package SAS (SAS version 9; SAS Institute Inc.). All p-values given are two sided, and $p \leq 0.05$ was considered statistically significant.

RESULTS

Nineteen of 25 invited subjects showed up on the study day and gave written informed consent. All had normal sinus rhythm in the prestudy ECG, and none had any underlying illness. No participant dropped out during the investigation.

The 19 participants consisted of eight male and 11 female subjects. Participants' median age was 24.6 years (IQR, 22.2–25.6 years), median height was 174 cm (IQR, 165–179 cm), and median weight was reported at 66 kg (IQR, 59–78 kg). The median body mass index was documented at 22 kg/m^2 (IQR, 20–24 kg/m^2). Thoracic impedance measurements were all within the acceptable range provided by the AED manufacturers. All 19 participants were tested in two different positions at four sites with five different AEDs; 760 tests were therefore performed.

Measurements of electric and magnetic fields conducted in the Auhof area using the electromagnetic field analyzer EFA-300 are displayed in Table 1. The primary

Table 1
Measurements of Electric and Magnetic Fields Conducted in the Auhof Area Using the Electromagnetic Field Analyzer EFA-300

Site	Magnetic Field (μT)	Electric Field (kV/m)
Auhof 1	1.5–1.5	2.96–2.96
Auhof 2	149–158	0.007–0.009
Auhof 3	45–46	0.008–0.008
Auhof 4	2.0–2.0	3.93–4.09

Data are displayed as the range of three measurements.

outcome variable was the absolute number of shocks advised in the presence of sinus rhythm. Of 760 tests run in the presence of strong electromagnetic fields, 18 (2.37%) cases of false-positive results occurred versus 742 (97.63%) of true-negative results. AED 1, AED 2, and AED 4 (each $n = 152$) showed no false-positive results. However, it is possible that the true false-positive results for these three AEDs are >1 (one-sided 95% CI = 0% to 2%). Further details are provided in Table 2.

The secondary outcome was the number of impaired analyses caused by incorrectly detected patient movements or electrode failure. Of the 760 tests run in the presence of strong electromagnetic fields, no electrode failure was detected, and there were 27 occurrences (3.55%) of motion detected by an AED. AED 1 incorrectly detected patient motion in two of 152 cases (1.32%), AED 2 and AED 3 did not detect mock patient movement ($n = 152$), AED 4 detected motion in six of 152 cases (3.95%), and AED 5 detected motion in 19 of 152 cases (12.5%). A full overview and further details are displayed in Table 2.

Probability estimations were calculated for AED 3 and AED 5 with false-positive results for our primary outcome. The mean probability of a false-positive decision was significantly ($p = 0.0365$) lower at 0.6% (95% CI = 0.1% to 3%) for AED 3 compared with 3.5% (95% CI = 1% to 11%) for AED 5 regarding all circumstances given. To determine to what extent angle, frequency of current, or type of field were able to contribute to observed error probabilities in ECG analysis algorithm, estimations were calculated for each factor.

Regarding the angle in which the patient was positioned in relation to the power source, the mean probability of a false-positive shock decision was 1.5% (95% CI = 0.4% to 5.2%) for the perpendicular position; this did not differ significantly ($p = 1.0$) from the mean probability of 1.5% (95% CI = 0.4% to 5.2%) for the parallel orientation. In contrast, the mean probability of a false-positive shock decision in the presence of a 50-Hz field was estimated significantly lower ($p = 0.0139$) at 0.3% (95% CI = 0.03% to 3%) than in the presence of a 16.7-Hz field at 6.4% (95% CI = 2.8% to 14%). The probability of a false-positive shock decision was not significantly higher ($p = 0.0517$) in the presence of a magnetic field (mean probability, 2.7%; 95% CI = 0.8% to 8.9%) compared with a predominantly electric field (mean probability, 0.08%; 95% CI = 0.02% to 3.6%).

Probability estimations were calculated for AEDs with false-positive results (AED 1, AED 4, and AED 5) in regard to our secondary outcome. The mean probability for detecting mock patient movements was significantly ($p = 0.0028$) lower at 0.3% (95% CI = 0.05% to 2.0%) for AED 1 and AED 4 at 1.0% (95% CI = 0.2% to 4.1%) compared with AED 5 at 4.0% (95% CI = 1.2% to 12.2%). Detailed error estimation calculation for incorrectly detected patient movements are displayed in Table 3.

Pairwise comparisons of AED 1, AED 4, and AED 5 to detect mock patient movements showed a significantly higher OR for AED 5 compared with AED 4 (OR, 4.16; 95% CI = 1.05 to 16.59; $p = 0.0416$) and compared with AED 1 (OR, 13.21; 95% CI = 1.83 to 91.85; $p = 0.0074$). AED 4 did not show a significantly higher OR than AED 1 (OR, 3.11; 95% CI = 0.37 to 25.83; $p = 0.4060$).

DISCUSSION

Our findings show that electric and magnetic fields are able to interfere with ECG registration and interpretation by AEDs. Shocks were advised to be delivered in healthy subjects in the presence of a sinus rhythm by two of five AEDs. The error of detecting false shockable rhythms occurred during three different tests in those two devices. Because false-positive results did not occur in the other three devices, we conclude that AED models of different manufacturers are unequal in regard to susceptibility to electric or magnetic interference, which is consistent with existing data.[13]

The occurrence of false-positive shock decisions was dependent on the EMI characteristics present at the specific site. Only AED 5 recommended shocks in the presence of sinus rhythm in three different study locations with 50-Hz and 16⅔-Hz electric and magnetic fields present. The second device, AED 3, which erroneously

Table 2
Absolute Numbers of False-positive Decisions Listed According to Their Occurrence and the Specific AED Model

				AED 1		AED 2		AED 3		AED 4		AED 5	
Site	Angle (°)	Frequency of Current (Hz)	Field Type	Shock Advised	Motion Detected	Shock Advised	Motion Detected	Shock Advised	Motion Detected	Shock Advised	Motion Detected	Shock Advised	Motion Detected
1	0	50	Electric	0/19	0/19	0/19	0/19	0/19	0/19	0/19	0/19	0/19	0/19
1	90	50	Electric	0/19	0/19	0/19	0/19	0/19	0/19	0/19	0/19	0/19	0/19
2	0	16⅔	Magnetic	0/19	1/19	0/19	0/19	2/19	0/19	0/19	0/19	3/19	7/19
2	90	16⅔	Magnetic	0/19	1/19	0/19	0/19	1/19	0/19	0/19	0/19	6/19	9/19
3	0	50	Magnetic	0/19	0/19	0/19	0/19	0/19	0/19	0/19	1/19	1/19	0/19
3	90	50	Magnetic	0/19	0/19	0/19	0/19	0/19	0/19	0/19	0/19	2/19	0/19
4	0	16⅔	Electric	0/19	0/19	0/19	0/19	0/19	0/19	0/19	3/19	3/19	2/19
4	90	16⅔	Electric	0/19	0/19	0/19	0/19	0/19	0/19	0/19	2/19	0/19	1/19

AED = automated external defibrillator.

Table 3
Probability of Incorrectly Detected Patient Movements

		Mean Probability (%)	95% CI (%)	p-value
Angle (°)	90	1.0	0.3, 4	NS
	0	1.1	0.3, 4.4	
Frequency (Hz)	16.7	6.4	3.1, 12.7	0.0005
	50	0.2	0.02, 1.4	
Type	Electric	0.6	0.1, 2.7	0.0333
	Magnetic	1.9	0.5, 6.7	

Data are given as mean probability and 95% CI dependent on angle, frequency, and type of the predominant field generated by an electrical source.

prompted to shock, was only susceptible to a magnetic field of 16⅔ Hz. These results may be explained by different hardware or software filters arranged within the devices to avoid impairment of correct ECG analysis. Recent literature describes sufficient ECG filtering methods to suppress 16⅔-Hz noise.[15]

With literature available about frequent electrode failures or mock patient movement detections, we expected such errors to occur frequently in our study.[12] However, three devices had difficulties distinguishing between real patient movements and electromagnetic noise. In regard to our probability estimation calculations, there were significant differences between these three devices, dividing them into a group of AEDs with minor problems with the interpretation of misleading ECG signals and one device with a significantly poorer performance.

None of the devices reported electrode failures. Also, thoracic impedance measurements showed no subject to be out of the range of valid ECG analysis. Our study showed not only results in regard to mock electrode failures but also data showing no effect of EMI on proper ECG analysis of AEDs.[14] Because former studies had a different design using ECG simulators instead of human subjects, this observation could be explained by electric and magnetic interference of the ECG simulator or the signal provided itself. Furthermore, we tested recently developed AEDs that may have substantially different technical designs.

Because previous investigations hypothesized that the cable connecting the pads with the AED may be a source of EMI interference, the attachment of the two cables was suspected to be a crucial factor of influence. Therefore, we expected less difficulties with AEDs using attached electrode wires (AED 1, AED 3, and AED 5).[13] However, none of the devices using loose cables (AED 2 and AED 4), which allowed them to be arranged as a kind of loop, thereby increasing susceptibility to magnetic induction, had difficulties with ECG analysis. Both devices that prompted users to deliver a shock in the presence of sinus rhythm used attached wires. Therefore, it is our impression that the arrangement of the electrode-connecting cable is not responsible for misinterpretation of ECG rhythms in the presence of electric or magnetic fields.

LIMITATIONS

Our study sites were selected because of their strong electromagnetic fields. Naturally, these are areas of restricted access. Further research will be necessary to evaluate the impact of EMI on AED ECG analysis in places accessible by the general public. It was also beyond the scope of our study to identify the exact hardware or software configuration that made AEDs susceptible to electric or magnetic interference.

We decided to investigate on human subjects, because no literature available indicated that data collected with ECG simulators would allow appropriate extrapolation into a human population. Therefore, we were not able to study anything other than false-positive decisions of AEDs in the presence of sinus rhythm. Our data are strictly limited to this error, regarded as the most dangerous and unfavorable event. It remains unclear if any of the devices that proved to be unsusceptible to EMI in our study design would produce false-negative results under the influence of EMI and may advise against necessary shocks in the presence of ventricular fibrillation or pulseless ventricular tachycardia.

CONCLUSIONS

Weakened ECG signal quality can lead to false-positive shock decisions and may provoke hazardous events. Previous studies suggest that all named AEDs are safe to use in public places; however, differences in safety emerge in the presence of strong electromagnetic fields. Those AED models that showed susceptibility to EMI of certain characteristics should not be used in areas with these EMI present. Because some AED models proved to be safe even under these very special circumstances, it may be useful to consider specific safety requirements dependent on the planned location of AED implementation or technical upgrades in vulnerable AEDs. If devices have already been implemented in locations with strong EMI and susceptible AEDs cannot be replaced, the working personnel should be informed about the potential risks, and evacuation of unconscious patients from the site of EMI should be planned in advance according to local requirements to establish standard emergency operating procedures. Emergency response personnel should be informed about the possibility of EMI during ECG registration and analysis by AEDs to evacuate patients out of anomalous areas before AEDs are attached and shock recommendations are followed. It may be advisable to avoid using fully automated external devices in certain settings with certain EMI present.

References

1. ÖSTAT, Statistisches Jahrbuch 2001, 25. Jahrgang. 2001, Statistik Austria.
2. Gaul GB, Gruska M, Titscher G, et al. Prediction of survival after out-of-hospital cardiac arrest: results of a community-based study in Vienna. Resuscitation. 1996; 32:169–76.
3. State-specific mortality from sudden cardiac death—United States, 1999. MMWR Morb Mortal Wkly Rep. 2002; 51(6):123–6.
4. Larsen MP, Eisenberg MS, Cummins RO, Hallstrom AP. Predicting survival from out-of-hospital cardiac arrest: a graphic model. Ann Emerg Med. 1993; 22:1652–8.

5. Stiell IG, Wells GA, Field B, et al. Advanced cardiac life support in out-of-hospital cardiac arrest. N Engl J Med. 2004; 351:647–56.
6. Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Public use of automated external defibrillators. N Engl J Med. 2002; 347:1242–7.
7. Bur A, Kittler H, Sterz F, et al. Effects of bystander first aid, defibrillation and advanced life support on neurologic outcome and hospital costs in patients after ventricular fibrillation cardiac arrest. Intensive Care Med. 2001; 27:1474–80.
8. Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Part 4: the automated external defibrillator: key link in the chain of survival. The American Heart Association in Collaboration with the International Liaison Committee on Resuscitation. Circulation. 2000; 102(8 Suppl): I60–76.
9. DF 39 - 1993 Standard for Automatic External Defibrillators and Remote-Control Defibrillators. Arlington, VA: Association for the Advancement of Medical Instrumentation, 1993.
10. Ventricular Arrhythmia Detection Algorithms: Recommended Practice for Testing and Reporting Performance Results of Ventricular Arrhythmia Detection Algorithms. Association for the Advancement of Medical Instrumentation. ECAR, 1997.
11. Automatic external defibrillators for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety. A statement for health professionals from the American Heart Association Task Force on Automatic External Defibrillation, Subcommittee on AED and Efficacy. Biomed Instrum Technol. 1997; 31:238–44.
12. Schlimp CJ, Breiteneder M, Lederer W. Safety aspects for public access defibrillation using automated external defibrillators near high-voltage power lines. Acta Anaesthesiol Scand. 2004; 48:595–600.
13. Kanz KG, Kay MV, Biberthaler P, et al. Susceptibility of automated external defibrillators to train overhead lines and metro third rails. Resuscitation. 2004; 62:189–98.
14. Stolzenberg BT, Kupas DF, Wieczorek BJ, Sole DP. Automated external defibrillators appropriately recognize ventricular fibrillation in electromagnetic fields. Prehosp Emerg Care. 2002; 6:65–6.
15. Christov IG II. Public access defibrillation: suppression of 16.7 Hz interference generated by the power supply of the railway systems. Biomed Eng Online. 2005; 4(1):16.

Automated External Defibrillators Appropriately Recognize Ventricular Fibrillation in Electromagnetic Fields

Brett T. Stolzenberg, MD, Douglas F. Kupas, MD, Brian J. Wieczorek, MD, David P. Sole, DO

Abstract

Objectives. Automated external defibrillators (AEDs) are increasingly available in industrial settings, but many industries have high electromagnetic fields (EMFs), which can interfere with the function of electronic devices. This study evaluated the performance of several AEDs when exposed to high EMFs. **Methods.** Three commercially available AEDs were evaluated in the setting of a public utility coal-fired electrical generation plant. Each AED was placed in three areas of high EMF ranging from 310 to 1,600 milligauss. A signal generator, used to simulate various cardiac rhythms, was connected to the AEDs. Rhythms simulated were ventricular fibrillation, asystole, and normal sinus rhythm. Each of the AED's interpretations of various rhythms were evaluated in the different EMF settings. **Results.** Rhythms of ventricular fibrillation, asystole, and normal sinus rhythm were correctly recognized by each AED in each of the three areas of high EMF. Each AED appropriately recommended defibrillation when presented with ventricular fibrillation. No misinterpretations or inappropriate defibrillations were observed. **Conclusion.** Electromagnetic fields generated by an electrical power plant did not interfere with three commercial AEDs' abilities to correctly interpret simulated rhythms and recommend appropriate defibrillation. **Key words:** ventricular fibrillation; electromagnetic field; electric countershock; defibrillation; resuscitation; automated external defibrillators.

PREHOSPITAL EMERGENCY CARE 2002;6:65–66

Sudden cardiac death is a leading cause of mortality each year in the United States. It is estimated that 450,000 deaths occur annually and that 80–90% of these events are related to ventricular fibrillation.[1] Often the event is precipitated by myocardial ischemia that subsequently leads to an arrhythmia, most commonly ventricular fibrillation. Early cardiopulmonary resuscitation (CPR) and defibrillation are the most effective treatments for maximal survival. The American Heart Association recognizes the importance of these therapies and believes 100,000 lives could be saved annually.[2] For this reason first responders in many settings, including industrial arenas, now use automated external defibrillators (AEDs).

With AEDs continuing to be placed in more areas, many in extreme environmental conditions, the limits of this technology need to be examined. Numerous studies indicate that implantable cardiac defibrillators may be affected by electromagnetic interference[3,4]; however, the literature is sparse when evaluating external defibrillators in these situations. Electromagnetic flux is a measure of the magnetism that is generated around an object when current is traveling through a conductor. The larger the electromagnetic field, the greater the influence, potential noise, disruption, or distortion of a signal that a monitoring device may measure. For that reason we set out to determine the impact that electromagnetic flux has on AEDs. Our null hypothesis stated that AEDs' function will not be adversely affected by electromagnetic flux.

Methods

Three commercial AEDs were evaluated. The models were SurVivaLink First Save AED (model #9110, SurVivaLink Corporation, Minneapolis, MN), Physio-Control Life Pak 300 (part #804900-03, Physio-Control, Redmond, WA), and the Zoll 1600 Defibrillator (serial #0776, Zoll Medical Corporation, Burlington, MA).

The three AEDs were evaluated in three different locations in a Pennsylvania Power and Light Utilities, Inc., a coal-burning/steam-generating electrical power plant located in Washingtonville, Pennsylvania. The locations selected were areas of high electromagnetic flux that were within 10 feet of the electromagnetic flux-generating power source. Magnetic flux was determined at three locations using Emdex II Gauss Meter by Entertech (model #1170, Entertech, Campbell, CA). Three readings of magnetic flux at each location were obtained just prior to AED testing. Readings at the main transformer were 1,427–1,558 milligauss, mid-range breaker 550–650 milligauss, and at the generator 310–425 milligauss. Electric fields were not tested.

Rhythms were generated by a patient simulator manufactured by Physio-Control (part #803499-00). The generator simulated rhythms of ventricular fibrillation and normal sinus rhythm. Turning the generator off simulated asystole. Training electrodes (Physio-Control AED-T #3006007-00) were connected to the rhythm simulator.

The three AEDs were tested in each of the three loca-

Received March 29, 2001, from the Geisinger Medical Center (BTS, DFK, BJW, DPS), Danville, Pennsylvania. Revision received August 30, 2001; accepted for publication September 1, 2001.

Presented as a poster at the American College of Emergency Physicians Research Forum, Las Vegas, Nevada, October 1999.

Address correspondence and reprint requests to: Douglas F. Kupas, MD, Geisinger Medical Center, 100 North Academy Avenue, Danville, PA 17822. e-mail: <dkupas@geisinger.edu>.

tions. Each AED's original pads were connected to the rhythm simulator's training electrodes. The distal ends of the training electrodes from the rhythm simulator provided a platform so that all three AEDs could be connected at the same time. This arrangement allowed all three AEDs to simultaneously receive the same rhythm. This also permitted independent evaluation of the shockable and nonshockable rhythms by an AED other than the AED that was analyzing and delivering a defibrillating discharge.

In each of the three locations, each AED was exposed to each rhythm two times. Rhythms simulated were ventricular fibrillation, normal sinus rhythm, and asystole. Recommendations of defibrillation or no defibrillation were recorded. Descriptive statistics were used to interpret the data.

RESULTS

All three of the AEDs functioned appropriately in the three different electromagnetic field (EMF) settings. Each AED appropriately recognized each rhythm in each setting and either recommended defibrillation when presented with ventricular fibrillation or did not recommend defibrillation when presented with normal sinus rhythm or asystole. No misinterpretations or inappropriate defibrillations were observed.

DISCUSSION

A previous study evaluated the sensitivity and specificity of various AEDs for detecting ventricular fibrillation. This study reported numbers of 92% and 100%, respectively.[5] However, extreme environmental conditions, such as heat, cold, moisture, and electrical interference, theoretically may alter their ability to correctly interpret cardiac rhythms. This study shows appropriate function of AEDs in extraordinarily high EMF environments. Despite this being a bench study, we have no reason to believe that these data cannot be extrapolated to the clinical setting. This study supports the use of AEDs in industrial settings, and areas of high EMF do not appear to interfere with the function of these devices.

CONCLUSION

Electromagnetic fields generated by an electrical power plant did not interfere with the ability of three commercial AEDs to correctly interpret simulated rhythms and recommend appropriate defibrillation.

The authors thank the management of Pennsylvania Power and Light Utilities, Washingtonville Station, for their assistance with this project.

References

1. Gillum RF. Sudden coronary death in the United States. Circulation. 1989;79:756-65.
2. Ginsburg W. Prepare to be shocked: the evolving standard of care in treating sudden cardiac arrest. Am J Emerg Med. 1998; 16:315-9.
3. Bassen HI, Moore HJ, Ruggera PS. Cellular phone interference testing of implantable cardiac defibrillators in vitro. Pacing Clin Electrophysiol. 1998;21:1709-16.
4. Schmitt C, Brachmann J, Waldecker B, et al. Implantable cardioverter defibrillator: possible hazards of electromagnetic interference. Pacing Clin Electrophysiol. 1991;14:982-5.
5. Stults KR, Brown DD, Kerber RE. Efficacy of an automated external defibrillator in the management of out-of-hospital cardiac arrest: validation of the diagnostic algorithm and initial clinical experience in a rural environment. Circulation. 1986;73:701-9.

The Safe Use of Automated External Defibrillators in a Wet Environment

Tom Lyster, MS, Dawn Jorgenson, PhD, Carl Morgan, MS

Abstract

There has been concern regarding potential shock hazards for rescuers or bystanders when a defibrillator is used in a wet environment and the recommended safety procedure, moving the patient to a dry area, is not followed. **Objective.** To measure the electrical potentials associated with the use of an automated external defibrillator (AED) in a realistically modeled wet environment. **Methods.** A raw processed turkey was used as a patient surrogate. The turkey was placed on a cement floor while pool water was applied to the surrounding area. To simulate a rescuer or bystander in the vicinity of a patient, a custom sense probe was constructed. Defibrillation shocks were delivered to the turkey and the probe was used to measure the voltage an operator/bystander would receive at different points surrounding the surrogate. The test was repeated with salt water. **Results.** The maximum voltage occurred approximately 15 cm from the simulated patient and measured 14 V peak (current 14 mA peak) in the case of pool water, and 30 V peak (current 30 mA peak) in the case of salt water. **Conclusions.** Thirty volts may result in some minor sensation by the operator or bystander, but is considered unlikely to be hazardous under these circumstances. The maximum currents were lower than allowed by safety standards. Although defibrillation in a wet environment is not recommended practice, our simulation of a patient and a rescuer/bystander in a wet environment did not show significant risk should circumstances demand it. **Key words:** automated external defibrillators; cardiac arrest; resuscitation; emergency medical services; adverse effects.

PREHOSPITAL EMERGENCY CARE 2003;7:307–311

The use of automated external defibrillators (AEDs) to treat sudden cardiac arrest (SCA) in the out-of-hospital environment has continued to increase.[1] When defibrillation is needed in nonideal field conditions, rescuers may be concerned about the possibility of electrical shock hazard.[2] Specifically, there has been concern of shock hazards for the operator or bystanders when defibrillators are used in wet environments and the recommended safety procedure, moving the patient to a dry area, is not followed.[3] One study reported that 59% of emergency medical services (EMS) personnel reported the need to defibrillate in situations with perceived moisture hazards.[3] The purpose of this study was to measure the electrical potentials associated with the use of an AED in a realistically modeled wet environment.

When a patient is defibrillated externally, voltage at the defibrillation pads induces current in the patient's chest. These currents, in turn, project a somewhat complex potential gradient (voltage pattern) across the surface of the patient's skin. If the patient is resting on an insulating surface, all defibrillation currents are constrained to flow within the patient. However, if the patient is resting on a somewhat conductive material, such as a wet surface, the potential gradients present on the chest also may induce stray currents in the surrounding surface. The passage of stray currents may, in turn, induce potential gradients surrounding the patient. It is the presence of these potential gradients near the patient that has prompted concern of electrical shock hazards to caregivers or bystanders during delivery of defibrillation shocks. For example, if a bystander is in close conductive contact with the surface in two spots (e.g., standing barefoot on two feet), the concern has been that potential gradients may translate into a voltage sufficient to give an electrical shock.

Historically, patients have been defibrillated without harm on both insulating and conductive surfaces. For example, dry flooring (such as wood) does not conduct stray currents or induce potential gradients around the patient. At the other extreme, patients on metal surfaces (such as the floor of a helicopter[4]) also may be defibrillated safely. In this case, although currents may flow in the metal, the high conductivity of the material supports no appreciable potential gradients across its surface.

However, in the case of a patient being treated on a wet surface, the intuitive case for safety is less clear cut. For example, at poolside, a wet surface may be sufficiently conductive to support stray currents during defibrillation, but not so conductive as to short out stray potentials. In this study, we investigated the poolside (or dockside) case for electrical defibrillation hazard. Measurements were taken during simulations of 1) a rescuer or bystander standing in close proximity while a defibrillation shock was delivered and 2) a rescuer or bystander touching the defibrillator (e.g., pressing the shock button) during shock delivery. Note that this study did not measure effects of direct rescuer or bystander contact with a patient during

Received November 27, 2002, from Philips Medical Systems, Seattle, Washington (TL, DJ, CM). Revision received March 11, 2003; accepted for publication March 11, 2003.

Supported by Philips Medical Systems, Seattle, WA.

Address correspondence and reprint requests to: Tom Lyster, MS, Philips Medical Systems, 2301 5th Avenue, Suite 200, Seattle, WA 98121. e-mail: <tom.lyster@philips.com>.

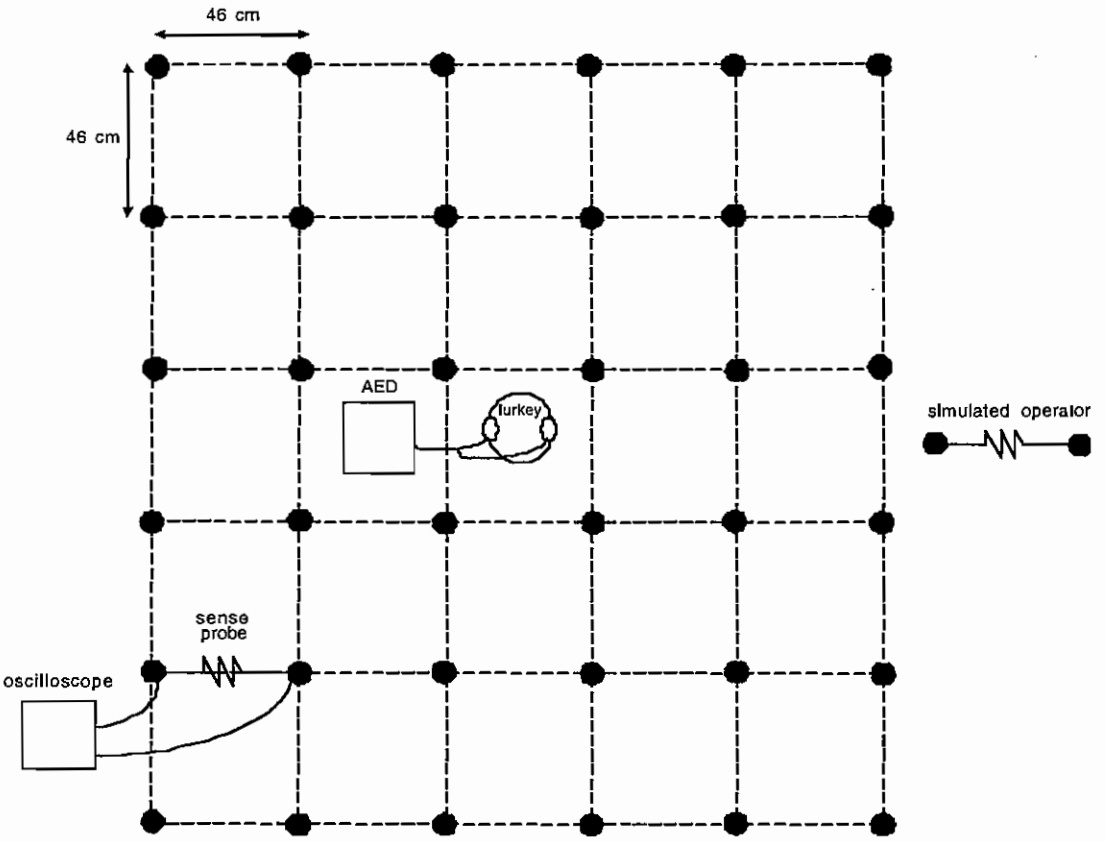


FIGURE 1. Test setup for measuring the voltage a simulated operator/bystander would receive at different points surrounding the surrogate patient. AED = automated external defibrillator.

shock delivery, which is warned against in defibrillator operating instructions.

METHODS

For this study, we established simulated rescue environments on a wet concrete surface and measured potentials near the test subject that were created during defibrillation. It was necessary to use an electrically realistic patient surrogate for defibrillation testing. In the past, animals have been used for this purpose. In this case, we elected to use a large (12.8 kg), raw, processed turkey with defibrillation impedance that compares favorably with human defibrillation impedance. Additionally, the skin contact area of the turkey with the concrete surface compared favorably with the electrically active area of a human thorax during defibrillation.

To simulate an operator or bystander in the vicinity of a patient, we constructed a custom sense probe with a distance of 46 cm (18 in) between 2 metal contact plates. Each plate was 8 cm in diameter. The two contact plates represented knees, hands, or feet during contact with a wet surface and permitted measurement of the voltage an operator/bystander would receive during defibrillation. A 1,000-ohm resistor was placed between the two conductive plates to simulate the operator/bystander impedance. This value is consistent with industry standards.[5]

The turkey was placed on a cement area in the center of a grid (Fig. 1). The grid provided measurement points marked with masking tape at the corners of 46-cm squares. Adhesive defibrillation pads (model DP2; Philips Medical Systems, Seattle, WA) were placed on the skin surface of the turkey on each side of the breast approximating placement on a human thorax and connected to an AED (ForeRunner model EM; Philips Medical Systems). The AED was positioned in the center of a grid square next to the turkey. Chlorinated pool water was applied amply to the surrounding area to fully moisten the cement and create randomly scattered standing puddles throughout the grid area. The simulated operator (sense probe) was sequentially placed across each set of grid points in both horizontal and vertical directions surrounding the turkey.

For each position, one manual shock was delivered to the turkey through the defibrillation electrodes. The differential voltage generated across the sense probe was recorded on an oscilloscope (Tektronix model 2212,

The Safe Use of Automated External Defibrillators in a Wet Environment

Tom Lyster, MS, Dawn Jorgenson, PhD, Carl Morgan, MS

Abstract

There has been concern regarding potential shock hazards for rescuers or bystanders when a defibrillator is used in a wet environment and the recommended safety procedure, moving the patient to a dry area, is not followed. **Objective.** To measure the electrical potentials associated with the use of an automated external defibrillator (AED) in a realistically modeled wet environment. **Methods.** A raw processed turkey was used as a patient surrogate. The turkey was placed on a cement floor while pool water was applied to the surrounding area. To simulate a rescuer or bystander in the vicinity of a patient, a custom sense probe was constructed. Defibrillation shocks were delivered to the turkey and the probe was used to measure the voltage an operator/bystander would receive at different points surrounding the surrogate. The test was repeated with salt water. **Results.** The maximum voltage occurred approximately 15 cm from the simulated patient and measured 14 V peak (current 14 mA peak) in the case of pool water, and 30 V peak (current 30 mA peak) in the case of salt water. **Conclusions.** Thirty volts may result in some minor sensation by the operator or bystander, but is considered unlikely to be hazardous under these circumstances. The maximum currents were lower than allowed by safety standards. Although defibrillation in a wet environment is not recommended practice, our simulation of a patient and a rescuer/bystander in a wet environment did not show significant risk should circumstances demand it. **Key words:** automated external defibrillators; cardiac arrest; resuscitation; emergency medical services; adverse effects.

PREHOSPITAL EMERGENCY CARE 2003;7:307–311

The use of automated external defibrillators (AEDs) to treat sudden cardiac arrest (SCA) in the out-of-hospital environment has continued to increase.[1] When defibrillation is needed in nonideal field conditions, rescuers may be concerned about the possibility of electrical shock hazard.[2] Specifically, there has been concern of shock hazards for the operator or bystanders when defibrillators are used in wet environments and the recommended safety procedure, moving the patient to a dry area, is not followed.[3] One study reported that 59% of emergency medical services (EMS) personnel reported the need to defibrillate in situations with perceived moisture hazards.[3] The purpose of this study was to measure the electrical potentials associated with the use of an AED in a realistically modeled wet environment.

When a patient is defibrillated externally, voltage at the defibrillation pads induces current in the patient's chest. These currents, in turn, project a somewhat complex potential gradient (voltage pattern) across the surface of the patient's skin. If the patient is resting on an insulating surface, all defibrillation currents are constrained to flow within the patient. However, if the patient is resting on a somewhat conductive material, such as a wet surface, the potential gradients present on the chest also may induce stray currents in the surrounding surface. The passage of stray currents may, in turn, induce potential gradients surrounding the patient. It is the presence of these potential gradients near the patient that has prompted concern of electrical shock hazards to caregivers or bystanders during delivery of defibrillation shocks. For example, if a bystander is in close conductive contact with the surface in two spots (e.g., standing barefoot on two feet), the concern has been that potential gradients may translate into a voltage sufficient to give an electrical shock.

Historically, patients have been defibrillated without harm on both insulating and conductive surfaces. For example, dry flooring (such as wood) does not conduct stray currents or induce potential gradients around the patient. At the other extreme, patients on metal surfaces (such as the floor of a helicopter[4]) also may be defibrillated safely. In this case, although currents may flow in the metal, the high conductivity of the material supports no appreciable potential gradients across its surface.

However, in the case of a patient being treated on a wet surface, the intuitive case for safety is less clear cut. For example, at poolside, a wet surface may be sufficiently conductive to support stray currents during defibrillation, but not so conductive as to short out stray potentials. In this study, we investigated the poolside (or dockside) case for electrical defibrillation hazard. Measurements were taken during simulations of 1) a rescuer or bystander standing in close proximity while a defibrillation shock was delivered and 2) a rescuer or bystander touching the defibrillator (e.g., pressing the shock button) during shock delivery. Note that this study did not measure effects of direct rescuer or bystander contact with a patient during

Received November 27, 2002, from Philips Medical Systems, Seattle, Washington (TL, DJ, CM). Revision received March 11, 2003; accepted for publication March 11, 2003.

Supported by Philips Medical Systems, Seattle, WA.

Address correspondence and reprint requests to: Tom Lyster, MS, Philips Medical Systems, 2301 5th Avenue, Suite 200, Seattle, WA 98121. e-mail: <tom.lyster@philips.com>.

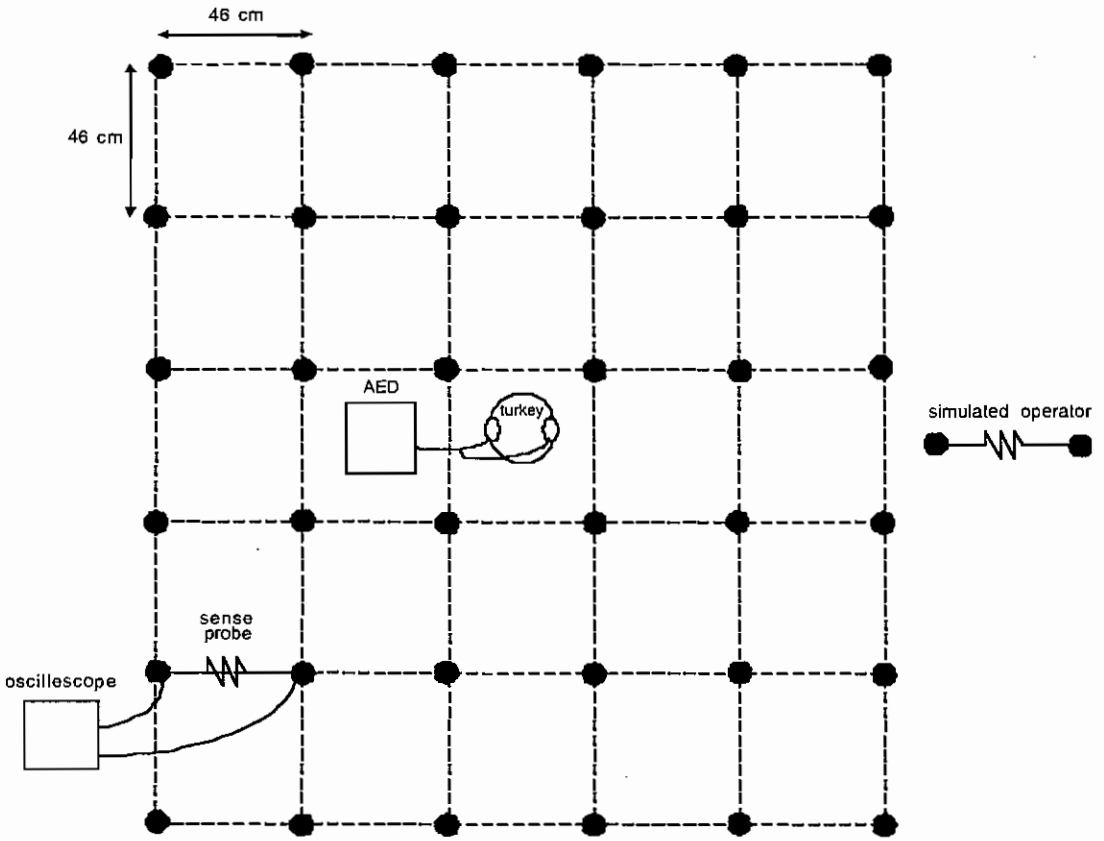


FIGURE 1. Test setup for measuring the voltage a simulated operator/bystander would receive at different points surrounding the surrogate patient. AED = automated external defibrillator.

shock delivery, which is warned against in defibrillator operating instructions.

METHODS

For this study, we established simulated rescue environments on a wet concrete surface and measured potentials near the test subject that were created during defibrillation. It was necessary to use an electrically realistic patient surrogate for defibrillation testing. In the past, animals have been used for this purpose. In this case, we elected to use a large (12.8 kg), raw, processed turkey with defibrillation impedance that compares favorably with human defibrillation impedance. Additionally, the skin contact area of the turkey with the concrete surface compared favorably with the electrically active area of a human thorax during defibrillation.

To simulate an operator or bystander in the vicinity of a patient, we constructed a custom sense probe with a distance of 46 cm (18 in) between 2 metal contact plates. Each plate was 8 cm in diameter. The two contact plates represented knees, hands, or feet during contact with a wet surface and permitted measurement of the voltage an operator/bystander would receive during defibrillation. A 1,000-ohm resistor was placed between the two conductive plates to simulate the operator/bystander impedance. This value is consistent with industry standards.[5]

The turkey was placed on a cement area in the center of a grid (Fig. 1). The grid provided measurement points marked with masking tape at the corners of 46-cm squares. Adhesive defibrillation pads (model DP2; Philips Medical Systems, Seattle, WA) were placed on the skin surface of the turkey on each side of the breast approximating placement on a human thorax and connected to an AED (ForeRunner model EM; Philips Medical Systems). The AED was positioned in the center of a grid square next to the turkey. Chlorinated pool water was applied amply to the surrounding area to fully moisten the cement and create randomly scattered standing puddles throughout the grid area. The simulated operator (sense probe) was sequentially placed across each set of grid points in both horizontal and vertical directions surrounding the turkey.

For each position, one manual shock was delivered to the turkey through the defibrillation electrodes. The differential voltage generated across the sense probe was recorded on an oscilloscope (Tektronix model 2212,

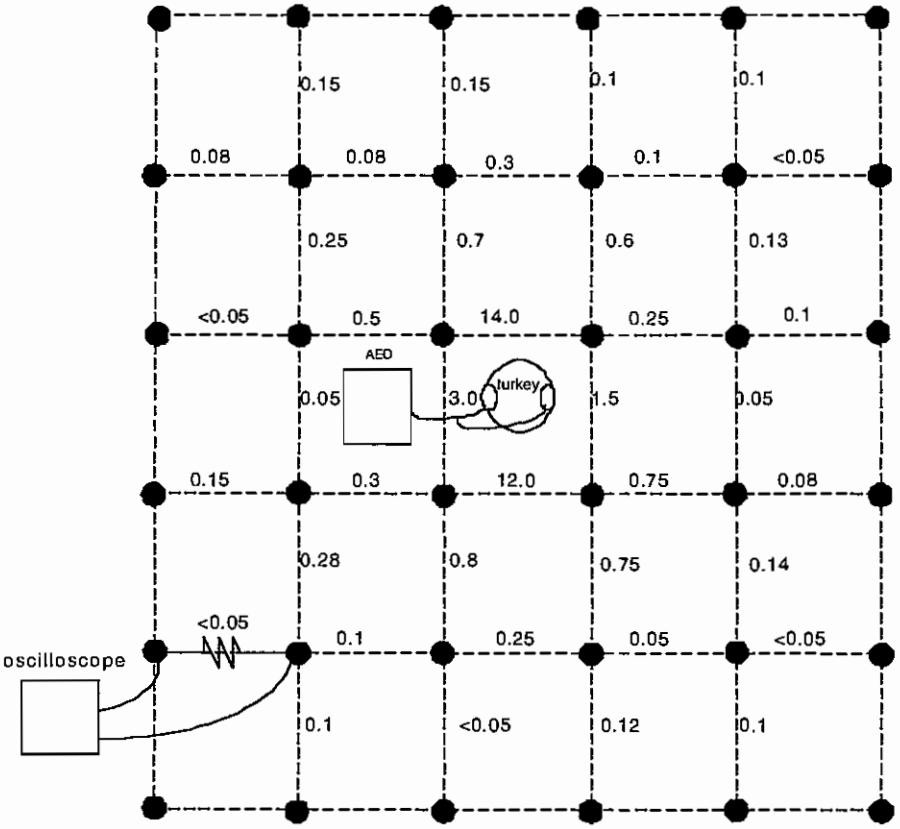


FIGURE 2. Pool water test. This grid shows the leading edge peak voltage (V) recorded during a defibrillation shock at each location on the grid. The recorded voltages correspond to a sense probe position lying along the line adjacent to each recorded value. AED = automated external defibrillator.

Beaverton, OR) using a high-voltage differential amplifier (Tektronix model P5205). The leading edge peak voltage was recorded for each shock. Three additional measurements were made by placing the conductive plates such that one plate was on the AED and the other plate was on the surrounding cement in three orthogonal positions. This measurement simulated someone touching the AED (e.g., pressing the shock button) and the cement. If a section of the cement started to dry out, additional pool water was re-applied. After all voltage measurements were recorded, the cement was allowed to dry and salt (sea) water was then applied in the same manner and the test was repeated.

Results

Pool Water Test

The grid in Figure 2 shows the leading edge peak voltage recorded during a defibrillation shock at each location on the grid during the pool water test. The recorded voltages correspond to a sense probe position lying along the line adjacent to each recorded value. The maximum voltage was 14 V. The peak voltages that resulted from placing one conductive plate on the AED and the other on the cement in three orthogonal positions surrounding the AED were less than 0.05 V peak per measurement. Approximately 45 shocks were delivered.

Salt Water Test

The grid in Figure 3 shows the leading edge peak voltage (in Volts) recorded during a defibrillation shock at each location on the grid during the salt water test. The recorded voltages correspond to a sense probe position lying along the line adjacent to each recorded value. The maximum voltage was 30 V. The peak voltages that resulted from placing one conductive plate on the AED and the other on the cement in three orthogonal positions surrounding the AED were 0.4 V peak or less per measurement. Approximately 45 shocks were delivered.

The initial defibrillation impedance for the turkey was 57 ohm. This value slowly decreased during the testing to 48 ohm after approximately 90 shocks. The

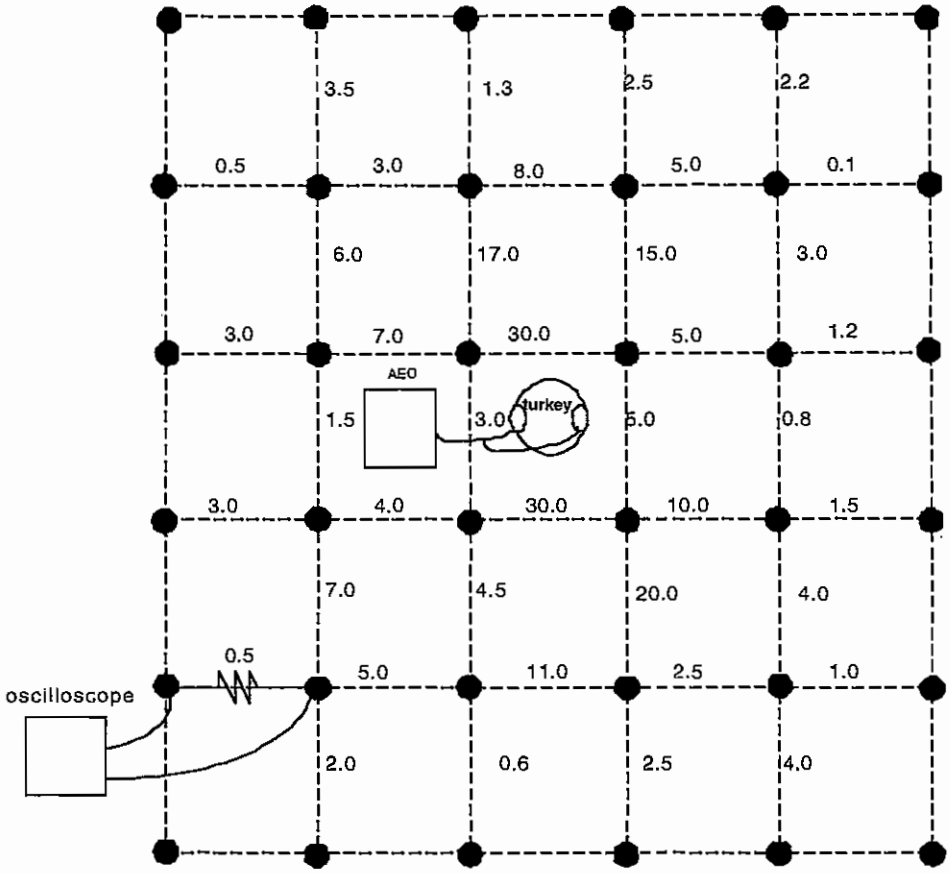


FIGURE 3. Salt water test. This grid shows the leading edge peak voltage (in Volts) recorded during a defibrillation shock at each location on the grid. The recorded voltages correspond to a sense probe position lying along the line adjacent to each recorded value. AED = automated external defibrillator.

defibrillation impedance for the turkey was within the range reported for humans.[6] The length of the defibrillation pulse, approximately 10 ms, was also within the range of that typically applied to humans.[6] The current an operator or bystander would receive can be calculated by dividing by the operator impedance (1,000 ohm). This results in a maximum current of 14 mA in the case of pool water and 30 mA in the case of salt water.

DISCUSSION

The maximum voltage recorded occurred at a distance of approximately 15 cm from the simulated patient and was 14 V peak in the case of pool water, and 30 V peak in the case of salt water. Thirty volts may result in some minor sensation (e.g., tingling) by the operator or bystander, but is considered unlikely to be hazardous under these circumstances. Similar voltages in other environments have not proved to be hazardous. For example, aircraft and helicopter batteries are 28 V, and routinely are handled in wet or marine environments without incident.

The physiologic effects of very-short-duration (10 ms), small-amplitude current are not well quantified. We know that the threshold of perception (the minimum current an individual can detect) is approximately 2 to 10 mA for continuous direct-current (DC) current.[7] In addition, the threshold current for inducing ventricular fibrillation (VF) rapidly increases for alternating-current (AC) shocks less than 1 sec,[7] suggesting that the possibility of inducing VF with a 10-ms pulse is very small. The recommended limit in defibrillator safety tests[5] for transient leakage current during discharge (i.e., current flowing through the body of a rescuer who simultaneously touches either the electrode or the patient and ground) is 50 mA DC, for a duration of less than 10 ms. The maximum observed currents of 14 mA and 30 mA for pool and salt water, respectively, are within these suggested limits and thus unlikely to cause more than minor sensation.

The measured voltages dropped off quickly as the distance between the sense probe and the patient increased. At a distance of approximately 60 cm (2 ft) from the patient, the maximum voltage was 0.28 V

peak (current 0.28 mA peak) in the case of pool water, and 11 V peak (current 11 mA peak) in the case of salt water. Eleven volts is unlikely to cause any operator or bystander sensation or risk in this environment. At a distance of approximately 90 cm (3 ft) from the patient, the maximum voltage was 0.15 V peak (current 0.15 mA peak) in the case of pool water, and 4 V peak (current 4 mA peak) in the case of salt water. At 90 cm and beyond, there is virtually no expected operator or bystander sensation or risk in this environment. The maximum voltage recorded when the sense probe was touching the AED, simulating touching the shock button, was 0.4 V peak (current 0.4 mA peak) or less, resulting in no sensation or risk.

The observations of this study may seem counterintuitive in the face of a lifetime of dire warnings about the use of electricity near water. However, the relatively benign observations of this study are the result of defibrillator design practices. Defibrillators are designed expressly to deliver currents electrically isolated from the earth. As a result, currents entering the chest through one electrode pad exit the chest and return to the defibrillator through the other electrode pad and do not seek to escape to the earth.

In contrast, most traditional electrical hazard warnings are associated with equipment connected to AC power mains, which have an earth connection. Unlike defibrillators, such equipment may not provide electrical isolation. As a result, leakage currents from such equipment may seek to flow to the earth, even if the pathway is through an unwary operator. Some equipment connected to power mains may thus be hazardous when used in wet environments. A well-known example is a hair dryer improperly used in the shower. It is thus not paradoxical that a patient accidentally electrocuted in a shower by a hair dryer may be rescued safely by a defibrillator in the same environment.

Note that this study did not measure effects of direct rescuer or bystander contact with a patient during shock delivery, which is warned against in defibrillator operating instructions. Direct contact may indeed result in a significant shock to the rescuer or bystander.

LIMITATIONS

This study assumes that the operator/bystander did not make direct contact with the patient during defibrillation, which is warned against in the product labeling. The characteristics of the patient surrogate and the rescuer/bystander were designed to be reasonable approximations of actual human subjects. Our conclusions are limited to the circumstances of our simulation. Actual patient and rescuer/bystander characteristics and environmental situations will vary, and these variations could cause different results. The results of this study should never be extrapolated to other electrical equipment. In addition, our study used a relatively low-energy biphasic defibrillation waveform, as delivered by the ForeRunner AED. Results could differ if a higher energy defibrillator is used.

CONCLUSION

Although defibrillation in a wet environment is not recommended practice, our limited simulation of a patient and an operator/bystander in a wet environment did not show significant risk should circumstances demand it. The maximum voltage recorded occurred at a distance of approximately 15 cm from the simulated patient and was 14 V peak in the case of pool water, and 30 V peak in the case of salt water. Thirty volts may result in some minor sensation (e.g., tingling) by the operator or bystander, but is considered unlikely to be hazardous under these circumstances.

References

1. Marenco JP, Wang PJ, Link MS, Homound MK, Estes NAM. Improving survival from sudden cardiac arrest, the role of the automated external defibrillator. JAMA. 2001;285:1193-200.
2. Gibbs W, Eisenberg M, Damon SK. Dangers of defibrillation: injuries to emergency personnel during patient resuscitation. Am J Emerg Med. 1990;8:101-4.
3. Miller LV, Brennan R. Cardiac defibrillator use in potentially hazardous situations. Biomed Sci Instrum. 1982;18:87-90.
4. Dedrick DK, Darga A, Landis D, Burney RE. Defibrillation safety in emergency helicopter transport. Ann Emerg Med. 1989; 18:69-71.
5. Line-powered defibrillators. Health Dev. 1983;12:298.
6. Poole JE, White RD, Kanz K, et al. Low-energy impedance-compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out-of-hospital cardiac arrest. J Cardiovasc Electrophysiol. 1997; 8:1373-85.
7. Olson WH. Electrical Safety. In: Webster JG (ed). Medical Instrumentation Application and Design. Boston: Houghton Mifflin Company, 1978.

ELSEVIER

Resuscitation 59 (2003) 225–233

RESUSCITATION

www.elsevier.com/locate/resuscitation

AED use in businesses, public facilities and homes by minimally trained first responders

Dawn B. Jorgenson *, Teresa Skarr, James K. Russell, David E. Snyder, Karen Uhrbrock

Philips Medical Systems, 2301 5th Avenue, Suite 200, Seattle, WA 98121, USA

Received 6 December 2002; received in revised form 16 May 2003; accepted 16 May 2003

Abstract

Background: Automated external defibrillators (AEDs) have become increasingly available outside of the Emergency Medical Systems (EMS) community to treat sudden cardiac arrest (SCA). We sought to study the use of AEDs in the home, businesses and other public settings by minimally trained first responders. The frequency of AED use, type of training offered to first responders, and outcomes of AED use were investigated. In addition, minimally trained responders were asked if they had encountered any safety problems associated with the AED. *Methods:* We conducted a telephone survey of businesses and public facilities (2683) and homes (145) owning at least one AED for at least 12 months. Use was defined as an AED taken to a medical emergency thought to be a SCA, regardless of whether the AED was applied to the patient or identified a shockable rhythm. *Results:* Of owners that participated in the survey, 13% (209/1581) of businesses and 5% (4/73) of homes had responded with the AED to a suspected cardiac arrest. Ninety-five percent of the businesses/public facilities offered training that specifically covered AED use. The rate of use for the AEDs was highest in residential buildings, public places, malls and recreational facilities with an overall usage rate of 11.6% per year. In-depth interviews were conducted with lay responders who had used the AED in a suspected cardiac arrest. In the four cases where the AED was used solely by a lay responder, all four patients survived to hospital admission and two were known to be discharged from the hospital. There were no reports of injury or harm. *Conclusions:* This survey demonstrates that AEDs purchased by businesses and homes were frequently taken to suspected cardiac arrests. Lay responders were able to successfully use the AEDs in emergency situations. Further, there were no reports of harm or injury to the operators, bystanders or patients from lay responder use of the AEDs.

Keywords: Automated external defibrillator; Cardiac arrest; Resuscitation; Emergency medical services; Safety; Training

Resumo

Contexto: Os Desfibrilhadores Automáticos Externos (AEDs) têm sido disponibilizados de modo crescente fora da comunidade de Sistemas Médicos de Emergência (EMS) para tratamento da paragem cardíaca súbita (SCA). Propusemo-nos estudar a utilização de AEDs no domicílio, nos locais de negócios e noutros locais públicos, por primeiros reanimadores com treino mínimo. Foram analisadas a frequência de utilização do AED, o tipo de treino dos primeiros reanimadores e os resultados da AED. Além disso, perguntou-se aos reanimadores se tinham encontrado algum problema de segurança associado ao AED. *Métodos*: Fizemos um inquérito telefónico a locais públicos e de negócios (2683) e a domicílios (145) em que houve pelo menos um AED durante 12 meses. A utilização foi definida como o transporte de um AED para uma emergência médica interpretada como SCA, independentemente de o AED ser utilizado no doente ou da identificação de um ritmo desfibrilhável. *Resultados*: Dos detentores de AED que participaram no inquérito, 13% (209/1581) de locais de negócios e 5% (4/73) de domicílios responderam com o AED a uma suspeita de paragem cardíaca. Noventa e cinco por cento das instituições públicas / de negócios ofereceram treino que cobria especificamente o uso de AED. A taxa de uso de AEDs foi maior nos prédios residenciais, locais públicos, comerciais e recreativos, com uma taxa de uso global de 11,6% por ano. Foram conduzidas entrevistas aprofundadas a reanimadores leigos que utilizaram o AED numa

* Corresponding author. Tel.: +1-206-664-5789; fax: +1-206-664-2070.
E-mail address: dawn.jorgenson@philips.com (D.B. Jorgenson).

0300-9572/03/$ - see front matter © 2003 Elsevier Ireland Ltd. All rights reserved.
doi:10.1016/S0300-9572(03)00214-4

suspeita de paragem cardíaca. Nos 4 casos em que o AED foi utilizado apenas por um reanimador leigo, todos os doentes sobreviveram até à admissão hospitalar e dois deles tiveram alta do hospital. Não se registaram danos. *Conclusões*: Este inquérito demonstrou que os AEDs adquiridos para locais de negócios e domicílios foram frequentemente transportados para situações suspeitas de paragem cardíaca. Os reanimadores leigos foram capazes de usar com sucesso os AEDs em situações de emergência. Além disso, não houve registo de danos ou lesões provocados pelo uso de AEDs por reanimadores leigos, nos operadores, testemunhas ou doentes.

Palavras chave: Desfibrilhação automática externa; Paragem cardíaca; Ressuscitação; Serviços Médicos de Emergência; Segurança; Treino

Resumen

Antecedentes: Los desfibriladores automáticos externos (AEDs) se han hecho progresivamente disponibles fuera de la comunidad de los sistemas de emergencias médicas(EMS) para tratar paro cardiorrespiratorio súbito (SCA). Buscamos estudiar el uso de AEDs en el hogar, en oficinas de negocios y otros ambientes comunitarios por primeros respondedores con entrenamiento mínimo. Se investigaron la frecuencia de uso de los AED, tipo de entrenamiento ofrecido a los primeros respondedores y resultado del uso de los AED. Además se les preguntó a los primeros respondedores mínimamente entrenados si habían encontrado problemas de seguridad asociados con el AED. Métodos: Condujimos una encuesta telefónica en edificios públicos y de negocios(2683) y en hogares (145) que poseían al menos un AED por un período de al menos 12 meses. Se definió uso como el haber llevado el AED a una emergencia médica que se cree sea un SCA, sin importar si acaso se aplicó el AED al paciente o si se identificó un ritmo que requiriera descarga. *Resultados*: De los dueños que participaron en la encuesta, el 13% (209/1581) de las oficinas y 5% (4/73) de los hogares habían respondido con el AED ante la sospecha de un paro cardíaco. 95% de los edificios públicos o de negocios ofrecieron un entrenamiento que cubría específicamente el uso de AEDs. La frecuencia de uso de los AEDs fue mas alto en los edificios residenciales, sitios públicos, centros comerciales y establecimientos de recreación con una tasa de uso global de 11.6% por año. Se realizaron entrevistas mas profundas a aquellos primeros respondedores que habían usado los AEDs en un caso de sospecha de paro cardíaco. En los 4 casos en que el AED fue usado solo por el primer respondedor, los 4 pacientes sobrevivieron a la admisión hospitalaria y dos fueron dados de alta vivos del hospital. No hubo reportes de lesión o daño. *Conclusiones*: Esta investigación demuestra que los AEDs comprados por negocios y hogares fueron llevados con frecuencia a casos de sospecha de paro cardíaco. Los reanimadores legos fueron capaces de usar exitosamente el AEDs en situaciones de emergencias. Mas aún, no hubo reportes de daño o lesión a los operadores, testigos o pacientes cuando se usaron los AEDs operados por legos.

Palabras clave: Desfibrilador automático externo (DAE); Paro cardíaco; Resucitación; Servicio de emergencias médicas; Seguridad; Entrenamiento

1. Introduction

Automated external defibrillators (AEDs) have become increasingly available outside of the Emergency Medical Systems (EMS) community for the treatment of sudden cardiac arrest (SCA). SCA has been described as a major clinical and public health problem resulting in 250 000–450 000 deaths per year [1,2]. Early defibrillation has been shown to be effective in improving survival from out of hospital cardiac arrest. However, most communities and areas have limited rapid access by EMS, and response times are fundamentally limited to several minutes or more. One approach has been to expand emergency medical services via widespread deployment of AEDs. AEDs have been demonstrated to be reliable and intuitive to use, and advancements in technology have resulted in reductions in size, weight, cost and maintenance [3,4]. The AHA Automated External Defibrillation/Public Access Defibrillation (PAD) panel has called for the establishment of PAD programs under some circumstances where training and equipping laypersons to function as first responders in the community is likely to be beneficial [5]. This has resulted in programs with trained first responders using AEDs in addition to traditional paramedics and firefighters [6]. AEDs have been successfully used by police officers [7], flight attendants in airplanes and airports [8,9], and by security guards in casinos [10], to name a few. There have also been some programs that target the home, where 70% of all SCAs occur [11–14].

Although widespread availability of AEDs holds promise for improving survival from SCA, questions remain regarding where AEDs should be placed and the level of care lay responders will provide in an emergency situation. The placement of AEDs in public settings, office buildings and homes is largely untested. To our knowledge, safety problems or adverse events associated with AED use by minimally trained responders have not been reported in the literature. Thus, we hypothesized that there would be no safety problems specific to lay responder use of AEDs. This survey sought to study the use of AEDs in the home, businesses and public settings by minimally trained first responders. The frequency of AED use, type of training offered to first responders, and outcomes of AED use were investigated. In addition, minimally trained responders were asked if they

had encountered any safety problems associated with the AED.

2. Methods

We conducted a telephone survey of businesses and public facilities (2683) and homes (145) owning at least one AED for at least 12 months. The sites were identified using the customer database of a single AED manufacturer (Philips Medical Systems, Seattle, WA, USA). Sites identified as part of emergency medical services or employing non-lay responders were excluded (e.g. medical doctors, nurses, firefighters, police officers, and ambulance personnel). Military sites and sites that were outside the US were excluded in addition to sites that had previously published on AED use (e.g. some casinos and airlines). All other customer sites were included. The telephone survey was conducted in January and February 2002. The AEDs were commercially available, and Institutional Review Board approval for the survey was not required.

The initial contact, conducted by an independent contract telephone research center, was used to confirm AED ownership, investigate training and AED policy (at businesses/public facilities), and determine whether any of the customers' AEDs had been used. Use was defined as an AED taken to a medical emergency thought to be a SCA, regardless of whether the AED was applied to the patient or identified a shockable rhythm. If a site reported they routinely brought their AEDs to all medical emergencies (regardless of the situation), the uses were excluded except for those instances where the medical emergency was thought to be a cardiac arrest. For the businesses and public facilities, the surveyor asked to speak with the person most responsible for the AED or the AED program coordinator if there was one. If an AED use had occurred, contact information was requested of the primary person who actually used the AED or someone who was present during the use or knowledgeable about the use.

If a lay responder had used the AED (in the home or business setting), a nurse trained in emergency medical procedures and familiar with the AED conducted a further in-depth interview. At least seven attempts were made to contact each site in order to reach as many as possible. All sites received two sets of AED pads (about $60 value) for participating in the initial survey. The in-depth interview consisted of a series of questions regarding the user's training, background and the AED use. In addition, the responder was asked to describe the use in his or her own words.

3. Results

3.1. Homes

The manufacturer's customer database contained 145 home contacts meeting the inclusion criteria of owning an AED for at least 12 months. Of these, 54% (78) were contacted successfully, 46% (67) were not reachable by telephone or refused to participate. Among those successfully contacted, three reported they had purchased an AED but no longer had it and two reported there was no one able to answer questions about an AED purchase. This resulted in 50% (73) of homes remaining in the survey. Of the 73 homes, 5% (four) said the AED had been used. Two of the four reporting a use participated in the in-depth interview.

3.2. Businesses and public facilities

The manufacturer's customer database contained 2683 business and public facility contacts meeting the inclusion criteria of owning an AED for at least 12 months. Sixty-one percent (1645) were contacted successfully, 39% (1039) were not reachable by telephone or refused to participate. Forty-one reported they had purchased an AED but no longer had it, and 17 reported there was no one knowledgeable about an AED purchase. This resulted in 59% (1586) of businesses remaining in the survey. The types of businesses and public facilities and number of sites are listed in Table 1.

During the course of the initial business survey, five home offices were identified. The fact that they were *home* offices was not discovered until an AED use had been noted and further questioning revealed the specific location. The home office sites did not complete the remainder of the business survey; instead they were referred directly to the nurse for an in-depth interview. Three of the five were available for in-depth interviews; the other two could not be reached. Other home offices likely remained in the business list that were not identified as such because there was no AED use.

Of the 1581 businesses (excluding the five home offices) that completed the business survey, 13% (209) said an AED had been used at least once. The 209 businesses that reported at least one AED use were asked about the location or setting of the AEDs (Table 2). Most of the locations were in manufacturing facilities, office buildings, security/emergency vehicles and entertainment complexes. The number of employees at the sites ranged from less than ten to greater than 5000, and the mean was estimated to be 1296 employees. The largest percentage (31%) had between 101 and 500 employees. Five percent of the businesses with at least one use had ten or fewer employees.

Table 1
Number of sites and AED use by market type

Market	Usage rate (% of devices used/year of service) [95% CI]	Years of service	Number of sites	Probability of a use for each AED during a 10 year period (%)
Home	1.5 [0.3–4.3]	238	78	13.9
Educational facilities	7.8 [5.2–11.4]	394	96	54.2
Government	2.3 [1.4–3.5]	963	86	20.5
Industry/workplace	6.2 [5.6–6.9]	7076	961	46.2
Public places	50.0 [32.4–73.8]	65	27	99.3
Recreational facilities	32.7 [29.8–35.8]	1597	305	96.2
Residential buildings	93.7 [77.6–112.1]	111	28	100
Shopping malls	45.3 [29.0–67.4]	54	19	98.9
Travel and tourism	15.2 [12.4–18.5]	708	97	78.1
Total	11.6 [10.9–12.2]	11206	1697	68.7

CI, confidence interval.

Table 2
Locations and settings of AEDs as reported by business/public facilities with at least one use

Location	% (*n*)	Location	% (*n*)
Manufacturing facility	14.6% (34)	Health/medical dept	3.9% (9)
Large office building	12.9% (30)	Ski resort/patrol	3.9% (8)
Security/emergency vehicle	12.0% (28)	Airplane	3.0% (7)
Small office building	10.3% (24)	Mall	1.7% (4)
Entertainment complex	8.6% (20)	Airport	1.7% (4)
Fitness/recreation center	6.9% (16)	Security office	1.7% (4)
Golf course	5.2% (12)	Aboard ship	1.7% (4)
Educational building	3.9% (9)	Church	0.9% (2)
Hotel/motel	3.9% (9)	Other	3.9% (9)
Total $n = 233$			

Note that more than one location may have been reported by each business/public facility.

Of the 209 businesses reporting use of an AED, 95% (199) had offered training in CPR that specifically covered how to use an AED. Four-percent (nine) had offered no such training and less than 1% (one) did not know. Table 3 contains the total time reported for CPR and/or AED training and the retraining intervals. The 209 businesses were asked if they had a policy or procedure that required review of an AED use by a physician or anyone else. Forty-four percent (92) required review of an AED use by a physician, 24% (50) required review by someone with formal medical training (e.g. nurse, EMT), and 25% (53) did not require any review of an AED use. The remaining were reviewed by persons with no medical training 2% (four) or the respondent did not know 5% (ten).

The businesses/public facilities and homes reported that there were an estimated 1196 uses, i.e. where the AED was taken to a patient's side for a suspected cardiac arrest. Rate of use (percent of devices used per AED Years of Service, i.e. %/AEDY) was estimated as a Poisson rate with 95% confidence intervals in nine market segments (Table 1). Note that some sites estimated their total use number and said that accurate records were not available. Also, a single device may have been used more than once and many sites reported multiple uses. Manufacturer's shipment records provided a maximum number of AED Years of Service for each site based on the history of AED shipments to 1697 sites. 'Public places' contains miscellaneous public facil-

Table 3
CPR and/or AED training times and retraining intervals

% (*n*)[a]	Total time for CPR and/or AED training	% (*n*)[a]	Retraining intervals
52% (109)	4–8 h	47% (98)	One time per year
29% (60)	1–4 h	16% (33)	Two times per year
5% (11)	More than 1 day	11% (23)	Three to four times per year
5% (10)	Less than 1 h	11% (23)	Monthly or more often
1% (2)	Varied	15% (32)	Not on a regular basis or rarely or unknown
8% (17)	Unknown or not offered		
Total $n = 209$		Total $n = 209$	

[a] Percentages rounded.

ities that were not included in the other categories. 'Residential buildings' includes apartments and other multi-family dwellings.

Rate of use ranged from 1.5%/AEDY in the home market to as high as 93.7%/AEDY in residential buildings. Public buildings, shopping malls and recreational facilities also reported high rates of use. An examination of the data reported by residential buildings revealed two sites with outlying numbers; one reporting 50 uses and the other 60 uses. We have no specific reason to doubt this large number of uses, but note that removal of these outlying numbers would result in a use rate of 8.0%/AEDY (95% CI [3.7–15.3]). This rate, excluding these outliers, is more in keeping with other moderate density sites, such as educational facilities and industrial sites. The last column in Table 1 shows the probability, using the Poisson distribution, of at least one use of an AED over a 10-year period (a typical life-time for an AED) in each market segment. The probability using data from all sites, over a 10-year period, was 68.7%.

The 209 businesses were asked the outcome of the suspected cardiac arrest incident. Note that confirmation of SCA or patient outcomes was not available and these patients may not have had the AED applied or received a shock during these incidents. Businesses reported that 88% (183) knew the outcome, 8% (17) did not know and 4% (nine) were unwilling to say. There were a total of 232 incidents with a known outcome (note that some sites with larger numbers of uses did not report the outcomes). The respondents reported 63% (145) survived, 3% (eight) survived the incident but died in the ambulance or during transport, 5% (11) survived the incident but died in the hospital and 29% (68) did not survive the incident.

To learn more about minimally trained AED users, the businesses/public facilities were asked if there were any individuals who used the AED that were NOT medical professionals, e.g. physicians, nurses or paramedics. Thirty-three sites responded that there was at least one use with responders who did not have formal medical training. Only 12 of the businesses/public facilities were willing and able to allow an in-depth interview with the caregivers (the remaining were unwilling, could not be reached, the responders were not employed by the organization or the person was no longer with the organization).

3.3. *In-depth interviews*

There was a total of 17 in-depth interviews; 12 were from businesses, two from homes and three from home offices (Table 4 and Fig. 1). The in-depth interviews were targeted at lay responders or non-professionals; however, in four cases, bystanders who where physicians or nurses were involved in the response. There was one responder who reported he had been trained as an EMT-D more than 10 years previously; his company was currently offering AED training on a quarterly basis. One responder was an EMT-B. One home user had trained himself at home by watching an AED training video several times. The remaining 59% (ten), had received AED/CPR training courses within 1 year of the AED use. In one case, training had occurred just 2 weeks prior to the event.

Five uses were in homes or home offices, 11 occurred in buildings, and one on a golf course (Table 4). The average patient age was estimated at 59 years; 75% of the patients were male. The caregivers' average age was 42 years; 80% were male. The caregivers were asked about their relationship to the patient. In one case (home user) the caregiver was the patient's husband, four caregivers were co-workers, two were acquaintances, and the remaining ten had no relationship to the patients.

Of the 17 uses, pads were applied in 13 cases (76%), while in four cases the patient was responsive and breathing and the pads were never applied. In two of the 13 cases where pads were applied, the patient was responsive. Note that these applications were done in spite of AED instructions, which specify that the device be placed only on *un*responsive patients. One of the responsive patients had an extremely high fever (home user) and the other complained of chest pain with intermittent breathing and consciousness. In both instances, the AED appropriately did not advise a shock. Local EMS or 911 was called simultaneously or before AED use in ten cases where the patient was unresponsive and pads were applied, and in the remaining case EMS was called but the time of the call was unknown.

Prior to EMS arrival, shocks were delivered in eight of the 11 cases (73%) where pads were applied to an unresponsive patient. In the three cases where pads were applied to unresponsive patients but no shock was advised, two patients were reported in asystole and died, and one patient had a non-shockable rhythm (specific rhythm details unavailable), was transported by EMS and survived. The average number of shocks delivered to the eight patients with shockable rhythms was 2.1. Two patients received additional shocks from EMS. Six of the eight patients (75% [95% confidence interval, 35–95%]), survived at least to hospital admission; the remaining two were transported but did not survive. Three (50% [95% confidence interval 15–85%]) of those admitted to the hospital were known to have been discharged; one died in-hospital, the outcome of the remaining two was unknown. Examining only those four cases where the patient was treated with the AED solely by a lay rescuer (excluding the MDs, nurse and EMTs), all four survived to hospital admission and at least two were discharged from the hospital.

Table 4
Summary of in-depth interviews on AED uses

Case	Highest level of responder training	Location	Patient responsive?	Pads applied?	Number shocks	Outcome
1	Watched video	Home	Y	Yes	0	NSA, applied to wife due to high fever
2	EMT-B	School	N	Yes	1	Two additional shocks from EMS, pulse and breathing on scene, survived to hospital, outcome unknown
3	EMT-D	Business	N	Yes	0	NSA, asystole, did not survive
4	AED/CPR	Government building	N	Yes	1	Survived, discharged from hospital
5	AED/CPR	Athletic facility	N	Yes	1	Survived, discharged from hospital
6	AED/CPR	Golf course	N	Yes	3	Survived to hospital admission, outcome unknown
7	AED/CPR	Home office	Y	No	na	AED not needed, chest pain
8	MD	Home	N	Yes	0	NSA, asystole, did not survive
9	AED/CPR	School	Y	No	na	AED not needed, chest pain
10	MD	Building	N	Yes	2	Additional shocks from EMS, pulse and breathing on scene, survived, discharged from hospital
11	MD	Home office	N	Yes	1	Did not survive
12	AED/CPR	Office building	Y	No	na	AED not needed, responsive and breathing
13	AED/CPR	Home office	N	Yes	2	Survived to hospital admission, died in-hospital
14	Nurse	Government building	N	Yes	6	Did not survive
15	AED/CPR	Manufacturing building	N	Yes	0	NSA, unresponsive, breathing and pulse present, EMS transported, returned to work
16	AED/CPR	Athletic facility	N	No	na	AED not needed, unresponsive, severe fall, breathing and pulse present
17	AED/CPR	Hotel	Y	Yes	0	NSA, chest pain, intermittent breathing, passed out

na, not applicable, NSA, no shock advised.

Looking exclusively at the five home or home office uses; in three cases, no shocks were delivered. In the first case with no shocks, pads were applied to a conscious patient (with fever) and no shock was advised; in the second case pads were not applied because the patient was responsive; and in the last case, the patient was in asystole and the AED advised no shock. In the two cases with shocks delivered, one patient received one shock but did not survive, and the other patient received two shocks and survived to hospital admission, but died in-hospital.

In each of the 13 cases where pads were applied, the respondent was asked about any safety issues or injury to the rescuer, bystanders or patient. No issues or injuries were reported. All respondents reported that they felt adequately trained and if the need arose, they would want to respond and use the AED again. Many additionally expressed satisfaction at being able to help and having the AED available.

4. Discussion

This study investigates the use of AEDs in non-EMS settings and the results of allowing laypersons to use AEDs. The survey of business and home AED purchasers revealed a high percentage of the devices had been used. Respondents reported that 13% (209/1581) of businesses and 5% (4/73) of homes had brought the AED to a suspected cardiac arrest. The usage rate for the AEDs was highest in residential buildings, public places, malls and recreational facilities with an overall usage rate of 11.6% per year. In a study by Gratton et al. they discuss the use of a criteria of one cardiac arrest per year at a given location such as a pool or mall to warrant public-access AED placement and personnel training [15]. In another study by Becker et al., also investigating locations of cardiac arrest and placement of AEDs, they define locations with a relatively high incidence of cardiac arrest as $\geq 3\%$ per site per year [16]. Our overall usage rate of 11.6% per year reflects cases where the AED was taken to a medical emergency suspected to be a cardiac arrest. We do not know the true incidence of arrests in these patients and how many benefited from the AED. Nevertheless, even if a small portion of the suspected arrests were cases where a patient did benefit from the application of an AED, the overall rate of use was high by these criteria.

No harm or injuries to the rescuer, patients or bystanders were reported during these actual emergencies, supporting our hypothesis that lay responder use of AEDs did not result in any new safety issues. The absence of any reported safety concerns further supports AED use by minimally trained responders. In two cases pads were applied to responsive patients (against AED instructions for use); one patient had a high fever and one patient had chest pains with intermittent breathing

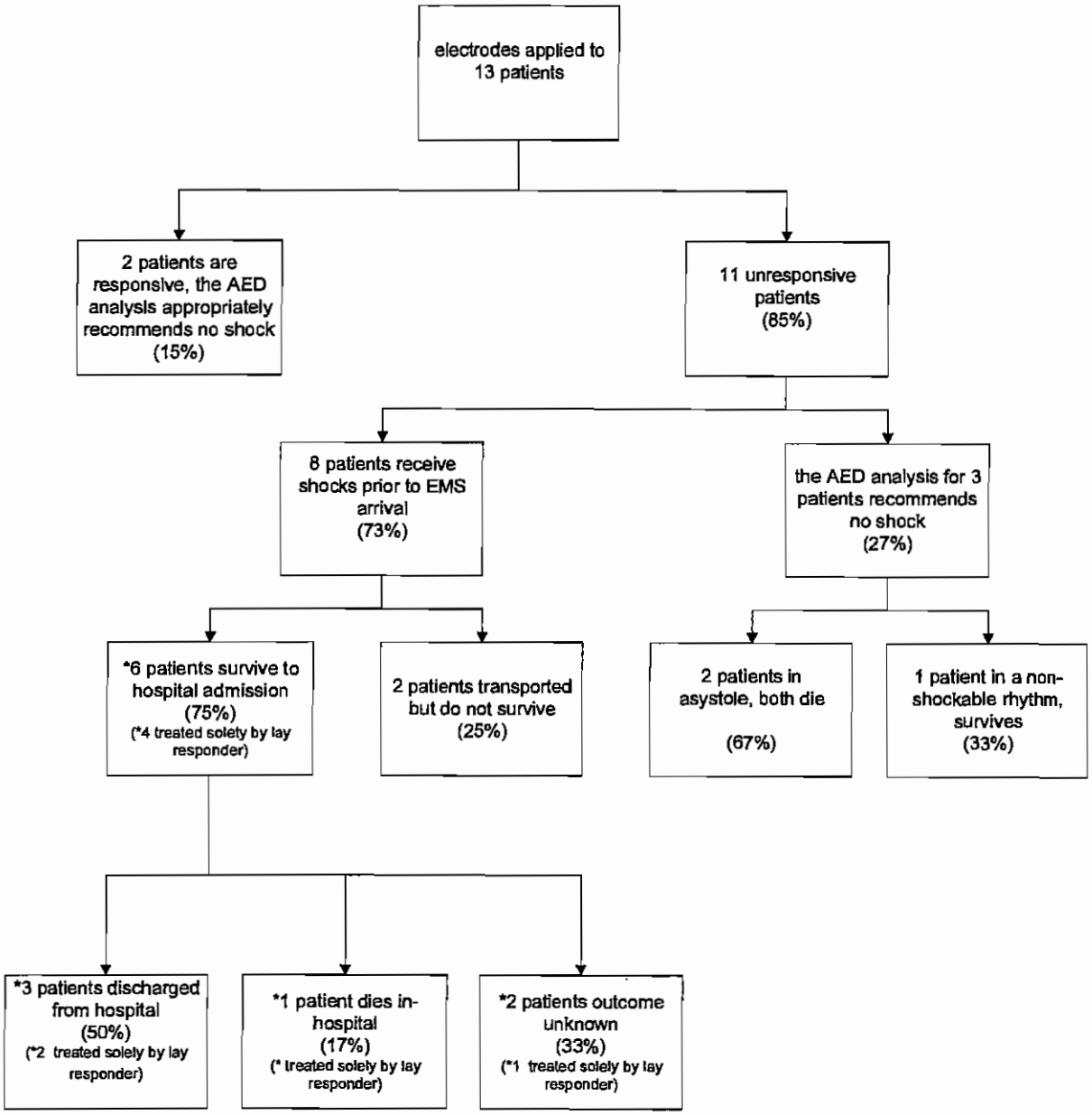


Fig. 1. Flow chart of in-depth interviews of AED uses.

and consciousness. In both instances, the AED appropriately did not advise a shock.

Previous studies have looked at the ability of family members to use an AED in simulated scenarios and real emergencies [11,14]. In the home, where 70% of cardiac arrests occur, AED use has been studied, mostly in the homes of high-risk patients [11,12,17]. A study by Moore et al. suggested that most family members could learn to use an AED, and under simulated conditions could provide defibrillation shocks an average of 8 min faster than typical response times of emergency medical technicians [14]. Chen et al. concluded that the psychological impact of the presence of AEDs in the homes of most postmyocardial infarction patients was positive [13]. In the present survey, two patients received shocks in the home/home office environment and one of these patients survived to hospital admission.

The study of AED use by lay responders in businesses and public places has been limited. Cummins et al. concluded in 1989 that most lay responders could operate an AED successfully during a simulated cardiac arrest more than 1 year after initial training [18]. Using newer AED technology, a recent study reported the successful use of AEDs in Chicago airports by random bystanders [9]. In the study, six of the 11 successfully resuscitated patients were resuscitated by persons with

no prior use of an AED or training [9]. The authors of the airport study concluded that lack of training should not constrain attempts to use a defibrillator in emergencies.

Although only a small number participated in the in-depth interview, survival was good with 75% [95% confidence interval 35–95%] of those shocked being admitted to the hospital and at least 50% [95% confidence interval 15–85%] being discharged. Examining only those four cases where the patient was treated with the AED solely by a lay rescuer prior to EMS arrival (excluding the MDs, nurse and EMTs), all four survived to hospital admission and at least two were discharged from the hospital. Other studies of trained first responders using AEDs have reported similar survival rates. Survival to hospital discharge for patients whose initial rhythm was VF was 53% in a study of AED use by security guards in casinos [10] and 40% in an airline study with trained flight attendants [8]. Both these studies demonstrated that trained personnel, whose job involved first aid, could effectively use AEDs with good success.

Through education and increased awareness, more businesses and public places are setting up AED programs to protect their employees and the public. Many states have Good Samaritan laws that protect AED users from legal liability under certain circumstances. The passage of these laws has helped remove barriers to placing AEDs in businesses and public locations. Other barriers have been removed with the continued technological advancement of AEDs, making them easier to use by laypersons and minimizing risk of physical injury to rescuers, bystanders and the patient. In this survey, lay users were able to use the AEDs and reported that their training was adequate and if the need arose they would want to respond and use the AED again. This successful lay responder use of AEDs may lend further evidence and support to removal of the current prescription requirement for the purchase of an AED [19].

This study was limited in that only a portion of those purchasing AEDs (50% of homes and 59% of businesses) participated in the survey. The survey only included customers from a single AED manufacturer. Further, only a small portion of those who had used an AED participated in the in-depth interview. The sample of those who completed either type of interview was not random and was subject to the bias of those responding to the survey. At least seven attempts were made to contact each site; however, some did not return calls or were unwilling to participate. AED users may have been more likely to participate in the survey following a positive experience with the AED. Responses of those surveyed were not confirmed and detailed information such as response times was not available. Home offices were not identified in the business group until an AED use had been noted and further questioning revealed the location. Thus the proportion of home offices having an AED use could not be estimated. In a previous study of trained laypersons using AEDs [18], there was some failure to recognize cardiac arrest and quickly apply the AED. This study only investigated cases where an AED use was reported; thus this type of recognition failure was not identified.

5. Conclusions

In this survey, AEDs purchased by businesses and homes were taken frequently to suspected cases of cardiac arrest. Lay responders were able to use the AEDs successfully in emergency situations. Survey respondents reported that during lay responder use, there were no reports of harm or injury to the AED operators, bystanders or patients from the AEDs.

Acknowledgements

We would like to thank Robin Havrda, Carol Bowen, and Ellyn Murphy for their contributions to the survey.

References

[1] Zheng Z, Croft JB, Giles WH, Mensah GA. Sudden cardiac death in the United States, 1989 to 1998. Circulation 2001;104:2158–63.
[2] Myerburg RJ. Sudden cardiac death: exploring the limits of our knowledge. J Cardiovasc Electrophysiol 2001;12:369–81.
[3] Marenco JP, Wang PJ, Link MS, Homoud MK, Estes NAM. Improving survival from sudden cardiac arrest, the role of the automated external defibrillator. J Am Med Assoc 2001;285:1193–200.
[4] Varon J, Sternbach GL, Marik PE, Fromm RE. Automatic external defibrillators: lessons from the past, present and future. Resuscitation 1999;41:219–23.
[5] Atkins DL, Bossaert LL, Hazinski MF, Kerber RE, Mancini MB, Ornato JP, Perberdy MA, Quan L, Tang W, Timerman S, Weisfeldt ML, White RD. Automated external defibrillation/public access defibrillation. Ann Emerg Med 2001;37:S60–7.
[6] Caffrey S. Feasibility of public access to defibrillation. Curr Opin Crit Care 2002;8:195–8.
[7] White RD, Hankins DG, Atkinson EJ. Patient outcomes following defibrillation with a low energy biphasic truncated exponential waveform in out-of-hospital eardiac arrest. Resuscitation 2001;49:9–14.
[8] Page RL, Joglar JA, Kowal RC, Zagrodsky JD, Nelson LL, Ramaswamy K, et al. Use of automated external defibrillators by a US airline. New Engl J Med 2000;343:1210–6.
[9] Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Puhlic use of automated external defibrillators. New Engl J Med 2002;347:1242–7.
[10] Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes of rapid defibrillation by seeurity officers after cardiac arrest in casinos. New Engl J Med 2000;343:1206–9.

[11] Eisenberg MS, Moore J, Cummins RO, Andresen E, Litwin PE, Hallstrom AP, Hearne T. Use of the automatic external defibrillator in homes of survivors of out-of-hospital ventricular fibrillation. Am J Cardiol 1989;63:443–6.
[12] Moore JE, Eisenberg MS, Andresen E, Cummins RO, Hallstrom A, Litwin P. Home placement of automatic external defibrillators among survivors of ventricular fibrillation. Ann Emerg Med 1986;15:811–2.
[13] Chen MA, Eisenberg MS, Meischke H. Impact of in-home defibrillators on postmyocardial infarction patients and their significant others: an interview study. Heart Lung 2002;31(3):173–85.
[14] Moore JE, Eisenberg MS, Cummins RO, Hallstrom A, Litwin P, Carter W. Layperson use of automatic external defibrillation. Ann Emerg Med 1987;6:669–72.
[15] Gratton M, Lindholm DJ, Campbell JP. Public-access defibrillation: where do we place the AEDs. Prehosp Emerg Care 1999;3:303–5.
[16] Becker L, Eisenberg M, Fahrenbruch C, Cobb L. Public location of cardiac arrest implications for public access defibrillation. Circulation 1998;97:2106–9.
[17] McDaniel CM, Berry VA, Haines DE, DiMarco JP. Automatic external defibrillation of patients after myocardial infarction by family members: practical aspects and psychological impact of training. Pacing Clin Electrophysiol 1988;11:2029–34.
[18] Cummins RO, Schubach JA, Litwin PE, Hearne TR. Training laypersons to use automatic external defibrillators: success of initial training and 1-year retention of skills. Am J Emerg Med 1989;7:143–9.
[19] Weaver WD, Peberdy MA. Defibrillators in public places—one step closer to home. New Engl J Med 2002;347:1223–4.

ELSEVIER

Resuscitation 64 (2005) 269–277

RESUSCITATION

www.elsevier.com/locate/resuscitation

The Department of Health National Defibrillator Programme: analysis of downloads from 250 deployments of public access defibrillators☆

Richard Whitfield[a], Michael Colquhoun[a], Douglas Chamberlain[a,*], Robert Newcombe[a], C. Siân Davies[b], Roger Boyle[b]

[a] *Prehospital Emergency Research Unit and Wales Heart Research Unit, School of Medicine, Wales College of Medicine, Cardiff University, Heath Park, Cardiff CF14 4XN, UK*

[b] *Department of Health, Standards and Quality Group, Coronary Heart Disease, 407 Wellington House, 133-155 Waterloo Road, London SE1 8UG, UK*

Abstract

From April 2000 to November 2002, the Department of Health (England) placed 681 automated external defibrillators (AEDs) in 110 public places for use by volunteer lay first responders. An audit has been undertaken of the first 250 deployments, of which 182 were for confirmed cardiac arrest. Of these, 177 were witnessed whilst 5 occurred in situations that were remote or initially inaccessible to the responders. The response interval between collapse and the initiation of CPR or AED placement was estimated to be 3–5 min in most cases.

Ventricular fibrillation or rapid ventricular tachycardia (one case) was the first recorded rhythm in 146 cases (82%). In all, 44 of the 177 witnessed cases are known to have survived to hospital discharge (25%). Complete downloads are available for 173 witnessed cases and of these 140 were shocked: first-shock success, defined as termination of the fibrillatory waveform for 5 s or more, was achieved in 132 of them. When data quality permitted, the downloads were analysed with special reference to the numbers of compressions given and also to interruptions in compression sequences for ventilations, for rhythm analysis by the AED, for clinical checks, and for unexplained operator delays.

The average rate of compressions during sequences was 120 min^{-1}, but because of interruptions, the actual number administered over a full minute from the first CPR prompt was a median of only 38.

The speed of response by the lay first responders in relation to AED use was similar to that reported for healthcare professionals.

Keywords: Public access defibrillation; Automated external defibrillators (AEDs); Cardiopulmonary resuscitation (CPR); Chest compressions; Compression ventilation ratio

1. Introduction

First responder and public access defibrillation are widely recommended strategies to achieve more rapid defibrillation and thereby provide definitive treatment for victims of sudden out-of-hospital cardiac arrest [1–3]. Important factors that determine the potential success of this strategy include: the proportion of victims with shockable rhythms as the immediate cause, the delay between collapse and delivery of shocks, the presence of serious co-morbidity, and the expertise of the first responders both in regard to conventional basic life support (BLS) and the use of the automated external defibrillators (AEDs). Insight into these factors will help to predict the value of first responder programmes, identify factors that might improve results, and define training requirements.

The Department of Health (DH) in England has a National Defibrillator Programme that placed 681 automated external defibrillators (AEDs) in 110 public places from April 2000 to November 2002 as suitable sites were identified and personnel were trained [4–6]. The first responders are lay volunteers who work at the site where the AED is installed; they record details of each AED deployment and resuscitation attempt on a specially designed AED event form. This paper provides a detailed analysis of information obtained from the AED event report forms and the downloads of electronic data recorded by the AEDs during the first 250 deployments; there is special

☆ A Spanish and Portuguese translated version of the Abstract and Keywords of this article appears at 10.1016/j.resuscitation.2005.01.003.

* Corresponding author. Present address: 25 Woodland Drive, Hove, Sussex BN3 6DH, UK. Tel.: +44 1273 380 670; fax: +44 1273 566 526.
E-mail address: chambda@pavilion.co.uk (D. Chamberlain).

0300-9572/$ – see front matter © 2005 Elsevier Ireland Ltd. All rights reserved.
doi:10.1016/j.resuscitation.2005.01.003

reference to cases of cardiac arrest. Included in this report is the first large-scale detailed analysis of the performance of trained lay first responders—who are neither healthcare professionals nor (with few exceptions) members of a disciplined force.

Details of tbe National Defibrillator Programme, an evaluation of the training programme, and earlier information on clinical outcome are described elsewhere [4–6].

2. Methods

2.1. Clinical data

The AED event forms record the site of the cardiac arrest, the sex and approximate age of the victim, whether CPR and shocks were administered, the initial outcome, and the receiving hospital. Estimates of the delays between collapse and responses were usually available. These data were supplemented in a few instances by additional information provided by healthcare professionals or police attending the scene.

2.2. AEDs and downloads

In this first phase of the national defibrillator programme, two models of AED were used: the Medtronic Physio-Control Lifepack 500 (MP-C) and the SurvivorLink (now Cardiac Science) FirstSave (SL). The electronic downloads were made available as hard copy for ease of analysis and consistency of interpretation. These depict the ECG in real time with markers superimposed showing the timings of the audio prompts and other major actions of the device. These markers annotate, for example, 'Patient connected' (MP-C) or 'Electrodes placed' (SL) at the start of the event. Similarly, the periods of rhythm analysis, capacitor charging, and the timing of shock delivery are clearly indicated. The records do not show the audio instructions given to the rescuer, but the manufacturers prepared templates showing the standard markings placed on simulated downloads providing the actual words of command with a precise indication of when the commands started and finished. The timing of the operators' responses in relation to the instructions could therefore be assessed. The voice prompts provided by the two AED models are different, a fact that influenced to a minor degree some details of the intervals that were recorded.

2.3. Analysis of downloads

Cases with shockable rhythms show some differences in the procedures and sequences of instruction compared with those appropriate to asystole, bradycardia, or other non-shockable rhythms. Separate data sets were therefore kept for shockable and non-shockable rhythms.

The delay between switching on the AED and the first ECG recording was measured, as was the interval between the start of automatic rhythm analysis and the delivery of any first shock. The rhythm after all first shocks was noted.

The performance of chest compressions can be recognised in most downloads by the distinctive pattern of artefact superimposed on the ECG. They could be counted readily when the underlying rhythm was asystole and also in ventricular fibrillation if the compression artefact resulted in large deflections (Fig. 1). In some other cases of ventricular fibrillation, compressions can be distinguished from the irregular waveform with more difficulty, but can be counted with acceptable accuracy (Fig. 2). Interpretation is aided by experience, but to minimize any subjective element each record was examined by two researchers so that a consensus could be reached in all cases. Ventricular fibrillation may, however, mask compression artefact for reasons that may be more complex than superimposition of waveforms [7] so that no meaningful data

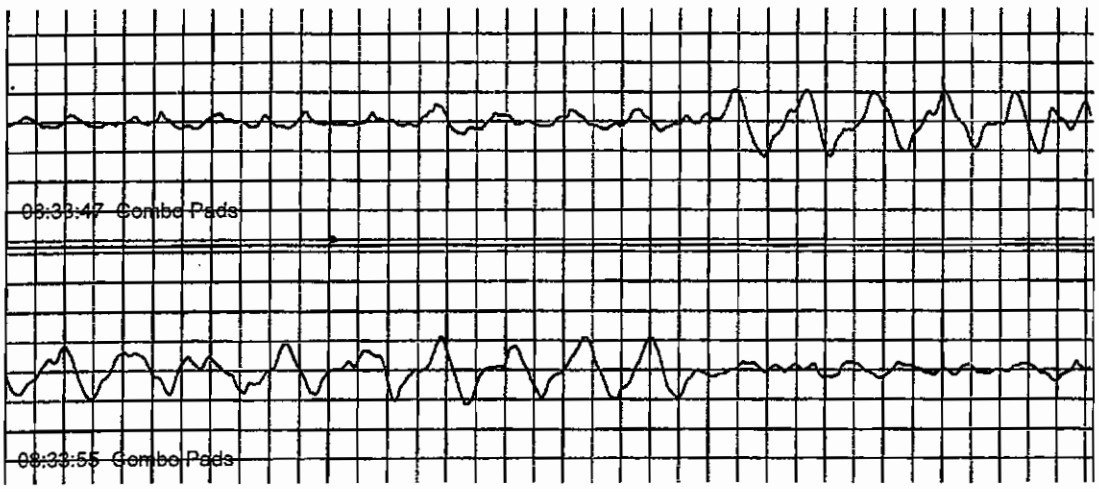


Fig. 1. An example of compression artefact superimposed on the waveform of ventricular fibrillation. The compression artefact is of large amplitude that can easily be counted.

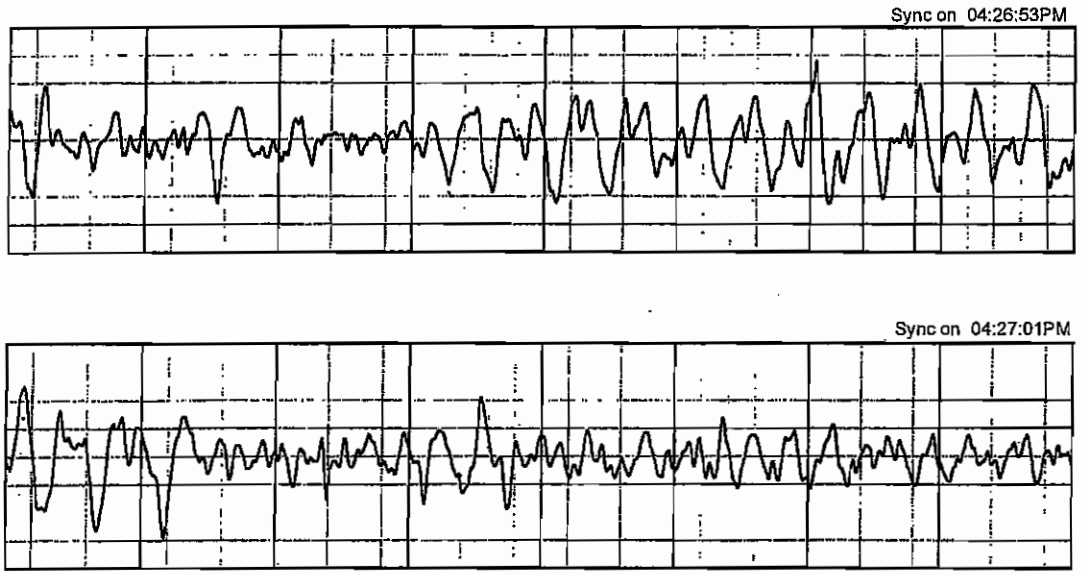


Fig. 2. An example of compression artefact that can be distinguished from the fibrillation waveform with some difficulty but can be counted with acceptable accuracy.

can be collected (Fig. 3). Analysis was therefore incomplete for some downloads.

The delay from the end of the first spoken CPR prompt to the first compression was measured whenever it was possible to do so. The first two cycles of chest compression and the first two pauses for ventilation were analyzed. This enabled the calculation not only of the rate of compressions during the sequences but also – by extrapolation – of the number of chest compressions that would be delivered with standard CPR given over a full uninterrupted minute. When a readable ECG record continued for a sufficient period, the number of compressions for a timed minute was counted directly. The longest period in the first 5 min of the recording during which neither compressions nor QRS complexes were present was also noted. Such intervals occur during ventilation pauses, during mandatory 'hands-off' time during rhythm analysis,

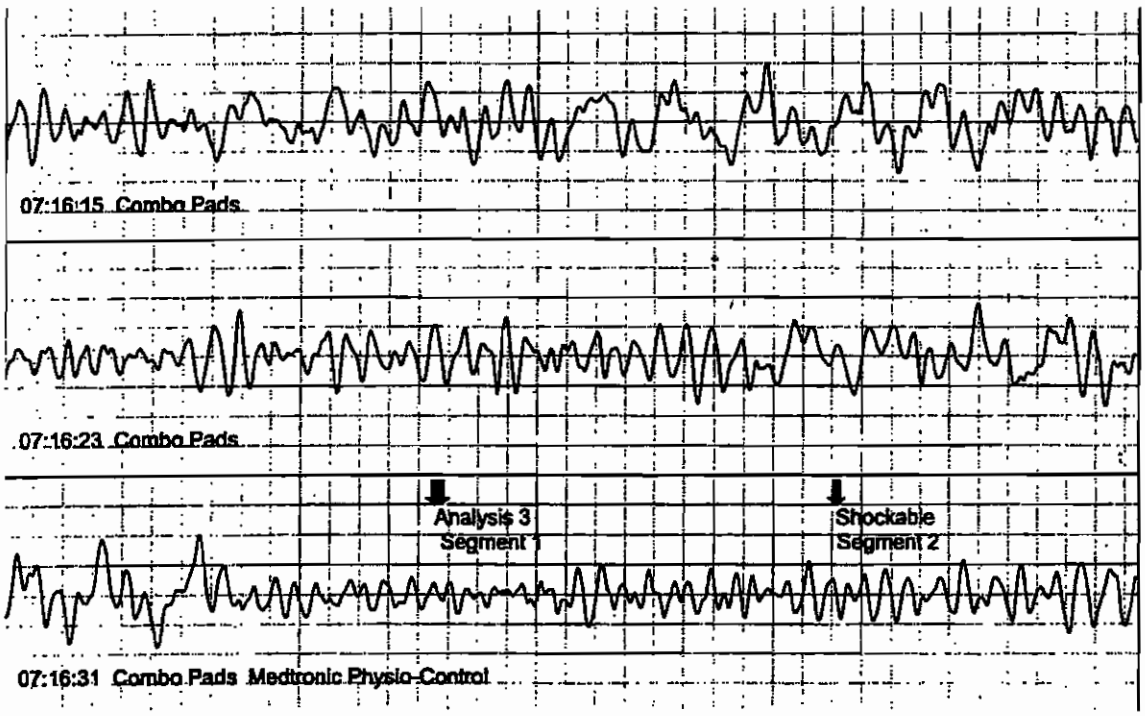


Fig. 3. An example of the waveform of ventricular fibrillation almost totally obscuring the artefact from chest compressions.

as well as for unexplained reasons perhaps related to operator performance. No attempt was made to apportion the contributions of these three possible causes.

2.4. Clinical outcome

Both the AED event form and the download of the event provide data up to the end of the contribution made by the first responders to the resuscitation attempt. The forms usually show whether the casualty was recognised as dead at the scene or was handed over to care by ambulance personnel. Additional information was obtained from receiving hospitals when it was appropriate to obtain it: survivors were generally willing for information on outcome to be made known to the National Defibrillator Team in the Department of Health after they had been informed of the programme and learnt of our interest.

2.5. Statistics

Except where stated otherwise, medians are given. Confidence intervals for proportions were calculated using the method of Wilson [8].

3. Results

3.1. Overall numbers

Most downloads showed ECG rhythms associated with cardiac arrest, but in some cases the AED was applied to individuals who had collapsed or who had caused concern to responders for reasons other than cardiac arrest. A breakdown of the AED deployments that provided data for this analysis is shown in Fig. 4, together with the proportions of cardiac arrest cases with shockable or non-shockable rhythms.

Of the 250 uses, 182 were for confirmed cardiac arrests. Five of them occurred in inaccessible or remote places and were therefore unwitnessed—with very late deployment of AEDs. Thus, 177 witnessed arrests of presumed cardiac origin were attended by first responders. Complete downloads were available for analysis in 173 cases, excerpts were available in one, and four were lost because of technical reasons. Demographic information was known for most but not all cases. Of the 171 cases for whom sex was recorded, 87% were male. The mean age (estimated in some cases) was 63 years (range 30–91).

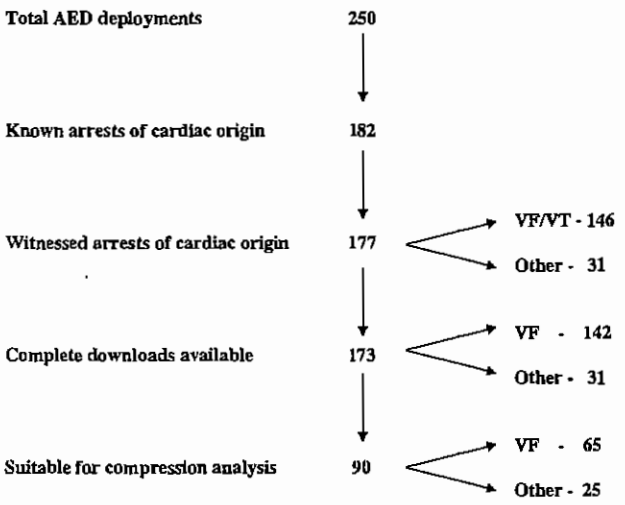


Fig. 4. A flow chart showing the breakdown of 250 AED deployments that form the basis of this report.

3.2. Site and rhythm of arrests (Table 1)

Most witnessed cardiac arrests occurred where the density of AEDs was greatest—in airports (101 cases) and railway stations (58 cases). The percentages known to have had shockable rhythms in these locations, as determined by the first ECG record on the download, were 82 and 86% respectively: only one case had very rapid ventricular tachycardia and all others had ventricular fibrillation. In a single individual, the first complexes seen on the download (from a patient where the deployment had been precautionary) were sinus beats but ventricular fibrillation supervened shortly afterwards: this case has been included. Ventricular fibrillation was also the most common arrhythmia of cardiac arrest in sites other than airports and stations (72%) with an overall percentage for VF/VT for all sites of 82% (Table 1).

3.3. Intervals to resuscitation attempts

The estimated time (taken from the AED event forms) from collapse to the start of resuscitation, whether by CPR or the application of an AED, was a mean of 3.3 min (estimated) for the 112 cases in which this information was avail-

Table 1
Clinical cardiac arrests by type of site and first heart rhythm seen on download

Type of site	Total witnessed cardiac arrests	Known VF/VT	Known asystole	Known severe bradycardia	Known idiovent rhythm	Initial satisfactory rhythm
Airports	101	83 (82%; 95% CI 74–88%)	10 (10%)	5 (5%)	3 (3%)	0
Railway stations	58	50 (86%; 95% CI 75–93%)	2 (4%)	6 (10%)	0	0
Other	18	13 (72%; 95% CI 49–88%)	3 (17%)	2 (11%)	0	0
Total	177	146 (82%; 95% CI 76–87%)	15 (8%)	13 (7%)	3 (2%)	0

Percentages are shown in parentheses, with 95% confidence intervals for proportions who had known VF/VT by type of site. 'Other' sites include bus stations, underground stations, sea ports, and shopping mall.

Table 2
Components of delays from first record to shock that were achieved using the medtronic physiocontrol lifepak 500 (MP-C) and the surviva-link (now cardiac science) first save (SL) AEDs

	MP-C ($N=81$)	SL ($N=56$)
First record to start analysis	4.4 (0.2)	5.2 (0.1)
Start analysis to shock advised	5.5 (2.48)	9.0 (0)
Shock advised to charge delivered	10.6 (2.77)	8.5 (4.8)
Start analysis to shock delivered	16.8 (4.45)	17.7 (4.77)

Figures are medians in seconds, with inter-quartile ranges in parentheses. Data are available for 137 of the 140 cases of VF for shocks were given. In three cases the timing could not be recorded accurately either because of a brief lead disconnection or for technical reasons relating to printout annotations.

able. CPR was noted to have been given before use of the defibrillator in 129 of 177 instances, but with most of the other data boxes being blank. These data may therefore be incomplete. The median time from 'equipment on' to first ECG waveform record was 33 s, with 27% obtained within 20 s. Because of differences in the two AED models, we determined separately for each of them the components of the interval from the first ECG record to the delivery of any first shock (Table 2). Despite the differences in algorithms, the delay from the start of the first analysis to shock delivery, used as a comparator of AED performance, was very similar for the two AED models.

3.4. Outcome of cardiac arrest (Table 3)

In all, 44 of 177 cases of witnessed cardiac arrest survived (25%), 42 from VF, 1 from VT, and one from asystole on the first recorded ECG. Thus, of those with shockable rhythms, 43 of 146 survived (29%), but only one case with a non-shockable rhythm was resuscitated successfully. No statistical difference was found between sites, but of those who collapsed in railway stations, 38% were discharged from hospital alive compared with 25% from airports, and 23% from other types of location (Table 3).

3.5. Shock success

From the 143 cases of ventricular fibrillation or tachycardia from witnessed arrests for which downloads were available (142 complete and one with edited highlights only) one or more shocks (range 1–16) were administered in 140 of them. One fine VF waveform was below the sensitivity of the algorithm, and equipment or operator failure occurred twice. The first shock terminated the arrhythmia at least transiently (more than 5 s) in 132 cases: 100 and 90% first-shock success for the two AED models that were used, each model being deployed in different environments. In 74 of these only 1 shock was required until the patient was transferred to paramedic care, still with a coordinated rhythm. None of the eight individuals without first-shock success – transient or persistent – survived to hospital discharge. Of the 44 survivors, 32 required only 1 shock on site, whilst 12 required 2 or more.

Table 3
Outcome of clinical cardiac arrest by type of site and initial rhythm

Patient group	Known VF/VT		All rhythms
Type of site	Proportion surviving (%)	95% confidence interval (%)	Proportion surviving (%)
Airports	21/83 (25)	17–35	22/101 (22)
Railway stations	19/50 (38)	26–52	19/58 (33)
Other	3/13 (23)	8–50	3/18 (17)
Total	43/146 (29)	23–37	44/177 (25)

Percentages are shown in parentheses, with 95% confidence intervals for survival proportions of those with known VF/VT by type of site.

The median post first-shock asystolic interval was 18 s (5 s in survivors). The asystole was terminated by an idioventricular rhythm in most cases, but by ventricular fibrillation or ventricular tachycardia in 29 instances (with 13% eventual survival), and by supraventricular rhythms in 18 instances (with 56% survival). Asystole was persistent in eight cases (with no survival).

3.6. Delay to compressions for rhythm and clinical checks

For cases with non-shockable rhythms, the median interval between the instruction for 'hands-off' (start of analysis) and the instruction to 'start CPR' was 20 s, with only a small difference between the types of AED. Operator delay before compressions were started, averaging an additional 7 s, must be added to this figure.

In the cases with ventricular fibrillation, the median interval from shock delivery to the first visible compressions was 34 s of which 10 s was due to operator delay.

3.7. Compression numbers (Fig. 5)

The number of compressions in the sequences varied considerably in the 90 cases that were suitable for this type of analysis. Cycles of 13–17 (approximating to the recommended 15) compressions were seen in 59 cases—but in the remaining 31, cycles approximating to either 5 or 10 compressions were used. Overall, the compression rate during the sequences of compressions was a mean of 120 min^{-1}. The time of the pause for ventilation after the first cycle of compressions was 6.3 s (median) and after the second cycle the pause was 6.0 s. The number of compressions that would be delivered during each full minute of uninterrupted CPR – calculated from the first two full cycles of compressions and pauses extrapolated to a notional number per minute – was 55. But taking into account the initial delay in starting compressions and other unexplained interruptions, the number of compressions actually given in a full minute from the start of the first CPR prompt as measured in 90 cases was only 38 (Fig. 5).

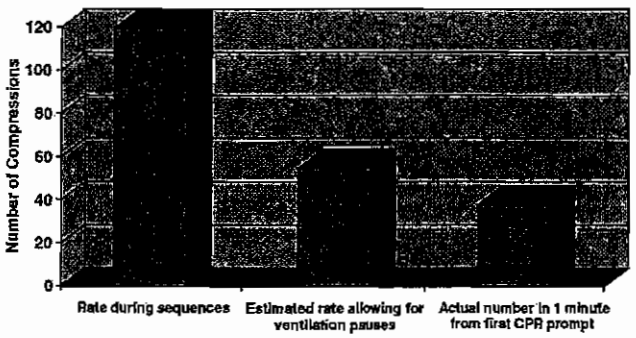


Fig. 5. A graph showing how compressions given at a satisfactory rate during the sequences provide appreciably fewer in a minute than might be expected because of ventilatory pauses (second column) and with both ventilatory and other interruptions (third column). See text.

3.8. *Unexplained interruptions to compressions*

The longest interval in the first 5 min of each download without either ventricular activity or evidence of compressions was measurable in 148 downloads. The median was 22.8 s (IQ range 26.6), but in 13 cases over a minute of unassisted asystole was seen during the resuscitation attempt.

4. Discussion

The Department of Health National Defibrillator Programme has provided the opportunity for the first large-scale detailed analysis of events associated with public access on-site defibrillation by lay responders. In addition to presenting the clinical results of the programme, we have been able to make important observations on the rhythms of cardiac arrest in busy public locations, to examine the performance of the trained lay rescuers, and to assess the effectiveness of the AEDs that were used.

4.1. *Programme policy and clinical results*

The criterion of successful resuscitation was discharge alive from hospital. The 25% observed survival was appreciably higher than is generally obtained with out-of-hospital cardiac arrests treated by conventional ambulance systems. An important factor relating to the relatively high success rate was the short response times that were achieved, with most estimates of the delay from collapse to first resuscitation attempts being within 4 min. This brief period is the so-called 'electrical phase' for resuscitation attempts when defibrillation for shockable rhythms has an appreciable likelihood of success [9]. In most pre-hospital situations, however, a 4-min target is difficult to achieve. In this programme, AEDs were placed 'on-site' in sufficient density to achieve placement within an estimated brisk 2 min walk-time, but inevitably the speed of response was subject to the availability and location of a trained responder at the site. The equipment is displayed in open areas and its use is not restricted: but the programme does not seek to involve members of the public in the use of AEDs as at O'Hare airport in Chicago [10] where frequent public service announcements draw attention to the availability of AEDs and provide instruction in their use. However, the policy of offering training to as many staff as are willing to volunteer does ensure that trained rescuers are usually close at hand.

The differences between the complementary strategies of 'on-site' and 'transported' AEDs have been discussed previously [6], with the former generally offering more rapid responses at the cost of a higher density of units. Nevertheless, it cannot be assumed that all on-site schemes can have a similar success rate. The areas for AED deployment are frequented by large numbers of people and are known to the emergency services as places where cardiac arrest has occurred frequently in the past. Continuing experience should guide future policies on deployment to achieve clinical and cost effectiveness.

4.2. *Nature of the cardiac arrests and implications for future programmes*

A surprising factor that also contributed to the success of the resuscitation efforts was the high proportion of individuals found to be in ventricular fibrillation, and therefore potentially treatable by shocks. Prospects are always poor for those without a waveform that can respond to defibrillation, as indeed is reflected in the present results. One potential barrier to improving results of pre-hospital resuscitation is perceived as the relatively high number of those with out-of-hospital cardiac arrest who are found in pulseless electrical activity or in asystole. The proportion of cases found at the time of first ECG registration with shockable rhythms is reported to have declined in recent years and is now appreciably below 50% in some series relying on conventional methods of response [11–13].

We believe that two factors have contributed to the high proportion of shockable rhythms in this series. The first is the relatively brief average delay between collapse and the first recording of heart rhythm. Fibrillatory waveforms decay over minutes—and as amplitude decreases the records become indistinguishable from that of asystole. Data from Gothenburg in which the incidence of fibrillation was plotted against time from collapse did, however, suggest by extrapolation that the percentage of cases at time zero may be close to 80% [14], a figure similar to that found in our series. The second factor that may increase the proportion of cardiac arrest cases with VF probably relates to the circumstances of cardiac arrest. Most of our AEDs are in airports or railway stations, busy public places where some passengers are likely to experience high levels of adrenergic drive that may be sufficient to induce ventricular fibrillation in those who are vulnerable because of ischaemic heart disease or other pre-existing cardiac conditions.

The combination of short response times and the likelihood of adrenergic factors in the aetiology of arrests are characteristic of the sites with the best results previously

reported for out-of-hospital resuscitation: they include an airport scheme [10], gaming casinos [15], and rehabilitation programmes [16]. This assumption does, however, suggest the possibility that the proportion with shockable rhythms – and therefore the relatively high success rate – may not be replicated when the national defibrillator programme is widened to areas that might be less likely to be associated with excitement or anxiety. The initial strategy was clearly appropriate, but only further observations can show whether or not treatment of cardiac arrests in other environments achieved after short response intervals have a similarly high proportion of shockable rhythms—an important reason for continuing careful audit.

4.3. Compression rates and numbers

Only 38 compressions were given over a timed 1 min period (despite a satisfactory compression rate during the sequences of compressions). The figure is very similar to that noted in Amsterdam, where police first responders performed CPR on average for only 36% of the time in 96 subjects with shockable rhythms [17]. At recommended rates, this equates to 36 compressions per minute. An important potential cause lies in the current recommendation for a ratio of 15 compressions to 2 breaths, necessitating frequent interruptions in compression—and the potential for protracted delays if ventilation proves difficult. In the series presented here, however, the delays for ventilation were close to the four seconds per breath recommended in current international guidelines [18], and considerably briefer than those observed in single rescuer manikin simulations where delays of 14–16 s have been reported [19,20].

The unexplained pauses in compression sequences seen on the event downloads are a feature common to other similar observations. The causes are usually unknown and doubtless multi-factorial. The distraction of giving or receiving information particularly after the arrival of other personnel may be among the more important. We consider that the need to avoid unnecessary pauses should be much more strongly emphasized in all CPR training. Only highly trained and disciplined operators can be expected to achieve the number of compressions in any minute that is assumed possible by the current guidelines for BLS. Guidelines should, however, take due account of the understandable difficulties facing lay personnel and first responders: longer compression sequences can deliver appreciably more compressions in any given time as has been demonstrated by computer simulation and by observations during experimental programmes [21–23]. A second crucial factor limiting the number of compressions given during a resuscitation attempt relates to the operational characteristics of the AEDs. This is addressed in the following section.

4.4. Effectiveness and limitations of the AEDs

Two models of AEDs were used for this first phase of the Department of Health programme. Both proved to be satisfactory in that lay responders were able to use them effectively, and reliability was acceptable. Only a single definite AED malfunction prevented the possibility of a successful resuscitation. The high rate of first-shock defibrillation indicated the efficacy of the biphasic waveform (employed in both models) that is believed to be superior to the older monophasic variants [24,25]. In addition to the waveform, other factors influence first-shock success: it cannot be high if response times are necessarily relatively long, for example where AEDs are transported to general community emergencies rather than being used on-site [26]. With existing algorithms and guidelines this has a particularly important advantage because repeated analyses encroach on effective resuscitation time.

An additional limitation of the use of AEDs for management of cardiac arrest relates to the enforced interruptions of compressions (in addition to those required for ventilation) whilst analysis is performed and whilst checks are made for the presence of pulse or circulation. The interval between the instruction for 'hands-off' (for analysis) and the instruction to 'start CPR' for the two models of AEDs used in this programme differed by only a few seconds; some individual variations were caused by inadvertent motion artefact or by permissible variables such as normal fluctuations in the operating conditions of batteries. But added to these mandatory 'system' delays are 'operator' delays. For example, the instruction 'start CPR' must be converted into actions by the rescuer. This is not instant: in this experience it accounted for an additional delay of 7–10 s (slightly longer after a shock had been delivered). Thus, many factors contribute to the number of compressions actually achieved in most resuscitation attempts. Sunde et al. [26] have commented that compressions may be given for only half the time during resuscitation, citing in particular ECG analysis and defibrillation attempts; with a three shock sequence the latter may last 45–60 s. Their suggestion that this does not permit adequate perfusion to the brain and heart would now be widely agreed.

Recent studies have shown very clearly that even very brief hands-off periods limit the possibility of successful resuscitation. Near continuous chest compression is needed to maintain coronary perfusion pressure [21,27,28] and to avoid the distortion in left ventricular geometry [29] with consequent reduction in contractile power [30]. Even 20 s hands-off during human cardiac arrest causes deterioration in fibrillatory waveform that decreases the possibility of successful defibrillation [31]. In the Department of Health programme, the adverse effects of delays for rhythm and circulation checks were mitigated by the high rate of first-shock success. Even brief periods of coordinated rhythm can improve the physiology of the heart after cardiac arrest. In most instances, where response times are longer, this delay factor becomes more important—as it may have been to our cases who did not respond to the first shock. Faster rhythm analysis algorithms with the ability to analyze during chest compressions could enhance future survival rates. CPR prompts might usefully encourage rescuers to re-start compressions as soon as pulse

or circulation checks are complete rather than being delayed for a set number of seconds.

4.5. Shock administration

The mean number of shocks in this group of 140 patients was 2.2 which is lower than has generally been reported. Sunde et al. [26] quoted a median of six shocks per patient before hospital admission in Oslo, and reviewed other series. Our data, however, relates only to the period before patients were transferred to ambulance care, and therefore does not necessarily report the complete pre-hospital experience. The time to first shock from the start of monitoring (Table 2) was very similar to the 19 s reported from Oslo where the ambulances are staffed by paramedics and (usually) by physicians. This suggests that the lay responders performed as efficiently as professionals in the speed of shock administration. Our finding that most survivors required only one shock on site is in line with other experience [32], though we do not know what subsequent treatment by the ambulance service was required.

4.6. Limitations to the study

Confidentiality rules in the United Kingdom preclude systematic follow up of individual patients, but hospital staff were willing to seek approval for information to be passed on. Thus, despite the constraints that hinder the collection of audit data, we believe that the data supplied by the defibrillation team when following up the events are reasonably complete. Systematic follow up of survivors beyond hospital discharge, preferably to one year as recommended by the international Utstein agreement [33] is, however, impossible in this national study. Response intervals were necessarily only estimates. Compression rates could not be measured with acceptable precision in all cases of ventricular fibrillation so that the data as reported are necessarily incomplete. Close approximations were made in some cases where compression rates and artefact were variable but data that was not regarded as meaningful were excluded.

4.7. Implications

The initial experience of the Department of Health (England) national programme for placing AEDs in public places has confirmed the potential for saving lives of this type of initiative. The strategy of selecting busy sites selected on the basis of the previous incidence of cardiac arrest recorded by emergency services was appropriate. The lay first responders generally managed the AEDs and attempted resuscitation with commendable competence. Future training and retraining, however, needs to emphasise the importance of continuing compressions at all times except for mandatory pauses—and these must be as brief as possible. The factors that limit the number of compressions that can be given, particularly when AEDs are used, are now better understood. The present compression-ventilation ratio is not ideal for non-healthcare professionals, and manufacturers are already investigating ways of limiting the duration of interruptions for AED rhythm analysis. Survival results will always depend, however, not only on the skill of operators, CPR guidelines, and characteristics of the equipment, but also on the response times that can be achieved. This audit has demonstrated convincingly the potential of short response times in a community setting.

Acknowledgements

The audit would not have been possible without the help of a dedicated team within the Department of Health: Anna Oakley, Helen Williams and Rachael Priest. We are also indebted to the manufactures of the two models of AED used in this study for making available templates that helped in the analyses. We wish particularly to acknowledge the support of hospital staff, patients, and their families for allowing the programme to receive outcome data after successful resuscitation. DAC is supported at the Wales College of Medicine (on an expenses only basis) by the Laerdal Foundation.

References

[1] Early Defibrillation Task Force of the European Resuscitation Council. The 1998 European Resuscitation Council guidelines for the use of automated external defibrillators by EMS providers and first responders. Resuscitation 1998;37:91–4.
[2] Public Access Defibrillation: A Statement for Healthcare Professionals from the American Heart Association Task Force on Automatic External Defibrillation. Circulation 1995;92:2763.
[3] Priori SG, Bossaert LL, Chamberlain DA, et al. Policy Conference. ESC-ERC recommendations for the use of automated external defibrillators (AEDs) in Europe. Resuscitation 2004;60:245–52.
[4] Davies CS, Colquhoun M, Graham S, Evans T, Chamberlain D. Defibrillators in public places: the introduction of a national scheme for public access defibrillation in England. Resuscitation 2002;52:13–21.
[5] Woollard M, Whitfield R, Smith A, et al. Skill acquisition and retention in automated external defibrillator (AED) use and CPR by lay responders: a prospective study. Resuscitation 2004;60:17–28.
[6] Davies CS, Colquhoun M, Boyle R, Chamberlain D. A national programme for on-site defibrillation by lay persons in selected high risk areas: initial results. Heart, 2005; in press.
[7] Langhelle A, Eftestøl T, Myklebust H, Eriksen M, Holten BT, Steen PA. Reducing CPR artefacts in ventricular fibrillation in vitro. Resuscitation 2001;48:279–91.
[8] Wilson EB. Probable inference, the law of succession, and statistical inference. J Am Stat Ass 1927;22:209–12.
[9] Weisfeldt ML, Becker LB. Resuscitation after cardiac arrest: a 3-phase time-sensitive model. JAMA 2002;288:3035–8.
[10] Caffrey SL, Willoughby PA, Pepe PE, Becker LB. Public use of automated external defibrillators. N Engl J Med 2002;347:1242–7.
[11] Parish DC, Chandra KMD, Dan FC. Success changes the problem: Why ventricular fibrillation is declining, why pulseless electrical activity is emerging, and what to do about it. Resuscitation 2003;58:31–5.
[12] Kuisma M, Repo J, Alaspaa A. The incidence of out-of-hospital ventricular fibrillation in Helsinki, Finland, from 1994 to 1999. Lancet 2001;358:473–4.

[13] Herlitz J, Engdahl J, Svensson L, Young M, Ängquist K-A, Holmberg S. Decrease in the occurrence of ventricular fibrillation as the initially observed arrhythmia after out-of-hospital cardiac arrest during 11 years in Sweden. Resuscitation 2004;60:283–90.
[14] Holmberg M, Holmberg S, Herlitz J. Effect of bystander cardiopulmonary resuscitation in out-of-hospital cardiac arrest patients in Sweden. Resuscitation 2000;47:59–70.
[15] Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. N Engl J Med 2000;343:1206–9.
[16] Van Camp SP, Peterson RA. Cardiovascular complications of outpatient cardiac rehabilitation programs. JAMA 1986;256:1160–3.
[17] van Alem AP, Sanou BT, Koster RW. Interruption of cardiopulmonary resuscitation with the use of the automated external defibrillator in out-of-hospital cardiac arrest. Annu Emerg Med 2003;42:449–57.
[18] The American Heart Association in Collaboration with the International Liaison Committee on Resuscitation (ILCOR). Guidelines 2000 for cardiopulmonary resuscitation and emergency cardiovascular care: an international consensns on science. Resuscitation 2000;46:1–447.
[19] Assar D, Chamberlain D, Colquhoun M, et al. Randomised controlled trials of staged teaching for basic life support. 1. Skill acquisition at bronze stage. Resuseitation 2000;45:7–15.
[20] Heidenreich JW, Tigdon TA, Kern KB, et al. Single-rescuer cardiopulmonary resuscitation: 'two quick breaths' – an oxymoron. Resuscitation 2004;62:283–9.
[21] Sato Y, Weil MH, Sun S, et al. Adverse effects of interrupting precordial compression during cardiopulmonary resuscitation. Crit Care Med 1997;25:733–6.
[22] Berg RA, Sanders AB, Kern KB, et al. Adverse hemodynamic effects of interrupting chest compressions for rescue breathing during cardiopulmonary resuscitation for ventricular fibrillation cardiac arrest. Circulation 2001;104:2465–70.
[23] Babbs CF, Kern KB. Optimum compression to ventilation ratios in CPR under realistic, practical conditions: a physiological and mathematical analysis. Resuscitation 2002;54:147–57.
[24] Martens PR, Russell JK, Wolcke B, et al. Optimal response to cardiac arrest study: defibrillation waveform effects. Resuscitation 2001;49:233–43.
[25] van Alem AP, Chapman FW, Lank P, Hart AAM, Koster RW. A prospective, randomised and blinded comparison of first shock success of monophasic and biphasic waveforms in out-of-hospital cardiac arrest. Resuscitation 2003;58:17–24.
[26] Sudne K, Eftestøl T, Askengerg C, Steen PA. Quality assessment of defibrillation and advanced life support using date from the medical control module of the defibrillator. Resuscitation 1999;41:237–47.
[27] Sanders AB, Kern KB, Atlas M, Bragg S, Ewy GA. Importance of the duration of inadequate coronary perfusion pressure on resuscitation from cardiac arrest. J Am Colloid Cardiol 1985;6:113–8.
[28] Paradis NA, Martin GB, Rosenberg J, et al. Coronary perfusion pressure and the return of spontaneous circulation in human cardiopulmonary resuscitation. JAMA 1990;263:1106–13.
[29] Steen S, Liao Q, Pierre L, Paskevicius A, Sjöberg T. The critical importance of minimal delay between chest compressions and subsequent defibrillation: a haemodynamic explanation. Resuscitation 2003;58:249–58.
[30] Frenneaux M. Cardiopulmonary resuscitation – some physiololgical considerations. Resuscitation 2003;58:259–65.
[31] Eftestøl T, Sunde K, Steen PA. Effects of interrupting precordial compressions on the calculated probability of defibrillation success during out-of-hospital cardiac arrest. Circulation 2002;105:2270–7.
[32] Dalzell GW, Adgey A. Determinants of successful transthoracic defibrillation and outcome in ventricular fibrillation. Br Heart J 1991;65:311–6.
[33] Recommended guidelines for uniform reporting of data from out-of hospital cardiac arrest: the 'Utstein style'. Prepared by a task force of representatives from the European Resuscitation Council, American Heart Association, Heart and Stroke Foundation of Canada, Australian Resuscitation Council. Resuscitation 1991;22:1–26.

ELSEVIER

Resuscitation 59 (2003) 181–188

RESUSCITATION

www.elsevier.com/locate/resuscitation

VF recurrence: characteristics and patient outcome in out-of-hospital cardiac arrest

Anouk P. van Alem [a,*], Jelle Post [a], Rudolph W. Koster [b]

[a] *Department of Cardiology, Academic Medical Centre, room B2-239, Meibergdreef 9, 1105 AZ Amsterdam, Netherlands*
[b] *Department of Cardiology, Academic Medical Centre, room B2-238, Meibergdreef 9, 1105 AZ Amsterdam, Netherlands*

Received 11 February 2003; received in revised form 2 May 2003; accepted 9 May 2003

Abstract

Background: Refibrillation after successful defibrillation in out-of-hospital cardiac arrest is a frequent event. Little is known of factors that predispose to the occurrence of refibrillation. The effect of recurrence of ventricular fibrillation (VF) on survival is not known. *Methods:* Data of patients in out-of-hospital cardiac arrest were collected in a combined first responder and paramedic programme in Amsterdam, the Netherlands. Continuous recorded rhythm data of 322 patients covering the entire out-of-hospital resuscitation attempt was included in the analysis. Recurrence of VF was recorded, the patient and process characteristics were analysed in relation to the occurrence of refibrillation. The number of refibrillations was related to survival. *Results and conclusion:* Of the studied patients 79% had at least one recurrence of VF, and a median number of two times 25–75%; one to four times). The median time from successful first shock to VF recurrence was 45 s (25–75%: 23–115 s). A significant inverse relation was found between the number of refibrillations and survival of out-of-hospital cardiac arrest. The recurrence of VF was independent of the underlying cardiac disorder, the time to defibrillation, the defibrillation waveform and other characteristics of the patient and the process. Anti-arrhythmics should be considered in all patients found in VF to reduce the number of recurrences.

Keywords: Ventricular fibrillation; Defibrillation; Out-of-hospital CPR

Resumo

Contexto: A recorrência da fibrilhação ventricular (FV) na paragem cardíaca extra-hospitalar, após desfibrilhação bem sucedida, é um acontecimento frequente. Os factores predisponentes ao seu aparecimento são pouco conhecidos. As consequências da recorrência da FV na sobrevida ainda não é conhecida. *Métodos:* Foram analisados dados de doentes em paragem cardíaca ocorrida fora do hospital a partir de um projecto de "first responder" e paramédicos, em Amesterdão, na Holanda. O estudo analítico incluiu os registos electrocardiográficos contínuos de 322 doentes, cuja reanimação ocorreu fora do hospital. Registaram-se as situações de recorrência de FV, foram analisados os processos e as características dos doentes em relação à recorrência da FV. Esta recorrência foi relacionada com a sobrevida. *Resultados e conclusão:* Dentro dos doentes estudados a recorrência da FV ocorreu uma vez em cerca de 79% casos e em média duas vezes em 25-75% casos. O tempo médio entre o primeiro choque e a recorrência de FV foi de 45 s (25-75%: 23-115 s). Foi verificada uma relação inversa entre o n° de refibrilhações e a sobrevida da PCR fora do hospital. A recorrência da FV foi independente da doença cardíaca de base, do tempo de desfibrilhação, da curva de desfibrilhação e de outras características do doente e do processo. Os antiarrítmicos deverão ser considerados em todos os doentes encontrados em FV, para reduzir o n° de recorrências.

Palavras chave: Fibrilhação ventricular; Desfibrilhação reanimação fora do hospital

* Corresponding author. Tel.: +31-20-566-7644; fax: +31-20-566-6809.
E-mail address: a.p.vanalem@amc.uva.nl (A.P. van Alem).

0300-9572/03/$ - see front matter © 2003 Elsevier Ireland Ltd. All rights reserved.
doi:10.1016/S0300-9572(03)00208-9

Resumen

Antecedentes: La refibrilación después de una desfibrilación exitosa en paro cardíaco extrahospitalario es un evento frecuente. No se conoce el efecto de la recurrencia de la fibrilación ventricular (VF) sobre la sobrevida. *Métodos*: Se recogieron los datos de los pacientes de paro cardíaco extrahospitalario en un programa de respuesta combinada de paramédicos y primeros respondedores en Ámsterdam, en los países bajos. Se incluyeron en el análisis los registros continuos de ritmo de 322 pacientes, cubriendo todo el intento de reanimación extrahospitalaria. Se registró la recurrencia de la VF, se analizaron las características del paciente y del procedimiento en relación con la ocurrencia de la refibrilación. El número de refibrilaciones se relacionó con sobrevida. *Resultados y conclusiones*: El 79% de los pacientes estudiados presentaron al menos una recurrencia de VF, con una mediana de dos veces 25-75%, una a cuatro veces).La mediana de tiempo desde la primera descarga desfibriladora a la recurrencia de VF fue de 45 s (25-75%: 23-115 s). Se encontró una relación inversa significativa entre el número de refibrilaciones y la sobrevida al paro cardíaco extrahospitalario. La recurrencia de la VF fue independiente de la alteración cardíaca subyacente, tiempo hasta la desfibrilación, forma de onda de la descarga y de otras características del paciente y del procedimiento. Deben considerarse los antiarrítmicos en todos los pacientes encontrados en VF para reducir el número de recurrencias.

Palabras clave: Fibrilación ventricular; Desfibrilación; Reanimación cardiopulmonar (RCP) extrahospitalaria

1. Introduction

Refibrillation after successful defibrillation in out-of-hospital cardiac arrest is a frequent event but its cause, consequence and management have not been clarified [1–3]. Recently in an observational study of out-of-hospital cardiac arrest the occurrence and frequency of refibrillation has not been found to affect survival [2]. The effect of the waveform of defibrillation on the occurrence of refibrillation is unknown.

This observational study examines the characteristics of VF recurrence in out-of-hospital cardiac arrest patients, patient characteristics and process characteristics on VF recurrence, and the relation between VF recurrence and survival of out-of-hospital cardiac arrest. Moreover, this study describes the recognition of refibrillation by the automated external defibrillator (AED) and paramedics using manual defibrillators.

2. Material and methods

2.1. Study design

Between January 2000 and June 2002 data of all patients in cardiac arrest, identified by the emergency medical system (EMS) dispatch centre, were collected prospectively. For the purpose of this analysis, patients with VF as initial rhythm in whom resuscitation was attempted were included. Patients below the age of 18 years were excluded.

The study area included the city of Amsterdam and urban and rural surrounding areas, including 1.6 million inhabitants and covering 885 sq. km.

2.2. EMS

The EMS consisted of police and fire fighter first responders, equipped with an AED and ambulances equipped with a manual defibrillator and manned with a team qualified to perform advanced cardiopulmonary life support (ACLS). The first responders and ambulances were equipped with both biphasic (biphasic truncated exponential) waveform and monophasic (monophasic damped sine) waveform defibrillators (LIFEPAK 500 and LIFEPAK 12 (Medtronic Physio-Control, Redmond, WA, USA), respectively). When the first responders arrived first at the scene they used the AED. The AED was programmed to analyse the rhythm 60 s after one or more shocks and 180 s after the initial analysis indicated a non-shockable rhythm or when, in a subsequent analysis, no shock was advised. When the ambulance arrived, the paramedics took over the resuscitation and used their own manual device. The energy protocol for all defibrillators was 200, 200 and 360 J thereafter as needed for defibrillation.

In the beginning of the study the first choice of antiarrhytbmic treatment in persistent VF was lidocaine. During the study the new guidelines were introduced and amiodarone was used. No standard protocol existed for recurrent VF.

2.3. Data collection

Data collection took place on scene by dedicated data collectors. Data were obtained on the circumstances of the arrest, the complaints of the patient prior to collapse, the estimated time of collapse, witnesses, bystander cardiopulmonary resuscitation, sequence of events, and relevant time points and time intervals, by directly interviewing all persons involved. The continuous rhythm data from the AEDs and manual defi-

brillators were downloaded into a laptop computer at the scene. Deviations of internal clocks were corrected by comparison with radio-controlled wristwatches. Date of death or discharge was obtained from hospital records. Medical history was obtained from the charts of the patient admitted to the ICU.

2.4. Rhythm and data analysis

The rhythm data extended from connection of the electrodes to the arrival at the hospital. The rhythm data was analysed independently by a researcher and a physician, both experienced in rhythm analysis. If necessary, agreement was sought. All rhythm analysis was constrained to the first eight shocks. Rhythms were categorised as VF (a disorganised rhythm, with a median amplitude of >100 μV), asystole (<100 μV) or organised rhythm (one or more QRS complexes). Shock success was defined as the termination of VF at 5 s after the shock. Persistent VF was defined as VF at 5 s after the shock. Refibrillation was defined as the recurrence of VF after a successful shock. The rhythm before each shock, the time of each shock delivery, rhythm at 5 s after each shock, the occurrence of VF recurrence, the rhythm before VF recurrence and the time of VF recurrence were recorded.

Return of spontaneous circulation (ROSC) was defined as the return of palpable pulse for at least 15 s. Patients were classified as having a history of ischaemic heart disease when their medical history included angina pectoris, myocardial infarction, coronary bypass surgery or angioplasty. Based on complaints prior to the collapse and the ECG or laboratory findings during admission, patients were classified as having signs of acute ischaemia prior to collapse. This could not be determined in patients in whom the complaints prior to the collapse were unknown and who died before hospital admission.

2.5. Ethics

Medical ethics committees from participating hospitals and EMS approved the study. Authorisation for study of patient data was obtained from patients or family members post resuscitation, and all consented to provide access to their medical records.

2.6. Statistical methods

Time intervals are expressed in medians and 25–75% percentiles. Significance was tested by calculating the Chi-square statistic for proportions and the Mann–Whitney U-test for continuous variables. Significance was accepted when a two-sided P-value was <0.05 or the confidence interval did not include unity. Trends were tested with the Chi square test for trends. All statistics were performed in SPSS 10.0 for the Apple Macintosh.

3. Results

3.1. Inclusion

In the study-period 682 cardiac arrests were directly identified by the EMS dispatch centre. VF was the initial rhythm of 380 patients (56%). Of these, 322 patients could be included in the analysis (Fig. 1). The median duration of the continuously recorded rhythm data was 35 min (25–75%; 27–42 min).

3.2. VF recurrence

VF recurrence occurred at least once in 79% of the patients. The characteristics of the VF recurrence are shown in Table 1. In general, the incidence of subsequent recurrence after a successful shock was 69% (810/1170). Fig. 2 shows in a cumulative graph the time interval from the successful first shock to VF recurrence. The patient and process characteristics and outcome, stratified for VF recurrence, are shown in Table 2. None of the variables was significantly different in the group with or without VF recurrence except the time to ROSC, which was of significantly longer duration in patients with at least one VF recurrence.

The percentage of VF recurrence was 78% after the successful first shock by first responders and 75% after the successful first shock by the paramedics (ns).

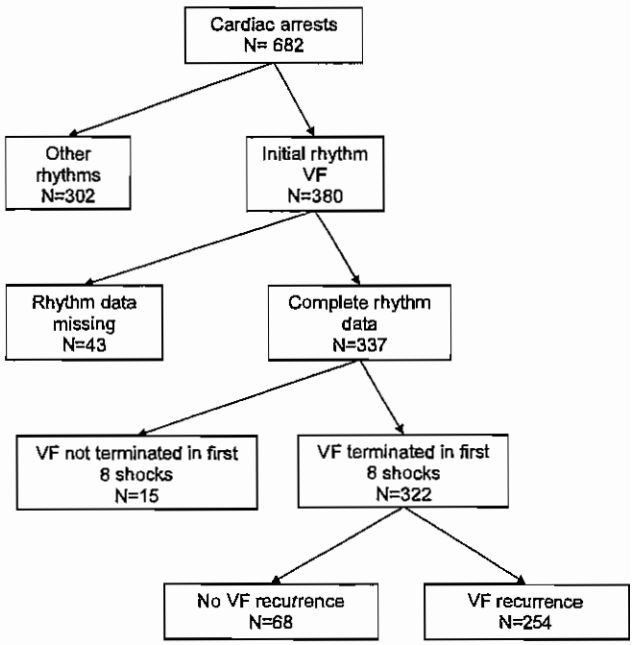


Fig. 1. Flowchart showing the patients in and excluded in the aualysis.

Table 1
Descriptive of VF recurrence

Description of VF recurrence[a]	$n = 322$
Total amount of shocks for VF	1453
Total amount of successful shocks	1170
Total amount of VF recurrences	810
Termination of VF with first shock	257/322 (80%)
VF recurrence after successful first shock	197/257 (77%)
Patient with a least once VF recurrence after a successful shock	254/322 (79%)
Frequency of VF recurrence per patient, median (25–75%)	2 (1–4)
Time to VF recurrence after successful first shock[b]	45 (23–115)
Time to 2nd–8th VF recurrence after a successful shock	52 (22–122)
Rhythm before VF recurrence	
Asystole	94 (48%)
Organised rhythm	103 (52%)

[a] All analyses concern the first eight shocks.
[b] All time intervals are in seconds, median (25–75%).

3.3. Waveform

The biphasic waveform defibrillator had a higher success percentage in terminating VF with a single shock: 91% for a biphasic shock and 75% for a monophasic shock, $P = 0.001$. The rate of refibrillation was 79% after a successful monophasic shock and 74% after a successful biphasic shock (ns). The median time interval from successful shock to refibrillation was 49 s (25–75%: 27–119 s) after a monophasic shock and 36 s (25–75%: 17–77 s) after a biphasic shock (ns).

3.4. VF recurrence and survival

Fig. 3 shows the relation between the number of VF recurrences during the resuscitation attempt and survival to hospital discharge. There is a trend to decreased survival with increasing recurrence of VF. The linear association of this trend is significant ($P = 0.005$).

3.5. Recognition of VF recurrence

Time to delivery of the second shock for recurrent VF is shown in Fig. 4. This cumulative curve shows that the median time from recurrence to next shock when using an AED was a median 75 s (25–75%: 58–87 s). When a manual defibrillator, operated by the paramedics was used the time from VF recurrence to consecutive shock was a median of 43 s (25–75%: 22–110 s).

4. Discussion

Time to first defibrillation has been established as the most critical intervention for survival of cardiac arrest [4,5]. Survival also depends on many other patient and process characteristics and on the further treatment. This study found the number of refibrillations to be another factor determining survival of out-of-hospital cardiac arrest. In this study the recurrence of VF was independent of the underlying cardiac disorder, the time to defibrillation, the defibrillation waveform and other characteristics of the patient and the process.

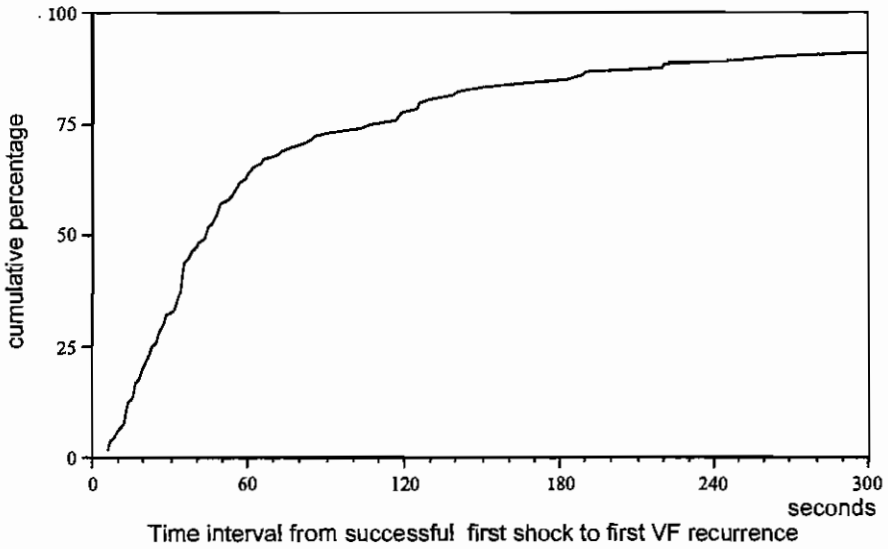


Fig. 2. Cumulative graph showing the time interval from the successful first shock to the recurrence of VF, $n = 197$. The median time was 45 s (25–75%: 23–115).

Table 2
Univariate analysis of occurrence of VF recurrence after a successful shock

	No VF recurrence[a], $n=68$	≥ One time VF recurrence, $n=254$	P-value
Age, years ± S.D.	66 ± 13	65 ± 13	0.6
Gender			
Female	22% (15)	17% (43)	0.3
Male	78% (53)	83% (211)	0.3
Weight, kg ± S.D.	82 ± 15	84 ± 15	0.4
History of ischaemia[b]	65% (24/37)	74% (125/168)	0.3
Acute ischemia[c]	47% (27/58)	57% (116/204)	0.2
Witnessed arrest	91% (62)	94% (240)	0.4
Bystander CPR	59% (40)	52% (131)	0.2
Time to CPR[d]	240 (60–433)	240 (60–540)	0.9
Time to first shock[d]	658 (550–759)	672 (546–900)	0.5
Time to ACLS[d]	810 (658–975)	840 (660–1020)	0.2
ROSC	62% (42)	66% (168)	0.5
Shocks to ROSC, median (25–75%)	1 (1–1)	5 (2–7)	<0.001
Time to first ROSC[d]	870 (648–1185)	1350 (931–1881)	<0.001
Admission	54% (37)	66% (168)	0.5
Survival to hospital discharge	24% (16)	20% (50)	0.5

CPR denotes cardiopulmonary resuscitation, ACLS denotes advanced cardiopulmonary life support, and ROSC denotes return of spontaneous circulation.

[a] All analyses concern first eight shocks.

[b] Patients history was only registered for the patients admitted to a hospital.

[c] In these patient there were signs of acute ischaemia based on complaints prior to collapse, on ECG or laboratory findings. In 60 patients there was not enough information available.

[d] Time intervals are measured from the moment of the collapse. The moment of collapse could only be estimated in patients with a witnessed cardiac arrest. Time intervals are in seconds, median (25–75%).

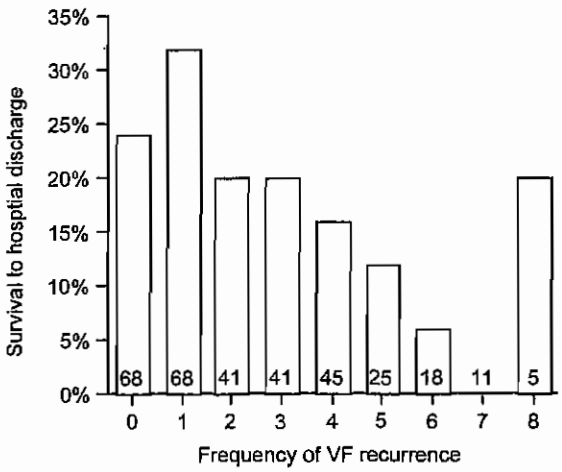


Fig. 3. Bar graph illustrates the frequency of VF recurrence in relation to survival to hospital discharge. The linear association is significant ($P=0.005$). The numbers in the base of the bars represent the number of patients included in the group.

4.1. Occurrence of refibrillation

It is important to make a distinction between persistent VF and VF recurrence, since the mechanisms of failure to defibrillate and refibrillation are considered to be different [1,6,7]. This distinction is not simply made during resuscitation but may be relevant for administration and understanding the mechanism of action of anti-arrhythmics, such as amiodarone, indicated for shock refractory VF [8,9]. We defined persistent VF as VF present at 5 s after the shock and a successful shock as termination of VF at 5 s. This definition of shock success is recommended by others [1,10], and can be judged with confidence when baseline drift and artefacts after a shock have disappeared but may occasionally misclassify recurrence as persistence of VF. Our observed rate of VF recurrence after a successful shock (69%) is comparable with the study of Weaver et al. who observed 68% refibrillation after a successful shock [11]. Our observed percentage of patients with VF recurrence (79%) was higher than in the study of White et al. who observed VF recurrence in 64% of patients [2].

4.2. Effect of recurrence on survival

We found an inverse relation between the number of VF recurrences and survival. Obviously, when recurrent VF occurs, more shocks were needed to achieve ROSC and the time to ROSC was significantly longer. Longer or repeated circulatory arrest could explain this inverse relation. Another explanation could be the damaging effect on the myocardium when more defibrillation shocks and higher cumulative energy was needed. It is also possible that recurrence is promoted by more extensive myocardial ischaemia with more extensive pump failure and failure to achieve ROSC.

Weaver described an inverse relation between the number of shocks a patient received and the chance of

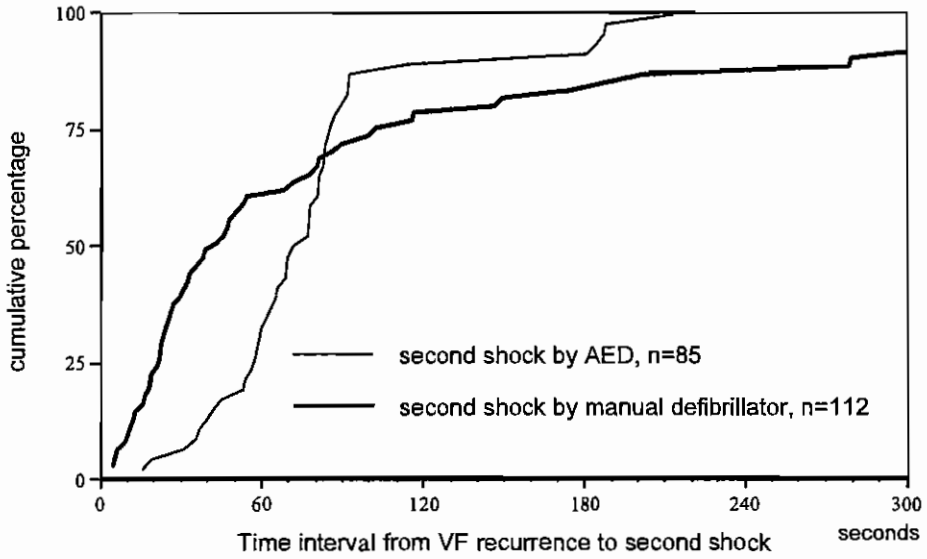


Fig. 4. Cumulative graph showing the time interval in seconds from VF recurrence to tbe subsequent sbock from the AED operated by first responders and the manual defibrillator operated by the paramedics. The paramedics rapidly shocked over 60% of the patients with refibrillation within 1 min, but after 3 min they only had shocked 85% of the patients. In contrast, the AED only shocked 30% of the recurrences in 1 min but after 4 min all patient with VF recurrence were sbocked.

survival, but they did not make the distinction between shocks delivered for persistent VF and recurrent VF. White et al. [2] in a recent study, could not demonstrate a relation between the occurrence and frequency of refibrillation and survival. In their analysis, with a limited number of patients, only the occurrence and frequency of refibrillation during first responder defibrillation were included while it is to be expected that many recurrences took place during subsequent paramedic care.

4.3. Treatment of refibrillation

First responders with AEDs and paramedics with manual defibrillators acted differently when defibrillation occurred. The paramedics recognised VF recurrence quickly in most cases and delivered a second shock rapidly (over 60% of recurrences were shocked within 1 min) but after 5 min they only had shocked about 85% of the recurrences. It is possible that this delay was caused by other activities by paramedics, such as ACLS measures including intubation and administering medication, competing for their attention and not giving priority to defibrillation. The AED shocked only 30% of the recurrences within 1 min but after 3.5 min all patients with recurrence received a shock. The AED was programmed to perform an automated rhythm analysis 60 s after the first shock. When no VF was present at the time of this analysis the next rhythm analysis was performed 3 min later. So all recurrences occurring in the 1st min after the shock were recognised at 1 min and defibrillated 20 s later. When the time to VF recurrence was more then 1 min this was recognised in the second analysis, 3 min later.

4.4. Waveform

The biphasic waveform is superior to the monophasic waveform in efficacy and safety in termination of VF [12–17]. In animal laboratory studies, the depression of myocardial function was less after biphasic waveform defibrillation than after monophasic waveform defibrillation. In agreement with these previous studies we observed a significant better defibrillation rate with biphasic defibrillators, but no relation was found between the defibrillation waveform after the successful first shock and the occurrence of refibrillation or time to refibrillation, consistent with the study of Gliner et al. [1].

4.5. Ischaemia

In animal and in vitro studies [7,18,19], VF recurrence is recorded as partly attributable to ischaemia. In several clinical studies it is assumed that refibrillation is attributable to the underlying disease [1,2], but in our study we could not demonstrate a clear difference in the occurrence of VF recurrence in patients with signs of acute ischaemia or with a history of ischaemic heart disease. This can be explained by the fact that VF in itself leads to myocardial ischaemia and, therefore, could have obscured the distinction between ischaemia as cause or as subsequence.

4.6. How to respond to recurrent VF?

We observed a relation between recurrence of VF and survival, but our study was not designed to prove a causal relatiou. However, with the observed high rate of VF recurrence (79%) aggressive anti-arrhythmic treatment after defibrillation should be considered. The distinction between persistence (for which amiodarone is indicated [8,9]) and immediate recurrence (for which lidocaiue is probably effective [20,21]) is difficult. But for reasons of simplicity amiodarone may be the first choice, to be given immediately after the first VF episode has terminated. Ideally such a new protocol should be tested in randomised studies.

4.7. Limitations

The analysis was confined to the 322 patients with complete rhythm data of VF cardiac arrests. In 43 patients rhythm data was missing, caused by practical factors (i.e. lost files, no continuous data, transmission errors) but there was no indication that selection bias had occurred.

The analysis of the waveform of defibrillation was confined to the first shock, because of the mixture of biphasic and monophasic waveform defibrillators (both AEDs and manual defibrillators), which could be used in an individual patient. Outcomes of the two groups reported beyond the first shock would reflect this mixed monophasic and biphasic therapy.

5. Conclusions

Refibrillation occurs in the majority of cases during out-of-hospital cardiac arrest and is negatively associated with survival. Refibrillation was neither associated with the type of shock waveform nor with patient- or process characteristics.

Anti-arrhythmics should be considered after defibrillation in all patients found in VF and not only for persistent VF.

Acknowledgements

This study was supported by a grant from The Netherlands Heart Foundation (grant 98.179) and an unrestricted grant from Medtronic Physio-Control, Redmond, WA, USA.

References

[1] Gliner BE, White RD. Electrocardiographic evaluation of defibrillation shocks delivered to out-of-hospital sudden cardiac arrest patients. Resuscitation 1999;41:133–44.
[2] White RD, Russell JK. Refibrillation, resuscitation and survival in out-of-hospital sudden cardiac arrest victims treated with biphasic automated external defibrillators. Resuscitation 2002;55:17–23.
[3] Blouin D, Topping C, Moore S, Stiell I, Afilalo M. Out-of-hospital defibrillation with automated external defibrillators: postshock analysis sbould be delayed. Ann Emerg Med 2001;38(3):256–61.
[4] Eisenberg M, Bergner L, Hallstrom A. Out-of-hospital cardiac arrest: improved survival with paramedic services. Lancet 1980;1:812–5.
[5] Waalewijn RA, de Vos R, Koster RW. Out-of-hospital cardiac arrests in Amsterdam and its surrounding areas: results from the Amsterdam resuscitation study (ARREST) in 'Utstein' style. Resuscitation 1998;38:157–67.
[6] Li H, Jones D, Yee R, Klein G. Defibrillation shocks produce different effects on Purkinje fibers and ventricular muscle: implications for successful defibrillation, refibrillation and post-shock arrhythmia. J Am Coll Cardiol 1993;22:607–14.
[7] Qin H, Walcott GP, Killingsworth CR, Rollins DL, Smith WM, Ideker RE. Impact of myocardial ischemia and reperfusion on ventricular defibrillation patterns, energy requirements, and detection of recovery. Circulation 2002;105:2537–42.
[8] Kudenchuk PJ, Cobb LA, Copass MK, et al. Amiodarone for resuscitation after out-of-hospital cardiac arrest due to ventricular fibrillation. New Engl J Med 1999;341:871–8.
[9] Dorian P, Cass D, Scbwartz B, Cooper R, Gelaznikas R, Barr A. Amiodarone as compared with lidocaine for shock-resistant ventricular fibrillation. New Engl J Med 2002;346:884–90.
[10] Poole J, White R, Kanz K, et al. Low-energy impedance-compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out-of-hospital cardiac arrest. LIFE Investigators. J Cardiovasc Electrophysiol 1997;8:1373–85.
[11] Weaver W, Cobb L, Copass M, Hallstrom A. Ventricular defibrillation—a comparative trial using 175-J and 320-J shocks. New Engl J Med 1982;307:1101–6.
[12] Gliner BE, Lyster TE, Dillion SM, Bardy GH. Transthoracic defibrillation of swine with monophasic and biphasic waveforms. Circulation 1995;92:1634–43.
[13] Bardy GH, Ivey TD, Allen MD, Johnson G, Mehra R, Greene HL. A prospective randomized evaluation of biphasic versus monophasic waveform pulses on defibrillation efficacy in humans. J Am Coll Cardiol 1989;14:728–33.
[14] Bardy GH, Marchlinski FE, Sharma AD, et al. Multicenter comparison of truncated biphasic shocks and standard damped sine wave monophasic shocks for transthoracic ventricular defibrillation. Circulation 1996;94:2507–14.
[15] Tang W, Weil MH, Sun S, et al. The effects of biphasic and conventional monophasic defibrillation on postresuscitation myocardial function. J Am Coll Cardiol 1999;34:815–22.
[16] Tang W, Weil MH, Sun S, et al. A comparison of biphasic and monophasic waveform defibrillation after prolonged ventricular fibrillation. Chest 2001;120:948–54.
[17] Higgins SL, Herre JM, Epstein AE, et al. A comparison of biphasic and monophasic shocks for external defibrillation. Prehosp Emerg Care 2000;4:305–13.
[18] Axelrod P, Verrier R, Lown B. Vulnerability to ventricular fibrillation during acute coronary arterial occlusion and release. Am J Cardiol 1975;36:776–82.

[19] Zaugg CE, Wu ST, Barbosa V, et al. Ventricular fibrillation-induced intracellular Ca^{2+} overload causes failed electrical defibrillation and post-shock reinitiation of fibrillation. J Mol Cell Cardiol 1998;30:2183–92.
[20] Lie KI, Wellens HJ, van Capelle FJ, Durrer D. Lidocaine in the prevention of primary ventricular fibrillation. A double-blind, randomized study of 212 consecutive patients. New Engl J Med 1974;291:1324–6.
[21] Koster RW, Dunning AJ. Intramuscular lidocaine for prevention of lethal arrhythmias in the prehospitalization phase of acute myocardial infarction. New Engl J Med 1985;313:1105–10.

Resuscitation (2008) 79, 28–33

available at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/resuscitation

CLINICAL PAPER

A high peak current 150-J fixed-energy defibrillation protocol treats recurrent ventricular fibrillation (VF) as effectively as initial VF☆

Erik P. Hess[a], James K. Russell[b], Ping-Yu Liu[c], Roger D. White[d,*]

[a] Department of Emergency Medicine, Mayo Clinic College of Medicine, 200 First Street SW, Rochester, MN 55905, USA
[b] Philips Medical Systems, 2301 Fifth Avenue, Suite 200, Seattle, WA 98121, USA
[c] Fred Hutchinson Cancer Research Center, Seattle, WA 98109, USA
[d] Department of Anesthesiology and Division of Cardiovascular Diseases, Department of Internal Medicine, Mayo Clinic College of Medicine, City of Rochester Early Defibrillation Program, 200 First Street SW, Rochester, MN 55905, USA

Received 5 March 2008; received in revised form 18 April 2008; accepted 28 April 2008

KEYWORDS
Automated external defibrillator (AED);
Defibrillation;
Cardiac arrest;
Cardiopulmonary resuscitation (CPR);
Return of spontaneous circulation;
Resuscitation;
Emergency medical services

Summary
Objective: We tested the hypothesis that the frequency of shock success differs between initial and recurrent episodes of ventricular fibrillation (VF).
Methods: Out-of-hospital cardiac arrest patients presenting with VF from December 1996 to February 2007 defibrillated using an AED with a fixed-energy protocol (150 J) (Philips Medical Systems, Seattle, WA) were included for analysis. We defined shock success as termination of VF within 5 s post-shock (either asystole or organized rhythm). Generalized estimating equation (GEE) analysis was used to adjust for the interrelatedness of shocks within each patient.
Results: One hundred and three events occurred during the study period. Patient characteristics included: mean age 64.4 years, 82.5% male, and 81.6% bystander witnessed. Synchronized call-to-shock time was 6.4 ± 2.3 min (mean ± S.D.). VF recurred in 64 (62.1%) patients. Two hundred and fifty-seven shocks delivered for initial (101) or recurrent (156) VF were available for analysis. Initial shocks terminated VF in 93/101 (92.1%); subsequent shocks terminated recurrent VF in 140/156 (89.7%). GEE odds ratio for shock type (initial versus refibrillation) was 1.10 (95% CI 0.37–3.24, $p = 0.87$). After adjusting for potential confounders, shock type remained insignificant (OR 1.14, 95% CI 0.41–3.2, $p = 0.80$). We observed no significant difference in ROSC (34.4% versus 46.2%, $p = 0.23$) or survival (37.5% versus 41.0%, $p = 0.72$) between those with and without VF recurrence.

☆ A Spanish translated version of the summary of this article appears as Appendix in the final online version at doi:10.1016/j.resuscitation.2008.04.028.

* Corresponding author. Tel.: +1 507 255 4235; fax: +1 507 255 6463.
E-mail address: white.roger@mayo.edu (R.D. White).

0300-9572/$ – see front matter
doi:10.1016/j.resuscitation.2008.04.028

Conclusions: We observed no significant difference in the frequency of shock success between initial and recurrent episodes of VF using this AED with a 150 J fixed-energy protocol. VF recurrence is common and does not adversely affect shock success, ROSC or survival.

Introduction

Defibrillation is conventionally defined as removal of ventricular fibrillation (VF) within 5 s of shock delivery.[1–3] Biphasic defibrillators terminate VF with the initial shock in over 90% of cases when used in accordance with manufacturers' recommendations.[4,5] However, defibrillation does not correct the underlying abnormality responsible for initiation of VF, and VF has been reported to recur in 52–69% of patients while under the care of first responders.[4,6–8] Evidence from a recent clinical trial suggests that higher rates of termination of recurrent episodes of VF may be achieved with an escalating higher energy protocol (200–300–360 J) than with a fixed, lower energy protocol (150–150–150 J).[9] In our EMS system, a fixed-energy 150-joule (J) protocol has been employed by first responder AEDs since 1996.[10] We examined our defibrillation data to test the hypothesis that the frequency of shock success differs between initial and recurrent episodes of VF.

Methods

Study setting and population

We have described the materials and methods employed in this study in several previous publications.[10–14] This report is part of an ongoing Institutional Review Board-approved observational outcome study of all consecutive patients with non-traumatic out-of-hospital cardiac arrest (OHCA) treated by first responder personnel (police officers and firefighters) in our public service area (population in 2006, 138,221). This included patients within the city of Rochester, MN and the surrounding area. We included patients who suffered atraumatic OHCA of documented or presumed cardiac etiology, had VF as the initial rhythm, and were treated by first responder personnel between December 1996 and February 2007.

Defibrillator waveform and energy levels

Beginning in December 1996, Forerunner AEDs (Philips Medical Systems, Seattle, WA), were deployed by first responders, first by police and subsequently by both police and fire rescue personnel. The defibrillators use a biphasic truncated exponential waveform with a fixed 150 J energy protocol.

Classification of post-shock rhythms and definition of shock success

The rhythm at 5 s following each shock was characterized as VF (disorganized, median peak-to-peak amplitude >100 μV), asystole (amplitude <100 μV), or organized (one or more QRS complexes in the 5 s post-shock period). Three authors (RDW, EPH, JKR) independently reviewed and classified post-shock rhythms. Disagreements were resolved by consensus. Shock success was defined as conversion of VF to a non-VF rhythm, either asystole or OR, the latter with or without restoration of spontaneous circulation (ROSC).

Outcomes

The primary outcome was termination of VF within 5 s of shock delivery without need for ALS interventions, including pharmacologic therapy (e.g., epinephrine or vasopressin). The secondary outcome was neurologically intact survival to hospital discharge. By convention, neurologically intact survival was defined as an overall performance category (OPC) score of 1 or 2 (1, good recovery; 2, moderate disability but independent; 3, severe disability but conscious; 4, persistent vegetative state; 5, death).[15]

Statistical analysis

For comparison of ROSC, survival, and EMS event data, patients were divided and analyzed in two groups—initial and recurrent VF. We used χ^2 analysis to test for differences between the groups. All probability tests were two-tailed. We considered p-values of <0.05 to be statistically significant.

Because response to shocks in each patient may be more related to one another than to shocks between patients, generalized estimating equation (GEE) analysis, a technique that accounts for repeated measures, was used to adjust for the interrelatedness of shocks within each patient.[16] GEE was used to assess the association between shock type (presenting versus refibrillation) and shock success in both univariate and multivariate models. To explore further whether shock success decreased with each successive shock, the variable "shock type" was also analyzed as an ordinal variable with five categories (i.e., shocks 1, 2, 3, 4, and ≥5). In addition, we compared shock success between pairs of successive shocks (i.e., shock # X and $X+1$) in patients who received at least two shocks.

Finally, we used multivariate logistic regression to determine the association between refibrillation and neurologically intact survival to hospital discharge and to identify independent predictors of survival. All analyses were performed using SAS™ software, Version 9.1.3 (SAS Institute Inc., Cary, North Carolina, USA).

Results

Description of patient population and defibrillation data

A total of 103 cardiac arrests with VF as the initial rhythm presented during the study period. VF recurred in 64 (62.1%) patients while under the care of first responders (before

Table 1 Characteristics of all cardiac arrest patients presenting in ventricular fibrillation

Variable	Overall $n=103$
Age, mean (S.D.)	64.4 (13.8)
Sex, *n* (%)	
Female	18 (17.5)
Male	85 (82.5)
Bystander witnessed, *n* (%)	
Yes	84 (81.6)
No	19 (18.5)
Time from call receipt to first shock in minutes, mean (S.D.)	6.3 (2.3)
ROSC with shocks only, *n* (%)	
Yes	40 (38.8)
No	63 (61.2)
Neurologically intact survival	
Yes	40 (38.8)
No	63 (61.2)

ROSC: return of spontaneous circulation.

Table 2 Data for patients with and without recurrent ventricular fibrillation (VF)

Variable	VF recurrence $n=64$	No VF recurrence $n=39$
Age, mean (S.D.)	64.7 (14.1)	63.9 (13.5)
Sex, *n* (%)		
Female	9 (14.1)	9 (23.1)
Male	55 (85.9)	30 (76.9)
Bystander witnessed, *n* (%)		
Yes	53 (82.8)	31 (79.5)
No	11 (17.2)	8 (20.5)
Time from call receipt to first shock in minutes, mean (S.D.)	6.6 (2.7)	5.9 (1.4)
ROSC with shocks only, *n* (%)		
Yes	22 (34.4)	18 (46.2)
No	42 (65.6)	21 (53.9)
Neurologically intact survival to hospital discharge		
Yes	24 (37.5)	16 (41.0)
No	40 (62.5)	23 (59.0)

ROSC: return of spontaneous circulation.

initiation of advanced life support interventions). Descriptive characteristics of the study population are displayed in Table 1. ROSC with shocks only was obtained in 40 (38.8%) patients, and 40 (38.8%) survived neurologically intact. Table 2 displays baseline characteristics of patients with and without VF recurrence. We observed no significant difference in the frequency of ROSC with shocks only between the two groups (34.4% versus 46.2%; $p=0.23$; absolute difference 11.8%; 95% CI −7.7 to 31.3). We also noted no difference in the percentage of patients who survived neurologically intact between the two groups (37.5% versus 41.0%; $p=0.72$; absolute difference 3.5%; 95% CI −15.9 to 23.0).

First responders delivered 264 shocks prior to advanced life support interventions. We were unable to classify post-shock rhythms for seven shocks due to artifact at 5 s from the shock, leaving 257 available for analysis (Fig. 1). Overall shock success for all VF episodes was 233/257 (90.7%). One hundred and six (41.2%) post-shock rhythms were classified as OR, 127 (49.4%) as asystole, and 24 (9.3%) as VF.

First shocks terminated VF in 93/101 (92.1%) cases. 140/156 (89.7%) shocks delivered for refibrillation terminated VF (absolute difference = 2.4%). Of the eight cases of refractory VF which were not terminated by the first shock, six were terminated with a second shock, one was terminated with a third shock, and one remained in VF at the end of BLS care. Among patients with ≥2 shocks ($n=64$), 194/218 (89.0%) shocks terminated VF.

Analysis of multishock data

In the univariate GEE model with "shock type" (initial versus refibrillation) as the independent variable, the odds ratio for shock success was not significant (OR

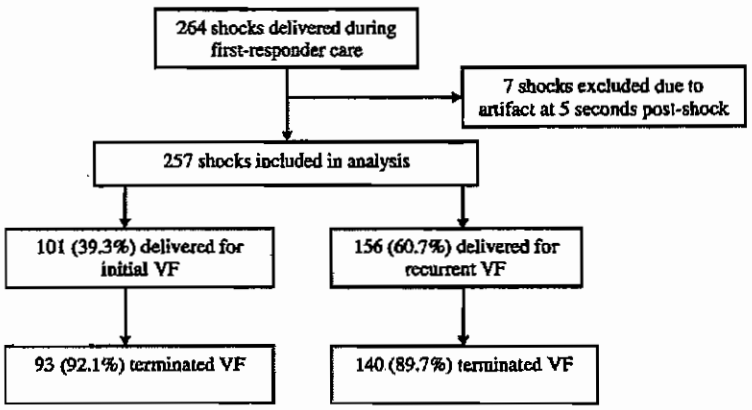


Figure 1 Flow diagram of shocks delivered during first responder care. VF, ventricular fibrillation.

Table 3 Shock success rate by shock number

Shock number	Shock success rate (total number of shocks = 257)
1	93/101 (92.1%)
2	58/63 (92.1%)
3	37/41 (90.2%)
4	18/21 (85.7%)
≥5	27/31 (87.1%)

1.10, 95% CI 0.37–3.24, $p=0.87$). After adjusting for age, sex, call-to-shock time, and bystander-witnessed arrest in the multivariate model, the odds ratio for shock success remained insignificant (OR 1.14, 95% CI 0.41–3.2, $p=0.80$). We also conducted univariate and multivariate analyses in the bystander-witnessed subgroup and observed similar results.

Table 3 displays the frequency of shock success by shock number. Shock success was similarly high in each shock subgroup. Because each successive shock number selects out successful defibrillations from the previous group, the frequencies in this table may be affected by selection bias. To reduce the risk of selection bias, we also assessed shock success in pairs such that only patients who received at least two, three, and four shocks were included in each successive comparison (Table 4). Among patients with both shock X and shock $X+1$ ($X=1$, 2, and 3), we observed no suggestion of any decrease in shock success for shock $X+1$.

Predictors of neurologically intact survival

We identified three independent predictors of neurologically intact survival to hospital discharge with multivariate logistic regression, including age, call-to-shock time, and bystander-witnessed arrest (Table 5). The odds ratio for refibrillation was not significant. We noted similar results in the bystander-witnessed subgroup.

Discussion

Summary of major findings

In this study we observed no significant difference in the frequency of shock success between initial and recurrent episodes of VF using a biphasic truncated exponential waveform defibrillator with a fixed 150 J energy protocol (Philips Medical Systems, Seattle, WA). The odds ratio for shock success based on shock type (initial versus refibrillation) in both univariate and multivariate GEE models was not significant. We noted a similar percentage of patients with ROSC with shocks only and with neurologically intact survival to hospital discharge in those with and without VF recurrence. Over 90% of VF episodes were terminated with one shock. Examination of our data suggests that changing from a non-escalating (150–150–150 J) to an escalating (200–300–360 J) energy protocol would offer little, if any incremental benefit in our practice setting.

Strengths and limitations of the study

The strengths of this study primarily relate to complete data capture and close follow-up of all patients. Although we could not classify a few post-shock rhythms due to artifact at 5 s post-shock, ECG data were available in all patients. All patients who survived to hospital admission were transferred to one hospital, and outcome data were available for all these patients. Finally, we analyzed the data to determine if any decrease in shock success occurred between initial and subsequent shocks. The variable "shock type" was analyzed both as a binary (initial versus refibrillation) variable within a GEE model and as an ordinal variable with five categories. In addition, we analyzed the frequency of shock success in pairs of successive shocks, reducing the risk of selection bias in the analysis.

Our study is limited primarily by its observational design and relatively small sample size. Unmeasured confounding

Table 4 Comparison of shock success rates between shock X and $X+1$ in patients who received at least $X+1$ shocks

Shock numbers compared	N	Shock X (%)	Shock $X+1$ (%)	Difference $(X+1)-X$[a] (%)	p[b]	One-sided 95% confidence lower limit (%)
1 and 2	62	87.1	91.9	4.8	0.55	−4.0
2 and 3	40	87.5	90.0	2.5	1.00	−6.7
3 and 4	21	81.0	85.7	4.7	1.00	−3.1

[a] For the shock $(X+1)$ success − shock X success rate difference.
[b] p value by the McNemar's test for paired binary data.

Table 5 Results of multivariate logistic regression predicting neurologically intact survival to hospital discharge

Variable	Odds ratio	95% confidence interval	p Value
Age (increase of 1 year)	0.93	0.89–0.97	0.0003
Sex (female vs. male)	0.72	0.18–2.84	0.64
Call-to-shock time (increase of 1 min)	0.64	0.47–0.87	0.004
Any refibrillation (no vs. yes)	1.07	0.39–2.93	0.90
Bystander witnessed (no vs. yes)	0.07	0.01–0.63	0.02

factors may have contributed to the frequency of shock success. However, we measured response to shocks only during BLS care; we excluded all shocks delivered after administration of epinephrine or other medications. This approach limits potential confounding that could have been introduced during resuscitative efforts. Moreover, the high rate of shock success for both initial and recurrent VF episodes suggests that VF termination is relatively insensitive to underlying differences between patients. Although the relatively small sample size limits our statistical power to show a difference in frequency of shock success, the absolute difference observed was small (2.4%). Even if a larger sample size should provide sufficient power to detect a difference smaller than 2%, the difference would not likely be clinically significant.

Comparison with other published studies

Findings from a recent clinical trial suggest that higher refibrillation termination rates may be achieved with an escalating higher energy protocol (200–300–360 J) than with a fixed, lower energy protocol (150–150–150 J).[9] Examination of our data revealed no significant decrease in VF termination rates between shocks delivered for initial versus recurrent VF. One potential explanation for the differences observed beyond that due to study design relates to the likely determinants of defibrillator effectiveness. Medtronic (LIFEPACK 500) designed the non-escalating fixed-energy defibrillators used in the BIPHASIC study, and Philips (ForeRunner) designed the defibrillator used in the current investigation. Although both AEDs deliver 150 J of energy with each shock, the voltage, peak current, and pulse duration of the defibrillatory waveform differ between the devices. A more detailed discussion of the differences in defibrillator and waveform designs can be found elsewhere.[17]

van Alem et al. also conducted a prospective observational study focusing on VF recurrence.[7] Three hundred and eighty consecutive OHCA victims with VF as the initial rhythm were enrolled over 2 years. Refibrillation occurred at least once in 79% of cases. VF termination rates were not reported and thus cannot be compared with our findings. However, these investigators observed an inverse relationship between the number of VF recurrences and survival to hospital discharge. In a previous publication, we found no relationship between the mean number of VF recurrences and survival to hospital discharge.[4] One potential explanation for this difference is the relatively lower survival rate in the van Alem et al. study relative to our experience (20% and 24% versus 37.5% and 41.0% for those with and without VF recurrence, respectively). This survival difference may potentially confound the relationship between the number of VF recurrences and outcome.

Conclusions

We observed no significant difference in the frequency of shock success between initial and recurrent episodes of VF using a biphasic truncated exponential waveform defibrillator with a 150 J fixed-energy protocol (Forerunner AED, Philips Medical Systems, Seattle, WA). Differences in biphasic waveform design between commercially available AEDs may impact shock success. VF recurrence is common and does not adversely affect shock success, ROSC or survival.

Conflict of interest

Dr. Russell is employed by Philips Medical Systems. Dr. Liu is a paid consultant for Philips Medical systems. The remaining authors have no conflicts of interest to disclose.

Acknowledgments

The authors express thanks to the city of Rochester police and fire department personnel and to Sarah Meyer for her secretarial support.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.resuscitation.2008.04.028.

References

1. Gliner BE, White RD. Electrocardiographic evaluation of defibrillation shocks delivered to out-of-hospital sudden cardiac arrest patients. Resuscitation 1999;41(2):133–44.
2. Part 5. Electrical Therapies: Automated External Defibrillators, Defibrillation, Cardioversion, and Pacing. *Circulation* 2005;112(Suppl. 24):IV-35–46.
3. Part 6. Advanced Cardiovascular Life Support. Section 2. Defibrillation. *Circulation* 2000;102(90001): I-90–4.
4. Hess EP, White RD. Recurrent ventricular fibrillation in out-of-hospital cardiac arrest after defibrillation by police and firefighters: implications for automated external defibrillator users. Crit Care Med 2004;32(Suppl. 9):S436–9.
5. Hess EP, White RD. Ventricular fibrillation is not provoked by chest compression during post-shock organized rhythms in out-of-hospital cardiac arrest. Resuscitation 2005;66(1):7–11.
6. Weaver WD, Cobb LA, Copass MK, Hallstrom AP. Ventricular defibrillation—a comparative trial using 175-J and 320-J shocks. *N Engl J Med* 1982;307(18):1101–6.
7. van Alem AP, Post J, Koster RW. VF recurrence: characteristics and patient outcome in out-of-hospital cardiac arrest. Resuscitation 2003;59(2):181–8.
8. Blouin D, Topping C, Moore S, Stiell I, Afilalo M. Out-of-hospital defibrillation with automated external defibrillators: postshock analysis should be delayed. Ann Emerg Med 2001;38(3):256–61.
9. Stiell IG, Walker RG, Nesbitt LP, et al. BIPHASIC Trial: a randomized comparison of fixed lower versus escalating higher energy levels for defibrillation in out-of-hospital cardiac arrest. Circulation 2007;115(12):1511–7.
10. White RD, Bunch TJ, Hankins DG. Evolution of a community-wide early defibrillation programme experience over 13 years using police/fire personnel and paramedics as responders. Resuscitation 2005;65(3):279–83.
11. White RD, Vukov LF, Bugliosi TF. Early defibrillation by police: initial experience with measurement of critical time intervals and patient outcome. Ann Emerg Med 1994;23(5):1009–13.
12. White RD, Hankins DG, Bugliosi TF. Seven years experience with early defibrillation by police and paramedics in an emergency medical services system. Resuscitation 1998;39(3):145–51.

13. Campbell RL, Hess EP, Atkinson EJ, White RD. Assessment of a three-phase model of out-of-hospital cardiac arrest in patients with ventricular fibrillation. Resuscitation 2007;73(2):229–35.
14. White RD, Asplin BR, Bugliosi TF, Hankins DG. High discharge survival rate after out-of-hospital ventricular fibrillation with rapid defibrillation by police and paramedics. Ann Emerg Med 1996;28(5):480–5.
15. Jennett B, Bond M. Assessment of outcome after severe brain damage. Lancet 1975;1(7905):480–4.
16. Zeger SL, Liang KY. Longitudinal data analysis for discrete and continuous outcomes. Biometrics 1986;42(1):121–30.
17. Tang W, Weil MH, White RD. Letter by Tang et al. regarding article, "BIPHASIC trial: a randomized comparison of fixed lower versus escalating higher energy levels for defibrillation in out-of-hospital cardiac arrest". Circulation 2007;116(19):e522.

AED Use in a Passenger During a Long-Haul Flight: Repeated Defibrillation With a Successful Outcome

HEINI HARVE, OLAVI HÄMÄLÄINEN, JOUNI KUROLA, AND TOM SILFVAST

HARVE H, HÄMÄLÄINEN O, KUROLA J, SILFVAST T. *AED use in a passenger during a long-haul flight: repeated defibrillation with a successful outcome.* Aviat Space Environ Med 2009; 80:405–8.

Introduction: Sudden cardiac arrest is one of the leading causes of death, and early defibrillation of ventricular fibrillation (VF) is the single most important intervention for improving survival. The automated external defibrillator (AED) and the concept of public access defibrillation provide a solution to shorten defibrillation delays. Commercial aircraft create a unique environment for the use of the AED since an emergency medical service system (EMS) response is not available. We review published studies on this subject and describe the case of a passenger who developed VF during an intercontinental flight and was successfully resuscitated despite recurrent episodes of VF. *Case Report:* A 60-yr-old man developed VF during a flight from Tokyo to Helsinki. VF frequently recurred and shocks were delivered 21 times altogether. The aircraft was diverted to the city of Kuopio. When the local EMS crew encountered the patient 3 h after the onset of the cardiac arrest, the rhythm again converted to VF and three further shocks were delivered. The patient recovered, and 3 wk later he was transported to his home country, fully alert. *Discussion:* There are three large studies reporting placing AEDs on commercial aircraft. No harm for co-passengers or malfunctions were reported. Survival rates have been higher than those obtained by well-performing EMS. According to previous studies, placing AEDs on commercial aircraft is also cost effective. The absence of a suitable diversion destination should not influence the rescuers' decision to attempt CPR on board.

Keywords: ventricular fibrillation, cardiac arrest, automated external defibrillator, public access defibrillation.

SUDDEN CARDIAC ARREST (CA) is one of the leading causes of death in Europe (12). Early defibrillation of ventricular fibrillation (VF) is the single most important intervention for improving survival from adult out-of-hospital cardiac arrest (4). In this situation, current cardiopulmonary resuscitation (CPR) guidelines advocate defibrillation within 5 min (5).

The automated external defibrillator (AED) and the concept of public access defibrillation may be a solution to shorten defibrillation delays. According to the European Resuscitation Council, a public access defibrillation program should not merely include AED available to the public, but also be a planned and trained response system, including training of lay rescuers in CPR and use of the AED, linking the program with the local emergency medical services (EMS) system, and a process of continuous quality improvement (5). Recent studies have shown that these programs are associated with high survival rates from VF when devices have been placed in certain risk sites and used by trained laypersons (7,10,11).

Commercial aircraft represent a demanding environment for the use of the AED. During the flight, the services of the EMS system are not available until diversion and landing of the airplane, creating a delay that eliminates all but the most remote chance of survival in a CA patient. Yet the risk of a cardiac event may increase during a flight due to various reasons, e.g., reduced oxygen tension in the cabin, disruption of circadian rhythms, and apprehension of the passenger (1).

The deployment of AED in aircraft has enabled early defibrillation during the flight, even in the absence of medical personnel (2,10,11). Although the main purpose for the use of AED is defibrillation, the devices have also been used for monitoring purposes, assisting volunteer medical personnel in emergencies in which CA is not present. Though the use of AED as cardiac monitors in flight is controversial, Page et al. did not find complications of its use as a monitor by passenger-physicians (11).

The cost effectiveness of placing AED on commercial aircraft have been claimed to compare favorably with the cost effectiveness of other widely accepted medical interventions and health policy regulations, especially on large-capacity aircraft (3,6). It has even been estimated that the number of sudden deaths from CA during scheduled flights is greater than the number caused by aircraft accidents (10).

Finnair is one of the world's oldest operating airlines, established in 1923. A strong focus of the company's operations is on transporting passengers between Europe and Asia via Helsinki. The fleet consists of 63 aircraft. During the calendar year 2007, a total of 7,457,800 passengers were carried on scheduled passenger traffic routes and 1,700,600 on domestic routes. The number of charter passengers was 1,195,400. Finnair started placing

From Hyvinkää Hospital, Department of Anesthesia and Intensive Care, Hyvinkää, Finland; Finnair Health Services, Helsinki-Vantaa Airport, Finland; Kuopio University Hospital, Department of Anesthesia and Intensive Care, Kuopio, Finland; and Helsinki University Hospital, Department of Anesthesia and Intensive Care, Helsinki, Finland.

This manuscript was received for review in May 2008. It was accepted for publication in January 2009.

Address reprint requests to: Heini Harve, Leikkaus- ja anestesiayksikkö, Hyvinkään Sairaala, Sairaalankatu 1, FIN-05850 Hyvinkää, Finland; heini.harve@helsinki.fi.

DOI: 10.3357/ASEM.2340.2009

AED in airplanes in 1990 and today all aircraft except a few small ones on domestic routes are equipped with AED.

All flight attendants are trained in basic life support techniques and in the use of an AED during a 36-h first aid training course. Thereafter, both basic life support, including the assessment of vital signs, and the use of an AED is practiced during annual training sessions. Cabin Safety Manuals also containing first aid instructions are carried on board all aircraft. The basic life support and defibrillation training and the first aid instructions adhere to the European Resuscitation Council Guidelines for Resuscitation 2005 (5). For resuscitation purposes, AED have been needed once to three times a year; more often they have been used to monitor the heart rhythm of acutely sick passengers. The European Resuscitation Council Guidelines for Resuscitation 2005 are the reference guidelines when cooperating with volunteer medical personnel on board. Regardless of nationality, most doctors and other medical professionals are familiar with these or the International Liaison Committee on Resuscitation guidelines.

In the case of a major medical emergency, the members of the cabin crew act according to issued instructions, which include alerting the whole cabin crew, informing the pilot, bringing the AED and the emergency medical kit aside the patient, calling for a physician on the public address system, and initiating first aid measures. According to Finnish legislation, medical personnel have a duty to offer help within the limits of their competence in the case of a medical emergency. Finnair has liability insurance for medical professionals who volunteer to help in the case of a medical emergency on board. The cabin crew does not check credentials of the volunteering passenger since this would be difficult, and strict control would take precious time from the care of a critically ill patient. In the case of a medical emergency on board, a member of the cabin crew leads the action and volunteer medical personnel act as consultants. Finnair Leisure flights and long-haul flights are covered by MedLink services (MedLink Global Response Center, Phoenix, AZ). MedLink provides the flight crew 24/7 access to emergency physician consultation.

CASE REPORT

A 60-yr-old Japanese male passenger developed VF while in Russian airspace during a direct Finnair flight from Tokyo to Helsinki. As the passenger was witnessed to be unconscious, the cabin crew was alerted, the AED (Heartstart® FR2, Laerdal, Stavanger, Norway), and the emergency medical kit were brought to the patient, and a call for a physician was made on the public address system. The full contents of the Finnair onboard emergency medical kit meet the requirements of Joint Aviation Authorities and are described here.

The contents of the Finnair Emergency Medical Kit and the Intravenous Kit:

- Blood pressure meter (nonmercury);
- Stethoscope;
- Tourniquet;
- Syringes: 1 ml, 2 ml, 5 ml, and 10 ml;
- Injection needles;
- Oropharyngeal airway tube (child and adult);
- Antiseptic wound cleaner;
- Catheter;
- Disposable resuscitation aid;
- Needle disposal box;
- Disposable gloves;
- Surgical gloves (large, medium, and small);
- Adhesive tape;
- Intravenous catheters (green, pink, and blue);
- Tape to attach the IV catheters;
- Bandages;
- Solution tubing set;
- Report forms;

Medications:

- Inj. Epinephrine 1 mg · ml^{-1} (1 ml and 5 ml);
- Inj. Atropine 1 mg · ml^{-1};
- Inj. Hyoscinbutylbromide 20 mg · ml^{-1};
- Inj. Digoxin 0.25 mg · ml^{-1};
- Inj. Theophylline 20 mg · ml^{-1};
- Inj. Furosemide 10 mg · ml^{-1};
- Inj. Glucagon 1 mg · ml^{-1};
- Inj. Morphine 20 mg · ml^{-1};
- Inj. Promethazine 25 mg · ml^{-1};
- Inj. Metoclopramide 5 mg · ml^{-1};
- Inj. Hydrocortisone 125 mg · ml^{-1};
- Inj. Metoprolol 1 mg · ml^{-1};
- Inj. Diazepam 5 mg · ml^{-1};
- Tabl. Methylergonovine 0.125 mg;
- Aerosol. Isosorbide dinitrate 1.25 mg/dose;
- Inhal. Albuterol 0.1 mg/dose;
- Tabl. Meclizine 25 mg;
- Lactated Ringer's Solution 500 ml; and
- Physiological saline 9 mg · ml^{-1}, 500 ml.

There happened to be a Japanese medical doctor and an Australian registered nurse on board. The exact time when the patient became unconscious was not known, but the cabin crew was alerted at 23:25. Data stored on the AED's memory card were extracted to further document the management of the incident (**Fig. 1**). The correctness of the rhythm analysis was checked independently by two medical doctors.

The AED detected VF and the patient was defibrillated. The rhythm converted to sinus rhythm and return of spontaneous circulation (ROSC) was achieved after the first shock. Spontaneous respiration was restored and the patient responded to stimuli. An intravenous line was established. VF frequently recurred 20 times during the flight and shocks were delivered 21 times altogether. After each shock ROSC and spontaneous respiration was achieved. Between the periods of VF the patient was responding to stimuli, but the Glasgow Coma Scale was not rated. The details of the management of the emergency are described as follows (Start and end times are presented in GMT + 02:00; Helsinki):

23:25 GMT + 02:00
00:00:00 Device on
00:00:22 Pads on
00:00:42 Shock 1 delivered
00:02:00 Intravenous line was established
00:03:04 Shock 2 delivered
00:04:08 Shock 3 delivered
00:05:12 Shock 4 delivered
00:06:34 Shock 5 delivered
00:08:16 Shock 6 delivered
00:09:14 Shock 7 delivered
00:10:22 Shock 8 delivered
00:11:16 Shock 9 delivered

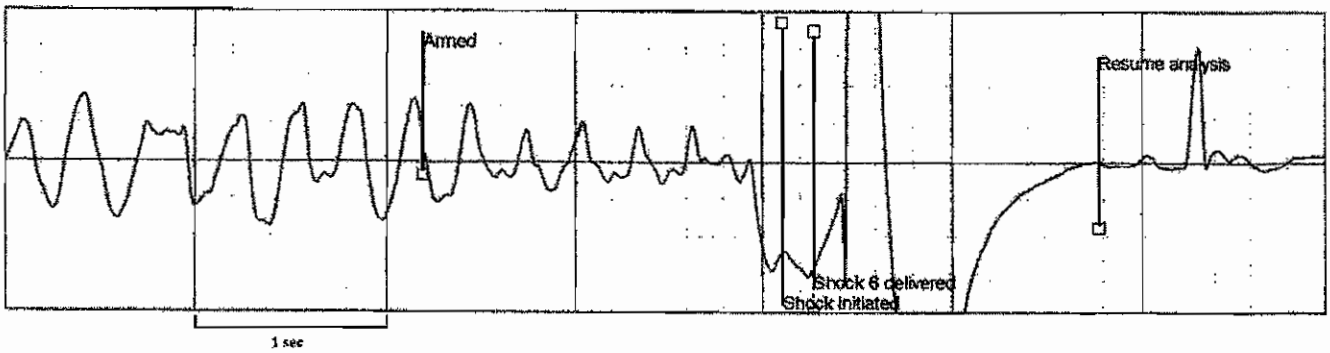


Fig. 1. A printout of the memory card of the AED shows VF, the sixth shock, and the following sinus rhythm.

00:12:49 Shock 10 delivered
00:14:39 Shock 11 delivered
00:15:57 Shock 12 delivered
01:30:21 Shock 13 delivered
01:32:35 Shock 14 delivered
01:33:24 Shock 15 delivered
01:34:30 Shock 16 delivered
01:35:45 Shock 17 delivered
01:37:37 Shock 18 delivered
01:39:37 Shock 19 delivered
01:42:14 Shock 20 delivered
01:44:59 Shock 21 delivered
03:10:00 The EMS crew reached the patient
03:11:33 Shock 22 delivered
03:13:00 Shock 23 delivered
03:16:48 Shock 24 delivered
03:18:36 Pads off
14:43 GMT + 02:00

The crew also contacted MedLink Services for medical supervision, and on its advice the captain made a decision to divert to the city of Kuopio in Eastern Finland. The city of Kuopio was chosen because it was the first suitable airport for diversion with adequate EMS and intensive care facilities. The aircraft was met by the local EMS system immediately after landing. When the EMS crew encountered the patient at 14:35, 190 min after the onset of the CA, the rhythm again converted to VF and CPR was started. Three further shocks were delivered and permanent ROSC followed with a stable sinus rhythm. A laryngeal mask airway was inserted to secure the airway. In all, the patient received 24 defibrillatory shocks. The management of the emergency followed the European Resuscitation Council Guidelines 2005 (5).

The patient was transferred to the emergency department at the Kuopio University Hospital. On admission at 15:30, the patient had stable hemodynamics and his Glasgow Coma Scale was rated at 11. Serum potassium was 7.1 mmol · L^{-1}, the MB isoenzyme of creatine kinase was 17.5 μg · L^{-1}, and the cardiac troponin T was 0.18 μg · L^{-1}. The patient was intubated and transferred to the Intensive Care Unit.

Next day the patient was extubated. He was fully conscious with Glasgow Coma Scale 15 and hemodynamics were stable. His recovery was complicated the following night when he developed severe bradycardia, which turned into pulseless electrical activity. CPR was started, endotracheal intubation was performed, and 2 mg epinephrine was administered intravenously before ROSC was achieved. The patient subsequently developed pneumonia and cardiac insufficiency and remained intubated for the next 7 d. The patient was transported to his home country 3 wk after the CA with Glasgow Coma Scale 15. The Overall Performance Category Scale was rated to be 3 and the Cerebral Performance Categories Scale 2. The long-term survival of the patient is not known because the patient could not be contacted in Japan.

DISCUSSION

There are few reports on airline AED programs or on CA treatment during flights. Some case reports describe successful in-flight resuscitation. The first two patients who developed VF and who were successfully resuscitated using AED during flights were described by O'Rourke and Donaldson in the early 1990s (9). Khan et al. described a successful onboard resuscitation of a 72-yr-old female passenger who developed recurrent VF and was defibrillated four times (8). The patient died in a local hospital after diversion of the aircraft. To our knowledge reports on survival after persistently recurring VF requiring several shocks and such a long-duration resuscitation aboard aircraft have not been published. In the in-hospital environment, Yu et al. recently described the survival of a 27-yr-old woman after 280 min of CPR (13).

AED were installed on Australian Qantas aircraft and major terminals in 1991 (10). A total of 370 chief pursers were trained to use the AED. During a 65-mo period, AED were used on 109 occasions, including 46 CA situations. Of these CA, 27 episodes occurred on aircraft and 19 in terminals. VF was the initial cardiac rhythm in 6 patients aboard aircraft and in 17 patients in terminals. Defibrillation successfully terminated VF in 5/6 and 16/17 patients, respectively. Long-term survival was documented in 2/6 and 4/17 patients.

American Airlines began to equip its aircraft with AED in 1997. All flight attendants were trained to use the devices. During a 2-yr period, AED were used 191 times on aircraft and 9 times in terminals. Altogether, 36 CA were reported, 29 on aircraft and 7 in terminals. VF was documented in 14 patients. Shock was withheld at the family's request in one patient. Two other patients were defibrillated, but the electrocardiographic data were lost. Of 15 patients who were defibrillated, 6 were discharged to their homes from the hospital (11).

Between November 2002 and November 2003 Air France reported 12 CA on board, in which 5/12 defibrillatory shocks were initially advised (2). The survival rate for getting to the hospital after in-flight CA was 3/12. The survival rate for discharge from the hospital following in-flight shocks was 2/5. The number of diversions was reported to have decreased after the implementation of AED on board because asystolic patients not responding to resuscitation were considered to be dead and not require further actions by the crew.

The sensitivity and specificity of AED were reported to be 100% in all three studies on AED programs mentioned above (2,10,11). No harm for co-passengers or malfunctions were reported. The survival rates that the airlines have reported after implementation of AED on board have been higher than that obtained by the best EMS (11). Problems and delays in recognition of a CA have been reported in two studies (2,10). Unconscious passengers were assumed to be asleep and not identified as being victims of a CA. These patients did not survive.

The special character of the Finnair defibrillation program is the extensive 36-h training compared with the 4-h training of the Air France and American Airlines programs (2,11). Qantas trained only chief pursers to use an AED while all flight attendants were trained in basic life support (10). The airlines' defibrillation programs are good examples of highly developed and continuously improved efforts to increase the chances of survival of passengers who develop CA during flight. The AED are placed on actual risk sites out of reach of local EMS. The rescuers are lay persons who are continuously trained, but they are not volunteers as in many other public access defibrillation programs. Reports indicate that both the lay rescuers and their employers have been satisfied with these programs, and according to previous studies (3,6), placing AED on commercial aircraft is also cost effective. This paper gives level four evidence that success may prevail even after many hours of repeated resuscitation attempts for a recurrent VF if ROSC is temporarily achieved. The absence of a suitable diversion destination should not influence on the rescuers' decision to attempt CPR.

ACKNOWLEDGMENTS

We wish to express our gratitude to MA Mari Harve; Instructor Hannele Saren, Finnair Safety Training Department, and Cabin Safety and First Aid Specialist Marja Vaitinen, Finnair.

Authors and affiliations: Heini Harve, M.D., Department of Anesthesia and Intensive Care, Hyvinkää Hospital, Hyvinkää, Finland; Olavi Hämäläinen, M.D., Ph.D., Finnair Health Services, Helsinki-Vantaa Airport, Finland; Jouni Kurola, M.D., Ph.D., Department of Anesthesia and Intensive Care, Kuopio University Hospital, Kuopio, Finland; and tom Silfvast, M.D., Ph.D., Department of Anesthesia and Intensive Care, Helsinki University Hospital, Helsinki, Finland.

REFERENCES

1. Aerospace Medical Associatation. Medical guidelines for airline travel, 2nd edition. Aviat Space Environ Med 2003; 74 (5, Suppl.):A1–19.
2. Bertrand C, Rodriguez Redington P, Lecarpentier E, Bellaiche G, Michel D, Teiger E, et al. Preliminary report on AED deployment on the entire Air France commercial fleet: a joint venture with Paris XII University Training Programme. Resuscitation 2004; 63:175–81.
3. Cram P, Vijan S, Wolbrink A, Fendrick AM. The impact of including passive benefits in cost-effectiveness analysis: the case of automated external defibrillators on commercial aircraft. Value Health 2003; 6:466–73.
4. Cummins RO, Ornato JP, Thies WH, Pepe PE. Improving survival from sudden cardiac arrest: the "chain of survival" concept. A statement for health professionals from the Advanced Cardiac Life Support Subcommittee and the Emergency Cardiac Care Committee, American Heart Association. Circulation 1991; 83:1832–47.
5. European Resuscitation Council. European Resuscitation Council guidelines for resuscitation 2005. Resuscitation 2005; 67 (Suppl. 1):S1.
6. Groeneveld PW, Kwong JL, Liu Y, Rodriguez AJ, Jones MP, Sanders GD, Garber AM Cost-effectiveness of automated external defibrillators on airlines. JAMA 2001; 286:1482–9.
7. Hallstrom AP, Ornato JP, Weisfeldt M, Travers A, Christenson J, McBurnie MA, et al. Public-access defibrillation and survival after out-of-hospital cardiac arrest. N Engl J Med 2004; 351: 637–46.
8. Kahn RA, Ruckman RF, Brown SB. Case 3–2006: cardiac arrest at 30,000 feet. J Cardiothorac Vasc Anesth 2006; 20:438–44.
9. O'Rourke M, Donaldson E. Management of ventricular fibrillation in commercial airliners. Lancet 1995; 345:515–6.
10. O'Rourke MF, Donaldson E, Geddes JS. An airline cardiac arrest program. Circulation 1997; 96:2849–53.
11. Page RL, Joglar JA, Kowal RC, Zagrodzky JD, Nelson LL, Ramaswamy K, et al. Use of automated externaldefibrillators by a U.S. airline. N Engl J Med 2000; 343: 1210–6.
12. 5ans S, Kesteloot H, Kromhout D. The burden of cardiovascular diseases mortality in Europe. Task Force of the European Society of Cardiology on Cardiovascular Mortality and Morbidity Statistics in Europe. Eur Heart J 1997; 18: 1231–48.
13. Yu HY, Yeh HL, Wang SS, Tsai MK, Chen YS, Ko WJ, Lin FY. Ultra long cardiopulmonary resuscitation with intact cerebral performance for an asystolic patient with acute myocarditis. Resuscitation 2007; 73:307–8.

ORIGINAL CONTRIBUTION

Recalls and Safety Alerts Affecting Automated External Defibrillators

Jignesh S. Shah, MD
William H. Maisel, MD, MPH

Context Automated external defibrillators (AEDs) play a key role in the community resuscitation of persons with cardiac arrest and are of proven clinical benefit. Although AEDs are complex medical devices designed to function during life-threatening emergencies, little is known about their reliability.

Objectives To determine the number and rate of AED recalls and safety alerts, to identify trends in these rates, and to identify the types of malfunctions prompting AED and AED accessory advisories.

Design and Setting Analysis of weekly US Food and Drug Administration (FDA) Enforcement Reports between January 1996 and December 2005 was performed to identify all recalls and safety alerts (collectively referred to as "advisories") involving AEDs and AED accessories. Confirmed AED device malfunctions were identified by reviewing AED-related adverse events reported to the FDA.

Main Outcome Measures Number of AEDs and AED accessories subject to FDA recall or safety alert between January 1996 and December 2005; annual AED advisory rates; and number of confirmed fatal AED-related device malfunctions reported to the FDA.

Results During 2.78 million AED device-years of observation, 52 advisories (median [25th and 75th percentiles], 4.5 [3.0 and 5.0] per year) affecting 385 922 AEDs and AED accessories were issued. The mean (SE) annual number of AEDs affected by advisories was 5.1 (1.5) devices per 100 AED device-years. Overall, 21.2% of AEDs distributed during the study period were recalled, most often because of electrical or software problems. The AED advisory rate did not significantly increase during the study period, although the annual number of AED advisories (P for trend=.02) and AED advisory devices (P for trend=.01) did increase. Confirmed fatal AED-related device malfunctions occurred in 370 patients.

Conclusions Automated external defibrillators and AED accessory advisories occur frequently and affect many devices. Actual AED malfunctions do occur occasionally, although the number of observed malfunctions is small compared with the number of lives saved by these important devices. As the prevalence of AEDs continues to increase, the number of devices affected by advisories can also be expected to increase. Efforts should be directed at developing a reliable system to locate and repair potentially defective devices in a timely fashion.

JAMA. 2006;296:655-660 www.jama.com

SUDDEN CARDIAC DEATH IS A leading cause of mortality in the United States, accounting for nearly 330 000 deaths annually.[1] Successful resuscitation of persons with cardiac arrest depends on prompt emergency care, with early defibrillation a key component to improved survival.[2] The advent of automated external defibrillators (AEDs) and their increasingly widespread distribution in public places has been an important development that has resulted in improved survival of persons with cardiac arrest.[3-8]

Automated external defibrillators provide automated rhythm analysis, voice commands, and shock delivery.[1] Several clinical trials have demonstrated that AEDs are safe and clinically effective and that they may be used appropriately by individuals with as little as a sixth-grade education.[3-10] Indeed, widespread installation of AEDs has occurred in a number of public places, including many airports, casinos, sports arenas, and shopping centers, and has resulted in the saving of innumerable lives.[3-7] Because of the important lifesaving potential of AEDs and their ease of use, the US Food and Drug Administration (FDA) has approved some models for home use without a prescription.[11]

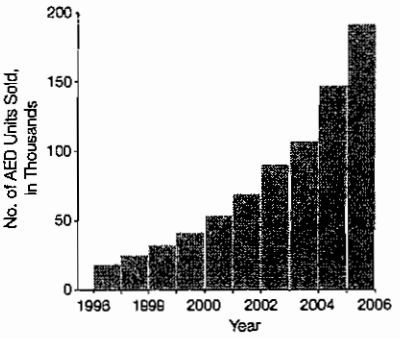
While easy to use, AEDs are technically complex devices that occasionally malfunction.[12] The FDA is responsible for the safety and oversight of all medical devices in the United States. Weekly FDA Enforcement Reports are issued that include recalls and safety alerts (collectively referred to as "advisories"), a number of which have involved AEDs.[13] Advisories are usually issued to notify the public about potentially defective devices that may not function as intended. Implantable cardioverter-defibrillators (ICDs), devices similar to AEDs, have been subject to frequent recall by the FDA because of observed malfunctions affecting device performance and reliability.[14,15] Whether AEDs are likewise prone to FDA recall is not known.

Because AEDs have become more sophisticated and increasingly preva-

See also p 700 and Patient Page.

Author Affiliations: Cardiovascular Division, Department of Medicine, Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, Mass. Corresponding Author: William H. Maisel, MD, MPH, Cardiovascular Division, Beth Israel Deaconess Medical Center, 185 Pilgrim Rd, Baker 4, Boston, Mass 02215 (wmaisel@bidmc.harvard.edu).

Figure 1. Annual Number of Automated External Defibrillator (AED) Units Sold



The annual number of AEDs sold increased approximately 10-fold from 1996 to 2005.

lent, safety issues affecting device performance may become more common. Given the potentially lifesaving role of AEDs, monitoring of device performance is important. Surprisingly, minimal public data concerning the technical performance of AEDs are available. The purpose of this study was to determine the number and rate of AED safety alerts and recalls, to identify the types of malfunctions prompting AED advisories, and to identify trends in AED performance.

METHODS

Safety Alerts and Recalls

All FDA safety alerts and recalls (collectively referred to as "advisories") affecting AEDs or AED accessories were identified by reviewing weekly FDA Enforcement Reports between January 1996 and December 2005.[13] Each advisory is classified by the FDA into 1 of 4 categories: class I (reasonable probability that use of the product will cause serious adverse health consequences); class II (use of the product may cause temporary or medically reversible adverse health consequences or the probability of adverse health consequences is remote); class III (use of the product is not likely to cause adverse health consequences); or safety alerts (a communication issued to inform of the potential risk of substantial harm from a medical device—may be of same importance as class I, class II, or class III recall). Only advisories affecting AEDs (FDA product codes MKJ, NPN, and NSA) or critical AED accessories (ie, batteries, capacitors, cables, resistors, electrode pads, and the like) were included. Advisories affecting external defibrillators without automated functions and advisories affecting noncritical accessories (ie, where accessory malfunction would not affect life-sustaining device performance) were excluded from the study.

The number of AEDs affected by advisories was determined from FDA Enforcement Reports. The number of "at risk" AEDs in the United States was estimated by identifying all US AED manufacturers and reviewing all available relevant US Securities and Exchange Commission annual reports for the study period.[16-21] In addition, independent financial market research reports were reviewed to verify the findings.[22] The annual AED advisory rate was then calculated by dividing the annual number of AEDs affected by FDA advisories by the estimated total number of AEDs at risk in a given year. It was assumed that once an AED was distributed, it remained in service.

Device Malfunctions

Because advisories represent the potential for device malfunction, additional analysis was performed to assess actual AED malfunctions. All AED and AED accessory adverse event reports involving a patient death and submitted to the FDA between July 1996 and December 2005 were analyzed. Manufacturers are required to report to the FDA any medical device–related event or malfunction that caused or could have caused serious injury or death to a patient. These reports are entered into the publicly searchable Manufacturer and User Facility Device Experience (MAUDE) database.[12] Each MAUDE AED report was independently reviewed in detail by 2 physicians and was classified into 1 of the following categories: (1) device malfunction; (2) no device malfunction; or (3) indeterminate (insufficient data to classify event). The AED or AED accessory was considered to have malfunctioned only if: (1) manufacturer analysis confirmed the malfunction or (2) the device was not returned to the manufacturer for analysis but the malfunction was witnessed and confirmed by trained health care personnel on the scene. Only malfunctions that occurred during sustained ventricular arrhythmias were counted. When available, manufacturer analysis of stored electrograms was used for arrhythmia classification. When stored electrograms were not available for analysis, the device's automated analysis was used. If AED rhythm analysis and on-site health care personnel analysis did not agree, the event was classified as indeterminate. Unsubstantiated claims of device malfunction or reports containing insufficient information were not counted as device malfunction. Only true, definite device malfunctions were counted. Malfunction classification disagreements were resolved by consensus of the 2 physician adjudicators.

Statistical Methods

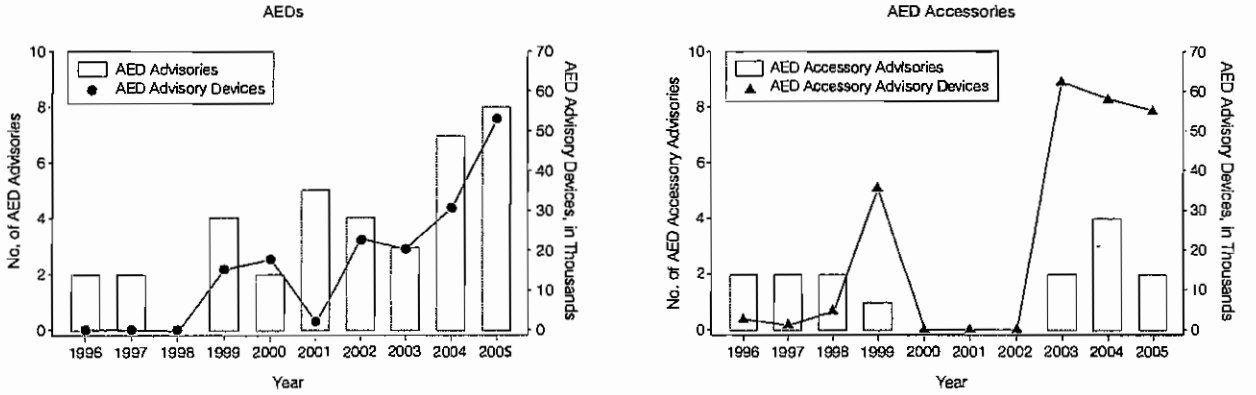
Statistical comparisons were performed using SAS statistical software (version 9.1, SAS Institute, Cary, NC). A 2-sided P value of .05 or less was interpreted as being statistically significant. Student t and χ^2 tests were used to compare continuous and discrete outcomes, respectively. Mantel-Haenszel χ^2 tests were used to assess for trends during 3 time periods that were selected a priori: 1996-2000, 2001-2005, and 1996-2005. Although the precise number of annual AED units distributed was determined, sensitivity analysis was performed to account for potential inaccuracies in manufacturer reporting of AED sales.

RESULTS

Number of AEDs

The annual number of AEDs marketed is shown in FIGURE 1. The mean (SD) annual number of AEDs marketed was 77 539 (57 362). In total, 775 387 AEDs were marketed during the study, with the annual number of

Figure 2. Annual Automated External Defibrillator (AED) and AED Accessory Advisories and Units Affected



The annual number of AED advisories and AED units affected by advisories is shown (left panel). Between 1996 and 2005, 37 AED advisories affecting 164102 AEDs were issued. The annual number of AED accessory advisories and AED accessory units affected by advisories is shown (right panel). Between 1996 and 2005, 15 AED accessory advisories affecting 221 820 AED accessories were issued.

units sold increasing approximately 10-fold during the study (approximately 30% per year), from 18 645 in 1996 to 192 400 in 2005. A total of 2.78 million device-years of observation occurred during the study period.

Number, Type, and Rate of Advisories

There were 52 advisories during the study period affecting 385 922 AEDs and AED accessories (FIGURE 2). Between January 1996 and December 2005, 37 AED advisories (range, 0-8; median [25th and 75th percentiles], 3.5 [2.0 and 5.0] advisories per year) affecting 164 102 AEDs (mean [SE], 16 410 [5409] AEDs per year) and 15 AED accessory advisories (range, 0-4; median [25th and 75th percentiles], 2 [0 and 2] advisories per year) affecting 221 820 AED accessories (mean [SE], 22 182 [8725] AED accessories per year) occurred. Automated external defibrillators were recalled in 9 of the 10 study years, and AED accessories were recalled in 7 of the 10 years studied. No year was advisory free. The annual number of AEDs affected by advisories varied from a low of 0 in 1998 to a high of 53 323 in 2005.

The annual number of AED accessories affected by advisories ranged from 0 (2000-2002) to 62 778 (2003). Overall, 21.2% of AEDs were affected by advisories during the study period. Every major AED manufacturer recalled products during the study period. Recalls and safety alerts more often involved AEDs than AED accessories (mean [SE], 3.7 [0.8] vs 1.5 [0.4] advisories per year, respectively; $P=.02$).

Of the 37 AED advisories, most were classified by the FDA as either class I (4 advisories [10.8%]) or class II (31 advisories [83.7%]). In contrast, all but 1 (14 advisories [90.3%]) of the AED accessory advisories were judged to be class II recalls. Advisories affecting AEDs were most often issued because of electrical (8 advisories affecting 31 906 devices) or software-related issues (6 advisories affecting 12 311 devices) (TABLE 1). Failure of the device to detect the arrhyth-

Table 1. Type and Frequency of Automated External Defibrillator (AED) and AED Accessory Advisories

Reason for Advisory	No. (%)	
	AED Advisories	AED Units Affected
Battery	3 (8.1)	20 651 (12.6)
Capacitor	3 (8.1)	6840 (4.2)
Electrical	8 (21.6)	31 906 (19.4)
Failure to detect*	4 (10.8)	31 963 (19.5)
Failure to shock*	5 (13.5)	51 545 (31.4)
Miscellanous hardware	4 (10.8)	6439 (3.9)
Software	6 (16.2)	12 311 (7.5)
Other	4 (10.8)	2447 (1.4)
AED Total	37 (100)	164 102 (100)
	AED Accessory Advisories	AED Accessory Units Affected
Battery accessory	3 (20)	5916 (2.7)
Cable	7 (46.7)	148 243 (66.8)
Labeling	1 (6.7)	16 736 (7.5)
Pads	4 (26.7)	50 925 (23.0)
AED Accessory Total	15 (100)	221 820 (100)
AED and AED Accessory Total	52 (100)	385 922 (100)

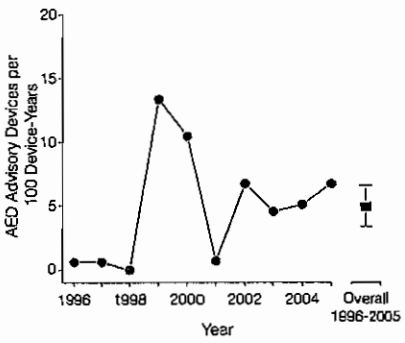
*More specific mechanism of potential failure not reported. These advisories may be due to hardware or software abnormalities.

Table 2. Examples of Automated External Defibrillator (AED) and AED Accessory Advisories

FDA Advisory Classification	Description	Device
Class I	Affected AED may shut itself off before delivering shock	AED
	AED may display error message, fail to analyze the patient's ECG, and fail to deliver the appropriate therapy	AED
Class II	AED may fail to operate because of faulty component in circuit board	AED
	Pads may fail because of excessive corrosion of the electrode	AED Accessory
Class III	AED does not display the alarm off indicator	AED
	External case of the AC power charger may exhibit localized melting	AED Accessory

Abbreviations: ECG, electrocardiogram; FDA, Food and Drug Administration.

Figure 3. Automated External Defibrillator (AED) Advisory Rates for 1996 to 2005



The annual AED advisory rate ranged from 0 to 13.6 advisory devices per 100 AED device-years at risk. Overall, the mean (SE) annual rate of AED advisory during the study period was 5.1 (1.5) per 100 AED device-years.

mia, failure to deliver the programmed shock, and battery issues accounted for the majority of the other recalls. Automated external defibrillator accessory advisories were most often issued because of defects in AED cables or electrode pads (11 advisories affecting 199 168 AED accessories [89.7%]). Selected examples of specific AED and AED accessory advisories are shown in TABLE 2.

The annual AED advisory rate ranged from 0 to 13.6 per 100 AED device-years at risk. The mean (SE) annual rate of AED advisories during the study period was 5.1 (1.5) per 100 AED device-years (FIGURE 3). The annual rate of AED advisories did not significantly increase during the 3 time periods selected a priori: 1996-2000 (P for trend=.11); 2001-2005 (P for trend=.19); 1996-2005 (P for trend=.33). However, between 1996 and 2005 there was a significant increase in the annual number of AED advisories (P for trend=.02) and in the annual number of AED advisory devices (P for trend=.01).

Recent Advisories and Alerts

During the first half of 2006 (January through June), there were an additional 6 advisories affecting 28 795 devices. Five advisories affecting 27 530 AEDs and 1 advisory affecting 1265 AED accessories were reported.

Analysis of Malfunction Reports

A total of 801 AED or AED accessory adverse event reports involving a death were reported to the FDA during the study period. Fewer than half of the reported device failures were classified as confirmed device malfunctions (370 reports [46.1%]). The remaining reports (431 reports [53.9%]) were adjudicated as either no malfunction or indeterminate. Specific examples of reported adverse events are described in the BOX.

Sensitivity Analysis

Sensitivity analysis was performed to assess the impact of potential inaccuracies in manufacturer reporting of AED sales and to account for potential changes in AED longevity. The observed increasing trends in number of AED advisories and number of AED advisory devices were unaffected by even 50% increases or decreases in annual AED sales or device longevity.

COMMENT

Automated external defibrillators are complex medical devices designed to function during life-threatening emergencies. These devices have saved numerous lives over the past decade but do occasionally malfunction.[12] Despite exponential growth in the AED industry and increasing evidence that early defibrillation is a critical component to the survival of persons with cardiac arrest, little is known about AED performance. This study reassuringly demonstrates that despite increasing AED complexity, the AED advisory rate did not significantly increase during the study period.

However, AED and AED accessory advisories do occur frequently. The annual number of AED advisories and the annual number of AEDs affected by advisories increased, and numerous confirmed AED malfunctions occurred during the past decade. Still, the total number of device malfunctions is small compared with the number of lives saved. Indeed, hundreds of thousands of patients underwent attempted resuscitation of ventricular arrhythmias by an AED during the study period accounting for thousands of lives saved.[23]

Sudden cardiac death is a leading cause of cardiovascular mortality in the community. Increasing evidence suggests that time to defibrillation for out-of-hospital patients with a shockable rhythm is the most important determinant of survival.[1,2,8] Numerous studies have demonstrated clinical benefit of AEDs in public gathering places such as airports, casinos, schools, and public arenas.[3-7] These clinical trials have demonstrated that approximately 40% to 70% of the patients in shockable rhythms treated in a timely fashion by an AED will survive.[1] However, because AED clinical trials have been designed to evaluate the device's clinical efficacy and not its technical performance, studies have been underpowered to evaluate the incidence of rare but important device malfunctions. In contrast, the current

study involved 2.78 million device-years of observation.

Advisories from the FDA indicate the potential for a device to malfunction, not an actual device malfunction. As such, they are a surrogate marker of device reliability. In general, advisories are issued by the FDA when a product may not function as intended and the potential malfunction could result in patient harm. Importantly, some advisories are issued even when the risk of device failure is less than 1%. Timely communication of advisory information to device end users is of critical importance, as some units may require repair or replacement. Manufacturer response after issuing an advisory is variable. While some offer repair or replacement at no cost, others have simply recommended discontinuing device use without offering a remedy.[24-26] However, it is often impossible to predict who the actual end user of the device will be in any given emergency. While a patient's ICD is routinely "registered" with the manufacturer at the time of implantation, no such process reliably occurs with AEDs. This creates a challenge for the FDA and industry to develop a reliable system that will permit timely, accurate communication to potential users and identification of affected advisory devices. Current advisory notification schemes arguably do not adequately inform the public. The inability to track devices and end users makes it impossible to know how many AED units were actually fixed or taken out of service during the study period because of these advisories.

The actual clinical implications of the AED and AED accessory advisories are difficult to estimate because some advisory devices may never be used, and others may be used repeatedly. While the weekly FDA Enforcement Reports and manufacturer Securities and Exchange Commission filings used for the advisory analysis are robust and allow for accurate determination of advisory numbers and rates, no such benefit exists for analysis of actual device malfunctions presented in the FDA MAUDE database. The MAUDE database is widely recognized to be subject to potential underreporting of device failures.[27] In addition, many reports of device "failures" are cryptic and contain insufficient information to determine whether a true device malfunction has occurred. By counting only confirmed device malfunctions, this study demonstrates that numerous actual AED malfunctions have occurred. Because AEDs, by their very nature, are used in critically ill patients, it is not possible to predict whether a given device malfunction directly led to a patient's death.

Hardware malfunctions were the most common type of failure observed for AEDs. Often, these failures result in the inability of the device to deliver life-sustaining therapy because of failure of the device to power on, failure of the device to charge, or failure of the device to deliver a shock. Similar hardware failures have been observed in ICDs.[15] Although ICDs and AEDs share many similarities, the majority of AED manufacturers do not make ICDs. Therefore, the AED safety issues described in this study are distinct from those recently described for ICDs.[14] Every major AED manufacturer recalled products during the study period, suggesting that this is an industry-wide issue and not specific to a single device or manufacturer.

A possible limitation to our study was that advisory classification was based on the FDA- and manufacturer-reported cause of device malfunction. While the precise number of recalled units with the potential to malfunction is known, the actual number of device failures is not. However, it is evident that AED malfunctions do occasionally occur and may contribute to adverse patient outcomes. It was assumed that all AEDs remained in service once distributed. If devices were actually removed from service, the true advisory rate may be underestimated by this study. Sensitivity analysis, however, demonstrated that the reported trends of an increasing number of AED advisories and an increasing number of AED advisory devices were insensitive to even moderate changes in annual AED sales and AED longevity. A changing threshold by manufacturers or the FDA to issue an advisory could account for some of the observed increase in the number of ad-

Box. Examples of Automated External Defibrillator Malfunction Classifications

Confirmed Device Failure

While attempting to defibrillate a patient in cardiac arrest, the device made a loud "bang" sound and displayed an error message. The device was then unable to charge or discharge energy.

While attempting to defibrillate a patient in ventricular fibrillation, an "internal dump overload" message was displayed and the device failed to discharge. Another device was obtained and the patient was defibrillated. The patient died the next day.

Not a Device Failure

The defibrillator was applied to the patient, voice instructions were heard, but then the device displayed a red "X" and was not responsive. Five minutes later, a second defibrillator arrived and several shocks were administered for ventricular fibrillation. The patient did not survive. It was later determined that the battery had dislodged from the first defibrillator. Device check confirmed normal device function.

Complainant alleged that when they discharged the energy, the device did not appear to shock the patient, as there was no muscle response from the patient. Subsequent review of the device report indicated that the shock was delivered to the patient.

visories and advisory devices, but would not diminish the public health consequences of these recalls.

CONCLUSIONS

Automated external defibrillator and AED accessory advisories occur frequently and affect many devices. Actual AED malfunctions do occur occasionally, although the number of observed malfunctions is small compared with the number of lives saved. As the prevalence of AEDs continues to increase, the number of devices affected by advisories can also be expected to increase. Efforts should be directed at developing a reliable system to locate and repair potentially defective devices in a timely fashion.

Author Contributions: Dr Maisel had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Shah, Maisel.
Acquisition of data: Shah, Maisel.
Analysis and interpretation of data: Shah, Maisel.
Drafting of the manuscript: Shah, Maisel.
Critical revision of the manuscript for important intellectual content: Shah, Maisel.
Statistical analysis: Maisel.
Administrative, technical, or material support: Maisel.
Study supervision: Maisel.
Financial Disclosures: None reported.
Disclaimer: Dr Maisel is a US Food and Drug Administration (FDA) consultant and chair of the FDA Circulatory System Medical Device Advisory Panel. The opinions expressed herein are the personal views of the authors and do not necessarily represent the policies, practices, positions, or opinions of the FDA.

REFERENCES

1. ECC Committee, Subcommittees and Task Forces of the American Heart Association. 2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation*. 2005;112(suppl 24):IV1-IV203.
2. Hazinski MF, Idris AH, Kerber RE, et al. Lay rescuer automated external defibrillator ("public access defibrillation") programs: lessons learned from an international multicenter trial: advisory statement from the American Heart Association Emergency Cardiovascular Committee; the Council on Cardiopulmonary, Perioperative, and Critical Care; and the Council on Clinical Cardiology. *Circulation*. 2005;111:3336-3340.
3. Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. *N Engl J Med*. 2000;343:1206-1209.
4. Hallstrom AP, Ornato JP, Weisfeldt M, et al; Public Access to Defibrillation Trail Investigators. Public access defibrillation and survival after out-of-hospital cardiac arrest. *N Engl J Med*. 2004;351:637-646.
5. White RD, Asplin BR, Bugliosi TF, Hankins DG. High discharge survival rate after out-of-hospital ventricular fibrillation with rapid defibrillation by police and paramedics. *Ann Emerg Med*. 1996;28:480-485.
6. Stiell IG, Wells GA, Field BJ, et al. Improved out-of-hospital cardiac arrest survival through the inexpensive optimization of an existing defibrillation program. *JAMA*. 1999;281:1175-1181.
7. Page RL, Joglar JA, Kowal RC, et al. Use of automated external defibrillators by a U.S. airline. *N Engl J Med*. 2000;343:1210-1216.
8. Marenco JP, Wang PJ, Link MS, Homoud MK, Estes NA III. Improving survival from sudden cardiac arrest: the role of the automated external defibrillator. *JAMA*. 2001;285:1193-1200.
9. Gundry JW, Comes KA, DeRook FA, et al. Comparison of naïve sixth-grade children with trained professionals in the use of an automated external defibrillator. *Circulation*. 1999;100:1703-1707.
10. Atkins DL, Kenney MA. Automated external defibrillators: safety and efficacy in children and adolescents. *Pediatr Clin North Am*. 2004;51:1443-1462.
11. FDA clears over-the-counter sale of automatic external defibrillator. http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01314.html. US Food and Drug Administration Web site. Accessed May 2, 2006.
12. Manufacturer and User Facility Device Experience Database-(MAUDE). US Food and Drug Administration Web site. http://www.fda.gov/cdrh/maude.html. Accessed February 20, 2006.
13. FDA Enforcement Report Index. US Food and Drug Administration Web site. http://www.fda.gov/opacom/Enforce.html. Accessed February 16, 2006.
14. Maisel WH. Safety issues involving medical devices: implications of recent implantable cardioverter-defibrillator malfunctions. *JAMA*. 2005;294:955-958.
15. Maisel WH, Sweeney MO, Stevenson WG, Ellison KE, Epstein LM. Recalls and safety alerts involving pacemakers and implantable cardioverter-defibrillator generators. *JAMA*. 2001;286:793-799.
16. About Cardiac Science Corporation. Cardiac Science Web site. http://www.cardiacscience.com/about/index.htm. Accessed February 17, 2006.
17. Form 10-K: US Securities and Exchange Commission Annual Report, Cardiac Science, Inc. 2004. US Securities and Exchange Commission Web site. http://www.sec.gov/Archives/edgar/data/876188/000119312504042358/d10k.htm#toc70301_2. Accessed February 16, 2006.
18. Form 10-K: US Securities and Exchange Commission Annual Report, Zoll Medical Corporation. US Securities and Exchange Commission Web site. 2004. http://www.sec.gov/Archives/edgar/data/887568/000119312504216647/d10k.htm. Accessed February 20, 2006.
19. Committed to Simplicity: Annual Review 2004. Koninklijke Philips Electronics NV Web site. 2004. http://www.philips.com/assets/Downloadablefile//Philips_AnnualReview2004_2-13731.pdf. Accessed February 25, 2006.
20. Survivalink Corp. Prospectuses and communications, business combinations. US Securities and Exchange Commission Web site. http://www.sec.gov/cgi-bin/browse-edgar?company=Survivalink&CIK=&filenum=&State=&SIC=&owner=include&action=getcompany. Accessed May 4, 2006.
21. Form 10-K: US Securities and Exchange Commission Annual Report, Meditronic Inc. US Securities and Exchange Commission Web site. 2005. http://www.sec.gov/Archives/edgar/data/64670/000089710105001490/0000897101-05-001490-index.htm. Accessed May 4, 2006.
22. Arrow AK. *US Equity Research: Medical Technologies in Perspective: 1H04*. New York, NY: Lazard Frères & Co; 2004:78-81.
23. Philips HeartStart Home OTC Defibrillator: FDA Panel Presentation [AED use estimates through 12/31/2003]. US Food and Drug Administration Web site. http://www.fda.gov/ohrms/dockets/ac/04/briefing/2004-4D63b2_04_HSHD%20Presentation-Final.ppt. Accessed May 2, 2006.
24. Urgent-Medical Device Recall: LIFEPAK CR Plus and LIFEPAK EXPRESS automated external defibrillators. Medtronic Inc Web site. 2006. http://www.medtronic-ers.com/notices/CR/. Accessed June 21, 2006.
25. Heartsine Technologies, Inc. issues worldwide recall of certain automatic external defibrillators. US Food and Drug Administration Web site. March 18, 2005. http://www.fda.gov/oc/po/firmrecalls/heartsine03_05.html. Accessed June 21, 2D06,.
26. Access Cardiosystems, Inc., issues worldwide AED recall. November 26, 2004. http://www.early-defib.org/news.asp?news_id=131. National Center for Early Defibrillation Web site. Accessed June 21, 2006.
27. Maisel WH. Medical device regulation: an introduction for the practicing physician. *Ann Intern Med*. 2004;140:296-302.

News & Events

FDA NEWS RELEASE

FOR IMMEDIATE RELEASE
August 10, 2006

Media Inquiries:
Heidi
Valetkevitch, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

Journal of American Medical Association Article on Recalls and Safety Alerts Affecting Automated External Defibrillators

Automatic external defibrillators (AEDs) are important medical devices. Numerous studies have shown that thousands of lives are saved each year using these devices to treat patients in sudden cardiac arrest. In the past decade, these devices have become simpler to use and have been placed in more public places like airports and schools.

A recent article in the Journal of American Medical Association (JAMA) titled Recalls and Safety Alerts Affecting Automated External Defibrillators helps inform the public about the safety of AEDs. FDA supports the kind of research and most of the conclusions reached in the JAMA article are consistent with FDA's own findings. However, there are a few points on which the agency differs.

First, the authors assert that manufacturers are unable to track AED units, making it impossible to know how many AED units were actually fixed or taken out of service. However, under FDA regulations, manufacturers are required to track AEDs and are doing so with processes in place to identify the location of a device in the event of a recall. Our records show that these devices are being tracked with a high level of accuracy. In fact, more than 95 percent of the AEDs affected by Class I recalls in 2005 were returned to the manufacturers or taken out of service. Fewer than three percent were lost or stolen.

Second, the authors state that there has been an increase in the number of AEDs affected by advisories during the study period. This is true, however, FDA believes that improvements in the devices' ability to self-diagnose hardware and software problems may contribute to this trend. This capability may result in users reporting problems before a device is ever used on a patient. Also, while more than 21 percent of AEDs were affected by an advisory, it does not necessarily mean that they malfunctioned. A device advisory is issued when a medical device has the

potential to exhibit a certain failure mode, not only when a device has, in fact, failed.

We continue to depend on our ability to work with owners of AEDs when these devices are subject to a recall and have taken steps in recent months to improve our communication and collaboration with the broader community. AED users should continue to report device malfunctions to the manufacturer and to FDA. In addition, users should heed device error messages and warnings during regular device self-checks and respond appropriately to recall notices and safety alerts.

For more information, visit www.fda.gov.

#

RSS Feed for FDA News Releases [what is RSS?]

ELSEVIER

Resuscitation 61 (2004) 143–147

RESUSCITATION

www.elsevier.com/locate/resuscitation

Adherence to guidelines when positioning the defibrillation electrodes

Jouni Nurmi [a,*], Per Rosenberg [b], Maaret Castrén [a]

[a] *Uusimaa EMS, Helsinki University Hospital, Eteläinen Hesperiankatu, 22A 26, Helsinki 00100, Finland*
[b] *Department of Anaesthesiology and Intensive Care Medicine, Helsinki University Hospital, Helsinki, Finland*

Received 22 October 2003; received in revised form 8 December 2003; accepted 2 January 2004

Abstract

Background: Placement of the defibrillation electrodes affects the transmyocardial current and thus the success of a defibrillation attempt. In the international guidelines 2000, the placement of the apical electrode was changed more laterally to the mid-axillary line. Finnish national guidelines, based on the international guidelines, were published in 2002. *Objectives:* The purpose of this study was to determine to what extent health care professionals adhere to the new guidelines when positioning the electrodes. *Methods:* Professionals were recruited from emergency medical services, university hospitals and primary care. Not revealing the purpose of the test, participants were asked to place self-adhesive electrodes on a manikin as they would do in the resuscitation situation and to answer a questionnaire about resuscitation training and familiarity with the guidelines. The distance of electrodes from the recommended position was measured in horizontal and vertical planes. *Results:* One-hundred and thirty six professionals participated in the study, and only 25.4% (95% CI 18.5–32.9) of them placed both electrodes within 5 cm from the recommended position. The majority of the participants placed the apical electrode too anteriorly. Of the participants, 36.0% were not aware of the new guidelines. Awareness of the guidelines did not increase the accuracy in electrode placement. *Conclusions:* The publication of the national evidence based resuscitation guidelines did not seem to have influenced the practice of placement of the defibrillation electrodes to any major extent. The correct placement of the electrodes needs be emphasized more in the resuscitation training.

Keywords: Guidelines; Defibrillation; Electrodes

Resumo

Contexto: A posição dos eléctrodos de desfibrilhação afecta a passagem da corrente transmiocárdica e portanto o sucesso da tentativa de desfibrilhação. Nas recomendações internacionais de 2000, a posição dos eléctrodos apicais foi alterada para no sentido lateral, para a linha médio-axilar. As guidelines nacionais finais, baseadas nas guidelines internacionais, foram publicadas em 2002. *Objectivos:* A proposta deste estudo foi determinar em que medida os profissionais de saúde aderem às novas guidelines quando posicionam os eléctrodos. *Método:* os profissionais foram recrutados dos serviços de emergência médicos, hospitais universitários e cuidados primários. Sem revelar os objectivos do estudo, pediu-se aos participantes que posicionassem eléctrodos auto-adesivos num manequim, como fariam numa situação de reanimação e para responderem a um questionário acerca do treino da reanimação e da familiaridade com as guidelines. A distância dos eléctrodos da posição recomendada foi medida nos planos horizontal e vertical. *Resultados:* Participaram no estudo cento e trinta e seis profissionais e só 25.4% (95% CI 18.5–32.9) colocaram ambos os eléctrodos à distância de 5 cm das posições recomendadas. A maioria dos participantes colocou os eléctrodos apicais numa posição demasiado anterior. Trinta e seis por cento dos participantes não estavam a par das novas guidelines. O conhecimento das guidelines não aumentou a precisão na colocação dos eléctrodos. *Conclusão:* A publicação das novas guidelines nacionais de reanimação baseadas na evidência não parece ter influenciado, de forma evidente, a prática de colocação dos eléctrodos de desfibrilhação. A posição correcta dos eléctrodos necessita de ser mais enfatizada durante o treino da reanimação.

Palavras chave: Eléctrodos de desfibrilhação; Linha axilar média; Fibrilhação ventricular

* Corresponding author. Tel.: +358-50-5951576; fax: +358-9-2213195.
E-mail address: jouni.nurmi@helsinki.fi (J. Nurmi).

0300-9572/$ – see front matter © 2004 Elsevier Ireland Ltd. All rights reserved.
doi:10.1016/j.resuscitation.2004.01.004

Resumen

Antecedentes: La ubicación de los electrodos de desfibrilación afecta la corriente transmiocárdica y, a través de ella, al éxito del intento de desfibrilación. En las guías internacionales 2000, la ubicación del electrodo apical fue cambiado mas lateralmente a la línea medio axilar. Las guías nacionales finlandesas, basadas en las guías internacionales, fueron publicadas en 2002. *Objetivos:* El propósito de este estudio fue determinar en que extensión el personal de salud adhiere las nuevas guías cuando posicionan los electrodos. *Métodos:* Se reclutaron profesionales de los servicios de emergencias médicas, hospitales universitarios y cuidados primarios. Sin revelarles el propósito de esta prueba, se les pidió a los participantes que ubicaran los electrodos autoadhesivos sobre un maniquí como lo harían en una situación de resucitación y se les pidió contestar un cuestionario acerca de entrenamiento en resucitación y familiaridad con las guías. La distancia entre los electrodos de la posición recomendada fue medida en planos horizontal y vertical. *Resultados:* Participaron en este estudio ciento treinta y seis profesionales, y solo el 25.4% (95% CI 18.5–32.9) de ellos ubicaron ambos electrodos dentro de 5 cm de la posición recomendada. La mayoría de los participantes ubicaron el electrodo apical demasiado anteriormente. De los participantes, 36.0% no estaban enterados de las nuevas guías. El estar al tanto de las nuevas guías no aumentó la precisión en la ubicación de los electrodos. *Conclusiones:* La publicación de las guías nacionales de resucitación basadas en evidencia no parecen haber influenciado la práctica de la ubicación de los electrodos de desfibrilación en mayor extensión. La ubicación correcta de los electrodos necesita ser más enfatizada en el entrenamiento de resucitación.

Palabras clave: Electrodos de desfibrilación; Línea medio axilar; Fibrilación ventricular

1. Introduction

Ventricular fibrillation (VF) is the most frequent initial rhythm in a witnessed sudden cardiac arrest and electrical defibrillation is the only effective treatment [1]. Success of defibrillation is dependent on delivering sufficient transmyocardial current to depolarize a critical mass of myocardium, estimated to be approximately 72–80% of the ventricular mass [2,3]. Factors affecting the transmyocardial current include transthoracic impedance, energy level and the ratio of current passing through cardiac tissue to current passing through non-cardiac tissues [4]. This ratio can be increased by optimizing the position of the defibrillation electrodes [5]. The current flow caused by defibrillation shock is mainly adopted by non-cardiac tissue [6,7].

The recommended position for the sternal electrode is right of the sternum, inferior to the clavicle [1]. In the 1998 guidelines of European Resuscitation Council (ERC), the recommended position of the apical electrode is defined as "over lower ribs in the mid/anterior axillary line" [8]. In 2000, the International Liaison Committee on Resuscitation (ILCOR) published guidelines which supersede guidelines of ERC and which recommend a more lateral position for the apical electrode, i.e. "to the left of the nipple with the center of the electrode in the mid-axillary line" [1].

In a study by Heames et al. [9] performed before the publication of the ILCOR guidelines in 2000, the majority of doctors positioned electrodes incorrectly. The most common error was to place the apical electrode too medially. Only 22% of the apical electrodes were placed within 5 cm of the position recommended by the ERC guidelines.

Based on the international guidelines, Finnish national evidence-based resuscitation guidelines were published in 2002. They include the new recommended electrode placement by ILCOR. The guidelines were published in Finnish in the Journal of the Finnish Medical Society Duodecim and mailed to the home of all members (80% of the Finnish physicians) and were also accessible free of charge at the Internet portal of the Society. The purpose of this study was to determinate the extent that health care professionals adhere to the new guidelines on positioning defibrillation electrodes.

2. Material and methods

Participants of the study were professionals whose duties included performing defibrillation in a resuscitation situation. They were recruited from three units of the university hospital, both from wards and emergency rooms, from one primary hospital and one health center providing primary care and from two testing situations for basic life support providers of emergency medical services in Uusimaa region. All personnel on duty on site at the moment of performing the study were recruited. The study took place 14 months after publishing the national guidelines.

In the trial, the participants were asked to attach the defibrillation electrodes (AED training pads, Laerdal Medical AS, Norway) on the chest of a resuscitation-training manikin (ResusciAnne®, Laerdal Medical AS, Norway) as they would do in a real resuscitation situation. After attaching the electrodes, the distance of the electrodes from the recommended positions in horizontal and vertical planes was measured. Electrode placement within 5 cm from the recommended position was determined as a correct placement. The participants also answered a questionnaire surveying their knowledge of the national guidelines. Special attention was paid to ensure that the test subjects did not discuss the test performance with each other.

The differences between the mean distances of electrodes from the recommended positions were analyzed using one-way ANOVA followed by Bonferroni's post hoc test to compare individual distances. The subgroups were compared with Fisher's exact test in case of two subgroups

and with chi-square in case of three subgroups. For proportions of correct placements in the subgroups, 95% CI were calculated by modified Wald method. All statistical analyses were performed using GraphPad Prism version 4.00 for Macintosh (GraphPad Software, San Diego, CA, USA).

3. Results

One hundred and thirty six professionals participated in the study. Fig. 1 shows the adherence to the current guidelines when positioning defibrillation electrodes in different subgroups regarding professions and institutions (Fig. 1A), resuscitation training (Fig. 1B) and knowledge of the resuscitation guidelines (Fig. 1C) of the participants. Of the physicians participating in the study, 10 were senior house officers in anesthesia and intensive care medicine. Only 25.0% (95% CI 18.5–32.9) of the participants placed both electrodes within 5 cm from the recommended position. In six cases (4.4%, 95% CI 1.8–9.5), the participant placed the sternal electrode to the left side and apical electrode to the right side of the patient's chest (reverse position). Fig. 2 shows the placements of the electrodes; the sternal electrode was commonly placed too medially and the apical electrode was often placed too anteriorly and, in general, farthest in distance from the recommended position in horizontal plane (Fig. 3). When the apical electrode was placed incorrectly, it was too anterior in 97.8% of the cases.

Of the participants, 22.8% (95% CI 16.5–30.6) had read the guidelines, 41.2% (95% CI 33.3–49.6) were aware of the guidelines and 36.0% (95% CI 28.4–44.4) were completely unaware of the guidelines. Only 9.6% (95% CI 5.6–15.8) of the participants recognized the picture of correct placement of electrodes used in the national guidelines to be the same as the one used in the most recent resuscitation training. The resuscitation guidelines had been discussed in the work community of 14.7% (95% CI 9.7–21.7) of the participants.

4. Discussion

This observational study shows that Finnish health care professionals with a duty to perform a defibrillation surprisingly often do not place defibrillation electrodes as recommended in both Finnish national resuscitation guidelines and ILCOR guidelines. Only a quarter of the participants placed both electrodes within 5 cm from the recommended position, which corresponds to the study by Heames et al. [9].

Although easily accessible, the national guidelines were not well known by health care professionals. In fact, about 40% of the participants were not aware of the existence of the guidelines. In surveys measuring barriers to adherence to guidelines, the awareness of guidelines has varied from 26% [10] to 99% [11]. In a literature based evaluation of quality of care in the United States a rough estimate was that 70% of patients received acute care as recommended while 30% received acute care which could be considered contraindicated [12].

The majority of the participants in the present study, who had read the guidelines, placed the apical electrode too anteriorly. One possible cause of poor adherence to the guidelines among these participants can be that the placement of the electrodes is traditionally illustrated with a frontal view picture. The frontal view is unable to show clearly the correct place of the apical electrode at the middle axillary line, which a more lateral view would do (Fig. 4). We suggest,

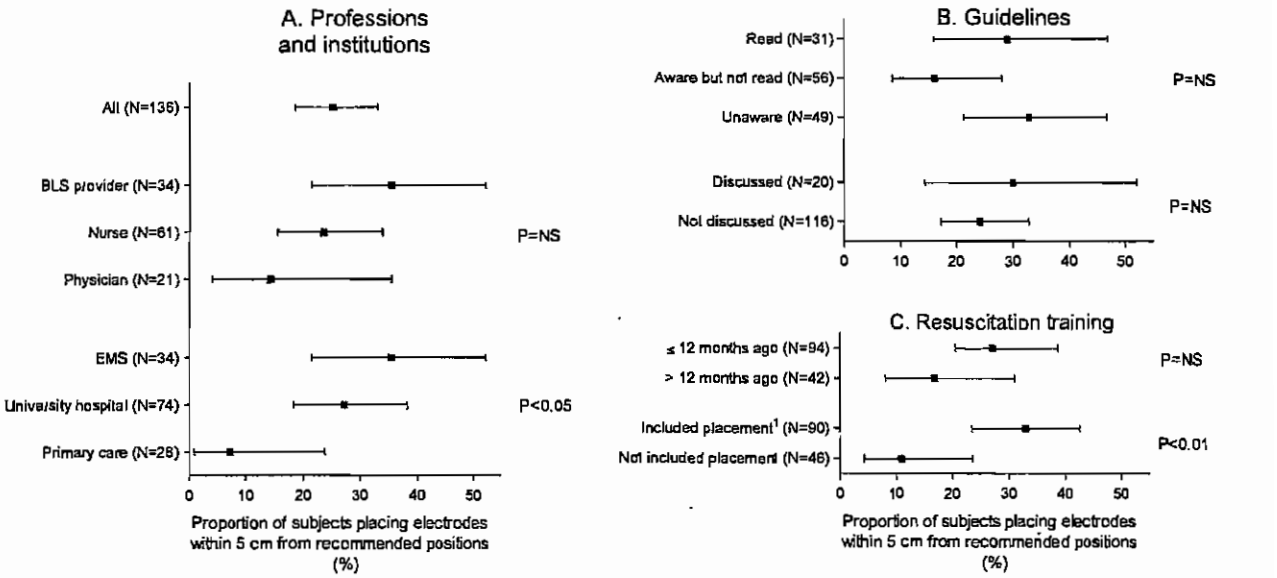


Fig. 1. (A–C) Proportion of correct defibrillation electrode placements in different subgroups with 95% confidence intervals. BLS, basic life support; EMS, emergency medical services. [1]Last defibrillation training included teaching the placement of defibrillation electrodes.

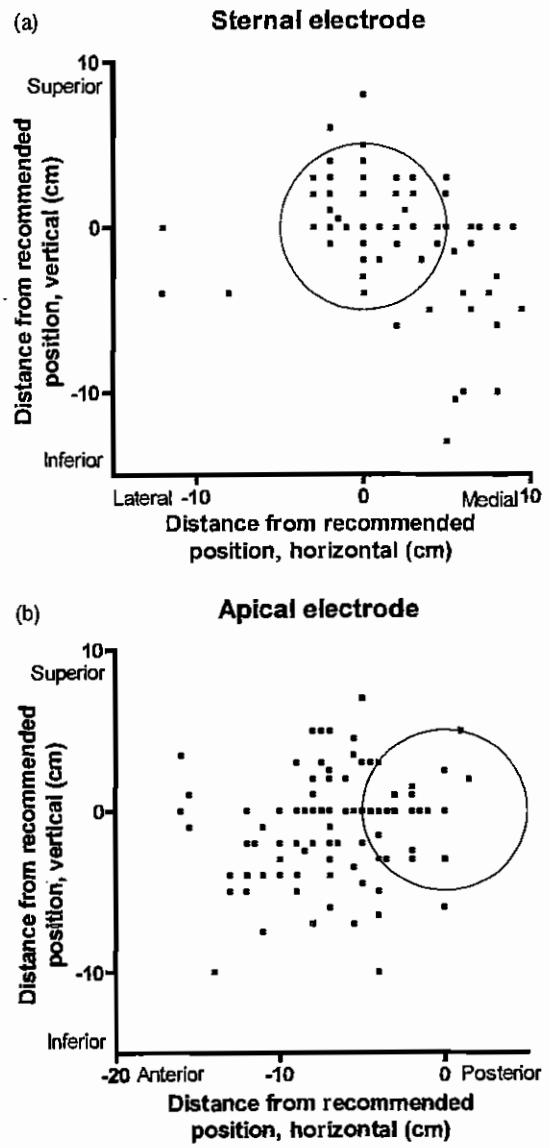


Fig. 2. The placements of the sternal and the apical electrodes. Recommended places of the electrodes are marked with circles radius 5 cm. Dots may overlap.

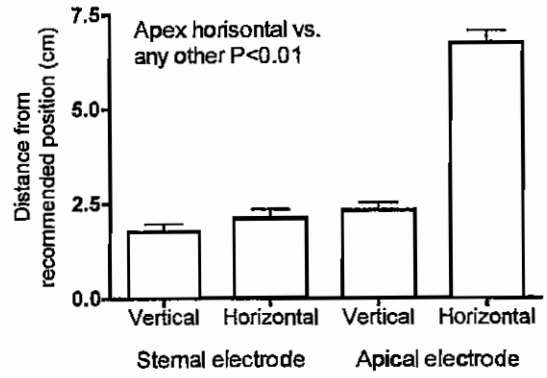


Fig. 3. Distances of the electrodes from recommended positions in vertical and horizontal planes.

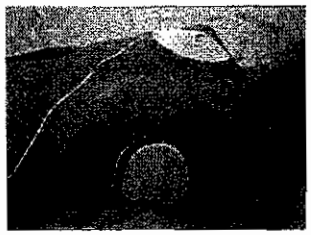


Fig. 4. The recommended placement of the electrodes.

that more attention should be paid to teaching correct positioning of the electrodes. This topic, which is essential for providing as effective defibrillation as possible, probably, has not been emphasized enough in resuscitation training and literature.

Participants whose last resuscitation training had included teaching of the placement of the electrodes and participants working frequently with emergencies, more often placed the electrodes correctly. This shows that by using some time for teaching adequate electrode placement, the electrodes are placed correctly three times more often. The duration from the last resuscitation training session did not seem to have any greater significance. However, participants whose last resuscitation training session had taken place less than a year ago generally placed the electrodes more accurately. This can be explained by the fact that the national guidelines were published about a year before the study.

On average, the performance of physicians regarding accuracy of electrode placement was rather poor. The physician subgroup was quite small and conclusions regarding lack of knowledge and training of physicians cannot be made. Earlier we have found that physicians working in hospitals clearly have less regular training and exercise in CPR as compared to, for example, nurses [13]. Nevertheless, the distribution of different professionals in the present study may follow the situation in hospitals, where ideally nurses perform a defibrillation before the physician arrives with the patient. The participants from EMS, emergency room or high dependency areas, who face emergency situations more often, followed the guideline considerably more often than participants from primary care or wards. In this study, basic life support providers of the EMS placed electrodes most often appropriately.

The recommended position of the defibrillation electrodes on the chest of the patient has been changed in the Guidelines 2000 [1]. However, the evidence that position of the defibrillation electrodes affects outcome of patient in ventricular fibrillation is still lacking. Botto and colleagues [14] have demonstrated within the patients with atrial fibrillation who underwent electrical cardioversion that position of the electrodes had an influence on the success rate of the cardioversion attempts. Measures of interelectrode impedance when using test-pulse method have demonstrated that positioning electrodes further apart decreases the shunt effect

of chest wall and thus increase the transmyocardial current [5] and the finding has been confirmed by finite element analysis [15]. However, the evident need to determine the optimal positioning of electrodes for defibrillation of ventricular fibrillation or ventricular tachycardia still exists.

5. Conclusion

About a year after publishing the national evidence based resuscitation guidelines our testing of practice in placement of the defibrillation electrodes revealed that the recommended changes had not been realized or implemented to any major extent. It is recommended that this crucial part of CPR management is strongly emphasized in training and exercises at all levels of acute care providers.

Acknowledgements

We wish to thank all persons that participated in the study and Laerdal Finland Oy for providing equipment needed to perform this study. This study was supported by The Laerdal Foundation for Acute Medicine.

References

[1] American Heart Association in Collaboration with International Liaison Committee on Resuscitation. Guidelines 2000 for cardiopulmonary resuscitation and emergency cardiovascular care: international consensus on science. Part 4. The automated external defibrillator: key link in the chain of survival. Circulation 2000;102(Suppl I):I60–76.

[2] Zipes DP, Fischer J, King RM, Nicoll A, Jolly WW. Termination of ventricular fibrillation in dogs by depolarizing a critical amount of myocardium. Am J Cardiol 1975;36:37–44.

[3] Sepulveda NG, Wikswo Jr JP, Echt DS. Finite element analysis of cardiac defibrillation current distributions. IEEE Trans Biomed Eng 1990;37:354–65.

[4] Truong JH, Rosen P. Current concepts in electrical defibrillation. J Emerg Med 1997;15:331–8.

[5] Caterine MR, Yoerger DM, Spncer KT, Miller SG, Kerber R. Effect of electrode position and gel-application technique on predicted transcardiac current during transthoracic defibrillation. Ann Emerg Med 1997;29:588–95.

[6] Deale OC, Lerman BB. Intrathoracic current flow during transthoracic defibrillation in dogs. Transcardiac current fraction. Circ Res 1990;67:1405–19.

[7] Lerman BB, Deale OC. Relation between transcardiac and transthoracic current during defibrillation in humans. Circ Res 1990;67:1420–6.

[8] Robertson C, Steen P, Adgey J, et al. The 1998 European Resuscitation Council guidelines for adult advanced life support: a statement from the Working Group on Advanced Life Support, and approved by the executive committee. Resuscitation 1998;37:81–90.

[9] Heames RM, Sado D, Deakin CD. Do doctors position defibrillation paddles correctly? Observational study. BMJ 2001;322:1393–4.

[10] Christakis DA, Rivara FP. Pediatricians' awareness of and attitudes about four clinical practice guidelines. Pediatrics 1998;101:825–30.

[11] Newton J, Knight D, Wollhead G. General practitioners and clinical guidelines: a survey of knowledge, use and beliefs. Br J Gen Pract 1996;46:513–7.

[12] Schuster MA, McGlynn EA, Brook RH. How good is the quality of health care in the United States? Millbank Quatr 1998;76:517–63.

[13] Skrifvars MB, Castren M, Kurola J, Rosenberg PH. In-hospital cardiopulmonary resuscitation: organization. Acta Anaesthesiol Scand 2002;46:458–63.

[14] Botto GL, Politi A, Bonini W, Broffoni T, Bonatti R. External cardioversion of atrial fibrillation: role of paddle position on technical efficacy and energy requirements. Heart 1999;82:726–30.

[15] Jorgenson DB, Haynor DR, Bardy GH, Kim Y. Computational studies of transthoracic and transvenous defibrillation in a detailed 3-D human thorax model. IEEE Trans Biomed Eng 1995;42:172–84.

Resuscitation (2008) 76, 226–232

available at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/resuscitation

CLINICAL PAPER

Cardiopulmonary resuscitation alone vs. cardiopulmonary resuscitation plus automated external defibrillator use by non-healthcare professionals: A meta-analysis on 1583 cases of out-of-hospital cardiac arrest☆

Tommaso Sanna[a,*], Giuseppe La Torre[c], Chiara de Waure[c], Andrea Scapigliati[b], Walter Ricciardi[c], Antonio Dello Russo[a], Gemma Pelargonio[a], Michela Casella[a], Fulvio Bellocci[a]

[a] *Institute of Cardiology, Catholic University of the Sacred Heart, Rome, Italy*
[b] *Institute of Anaesthesiology, Catholic University of the Sacred Heart, Rome, Italy*
[c] *Institute of Hygiene, Catholic University of the Sacred Heart, Rome, Italy*

Received 13 April 2007; received in revised form 30 July 2007; accepted 1 August 2007

KEYWORDS
Cardiopulmonary resuscitation (CPR);
Automated external defibrillator (AED);
Out-of-hospital CPR;
Meta-analysis

Summary
Background: Out-of-hospital cardiac arrest (OHCA) accounts for 250.000–350.000 sudden cardiac deaths per year in the United States. The availability of automated external defibrillators (AEDs) promoted the implementation of public access defibrillation programs based on out-of-hospital early defibrillation by non-healthcare professionals.
Aim of the study: To perform a systematic review and a meta-analysis of the pooled effect of studies comparing the outcome of pts receiving cardiopulmonary resuscitation plus AED therapy (CPR + AED) vs. cardiopulmonary resuscitation (CPR) alone, both delivered by non-healthcare professionals, for the treatment of OHCA.
Methods: We performed a search of the relevant literature exploring major scientific databases, carrying out a hand search of key journals, analysing conference proceedings and abstracts and discussing the topic with other researchers. Two analyses were planned to assess the outcomes of interest (survival to hospital admission and survival to hospital discharge).
Results: Three studies were selected for the meta-analysis. The first meta-analysis evidenced a RR of 1.22 (95% C.I.: 1.04–1.43) of surviving to hospital admission for people treated with

☆ A Spanish translated version of the summary of this article appears as Appendix in the final online version at 10.1016/j.resuscitation.2007.08.001.

* Corresponding author.
E-mail address: tommaso.sanna@rm.unicatt.it (T. Sanna).

doi:10.1016/j.resuscitation.2007.08.001

CPR+AED as compared to CPR-only. The second meta-analysis showed a RR of 1.39 (95% C.I.: 1.06–1.83) of surviving to hospital discharge for people treated with CPR+AED as compared to CPR-only.

Conclusions: The results of our meta-analysis demonstrate that programs based on CPR plus early defibrillation with AEDs by trained non-healthcare professionals offer a survival advantage over CPR-only in OHCA. The conclusions of our meta-analysis add to previous evidence in favour of developing public-health strategies based on AED use by trained layrescuers.

Background

Out-of-hospital cardiac arrest (OHCA) accounts for 250.000–350.000 sudden cardiac deaths (SCD) per year in the United States, thus representing a major public-health issue.[1–5] OHCA may be caused by asystole, electromechanical dissociation, pulseless ventricular tachycardia (VT) or ventricular fibrillation (VF).[6] While the prognosis of asystole and electromechanical dissociation remains poor despite advanced life support, pulseless ventricular tachycardia and ventricular fibrillation, which are the presenting rhythm of OHCA in 41–70% of cases,[7,8] can be effectively terminated by defibrillation. Unfortunately the probability of survival decreases of 5–10% per minute of delay in administration of defibrillation, thus making early defibrillation one of the most critical links in the chain of survival.[6] In the past, defibrillation had been used by healthcare professionals only (physicians, nurses, paramedics, emergency medicine technicians) with manual defibrillators, which require expertise in rhythm recognition and extensive resuscitation algorithms knowledge. With the availability of automated external defibrillators (AEDs), which do not require expertise in rhythm recognition or extensive resuscitation algorithm knowledge, the opportunity of using defibrillation has been extended to non-healthcare professionals.

The great epidemiological burden of OHCA and the availability of AEDs promoted the implementation of Public Access Defibrillation programs based on out-of-hospital early defibrillation by non-healthcare professionals, and qualitative reviews on this topic have been published.[9]

Aim of the study

The aim of the present study was to perform a systematic review and a meta-analysis of the pooled effect of studies comparing standard cardiopulmonary resuscitation (CPR) to CPR+AED use by non-healthcare professional first responders for treatment of OHCA.

Methods

Identification of relevant studies

Studies eligible for our meta-analysis were those randomised trials comparing survival in patients with OHCA treated by CPR+AED vs. CPR-only, both performed by non-healthcare professional first responders. We carried out a search of the relevant scientific literature using the Pubmed, Embase, Cochrane collaboration, Central Register of Controlled Trial databases and the "C2005 Evidence Evaluation Worksheets" which assisted the development of the ILCOR 2005 resuscitation guidelines. We also performed a hand search of major journals, discussed the topic with other researchers, explored conference proceedings and abstracts with the purpose of finding out other published studies. Limited attempt was made to identify unpublished studies. No limits were set on the searches in terms of date of publication or language. The end date of the search was 20/07/07.

The Pubmed search was performed using the keywords (automated external defibrillat*) OR (public access defibrillat*) and then restricted to 184 records with the search string proposed by Biondi-Zoccai et al.[10] and reported in Appendix A.

The search in the Embase database was performed using the keywords "public access defibrillation" OR "automated external defibrillation" and retrieved 305 references.

The search in the Cochrane Library was performed using the following specifications: "public access defibrillation" in title, abstract and keywords OR "automated external defibrillator" in title, abstract, keywords and retrieved 27 articles.

The "Worksheet BLS—What is the safety, effectiveness and feasibility of AED programs?" was selected and analysed from the "C2005 Evidence Evaluation Worksheets" collection, arranged to assist the development of the ILCOR 2005 resuscitation guidelines.[11] From this worksheet we selected those studies with a level of evidence 1 or 2 that were defined as "randomised clinical trials or meta-analyses of multiple clinical trials with substantial treatment effects" and "randomised clinical trials with smaller or less significant treatment effects", respectively.

Titles, abstracts and keywords of the selected articles were analysed independently by two researchers. Potentially eligible studies were retrieved and further analysed. The flow-chart of the study selection process is detailed in Figure 1. A targeted inquiry of major ongoing-trials databases was also performed to identify ongoing studies that may render the meta-analysis redundant. The inquiry of the United States National Institutes of Health ongoing-trial database at http://www.clinicaltrials.gov was performed selecting the keyword "automated external defibrillator" and retrieved six trials. The inquiry of the international ongoing-trial database at http://www.controlled-trials.com was performed selecting the keyword "automated exter-

nal defibrillator'' and retrieved eight trials. None of the selected trials appeared to have the potential to render our analysis futile.

Quality assessment and data extraction

We assessed the quality of studies applying the JADAD scale scores.[12] The JADAD scale is aimed at ensuring quality of meta-analyses. The quality is assessed by five different items (description of randomisation, description of blinding, description of withdrawals and drop-outs, appropriate randomisation, appropriate blinding in allocation). The JADAD scores may range from –2 to 5. The scores for the selected studies were independently computed by two different researchers. A priori, a score of 3 or above was considered enough to qualify the study for the analysis.

Data extraction from studies was separately performed by two researchers. Data on survival to hospital admission and discharge between both the CPR plus automated external defibrillator treated group and the CPR-only treated group were analysed on the basis of the ''intention to treat''.

Statistical analysis

Meta-analysis was performed using risks ratios (RRs) as a pooled effect estimate of treatment vs. control, since in the selected studies the considered outcomes were dichotomous. Random effects models were used to combine the data and statistical heterogeneity was assessed using the χ^2 test. Data were elaborated with the software Review Manager 4.2 (RevMan) for Windows.

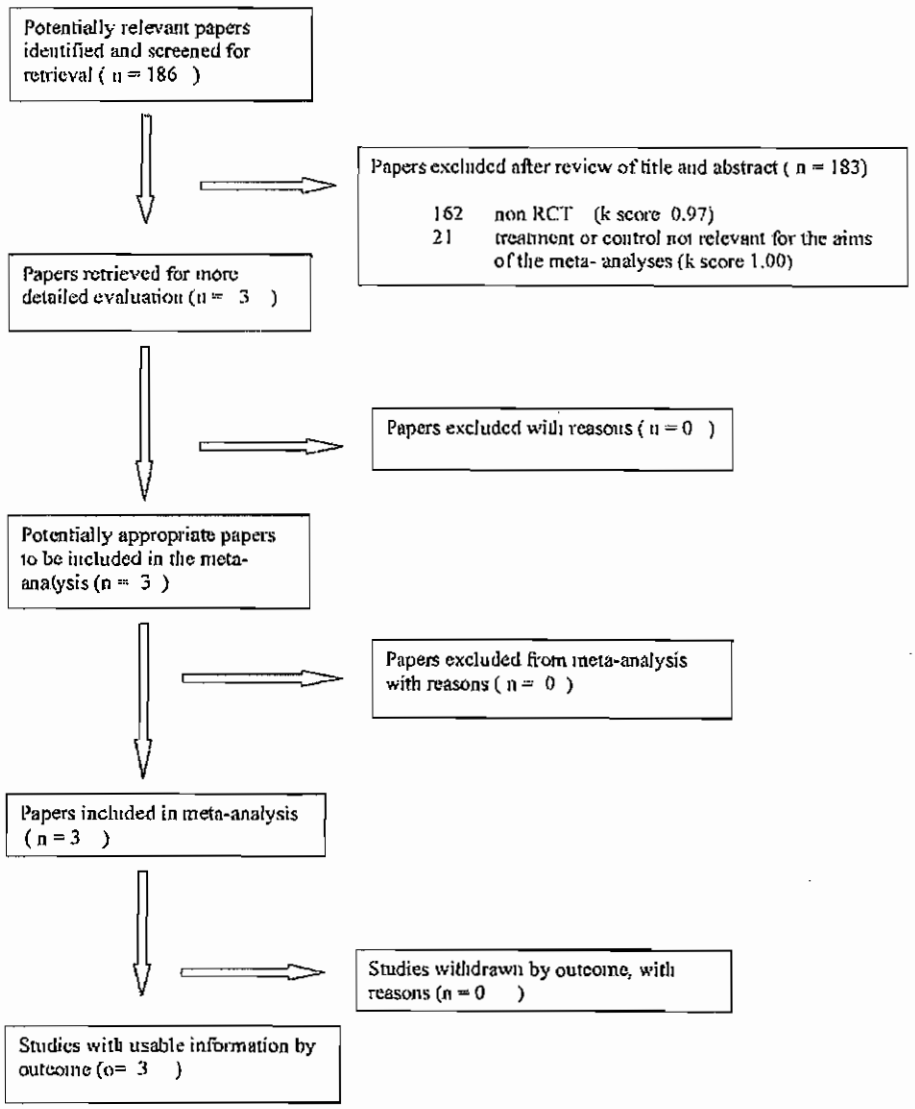


Figure 1 QUORUM statement flow-chart of study selection process.

Table 1 Characteristics and data of selected studies

	Kellerman et al. JAMA 1993	van Alem et al. BMJ 2003	Hallstrom et al. NEJM 2004
Active treatment	CPR + AED use by trained fire-fighters	CPR + AED use by trained fire-fighters or police	CPR + AED use by trained volunteer lay rescuers
Control treatment	CPR by trained fire-fighters	CPR by trained fire-fighters	CPR by trained volunteer lay rescuers
Treatment allocation	AED equipped areas vs. non AED equipped areas with cross-over	Cluster randomisation of AED equipped areas vs. non AED equipped areas with cross-over	Cluster randomisation of AED equipped areas vs. non AED equipped areas
Primary Endpoints	Survival at hospital admission Survival to hospital discharge Return of spontaneous circulation Neurological impairment	Survival at hospital admission Survival to hospital discharge Return of spontaneous circulation	Survival to hospital discharge
CPR + AED group (*n*)	447	243	107
Mean age (S.D.) in CPR + AED group	64.1 (15.3)	67 (14)	N.A.
Percentage (*n*) of men in CPR + AED group	60.9% (272)	77% (187)	N.A.
CPR-only group (*n*)	432	226	128
Mean age (S.D.) in CPR-only group	65.1 (15.2)	65 (14)	N.A.
Percentage (*n*) of men in CPR-only group	63.4% (274)	76% (172)	N.A.
Survival to admission	AED: 112 CPR: 101	AED: 103 CPR: 74	AED: 29 CPR: 50
Survival to discharge	AED: 40 CPR: 27	AED: 44 CPR: 33	AED: 30 CPR: 15
JADAD score	3	3	4

Results

Study selection process

The study selection process identified three studies eligible for the meta-analysis and their characteristics are summarised in Table 1.[13–15] The selected studies were all clinical trials. The intervention in the trials was the use of AED by non-healthcare professional rescuers in addition to CPR before the arrival of emergency medical services (EMS). The controls for each of the trials were considered appropriate for the purposes of the analysis. In the trial by Kellermann et al. fire-fighters in the control group performed CPR until EMS arrival. In the trial by van Alem et al. police units, but not fire-fighters, performed CPR until EMS arrival in the control group. In the study by Hallstrom et al. patients in the control group were attended by lay volunteers who performed CPR-only. *Randomisation*. The studies by van Halem and Hallstrom used cluster randomisation based on geographical areas, with a periodic cross-over design in the first one. The trial by Kellermann was defined by the authors as a non-randomised trial. However, allocation to active treatment or control was actually determined by chance depending on the availability of an AED on the fire-fighters rescue vehicle in the area; moreover a periodic cross-over design minimised bias. Additionally, the ILCOR 2005 scientific committee ranked this study as a *level of evidence 2* study (defined as "randomised clinical trials with smaller or less significant treatment effects"). *Setting*. All the studies

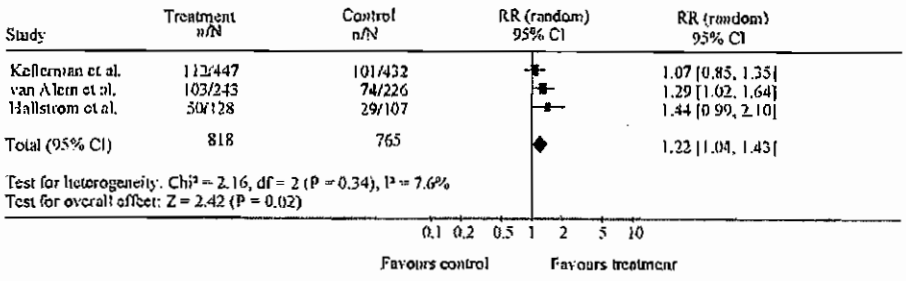


Figure 2 Meta-analysis: survival at hospital admission.

were carried out in the urban setting. *Blinding*. Blinding of patients and responders was not possible in any study.

Quality assessment and data extraction

Each of the selected studies was ranked of good quality according to the JADAD scale. The assigned scores were 3 for the study of Kellerman et al., 4 for the study of Hallstrom et al. and 3 for that of van Alem et al. Data on treatment allocation and survival to hospital admission and discharge were collected on 1583 cumulative cases of OHCA, and detailed results are presented in Table 1.

Statistical analysis

We performed two different meta-analyses on 1583 cases of OHCA exploring the effect of a CPR + AED vs. a CPR-only strategy deployed by lay rescuers on survival to hospital admission and on survival to hospital discharge.

The first meta-analysis evidenced a RR of 1.22 (95% C.I.: 1.04-1.43; $p=0.014$) of surviving at hospital admission for people treated with CPR + AED compared to CPR-only, and the chi square test did not show heterogeneity between studies ($p=0.34$) (Figure 2).

The second meta-analysis showed a RR of 1.39 (95% C.I.: 1.06–1.83; $p=0.019$) of surviving to hospital discharge for people treated with CPR + AED compared to CPR-only, and the chi square test did not show heterogeneity between studies ($p=0.70$) (Figure 3).

Considering a possible clustering in the studies, we performed a further analysis following the procedure described by Greenland,[16] and found an OR pooled of 1.30 (95% CI: 1.06–1.61; p for homogeneity = 0.217) for the first meta-analysis, and of 1.51 (1.20–2.05; p for homogeneity = 0.784) for the second one, respectively.

Funnel plots relative to the first and the second meta-analyses are shown in Figure 4.

The number *needed to treat* (NNT) was also computed for the two endpoints. The number of out-of-hospital cardiac arrests to be treated by trained non-healthcare professionals by CPR + AED to gain one survival to hospital admission was 17 (NNT = 17). The number of out-of-hospital cardiac arrests to be treated by trained non-healthcare professionals by CPR + AED use to gain one survival to hospital discharge was 24 (NNT = 24).

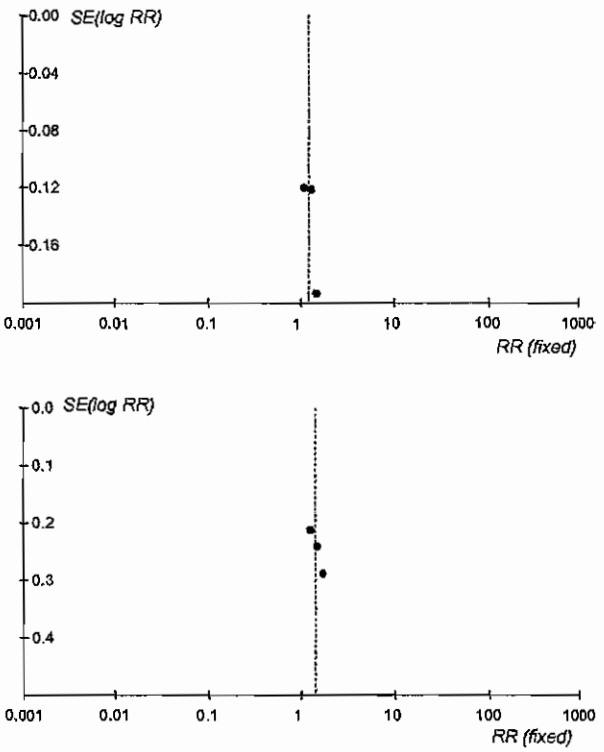


Figure 4 Funnel plot in relation to meta-analysis "survival to hospital admission" (top) and "survival to hospital discharge" (bottom).

Discussion

The great epidemiologic burden of sudden and unexpected cardiac death together with the availability of AEDs promoted the development of programs based on early defibrillation by non-healthcare professionals. However, clinical trials comparing CPR plus AED use by non-healthcare professionals against CPR-only before the arrival of EMS are only a few and show a modest benefit. In fact, even though the studies included in the analysis showed a survival benefit of being treating with an AED compared with CPR, none of them showed statistical significant confidence intervals, except for survival to hospital admission in the study by van Alem.

Usually, one of the aims of pooled analysis is to increase the power of the single studies, and in our case we obtained

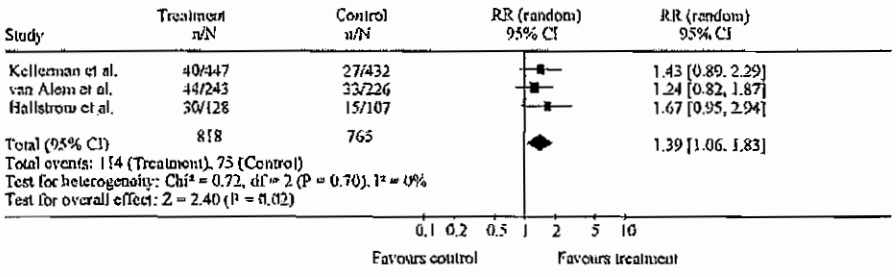


Figure 3 Meta-analysis: survival to hospital discharge.

results of individual trials adding up to 1583 cases of OHCA, demonstrating a survival benefit with significant 95% confidence intervals for both survival to hospital admission and discharge.

The results of a CPR + AED strategy delivered by lay rescuers are probably attributable to the recognised prognostic role of early defibrillation on those cardiac arrests with a shockable presentation rhythm.

We are aware of the limitations of our study. Resuscitation algorithms have changed significantly since the conduction of the studies included in our analysis. In more detail CPR-only before first shock delivery is currently advised for unwittnessed arrest, the chest compression–ventilation ratio and the DC shock delivery sequence has been modified. All of these modifications could significantly affect the results of similar analyses in the future. Moreover, the superiority of cardiac-only resuscitation over standard CPR has been recently emphasised.[17] Additionally, several differences should be pointed out. First, the performance of police or fire-fighters based programs could be different from that of lay volunteers based programs. Second, in the study by van Alem et al. both fire-fighters and police units attended cardiac arrests and performed early defibrillation in the AED group, while in the control group cardiac arrest was attended only by fire-fighters (and not by police units) and this may have biased the results. Third, the AED was deployed by mobile rescue units in the studies by Kellermann and van Alem while it is not entirely clear how the AED was deployed in the study by Hallstrom. Finally, the trial by Kellermann was defined by the authors as a non-randomised trial, but as already pointed out the allocation to active treatment or control was actually determined by chance by the availability of an AED on the fire-fighter rescue vehicle so that even the ILCOR 2005 scientific committee ranked this study as a level of evidence 2 study (defined as "randomised clinical trials with smaller or less significant treatment effects") in the development of international resuscitation guidelines. However, even in a sensitivity analysis excluding the study of Kellerman et al., the relative risks of survival to hospital admission and to hospital discharge still favoured the AED based approach (1.34 [1.09–1.64] and 1.38 [0.99–1.92], respectively).

The χ^2 test did not point out heterogeneity between studies, but we have to acknowledge that since the analysed trials are few the test had a low power; however, the p-values are higher than 0.10 which is the cut off often chosen when test power is low and the I^2 values are under 50%, thus allowing us to trust that studies are homogeneous enough. Finally, as funnel plots show (Figure 4), it is plausible that small studies with results worse than our pooled estimate were not published. The limited attempt to identify unpublished studies might have affected the results of our investigation.

Conclusion

The results of our meta-analysis demonstrate that programs based on CPR plus early defibrillation with AEDs by trained non-healthcare professionals offer a survival advantage over CPR-only in out-of-hospital cardiac arrest. The conclusions of our meta-analysis add to previous evidence in favour of developing public-health strategies based on AED use by trained lay-rescuers.

Conflict of interest

The authors declare no conflict of interest.

Appendix A

Randomised controlled trial [pt] OR controlled clinical trial [pt] OR randomised controlled trials [mh] OR random allocation [mh] OR double-blind method [mh] OR single-blind method [mh] OR clinical trial [pt] OR clinical trials [mh] OR (clinical trial [tw] OR ((singl* [tw] OR doubl* [tw] OR trebl* [tw] OR tripl* [tw]) AND (mask* [tw] OR blind* [tw])) OR (latin square [tw]) OR placebos [mh] OR placebo* [tw] OR random* [tw] OR research design [mh:noexp] OR evaluation studies [mh] OR follow-up studies [mh] OR prospective studies [mh] OR cross-over studies [mh] OR control* [tw] OR prospectiv* [tw] OR volunteer* [tw]) NOT (animal [mh] NOT human [mh]) NOT (comment[pt] OR editorial[pt] OR meta-analysis[pt] OR practice-guideline[pt] OR review[pt])

References

1. Gillum RF. Sudden coronary death in the United States: 1980–1985. Circulation 1989;79:756–65.
2. Escobedo LG, Zack MM. Comparison of sudden and non-sudden coronary deaths in the United States. Circulation 1996;93:2033–6.
3. Cobb LA, Fahrenbruch CE, Olsufka M, Copass MK. Changing incidence of out-of-hospital ventricular fibrillation 1980–2000. JAMA 2002;288:3008–13.
4. American Heart Association. Heart disease and stroke statistics 2005 update. Dallas, TX: American Heart Association; 2004.
5. Stiell IG, Wells GA, Field B, et al. Advanced cardiac life support in out-of-hospital cardiac arrest. N Engl J Med 2004;351(7):647–56.
6. European Resuscitation Council. Advanced Life support Manual;2006.
7. Cobb LA, Fahrenbruch CE, Olsufka M, Copass MK. Changing incidence of out-of-hospital ventricular fibrillation 1980–2000. JAMA 2002;288(23):3008–13.
8. Kuisma M, Repo J, Alaspaa A. The incidence of out-of-hospital ventricular fibrillation in Helsinki, Finland, from 1994 to 1999. Lancet 2001;358(9280):473–4.
9. Clare C. Do public access defibrillation (PAD) programs lead to an increase of patients surviving to discharge from hospital following out of hospital cardiac arrest? A literature review. Int J Nurs Stud 2006;43(8):1057–62.
10. Biondi-Zoccai GG, Agostoni P, Abbate A, Testa L, Burzotta F. A simple hint to improve Robinson and Dickersin's highly sensitive PubMed search strategy for controlled clinical trials. Int J Epidemiol 2005;34(1):224–5 [author reply 225].
11. ILCOR. Worksheet BLS—What is the safety, effectiveness and feasibility of AED programs? C2005 Evidence Evaluation Worksheets 2005. Available online at http://www.americanheart.org/downloadable/heart/1107551842234b.AED.Kos.27_jan_05.Final.pdf.
12. Jadad AR, Moore RA, Carroll D, et al. Assessing the quality of reports of randomized clinical trials: is blinding necessary? Control Clin Trials 1996;17(1):1–12.

13. Kellermann AL, Hackman BB, Somes G, Kreth TK, Nail L, Dobyns P. Impact of first-responder defibrillation in an urban emergency medical services system. JAMA 1993;270(14):1708–13.
14. van Alem AP, Vrenken RH, de Vos R, Tijssen JG, Koster RW. Use of automated external defibrillator by first responders in out of hospital cardiac arrest: prospective controlled trial. BMJ 2003;327(7427):1312.
15. Hallstrom AP, Ornato JP, Weisfeldt M, et al. Public-access defibrillation and survival after out-of-hospital cardiac arrest. N Engl J Med 2004;351(7):637–46.
16. Rothman KJ, Greenland S. Modern epidemiology. 2nd ed. Philadelphia: Lippincott-Raven; 1998.
17. The SOS-KANTO study group. Cardiopulmonary resuscitation by bystanders with chest compression only (SOS-KANTO): an observational study. *Lancet* 2007;369(9565):920–6.