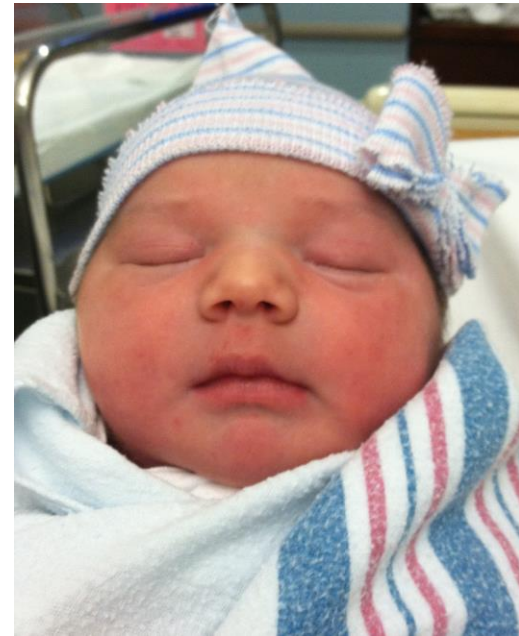


# The Early Limited Formula Study: Improving the Transition from Hospital to Home for Newborns with Pronounced Weight Loss

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# Funding

- HRSA/Maternal Child Health Bureau  
R40 MC26820
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- National Institute of Child Health and  
Human Development K23HD059818

# Outline

- **Early breastfeeding**
- Postnatal weight loss
- Postnatal breastfeeding with early limited formula



# Early feeding

- Volumes of colostrum are low, about 1-5 mL per feeding in the first 2-5 days
- Newborn weight loss is nearly universal
- Can lead to milk supply concern



# Early formula use

- Multiple studies show that early formula use is strongly associated with reduced breastfeeding duration (observational)
  - *Bolton et al., J Human Lact 2009: First-day formula use reduced breastfeeding duration by 10 days*
  - *DiGirolamo et al., Pediatrics 2008: Using formula in the nursery was associated with an OR of 0.35 (0.27, 0.47) for breastfeeding at 6 weeks*

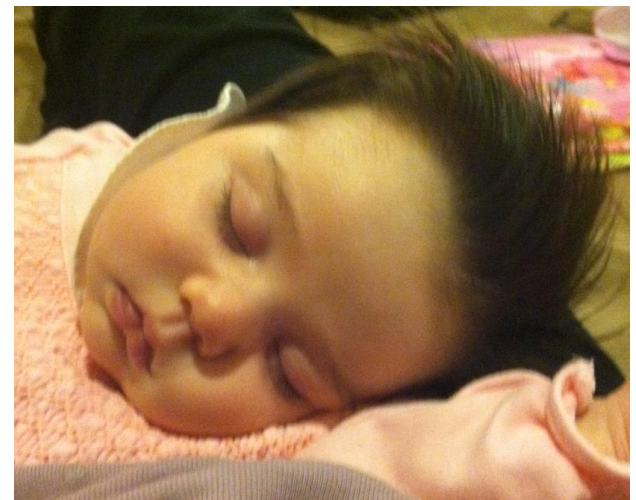
# Early formula and breastfeeding duration: Experimental evidence

- Gray-Donald 1985: No difference in breastfeeding rates between those assigned to a ward with formula restriction and without restriction (54% breastfeeding at 9 weeks in both groups)
- Schubiger 1997 (UNICEF): No difference between sites randomly assigned to supplement restriction and controls (57% vs. 55% at 6 months)



# Public health strategy

- Reduce early formula use to improve breastfeeding duration
  - *Centers for Disease Control and Prevention Healthy People 2020*
  - *World Health Organization/Baby Friendly Hospital Initiative*
  - *Joint Commission*



# Trends in breastfeeding

- Rates of early formula use have declined dramatically over the past 10 years in the U.S.
- However, breastfeeding rates at 6 months have been relatively stable ( $\approx 40\text{-}45\%$ )
- Rates of breastfeeding at 12 months remain low ( $\approx 20\%$ )



# Could outcomes be better if interventions were targeted based on weight loss?

- Weight loss is common for exclusively breastfed newborns and associated with increased risk of dehydration and hypernatremia
- Formula may be used in the context of pronounced weight loss
  - *10-25% of exclusively breastfed newborns lose  $\geq 10\%$  of their birth weight*

# Outline

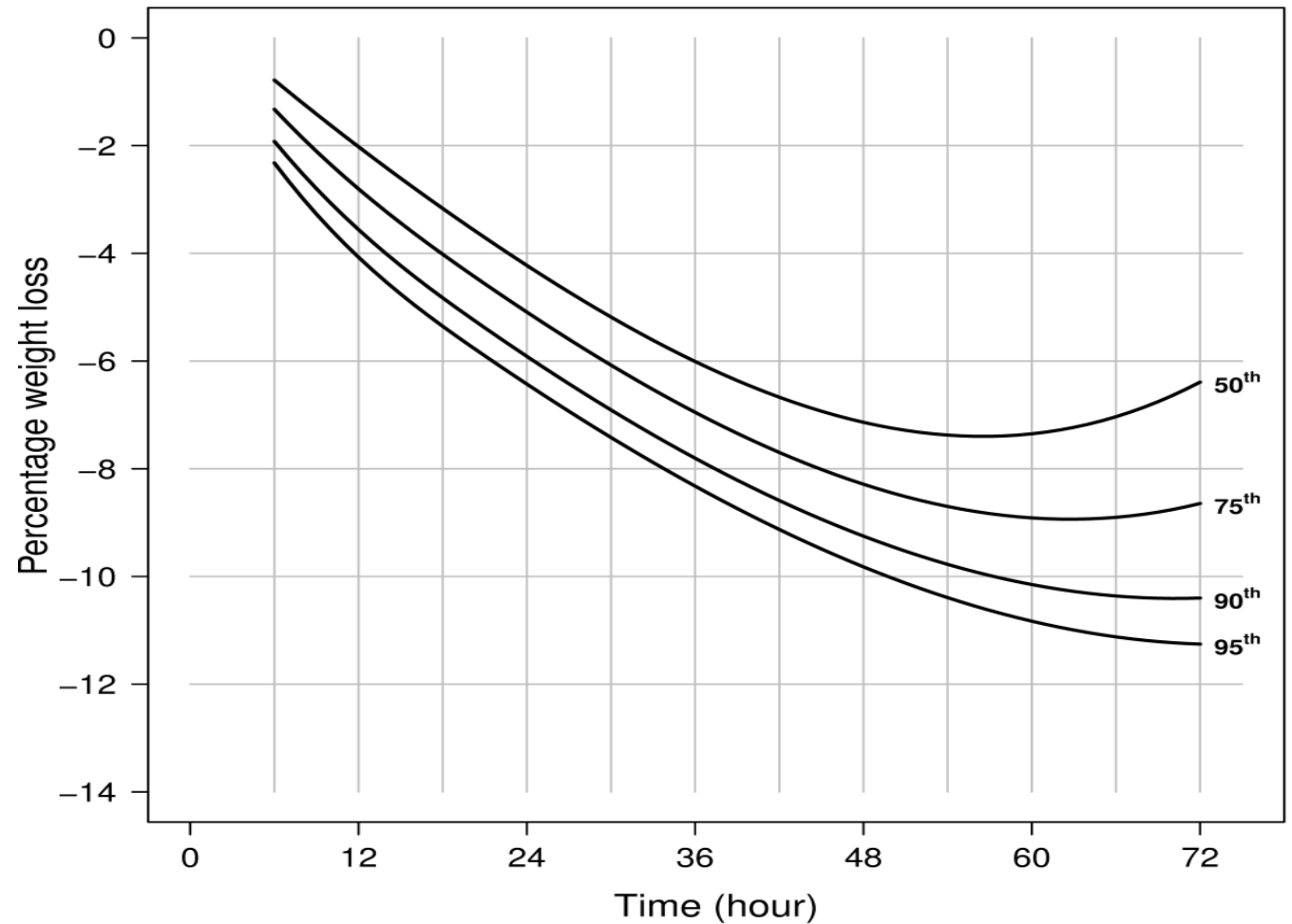
- Early breastfeeding
- **Postnatal weight loss**
- Postnatal breastfeeding with early limited formula



# Normal newborn weight loss patterns

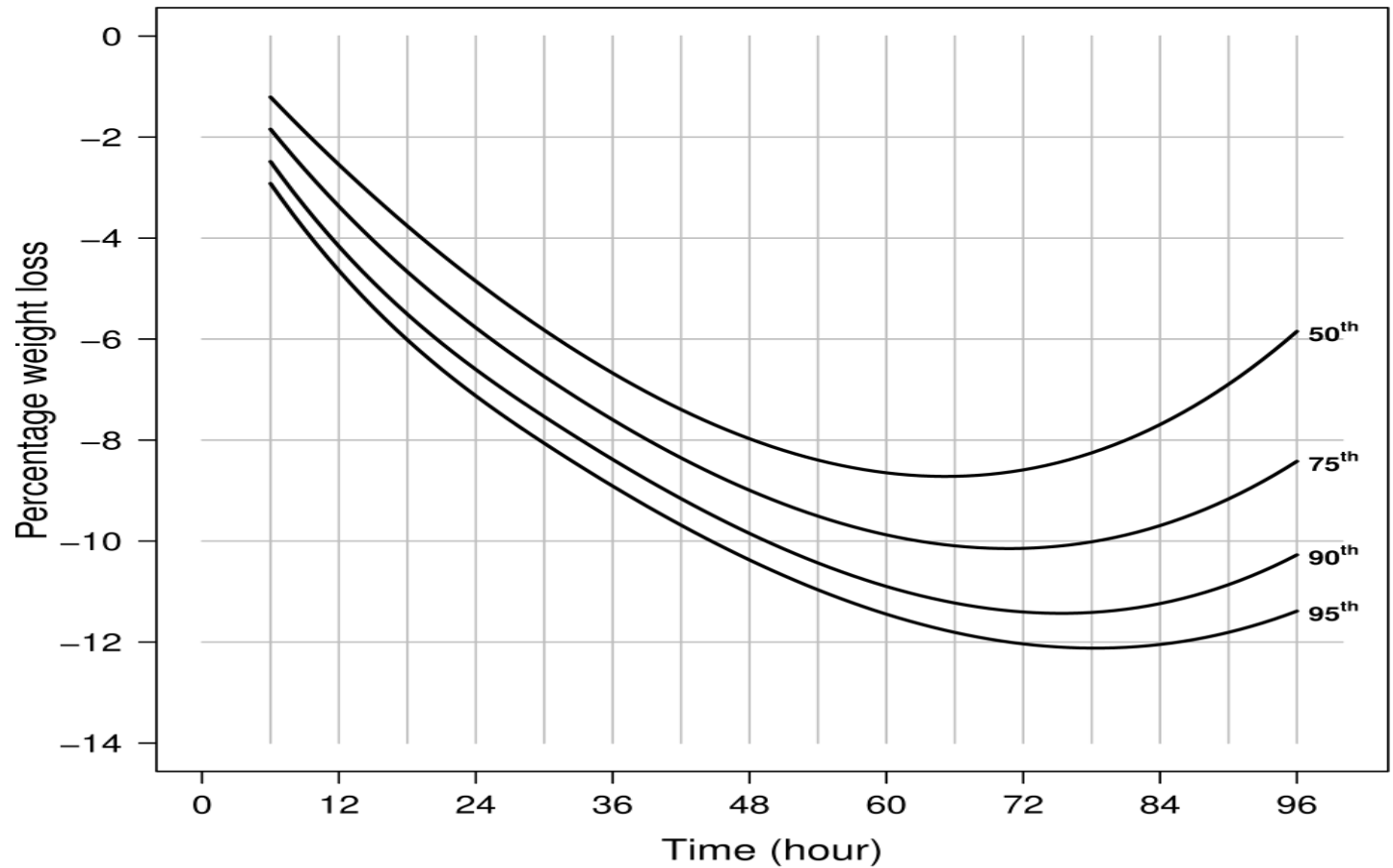
- $\approx 160,000$  healthy term babies born at 14 Kaiser Permanente Medical Center hospitals
- Data on inpatient weights and feedings
- All weights subsequent to the first supplementary feeding were excluded
- Included weights were prior to any supplementary feeding

# Results\*—Vaginal



\*Flaherman VJ et al. Pediatrics 2015

# Results—Cesarean





**newt**  
Newborn Weight Tool

PENNSSTATE HERSHEY  
Children's Hospital



## What is it?

"Newt is the first tool that allows pediatric healthcare providers and parents to see how a newborn's weight during the first days following childbirth compares with a large sample of newborns, which can help with early identification of weight loss issues."

Ian M. Paul, M.D., M.Sc.  
Chief, Division of Academic General Pediatrics  
Penn State Hershey Children's Hospital

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To start, we need a few details:

**Birth Weight** (kg or g)

---

**Birth Date**

---

**Birth Time** (24 hr)

00:00

**Delivery**

☒ Vaginal

☐ Cesarean

**Feeding Method**

☒ Breast Fed

☐ Formula Fed

Additional Measurement:

**Weight** (kg or g)

---

**Date**

---

**Time** (24 hr)

00:00

By using this tool, you agree to our [terms of service](#).

[Graph it](#)



# NEWT: The Newborn Weight Tool

[www.newbornweight.org](http://www.newbornweight.org)

UCSF Medical Center

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UCSF Benioff Children's Hospital





## What is it?

"Newt is the first tool that allows pediatric healthcare providers and parents to see how a newborn's weight during the first days following childbirth compares with a large sample of newborns, which can help with early identification of weight loss issues."

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To start, we need a few details:

<b>Birth Weight</b> (kg or g) <b>3100</b>	<b>Birth Date</b> <b>Apr 10</b>	<b>Birth Time</b> (24 hr) <b>1130</b>
<b>Delivery</b> <input type="radio"/> Vaginal <input checked="" type="radio"/> Cesarean	<b>Feeding Method</b> <input checked="" type="radio"/> Breast Fed <input type="radio"/> Formula Fed	

Additional Measurement:

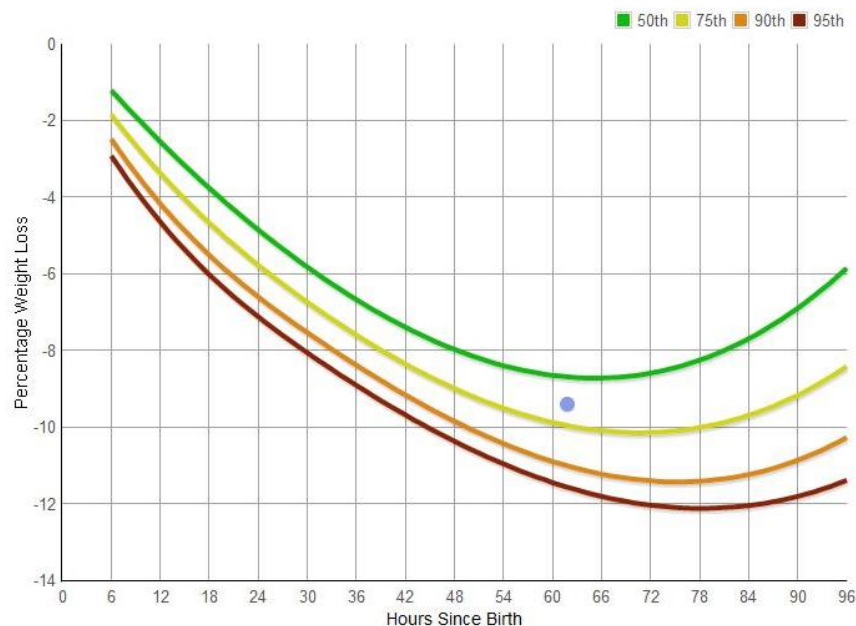
<b>Weight</b> (kg or g) <b>2810</b>	<b>Date</b> <b>Apr 13</b>	<b>Time</b> (24 hr) <b>0120</b>
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By using this tool, you agree to our [terms of service](#).

Graph it







newt



## Birth Details

Weight 3100 g Date Apr 10 Time 11:30

Cesarean Breast Fed [Edit Details](#)

## Measurements

Hour	Weight	Change	<a href="#">Add New</a>
Birth	3100 g	—	<a href="#">Edit</a>
61.8	2810 g	-9.4%	<a href="#">Edit</a> <a href="#">x</a>

PENNSTATE HERSHEY  
Children's Hospital

## How to read the results

Newt plots birth weights at intervals you define, with each point representing a percentage change from birth weight. The nomogram shows your measurements in relation to percentiles calculated from our data and research. Results that trend toward higher percentile levels may provide early identification of adverse weight loss conditions. [Learn more about Newt and the research that supports it, and why the data is only applicable in breast feeding situations.](#)

## Our Partners



# Outline

- Early breastfeeding
- Postnatal weight loss
- **Postnatal breastfeeding with early limited formula**



# Tailor breastfeeding with early weight loss?

## **Early limited formula (ELF)**

- Temporary: Begun early and stopped at the onset of mature milk production
- Limited, small volume (5, 10, 15 mL)
- Discontinued at the onset of mature maternal milk production

# Early limited-volume formula (ELF)

- Reduce the risk of dehydration and hypernatremia
- Maximize breastfeeding demand at the onset of mature milk production
- Preclude the development of anxiety and milk supply concern
- Potentially improve breastfeeding duration



# Early Limited Formula for Treating Lactation Concerns (ELF-TLC)

- Design: Randomized controlled trial
- Population: 164 healthy term infants from Penn State and San Francisco
  - Exclusively breastfed
  - Mothers had not yet had onset of copious milk production
  - Weight loss of  $\geq 75^{\text{th}}$  centile of NEWT



# ELF—Randomization arms

Intervention group:

10 mL extensively hydrolyzed formula following each breastfeeding by cup, spoon or syringe and NOT bottle. Discontinue formula at onset of mature milk production



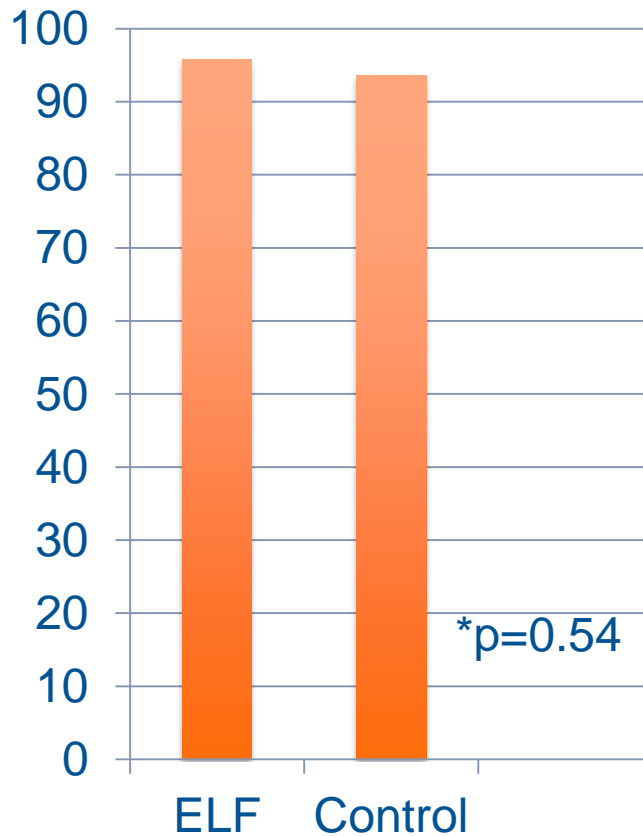
Control group:

Continue exclusive breastfeeding unless otherwise directed by health care provider

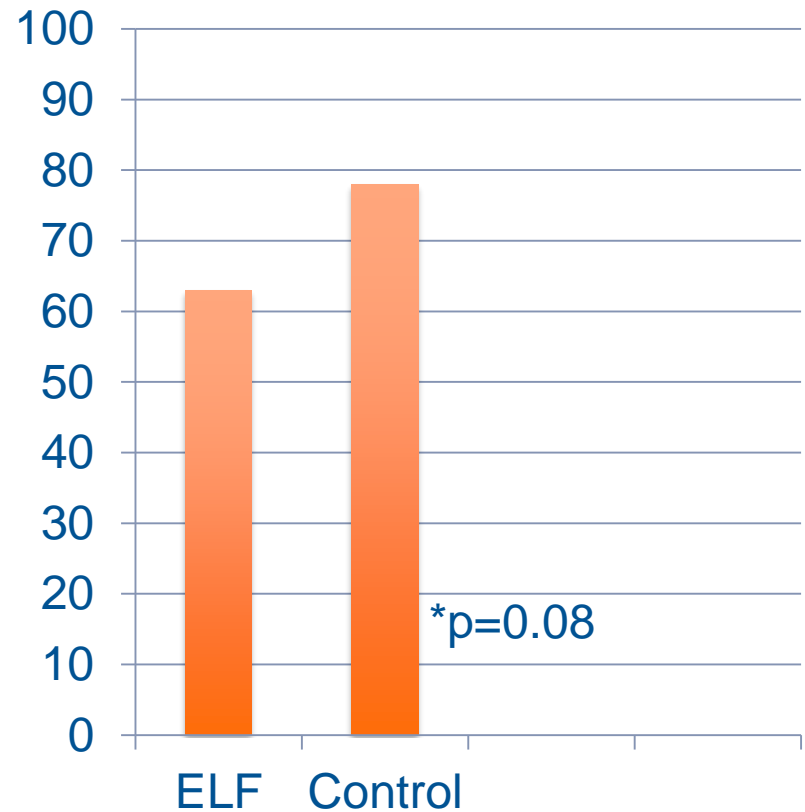


# Breastfeeding: 1 week

## Breastfeeding



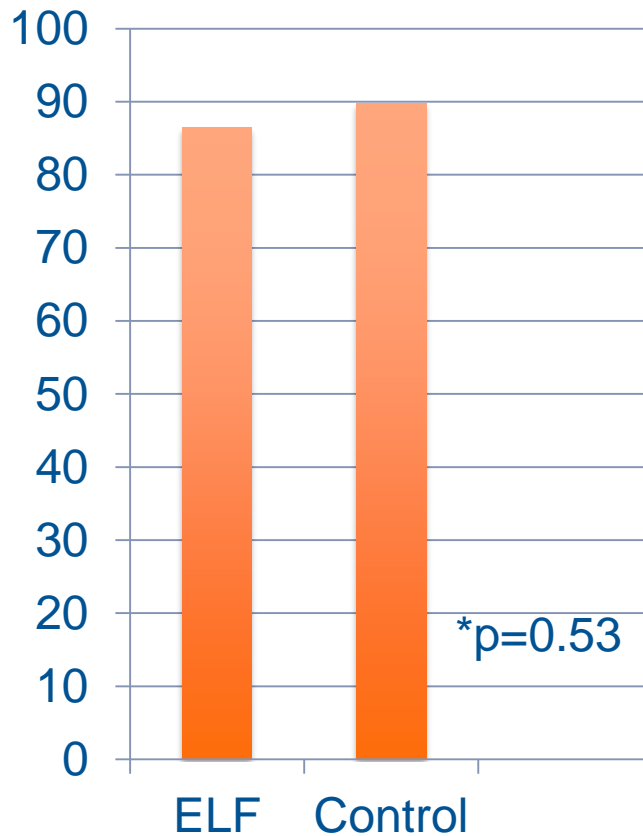
## Breastfeeding without formula



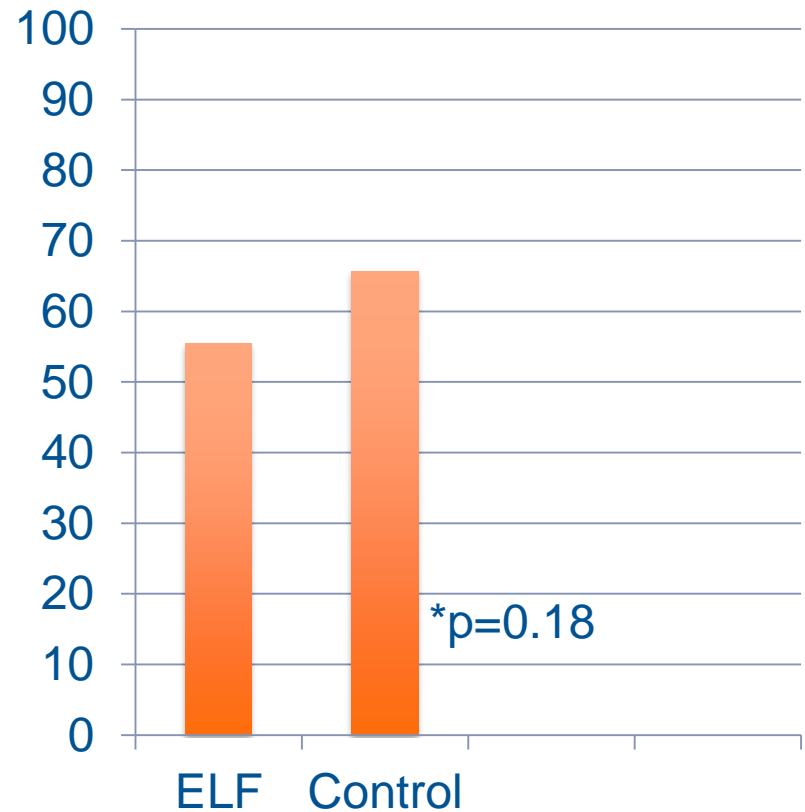


# Breastfeeding: 1 month

## Breastfeeding



## Breastfeeding without formula





# Maternal experience

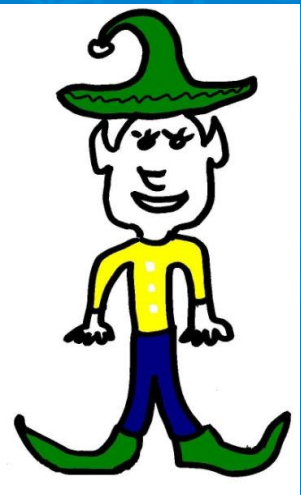
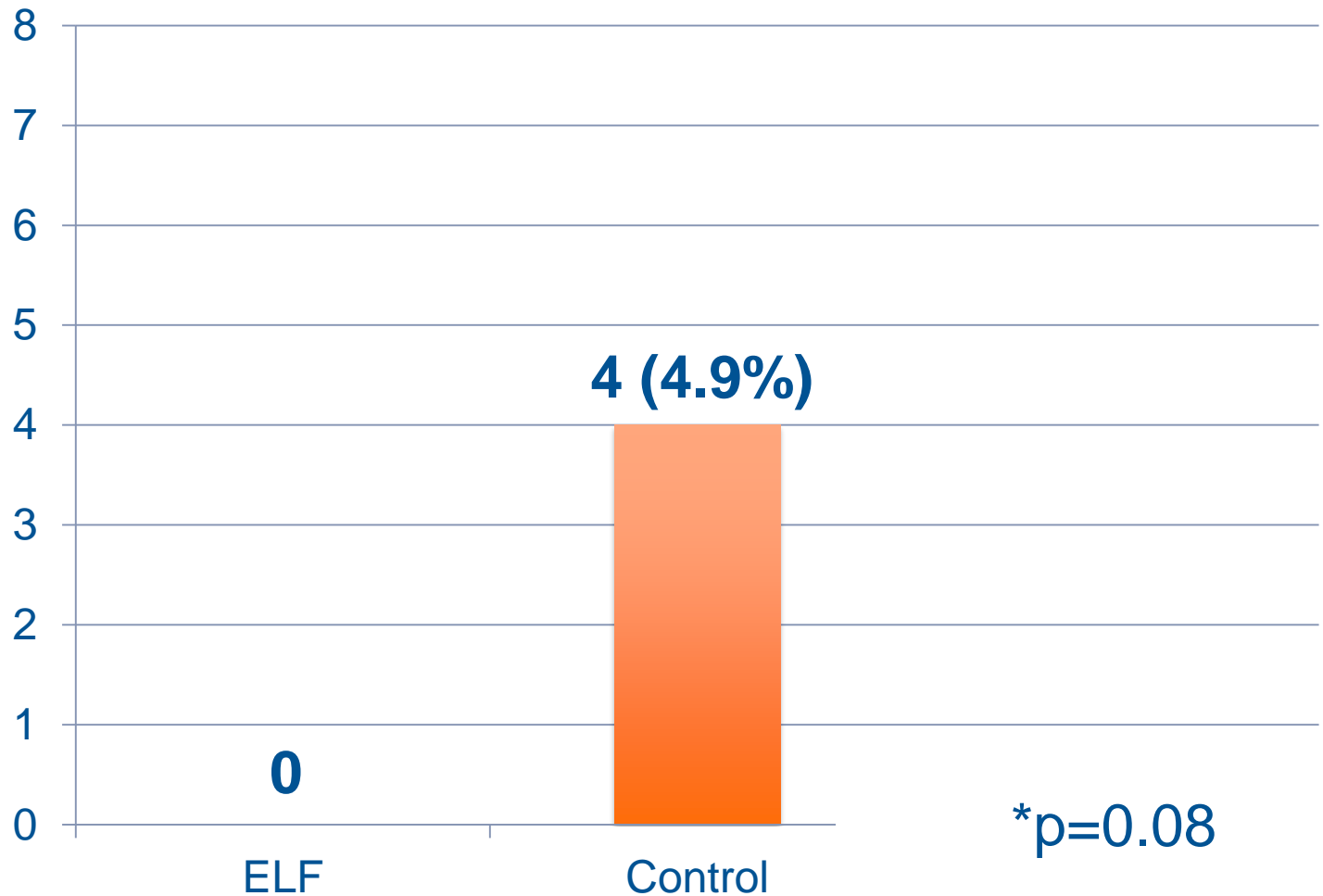
- Breastfeeding Self-Efficacy Scale—short form (BSES-SF)
- State Trait Anxiety Inventory (STAI), State subscale
- Edinburgh Postnatal Depression Scale (EPDS)
- Satisfaction with Maternal Newborn Care (SMNC)

	ELF	Control	P-value
BSES-SF 1 wk	52.6 ± 8.6	52.3 ± 11.5	0.87
STAI at 1 wk	29.0 ± 7.1	28.6 ± 8.7	0.76
STAI at 1 mo	28.5 ± 8.6	27.3 ± 8.1	0.39
Satisfaction with care (SMNC)	45.7 ± 7.9	47.7 ± 6.7	0.12
EPDS at 1 wk	4.7 ± 3.3	4.4 ± 3.9	0.61

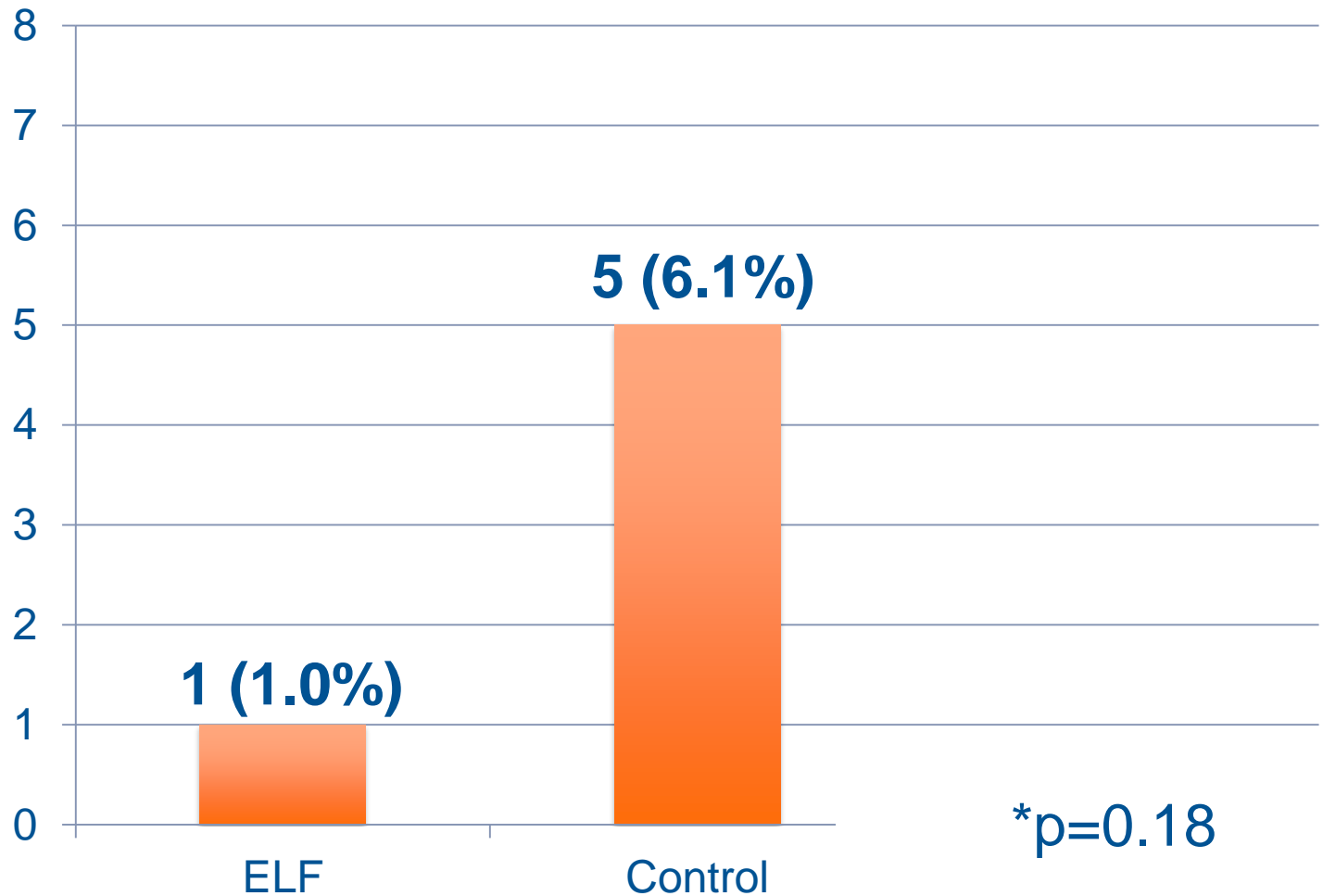
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# Readmissions at 1 week



# Readmissions at 1 month



# Intestinal microbiota

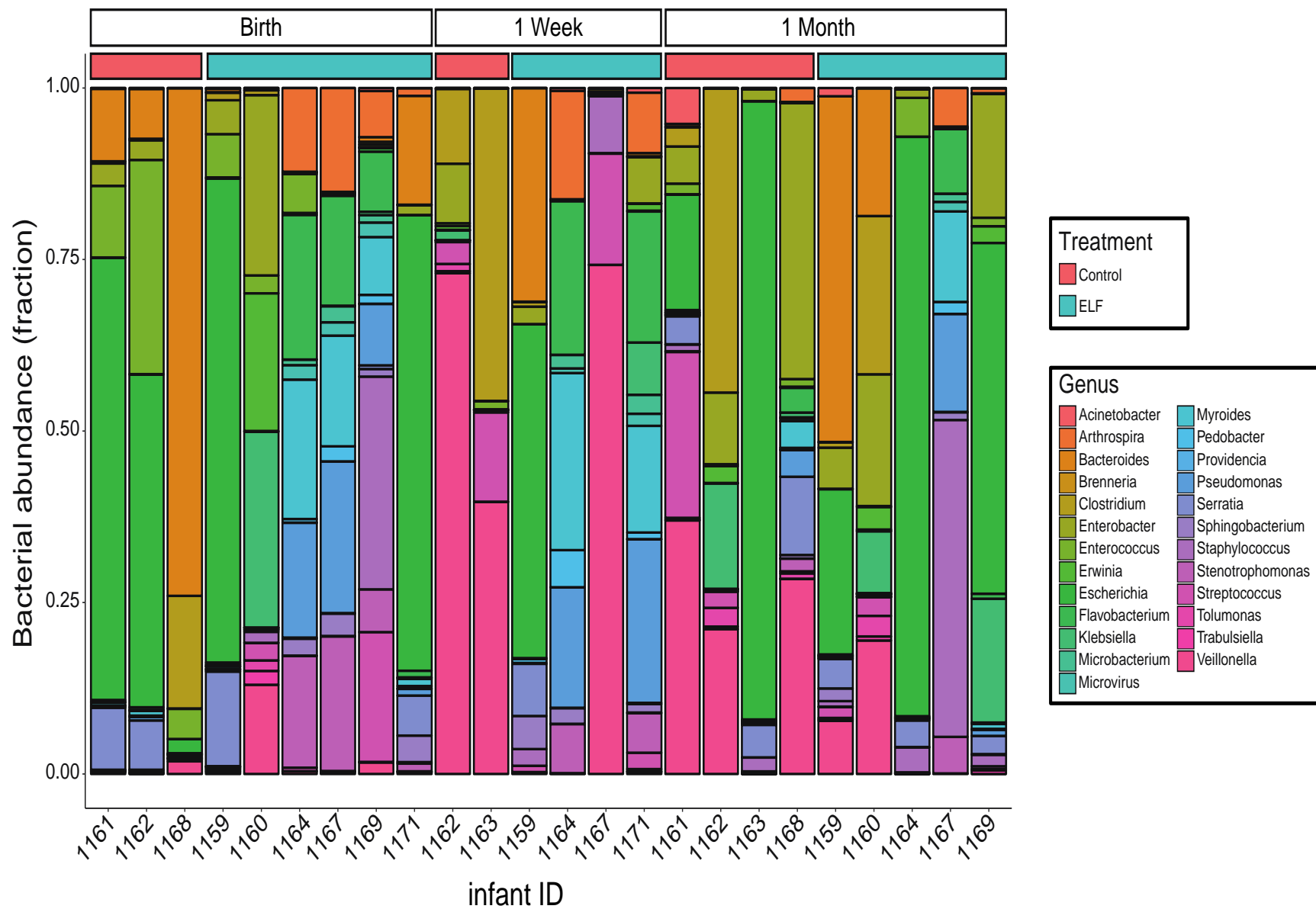
- Lactobacillus and Bifidobacteria have been shown to have increased abundance in breastfed infants compared to formula fed
  - *Also associated with decreased risk of allergy*
- Clostridia have been shown to have decreased abundance in breastfed infants
  - *Also associated with increased risk of eczema*
- We analyzed intestinal microbiota in a subcohort of 18 ELF-TLC infants



# Results—Microbiota

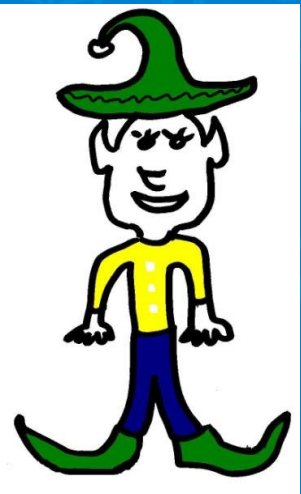
- All participants had large shifts in microbial abundance
  - *between birth and 1 week*
  - *between 1 week and 1 month*





# Results—Microbiota

- No differences in abundance of *Lactobacillus*, Bifidobacteria or Clostridia were detected between the ELF and control groups using linear regression
- Abundance of *Lactobacillus* and Bifidobacteria were very low ( $<0.1\%$ )



# Scientific implications

- For babies with early weight loss  $\geq 75^{\text{th}}$  percentile for hour of age, Early Limited Formula (ELF) :
  - *Did not impact rates of breastfeeding or formula use through 1 month*
  - *Did not impact maternal breastfeeding self-efficacy or experience*
  - *Did not have large clinical impact on intestinal microbiota*





# Relationship of formula to breastfeeding duration

- Numerous prior studies showing that initiating formula during the birth hospitalization reduces BF duration
- 2 prior RCTs: no impact of supplementing during the birth hospitalization<sup>1, 2</sup>
  - *Promotion of Breastfeeding Intervention Trial (PROBIT) cluster-randomized trial in Belarus 1996-7<sup>3</sup>*
- Overall hospital environment supportive of breastfeeding may be crucial



<sup>1</sup>Gray-Donald et al., Pediatrics 1985 <sup>2</sup>Schubiger et al, EJP 1997 <sup>3</sup>Kramer et al, AJCN 2003

# Readmissions

- Nationally, 1-2% of infants are readmitted<sup>1,2</sup>
- 6.1% of our control group was readmitted, suggesting our population was at high risk
- ELF-TLC: 4 infants readmitted in the first week in control group, none in ELF
  - *5 control infants total in the first month, 1 in ELF*
  - *Sample size was not adequate to find statistical significance*



<sup>1</sup>Young et al., Pediatrics 2013 <sup>2</sup>Escobar et al, ADC 2003

# Thank you!

- Dr. Romuladus Azuine, DrPH, MPH, RN and Crystal Lane, MS, MPH
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- Thomas Newman, MD, MPH, Kathryn Lee, PhD, RN and Charles McCulloch PhD



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