Why Exclusivity Matters:
TJC Perinatal Care Core Measure and the Impact of Just One Bottle

Lori Feldman-Winter, MD, MPH
Professor of Pediatrics
Cooper Medical School of Rowan University

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Disclosure

• I have no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider of commercial services discussed in this CME activity.

• I do not intend to discuss an unapproved/investigative use of a commercial product/device in my presentation.
Objectives

1. Describe the importance of exclusive breastfeeding for mother and baby
2. Discuss the impact of formula supplementation, just one bottle, on the infant microbiome and the effect on outcomes
3. Identify the Joint Commission Perinatal Care Core Measure of exclusive breast milk feeding
4. Define methods to improve rates of exclusive breast milk feeding in hospitals
Disease Protection in Children
“Dose Dependent”

1. AOM 50% less EBF>3-6 months
2. Atopic dermatitis less 42% EBF>3 months
3. LRTI and hospitalization less 72% with EBF>4 months
4. Asthma less 40% for EBF>3 months
5. Obesity less 4-24%; with EBF less 34%
6. T1DM less 19-27% EBF>3 months
7. T2DM less 39% with any BF vs. None
8. Cancer:
   1. ALL less 19% with BF>6 months
   2. AML less 15% with BF>6 months
9. SIDS less 36% with any BF vs. None
10. Gastro less 64% with any BF vs. None

## New Evidence Linking *Early* Supplementation with ALL

<table>
<thead>
<tr>
<th>ANY BREASTFEEDING</th>
<th>CASES (%) (ALL)</th>
<th>CONTROLS (%)</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Breastfeeding</td>
<td>35 (11)</td>
<td>40 (6)</td>
<td>Reference</td>
</tr>
<tr>
<td></td>
<td>279 (89)</td>
<td>623 (94)</td>
<td></td>
</tr>
<tr>
<td><strong>OR</strong></td>
<td><strong>0.52 (0.32 – 0.86)</strong></td>
<td></td>
<td></td>
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</table>

### Age of formula introduction

<table>
<thead>
<tr>
<th>AGE OF FORMULA INTRODUCTION</th>
<th>CASES (%)</th>
<th>CONTROLS (%)</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>75 (26)</td>
<td>191 (30)</td>
<td>Reference</td>
</tr>
<tr>
<td>&gt; 6 Months</td>
<td>60 (21)</td>
<td>126 (20)</td>
<td>1.15 (0.76 – 1.75)</td>
</tr>
<tr>
<td>2-6 months</td>
<td>56 (19)</td>
<td>114 (18)</td>
<td>1.12 (0.73 – 1.71)</td>
</tr>
<tr>
<td>15 days – 2 months</td>
<td>27 (9)</td>
<td>92 (15)</td>
<td>0.65 (0.38 – 1.10)</td>
</tr>
<tr>
<td>&lt; 14 days</td>
<td>75 (26)</td>
<td>108 (17)</td>
<td>1.57 (1.03 – 2.37)</td>
</tr>
</tbody>
</table>

**Greenop KR. Nutrition and Cancer 2015**
Breastfeeding Leads to Self-Regulation

- Exclusive breastfeeding *at breast* → 27%
- Expressed breast milk in bottle → 47%
- Combination breastfeeding Formula feeding, Breast/bottle → 56%
- All formula in a bottle → 68%

How often does your infant empty the bottle/cup after 7 months of age?

Exclusive 4 vs. 6 Months

Liesbeth D. et al. Pediatrics June 2010
Formula Supplementation Increases Risk of Ear, Sinus and Throat Infections Beyond Infancy

<table>
<thead>
<tr>
<th>Formula Supplementation</th>
<th>N</th>
<th>%</th>
<th>AOR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>BF&lt;6 mo with formula &lt;6 mo</td>
<td>440</td>
<td>44.6</td>
<td>Ref</td>
<td></td>
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<tr>
<td>BF \geq 6 mo with formula &lt; 6 mo</td>
<td>279</td>
<td>41.9</td>
<td>0.96</td>
<td>0.69-1.32</td>
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<tr>
<td>BF \geq 6 mo without formula &lt; 6 mo</td>
<td>389</td>
<td>34.2</td>
<td>0.70*</td>
<td>0.51-0.85</td>
</tr>
</tbody>
</table>

*P<0.01

Longitudinal data from the IFS II followed through age 6 years; AA and Hispanic mothers under-represented

Li R. Pediatrics September 2014
Epidemiological Evidence of Immune Modulation

• Non-EBF results in risk of autoimmune diseases; long after breastfeeding
  – Atopy and Asthma (response to LRTI)
  – Crohn’s and Ulcerative Colitis
  – Celiac
  – Leukemia
  – Type 1 DM
Allergies and Microbiome

• Breastfed babies at 1 and 6 mo. had distinct microbiome compositions compared to non-breastfed babies. These distinct compositions may influence immune system development.

• Breastfed babies at 1 mo. were at decreased risk of developing allergies to pets.

• Asthmatic children who had nighttime coughing or flare-ups had a distinct microbiome composition during the first year of life.

• Gut microbiome composition is associated with increasing Treg cells.

Johnson CC. The role of the early-life environment in the development of allergic disease. Immunology and Allergy Clinics of North America. 2015 Volume 35, Issue 1
Gut Colonization Essential to Prevent Allergy

• Newborn gut needs to be colonized shortly after birth
• Immune response to flora leads to:
  – Colonization with commensal bacteria
  – Development of immunologic tolerance
• Hygiene hypothesis
  – If not exposed and/or unable to properly handle flora (via HM) then allergy develops
Newborn Intestinal Immune System

http://www.customprobiotics.com/about_probiotics.htm

= commensal bacteria
= sIgA
= TGFβ
Specific Toll-like Receptors necessary for proper colonization

**TLR4** binds LPS producing Gram negative pathogens up regulated by HM

**TLR1,2** down regulated by HM binds Gram + bifidobacteria.
Exclusive Human Milk Necessary for Proper Colonization

- **Exclusive HM**: probiotic/commensal bacteria-bifidobacteria, and lactobacillus.
- Supported by complex system of HMO (not other prebiotics)
- Flora contribute to and are a marker of normal immune development, need certain toll-like receptors for hosting.
- **Formula feeding**: bacteroides, clostridia, streptococci.

*just one bottle...* leads to colonization with bacteria that induces an inflammatory response (enhanced by factors in human milk).

FF Skews Immune Cell Composition

- Distinct differences in circulating WBC at 6 mo.
- FF skewed toward naïve T cells, decrease in NK, CTL, and B cells, slower recruitment of T cells with effector functions for innate immunity
- If EBF were given IF at 4-6 mo. Pattern resembled FF infants

Andersson Y. et.al. J of Immunology 2009
Summary of Human Milk Influences on Gut Mucosa

**Oral Tolerance**-necessary to prevent systemic hypersensitivity, mediated through regulatory T cells, T cell anergy and clonal deletion

**Gut Colonization**-via maternal milk and vaginal birth hosted by appropriate down regulation of Toll-like receptors

**Microbiota-Epithelial Crosstalk**-structurally arranges lymphoid cells and signaling mRNA transcripts for specific TLR expression

**Induction of Intestinal Immune System**-induction of ILF, peyer’s patches and mesenteric lymph nodes
Supplementation in the Delivery Hospital Leads to Weaning by 6 weeks post-partum

Hospital factors affecting discharge feeding status among mothers who ever breastfed
(Apdated for maternal race/ethnicity, foreign birth, age, education, parity)

Adjusted odds ratio

- Baby sleeps in hospital room
- Breastfed within 1st hour
- Allowed to feed on demand
- Fed only breast milk before discharge
- Baby did not use pacifier
- Post-discharge help phone

Any breastfeeding, 8 wks post-partum
Exclusive breastfeeding, 8 wks post-partum

NJ PRAMS
Culture of Supplementation

• Market influence
• Nurse training and culture
• Physicians’ worry...
  – Dehydration
  – Jaundice
  – Hypoglycemia
  – Litigation!
Possible Reasons to Supplement

- Unresponsive hypoglycemia
- Severe maternal illness (psychosis, eclampsia, shock)
- Mother not available (maternal transfer)
- Galactosemia
- Infant unable to feed at breast (illness, congenital malformation)
- Few maternal medications
- LBW and sufficient milk is not available
- Delayed lactogenesis II (retained placenta, Sheehan), or primary glandular insufficiency
- Intolerable pain
When supplements are NOT Needed

- Colostrum QNS
- Teach how to use bottle
- Growth/appetite spurts, cluster feed
- Prevent Wt. loss
- Prevent hyperbilirubinemia
- Quiet a fussy baby
- Sleepy baby
- Let mother sleep
- Prevent hypoglycemia
- Breastfeeding “too” long to prevent damage and sore nipples
Another Reason NOT to Supplement

• Joint Commissions

• **Set Measure ID:** PC-05 & PC-05a

• **Performance Measure Name:** Exclusive Breast Milk Feeding

• **Description:** Exclusive breast milk feeding during the newborn's entire hospitalization
A New Core Measure Set Introduced April 2010, Endorsed by NQF in March 2012

The PC Core Measure Set comprises 5 main measures:

PC-01: Elective delivery
PC-02: Cesarean section
PC-03: Antenatal steroids
PC-04: Health care associated bloodstream infections in newborns
PC-05: Exclusive breast milk feeding
Mandatory in January 2014
PC-05 and PC-05a

• TJC defines exclusive breast milk feeding as newborn receiving only breast milk and no other liquids or solids except for drops or syrups consisting of vitamins, mineral, or medicines.

• Breast milk feeding includes expressed mother’s milk as well as donor human milk, both of which may be fed to the infant by means other than suckling at the breast.
Improving Performance on Perinatal Care Measures

Quality improvements in essential areas of patient safety, including perinatal care, rely on the performance of specific tasks. To help assess the effectiveness of patient care, The Joint Commission requires hospitals to submit data reports based on measures that meet certain criteria. These accountability measures are organized into “measure sets,” which are a unique group of action items specifically selected to optimize the care provided in each area.

Currently, general medical/surgical hospitals are required to submit data for a minimum of 4 measure sets (out of 14) via a vendor that has been evaluated and listed by The Joint Commission. This will change, however, in 2014. Beginning January 1, hospitals must submit data for 6 measure sets. According to the new guidelines, some of these sets will be mandatory for hospitals. Others will be discretionary. A number of health care organizations that are involved in perinatal care supported adoption of the measure (see the box on page 18).

Perinatal care will fall under the mandatory column for hospitals with 1,100 or more births annually. The Joint Commission PC-05 mandate requires hospitals to submit data on the Perinatal Care Measure Set.

- PC-03 Antenatal steroids
- PC-04 Health care–associated bloodstream infections in newborns
- PC-05 Exclusive breast milk feeding
- PC-05a Exclusive breast milk feeding considering mother’s choice

Beginning January 1, 2014, hospitals that see more than 1,100 births annually will be required to submit data on the Perinatal Care Measure Set.
Value Set for Mother’s Intention to Breastfeed (to capture PC—05a)

• Ask on admission...How do you intend to feed your baby? (response options)
  – **Breastfeeding** (interpreted as exclusive breastfeeding, breast milk feeding)
  – **Combination** breastfeeding or breast milk feeding plus formula
  – **No breastfeeding** (formula only)
  – Unsure

• Then provide skin to skin care
  – If breastfeeding happens then revisit with question, how would you like your infant be fed while here in the hospital? (up to 4 hours)
Important Definitions

• Documented Permanent Clinical Contraindications
  – Defined in Joint Commission PC05 Manual

• Documented Time-Limited Contraindication
  – Defined in Baby-Friendly USA Guidelines and Evaluation Criteria, Appendix A
  – Per clinicians’ context-specific assessment
  – Per facility policy
  – Not taken out of PC-05 denominator

• Documented and Supported Maternal Refusal
  – Clinician inquired about mother’s reasons / concerns, and
  – Clinician offers customized, evidence-based support and education, and
  – Mother’s request remains, and is documented.
  – Not taken out of PC-05 denominator

Infant “Reasons for Not Exclusively Feeding Breast Milk” (per The Joint Commission)

- Admitted to NICU during hospitalization
- Galactosemia (Diagnosis Code 11.21)
- Maple syrup urine disease
- Phenylketonuria
- Parenteral Infusion (Procedure Code 11.22)
- Experienced death
- Length of stay >120 days
- Enrolled in clinical trails
- Transferred to other facility
- Premature (Diagnosis Code 11.23)
- Very low birth weight
Maternal Contraindications to Breastfeeding (per The Joint Commission)

- HIV infection
- Human t-lymphotrophic virus type I or II
- Substance abuse and/or alcohol abuse (see ABM Protocol)
- Active, untreated tuberculosis
- Contraindicated medications (see LactMed)
- Undergoing radiation therapy
- Active, untreated varicella
- Active herpes simplex virus with breast lesions
- Admission to Intensive Care Unit (ICU) post-partum
- Dyad will be separated after discharge from the hospital, and the mother will not be providing care for the newborn after the hospitalization.
- Previous breast surgery where mother is unable to produce breast milk (diagnosed after clinical assessment)
- Breast abnormality where the mother is unable to produce breast milk (diagnosed after clinical assessment)
IMPORTANT
Other Clinical Indications

• Knowing indications for supplementation, mother-baby separations, delayed / early cessation of skin-to-skin may help guide your improvements.

• For Joint Commission, other reasons for supplementation are NOT excluded.
  – Indication for supplementation (e.g. hypoglycemia) is not a Joint Commission exclusion-still counted in the denominator
Revisions to PC-05a Exclusive Human Milk Feeding – Considering Mothers’ Intention
Beginning October 1, 2015

• Announced May 6, 2015 (supported by CDC, AAP, ACOG and AWHONN)

• PC-05 remains
  – maternal medical conditions are no longer excluded. (...because these conditions are unusual (affecting approximately 2 percent of patients)
  – PC-05 will continue to be an accountability measure that is publicly reported on The Joint Commission’s Quality Check® website
  – PC-05 will not be included in the Top Performer on Key Quality Measures® (expect 70% not 100%)
What is the role of the clinician?

• Present data on dashboard and at departmental meetings
• Develop action plans to decrease supplementation
• Help write or revise hospital policies
• Educate on the risks of supplementation
• Provide or refer for breastfeeding management
• Use QI strategies
Supplementing Breastfeeding

• What are medical indications for supplementation?
• Not the same as TJC defined reasons to use formula (these are medical contraindications to breastfeed)
• Weight loss?
• Jaundice?
• Hypoglycemia?
• Others?

Primum Non Noceri
“First do no harm!”
BFHI STEP 6

Give newborn breastfed infants no food or drink other than breastmilk, unless medically indicated.

• Understand physiology and define medical indications to supplement
• Determine if nurse and/or physician needs to order supplements with formula
• Revise protocols
The process for supporting mothers who request breastmilk substitutes must be been addressed including:

• Exploring and addressing the mother’s concern(s)

• Educating the mother regarding the negative consequences of feeding infants breastmilk substitutes

• Documentation of the education
Example if Mother Requests Supplementation

• Standardize education about the risks of supplementation
  – Mothers will be supported to exclusively breastfeed and educated about the risks of supplementation, however if a mother requests that her breastfeeding newborn receive formula staff will:
    • explore reasons for this request and address mothers concerns
    • educate the mothers about the negative consequences of feeding infant formula
    • document the education that has been provided in addition to documentation stipulated below.
Risks of Supplementation

• Effects on Mom
  – Decreases confidence
  – Decreases milk removal leading to increased autocrine control and decreased milk synthesis
  – Leads to premature weaning

• Effects on Baby
  – Increases risk of short and long term disease
  – Changes microbiology and immuno-biology of gut

• Effects on Dyad
  – Interferes with effective latch
  – Decreases hormonal stimulation via afferent nerve receptors
Documentation of Education

• All supplemental feedings will be documented in the infant’s medical record and include:
  – the need for supplementation
  – the initiation of the supplementation order
  – parental education and discussion
  – medical indication or reason for supplementation
  – type of supplementation
  – method of providing the supplementation
  – Volume given
Medical indications for supplementation with breastmilk substitutes will be addressed

• Indicate acceptable reasons to supplement
  – Address acceptable weight loss
  – Address hypoglycemia
  – Address hyperbilirubinemia
Medical Indications

• Does weight loss indicate dehydration or need for supplementation?
• What are the implications of no void in 24 hours?
• What if the baby has not latched in XX number of hours?
• What if the LATCH scores are <7?
Weight Loss in an Inner City Baby-Friendly Hospital

- Average infant weight loss: 4.9% (range 0.00%-9.9%)

- Weight loss >7% 20% (23/118)

- Weight loss >8% 7% (8/118)

- Weight loss >10% 0 infants

Income weight loss nadir was significantly associated with feeding category (p=0.00)

58.5% reached weight loss nadir by 2 days after birth.
What about the new weight loss nomograms?

Flaherman V. et al Pediatrics 135:2015
Bottom Line on Weight Loss

• One cannot use weight loss alone to indicate supplementation

• Must use clinical assessment, including breastfeeding, milk transfer, LATCH (or Mother-Baby assessment score- Mulford C)

• 6-7 % is the mean, may be less in more Baby-Friendly environments

• 10% is probably excessive if there is no other reason (lots of IV fluid at time of delivery, C-section, no latch or suckling in first few days)
Over-feeding in early life

- Exclusive breastfeeding:
  - 15-30cc day 1
  - 30-150cc day 2

- Exclusive formula feeding:
  - 60-90 cc every 2 to 3 hours each day; approx 24 ounces (720cc)
What is normal volume I/O’s?

- Intake on DOL #1 5-10 cc per feed (15-30 total)
- Intake on DOL #2-3 5-30 cc per feed (150-300)

Chen CF et al. Pediatrics & Neonatology 2011

Voids greater in FF
Stools greater in FF
What If Baby Has Not Latched in First 24 hours?

• Skin to skin facilitates early suckling, delay in skin to skin will make latch more difficult
• Decreased suckling will make jaundice more likely (described later)
• DOL #1 may be essentially NPO as long as suckling
• Use hand expression (pumping) and feed MOM
What if the LATCH is < 7?

Altuntas N et al Breastfeeding Medicine 2015
What about jaundice? Why do breastfeeding infants become jaundiced?

- Breastfed infants have prolonged period of physiologic jaundice
- Difficulties establishing breastfeeding will increase the likelihood of hyperbilirubinemia, not physiologic
- “starvation jaundice”
- Distinguish between early non-breastfeeding jaundice vs. breastmilk jaundice
Why Does Breastfeeding Lead to Early Onset Jaundice?

How can it be prevented?

**Early and frequent suckling**

Infant-

- stimulates passage of meconium
- Improves suckling technique to facilitate transition

Mom-

- Decreases chance of late Lactogenesis II
- Enhances production via prolactin
Hyperbilirubinemia and Breastfeeding Frequency

Yamauchi & Yamannouchi; Pediatr 1990:86(2):174
What is normal for an exclusively breastfed newborn?

Maisels J. Pediatrics July 2014
If you need to supplement with infant formula consider hydrolysate.

Revise Approach to Jaundice

- Establish new protocols
- Buy-in to maintain exclusive BF
- Consistent approach

Who is At Risk for Hypoglycemia?

- IDM (infant of a diabetic mother: gestational, Type 1 or Type 2 diabetes)
- LPT (late preterm infant: 34 0/7 to 36 6/7 weeks gestation)
- SGA (small for gestational age: birth weight less than 10th percentile)
- LGA (large for gestational age: birth weight greater than 90th percentile)
- Symptomatic (“jittery”) infant
First Steps of Protocol

• Try to feed at risk newborns immediately, but by no later than 30 to 60 minutes of life. Allow the infant to breastfeed or feed 3-5 ml/kg expressed colostrum (or formula if colostrum or donor milk unavailable)

• Obtain the first heel-stick blood glucose on all at-risk newborns no sooner than 30 minutes AFTER completion of the first feeding but by no later than 2 hours of life. Check immediately if infant symptomatic.
Screening and Management of Postnatal Glucose Homeostasis in Late Preterm and Term SGA, IDM/LGA Infants

Symptomatic and <40 mg/dL → IV glucose

**ASYMPTOMATIC**

<table>
<thead>
<tr>
<th>Birth to 4 hours of age</th>
<th>4 to 24 hours of age</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INITIAL FEED WITHIN 1 hour</strong></td>
<td><strong>Continue feeds q 2-3 hours</strong></td>
</tr>
<tr>
<td>Screen glucose 30 minutes after 1st feed</td>
<td>Screen glucose prior to each feed</td>
</tr>
<tr>
<td>Initial screen &lt;25 mg/dL</td>
<td>Screen &lt;35 mg/dL</td>
</tr>
<tr>
<td>Feed and check in 1 hour</td>
<td>Feed and check in 1 hour</td>
</tr>
<tr>
<td>&lt;25 mg/dL</td>
<td>25–40 mg/dL</td>
</tr>
<tr>
<td>IV glucose*</td>
<td>Refeed/IV glucose* as needed</td>
</tr>
<tr>
<td>25–40 mg/dL</td>
<td>&lt;35 mg/dL</td>
</tr>
<tr>
<td>Refeed/IV glucose* as needed</td>
<td>35–45 mg/dL</td>
</tr>
<tr>
<td></td>
<td>IV glucose*</td>
</tr>
<tr>
<td></td>
<td>Refeed/IV glucose* as needed</td>
</tr>
</tbody>
</table>

**Target glucose screen ≥45 mg/dL prior to routine feeds**

* Glucose dose = 200 mg/kg (dextrose 10% at 2 mL/kg) and/or IV infusion at 5–8 mg/kg per min (80–100 mL/kg per d). Achieve plasma glucose level of 40-50 mg/dL.

Symptoms of hypoglycemia include: Irritability, tremors, jitteriness, exaggerated Moro reflex, high-pitched cry, seizures, lethargy, floppiness, cyanosis, apnea, poor feeding.

AAP Committee on Fetus and Newborn. Pediatrics. 127(3); 2011:575-579
Conclusions

• Exclusive breastfeeding produces optimal health outcomes-know the science
• Exclusive breastfeeding requires support in multiple dimensions
• Physicians are necessary to support exclusive breastfeeding
• The Baby-Friendly Hospital Initiative, using quality improvement methods, helps to support exclusive breastfeeding
“If you always do what you always did, you will always get what you always got.”

-Albert Einstein