Human Milk:
A Source of More Life Than We Imagined

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Disclosures

- I personally prepared this slide deck; it is without commercial bias or influence
- I have received financial reimbursement for non-marketed, non-branded, non-promotional educational presentations through the Abbott Nutrition Health Institute (ANHI)

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Objectives

- Define the term “dysbiosis”
- Describe two functions of human milk oligosaccharides (HMOs) in the neonatal gut
- Discuss the concept of a “dose-response” in relation to using human milk in the preterm infant’s diet
- List three neonatal comorbidities that can be reduced with an exclusive human milk diet (EHMD)

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Microbiome and Dysbiosis

Role of Inflammation

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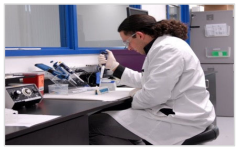
Human Milk: A Source of More Life Than We Imagined

Human Milk

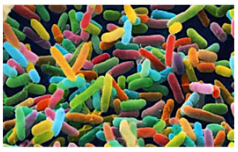
- *"A source of more life than we imagined."*



Jeurink PV, van Bergenhenegouwen J, Jiménez E, et al. Human milk: a source of more life than we imagine. *Benef Microbes.* 2013;4(1):17-30. doi:10.3920/BM2012.0040

Neonatal Microbiome

- *"The sum of all microbial life living in or on the human body."*



Gritz EC, Bhandari V. The human gut microbiome: a brief review. *Front Pediatr.* 2015;3:17. doi:10.3389/fped.2015.00017

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Human Milk: A Source of More Life Than We Imagined

- **"Evolutionary Biology"**
  - ***For millennia woman have labored and delivered/babies:***
    - At or very near term
    - Labor or not; with/without ROM
    - Vaginally delivered
    - Remained with their mother
    - Exposed to colostrum
    - Exclusively breastfed
    - Microbiome colonizes
    - Immune systems matures
    - Infant grows and develops

For the purpose of our discussion

LONG PERIODS OF TIME

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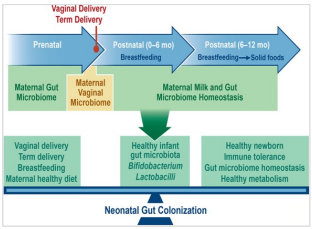
Factors and Functions Influencing the Infant Microbiome



Increasing Functionality

- ↑ *Lactobacillius* and *bifidobacteria*
  - Seems specific to early life
  - Geography, delivery, first feeding, and intra-postpartum antibiotic exposure
- Followed by *bacteroides* and *firmicutes*
- Functional capacity > microbial composition
- ***Contributes to infant's innate/adaptive emerging immune responses***

Kapourchali FR, Cresci GAM. Early-life gut microbiome—the importance of maternal and infant factors in its establishment. *Nutr Clin Pract*. 2020;35(3):386-405. doi:10.1002/ncp.10490

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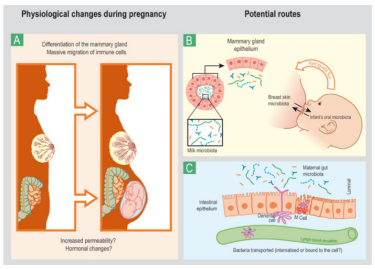
Human Milk: A Source of More Life Than We Imagined



Maternal Microbiome
Maternal Antibodies
"Bacterial Imprinting"

Korpela K, Helve O, Kolho KL, et al. Maternal fecal microbiota transplantation in cesarean-born infants rapidly restores normal gut microbial development: a proof-of-concept study. *Cell*. 2020;183(2):324-334.e5. doi:10.1016/j.cell.2020.08.047

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Human Milk: A Source of More Life Than We Imagined

- **"Evolutionary Discordance"**
  - ***In last 60+ years the complexity of pregnancy, labor, delivery, and neonatal care have changed***
    - Advanced maternal age
    - Assisted reproductive technology
    - Multiple gestation pregnancy
    - Premature delivery
    - Antibiotic exposure
    - Maternal morbidities
    - Maternal diet
    - Maternal obesity
    - Environmental toxins
    - ? Maternal microbiome

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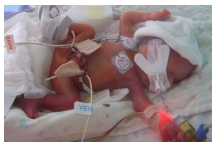
Human Milk: A Source of More Life Than We Imagined

- **"Evolutionary Discordance"**
  - **In last 60+ years those chances have resulted in practices that alter the infant's microbiome**
    - Preterm, near term, late term delivery
    - LBW, VLBW, ELBW; macrosomia, LGA
    - ↑ Elective/Non-Elective C/S
    - Labor or not; with/without ROM
    - Hyper-hygienic measures, antibiotics
    - ↓ Mother/infant contact
    - ↓ Exposure to colostrum
    - ↓ Breastmilk feeding
    - ? Microbiome colonization
    - ? Immune system matures
    - ? Infant grows and develops



B#P dwuqdd#P lfurelrp h
↓ Olp lwng#Dqwlerg|#Sdvvdjh
Ip p dwkuh#Ip p xqh#V|vwhp

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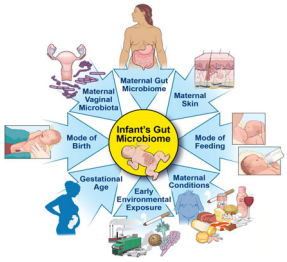
Human Milk: A Source of More Life Than We Imagined



Functions of the Microbiome

- Assists with essential nutrient synthesis absorption
- Influences the infant's growth
- Maintains intestinal mucosal barrier
- Generates SCFA – energy source
- Prevents pathogenic bacteria/endotoxin translocation
- Stimulates immune system maturation
- Provides anti-inflammatory signals to the host

Kapourchali FR, Cresci GAM. Early-life gut microbiome—the importance of maternal and infant factors in its establishment. *Nutr Clin Pract.* 2020;35(3):386-405. doi:10.1002/ncp.10490

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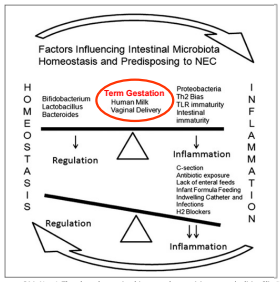
Dysbiosis: Inflammation and the "Big Umbrella"



Torrazza RM, Neu J. The altered gut microbiome and necrotizing enterocolitis. *Clin Perinatol.* 2013;40(1):93-108. doi:10.1016/j.clp.2012.12.009
Underwood MA, Umberger E, Patel R. Safety and efficacy of probiotic administration to preterm infants: ten common questions. *Pediatr Res.* 2020;88(Suppl 1):48-55. doi:10.1038/s41390-020-1080-6

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Dysbiosis: Inflammation and the Microbiome

- **Origin of dysbiosis in preterm infants:**
  - 37% of pregnant women receive antibiotics during pregnancy
  - 33% receive them in the intrapartum period
  - Early or prolonged ROM; maternal stress
  - Antenatal steroids → immune system
  - **64% of preterm infants delivered via C/S**
  - **85% of all ELBW infants receive at least one course of broad-spectrum antibiotics**
- **Dysbiosis is characterized by:**
  - Low diversity in the microbiome
  - Overall reduction in beneficial and/or commensal bacteria
  - ↑ Opportunistic pathogens of the gamma-proteobacteria class
  - **These factors interact to produce inflammation in the gut, which further perpetuates dysbiosis**
  - **The potential for dysbiosis, limited capacity for localization, and the potential initiation of systemic inflammation**

Groer MW, Miller EM, D'Agata A, et al. Contributors to dysbiosis in very-low-birth-weight infants. *J Obstet Gynecol Neonatal Nurs*. 2020;49(3):232-242. doi:10.1016/j.jogn.2020.02.003

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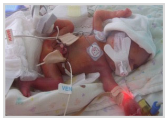
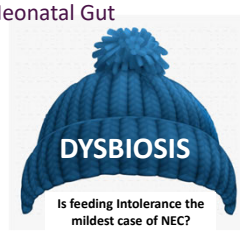
Dysbiosis and the Neonatal Gut

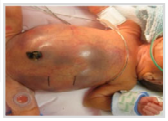
Incidence Estimate:
As high as 36%





Is feeding Intolerance the mildest case of NEC?
Is NEC the worse case of feeding intolerance?

Incidence Estimate:
~5% of VLBW infants



INFLAMMATION

Ahammad F, Begum T, Akter J, Nasrin E. Comparison of feeding intolerance between very preterm and moderate preterm neonates – a prospective cohort study. *J Pediatr Neonatal Care*. 2018;8(4):200-203. doi:10.15406/jpnc.2018.08.00330

Horbar JD, Edwards EM, Green berg LT, et al. Variation in performance of neonatal intensive care units in the United States [published correction appears in *JAMA Pediatr*. 2017;171(3):306]. *JAMA Pediatr*. 2017;171(3):e164396 doi:10.1001/jamapediatrics.2016.4396.

SOURCE: Adapted from B Modi, MD, in presentation; VON, Conference, Chicago, IL

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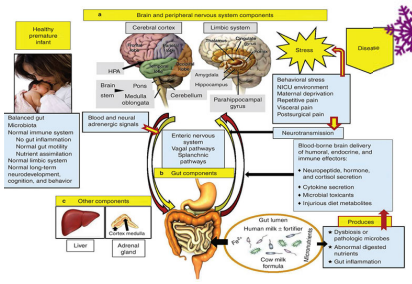
Dysbiosis and the Neonatal Gut-Brain Axis

- **Enteral Feeding and the neonatal gut-brain axis**
  - **↑Activation of inflammation**
  - **↓ Gut barrier function**
  - **↑ Bacterial translocation**
  - **↑ Activation of HPA**
  - **↑ Physiologic stress → ↑ cortisol**
  - **↑ Triggering further pro/anti-inflammatory gut/brain activity**
  - **↑ A hypermetabolic state**



Sherman MP, Zaghouani H, Niklas V. Gut microbiota, the immune system, and diet influence the neonatal gut-brain axis. *Pediatr Res*. 2015;77(1-2):127-135. doi:10.1038/pr.2014.161

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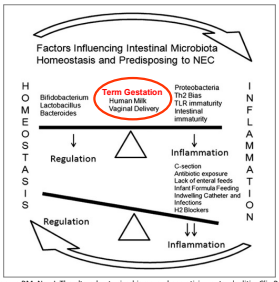
Dysbiosis: Inflammation and the *"Big Umbrella"*



Necrotizing Enterocolitis

Bronchopulmonary Dysplasia

Retinopathy of Prematurity

Late-Onset Sepsis

"The Burdens of Prematurity"

Torrazza RM, Neu J. The altered gut microbiome and necrotizing enterocolitis. *Clin Perinatol.* 2013;40(1)93-108. doi:10.1016/j.clp.2012.12.009
Underwood MA, Umberger E, Patel R. Safety and efficacy of probiotic administration to preterm infants: ten common questions. *Pediatr Res.* 2020;88(Suppl 1):48-55. doi:10.1038/s41390-020-1080-6

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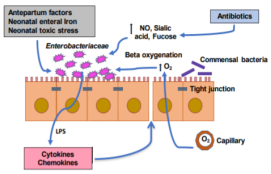
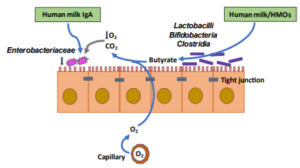
Dysbiosis: Inflammation and the Neonatal Gut

- **Inflamed neonatal bowel**



Dysbiosis Related Inflammation

- **Non-inflamed neonatal bowel**



Protective Role of Human Milk

Groer MW, Miller EM, D'Agata A, et al. Contributors to dysbiosis in very-low-birth-weight infants. *J Obstet Gynecol Neonatal Nurs.* 2020;49(3):232-242. doi:10.1016/j.jogn.2020.02.003

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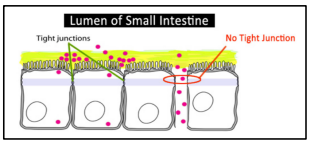
Human Milk Oligosaccharides (HMOs)

- **HMOs Beneficial Role in the Gut**
  - Function as **"PREBIOTICS"**
  - Release SCFA's
    - Provide energy source to gut cells
    - Facilitate production of gap junction proteins
    - ↓ ***"Translocation"*** of pathogens
  - Restricts pathogens entering into the systemic circulation
  - Provides diverse anti-inflammatory molecules



Lewis, Erin D. et al. (2016). The importance of human milk for Immunity in preterm infants. *Clinics in Perinatology,* 44(1); 23-47. DOI: https://doi.org/10.1016/j.clp.2016.11.008

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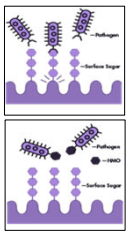
Human Milk Oligosaccharides (HMOs)

- **Beneficial Role in the Neonatal Gut**
  - **Anti-adhesive** antimicrobials
  - Serve as soluble **decoy receptors**
  - Prevent attachment of pathogens on mucosal/epithelial surfaces
  - Regulates immune-inflammatory processes connecting the intestine, liver, muscle, and brain (GBA)



Bode L (2012). Human milk oligosaccharides; every baby needs a sugar mama. *Glycobiology* 2299); 147-162 doi:10.1093/glycob/cws074; Jantscher-Renn E & Bode L Human milk oligosaccharides and their potential benefits Minerva Pediatr 2012;64:83-99

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Human Milk as a Biologic

Dysbiosis and Comorbidities

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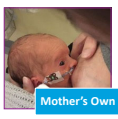
An Exclusive Human Milk Diet

ALL HUMAN SOURCED NUTRITION


Mother's Own Milk


Donor Human Milk


HM–Based Fortifiers


HM–Split Products

"Mother's own milk, fresh or frozen, should be the primary diet, and it should be fortified appropriately for the infant born weighing less than 1.5 kg."

American Academy of Pediatrics. Breastfeeding and the use of human milk. Section on Breastfeeding. *Pediatrics*. 2012;129(3):e827-e841. doi:10.1542/peds.2011-3552

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Human Milk: A Source of More Life Than We Imagined

- **Improved long-term health outcomes**
  - *American Academy of Pediatrics* [AAP] (2012)
  - 22 reviews of 14 different disease states
  - Progressing from infancy → adulthood
  - Lowered risk if exposed to human milk
  - Not even an "***exclusive diet***" of human milk

22 reviews of 14 disease states

L I F E S P A N

Condition	% Lower Risk
NEC	77
SIDS	36
RSV	74
Recurrent Otitis Media	77
URTI	63-72
Asthma	26-40
Atopic Dermatitis	27-42
Gastroenteritis	64
Inflammatory Bowel	31
Obesity	24
Celiac Disease	52
Type 1 Diabetes	30-40
Leukemia (ALL/AML)	20/15

American Academy of Pediatrics. Breastfeeding and the use of human milk. Section on Breastfeeding. *Pediatrics*. 2012;129(3):e827-e841. doi:10.1542/peds.2011-3552

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Human Milk: A Source of More Life Than We Imagined

AAP Policy: 2017

- ***"Human Milk is a Biological Product"***
  - **What is a biologic product?**
    - Biological products, or biologics, are medical products
    - Many biologics are made from a variety of natural sources (human cells, tissue, animal, microorganism)
    - Like drugs, some biologics are intended to treat diseases and medical conditions
    - **Biologics are used to prevent diseases**

U.S. Food and Drug Administration. FDA Basics; What is a biological product? U.S. Department of Health and Human Services. http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194516.htm. Page Last Updated: 05/31/2016

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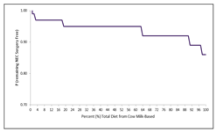
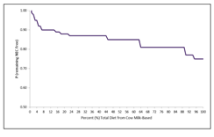
"Milk as Medicine"

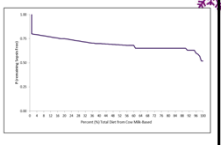
"Dose Response" **of an EHMD and why it matters**



For every 10% increase in CMBD a 12% INCREASE in NEC



For every 10% increase in CMBD a 21% INCREASE in SURGICAL NEC



For every 10% increase in CMBD 17.9% INCREASE in SEPSIS

Abrams SA, Schanler RJ, Lee ML, Rechtman DJ. Greater mortality and morbidity in extremely preterm infants fed a diet containing cow milk protein products. *Breastfeed Med*. 2014;9(6):281-285. doi:10.1089/bfm.2014.0024

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Exclusive Human Milk Diet and Dose Response

- **EHMD: multicenter retrospective cohort study**
  - **Objective**
    - To compare clinical outcomes in ***1587 extremely premature infants (birth weight <1250 g)*** before and after an institutional change to the use of an ***exclusive human milk diet (EHMD) including fortifiers*** from a diet that included cow milk–based (CMD) products (formulas and/or fortifiers)
  - **Method**
    - Conducted at four geographically disparate hospitals: ***Texas, California, Illinois, and Florida***
    - Each of the four hospitals reviewed charts from an equal period before and after implementing an exclusive human milk–based protocol

Hair AB, Peluso AM, Hawthorne KM, et al. Beyond necrotizing enterocolitis prevention: improving outcomes with an exclusive human milk-based diet [published correction appears in *Breastfeed Med.* 2017;12(10):663]. *Breastfeed Med.* 2016;11(2):70-74. doi:10.1089/bfm.2015.0134

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Exclusive Human Milk Diet and Dose Response

Study Hospital Feeding Protocols

Texas Children's Hospital (Houston)
- <1250 g BW to 34 weeks PMA
- Prolact+ fortification initiated at 60 mL/kg/day with Prolact+4 H²MF® human milk fortifier (human, pasteurized)
- At 100 mL/kg/day fortification increased to Prolact+6 H²MF® human milk fortifier (human, pasteurized)
- If weight gain was <15 g/kg/day, fortification increased to Prolact+8 H²MF® human milk fortifier (human, pasteurized) and then Prolact+10 H²MF® human milk fortifier (human, pasteurized)

Good Samaritan (San Jose)
- <1000 g BW protocol continued until 60 days of age
- Prolact+ fortification initiated at 100 mL/kg/day with Prolact+4 H²MF fortifier
- At 150 mL/kg/day fortification increased to Prolact+6 H²MF fortifier, Prolact+8 H²MF fortifier as needed

Northwestern (Chicago)
- <1000 g BW to 34 weeks PMA or 1500 g, then transitioned off
- Prolact+ fortification initiated at 100-120 mL/kg/day with Prolact+4 H²MF fortifier
- If weight gain was <15 g/kg/day, fortification increased to Prolact+6 H²MF fortifier
- Increased to Prolact+8 H²MF fortifier if low weight gain continued

Winnie Palmer Hospital (Orlando)
- ≤750 g BW and ≤26 weeks gestational age to 32 weeks PMA
- Prolact+ fortification initiated at 100-120 mL/kg/day with Prolact+4 H²MF fortifier
- If weight gain was deemed suboptimal by the attending doctor based on growth curve velocity, an additional 2-4 cal/oz of fortification was added to the feeds for a total of 6-8 kcal/oz

Hair AB, Peluso AM, Hawthorne KM, et al. Beyond necrotizing enterocolitis prevention: improving outcomes with an exclusive human milk-based diet [published correction appears in *Breastfeed Med.* 2017;12(10):663]. *Breastfeed Med.* 2016;11(2):70-74. doi:10.1089/bfm.2015.0134

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Exclusive Human Milk Diet and Dose Response

- **EHMD: multicenter retrospective cohort study**
  - EHMD group had significantly lower incidence of:

	CMD	EHMD	*P* Value
NEC	16.7%	6.9%	*P* < 0.00001
Mortality	17.2%	13.6%	*P* = 0.04
BPD	56.3%	47.7%	*P* = 0.0015
ROP	9.0%	5.2%	*P* = 0.003
PDA	64.7%	55.1%	*P* = 0.0001
Late-Onset Sepsis	30.3%	19.0%	*P* < 0.00001

What are we seeing here?

Role of similar pathophysiology of disease?

Similar protective benefits of an EHMD?

Hair AB, Peluso AM, Hawthorne KM, et al. Beyond necrotizing enterocolitis prevention: improving outcomes with an exclusive human milk-based diet [published correction appears in *Breastfeed Med.* 2017;12(10):663]. *Breastfeed Med.* 2016;11(2):70-74. doi:10.1089/bfm.2015.0134

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Exclusive Human Milk Diet and Dose Response

Bronchopulmonary Dysplasia (BPD)

- **Reduction in BPD with EHMD**
  - 8.6% less BPD (Hair AB et al 2016)
  - 9.0% less BPD (Assad M et al 2016)
  - 16.5% less BPD (Delaney Manthe E et al 2019)
  - 15.0% less BPD (Huston RK et al 2020)
- **Role of Increased Use of Human Milk?**
- **Role of Earlier Enteral Feeding?**
- **Role of Earlier Fortification?**

1 Assad M, Elliott MJ, Abraham JH. Decreased cost and improved feeding tolerance in VLBW infants fed an exclusive human milk diet. *J Perinatol*. 2016;36(3):216-220. doi:10.1038/jp.2015.168 **2** Delaney Manthe E, Perks PH, Swanson JR. Team-based implementation of an exclusive human milk diet. *Adv Neonatal Care*. 2019;19(6):460-467. doi:10.1097/ANC.0000000000000676 **3** Hair AB, Peluso AM, Hawthorne KM, et al. Beyond necrotizing enterocolitis prevention: improving outcomes with an exclusive human milk-based diet [published correction appears in *Breastfeed Med*. 2017;12(10):663]. *Breastfeed Med*. 2016;11(2):70-74. doi:10.1089/bfm.2015.0134 **4** Huston R, Lee M, Rider E, et al. Early fortification of enteral feedings for infants <1250 grams birth weight receiving a human milk diet including human milk based fortifier. *J Neonatal Perinatal Med*. 2020;13(2):215-221. doi:10.3233/NPM-190300

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Human Milk: A Source of More Life Than We Imagined

Retinopathy of Prematurity (ROP)

- **Reduction in ROP with EHMD**
  - 3.8% less ROP (Hair AB et al 2016)
  - Up to 26% less ROP (Assad M et al 2016)
  - 8.6% less ROP (O'Connor et al et al 2018)
  - 13.5% less ROP (Delaney Manthe E et al 2019)
- **Role of Increased Use of Human Milk?**
- **Role of Earlier Enteral Feeding?**
- **Role of Earlier Fortification?**

1 Assad M, Elliott MJ, Abraham JH. Decreased cost and improved feeding tolerance in VLBW infants fed an exclusive human milk diet. *J Perinatol*. 2016;36(3):216-220. doi:10.1038/jp.2015.168 **2** Delaney Manthe E, Perks PH, Swanson JR. Team-based implementation of an exclusive human milk diet. *Adv Neonatal Care*. 2019;19(6):460-467. doi:10.1097/ANC.0000000000000676 **3** Hair AB, Peluso AM, Hawthorne KM, et al. Beyond necrotizing enterocolitis prevention: improving outcomes with an exclusive human milk-based diet [published correction appears in *Breastfeed Med*. 2017;12(10):663]. *Breastfeed Med*. 2016;11(2):70-74. doi:10.1089/bfm.2015.0134 **4** O'Connor DL, Kiss A, Tomlinson C, et al. Nutrient enrichment of human milk with human and bovine milk-based fortifiers for infants born weighing <1250 g: a randomized clinical trial [published corrections appear in *Am J Clin Nutr*. 2019;110(2):529 and *Am J Clin Nutr*. 2020;111(5):1112]. *Am J Clin Nutr*. 2018;108(1):108-116. doi:10.1093/ajcn/nqy067

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Human Milk: A Source of More Life Than We Imagined

Late-Onset Sepsis (LOS)

- **Reduction in LOS with EHMD**
  - For every 10% ↑ CMBD 17.9% ↑ LOS
  - 11.3% reduction in LOS (Hair AB et al 2016)
  - 10.5% reduction in LOS (O'Connor et al 2018)
  - 12.5% less sepsis evals (Delaney Manthe E et al 2019)
- **Role of Increased Use of Human Milk?**
- **Role of Earlier Enteral Feeding?**
- **Role of Earlier Fortification?**

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Exclusive Human Milk Diet and Dose Response

- **Implementation of an EHMD and Neonatal Comorbidities**
  - **Goals**
    - EHMD for infants ≤1250 gm
  - **Results:**
    - N = 205 infants; 101 CMB-HMF and 104 infants EHMD
    - NEC rates not statistically relevant
    - Surgical NEC declined from 4 cases (57%) to 1 case (14.3%)
    - Significant decrease in number of LOS evaluations completed
    - ROP declined from 62% to 48.5% (*P* = .054)
    - BPD n EHMD group 48.5% in CMB-HMF 65% (*P* = .018)
    - Growth not statistically different
    - Financial audits showed products reimbursed at anticipated rate

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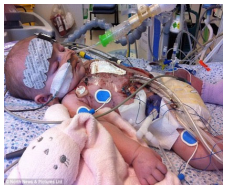
Exclusive Human Milk Diet: Emerging Populations

Infants with single ventricle physiology



- Congenital heart disease manifesting as single ventricle physiology
- RCT, post-surgical exclusive human milk (EHM) feeding with EHM fortification (Surgifort® human milk fortifier [human, pasteurized])
- Growth, LOS, feed tolerance, NEC, sepsis, and ND outcomes
- 100 patients randomized (pre-surgery) out of 106 needed
- Twelve centers nationally

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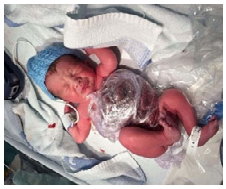
Exclusive Human Milk Diet: Emerging Populations

Congenital Gut Disorders (CGD) Study



- Gastroschisis, omphalocele, intestinal atresia
- Case-control, comparative effectiveness trial, (cohort, 2012-2015), n = 62/100-150
- >1250 g, >32 weeks EGA
- EHM with EHM fortification (Surgifort® fortifier and Prolact+ H²MF fortifier) following repair
- Time to full enteral feeds, days on TPN in neonates with CGD who receive an EHMD, vs those receiving partial and non-human milk diet
- Peak conjugated bilirubin, feeding tolerance/interruptions, sepsis, NEC, and death

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Let's Chat

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Collaborate With Clinical Experts

NICU Nurse Support for the NNP, CNS, RN, NICU Manager
NPAC@prolacta.com

NICU Dietitian Support
NAC@prolacta.com
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