

ADDRESSING THE NUTRITIONAL RISKS FOR LBW PREMATURE INFANTS

Low birth weight (LBW) premature infants face significant risks due to late, inadequate, and inappropriate nutrition, but there is a promising solution. For more than two decades, Prolacta Bioscience® has advanced the science of human milk to improve outcomes for tens of thousands of critically ill infants in neonatal care. Today, more and more hospitals are turning to Prolacta's fortifiers that are clinically proven as part of an exclusive human milk diet (EHMD). This nutritional solution is shown in a growing body of evidence to reduce the most serious complications of prematurity.



Bronchopulmonary Dysplasia (BPD)

Premature infants' undeveloped lungs put them at increased risk of BPD, which is associated with a number of complications:



Respiratory morbidity

Hospitalization for breathing difficulty, need for supplemental home oxygen after 3 months, need for mechanical ventilation, or symptoms despite use of inhaled corticosteroids¹



Long-term neurodevelopment delays

Increased risk of cerebral palsy,² delayed cognitive and educational progress,³⁻⁶ higher incidence of attention deficit disorder⁷



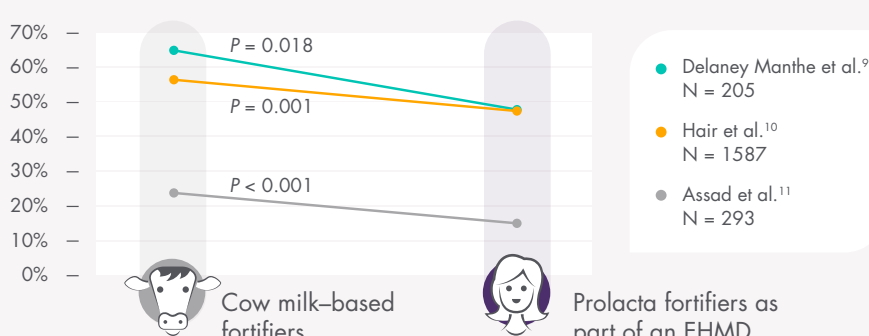
Hospitalization and cost burden

Longer hospital stays, more readmissions, 53% increase in hospitalization costs compared with very low birth weight (VLBW) infants without BPD⁸

What the research shows

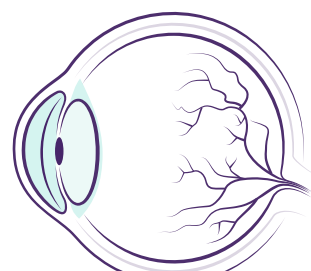
In three recent studies, the use of Prolacta's fortifiers as part of an EHMD led to **statistically significant decreases in BPD** (weighted average of 9.7%) among premature infants.⁹⁻¹¹ Another study revealed that time is of the essence: Early fortification with Prolacta's fortifiers as part of an EHMD led to a 15% reduction in the incidence of BPD, compared with late fortification.¹²

Impact of human milk-based fortifiers on BPD incidence

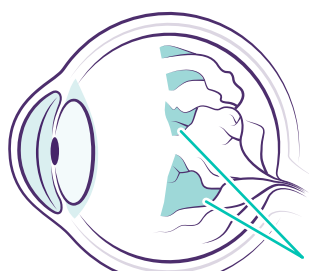


Retinopathy of Prematurity (ROP)

Abnormal development of retinal blood vessels elevates premature infants' risk of this potentially blinding disease. By **eliminating exposure to cow milk-based fortifiers**, clinicians can begin building a chain of protective health factors with an EHMD to reduce the overall risk of ROP.^{9,11}



Normal eye



ROP

Abnormal blood vessels

Less need for oxygen or ventilator support

Fewer comorbidities

Healthier microbiome¹³

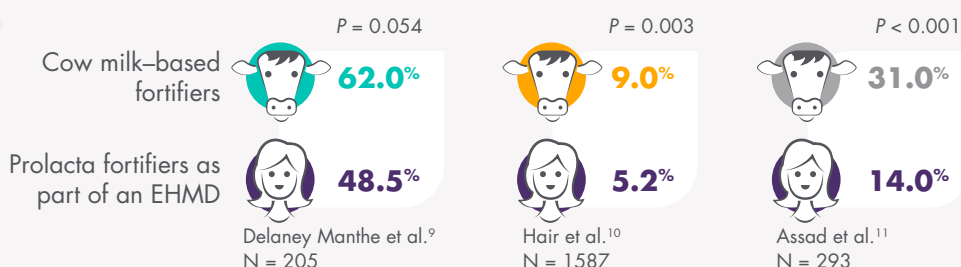
Reduced ROP risk

Adapted from information in Hair et al.¹⁰

What the research shows

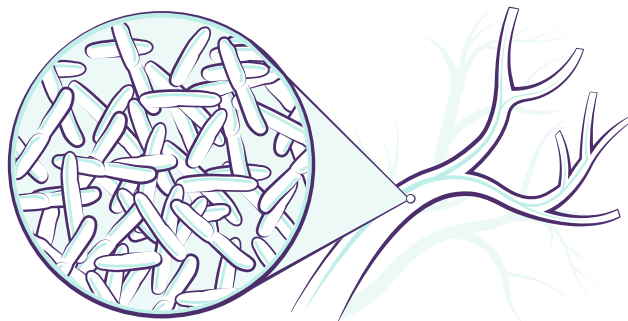
Three recent studies show a direct correlation between feeding protocols with Prolacta's products as part of an EHMD and **reduced incidence of ROP**.⁹⁻¹¹

Impact of human milk-based fortifiers on ROP incidence



Late-Onset Sepsis

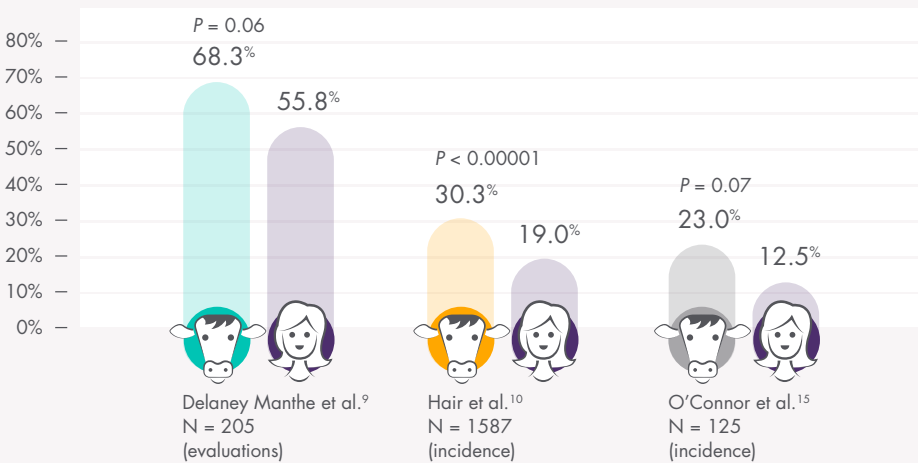
Premature infants have up to a 26.0% chance of developing late-onset sepsis, a leading cause of mortality in neonatal intensive care units.¹⁴ But this risk **drops when infants are nourished without the interruptions of feeding intolerance within the first days of life**.^{9,15} A well-tolerated EHMD, including Prolacta's fortifiers, enables clinicians to get to full feeds faster and remove the central line sooner.



What the research shows

Peer-reviewed research shows the **powerful impact of appropriate nutrition** in curbing the incidence of the complications of prematurity. In recent studies, premature infants fed Prolacta fortifiers as part of an EHMD were less likely to be evaluated for or diagnosed with late-onset sepsis.^{9,10,15}

Impact of human milk-based fortifiers on late-onset sepsis incidence^{10,15} and evaluations⁹



Meet Prolacta Bioscience

21
YEARS

Founded in 1999 to advance the science of human milk and address the nutritional risks for LBW premature infants

63k+
PREMATURE INFANTS¹⁶

The growing number of lives touched by Prolacta's products globally

100%
HUMAN MILK-BASED PRODUCTS

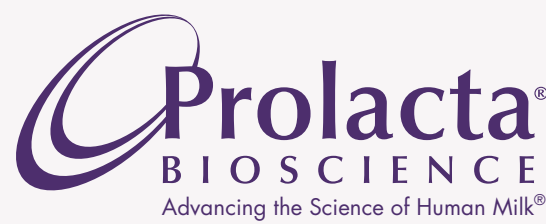
The first and only neonatal nutritional fortifiers carefully crafted exclusively from human milk

20+
DONOR MILK SCREENING TESTS

Ensuring the highest standards of safety and nutritional consistency

About Prolacta Bioscience

Established in 1999, we created the first and only neonatal nutritional fortifiers made from 100% human milk, rather than cow milk. Based in California with employees throughout the world, we're a privately held life sciences company that's touched the lives of more than 63,000 premature infants globally.¹⁶ We operate the first and only pharmaceutical-grade manufacturing facilities for testing and processing donor milk. We exceed food-product industry requirements by following stringent quality and safety standards based on those for the human blood and plasma industry.



1 Keller RL, Feng R, DeMauro SB, et al. Bronchopulmonary dysplasia and perinatal characteristics predict 1-year respiratory outcomes in newborns born at extremely low gestational age: a prospective cohort study. *J Pediatr*. 2017;187:89-97.e3. doi:10.1016/j.jpeds.2017.04.026 **2** Van Marter LJ, Kuban KC, Allred E, et al. Does bronchopulmonary dysplasia contribute to the occurrence of cerebral palsy among infants born before 28 weeks of gestation? *Arch Dis Child Fetal Neonatal Ed*. 2011;96(1):F20-F29. doi:10.1136/adc.2010.183012 **3** Jeng SF, Hsu CH, Tsao PN, et al. Bronchopulmonary dysplasia predicts adverse developmental and clinical outcomes in very-low-birthweight infants. *Dev Med Child Neurol*. 2008;50(1):51-57. doi:10.1111/j.1469-8749.2007.02011.x **4** Natarajan G, Pappas A, Shankaran S, et al. Outcomes of extremely low birth weight infants with bronchopulmonary dysplasia: impact of the physiologic definition. *Early Hum Dev*. 2012;88(7):509-515. doi:10.1016/j.earlhumdev.2011.12.013 **5** Short EJ, Kirchner HL, Assad GR, et al. Developmental sequelae in preterm infants having a diagnosis of bronchopulmonary dysplasia: analysis using a severity-based classification system. *Arch Pediatr Adolesc Med*. 2007;161(11):1082-1087. doi:10.1001/archpedi.161.11.1082 **6** Gray PH, O'Callaghan MJ, Rogers YM. Psychoeducational outcome at school age of premature infants with bronchopulmonary dysplasia. *J Paediatr Child Health*. 2004;40(3):114-120. doi:10.1111/j.1440-1754.2004.00310.x **7** Astbury J, Orgill AA, Bajuk B, Yu VY. Neonatal and neurodevelopmental significance of behaviour in very low birthweight children. *Early Hum Dev*. 1985;11(2):113-121. doi:10.1016/0378-3782(85)90098-2 **8** Lapcharoensap W, Bennett MV, Xu X, Lee HC, Dukhovny D. Hospitalization costs associated with bronchopulmonary dysplasia in the first year of life. *J Perinatol*. 2020;40(1):130-137. doi:10.1038/s41372-019-0548-x **9** 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:10.1038/jp.2015.168 **10** Hair AB, Peluso AM, Hawthorne KM, et al. Beyond necrotizing enterocolitis prevention: improving outcomes with an exclusive human milk-based diet. *Breastfeed Med*. 2016;11(2):70-74. doi:10.1089/bfm.2015.0134. Published correction appears in *Breastfeed Med*. 2017;12(10):663. doi:10.1089/bfm.2015.0134.correx **11** 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 **12** 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 **13** Stiemsma LT, Michels KB. The role of the microbiome in the developmental origins of health and disease. *Pediatrics*. 2018;141(4):e20172437. doi:10.1542/peds.2017-2437 **14** El Manouni El Hassani S, Berkhout DJC, Niemarkt HJ, et al. Risk factors for late-onset sepsis in preterm infants: a multicenter case-control study. *Neonatology*. 2019;116(1):42-51. doi:10.1159/000497781 **15** 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. *Am J Clin Nutr*. 2018;108(1):108-116. doi:10.1093/ajcn/nqy067. Published corrections appear in *Am J Clin Nutr*. 2019;110(2):529. doi:10.1093/ajcn/nqz091 and *Am J Clin Nutr*. 2020;111(5):1112. doi:10.1093/ajcn/nqaa042 **16** Estimated number of premature infants fed Prolacta's products from January 2007 to August 2020; data on file.