



When choosing nutrition for VLBW babies

COMPLICATIONS have COSTS

A 100% human milk-based diet can increase survival¹ and reduce the overall cost of care for very low birth weight (VLBW) infants between 500 and 1250 g.² Prolacta's line of products help maintain an exclusive human milk diet and can decrease costly complications associated with the intake of cow milk-based products.²



	PATIENT: SEAN WRIGHT WEIGHT: 1150 GRAMS DIET: COW MILK-BASED HUMAN MILK FORTIFIER*
Surgical necrotizing enterocolitis	\$198,040 ³
Late-onset sepsis	\$10,055 ⁴
Bronchopulmonary dysplasia	\$31,565 ⁴

* Added to human milk or donor milk when mother's own milk is unavailable

More than
53%

of infant deaths
are associated with
VLBW complications⁴

Approximately
23%

mortality rate for
VLBW infants⁴

Estimated annual
\$201,250

hospitalization cost
per infant^{6,10,†}

[†]57.5 days⁶ x daily NICU costs \$3,500¹⁰
These values are for illustrative purposes.
Cost calculations will vary by hospital.

When choosing nutrition for VLBW babies

Premature babies are at greater risk

Every year, roughly 55,000 premature infants are born weighing less than 1500 g.⁵ These very low birth weight premature infants spend an average of 57.5 days⁶ in the neonatal intensive care unit (NICU). The earlier a baby is born, the more severe the health problems can be.

Costly complications

Very low birth weight (VLBW) babies are at risk for prematurity-related morbidities and interventions, such as:

PARAMETER	COST*
Medical NEC	\$74,004 ³
Surgical NEC	\$198,040 ³
BPD	\$31,565 ⁴
Late-onset sepsis	\$10,055 ⁴
ROP requiring surgery	\$35,749 ⁷
PDA	\$49,457 ⁸
TPN per day	\$1,436 ⁹

*These values are for illustrative purposes. Cost calculations will vary by hospital.

The incremental cost of these morbidities and interventions can substantially increase the cost of NICU hospitalization.

VLBW infants have greater nutritional needs

Human milk provides needed protection.

Premature infants have significant nutritional requirements. Increased calories, protein, calcium, and other minerals are vital to their survival, growth, and development. During the last trimester, unborn babies receive vast amounts of nutrition through the umbilical cord. Very premature infants miss this crucial nutrition, and their dietary needs are greater than what breast milk alone can supply. This is why for preemies weighing less than 1500 g the American Academy of Pediatrics (AAP) recommends fortifying mother's milk or pasteurized donor human milk with protein, minerals, and vitamins to ensure optimal nutrition intake.¹¹

When choosing nutrition for VLBW babies

Prolacta makes the only HMF made exclusively from 100% human milk*

The term “Human Milk Fortifier” (HMF) is a generic product name for a nutritional supplement that is added to mom’s or donor breast milk to meet the dietary needs of premature babies in the neonatal intensive care unit (NICU). Some healthcare providers still mistakenly assume that “Human Milk Fortifier” may imply that the product is made from human milk, which is not the case.**

* See bottle label for added minerals

** Data on file

What is an exclusive human milk diet?

(EHMD)

An EHMD is achieved when 100% of protein, fat, and carbohydrates are derived from human milk. This diet includes a human milk-based HMF.

An EHMD for VLBW babies supports adequate growth,¹² can increase survival,¹ and can decrease costly complications associated with the intake of cow milk–based products.^{2,3,†}

† For babies weighing between 500 and 1250 g

An EHMD supports adequate growth

Improved survival rates of VLBW infants have shifted the focus of neonatal care to improving postnatal growth and nutrition—aiming to achieve growth rates that optimize later health outcomes.¹³

A feeding protocol for infants weighing between 500 and 1250 g that provides an exclusive human milk–based diet with early and rapid advancement of fortification is associated with weight gain exceeding targeted standards, with length and head circumference growth meeting targeted standard, and with a low rate of extrauterine growth restrictions.¹²

An exclusive human milk diet, devoid of cow milk-containing products, is associated with lower mortality and morbidity in extremely premature infants weighing between 500 and 1250 g without compromising growth.¹

When choosing nutrition for VLBW babies weighing between 500 and 1250 g at birth

An Exclusive Human Milk Diet can reduce the risk of NEC and Surgical NEC^{14,15}

(Demonstrated in 2 Randomized Clinical trials)

1 case

of NEC eliminated for every **10** babies fed an exclusive human milk diet.¹⁴

Significantly fewer

surgical NEC cases while receiving an EHMD, including Prolact+ H²MF®, when compared with infants receiving cow milk-based fortifier or, when mother's own milk was unavailable, preterm formula.¹⁴

77% reduction

in the odds of developing NEC while receiving an EHMD, including Prolact+ H²MF®, when compared with infants receiving cow milk-based fortifier or, when mother's own milk was unavailable, preterm formula.¹⁴

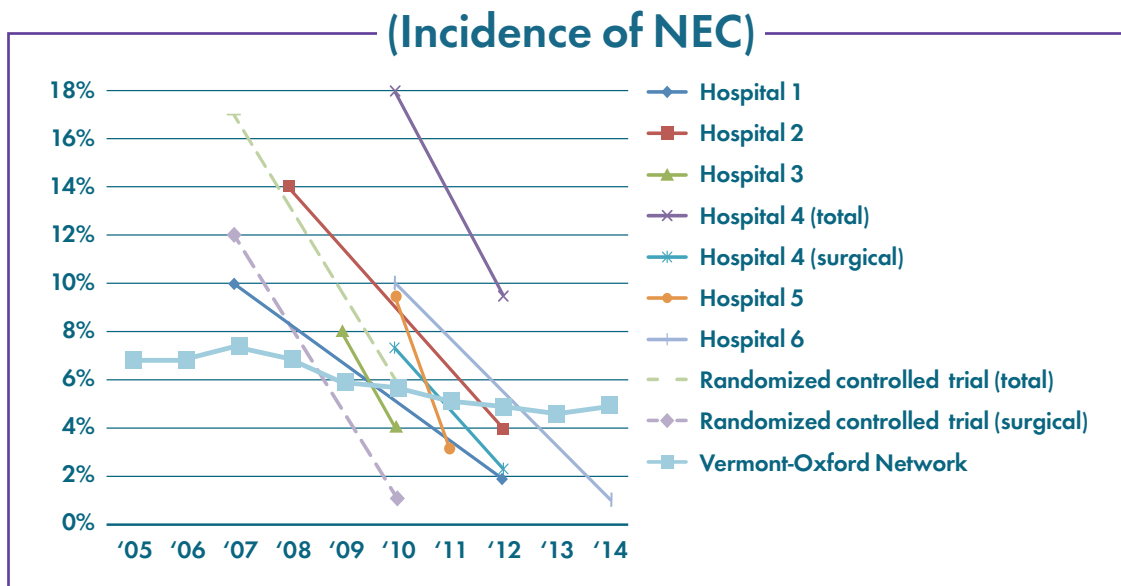
0 cases

in a second confirmatory study, of surgical NEC among infants fed a human milk-based diet vs preterm formula.¹⁵

A multivariate logistic regression analysis determined an odds ratio for NEC of 0.23 (95% confidence interval = 0.08, 0.66) with an exclusive human milk diet. There was a 77% reduction (P=.007) in the odds of developing NEC while receiving an exclusive human milk diet, including Prolact+ H²MF when compared with infants receiving cow milk-based fortifier, or when mother's own milk was unavailable, preterm formula. This peer-reviewed, randomized, controlled trial evaluated the benefits of an exclusive human milk diet for infants weighing between 500 g and 1250 g at birth (N=207).¹⁴

This multicenter, randomized, controlled trial compared an exclusive human milk diet vs preterm formula in extremely premature infants. There was a significant difference in median parenteral nutrition days: 27 vs 36 days with Prolact+ H²MF vs preterm formula, respectively (P=.04). Surgical NEC cases were significantly fewer with Prolact+ H²MF (0 cases) vs preterm formula (4 cases).¹⁵

Independent research has replicated the decrease in medical and surgical NEC reported in 2 randomized clinical trials^{16,*}

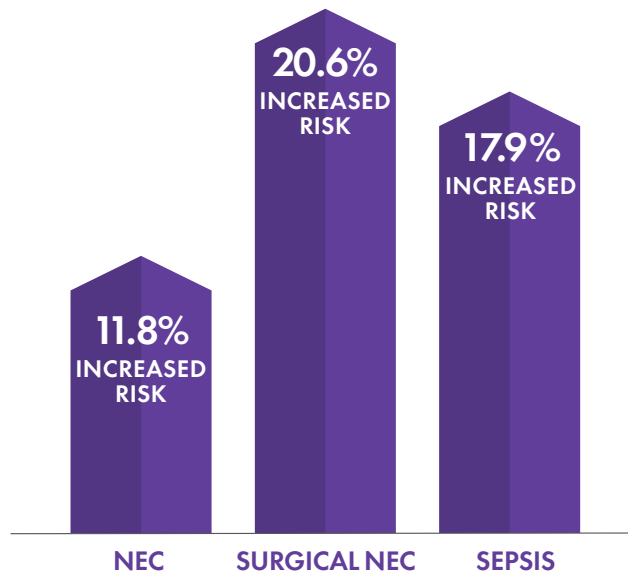


* Evaluation of NEC rates across multiple hospitals over the period of 2008-2014 for approximately 264,000 extremely preterm infants (<1250 g birth weight).

When choosing nutrition for VLBW babies

A cow milk–based diet (CMD) can increase medical complications and costs^{1,2,17}

Dose response relationship



A combined analysis of two randomized clinical studies demonstrates a dose response relationship that negatively effects patient outcomes. For every 10% increase in the volume of milk containing cow milk, the risk of NEC increases by 11.8%, surgical NEC by 20.6%, and sepsis by 17.9%.^{1,*}

* NEC 11.8% (95% confidence interval of 0.2% to 24.8%)
Surgical NEC 20.6% (95% confidence interval of 4.2% to 39.6%)
Sepsis 17.9% (95% confidence interval of 8.8% to 27.8%)

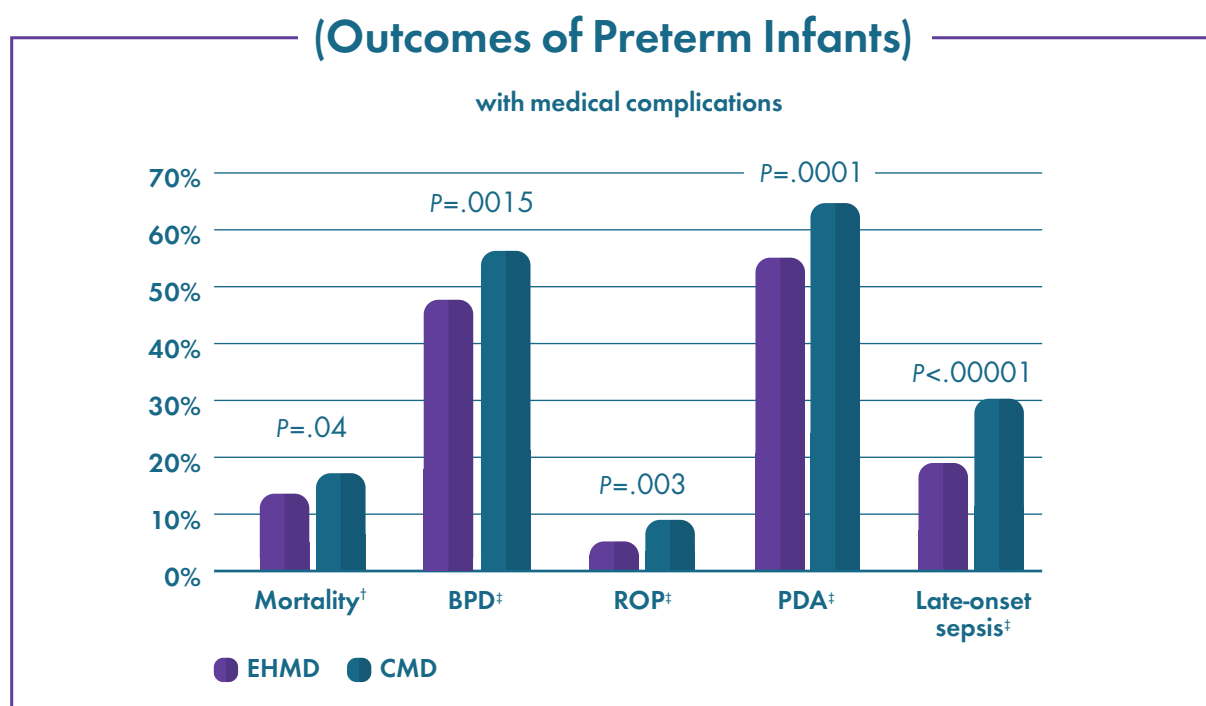


When choosing nutrition for VLBW babies weighing between 500 and 1250 g at birth

An Exclusive Human Milk Diet can reduce medical complications and interventions²

A large, multicenter, retrospective cohort study (1587 patients) reported the compared outcomes of extremely premature infants (<1250 g birth weight) who received a diet including cow milk-based products vs infants who received an exclusive human milk diet. The results are consistent in both academic and real-world nonacademic settings, across multiple geographically-diverse centers, and over a long period of time in a large study population.²

Significant reduction in incidence of medical complications in VLBW infants on EHMD vs CMD²



† Primary outcome
‡ Secondary outcome

9
fewer days
of TPN¹⁵

Shorter duration of TPN for infants fed a human milk-based diet vs preterm formula^{15,*}

In extremely preterm infants given exclusive diets of preterm formula vs human milk, there was a significant difference in median parenteral nutrition days: 27 vs 36 days with Prolact+ H²MF[®] vs preterm formula, respectively (P=.04).¹⁵

* This multicenter, randomized, controlled trial compared an exclusive human milk diet vs preterm formula in extremely premature infants.

94%

of VLBW babies fed an EHMD never had feeds held¹⁷

Up to

10

fewer days to achieve full feeds for VLBW babies fed an EHMD compared to VLBW babies on CMD (P<.001)¹⁷

When choosing nutrition for VLBW babies

An Exclusive Human Milk Diet can reduce hospital costs¹⁷

This single-center retrospective study assessed the benefits and costs of an EHMD in preterm infants (≤ 28 weeks) and/or VLBW (≤ 1500 g) vs a combination of mother's milk and cow milk-based fortifier; a mixed combination diet of mother's milk, cow milk-based fortifier, and formula; or a diet of formula only. The primary outcomes were length of stay (LOS), incidence of feeding intolerance, and time to full feeds. The secondary outcomes included the effect of the diet on the incidence of NEC and the cost-effectiveness of an EHMD.¹⁷

Despite the added cost of donor human milk and donor milk-derived fortifier, an EHMD is cost effective.¹⁷

(Cost Effectiveness)

4.5

fewer additional days of hospitalization for VLBW babies on EHMD compared with VLBW babies on CMD (P<.04)¹⁷

\$27,388

saved in total cost of hospitalization per infant observed for VLBW babies on EHMD compared with VLBW babies on CMD¹⁷

Potential cost savings associated with an EHMD

(Cost Savings Per Infant)

Reduction in LOS 4.5 days ^{17*} x daily NICU cost \$3,500 ¹⁰	\$15,750
9 fewer days of TPN ^{15,*} x average daily TPN cost \$1,436 ⁹	\$12,924
Reduction in the rate of medical and surgical NEC and associated NICU costs ^{3,*}	\$8,167

* For babies weighing between 500 and 1250 g
These values are for illustrative purposes. Cost calculations will vary by hospital.

Long-term cost savings

- Morbidities associated with prematurity predispose VLBW infants to long-term complications and increase the risk of neurodevelopmental and neurocognitive problems that can add to healthcare system and societal costs.⁴
- From a financial perspective, an EHMD for VLBW infants in the NICU has the potential for cost savings that will span their lifetime and result in healthcare system cost savings over the long term.^{3,14}

When choosing nutrition for VLBW babies weighing between 500 and 1250 g at birth

CHOOSE PROLACT+ H²MF

The only HMF made from donor human milk, and clinically proven to improve health outcomes^{1,*} and reduce hospital costs for critically-ill, extremely premature infants in the neonatal intensive care unit²



Prolact+4 H²MF®
24 Cal/fl oz**



Prolact+6 H²MF®
26 Cal/fl oz**



Prolact+8 H²MF®
28 Cal/fl oz**



Prolact+10 H²MF®
30 Cal/fl oz**

Contact Prolacta to speak to a member of our experienced Health Economics Team to schedule a Value Analysis. This service is provided as part of Prolacta's business offering. 888-PROLACT (888-776-5228) WWW.PROLACTA.COM

*When used as part of an EHMD.

**When milk being fortified is equal to 20 Cal/fl oz.

REFERENCES: 1. 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. 2. 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. 3. Ganapathy V, Hay JW, Kim JH. Costs of necrotizing enterocolitis and cost-effectiveness of exclusively human milk-based products in feeding extremely premature infants. *Breastfeed Med.* 2012;7(1):29-37. 4. Johnson TJ, Patel AL, Bigger HR, Engstrom JL, Meier PP. Economic benefits and costs of human milk feedings: a strategy to reduce the risk of prematurity related morbidities in very low birth weight infants. *Adv Nutr* 2014; 5:207-212. 5. Hamilton BE, Martin JA, Osterman MJ, M.H.S., Division of Vital Statistics. Births: Preliminary Data for 2015. *National Vital Statistics Reports.* 2016;65 (3): 1-15. 6. Johnson TJ, Patel AL, Jegier BJ, Engstrom JL, Meier PP. Cost of Morbidities in Very Low Birth Weight Infants. *The Journal of Pediatrics.* 2013;162(2). doi:10.1016/j.jpeds.2012.07.013. 7. Black L, Hulsey T, Lee K, Parks DC, Ebeling MD. Incremental hospital costs associated with comorbidities of prematurity. *Manag Care.* 2015;24(12):54-60. 8. Turck CJ, Marsh W, Stevenson JG, York JM, Miller H, Patel S. Pharmacoeconomics of surgical interventions vs. cyclooxygenase inhibitors for the treatment of patent ductus arteriosus. *J Pediatr Pharmacol Ther.* 2007;12(3):183-193. 9. Edwards TM, Spatz DL. Making the case for using donor human milk in vulnerable infants. *Adv Neonatal Care.* 2012;12(5):273-278. 10. Muraskas J, Parsi K. The cost of saving the tiniest lives: NICUs versus prevention. *Virtual Mentor.* 2008;10(10):655-658. 11. American Academy of Pediatrics. Breastfeeding and the use of human milk: section on breastfeeding. [published online ahead of print February 27, 2012]. *Pediatrics.* 2012;129(3):e827-e841. doi:10.1542/peds.2011-3552. 12. Hair AB, Hawthorne KM, Chetta KE, Abrams SA. Humanmilk feeding supports adequate growth in infants \leq 1250 grams birth weight. *BMC Res Notes.* 2013;6:459. 13. Rochow N, Raja P, Liu K, et al. Physiological adjustment to postnatal growth trajectories in healthy preterm infants. *Pediatric Research.* 2016;79(6):870-879. doi:10.1038/pr.2016.15. 14. Sullivan S, Schanler RJ, Kim JH, et al. An exclusively human milk-based diet is associated with a lower rate of necrotizing enterocolitis than a diet of human milk and bovine milk-based products. *J Pediatr.* 2010;156(4):562-567. 15. Cristofalo EA, Schanler RJ, Blanco CL, et al. Randomized Trial of Exclusive Human Milk versus Preterm Formula Diets in Extremely Premature Infants. *The Journal of Pediatrics.* 2013;163(6). doi:10.1016/j.jpeds.2013.07.011. 16. Lee ML, Rechtman DJ, Lucas A. The effect of an exclusive human milk (EHMD) diet on the incidence of necrotizing enterocolitis (NEC) in the US: an epidemiological evaluation. Poster presented at: 2nd International Neonatology Association Conference; July 2016; Vienna, Austria. 17. 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.