FACT SHEET

Necrotizing Enterocolitis (NEC)

- Necrotizing enterocolitis (NEC) is the most common serious intestinal disease among extremely preterm infants (preemies born < 28 weeks gestational age), and is one of the leading causes of mortality among these very young patients.[1]

- The amount of cow milk in a preterm infant's diet is a significant predictor of NEC and NEC surgery, according to a cohort study published in the journal *Breastfeeding Medicine*.[2] For each 10% increase in cow milk in the infant's diet, the risk of NEC increases by 11.8%, the risk of surgical NEC increases by 21% and the risk of sepsis increases by 17.9% in extremely premature infants born weighing less than 1,250g (2 lbs 12 oz).[2]

- Mortality for babies with NEC requiring surgical intervention can be as high as 50% and has not improved significantly over the past 30 years.[3]

Treatment

- All infants suspected of having NEC need to be treated with medicines and bowel rest. About one-third may need surgery to remove the affected part of the intestines. After diagnosis, treatment begins immediately and may include:
  - o Temporarily stopping all feedings
  - o Nasogastric drainage (inserting a tube through the nose into the stomach to remove air and fluid from the stomach and intestines)
  - o Intravenous (IV) fluids for fluid replacement and nutrition
  - o Antibiotics to treat or prevent infection
  - o Examinations and X-rays of the abdomen
  - o Consultation with a pediatric surgeon to discuss if surgery is needed

Health Impact

- Premature babies who require surgery for NEC have a high risk for developing future health problems. A health economic study published in *BMC Pediatrics* demonstrated that within the group of preemies observed at ages six to 12 months who survived surgery for NEC, those infants were:[4]
  - o Four times more likely to develop the chronic lung disease, bronchopulmonary dysplasia.
  - o Forty-seven times more likely to develop malabsorption syndrome, which is the inability to absorb nutrients, vitamins and minerals from the intestinal tract into the bloodstream.

- Within the group of preemies observed at ages 24-36 months, those who survived surgery for NEC were:[4]
  - o Five times more likely to develop bronchopulmonary dysplasia, a chronic lung disease
  - o Sixty-two times more likely to develop malabsorption syndrome. Other serious conditions noted in the study resulting from NEC or surgical NEC included a higher risk of developing cerebral palsy, various disorders of the gastrointestinal tract and neurodevelopmental delays.

- Several studies have reported that premature infants, specifically those born weighing 500-1,250g (1 lb 1 oz to 2 lbs 12 oz), who received an exclusive human milk diet (EHMD)[5], as opposed to cow milk-based preterm formula or cow milk-based fortifier, have a reduced risk of developing medical NEC or surgical NEC.[6,7,8]

- Prolact+ H²MF®, when used as part of an EHMD, is the first and only clinically proven human milk fortifier to reduce NEC, surgical NEC, sepsis, and mortality in premature infants weighing between 500-1,250g (1 lb 1 oz to 2 lbs 12 oz) at birth, compared to cow milk-based preterm formula or cow milk-based fortifier.[2,7,8,9]

References

1. Ganapathy V, et al. "Costs of Necrotizing Enterocolitis and Cost-Effectiveness of Exclusively Human Milk-Based Products in Feeding Extremely Premature Infants." *Breastfeeding Medicine*. February 2012. 7(1):29-37. doi: 10.1089/bfm.2011.0002. This cost-effectiveness analysis of 2,560 extremely premature infants less than 28 weeks gestational age in 257 hospitals nationwide, comparing the impact of an exclusive human milk diet composed of mother's milk fortified with a human milk-based fortifier versus mother's milk fortified with cow milk-based fortifier.

2. Abrams SA, et al. "Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products." *Breastfeeding Medicine*. June 2014. 9(6): 281-0285. doi:10.1089/bfm.2014.0024. This cohort study included 260 extremely preterm infants born weighing less than 1,250g who received a diet that ranged from 100% cow milk to 100% human milk.

3. Dominguez KM, et al. "Necrotizing Enterocolitis." *Clinics in Perinatology* June 2012. 39(2):387-401. doi:10.1016/j.clp.2012.04.011.

4. Ganapathy V, et al. "Long Term Healthcare Costs of Infants Who Survived Neonatal Necrotizing Enterocolitis: A Retrospective Longitudinal Study Among Infants Enrolled in Texas Medicaid." *BMC Pediatrics*. August 2013. 13(127):1-11. doi: 10.1186/1471-2431-13-127. This retrospective cohort study compared the healthcare costs between six and 36 months of chronological age, among 250 survivors of medical and surgical NEC, to that of 2,909 matched infants without a diagnosis of NEC during birth hospitalization.

5. An EHMD is when 100% of the protein, fat and carbohydrates in an infant's intake are derived solely from human milk.

6. Huston RK, et al. "Decreasing Necrotizing Enterocolitis and Gastrointestinal Bleeding in the Neonatal Intensive Care Unit: The Role of Donor Human Milk and Exclusive Human Milk Diets in Infants <1,500g Birth Weight." *ICAN: Infant, Child, & Adolescent Nutrition*. 10 January 2014. 13:127. doi: 10.1177/1941406413519267. The retrospective study of infants weighing 500-1,500g at birth and less than 32 weeks postmenstrual age compared those fed an exclusive human milk diet versus diets of mother's milk supplemented with banked human milk or formula plus cow milk-based fortifier.

7. Sullivan S, 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." *The Journal of Pediatrics*. April 2010. 156(4):562-567. doi: 10.1016/j.jpeds.2009.10.040. The randomized study of 207 infants weighing 500-1,250g compared the benefits of an exclusive human milk diet with a diet of both human milk-based and cow milk-based products.

8. Cristofalo EA, et al. "Randomized Trial of Exclusive Human Milk versus Preterm Formula Diets in Extremely Premature Infants." *The Journal of Pediatrics*. December 2013. 163(6):1592-1595. doi: 10.1016/j.jpeds.2013.07.011. The multicenter randomized controlled study examined 53 extremely premature infants weighing 500-1,250g who were fed either a bovine milk-based preterm formula or an exclusive human milk diet, comparing the duration of parenteral nutrition, growth and morbidity.

9. Hair A, et al. "Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based Diet." *Breastfeeding Medicine*. March 2016. 11(2): 70-74. doi:10.1089/bfm.2015.0134. The study included more than 1,500 infants weighing less than 1,250g at birth from four large centers in TX, IL, FL and Calif. Researchers compared data from approximately two years before and two years after the implementation of an exclusive human milk diet in the study centers' neonatal intensive care units. Infants who received a diet of mother's milk fortified with a cow milk-based fortifier and/or preterm formula, –were compared to infants who received an exclusive human milk diet, including mother's own or donor milk fortified with a Prolact+ H²MF®.
   NOTE: Used calculator from http://www.matthewb.id.au/converter/grams-to-pounds-and-ounces-converter.html to calculate and convert grams to pounds.

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