Standards and Practices for Human Milk Products

In this feature, Neonatal Intensive Care interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Terry S Johnson, APN, NNP-BC, MN.

Neonatal Intensive Care: What are the current practices in preparing and mixing human milk products for use in the NICU?
Terry S Johnson: The American Academy of Pediatrics (AAP) in its 2012 Policy on Breastfeeding and Use of Human Milk recommendation said that the benefits of human milk "are such that all preterm infants should receive human milk" and that "the potent benefits of human milk, mother's own milk, fresh or frozen, should be the primary diet." If a mother's own milk is "unavailable despite significant lactation support, pasteurized donor milk should be used." The AAP "supports the use of banked human milk as the 'first alternative' to mother's milk."

(American Academy of Pediatrics. Breastfeeding and the Use of Human Milk. Section on Breastfeeding. [originally published online February 27, 2012]. Pediatrics. DOI: 10.1542/peds.2011-3552)

The profound nutritional needs for growth and development of the premature infant require the fortification of mother's own milk or donor human milk. The AAP recommends human milk "should be fortified appropriately for the infant born weighing less than 1.5 kg."

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Current practice is often different from current recommendations. Many NICU's are "playing catchup" to the AAPs recommendations for human milk feeding. This is most frequently because of a lack of physical space and personnel. This can result in potential risk of bacterial contamination, human milk loss or wastage, and safety issues with misconnections.

Variation in clinical practice is also due to the rapidly evolving human milk usage in this population. Prolacta Bioscience is committed to advancing the science of human milk and its clinical usage in the NICU patient. This commitment extends beyond the quality taken in human milk product development, manufacturing, and safety to tools to facilitate best practices by clinicians using human milk.

NIC: Is there any standardization of practice that you observe?
TJ: I have observed incredible efforts on the part of NICU's and nursing and dietary staff to adhere to the "Guidelines for Infant Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities, second edition. American Dietetic Association, 2011." This publication provides current criteria to ensure both the safe administration of human milk and human milk split-products and to preserve the integrity and nutritional and immunologic value of human milk.

NIC: Are there new practices being introduced to enhance patient safety?
TJ: Patient safety is the number one priority when your patient population weighs less than 1500 grams and may be only 24 weeks gestational age. As NICU clinicians, we must be diligent in utilizing best practices with this vulnerable population. There are three important areas to ensure patient and product safety in the use of human milk in the NICU. The first has to do with the safety, quality, and integrity with which a mother's own milk and donor human milk are collected, maintained, screened, and handled prior to feeding. The second is in regards to tubing misconnections (see below). The third is the recent undertaking by the Academy of Nutrition and Dietetics (AND) to initiate an update of the "Guidelines for Infant Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities." This is currently underway.

NIC: Can you tell me about some of the concerns with the current practices in mixing and administration of human milk products in the NICU?
TJ: The clinical concerns with current practices is more related to the dramatic increased use of human milk in the NICU and a mismatch in space and personnel. Human milk utilization requires space, specialized equipment, and specific training of personnel to ensure its safe usage. Many NICU's do not have the availability of a "designated milk room or lab or preparation area." This necessitates the handling and mixing of human milk at the bedside and this is problematic. The NICU bedside is a high-traffic zone with multiple personnel and equipment moving through it continuously. In NICU's it is not uncommon that the bedside nurse will be trying to thaw, fortify, aliquot, and set up delivery of the milk in this limited space. Even with best of intents the risk for less than ideal aseptic handling of this milk, which is also a biologic fluid, can be compromised. Human milk is subjected to freezing, thawing, mixing, refrigeration and delivery times which increase the risk of bacterial growth. We are looking forward to innovations that have the potential to lessen the risk of introduction of environmental bacteria into the milk.

If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

NIC: We hear that Prolacta Bioscience is introducing a transfer lid in the near future that may address concerns about the risk of introduction of environmental bacterial into milk. Can you tell us about it?
TJ: Yes, Prolacta is currently conducting research and testing on an ancillary device for use specifically with its human milk products. The project evolved out of Prolacta Bioscience's concern and commitment to patient safety. Beginning in 2006, JCAHO identified safety concerns regarding tubing issues, including misconnections. This led to the International Organization for Standardization (ISO) release of ISO 80369-1:2010 in 2010, small bore connectors for liquids and gases in healthcare applications. ISO specified the intent for general requirements for small-bore connectors which were "used in medical devices or accessories intended for use with a patient" out of concern for real or potential risk of patient injury to death. Following on the ISO, in 2013 the Global Enteral Device Manufacturer Organization (GEDSA) was formed in 2010 to help introduce enteral feeding ISO standards and enhance patient safety. The formation of GEDSA was timely as The Joint Commission (JCAHO) released Sentinel Event Alert 53, Managing Risk During Transition to New ISO Tubing Connector Standards, in 2014. A sentinel event is an "unexpected occurrence that involves death or serious injury to patients". It is forwarded to all health care facilities, published in The Joint Commission newsletter, website, and materials, and is released to public media. A sentinel event requires immediate investigation, response from health care systems and is assessed on site visits to health care facilities.

NIC: How would a NICU and/or a NICU healthcare professional find value in using a transfer lid?
TJ: The transfer lid is a starting point of the evolving process in managing safe and aseptic enteral feeding administration. Overburdened nurses and milk techs in the NICU already manage multiple priorities. Limited numbers of NICUs have a separate milk processing/handling area for human milk storage and preparation. In most units, human milk is handled at the local bedside or in a common, multi-use area. Knowing that this is the state of practice, the use of transfer lids promotes aseptic maintenance of bottles and containers that are used in these multiple use areas. Using the transfer lid eliminates the practice of inserting multiple syringes into the bottle of human milk which can lead to the increased risk of contamination. The sterile and ready to use transfer lid reduces product exposure to the environment, especially due to the number of times the bottle is opened and accessed for dosing the human milk.

NIC: What impact do you see this having on feeds in the NICU?
TJ: First, and foremost is the reduction in risk of environmental contamination of human milk from limited contact from multiple syringe insertions or touch contamination from syringes sitting on a counter then being inserted in the milk. Secondly, the requirement of a feeding system that eliminates the potential for a misconnection between an enteral feeding line and another line such as an IV or vascular access or monitoring line is set for the state of California this year.

Terry's clinical experience has included the NICU, Special Care and Normal Newborn Nursery, as well as Developmental Followup Services.

A nationally known speaker and educator, Terry was the 2009 recipient of the Braden E. Griffin M.D. Memorial Lectureship Award from the University of Massachusetts Medical School. She was a 2007 fellow in the Patient Safety Leadership Fellowship Program through the Health Research and Educational Trust and the American Hospital Association. Terry was the 2006 recipient of the National Association of Neonatal Nurses SIG (Special Interest Group) Leadership Award. She also served on AWHONN's Advisory Committee for Care of the Late Preterm Infant.