Organization: Sinai Hospital of Baltimore

Solution Title: Got Milk? 100% Human Milk Diet

Focus Area: Other/Neonatal Intensive Care Unit

Program/Project Description, Including Goals: In April 2010, an article in *The Journal of Pediatrics* described the association between an exclusively human milk-based diet and lower rates of necrotizing enterocolitis (NEC) in high-risk infants in NICUs than with a diet of human and bovine milk products. In July 2011, the National Association of Neonatal Nurses published a position statement on the use of human milk and breastfeeding in the NICU. It states that human milk alone does not provide the levels of calories, protein and minerals that the very low birth weight (VLBW) infant requires for adequate growth, and that human milk fortifiers mixed with human milk should be used to enhance these essential nutritional components. Prolact+ H2MF was developed and marketed in 2011 as the first and only commercially available human milk fortifier (HMF) made from concentrated 100% human milk. These two evidence-based journal articles and the availability of human milk fortifier product sparked NICU nurses and neonatologists interest in an initiative to offer a 100% human milk diet (donor milk and human milk fortifier) for use with very low birth weight patients. The incident of NEC for Sinai Hospital’s NICU in 2011 was 10.4% versus the Vermont Oxford Network (VON) national data base of 5.8%; twice the national rate. The goals of the 100% human milk diet for VLBW infant were to:

- Reduce the incidence of NEC in the NICU by establishing clinical guidelines for use of a strictly human milk diet.
- Meet or exceed the benchmark for NEC incidence established by the Vermont Oxford Network (a national and international network of more than 900 NICU’s)

Process: Using evidence, a P-D-S-A framework, standardized guidelines and workflow redesign the strategies were to:

- Educate staff regarding evidence for use of human milk diet to create “buy-in”
- Establish criteria of who would receive Donor Milk and Prolacta
- Identify the key responsibilities and process for ordering, receiving, administering, and documenting use of Donor Milk and Prolacta

Solution: The initiative implementation process included an interdisciplinary and collaborative effort between Leadership, Nursing, Medicine, Blood Bank, Breastfeeding Committee, and other hospital support services and included the following:

- Donor Milk is considered a tissue in Maryland & therefore the hospital Blood Bank applied for a license to store & distribute donor milk & the HMF.
- Provider order sets were created in collaboration with Information Systems for computerized provider order entry (CPOE).
• Patient selection criteria were established and a policy was developed regarding the requesting, storing, & use of banked donor milk in the NICU.
• Infection Control assisted in the identification of any potential infection risks with this new practice.
• Clinical Engineering adapted the breast milk refrigerator to provide continuous donor milk temperature monitoring feedback to the Blood Bank

Measurable Outcomes:

As demonstrated in the graph, the percent of NEC prior to the implementation of a 100% human milk diet in the NICU at Sinai was 10.4% compared to the VON national database of 5.8%. After the implementation of a 100% human milk diet for neonates that met the criteria the percent of NEC in the NICU at Sinai was zero compared to the VON national database of 4.9%. Year to date at Sinai the percent of NEC in the NICU continues to be zero.

Sustainability: Support for mothers to continue to express breast milk for their infants is crucial to the success of reducing the incidence of NEC and to the initiative. In September 2012, the leadership for the NICU secured funding for ten breast pumps to support NICU mothers in initiating pumping within the first hour of the infant’s birth and for continued use once the mother is at home. In addition, nursing leadership presented a business case for the operational expenses for the initiative after which budget approval for fiscal year 2014 was secured. The 100% Human Milk Diet initiative team identified the following next steps to ensure sustainability:
• Continue to carefully monitor for proper ordering and mixing to reduce waste.
• Continue to monitor NEC incidence and compare to Vermont Oxford rates to examine long term data patterns.
• Investigate additional funding methods due to the high cost of Prolacta—philanthropy.
• Keep up to date with and contribute to developing research/trends regarding the relationship of NEC and a 100% human milk diet.
• Examine other costs and benefits such as quicker advancement to full feedings, less feeding intolerance, and less use of total parenteral nutrition.

Other hospitals in the state have consulted with the Sinai NICU leadership team, but they have not been successful in implementing a program of this type. On May 15, 2012, The Herman & Walter Samuelson Children’s Hospital at Sinai co-sponsored a program for area NICUs titled “Got Donor Milk? Using Banked Donor Milk to Reduce Morbidity and Mortality in Maryland’s NICUs.”

This program also received public recognition. On July 15, 2012, an article in The Baltimore Sun highlighted Sinai’s program. The hospital was also featured in a program segment on the CBS local evening news, and CBS News Online published a video segment highlighting how the program at Sinai has helped premature babies avoid the fatal disease that comes from intolerance of non-human milk. To date, Sinai is the only hospital in the state to provide this service. The success of this program would not have been possible without the continued efforts of NICU nurse leaders and support of Sinai Hospital executive team.

**Role of Collaboration and Leadership:** The implementation of this program involved the efforts of a variety of departments. NICU nursing leadership coordinated the 100% Human Milk Initiative. Updates on the project were discussed in the Department of Women’s Services and Pediatrics (DWSP) Multidisciplinary Committee (MDC) meetings.

When investigating the possibility of using Prolact+ H2MF, it was discovered that donor milk and human milk fortifier (HMF) is considered tissue in Maryland and therefore under the purview of the hospital Blood Bank. The NICU team partnered with Blood Bank manager to investigate bringing the product to Sinai. The Blood Bank applied for a license to store and distribute donor milk and the human milk fortifier (HMF) product in Sinai’s Blood Bank. The license was secured.

NICU nurses and neonatologists created provider order sets. They also worked with Breastfeeding Committee members to set patient selection criteria and draft a policy for requesting, storing and using banked donor breast milk in the NICU.

NICU nursing staff worked with the Infection Prevention and Control practitioner, to identify and address any potential infection risks related to this new practice. The Finance Department evaluated the financial impact of the program and established a general ledger account to track
the costs. NICU nursing leadership also worked with Clinical Engineering to adapt the breast milk storage unit to provide continuous donor milk temperature monitoring feedback to the Blood Bank. The Sinai Forms Committee approved patient consent forms, with NICU nursing leadership shepherding the forms through the process.

The nurse and physician team worked to determine the logistics of timely product ordering. They also developed a system to have an NICU nurse round daily with the physicians to discuss feeding plans and determine patient needs. These discussions resulted in the decision to place a daily order with the Blood Bank for product and donor milk. A tracking tool was developed to track mothers’ expressed milk volumes and the amount of wasted product.

Nursing prepared an education program for NICU staff and physicians that included the program objectives, rationale for using donor milk, clinical criteria for use, handling instructions, donor milk process and shipping, economic impact, Prolacta’s role in the program and mixing guidelines for the product. On March 1, 2012, the first patient received the HMF product.

**Innovation:** The NICU used the latest research to implement a change in practice that reduced a serious, life-threatening condition in at risk neonates. Sinai continues to be a leader for this initiative across the state and is seen as an authority on the use of a completely human milk diet.

**Related Tools and Resources:**

**References**


**Tools:**

- Donor Milk and Prolacta Order Set
- Policy: Use of Banked Donor Breast & Milk
- Consent Form

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