Implementing Pasteurized Donor Human Milk Programs in Level One and Two Nurseries: policies, barriers, and successes

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Implementing Pasteurized Donor Human Milk Programs in Level One and Two Nurseries

Policies, Barriers, and Successes

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Abstract

Pasteurized donor human milk (PDHM) as a form of feeding supplementation has been shown to prevent and lower rates of gastrointestinal infection and increase exclusive human milk consumption in critically-ill, low birth-weight, and premature newborns in level III and IV nurseries. Policies and procedures for the use of PDHM in level I and II nurseries, which care for “well” newborns and low birth weight newborns with non-life-threatening illness, respectively, have not been established. The objective of this research is to gather and summarize policies, procedures and experiences from four hospitals located in the northeast US that use PDHM in their level I/II nurseries. Data was collected from interviews with hospital administrators and from each hospital’s PDHM policies and procedures on PDHM procurement, storage and distribution, as well as patient inclusion criteria. Interview and policy/procedure data were analyzed to identify similarities, differences, successes, and barriers to PDHM program implementation and outcomes. Findings revealed that policies and procedures of all four hospitals cited five indications for PDHM supplementation: ineffective breastfeeding, preterm/late preterm birth, hypoglycemia, weight loss greater than 10%, and hyperbilirubinemia. One hospital did not include a step-by-step procedure on distributing PDHM, but the remaining three hospitals cited thirteen similar distribution steps. Three major barriers to the implementation and maintenance of each hospital’s PDHM program were funding, “ick” factor, and time limit on supplementation. Two successes reported by all four hospitals included increased exclusive human milk consumption rates and gratitude for PDHM as a supplement option. Although the number of hospitals sampled was limited to four, the findings were consistent, suggesting that this research can be used to develop a template on PDHM policy and procedures for level I/II nurseries in the US.
**Background/Introduction**

*Human Milk:*

Human milk is the most beneficial form of nutrition for all infants during early life. It provides energy, nutrients, and immunological factors that reduce the risk and incidence of many neonatal health problems including respiratory tract infections, ear infections, and gastrointestinal tract infections.\(^1\)\(^-\)\(^3\) The World Health Organization (WHO) recommends that all infants receive an exclusive human milk diet until six months of age.\(^4\)

Unfortunately, current rates of breastfeeding and exclusive human milk diet in the zero to six-month-old population in the United States remain much lower than the WHO recommendations: only 14% of infants exclusively receive human milk until six months. But one way to improve these rates is to increase the rates of exclusive human milk consumption during the initial postpartum hospital-stay period.\(^5\) *Healthy People 2020* set a goal of reducing by half the percent of infants who receive formula supplementation within the first two days of life from 24% to 14%.\(^6\)

An increase in the rates of exclusive breastfeeding, especially in the first few days of life, assumes that mothers have an adequate milk supply to provide to their infant. Unfortunately, many factors may prevent an infant from receiving his or her mother’s own milk after birth. Obstacles to adequate milk production include infant prematurity, insufficient latch and/or suckling; ineffective pumping or hand expression of breast milk; and maternal-child separation.\(^7\) In these cases, infants need supplemental milk, and one source of supplemental milk is Human Milk Banks.
**Human Milk Banks:**

The Human Milk Banking Association of North America (HMBANA), established in 1985, created guidelines to regulate and encourage the use of pasteurized donor human milk (PDHM) among infants needing supplementation. Currently, there are eighteen HMBANA-approved human milk banks in North America. The milk banks screen potential donors through medical questionnaires and blood tests; collect, combine, and pasteurize donated milk; test for microbiological impurities after pasteurization; freeze approved batches; and distribute the final product to hospitals. Indeed, the Academy of Breastfeeding Medicine, American Academy of Pediatrics, and US Surgeon General recommend that, if available, PDHM be the first form of supplementation, rather than bovine formula, for term infants.1-3

**PDHM in Critically-Ill Infants:**

In many US hospitals, PDHM use is incorporated into level III and IV neonatal intensive care units (NICU), which care for critically ill infants who are often born premature (<37 weeks gestation) and have a very low birth weight (<1500g). The prevalence of PDHM in level III and IV NICUs has allowed for researchers to examine the effects of PDHM versus bovine formula in this high-risk infant population. Four studies provide data that support PDHM as a valuable supplementation option, which provides sufficient nutrients for growth and development, promotes exclusive human milk consumption, and may reduce rates of necrotizing enterocolitis and respiratory support in very low birth weight infants.7, 9-11

In the first study, Cristofalo et al. performed a double-blind randomized control trial examining the duration of parenteral nutrition, growth, and necrotizing enterocolitis rates in extremely low birth weight infants consuming either PDHM or bovine formula.9 To qualify for the study, 53 infants from seven NICUs weighed between 500g (~1.1lbs) to 1250g (~2.75lbs) at
birth, received no breast milk from his or her mother, and initially received nutrition support as parenteral feeds. As the infants began to mature and qualify for enteral feeds, they were assigned to either a formula group (n=24) or PDHM group (n=29). As enteral nutrition volume increased (10-20ml/kg/day), parenteral nutrition was decreased.

The researchers discovered that the extremely low birth weight infants who received PDHM had a shorter duration of parenteral nutrition support (27 days) than infants receiving formula (36 days) (p=0.04). There was also a larger incidence of severe necrotizing enterocolitis that required surgery in the formula group (17%) in comparison to the PDHM group (0%) (p=0.036).

The second study, by Sullivan et al., performed a randomized control trial on infants weighing 500-1250g, but the authors of this study controlled the use of PDHM and bovine formula as a supplement to mother’s own milk. The 207 newborns in the study received parenteral nutrition as his/her first feed, but when transitioning to enteral feeds all infants’ mothers intended on providing her own breast milk as the main nutrition source. When enteral nutrition began, the subjects were randomized into groups receiving either PDHM fortification or bovine formula fortification. The researchers recorded body weight daily, recumbent length weekly, and clinical signs and symptoms of infection (necrotizing enterocolitis and late onset sepsis).

Infants receiving exclusive human milk had significantly lower rates of necrotizing enterocolitis (8%) and necrotizing enterocolitis needing surgery (2%) compared to the bovine formula group (11% and 7% respectively). These data indicate a 77% reduction in the odds of developing necrotizing enterocolitis in extremely low birth weight infants consuming an exclusive human milk diet (OR=0.23, 95%CI, 0.08-0.66, p=0.007).
The third study was a pre-post retrospective study, in which Verd et al. examined outcomes of an exclusive human milk diet (mother’s milk supplemented with PDHM) in comparison to supplementation with bovine formula on infants born less than 1000g (<2.2lbs). The study included four university hospitals in Spain. Retrospective analysis of recorded data (SEN1500 database) identified all infants admitted to the hospitals NICUs from 2006 to 2012 and who weighed less than 1000g. The researchers obtained data on 148 infants who consumed mother’s milk supplemented with PDHM and 53 infants supplemented with preterm bovine-based formula.

The authors found that the extremely low birth weight infants who were supplemented with PDHM had reduced needs for respiratory support (24hrs mechanical ventilation, 63hrs oxygen supplementation) when compared to infants receiving formula (60hrs mechanical ventilation, 192hrs oxygen supplementation) (p<0.05).

In the fourth study, Kantorowska et al. used a retrospective cohort design to investigate if availability of PDHM in a hospital NICU from 2007 to 2013 affected exclusive human milk consumption and necrotizing enterocolitis rates in very low birth weight infants (≤1500g) (n=10,823). The researchers examined data from 22 California hospitals before having a PDHM program in place and after the transition to provide PDHM in the NICU through paired t-tests. Kantorowska et al. obtained exclusive human milk consumption data from the California Perinatal Quality Care Collaborative database and necrotizing enterocolitis rates from clinical medical records.

The 22 hospitals, which transitioned from not providing PDHM to having a PDHM NICU program in place, displayed that very low birth weight infants had increased rates of human milk consumption at discharge from 52.8% (pre-PDHM program) to 61.7% (post-PDHM
implementation) (p<0.0001). Rates of necrotizing enterocolitis in the studied population decreased from 6.6% (pre-PDHM program) to 4.3% (post-PDHM implementation) (p=0.0006).

**PDHM in Term Infants:**

Term infants, born 37 weeks gestation or later and placed in level I and II nurseries, are a lesser-studied population, but may also encounter medical situations that require nutritional support. These instances may include excessive weight loss, jaundice related to low nutrient intake, failure to latch, mother/newborn separation in combination with a lack of maternal milk supply, and hypoglycemia.⁵

Protocols for treating hypoglycemia specifically state that PDHM is an adequate supplement to manage a term infant’s blood glucose.¹² For example, a case report from the University of Iowa Children’s Hospital describes a term, small-for-gestational-age infant who was placed on a hypoglycemia protocol due to separation from his mother post-Cesarean section delivery and received a PDHM feeding.¹³ Once the mother was out of surgery and recovering, frequent breastfeeding occurred, categorizing the child as exclusively consuming human milk and avoiding synthetic formula supplementation.

Although successes to using PDHM in term infants have been reported, there are currently very few level I and II nurseries in the United States that provide PDHM. Throughout Massachusetts and New Hampshire only eight hospitals provide PDHM in their level I/II nurseries.¹⁴ All eight of these hospitals receive PDHM from Mothers Milk Bank Northeast (MMBNE). In 2012, MMBNE created *Use of Pasteurized Donor Human Milk as NICU Standard of Care*, a model policy for hospitals interested in using PDHM in level III NICUs.¹⁵ The next step for MMBNE is to create a similar model for a PDHM level I/II nursery program.
policy that will be available online to advise health care providers and hospitals that are interested in, but have not yet implemented, a PDHM program.

Research Objective:

The objective of this research is to gather and analyze information from level I/II nurseries that currently receive PDHM from MMBNE, that will allow for the future development of a template policy for level I/II nurseries nationwide.

Methodology

1. Overall Approach

To meet my research objective, I collected current policies and procedures and interviewed administrators at northeast United States hospitals that currently use PDHM in level I and II nurseries.

2. Identification of Potential Hospital Sites

Identification of all New Hampshire (NH) and Massachusetts (MA) hospitals receiving PDHM from MMBNE occurred through contact with the MMBNE executive director and supporting staff. Fifteen hospitals from MA and eight hospitals from NH receive PDHM from MMBNE; five hospitals in MA and three hospitals in MA receive PDHM for their level I/II nurseries.

3. Application for IRB approval

Submission of an application for this research project to the University of New Hampshire Institutional Review Board (IRB) occurred on December 4, 2015. The application included a brief description of the project including specific aims, research protocol, study personnel, potential risks and benefits, a hospital consent form, and a draft of potential hospital
interview questions. The proposed research received IRB approval on December 15, 2015. (See Appendix A for application and approval documents).

4. Finalization of Interview Questions

The Honors Thesis project committee (executive director of MMBNE, thesis advisor, and the co-founder of the Monadnock Region’s Community Coalition for the Promotion of Breastfeeding), a lactation counselor, and a registered nurse reviewed drafts of potential interview questions and provided feedback. This valuable feedback assisted in assessing the reliability of the questions and refining the final versions for the interviews. In January 2016, the interview questions were finalized, for use at each hospital visit and interview.

The ten questions focused on creation and management of each PDHM program as well as the perceived success and barriers throughout the process. Eight probing questions were separated into three main components: before implementation, management of the program, and outcomes. The final two questions were open-ended to prompt discussion of successes and barriers of PDHM program implementation.

5. Selection of four hospitals

Four hospitals (coded A, B, C and D) met the following three criteria and agreed to participate in this research project. First, the hospital must be within NH or MA and receive their pasteurized donor human milk from MMBNE. Second, the hospital must provide breastfeeding support through lactation consultants and not supply new mothers and babies with free formula samples. Third, the hospital’s level one and two program must have been implemented for at least three months prior to this research.
6. Collection of current policies and procedures

Prior to visiting the four hospitals, I collected current policies and procedures for procurement, storage, distribution, and patient inclusion criteria of PDHM in level I/II nurseries. Collection of policies and procedures took place through email with the hospital administrators.

7. Conducting interviews

Upon arrival at the hospital, an appropriate, private environment was selected to conduct the interview and the hospital administrator signed the IRB approved consent form. The hospital administrator was reminded that the interview and visit would take no more than one hour of his or her time. The interview was recorded using an audio recording device, and written notes that complemented the responses to the 10 interview questions were compiled to ensure that full details of the interview were captured. Lastly, information on on-site PDHM storage and distribution was collected by touring the facility at the conclusion of the interview.

8. Analysis of Data

Data from the PDHM program policies and procedures, qualitative interview questions, and observational site visits were tabulated in two tables (see Results). The tables include all four hospital administrators’ responses to each interview question, policies on what qualifications a newborn must meet to receive PDHM, procurement of PDHM, and storage and distribution methods. The tables allow for the hospitals PDHM programs to be compared and contrasted.

9. Summarization of Findings

A portion of these data was summarized for an oral, 15-minute presentation entitled “Pasteurized Donor Human Milk: in level one and two nurseries in the Northeast United States” for the April 2016 UNH Undergraduate Research Conference (See Appendix B for PowerPoint
The presentation focused on responses to interview questions, with a focus on successes and barriers, for all four programs. This thesis paper stands as the written report of all data collected from the four hospitals’ policies and procedures as well as responses to interview questions, meets the requirements of the UNH Honors Program, and will be uploaded to the UNH Honors Scholars Repository for future reference.

**Results**

Six qualifying hospitals in NH and MA with PDHM programs in their level I/II nurseries were contacted via email. Four of the hospitals administrators responded and agreed to participate in this research. Hospital characteristics are shown in Table 1.

<table>
<thead>
<tr>
<th>Hospital Characteristics</th>
<th>Hospital A</th>
<th>Hospital B</th>
<th>Hospital C</th>
<th>Hospital D</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Duration of Implementation</strong> (at interview)</td>
<td>21 months</td>
<td>72 months</td>
<td>6 months</td>
<td>21 months</td>
</tr>
<tr>
<td><strong>Births/year (n)</strong></td>
<td>720</td>
<td>1000</td>
<td>447</td>
<td>2000</td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td>MA</td>
<td>NH</td>
<td>NH</td>
<td>MA</td>
</tr>
</tbody>
</table>

**Policies and Procedures:**

Of the four hospitals, three provided PDHM policies and procedures through email before the on-site interview, while one provided the policies and procedures at the interview. Hospitals A, B, and D had very similar policy statements, including short-term supplementation for lack of mother’s own milk (Table 2).
Table 2. Policy Statement/Purpose

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Statement/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital A</td>
<td>PDHM offered for first 7 days of life to bridge the gap between birth and when mother’s milk supply is fully available</td>
</tr>
<tr>
<td>Hospital B</td>
<td>Human milk is the preferred baby milk to be given to breastfed babies needing short-term supplementation for various indications</td>
</tr>
<tr>
<td>Hospital C</td>
<td>To describe the procedure for obtaining, handling, tracking, and feeding of banked donor human milk</td>
</tr>
<tr>
<td>Hospital D</td>
<td>To provide guidelines for the use of PDHM for infants when mother’s own milk is unavailable or in low supply</td>
</tr>
</tbody>
</table>

The policies and procedures of all four hospitals had five similar indications for PDHM supplementation, including ineffective breastfeeding, preterm/late preterm birth, hypoglycemia, weight loss greater than 10%, and hyperbilirubinemia (Table 3).

Table 3. Indications for use of PDHM

<table>
<thead>
<tr>
<th>Indication</th>
<th>Policy &amp; Procedure (n)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Included</td>
</tr>
<tr>
<td>Ineffective breastfeeding (insufficient colostrum/breast milk)</td>
<td>4</td>
</tr>
<tr>
<td>Preterm/late preterm</td>
<td>4</td>
</tr>
<tr>
<td>Hypoglycemia</td>
<td>4</td>
</tr>
<tr>
<td>Excess weight loss (&gt;10%)</td>
<td>4</td>
</tr>
<tr>
<td>Hyperbilirubinemia</td>
<td>4</td>
</tr>
<tr>
<td>Dehydration</td>
<td>2</td>
</tr>
<tr>
<td>Mother intends to breastfeed</td>
<td>2</td>
</tr>
<tr>
<td>Small for gestational age</td>
<td>2</td>
</tr>
<tr>
<td>Feeding Intolerance/no audible swallows (first 18-24hrs)</td>
<td>2</td>
</tr>
<tr>
<td>Birth weight &lt;1500g</td>
<td>1</td>
</tr>
<tr>
<td>Allergy to cow’s milk/soy based formula</td>
<td>1</td>
</tr>
<tr>
<td>Separation from mother</td>
<td>1</td>
</tr>
<tr>
<td>Gastrointestinal related diagnosis</td>
<td>1</td>
</tr>
</tbody>
</table>

*n = number of hospitals

Twenty-four steps of PDHM use were identified in the policies and procedures (Table 4). One hospital did not include a step-by-step procedure for distributing PDHM; three hospitals cited thirteen similar steps in their guidelines.
Table 4. Procedure/steps of PDHM use

<table>
<thead>
<tr>
<th>Step</th>
<th>Policy &amp; Procedure (n)*</th>
<th>Included</th>
<th>Absent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Order from physician</td>
<td></td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Obtain informed consent</td>
<td></td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>PDHM from HMBANA milk bank</td>
<td></td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>PDHM placed in breast milk freezer immediately upon arrival</td>
<td></td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Notify milk bank if any broken seals or expired bottles</td>
<td></td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Thawed PDHM cannot be refrozen</td>
<td></td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Label thawed bottle (date thawed, thaw time, lot #)</td>
<td></td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Parents receive PDHM info/FAQ sheet</td>
<td></td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>PDHM can be used by more than one infant</td>
<td></td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Confirm order and patient with two registered nurses</td>
<td></td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>After distribution replace cap and return to breast milk refrigerator</td>
<td></td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Record PDHM feeding on medical record (sheet or electronic)</td>
<td></td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Pour prescribed volume of PDHM into individual feeding containers with infant name, DOB (or infant hospital label), and expiration date</td>
<td></td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Frozen PDHM stored at -20°C or cooler</td>
<td></td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Thaw frozen PDHM in warm water bath/Medela warmer</td>
<td></td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Record PDHM feeding on nursing intake and output sheet</td>
<td></td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Parent education documented in medical record</td>
<td></td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>PDHM log sheet includes infant’s hospital ID# and indication for use</td>
<td></td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>If PDHM is slushy/frozen in center, may be refrozen</td>
<td></td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Plastic insert used for thawing labeled with patient ID #</td>
<td></td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Swirl/mix PDHM prior to pouring</td>
<td></td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Wear gloves when distributing PDHM</td>
<td></td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>If patient has drank from PDHM bottle, bottle cannot be shared and must be discarded within 1 hr</td>
<td></td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

*n = number of hospitals

Interviews:

Administrators from all four hospitals participated in on-site, 30-45 minute interviews during the month of March 2016. The interview data is summarized in Table 5. All administrators noted that current funding was obtained through the hospital’s maternal-child health budget, yet one administrator noted her hospital received start-up funding through a grant. Every hospital provided staff education on PDHM through regular staff meetings. Signs and symptoms of need for nutritional supplementation was observed by nursing staff, while an order
for PDHM was written by a physician at each hospital. Oral and written parental consent for PDHM supplementation was received after education on both PDHM and formula by a health care professional at every hospital, and parental reactions to each supplementation option were dependent on previous knowledge of each option. At hospital discharge, all four programs stopped providing the hospital supply of PDHM to a supplemented infant, but provided a new physician PDHM order to the family to be filled at MMBNE independently. Finally, an increase in exclusive human milk consumption rates along with a decrease in the rate of formula consumption was reported by all of the hospitals after implementation of each PDHM program.

Additional information, which was not initiated through interview questions, was shared at all four interviews. This information yielded three major findings. First, three of the hospitals had a lengthy (>3 months) implementation process, which included revisions of policies and procedures as well as budgeting; in contrast, one hospital implemented their PDHM program within a week, due to the arrival of twins transferred from a nearby hospital, who were previously receiving PDHM as a nutrition supplement. Second, two hospitals created frequently asked question (FAQ) sheets for parents, to initiate a discussion of PDHM use and to help inform the decision to provide parental consent. Third, one hospital began to provide a PDHM supplementation information sheet within prenatal packets provided at prenatal obstetrician appointments to extend knowledge and inform expecting parents that PDHM existed as a supplementation option.
Table 5. Interview Results

<table>
<thead>
<tr>
<th>Interview Question</th>
<th># Hospitals with Affirmative Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How many babies are born at your hospital per year?</td>
<td></td>
</tr>
<tr>
<td>&lt;1000 births/year</td>
<td>2</td>
</tr>
<tr>
<td>≥1000 births/year</td>
<td>2</td>
</tr>
<tr>
<td>2. Where do you obtain funding for the pasteurized donor human milk (PDHM) program in level one/two nurseries and has this source changed since the start of your program?</td>
<td></td>
</tr>
<tr>
<td>Initial grant</td>
<td>1</td>
</tr>
<tr>
<td>Maternal-child health budget</td>
<td>4</td>
</tr>
<tr>
<td>3. Was staff education on PDHM use provided before the implementation of the PDHM program in level one/two nurseries? Please describe in detail.</td>
<td></td>
</tr>
<tr>
<td>Education presented at maternal-child health staff meeting</td>
<td>4</td>
</tr>
<tr>
<td>Education presented by executive director of milk bank</td>
<td>2</td>
</tr>
<tr>
<td>Education presented by Baby-Friendly committee</td>
<td>1</td>
</tr>
<tr>
<td>Education presented with poster by lactation consultant</td>
<td>1</td>
</tr>
<tr>
<td>Written module and brief exam</td>
<td>1</td>
</tr>
<tr>
<td>4. What was the biggest barrier your facility encountered in implementing PDHM in level one/two nurseries?</td>
<td></td>
</tr>
<tr>
<td>Support from hospital management</td>
<td>3</td>
</tr>
<tr>
<td>Cost of PDHM</td>
<td>2</td>
</tr>
<tr>
<td>“Ick” Factor</td>
<td>2</td>
</tr>
<tr>
<td>Duration of use</td>
<td>2</td>
</tr>
<tr>
<td>No barriers encountered</td>
<td>1</td>
</tr>
<tr>
<td>5. Of the health care professionals working at your facility, who is responsible for exploring diagnostic criteria and eligibility of a neonate to become a PDHM recipient?</td>
<td></td>
</tr>
<tr>
<td>Order from physician</td>
<td>4</td>
</tr>
<tr>
<td>Nursing staff observes initial signs of need</td>
<td>4</td>
</tr>
<tr>
<td>Parental consent obtained by nursing staff/lactation staff</td>
<td>3</td>
</tr>
<tr>
<td>Parental consent obtained by physician only</td>
<td>1</td>
</tr>
<tr>
<td>Approved for PDHM use by committee</td>
<td>1</td>
</tr>
<tr>
<td>Interview Question</td>
<td># Hospitals with Affirmative Response</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------</td>
<td>---------------------------------------</td>
</tr>
<tr>
<td>6. At what point do you seek parental consent for a child to receive PDHM supplementation and how do you do this?</td>
<td></td>
</tr>
<tr>
<td>When infant begins to show sign/symptoms of need for supplementation (borderline hypoglycemia, weight loss, low urination, etc.)</td>
<td>3</td>
</tr>
<tr>
<td>Immediately before use of supplement</td>
<td>1</td>
</tr>
<tr>
<td>PDHM and formula as supplement discussed at same time</td>
<td>4</td>
</tr>
<tr>
<td>Oral and written education on PDHM provided to parents</td>
<td>4</td>
</tr>
<tr>
<td>FAQ sheet of PDHM provided to parents</td>
<td>2</td>
</tr>
<tr>
<td>Oral and written consent from parents</td>
<td>4</td>
</tr>
<tr>
<td>7. Are parental reactions to PDHM as a supplementation option different from reactions to synthetic formula supplementation as an option, in level one and two nurseries? Please describe.</td>
<td></td>
</tr>
<tr>
<td>Dependent on parental background knowledge of PDHM</td>
<td>4</td>
</tr>
<tr>
<td>About 50% parents accepting of PDHM</td>
<td>3</td>
</tr>
<tr>
<td>&gt;75% parents accepting of PDHM</td>
<td>1</td>
</tr>
<tr>
<td>8. After hospital discharge, who is responsible for prescribing PDHM to the neonate?</td>
<td></td>
</tr>
<tr>
<td>Order from physician at hospital with level I/II program</td>
<td>4</td>
</tr>
<tr>
<td>Filled independently through MMBNE (not hospital supply)</td>
<td>4</td>
</tr>
<tr>
<td>9. What do you feel has been the biggest success with the implementation of a PDHM program in level one and two nurseries?</td>
<td></td>
</tr>
<tr>
<td>Gratitude from parents of PDHM as supplement option</td>
<td>4</td>
</tr>
<tr>
<td>Increase of hospital exclusive human milk consumption rates</td>
<td>3</td>
</tr>
<tr>
<td>Less delay of supplementation when medical need indicated</td>
<td>1</td>
</tr>
<tr>
<td>10. Since the implementation PDHM as a supplementation option in level one/ two nurseries, how have rates of synthetic formula use and exclusive breastfeeding rates during hospital stays changed?</td>
<td></td>
</tr>
<tr>
<td>Formula rates decreased after PDHM implementation</td>
<td>4</td>
</tr>
<tr>
<td>Exclusive human milk consumption rates increased after PDHM implementation</td>
<td>4</td>
</tr>
</tbody>
</table>
**On-Site Tour:**

After the interview, an on-site tour provided observational data on storage and distribution of PDHM. At all four hospitals, PDHM was kept in a separate section of dedicated breast milk refrigerators and freezers. One facility created a PDHM intake sheet including sections titled: *date received, batch number, expiration date, number of bottles, all bottles inspected for intact seal, and all bottles inspected for evidence of frozen state.*

In the hospitals with the lowest birth rates (Hospital A and Hospital C) storage and thawing of frozen PDHM occurred within the nursery. The hospitals with highest birth rates (Hospital B and Hospital D) had a separate room for storage and thawing of frozen PDHM and mother’s own milk. All thawed PDHM was located in a breast milk refrigerator within each hospital’s nursery. A paper log was located at every breast milk refrigerator and included a dedicated space to include the PDHM lot number, the amount of PDHM taken, and nurse initials for verification of order. Three of the hospitals also included a dedicated space for expiration date of PDHM. Two of the hospitals dedicated a spot on the PDHM log for a receiving infant’s ID number/sticker.

**Barriers:**

The interviewing and on-site visit process revealed three major barriers to the implementation and maintenance of a PDHM level I/II nursery program. Funding and the expense of PDHM, which is greater than the cost of bovine based infant formula, was brought up as a barrier twice, when the hospital administrator was asked where the program received funding from and when asked to identify barriers to program implementation. The second barrier encountered was a reported “ick” factor felt by some facility staff and infant parents, due to the fact that PDHM is a body fluid. The hospitals and their program managers addressed this barrier
by providing continuing education to staff and information sheets to parents referencing medical associations including the AAP and CDC to reinforce the safety of PDHM. The third major barrier included the necessity of two hospitals to put a time limitation on supplementation of PDHM. The high cost of PDHM, limited availability, and unexpected misuse from mothers who were attempting to sleep through the night or save their own breast milk, led to a policy on duration of PDHM use. While barriers were encountered, every facility included in this research maintained their PDHM program throughout the period of thesis project completion (May 2016) and plan to continue their program.

Successes:

Two successes were reported by all four hospitals: increased exclusive human milk consumption rates and gratitude for PDHM as a supplement option. For example, Hospital A observed increased human milk consumption rates increase from 59% to 71% immediately before PDHM program implementation to two years post-implementation, respectively (see Figure 1). Over the same time period, the percentage of infants born at the hospital were consuming less formula two years post-PDHM program implementation (16% to 11%). As formula use decreased, PDHM supplementation increased from 2% during the first quarter of use to 11% at two years post-PDHM program implementation (see Figure 2).

Figure 1. Exclusive Human Milk Consumption Rates
The administrator from Hospital A stated that the greatest success of the level I/II PDHM program and the reason the hospital provided PDHM was “for the gratefulness of the parents and patients … and [she] want[ed] people whom [exclusive human milk consumption] was important to, to have the choice” to provide their infant with a supplementation option that qualified as exclusive human milk rather than synthetic formula as the singular option. The administrator from Hospital B stated that the catalyst to providing PDHM was a set of preterm retro-transfer twins whom received PDHM supplementation at the previous hospital caring for them. The parents were extremely grateful that the twins were able to maintain their previous nutrition protocol by Hospital B providing PDHM and allowing future infants to benefit from PDHM as a supplementation option. The administrator from Hospital D also stated that parents who were resistant to formula supplementation, due to their knowledge of human milk as the best nutritional source for infants, were very thankful for a human milk supplementation option rather than a synthetic formula. THE PDHM supplementation option allowed and supported the previously mentioned families the chance to reach their exclusive breastfeeding goals.
Discussion

The objective of this research was to gather and analyze data from four MA and NH hospitals with level I/II nursery PDHM programs to allow for the future development of a template PDHM policy. The results provide three major findings. First, consistent messages were received from all four hospitals regarding similar policies and procedures as well as answers to interview questions. Second, exclusive human milk consumption rates increased after PDHM was provided. Third, the three major barriers to implementing a PDHM program identified (funding, “ick” factor, and duration) may be improved by same intervention: education of PDHM through paths already demonstrated by the interviewed hospitals.

Although only four hospitals from the northeast US were included in this research, the sample varied in ongoing program duration from six months to six years, and had birth rates from 447 infants per year to 2000 infants per year. Collection of PDHM program policies and procedures allowed for initial program similarities to be seen throughout the policy statement, indications of use, and the steps of providing PDHM to an infant. Interview questions allowed for further similarities to be seen between each hospital including funding from the maternal-child health budget, staff education at regular staff meetings, requiring an order from a physician to receive PDHM, PDHM education to parents, and oral and written consent received from parents. The perceived similarities between programs reinforced the notion that the subset of four hospitals was an adequate sample size for this research.

Every hospital administrator interviewed provided the response that the exclusive human milk consumption rates during hospital stay increased while formula supplementation rates decreased. Similar data were seen in the Kantorowska et al. study where percent of infants
consuming human milk at discharge before PDHM program implementation was 52.8%, and this increased to 61.7% after PDHM program implementation.\textsuperscript{11}

The three barriers identified from interview data- funding, “ick” factor, and duration of PDHM supplementation- all have a potential solution hypothesized and put into practice by the administrators interviewed. This solution is education on PDHM, its processing, and the importance of mother’s own milk. All four hospitals provided education to staff on the safety of PDHM from the medical questionnaire and blood screening of donors to the Holder pasteurization method, which eliminates harmful microbes from the donated milk.\textsuperscript{16} Staff education was imperative since the “ick factor” of PDHM was prevalent in staff, evidenced by a sample of staff members mentioning to parents that he/she would not provide PDHM to his/her own child. Three of the four hospitals also provided frequently asked question sheets to parents, which provided safety facts as well as reputable citations from medical associations such as the American Academy of Pediatrics and the US Surgeon General’s Call to Action. The education provided to hospital staff and parents allowed for a greater acceptance, less disgust, and increased use of PDHM throughout the newborn populations seen at the interviewed hospitals.

Education has the ability to affect funding of PDHM by providing more knowledge to the public. The supply of PDHM is dependent on mothers who donate breast milk. If more people become aware that donating extra breast milk is an option and will benefit sickly babies, more women may choose to take action. This has the potential of increasing PDHM supply, which would in turn, decrease cost of PDHM for the facilities purchasing it. Greater supply and availability at hospitals providing PDHM would allow for more newborns to access and benefit from PDHM supplementation.
Education that focuses of PDHM as a form of breast milk supplementation is also imperative. Parents to newborns needing supplementation to mother’s own milk must be made aware that PDHM is a supplementation, just like synthetic formulas. Although PDHM qualifies as human milk, it is inferior to mother’s own milk. As soon as it is available, whether through breastfeeding, hand expressing, or pumping, mother’s own milk should be provided to an infant. Education on the importance of mother’s own milk may decrease the amount of women abusing PDHM supplementation while their own milk is in adequate supply. This form of education would allow duration of PDHM supplementation to be shorter without putting an exact time limit on its use.

Limitations to this research include the hospital locations limited to the northeast US, and the brief length of research, as a one year long project. Additional research in the form of case studies and randomized control trials of PDHM use and benefits in term, non-critically ill infants would provide increased strength to the choice of facilities to incorporate PDHM programs in their level I/II nurseries.

**Conclusion**

While acknowledging limitations, the collection of policies and procedures, as well as interviewing hospital administrators at four level I/II PDHM nursery programs in MA and NH has provided consistent data and perceived successes. All four level I/II nursery PDHM programs continue to exist and improve the overall health of the hospital newborn population. Data from this research can be used to develop a template policy and procedures for level I/II nursery PDHM programs in the US.
References


Appendix A
B. Description of Project

1. INTRODUCTION Human milk is the most beneficial form of nutrition for all infants during early life. It provides energy, nutrients, and immunological factors that reduce the risk and incidence of many neonatal health problems including respiratory tract infections, ear infections, and gastrointestinal tract infections. Unfortunately, current rates of breastfeeding and exclusive human milk diet in zero to six-month-old infants in the United States are much lower than the Healthy People 2020 goals. These goals include doubling the percent of infants exclusively receiving human milk at 6 months from 14% to 26%, and reducing by half the percent of infants who receive formula supplementation within the first two days of life from 24% to 14.

An increase in the rates of exclusive human milk consumption assumes that every infant has a supply of his or her mother’s own breast milk available to them. Unfortunately, many factors may prevent an infant from receiving his or her mother’s own milk after birth. Lack of milk supply often occurs when the maternal body has not yet initiated adequate milk production due to premature delivery and lack of suckling stimulus for adequate hormone production. Premature infants, born before thirty-seven weeks gestation, and infants with critical illnesses at delivery are placed in level three neonatal intensive care units (NICU). Human milk, either from the infant’s mother or donated and pasteurized, has been shown to lower the rates of necrotizing enterocolitis in premature babies. Indeed, the 2011 Surgeon General’s Call to Action to Support Breastfeeding supports the use of safe banked donor human milk for fragile infants.

Mother’s Milk Bank Northeast (MMBNE) is one of twenty certified milk donation banks in the United States. In 2012, MMBNE created Use of Pasteurized Donor Human Milk as NICU Standard of Care, a model policy for hospitals interested in using pasteurized donor milk in level three NICUs. MMBNE wants to extend their reach and encourage the availability of pasteurized donor human milk in level one and two nurseries, which support “well” newborns and low birth-weight newborns with nonlife-threatening illnesses, respectively. Mothers of these well newborns may not yet have an adequate milk supply due to the same reasons as mothers of premature infants.

Several hospitals in the Northeast are already meeting the need for pasteurized donor human milk in their level one and two nurseries. By collecting information from these hospitals on procurement, storage, distribution, and patient inclusion criteria of pasteurized donor human milk, and archiving experiences from these hospitals, this project will baseline information for the development of a template policy to advise hospitals that are interested in, but have not yet implemented, pasteurized donor human milk programs in their level one and two nurseries.

2. SPECIFIC AIMS The objective of this research is to identify the successes and barriers to implementing pasteurized donor human milk programs in four northeast hospitals currently using pasteurized donor human milk in level one and two nurseries, and to develop guidelines to assist in the creation of future pasteurized donor human milk programs and policies of level one and two hospital nurseries nationwide.

3. RESEARCH PROTOCOL
   a. Setting: Tours and interviews will be conducted at each of four hospitals in NH
b. **Protocols:** Before visiting each hospital, I will collect their current guidelines for prescribing and distributing the pasteurized donor human milk in their level one and two nursery programs. These guidelines will be collected through MMBNE and email with the human donor milk program directors. Concurrently, I will create ten interview questions to be used at each hospital visit/interview. These questions will focus on the “why” behind the creation of each hospital’s policies of use and distribution of pasteurized donor human milk in level one and two nurseries (see Appendix A for a draft of potential interview questions). The questions will be shared with the members of my Honors Thesis project committee (executive director of MMBNE, thesis advisor, and the co-creator of the NH breastfeeding coalition). The questions will also be shared with local NH and MA lactation consultants. The results of the reviews by the committee and lactation consultants will allow me to assess the validity, reliability, and bias of the questions and edit accordingly. Next, I will visit each of the four hospitals and tour where the pasteurized donor human milk is stored and distributed. I will interview the appropriate hospital administrator in a quiet and private environment. The current hospital policies on their pasteurized donor human milk program will also be discussed in further detail if the prepared questions do not cover all major aspects of the program. If permission is granted, all interviews will be recorded and written notes will be taken to ensure that full detail of the interview is included and reduce potential memory lapse.

c. **Consent:** All participants will read and sign a consent form upon arrival.

4. **STUDY PERSONNEL:** The PI (Gale Carey) and undergraduate researcher Becky Smeltzer are the primary study personnel. Dr. Naomi Bar-Yam (Executive Director of MMBNE) and Dr. Becky Dunn (Chair of the NH Breastfeeding Task Force and Keene State College faculty member) are providing expertise and serve on Becky’s Honors Thesis Committee.

5. **DATA** Answers to qualitative interview questions will be transcribed from recordings and checked for accuracy by the study personnel. The recording device, copies of the recordings, and transcripts will be kept in the Carey laboratory in a locked room, accessible only by the study personnel.

Data from the qualitative interview questions and collected hospital guidelines of their pasteurized human donor milk programs will be compared and contrasted through the creation of a table. The table will include all four hospital’s responses of each individual question and policies on what qualifications a newborn must meet to receive donor milk, the quantity they will be allotted, milk storage methods and milk feeding regulations. The table will allow for similarities and differences of each hospital’s pasteurized donor human milk program to be compared. Recurring data reported by multiple hospitals will provide supported evidence of effective procedures and policies able to be replicated for success of implementation of pasteurized donor human milk programs in interested hospitals.

Only aggregate data will be reported and used in presentations and reports. A poster or oral presentation of the findings will be shared at the April 2016 UNH Undergraduate Research Conference (URC). Two written reports are expected to be produced. The first is a written
senior honors thesis, a requirement of the UNH Honors Program. The second is a set of written guidelines for the implementation of pasteurized donor human milk programs in level one and two nurseries that obtain their milk from MMBNE. The final version of these guidelines will include a sample policy of pasteurized donor human milk use, eligibility to receive donor milk, duration of use, ordering and storing donor milk, how to provide feedings, evaluation of donor milk use, and a patient information sheet. Once in its final form, the guidelines will be made available on the MMBNE website for use by hospitals and health care providers throughout the Northeast as well as the rest of the country.

6. **RISKS**  The risk of a breach of confidentiality will be minimized by keeping identities confidential through the numbering of each location site and lettering of hospital personnel, and known only to the study personnel. All data will be kept in a secure location.

7. **BENEFITS**  There are no direct benefits to the four interview participants. However, the pasteurized human donor milk program may benefit by gaining knowledge that will be used to develop guidelines for the use of donor milk at well baby nurseries nationwide.

C. References


Appendix A

Draft of Potential Interview Questions

1. Where does funding for the pasteurized donor human milk program in level one and two nurseries originate?
2. What type and form of staff education was provided (if any) before the implementation of the pasteurized donor human milk program in level one and two nurseries?
3. Of the health care professionals working at your facility, whom have the responsibility of exploring diagnostic criteria and eligibility of a neonate to become a pasteurized donor human milk recipient?
4. At what point do you seek out and maintain parental consent for their child to receive pasteurized donor human milk supplementation?
5. What has been the biggest barrier you have come across in implementing a pasteurized donor human milk program in level one and two nurseries?
6. How did you overcome the barrier previously mentioned?
7. What do you feel has been the biggest success with the implementation of a pasteurized donor human milk program in level one and two nurseries?
8. What are the biggest differences between the pasteurized donor human milk program in level one and two nurseries versus the pre-existing level three nursery program?
9. Have observed parental reactions to pasteurized donor human milk as a supplementation option in level one and two nurseries differed in comparison to reactions of synthetic formula supplementation as an option?
10. How have rates of use of synthetic formula as supplementation in level one and two nurseries changed since the implementation of pasteurized donor human milk as a supplementation option in level one and two nurseries?
CONSENT FORM FOR PARTICIPATION IN A RESEARCH STUDY

RESEARCHER AND TITLE OF STUDY
I am Becky Smeltzer and I am an undergraduate student in the UNH Nutrition program. This study, *Pasteurized Donor Human Milk Programs in Level One and Two Nurseries in the Northeast United States*, is being conducted for my senior Honors Thesis.

WHAT IS THE PURPOSE OF THIS STUDY?
The purpose of this study is to identify the successes and barriers to implementing pasteurized donor human milk programs in four northeast hospitals currently using pasteurized donor human milk in level one and two nurseries, and to develop sample guidelines to assist in the creation of future pasteurized donor human milk programs and policies of level one and two hospital nurseries nationwide.

WHAT DOES YOUR PARTICIPATION IN THIS STUDY INVOLVE?
Your participation, as one of four total interviewees, involves answering 10 questions related to your hospitals’ use of donor milk programs. Your verbal answers will be recorded, and later transcribed and analyzed. This interview is expected to require approximately one hour of your time.

WHAT ARE THE POSSIBLE RISKS OF PARTICIPATING IN THIS STUDY?
Participation in this study is expected to present minimal risk to you.

WHAT ARE THE POSSIBLE BENEFITS OF PARTICIPATING IN THIS STUDY?
There are no direct benefits to you. However, the pasteurized human donor milk program may benefit from your participation by gaining knowledge that will be used to develop guidelines for the use of donor milk at well baby nurseries nationwide.

IF YOU CHOOSE TO PARTICIPATE IN THIS STUDY, WILL IT COST YOU ANYTHING?
This study will not cost you anything.

WILL YOU RECEIVE ANY COMPENSATION FOR PARTICIPATING IN THIS STUDY?
You will not be compensated for your participation.

DO YOU HAVE TO TAKE PART IN THIS STUDY?
Your consent to participate in this research is entirely voluntary. If you refuse to participate, you will not experience any penalty or negative consequences.

CAN YOU WITHDRAW FROM THIS STUDY?
If you consent to participate in this study, you may refuse to answer any question and/or stop your participation in the study at any time without any penalty or negative consequences.

HOW WILL THE CONFIDENTIALITY OF YOUR RECORDS BE PROTECTED?
I seek to maintain the confidentiality of all data and records associated with your participation in this research. There are, however, rare instances when I am required to share personally-identifiable information (e.g., according to policy, contract, regulation). For example, in response to a complaint about the research, officials at the University of New Hampshire, designees of the sponsor(s), and/or regulatory and oversight government agencies may access research data. Audio recordings of the interview will be transcribed, and both recordings and transcribed data will be kept in a file cabinet, secure in Dr. Carey’s office. Only Dr. Carey and Becky Smeltzer will have access to the data. Recordings will be destroyed after transcription. All data will be kept coded and no individual results will be disclosed. All data will be reported in aggregate and participants, if they choose, can receive a summary of the findings. The results may be used in scientific reports, presentations (including the UNH Undergraduate Research Conference), and publications.

WHOM TO CONTACT IF YOU HAVE QUESTIONS ABOUT THIS STUDY
If you have any questions pertaining to the research you can contact Gale Carey at 603-862-4628 or gale.carey@unh.edu, or Becky Smeltzer at rpq38@wildcats.unh.edu to discuss them. If you have questions about your rights as a research subject you can contact Dr. Julie Simpson in UNH Research Integrity Services, 603-862-2003 or Julie.simpson@unh.edu to discuss them.

I, __________________________ CONSENT/AGREE to participate in this research study

_________________________________________  __________________________
Signature of Subject                        Date
University of New Hampshire

Research Integrity Services, Service Building
51 College Road, Durham, NH 03824-3585
Fax: 603-862-3564

15-Dec-2015

Carey, Gale B
Molecular, Cellular & Biomedical Sciences
Kendall Hall Rm 403
Durham, NH 03824-2500

IRB #: 6375
Study: Pasteurized Donor Human Milk Programs in Level One and Two Nurseries in the Northeast United States
Approval Date: 15-Dec-2015

The Institutional Review Board for the Protection of Human Subjects in Research (IRB) has reviewed and approved the protocol for your study as Exempt as described in Title 45, Code of Federal Regulations (CFR), Part 46, Subsection 101(b). Approval is granted to conduct your study as described in your protocol.

Researchers who conduct studies involving human subjects have responsibilities as outlined in the attached document, Responsibilities of Directors of Research Studies Involving Human Subjects. (This document is also available at http://unh.edu/research/irb-application-resources.) Please read this document carefully before commencing your work involving human subjects.

Upon completion of your study, please complete the enclosed Exempt Study Final Report form and return it to this office along with a report of your findings.

If you have questions or concerns about your study or this approval, please feel free to contact me at 603-862-2003 or Julie.simpson@unh.edu. Please refer to the IRB # above in all correspondence related to this study. The IRB wishes you success with your research.

For the IRB,

Julie F. Simpson
Director

cc: File
Appendix B
PASTEURIZED DONOR HUMAN MILK PROGRAMS

In Level One and Two Nurseries in the Northeast United States

By: Becky Smeltzer
What is Donor Milk?

Intro to PDHM

https://www.hmbana.org/milk-processing
A pathway to research

Mothers’ Milk Bank Northeast
Share the Health
My Objective

• Identify the successes and barriers of implementing a level I/II donor milk program.

Ultimate goal:
create template policy & procedures
Methods

- ID Hospitals
- Apply/Receive IRB Approval
- Finalize Interview Questions
Interview Questions

Before
- Funding
- Staff Education

During
- Obtaining Order/Consent
- Parental Reactions

After
- Exclusivity Rates
- Formula Rates
Methods cont.

Select 4 Hospitals

Conduct Interviews

Analyze Data & Summarize Findings

(HOSPITAL)

(TASCAM)

(YOUR FUTURE CALLS)
Results: Barriers

- Funding
- Duration
- “Ick” Factor
Results: Successes

Exclusive Human Milk

Formula Supplementation
Results: Successes
Summary

• 3 barriers

• 2 overwhelming successes
Conclusion

- Enough evidence to create template policy & procedures

- Template on Mothers Milk Bank website
Questions?

https://www.facebook.com/media/set/?set=a.592665387441106.1073741835.112642768776706&type=3