DONOR HUMAN MILK
ACCESS AND USE IN THE UNITED STATES:
FINDINGS AND RECOMMENDATIONS

Emily C. Taylor
Miriam H. Labbok

With additional editing by Kristin P. Tully

1 CGBI Deputy Director, Project Director of the Donor Human Milk Banking Project

2 CGBI Founding Professor and Director

3 Postdoctoral Research Associate

Carolina Global Breastfeeding Institute
Gillings School of Global Public Health
University of North Carolina at Chapel Hill

CAROLINA GLOBAL BREASTFEEDING INSTITUTE

Funded by the W.K. Kellogg Foundation Grant Number P3020886
Preface

The positive impact of human milk and breastfeeding for maternal and child health outcomes is well documented in the literature. Nonetheless, in the US, the minority of vulnerable infants receives any human milk feeding, let alone exclusive human milk feeding. This report was developed to support increased access to donor human milk and thereby promote health equity.

The authors thank the key informants for their time, candor, and thoughtful engagement. Further, we are grateful for their transparency and commitment to improvement in the field of human milk banking and related issues. The experts and stakeholders include Anna Coutsoudis, April Fogleman, Kiersten Israel-Ballard, Kathleen Marinelli, David Newburg, Carl Seashore, Peter Untalan, the Human Milk Banking Association of North America (HMBANA) with special thanks to Kim Updegrove and Pauline Sakomoto, Prolacta Bioscience, Inc., and the Academy of Breastfeeding Medicine. We also thank the UNC Gillings School of Global Public Health Maternal and Child Health graduate research assistants who displayed tremendous creativity and diligence in their semester-long inquiry into the world of donor human milk banking: Zakiyah Williams, Rachel Davis, Janvier Rwamjago, Barbara Burke, Katherine Peterman, Elizabeth Regan and Cecilee Steinmetz. We especially thank The W.K. Kellogg Foundation (WKKF) for their support for improving the landscape of breastfeeding in the United States.

This work was supported by a grant from WKKF to the Carolina Global Breastfeeding Institute as a First Food Field Builder. WKKF states the following goals (WKK14) for its First Food activities:

1. Improve children’s health by ensuring that more babies breastfeed or receive exclusive access to breast milk as their first food experience, and,
2. Eliminate health disparities by addressing barriers to breastfeeding in communities of color.

Complementary support for this project was provided by the Carolina Global Breastfeeding Institute endowment funds. The conclusions and recommendations herein are those of the authors, and do not necessarily represent those of the key Informants, stakeholders, graduate research assistants, WKKF, CGBI, or the University of North Carolina.

Finally, we wish to acknowledge the infants, women, and their families who suffer from premature birth and the extraordinary needs that are results of such challenging contexts. The mothers of all vulnerable babies seek the best path for their babies’ healing, growth, and development. This population deserves our best support, which includes the availability and use of human milk feeding.
Table of Contents

Executive Summary 2
 I. Introduction 6
 II. Approach and Methods 10
 III. Importance of Human Milk for Infant Health
   Clinical Significance of Human Milk
   Government and Professional Organization Support for Donor Human Milk Use
   History of Human Milk Banking in the United States
 IV. Current Status of Donor Human Milk Banking in the United States 30
   Current Major Approaches
   Prolacta Bioscience, Inc.
   Physician Perceptions
   Pasteurization Techniques
 V. Human Milk Sharing 91
   Buying and Selling Human Milk
   Ethical considerations
 VI. The Costs and Benefits of Human Milk Feeding 103
 VII. Conclusions, Recommendations and Next Steps: Building Consensus and Synergy 107
 References 121
Executive Summary

The importance for exclusive human milk feeding for infants, especially those in the neonatal intensive care unit (NICU), has been clearly documented in medical literature since the early 1980s. Since this time, research has continued to demonstrate the importance of human milk for decreasing risk of necrotizing enterocolitis (NEC) and other causes of child morbidity and mortality. However, hospital practices around infant feeding continue to lag behind scientific knowledge.

Human milk usage, including from infants’ own mothers and from donors, is of particular interest as we attempt to address disparities in infant mortality. The rates of infant mortality, preterm and very preterm childbirth, low birth weight and very low birth weight are all higher among African Americans in the United States than any other racial group (CDC, 2014). Therefore, it is vital that we promote the availability and use of mother’s own milk and donor human milk (DHM) in the NICU and other settings.

This report characterizes the current status of donor human milk banking in the United States. We suggest ways to improve DHM policy and practices with the goal of improving infant health outcomes. To this end, we conducted a review of the literature and a series of qualitative and quantitative studies. The formative work included key informant interviews, on-site human milk banking observations, surveys, and associated analyses. The findings are presented alongside a cost-benefit analysis and estimate of the current need for donor human milk in the US.

Findings include the need for 1) specific additional data collection by donor human milk banks, 2) additional coordination and information analysis across the US milk banks, 3) greater outreach and more inclusion of potential donors; 4) consideration of a significant increase in the
number of milk banks, including the possibility of hospital based units in large, level 3 or 4
maternity settings, 5) consideration of regulation of human milk sharing, with oversight and
cooperation of well-informed physicians, and, 6) the need for significantly increased research
resources. Common to all of these recommendations is the need for a national database on donor
human milk donors and recipients to promote equity in the use of this precious commodity.
Further, health provider education and breastfeeding support can be improved, particularly in
relation to the most vulnerable infants.

The concluding section of this report offers more details, including expanded areas of
research needs, overall recommendations for policy and practice, and suggested priority action
steps. Five overall recommendations are:

1. Demographic information should be collected nationally on both human milk donors
   (through HMBANA) and recipients (through hospitals and other distribution settings) to
   monitor and address equity in donor human milk distribution.

2. Common guidelines should be developed for use in organizational processing and
distribution of donor human milk. The guidelines should be widely disseminated, evaluated,
and regularly updated based on the latest research findings.

3. The federal government should be encouraged to fund the donor human milk research, as
   well as develop program and regulatory guidance.

4. There should be a national committee, including federal agencies, such as that called for in
   the Innocenti Declaration, to provide research, policy, and program oversight.

5. Any effort to increase donor human milk availability should be linked and mutually
   supportive with efforts to support maternal decisions to breastfeed, and to empower them to
   reach their breastfeeding goals.
Finally, it is noteworthy that the process of engaging in this work has already resulted in change. The Human Milk Bank Association of North America, which fully cooperated with this work, is expected to issue a new document in 2015 to address many of these issues, including assessment of demographics and geographic distribution of donors and recipients.
I. Introduction

“A healthy start is foundational to the American Dream” (Lu & Johnson, 2014)

Breastfeeding is the normal and optimal approach to infant and young child feeding, providing nutrition and immunological factors, while enhancing development and socio-psychological growth. It also has economic and environmental benefits over artificial and commercial baby foods. Whereas breastfeeding is the normative feeding behavior, feeding with infant formula is associated with significant risk for acute and chronic diseases for mothers and children (Creek et al., 2010). All children exposed to formula have the associated risks; however, such exposures are especially hazardous for preterm infants who are most vulnerable to life-threatening diseases such as necrotizing enterocolitis (NEC) (AAP, 2012a; Ip et al., 2007; Tully, 2002).

The use of formula for feeding infants by women capable of producing their own milk developed as a result of social, economic and commercial marketing pressures, as well as the conviction of the medical community at the time. Human milk banking, which offers milk to those who could not produce sufficient quantities, was first established as early as 1909 in Vienna, Austria. However, the commercial availability of cow’s milk-based baby foods reached a much wider audience. Today, research studies confirm that lactation and breastfeeding confers innumerable health and nurturance outcomes for mother and child. Awareness of the health implications of infant feeding has led to increased acceptance and support for breastfeeding and increased interest in the use of human milk for all infants.

As modern technologies advance, babies who are born very preterm have increased possibilities for survival. These vulnerable infants are in critical need of human milk to further protect their survival, health, and development. However, mothers of preterm infants often
experience milk production challenges. Women who deliver preterm have not experienced the physiologic and hormonal changes of a full-term gestation and, therefore, typically require additional support to begin producing milk and to build and maintain an adequate supply to meet their infants’ needs (Geddes, Hartmann, & Jones, 2013; Montagne, Cuillière, Molé, Béné, & Faure, 1999). If sufficient quantities of mother’s own milk is not available, donor human milk is the clinically recommended substitute (AAP, 2012a; Underwood, 2013). The World Health Organization examined infant feeding and established a priority list as in Table 1.

The need for human milk for improved outcomes for premature infants and other NICU patients, as well as all newborns, has been clearly documented since the early 1980s, when the research of Dr. Navidad Clavano in the Philippines was made widely known (Pincock, 2007). By shifting from formula to donated human milk in her NICU, she virtually eliminated necrotizing enterocolitis, the major single cause of deaths among premature infants. She also documented that the incidence of oral thrush, diarrhea, clinical sepsis, and death were “drastically reduced.” Despite the emergence of such evidence over 30 years ago, there is still a remarkable lack of access to donor human milk in the United States.

The W.K. Kellogg Foundation (WKKF) has developed a strong program on “First Food” seeking collective impact through a coordinated funding strategy to improve support for breastfeeding in the United States. There is a primary interest in racial equity, focused on those least likely to breastfeed, while recognizing that breastfeeding is becoming normative in all populations, and all racial groups have significant populations already breastfeeding. While rates of breastfeeding initiation, continuation and exclusivity are increasing among African Americans, who also suffer the double burden of higher rates of premature births and infant loss, there remains a gap between rates by race. As the gaps are not explained by socioeconomic
status or maternal education alone, many hypothesize that non-white women may be experiencing less support for breastfeeding. Accordingly, several efforts are addressing the social and health barriers for mothers of full term infants; however, it is not clear how the availability of human milk and concomitant support systems might impact the survival of the premature infants, contributing to the reduction in the high mortality rate among African-American infants (see Table 2). Therefore, a better understanding of donor milk banking and human milk use are widely accepted as critical strategies for decreasing infant morbidity and mortality in general (AAP, 2012) and are of particular interest in addressing the disparity in premature and term infant mortality rates. However, there is little in the way of systematic review regarding the current practice in the United States.

We conducted a comprehensive assessment of current factors effecting access to donor human milk. The purpose of the assessment was to inform efforts with the aim of improving access to donor human milk and reducing racial/ethnic disparities. This paper presents the findings of an exploration of the current status, related analyses and gleaning of practice implications related to donor milk banking. Recommendations are drawn from this work to help inform future thinking on breastfeeding and the use of donors’ and mothers’ milk to improve outcomes for our most vulnerable infants and young children.
## Table 1.
Milk for Low Birth Weight Babies: WHO Hierarchy of Feeding Priority
Modified from WHO (Arnold, 2006a and Arnold, 2002)

<table>
<thead>
<tr>
<th>Best母乳</th>
<th>Worst配方奶粉</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Mother’s own milk</th>
<th>Helps bonding</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Helps establish lactation</td>
</tr>
<tr>
<td></td>
<td>Good balance of nutrients (may need supplemental calcium, iron or vitamin D in some situations)</td>
</tr>
<tr>
<td></td>
<td>Prevents general infections and those to which mother is exposed in the baby’s environment</td>
</tr>
<tr>
<td></td>
<td>Easily digested</td>
</tr>
<tr>
<td></td>
<td>Supports normal gut development and normal gene expression</td>
</tr>
<tr>
<td>Donated fresh preterm milk</td>
<td>Good balance of nutrients (may need supplemental calcium and vitamin D)</td>
</tr>
<tr>
<td></td>
<td>Prevents general infections and those to which mother is exposed but not from baby’s environment</td>
</tr>
<tr>
<td></td>
<td>Easily digested</td>
</tr>
<tr>
<td></td>
<td>Supports normal gut development and normal gene expression</td>
</tr>
<tr>
<td>Donated fresh term mature milk</td>
<td>Prevents general infections</td>
</tr>
<tr>
<td></td>
<td>Easily digested, but [may] lack(s) adequate protein</td>
</tr>
<tr>
<td></td>
<td>Supports normal gut development and normal gene expression</td>
</tr>
<tr>
<td></td>
<td>Usually foremilk, so may lack fat</td>
</tr>
<tr>
<td>Pasteurized donated human milk</td>
<td>Immunologic factors are variously affected: secretory IgA, bifid growth factor and lysozyme (0-30% destroyed), lactoferrin (57% destroyed) and IgG (34% destroyed) so may be less effective in fighting certain infectious agents</td>
</tr>
<tr>
<td></td>
<td>May support normal gut development and normal gene expression</td>
</tr>
<tr>
<td></td>
<td>HIV, human T-lymphotrophic virus, CMV and many other bacteria, viruses destroyed</td>
</tr>
<tr>
<td></td>
<td>Easily digested</td>
</tr>
<tr>
<td>Preterm formula</td>
<td>Nutrients selected to be adapted to special needs but do not replicate human milk</td>
</tr>
<tr>
<td></td>
<td>Not necessarily as easily digestible as human milk</td>
</tr>
<tr>
<td></td>
<td>No immunologic properties</td>
</tr>
<tr>
<td></td>
<td>Increased risk of severe reactions and infections</td>
</tr>
<tr>
<td></td>
<td>Does not support normal gut development or normal gene expression</td>
</tr>
<tr>
<td>Ordinary formula</td>
<td>Wrong balance of nutrients</td>
</tr>
<tr>
<td></td>
<td>No immunologic properties, and therefore increased risk of severe reactions and infections</td>
</tr>
<tr>
<td></td>
<td>Less optimal growth and development</td>
</tr>
<tr>
<td></td>
<td>Difficult to digest and utilize</td>
</tr>
<tr>
<td></td>
<td>Does not support normal gut development or normal gene expression</td>
</tr>
</tbody>
</table>
Table 2.
Racial Disparities in United States Birth Outcomes and Infant Mortality
Data from Martin et al. (2013)

<table>
<thead>
<tr>
<th></th>
<th>Infant Mortality</th>
<th>Very Preterm Birth</th>
<th>Preterm Birth</th>
<th>Very Low Birthweight</th>
<th>Low Birthweight</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian</td>
<td>7.6</td>
<td>2.1</td>
<td>13.5</td>
<td>1.3</td>
<td>7.5</td>
</tr>
<tr>
<td>Asian and Pacific Islander</td>
<td>3.6</td>
<td>1.5</td>
<td>10.8</td>
<td>1.1</td>
<td>8.4</td>
</tr>
<tr>
<td>Black or African American</td>
<td>11.6</td>
<td>3.7</td>
<td>16.5</td>
<td>2.9</td>
<td>13.2</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>5.5</td>
<td>1.8</td>
<td>11.6</td>
<td>1.2</td>
<td>7.0</td>
</tr>
<tr>
<td>White, non-Hispanic</td>
<td>5.1</td>
<td>1.6</td>
<td>10.3</td>
<td>1.1</td>
<td>7.0</td>
</tr>
</tbody>
</table>
II. Approach and Methods

The Carolina Global Breastfeeding Institute (CGBI) employed a comprehensive approach in conducting this assessment of donor milk banking and human milk use in the United States, with the understanding that this document is designed to catalyze additional work. CGBI uses an iterative approach for all program work, known as ETIERS (Labbok, 2013) (see Figure 1). The concept of this model is that a representative team from the discipline, or ‘community,’ that will be impacted by the program should be involved at every stage of development, from the initial review of current status and literature, and at every step along the way. The concept also demands that the possibility of national scale-up in a sustainable manner be part of the discussion from the outset.

Using the ETIERS model for program improvement and change, we first developed the “community” team, including a subgroup of those with expertise in human milk banking. This team included representatives from milk banking, milk sharing, milk donors, milk recipients, potential users, clinicians, researchers and policy makers. Following this, in collaboration, we began the ‘exploration’ phase. This report reflects the exploration phase, and to a lesser extent,
translation and suggested innovations.

Figure 1: ETIERS
(with permission, Labbok 2013)

<table>
<thead>
<tr>
<th>Exploration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sustainable Scale-Up</td>
</tr>
<tr>
<td>“Community” Team</td>
</tr>
<tr>
<td>Translation</td>
</tr>
<tr>
<td>Replication</td>
</tr>
<tr>
<td>Innovative Implementation</td>
</tr>
<tr>
<td>Evaluation</td>
</tr>
</tbody>
</table>

Primary methods used in this paper include the following:

- **Systematic Literature Review**
- **Qualitative Methods**
  - Key Informant Interviews
  - On-Site Observation
  - Structured Content Analysis
  - Informal dialogue with experts
  - Community/stakeholders’ team inputs at many stages
- **Quantitative Methods**
  - Surveys of Physicians, Milk Bank Directors and Donors
  - Univariate and Bivariate analyses
  - Calculation of Potential Need
Ethical issues. A written summary of the assessment purpose, funding sources, and activities was provided to and welcomed by the Community Team and Human Milk Bank Association of North America (HMBANA) Research Committee in advance of any contact in order to support a positive, collaborative and transparent working relationship throughout. In addition, the Institutional Review Board of the University of North Carolina Chapel Hill approved all aspects of this assessment involving human subjects.

Systematic Literature Review

The systematic literature review included a comprehensive search of the refereed literature, using donor milk banking and related key words such as milk sharing and selling. MEDLINE, PUBMED, CINAHL and Google Scholar search engines were employed. The articles were reviewed in brief to establish a conceptual framework for the overall assessment, and to determine appropriate methodologies for qualitative data collection. The publications found to address the issues outlined above were reviewed and analyzed in-depth thereafter. This sequence was intended to: 1) inform the assessment, 2) prevent potential bias from reading numerous other scholars findings, interpretations and recommendations, 3) allow interpretation of assessment findings in light of available literature and 4) create a meaningful and informative summary of available literature for this report. The exploration of the literature for the quantitative aspects of this paper was carried out in a similar manner; however, there was a concentration on more recent articles and reviews, and on national data sources.

Qualitative Methods
Key Informant Interviews. A semi-structured interview guide was developed to obtain a description of knowledge, beliefs and practices related to human milk banking, and the use of donor human milk. Interviews were conducted with milk bank staff, health professionals, recipient parents, donors (past and present), milk sharing community leaders and others identified as having a stake in donor milk banking or access to donor human milk. The guide used main questions, follow-up questions, and probes. Research staff affiliated with the project reviewed the guides for face validity. The guide was pilot-tested with two individuals who worked with milk banks and who would not be engaged as research subjects. The guide was modified based on these pilot interviews to create the final version used in this study. Interviews were recorded using a digital audio recorder. Each interview lasted between 30 and 75 minutes. Verbatim, typed transcripts were created from the digitally recorded interviews.

Data (transcripts) were coded by 2-4 members of the assessment team (the Project Director and 1-3 Graduate Research Assistants receiving training in qualitative data analysis) using Atlas.ti and manual methods for identifying coding families (by theoretically-based hypothesis and observation of emergent themes). Inter-coder reliability was found to be high (coefficient=0.80). In addition, quotes were excerpted to illustrate main themes, and are presented in the findings of this report.

Onsite Donor Human Milk Bank Observation, with additional Key Informant Interviews. On-site observations were conducted to gather data on the processes and physical settings of human milk banks at four HMBANA milk banks (two community-based and two hospital-based) and at Prolacta Bioscience, Inc. The site visitor was trained in principles of observation data collection to ensure high quality and consistent data (CDC, 2008). Based on guidance from the site visitor, the milk bank directors selected the individuals willing and able to
represent a variety of roles and responsibilities, as well as those with diverse levels of awareness of and attitudes toward use of human milk, to serve as key informant interview respondents. Interviewers were not informed of respondents’ views prior to the interviews.

A total of 25 key informant interviews were completed: eighteen interviews were conducted during on-site visits to HMBANA milk banks, three at the HMBANA Conference, and four over the telephone: one each with representatives from Prolacta Bioscience, Inc., two popular milk sharing sites, and a popular milk selling site.

The human milk bank site visits included:

- Direct observation of milk banking processes, including receipt of raw milk, pasteurization, testing, distribution, billing, etc. Observation guides were developed to structure observations similarly across the sites. Space was included for open-ended field notes. Photos were taken where visual demonstration was appropriate. This method was selected to allow an outside observer to characterize processes that are sometimes so routinely carried out by the practitioner that it becomes difficult for them to describe in detail. Using this method allows the practitioner to conduct their activity with direct observation and inquiries coming from the observer to cover the ‘how’ and ‘why’.

- Review of print materials, including patient and provider education and promotion, billing documents, data collection forms, operating budgets, strategic plans, staffing plans, policies and procedures, site evaluations, etc.

- Interviews with staff, board members, milk donors and recipients, and local healthcare providers.

**Structured Content Analysis.** A structured content analysis was conducted to analyze public websites and print materials to learn about how information about human milk is being
communicated by the major organizations responsible for milk banking and facilitating milk sharing. Content analysis of websites was conducted on HMBANA, HMBANA Milk Banks, Prolacta Bioscience, Prolacta Milk Banks, milk sharing sites and milk selling sites. Of primary interest were: whose voice is being used (organization and individual, i.e. mother’s voice, baby’s voice, clinician’s voice), how is information communicated (topics selected, style of language, keywords, etc.), and to whom are they communicating and to what effect (target audience, response by comments and/or readership statistics, etc.). Content analysis was also conducted using print materials acquired at site visits and medical conferences (including patient and provider education and promotion, billing documents, data collection forms, operating budgets, strategic plans, staffing plans, policies and procedures, site evaluations, etc.). In addition to the content analysis methods used for websites, researchers were also able to inquire with the authors and recipients about the print materials in order to learn about the historical development process (i.e. Why did the author choose this tone? What are the financial implications of this policy?). The structured content analyses was useful in gathering lessons learned at local milk banks, within HMBANA and Prolacta, and facilitators of online milk sharing in a way that may benefit the field more generally.

**Informal Dialogue with Experts.** The authors also have access to professional society listservs and attend multiple technical meetings. Therefore, as this work proceeded, we were able to dialogue with additional individuals involved in the study or analysis of milk banking, and initiate and follow related discussions online. From these informal contacts, we learned of ongoing research, were able to follow professional discussions on physician mediated milk sharing, learned that similar issues were being addressed by Gates Foundation for international issues, and that there were a wide variety of pasteurization and related approaches under study.
Given the multitude of ongoing research on human milk, we continued to contact colleagues informally to ensure that others’ concurrent work was included in this report where possible. Of particular note, we contacted and were in discussion with Dr. Karen Israel-Ballard who is carrying out the review of milk banking for the Gates Foundation (Gates Foundation, 2012), and Dr. David Newburg, a well-known researcher on the components of human milk and their impact on health. These individuals have been added to the list of experts invited to review this paper in final draft.

**Community/stakeholders’ team inputs.** Several members of the community team met again mid-study in Chapel Hill, North Carolina to review findings up to that point in time. This contact led to changes in practices occurring within HMBANA prior to the finalization of this paper. These changes, as well as the suggestions and recommendations that emerged, are presented throughout this document.

**Quantitative Methods**

**Surveys of the Physicians, Milk Bank Directors and Donors.** CGBI conducted three surveys for this assessment. All were cross-sectional cohort studies conducted using an electronic survey tool.

**Survey of milk bank donors.** A survey of milk bank donors was designed to gain insight into the motivation for and experience of participating in the donation processes. An invitation to participate in the anonymous survey was posted on the Facebook pages of seven HMBANA milk banks, and on the HMBANA homepage. The posting solicited responses to the question: "As a current or former HMBANA milk bank donor, what would you say to convince one of your friends to donate their extra breast milk to a HMBANA milk bank?" A link to an electronic survey was provided, connecting Facebook users to a free-response box where donors could
provide a personalized answer. A total of 93 entries containing completed responses were collected and used during analysis. These responses were coded in compliance with the codebook generated for the Key Informant interviews. The data were analyzed for key themes, findings and recommendations.

*Survey of HMBANA milk bank directors.* The survey of Human Milk Bank Association of North America (HMBANA) milk bank directors was developed to ascertain current practices in documentation, data collection, sharing and analysis. The survey was distributed directly to HMBANA existing and developing milk bank directors. To enhance their willingness to participate, participants were not asked to provide personal identifiers. The survey consisted of three main sections: Collecting Data, Distributing Data and Registry Management. The Collecting Data section focused on logistical questions about what method is used for data collection, what data are collected, and the nature of the bank’s affiliation with milk depots. The Distributing Data section focused on locations to which the milk banks are distributing their milk, and whether or not they are able to meet all needs. The final section, Registry Management, was designed to assess the milk bank directors’ preferences for operating a centralized vs. decentralized data management system. Fifteen HMBANA milk bank directors participated. Basic descriptive statistical methods were employed to ascertain current practice and milk bank directors’ thoughts and preferences for data management in the future.

*Survey of physicians.* Following the interviews with the selected physicians associated with Human Milk Bank Association of North America (HMBANA), we carried out a survey of non-HMBANA-associated physicians. The Academy of Breastfeeding Medicine (ABM), an organization of physicians with a stated interest in breastfeeding and the use of human milk, emailed the anonymous Qualtrics survey to its membership. The survey was completed by 108
individuals. The 31 respondents who were not from the United States were excluded from this analysis, as were 6 that were incomplete, leaving 71 completed surveys for analysis. The electronic survey included 22 questions, including 6 addressing demographics and 3 addressing personal experience with breastfeeding and human milk use, 5 on attitudes, and 7 on practices, with one open-ended question asking respondents to describe areas of concerns relating to donor human milk and milk sharing. Frequency distribution, means and median calculations, and univariate and bivariate analyses were employed. Limitations include 1) results are not generalizable to all physicians, but rather were gathered to represent the knowledge, attitudes and practices of those who self-identify as highly interested in best practices in breastfeeding medicine in the United States, and 2) the limited number of responses does not allow for meaningful tests of significance, but does offer insight on issues of physician attitudes and practices.

**Calculating Potential Need.** The literature on premature infant birth rates was reviewed to identify available estimates. This was then used to inform the decision on what human milk usage data would be collected. Clinical data were extracted from the medical records of infants in the well-baby nursery (rooming-in) and infants admitted to the NICU at a prominent teaching hospital in the Southeast US, a facility making every effort to employ best practices in use of donor human milk. The aim was to assess the quantity of human milk needed for infants born at various gestational ages (GAs). Medical records of term infants were reviewed to identify those who were fed donor human milk in 2012 (N=116), as were those of all infants admitted to NICU in Q4 of 2012 (N=165). We recorded the quantity of donor human milk (fortified and unfortified), mother's own milk (fortified and unfortified, and quantifiable for expressed milk feedings only) fed, diagnosis, reason for supplementation, and amount of formula fed to each
infant. The volumes are analyzed in relation to gestational age at birth and for duration of NICU stay. Data were uploaded to Stata for analysis, in which we estimated the average amount of human milk used for each GA grouping.

Another estimate was provided from a Milk Bank-associated physician and the two data sets are compared. For the calculation of total need, the estimate of the number of births in each GA group was based on US data on the distribution of births by gestational age.

**Cost-Benefit Analysis.** The literature on the diagnoses of causes of death was reviewed to identify those associated with formula use in the NICU. The greatest cost savings occur when the risk of morbidity and mortality are the highest. Therefore, data are available on the association of non-human milk feeding with the occurrence of necrotizing enterocolitis (NEC), a common cause of increased length of stay in the NICU and which is very sensitive to formula feeding. In fact, the strongest statistical association and potential life savings are attributed to human milk-associated reductions in NEC. The relationship between the cost of feeding donor human milk to all premature infants (“Cost”) and the cost of the benefit in the reduction of the excess NEC that would occur without human milk (“Benefit”) is analyzed for a Cost-Benefit discussion. Given that this analysis is based only on the costs of NEC, it is conservative. However, there are costs associated with supporting the availability of human donor milk as well as supporting each mother to achieve as much milk production as feasible in her situation. Therefore, several models are developed, reflecting the inclusion of some of the additional costs such as maternal support for milk expression.
III. Importance of Human Milk for Infant Health

Clinical Significance of Human Milk

Exclusive human milk via feeding at the maternal breast is the recommended approach to ensuring optimal nutrition for infants for the first six months of life is human milk (AAP, 2012a; WHO/UNICEF, 2003). Human milk is composed of a unique blend of nutrients, enzymes, growth factors, hormones and immunologic and anti-inflammatory properties, which cannot be duplicated synthetically or by using components from other species (Ballard & Morrow, 2013). Human milk has significant health benefits for infants, particularly for those born preterm, over age-appropriate formula. For example, breastfeeding associated with a decrease in the risk of acute otitis media, nonspecific gastroenteritis, asthma, lower respiratory infection, atopic dermatitis, obesity, childhood leukemia, type I and type II diabetes, NEC and sudden infant death syndrome (Bachrach, Schwarz, & Bachrach, 2003; Duncan et al., 1993; Guise, Austin, & Morris, 2005; Ip et al., 2007; Kull, Almqvist, Lilja, Pershagen, & Wickman, 2004; Morrow Ruiz-Palacios, & Newburg, 2005; Taylor, Kacmar, Nothnagle, & Lawrence, 2005; Quigley & McGuire, 2014). Recent findings suggest that exposure to formula is also associated with greater than a four-fold increased incidence of pyloric stenosis (Krough et al., 2012).

The use of human milk in the feeding of preterm infants (born prior to 37 weeks of pregnancy) is a public health priority. Although these infants comprise only about 12% of all births, they contribute about 35% of all infant deaths. Further, this infant feeding is an equity issue in the US, as premature births occur at a much higher rate among African American mothers (see Table 2).

Human milk meets the changing needs of the child during the course of a single feeding, over a day, and over the course of infant and child development. A recent study detailed four
aspects of human milk — fat, which can represent up to 50% of infant energy intake, and lactose, protein, and total energy — and found dynamism over time between women and between breasts (Mitoulas et al., 2002). Other findings show that the human milk microbiome also changes during lactation (Cabrera-Rubio et al., 2012). *Weisella, Leuconostoc, Staphylococcus, Streptococcus*, and *Lactococcus* are predominant in colostrum samples, whereas in 1- and 6-month milk samples the typical inhabitants of the oral cavity (e.g., *Veillonella, Leptotrichia*, and *Prevotella*) increased significantly. This dynamism is not possible with pasteurized human milk or human milk substitutes. Further, the content of fresh human milk has been found to vary by childbirth experience; milk samples from women who underwent scheduled cesarean delivery contained a different bacterial community than did milk samples from individuals giving birth by vaginal delivery or unscheduled cesarean delivery, suggesting that it is not the operation per se but rather the absence of physiological stress or hormonal signals that could influence the transmission process into milk, rather than exposure to vaginal microbiota (Cabrera-Rubio et al., 2012).

Human milk feedings for very low birthweight infants reduces the risks and the associated costs of late onset sepsis and NEC (Meier & Bode, 2013). Hence, the lowest NICU costs occur among the very low birthweight infants who receive the highest average daily doses of human milk in days 1-28 (Patel et al., 2013). Donor human milk is a critical intervention to prevent morbidity, mortality, and complications in treatment, improving health outcomes in the short- and long-terms, and decreasing the length of stay for thousands of vulnerable infants each year (Arslanoglu, Zeigler, & Moro, 2010).

Screened and pasteurized donor human milk is often a recommended alternative in circumstances when a mother’s own milk is not available to meet the baby’s needs (AAP,
Research has shown that avoidance of formula feeding is associated with maturation, secure gut growth, and appropriate response to bacterial colonization, and ultimately decreased risk of NEC (Siggers, Siggers, Thymann, Boye, & Sangild, 2011). Meta-analysis assessing the effect of exclusively feeding of donor human milk to preterm infants (in comparison to exclusively feeding infant formula) find that the rate of NEC among formula fed infants is about 5 times that among human milk fed infants (Boyd, Quigley, & Brocklehurst, 2007). Another meta-analysis found that infants who received donor human milk were four times less likely to have confirmed NEC (RR 0.25; 95% CI 0.06 to 0.98) than infants who received infant formula (McGuire, 2003).

Unfortunately, nationally the racial distribution of the infants who receive human milk in the NICU is not tracked, nor are data collected on the amounts of milk provided to infants by demographic or clinical characteristics beyond hospitalization vs. outpatient status. Some maternity centers prioritize the use of human milk, while others continue to prioritize formula and non-human milk based fortifiers. While little racial differentiation in the use of donor human milk is expected within facilities, this issue has not as yet been assessed. We simply do not know, as one medical professional said, “If you don’t take the temperature, you don’t know if the patient has a fever.” Given that donor human milk feeding practices tend to be location specific, future research could survey the racial composition medical centers that do and do not use donor human milk. We recommend both of these analyses – overall comparison of distribution rates by infant race and ethnicity and a facility-based comparison.
Government and Professional Organization Support for Donor Human Milk Use

Professional Organization Support. Many professional organizations and government agencies support breastfeeding and the use of human milk for infant and young child feeding. Policy statements emphasize that breastfeeding is the normative standard for infant feeding and nutrition. All of the groups recommend exclusive breastfeeding for 6 months, followed by continued breastfeeding for at least one year or up to two years or longer. The general concept is that breastfeeding should continue as long as the mother and child desire. Many of these professional organizations also recognize that not all infants are able to receive mothers’ own milk, and therefore also explicitly support use of donor human milk, including those of physicians: American Academy of Pediatrics (AAP, 2012a), American Congress of Obstetricians and Gynecologists (ACOG, 2007), Academy of Breastfeeding Medicine (ABM, 2008), and American Academy of Family Practice (AAFP, 2012); those of other health professionals: Association of Women’s Health, Obstetrics and Neonatal Nurses (AWHONN, 1999), American Dietetic Association (ADA, 2009), National Association of Pediatric Nurse Practitioners (NAPNP, 2007), and American Public Health Association (APA, 2013); as well as US government agencies: the Department of Health and Human Services’ Offices on Women’s Health (US HHS OWH, 2000).

United States Government Support. United States governmental support for breastfeeding and use of donor human milk is seen across several federal agency initiatives. Healthy People 2020, continuing from earlier Healthy People goals to improve the health of the country, include an increased number of measures related to breastfeeding. For example, Maternal, Infant, and Child Health Objective 23 is to reduce the proportion of newborns that receive formula supplementation within the first two days of life. Increased use of donor human
milk use will be an essential component in enabling the achievement of this aim (US DHHS, 2010).


Banked donor human milk is not currently part of the federal regulation structure that protects consumer safety. Human milk is classified as a nutraceutical, which means a medically indicated food and it is a product that is dependent upon living human voluntary donation. Because of these complexities, the US Food and Drug Administration (FDA) has not yet identified the appropriate home for the topic. In the meantime, HMBANA and Prolacta Bioscience, as well as New York, California and Maryland, have individually developed guidelines and standards of practice, meaning processes and usage vary across the nation.

International Organization Support. Other countries have national policies related to donor human milk banking. There is documentation from global organizations to support the promotion, protection, and support of donor human milk banking as an integral part of child health and survival (Arnold, 2006a). Further, WHO/UNICEF (2003) note:

The vast majority of mothers can and should breastfeed, just as the vast majority of infants can and should be breastfed. Only under exceptional circumstances can a mother’s milk be considered unsuitable for her infant. For those few health situations where infants cannot, or should not, be breastfed, the choice of the best
alternative – expressed breast milk from an infant’s own mother, breast milk from a healthy wet nurse or a human-milk bank, or a breast milk substitute fed with a cup, which is a safer method than a feeding bottle and teat – depends on individual circumstances (p. 10).”

However, there are not yet global policy and guidelines for donor human milk banking. Major contributions to the international policy discussion regarding donor human have occurred in Brazil. This country has had donor human milk banks and has had them addressed in health policy for decades. Further, Brazil utilizes social service personnel, such as mail service personnel and firemen, to support this effort (Tully, 2001). Many other countries have milk banking policy incorporated into national public health policy and regulation, including France, Germany, Scandinavian countries, and other countries with socialized medicine approaches, such as the United Kingdom, where the provision of banked human milk is part of standard care (Arnold, 2006b; Springer, 2006). In Europe, there are 186 Human Milk Banks at this writing, and new banks are planned through the support of the European Milk Bank Association. In the US, there is no federal public health policy that addresses donor human milk despite the recent growth in the number of milk banks, payment issues, and demand vastly outweighing supply.

The Gates Foundation (2012) has recently engaged an international group of experts to examine best practices for global efforts to increase availability of human milk. This group is utilizing existing policy documents, federal and local health programs, and professional associations’ policies and reports to serve as an evidence-base to inform the establishment, increase or continuation of the provision of milk banking services.
History of Human Milk Banking in the United States

According to Baumslag and Michels (1995), early medical texts, artwork from ancient Greece and Egypt, and other historical documents suggest that women have shared their milk for thousands of years and longer. The earliest available human milk sharing literary reference is from the 2\textsuperscript{nd} century, a physician named Soranus of Ephesus warned that a mother's milk was not good for the first 20 days postpartum. In Ancient Greece, special slaves called "duolos" were used by some as wet nurses. Soranus promoted the use of these slaves between the ages of 20-40 and recommended that they be self-controlled, good-tempered, of good color, tidy, and Greek. There is also evidence to suggest that women living in the 13\textsuperscript{th} century made more money working as wet nurses than any other occupation available to women at that time. In the post-modern period, some groups maintain the belief that the ability to purchase and feed infants something other than mothers’ own milk is a symbol of high socio-economic class.

In the mid-19\textsuperscript{th} century, there was an increased medicalization of childbirth and infant care. By the late 19\textsuperscript{th} century, mass-produced infant formulas were developed and were being broadly advertised directly to consumers and health professionals. Early in the 20\textsuperscript{th} century, the belief in disease transfer via microbes began to proliferate. Some physicians hypothesized that human milk may be a vehicle for disease transmission, and documented incidence of wet nursing decreased. Around this time, medical and social texts include discussion of the potential merits of artificial baby milk (now known as infant formula), especially in texts regarding how to feed infants whose mothers were unable to provide their own milk. The early artificial feeding products commonly resulted in infant death, most likely due to inadequate sterilization and hygiene practices. Concern about the correlation between infant formula and mortality spurred exploration of how human milk could be provided to the most vulnerable infants. In 1909, the
first donor human milk bank opened in Vienna, Austria. These pioneers laid the foundation for how to recruit donors, collect and distribute the donor milk to vulnerable infants. In the first decade of the twentieth century, the first American milk bank opened at the Boston Floating Children’s Hospital. These milk banks both collected and distributed unprocessed milk to ill and premature infants, and reported positive results in babies whose survival was unexpected. Boston Floating Children’s Hospital paid donors for their milk, and charged between $0.10 and $0.30 per ounce to the recipients (Jones, 2003). Women could sell between 15 and 72 ounces of their milk per day, and only 40 donors were approved.¹ This marked the first time in that any human bodily product was sold or shared in a disembodied form (meaning not communicated directly from donor to recipient as in wet nursing or early blood transfusion procedures) (Swanson, 2011). It was also a time of great medical experimentation, in which clinicians and scholars attempted to purify and preserve expressed human milk using various methods, many borrowed from the dairy industry (Jones, 2003).

When the United States passed the Sheppard-Towner Act in 1921, federal funds supported the establishment of “Milk Stations” throughout the country. The primary purpose of these centers was to pasteurize cow’s milk for distribution, but many also chose to pasteurize donated human milk to promote the well-being of sick and premature infants (Arnold, 2008). At this time, many donors stopped working as wet nurses (who were commonly considered domestic servants) and began to contribute as formal donors at a time when “medical therapeutics” was increasingly accepted. Lactating women went to the milk stations to express their milk under supervision, being paid by the ounce (Jones, 2003). Donor payment was short-

¹ Compare this to current practice, in which donors typically express 4-10 ounces / day for the milk bank, and HMBANA milk banks approved 3,000+ donors in 2011 (HMBANA, 2011a).
lived, due to (seemingly un-prompted) concerns that donors would deny their milk to their own infants or alter their milk in order to increase the volume.

There were milk stations in more than 20 cities in the United States by 1929. In the 1930s, British and German milk bankers offered guidelines, which were expanded and adapted by the American Academy of Pediatrics in 1943. The American Medical Association offered a supportive position statement, and existing American milk banks/stations adopted the protocols with various levels of adherence and “creativity.” When blood banks began to proliferate in the United States in the 1950s, the expectation for highly medicalized donation processes led to the further development of guidelines for formal donor human milk banking. Milk banking moved towards the blood-banking model (which was being developed as part of the war effort). Part of these efforts included the end of monetary compensation and instead, women received incentives such as clothing swaps (Swanson, 2011). By the 1980s, an estimated 30 milk banks were operational in the United States (Jones, 2003).

The Human Milk Banking Association of North America (HMBANA) was established in 1985 primarily to establish standards for all North American milk banks. HMBANA collaborated with the United States Food and Drug Administration, the Centers for Disease Control and Prevention and the American Academy of Pediatrics to develop guidelines for collection, processing and distribution of donor human milk (HMBANA, 1990). Guidelines and recommendations for donor milk banking became more and more stringent as the HIV/AIDS epidemic spread globally. Many donor human milk banks closed, though it is unknown whether they closed due to fear of spreading the disease through milk (at a time when it was still unknown what the disease was, let alone how it spread), actual or anticipated decrease in demand, or other reasons. As bacteriology and virology have advanced in general, and
knowledge about human milk has grown, milk banking standards are continuously revised (Jones, 2003).

The private company Prolacta Bioscience, Inc. recognized this momentum in their development of a for-profit approach to donor human milk nutritional products that would include a program of research. Additional for-profit and not-for-profit milk banks are in development stages, as recognition of the need for human milk for human children increases. Additionally, products such as calorie or content-specific milks and human-milk-based human milk fortifiers, are receiving increased attention in medical literature and clinical practice.
IV. Current Status of Donor Human Milk Banking in the United States

A donor human milk bank “is a service established for the purpose of collecting, screening, processing, storing, and distributing donated human milk to meet the specific needs of individuals for whom human milk is prescribed by health care providers who are licensed to prescribe” (Lawrence & Lawrence, 2011). In the United States, there are two primary models of milk banks: non-profit milk banks (associated with Human Milk Banking Association of North America) and for-profit milk banks (associated with Prolacta Bioscience, Inc.). Both HMBANA and Prolacta declare that neither has a financial relationship with any infant formula manufacturers or distributors at this time.

United States Food and Drug Administration

In the United States, human milk is currently regulated and inspected as food. Human milk fortifier, human milk caloric fortifier, and human milk-based preterm formula are regulated as exempt infant formula. All are therefore exempt from FDA regulation of human cells, tissues or medications and devices. \textit{FDA 7341.002 – Inspection of Human Cells, Tissues and Cellular and Tissue-Based Products} describes which donor products are subject to registration and listing, screening and testing of donors, Good Tissue Practice requirements, labeling and reporting requirements, and inspection and enforcement provisions. This includes bones, skin, semen, oocytes and embryos. Other products involving living human donors, including blood, have other regulations specific to them. According to the US FDA Compliance Program Guidance Manual on the Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Products, milk (like cells “derived from animals other than humans”) is exempted as a “secretion” and is therefore not covered by this compliance program. This is due, in part, to the fact that human milk is collected and initially stored in locations uncontrolled by manufacturers or distributors,
making the controls and risk management procedures for donor milk banking completely
different from that used for all other products that include human cells. In other words, donor
human milk is currently regulated using the same methods as are used for cow milk infant
formula. However, FDA officers do visit donor human milk banks and hold them to safety
standards in accordance with the Bioterrorism Act of 2002.

Therefore, donor human milk must be pasteurized according to the FDA’s “Pasteurized
Milk Ordinance” (US FDA, 2011b). Specifically, the Infant Formula Act of 1980 is an
amendment to the Federal Food, Drug and Cosmetic Act, which established requirements for
quality control testing, quality testing, good manufacturing practice, registration, record keeping
and recalls. California and Texas have recognized the HMBANA guidelines as the standard for
human milk banking in their states, both through legislative action. New York State has statutory
oversight of donor human milk banks, requiring a tissue bank license for donor milk banks
operating and/or distributing donor milk in the state. Milk selling and sharing outside of
HMBANA and Prolacta currently falls outside of all regulation efforts, federal and state.

In December, 2010, the FDA Pediatric Advisory Committee (FDA PAC) convened a
meeting to “obtain a better understanding of current practices, infectious disease risk, state
regulations and mitigation strategies currently used to avoid contamination of donated milk.”
The FDA PAC heard from experts in the field, including HMBANA and Prolacta affiliates,
unaffiliated university researchers, and members of the public engaged through an official
Federal Register announcement to speak at an Open Public Hearing session of the meeting. The
meeting had four major themes:

1. Endorsement of human milk banking by the Pediatric Therapeutics Committee of the
FDA.
2. Concern about Internet and person-to-person milk exchange, which the FDA strongly discourages.

3. Need to address currently inconsistent and lacking state regulations for donor human milk in order to attend to “illegitimate milk banking operations” (though it was acknowledged that HMBANA and Prolacta processing approaches appropriately mitigate risk) (US FDA, 2011a).

4. Need for additional data. There was consensus that there is a need for further research on the risks and benefits of pasteurized donor human milk, human and cow’s milk fortifiers, and exclusive versus supplemental feedings. The FDA has encouraged HMBANA and Prolacta to create a registry to generate an outcome profile for recipients of donor human milk (and related products) (ADA, 2011). However, this has not as yet been done.

In the three years subsequent to this meeting, the FDA Working Group on Infant Formula has continued to hold internal and external discussions and explorations in the field in an effort to determine appropriate regulation and inspection of banked donor milk. According to one milk bank affiliate, “They’re just not caught up…FDA regulation would give us clout with the insurance companies…Without regulation, the insurance companies are not willing to pay attention to us and that’s a crime, really. I think informed regulation is the ideal to bring donor human milk to all vulnerable babies who need it.” There is consensus among non-profit and for-profit milk banking organizations that federal regulation would contribute to promoting the safety of milk for recipients: “There is no such thing as good enough standards in this work. We must use a continuous improvement model, which will mean that regulation gets established and evolves over time in response to new knowledge…We are all concerned about what we don’t yet
know. Still, we must start somewhere.” There is also reasonable consensus around a hybrid regulatory model, merging biologics and food.

During the assessment period for this report, one donor milk bank initiated a voluntary recall of one batch of pasteurized human milk after one donor whose milk was pooled into the batch tested positive for hepatitis B (US FDA, 2013). The milk bank director involved reported the cause for concern to the FDA, and worked with FDA staff to recall the milk, analyze, and correct the error.

In response to greater than fifty recalls on infant formula in a thirty year span, and in an effort to curb that trend, the FDA issued *Interim Final Rule: Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements and Records and Reports, for Infant Formula* on June 9, 2014 (effective July 10, 2014). At present, per FDA Center for Food Safety and Applied Nutrition determination, any entity that supplies human milk or human milk products, must comply with federal regulations governing the production and labeling of such items as covered by statute in 21 CFR 100-169, and, in particular, parts 105-107 dealing with infant foods. With this, when recalls are merited, human milk must now be recalled in a similar manner as any other commercially available food.

**Impact of Availability of Donor Milk Banks on Facility-Level Rates of Any and Exclusive Breastfeeding**

The availability of donor milk banks increases the use of human milk, both donor and mothers’ own, in NICUs (Arslanoglu et al., 2013). Arslanoglu and colleagues (2013) examined hospitals with and without on-site human milk banks, comparing rates of ‘any and exclusive breastfeeding’ and ‘exclusive formula feeding’ at discharge. Exclusive breastfeeding rate at discharge was significantly higher in NICUs with a milk bank than in NICUs without (29.6% vs.
16.0%, respectively). The rate of any breastfeeding at infant discharge tended to be higher in the
NICUs with a bank (60.4% vs. 52.8%), and exclusive formula rate was lower in the NICUs with
banks (26.5% vs. 31.3%), however neither was statistically significant. In sum, the use of
mother’s milk may be mediated by the existence of a local human milk bank.

**Billing and Reimbursement of Banked Donor Human Milk**

Pasteurized donor human milk is a life-saving intervention with support from all major
medical organizations and the federal government. Despite its critical role in morbidity and
mortality, there are problems with donor human milk reimbursement from third party payers.
This financial barrier perpetuates inequities in health care and outcomes, by state, hospital, and
patient.

In current national policy, each State is responsible for its own Medicaid program. The
type, amount, duration, and scope of Medicaid services is determined within broad federal
guidelines. In practice, private third-party payers typically look to State Medicaid frameworks to
establish the minimum coverage. Therefore, expanding Medicaid coverage for donor human
milk will likely impact both Medicaid beneficiaries and the privately insured. Some milk banks
have found greater success with private insurers, due to the idea that “these kids will be [the
insurer’s] responsibility for a long time” and preventive medicine is cost-saving.

Under federal policy, States are required to cover certain "mandatory benefits" for
Medicaid recipients. Mandatory Medicaid benefits include outpatient hospital services and
certified pediatric services under CHIP. States may also choose to provide other "optional
benefits" for which they receive federal matching funds. Providing coverage for prescribed
drugs, preventive services, and durable medical equipment is optional (meaning that there are
federal matching funds for some, however federal matching funds do not cover all of these categories). Further, States may choose to provide other coverage with no federal support.

A complete survey of State Medicaid offices would help to characterize the current situation. Based on communications with Prolacta, HMBANA Milk Bank Directors, hospital administrators and milk recipients, Medicaid reimbursement for banked donor milk is highly variable. Only California, Maryland, and Texas Medicaid programs are reported to reimburse consistently. Kentucky has legislation stating that insurers must pay for a 100% human milk diet for NICU infants, but it is unfunded and, therefore, largely un-enforced. Most other State Medicaid programs do not cover human milk prescriptions, regardless of in-patient or out-patient status or clinical need. Many state Medicaid programs will reimburse hospitals for banked donor human milk as part of in-patient daily capitation rates, shifting the onus to the hospital to make the cost-benefit decision.

Only two state Medicaid programs, California and Texas, explicitly state that they will cover donor human milk in the out-patient setting, and both require demonstration of medical need in the form of a prescription. In this case, the hospital and/or milk banks can bill Medicaid directly, greatly easing the burden for recipient families. In other states, the families of out-patient recipients must seek coverage independently. This process entails not only acquiring a letter of medical necessity from a physician, but also submitting the claims and appeals independently. Given that families with children who have special healthcare needs (including trying to establish, increase, and/or maintain one’s own milk supply), the pathway to obtaining donor human milk in the current system is often prohibitive.

Reimbursement for donor human milk is highly variable and does not depend on whether the claim comes from a donor human milk bank or insured individuals. While most donor human
milk banks strive provide milk to all with a demonstrated clinical need availability is not always possible due to payment issues. One donor human milk bank director explained, “For our outpatients, we have no choice but to wait for pre-approval or request payment up front.” A donor human milk bank staff member stated, “We’ll have an insurance company pay for a whole bunch of milk for one patient with a diagnosis, then nothing for another child with the same situation. I’ve even had it vary by which staff member receives the claim that month. Because every employer has a different plan, coverage will vary by company, employer, child, and diagnosis. I probably spend 25% of my time processing claims and appeals due to the inconsistency.”

As part of the Affordable Care Act of 2010, public and private health insurers are required to cover breastfeeding support and supplies. This expansion is relevant in that it will support more women to directly breastfeed or express their own milk for their babies. And, it is likely to increase breastfeeding duration and exclusivity, potentially expanding the number of women with milk to donate. The legislation, however, does not address donor human milk. Further, federal policy prohibits WIC coverage for donor human milk. Therefore, in the WIC program, infants with special healthcare needs can receive free specialty formulas, but they cannot receive free or reimbursed donor human milk.

As was previously stated, when donor human milk is covered for in-patients, the milk is being included in daily capitation rates (except in California, Maryland, and Texas). Each hospital currently individually weighs the cost, clinical, legal, and ethical implications for using the donor human milk. In most hospitals, infant formulas (including specialty types) are provided free of charge by the manufacturers. Even at Baby-Friendly accredited hospitals, which that are required to pay fair market value, formula typically costs less than 5% of the cost of donor
human milk. If simply comparing the costs of infant feeding using formula or donor human milk, there is no contest. However, hospitals also account for the potential cost-savings and ethics associated with the many benefits of using donor human milk, including fewer days of parenteral feedings, shorter length of infant hospitalization, and decreased risk of NEC. To date, only the most motivated and progressive hospitals in the United States use donor human milk.

Prolacta’s human milk fortifiers are sold to the hospitals, which are advised to seek reimbursement from third party payers. While coverage remains inconsistent, rates of reimbursement are generally high. The company advises hospitals on how to bill for all products (not just fortifiers). Hospitals are having the most success in billing for the products as medical/surgical supply, sterile supply, or general pharmacy. Descripts such as “cow milk-based fortifier” or “donated breast milk” are avoided. Hospitals instead describe the fortifiers using their product names, such as Prolact+4, Prolacta+6, or Prolact+8 H²MF high-risk infant supplement (Prolacta Bioscience, 2014a).
Current Major Approaches

The primary groups involved in human milk banking include Human Milk Banking Association of North America (HMBANA) and Prolacta Bioscience, Inc. The map below illustrates the locations of HMBANA human milk banks in the United States and areas for which reported requests for milk were not fully met.

Human Milk Banking Association of North America (HMBANA)

HMBANA is the professional organization for donor human milk banking professionals, and member organization for non-profit human milk banks in the United States. Milk banks
associated with HMBANA in the US include thirteen fully operational, three in the advanced planning stages, and one in the early planning stages. Milk depots for HMBANA currently number 156. These sites are designated to collect donated human milk, which will then be shipped to an affiliate milk bank for processing and distribution (HMBANA, 2014).

HMBANA Guidelines of the Establishment and Operation of a Donor Human Milk Bank were established in 1990 as a result of a multi-disciplinary group of healthcare providers. The stakeholders included the CDC and the FDA. The Guidelines are now published in their 17th edition. The document is meant to reflect the latest scientific understanding, optimal clinical practice, and social ethics in donor human milk banking. HMBANA, with a multi-disciplinary committee that includes healthcare providers and donor human milk bank directors, re-assesses and updates the guidelines, including in response to US food and beverage regulations, tissue banking guidelines, and scientific advances. The Guidelines are published every two years, with interim updates as needed, such as the Ebola screening requirements that were created in 2014. The Guidelines are considered a minimum standard for all HMBANA milk banks. HMBANA milk banks conduct an annual self-assessment and also have annual assessments conducted by a peer milk bank or equivalent public health authority, all of which use the “Annual Assessment of Adherence to HMBANA Guidelines.” The results of these investigations are submitted to HMBANA’s Executive Board, and the banks are provided with a timeframe for remediation before suspension if they are found to have any non-adherence (HMBANA, 2011b).

HMBANA milk banks are required to operate using an administrative structure that guarantees checks and balances, including a medical director and/or an advisory board with representatives of appropriate medical fields. The Guidelines describe in detail the minimum standards for donor screening (including inclusion and exclusion criteria, and temporary
disqualification), serological tests, donor approval, and donor education procedures. Milk bank procedures including equipment and handling are described, and closely match those required of tissue banks by the FDA. The Guidelines are highly specific regarding the processing of donor human milk, and provide step-by-step directions for defrosting and pooling, heat processing, post-testing, storing and labeling, and shipping. The document specifies that donor milk is only to be dispensed according to hospital purchase orders or prescription. The Guidelines also describe steps that a milk bank should take if supply of donor human milk is inadequate to meet demand.

HMBANA donor human milk banks are required to keep administrative records that enable them to track milk by donor, bottle number, and batch number, in case the need for a recall. The HMBANA milk banks are also required to keep records of recipients. Donor human milk “recipients” are often hospitals. Therefore, distribution data by patient demographics or recipient health outcomes is not currently possible (HMBANA, 2011a).

**Target Pooling and Labeling for Selective Distribution.** Whether the calorie count in donor human milks, or another aspects of human milk composition, affect infant growth and development is unclear (Boyd et al., 2007). This contested information is critical to determining whether recipients of donor human milk benefit from fortification for higher-calorie milk and/or target pooling. In addition to the health implications, creating specialized donor human milk content increases the cost, and therefore the availability, of the milk.

The National Institutes of Health commissioned a systematic review of the difference between banked preterm milk versus banked term milk in promoting growth and development in low birth weight babies (Dempsey & Miletin, 2010), but there was a complete absence of studies meeting the inclusion criteria. There is no commonly-accepted definition of “pre-term milk,” and
the term itself is a misnomer, given that the milk of mothers who give birth to preterm infants have higher caloric density for 2-3 weeks before transitioning to milk of similar composition to that made by mothers of term infants. Nonetheless, several milk banks have started to practice “target pooling.” Donations from women who are known to have high calorie milk are selected and then this milk is pooled. The result is high-calorie human milk (which is 20-24 calories per ounce). This milk is often referred to as “preterm,” “hospital-grade” or Cadillac” milk. The milk banks justify this approach, in part, due to the practical reason that providers have said they will not prescribe “term” human milk or human milk with unknown calorie counts. Other clinicians report that they will use lower calorie donated human milk, but only in conjunction with milk fortifiers. Only one provider spoke to the contrary:

Until there is good evidence that the high-cal milk is actually better, I will keep prescribing the affordable ‘regular people milk’ so that I can ensure my patients don’t run the risk of infection from formula or fortifiers. We never used to worry about that until [a company] came and told us we needed to. Babies have been doing better on donor milk well before any fancy milk analyzer was invented.

Lower calorie milk is often referred to as “out-patient milk.” This milk is sometimes offered as a compromise when milk banks cannot meet hospitals’ demand for “hospital-grade milk.”

An additional issue in selective human milk pooling is the gestational age at birth, which is used to define “preterm milk.” The Connecticut Human Milk Research Center survey of HMBANA milk banks found that the definition varied from bank to bank. When considering which donors’ milk to include when pooling for preterm milk, the gestational ages of birth ranged from less than or equal to 32 weeks to 40 weeks (Brownell, Lussier, Herson, Hagadorn,

---

2 All Prolacta products are target pooled for a specific nutritional composition.
& Marinelli, 2014). This is likely because some milk banks will pool high calorie milk into preterm milk, even if the milk is from a donor who gave birth at term. Further, not all HMBANA banks are processing donor human milk for specific calorie counts. As more research studies assess the variability in human milk composition over time, and the components in human milk that most impact the growth and development of preterm infants, it may helpful to adopt consistent definitions of all study variables.

**Cost of Milk.** All HMBANA Milk Banks are required to operate as non-profit entities. A reason that women choose to share their milk to other mothers rather than donating to a human milk bank is their perception that *donated* milk is sold for others’ monetary profit. However, HMBANA Milk Banks do not “sell milk.” Rather, they bill for the costs of processing the milk and organizational overhead. In order to supply high calorie donor human milk, some banks purchase and maintain more expensive equipment, which increases the processing fees. Human milk that is not target pooled is commonly billed at around $3.50 per ounce. On the other hand, human milk that is pooled to have precise calories per ounce is may be billed at nearly twice this cost.

Most banks keep costs down by using donated space, volunteer staff, and pro bono professional services. HMBANA banks’ annual budgets indicate that the banks operate using grants, in-kind donations (including equipment), and money earned through fundraising. At a minimum, operation of a donor human milk bank involves:

- Recruiting, screening, tracking, and counseling donors;
- Testing, pooling, pasteurizing, and analyzing milk;
- Storing milk; and
- Receiving orders and distributing milk.
Other efforts needed for successful human milk bank operation include educating and engaging potential donors, educating physicians to prescribe human milk, and other tasks that increase the capacity of a milk bank (HMBANA, 2011b).

HMBANA Milk Banks’ operating budgets are highly variable. The operating budget is largely correlated with the capacity for operation; put simply: more money = more milk. Despite the unmet need for human milk in the United States, some donor human milk bank staff worry about increasing the numbers of donors because they lack the capacity to process more milk. For some, partnering with milk depots has assuaged this concern. Milk depots help with the issue of limited storage space because quantities of milk can usually be kept at the depot until ready to be pasteurized, then stored at the bank for only a brief time before being distributed. Still, the depots require close coordination with milk banks for storage, labeling, shipping, and receiving issues.

Information Management. The HMBANA Guidelines require record keeping for milk safety purposes. Information currently collected only pertains to the donor screening procedure, and milk batching and distribution for tracking purposes (HMBANA, 2011b). Our survey of fifteen donor human milk bank directors (representing 13 milk banks) indicates that a variety of data collection systems are in use, including hard copy, Microsoft Excel, various professional database systems including Timeless, Access, Filemaker, and Neoteric. Some milk banks reported using more than one of the aforementioned systems, with some using a combination of hard copy and an electronic system.

Data currently collected. We also found that the majority of the donor human milk banks collect information on the total ounces of donor milk processed, total ounces dispensed, individual donor’s milk volume and total ounces dispensed by purpose (hospital, out-patient, etc.). However, there was variation regarding the demographic information collected about both
donors and recipients (see Table 3). Three of 13 milk banks collected information about the age of recipients, one collected information about race of donors but not of recipients, one asked about educational attainment of donors but not of recipients, and none assessed religious affiliation.

Table 3. 
HMBANA milk bank directors’ accounts of data currently collected and recommendations for future data collection.

<table>
<thead>
<tr>
<th>Data Category</th>
<th>Number of donor human milk banks that currently document data</th>
<th>Number of donor human milk banks that indicate that data should be collected and centrally compiled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Ounces Processed</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Total Ounces Dispensed</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>Ounces Dispensed by Purpose</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>(in-patient, out-patient, research)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raw Milk Dispensed to Bank</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>Pasteurized Milk Dispensed to Bank</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>Individual Donor’s Volume</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td># of New Outpatient Recipients</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>Diagnosis for Outpatient Recipients</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>Total # of Approved Donors</td>
<td>11</td>
<td>12</td>
</tr>
<tr>
<td>Total # of Unapproved Donors</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>Age of Recipients</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Confirmed Positive Blood Tests</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Racial Distribution of Donors</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Racial Distribution of Recipients</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Household Income of Donors</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>----------------------------</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Household Income of Recipients</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Education Attainment of Donors</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Education Attainment of Recipient Mothers</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Religious Affiliation of Donors</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Religious Affiliation of Recipients</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Birth Order of Recipients</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>How Donors Discovered Banking</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>How Donors are Referred to Bank</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>% of Demand Satisfied</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>% of Demand Satisfied for Recipients with Prescriptions</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

**Current data systems.** Nine of the fourteen respondents stated that they were currently using their preferred method(s) of documentation, data collection, and data storage. Despite the fact that nine of these respondents stated that their current method was their preferred method, there were ten free-text responses to the question of why they were not using their preferred method, and seven respondents mentioned a need to increase electronic database use. The four banks that reported not using their preferred system each responded with commentary regarding the reason(s) why:

- A new system is in development or they are in the process of purchasing a databases
- Database expense
Would rather use an “all-database” that would permit examination of a large amount of data.

**Acceptability of a centralized data system.** The majority of HMBANA milk bank directors responded that they either agreed (n=3) or strongly agreed (n=7) that there should be a centralized data management system (10 of 13). The other 3 milk banks responded that they were impartial or neutral to centralized data management development. One director responded:

HMBANA already collects data. HMBANA does not need a ‘registry.’ We have our own system which has worked well and we are in the process of considering what additional data we would like to collect.

We therefore infer that donor human milk bank directors would generally accept the creation of a universal database system.

**Data for future collection.** When the milk bank directors were asked what data were important to collect, the results mirrored what was already being collected (see Table 3). There was a strong emphasis on the total ounces dispensed, purpose for use, and raw and pasteurized milk dispensed. Only two milk bank directors responded that it was important to collect information on race, household income, educational attainment, or religious affiliation. Milk bank directors were allowed to type in any additional comments, and two reported that it would be helpful to know what processing fees are applied to pasteurized milk across milk banks.

**Access to centralized data.** When milk bank directors were asked who they thought should have access to the HMBANA Donor Human Milk Registry, eight out of twelve milk banks responded that HMBANA milk bank directors should have access to all the other milk banks’ data. Another three responded that each milk bank director should only have access to aggregated data of all HMBANA milk banks,
Centralized data system maintenance. Ten out of twelve milk bank directors reported that they felt that responsibility for a centralized database would be either the HMBANA executive board or other administrator(s) to maintain this database. Some directors suggested that an outside agency could help facilitate the process while working with a HMBANA member of to maintain the database. An agency that is knowledgeable about HMBANA and human milk or similar tissue donation organizations may help to organize the data in a way that is useful and can be readily interpreted so that appropriate changes and suggestions can be made. A centralized database may facilitate HMBANA and milk bank director understanding of where to focus improvement and efficiency efforts.

Barriers to a centralized database. There are barriers that could prevent the successful development of a centralized HMBANA database. Donors may be reluctant to provide information if they perceive that either themselves or their milk may be viewed or treated differently based on demographics. Therefore, the stakeholders suggest, it is better to not ask for this information so as to not potentially make donors feel uneasy or make them feel that the information matters significantly. Other potential barriers to a centralized database are structural. Currently, each HMBANA milk bank is operated on its own within the HMBANA protocol. Furthermore, hospital-based donor human milk banks are typically required to use the electronic record-keeping protocols of their host hospital. Further, the role of hospitals as the primary ‘consumers’ of donor human milk from the banks may present a major barrier to collecting data on recipients. All hospitals have their own record keeping system for data collection and storage, particularly with NICU infants who may have severe medical conditions that require more detailed information to be tracked.
For HMBANA to create an effective centralized data collection system, it would also require a degree of collective identity, mentality, and culture. Milk bank directors may be reluctant because of a desire to follow their own procedures and keep their logistics the way that they have been successfully operating. However, further exploration of having a centralized database is important to work towards consistency across milk banks in regards to the type of data that is collected while maintaining the independence that the milk banks have as separate entities. Finally, HMBANA does not currently provide financial support to their donor human milk banks, so the expense of a centralized database is an additional constraint.

It was unexpected that only one of the donor human milk banks surveyed reported collecting any information about race and educational attainment. Even in this one case, it is only collected on donors, not on recipients. Household income, socioeconomic status, and religious affiliation of donors and/or recipients are not currently collected by any HMBANA bank. Additionally, only two of the 13 milk banks responded that the demographic information listed in Table 3 should be collected, documented, and sent to HMBANA. There are several reasons to consider collecting and tracking this type of data; being able to monitor the socioeconomic status and race of the populations being served is vital to monitoring equity in milk distribution.

We therefore recommend that HMBANA develop a centralized database, not only containing information that donor human milk banks are currently required to document, but also containing the following new information on both donors and recipients:

- Maternal age
- Maternal race and ethnicity
- Household income
- Maternal education attainment
• Percent of demand satisfied for hospital consumers
• Percent of demand satisfied for out-patient recipients with prescriptions
• Infant age

More research will also be needed to determine how HMBANA can partner with the hospitals they serve to obtain specific information about the recipients while adhering to the Health Insurance Portability and Accountability Act (HIPAA).

Findings from a recent study by The Connecticut Human Milk Research Center (Brownell et al., 2014), were consistent with our conclusion that the definitions, collection, and management of data on human milk donors and donor human milk bank operations are currently inconsistent. This group suggests that a more consistent and transparent data system may help facilitate the integration of donor human milk programs into standard NICU practice as providers’ concerns about human milk safety and efficacy may be alleviated by the fuller information. Their work supports our call for a centralized data repository, similar to the Vermont Oxford Network Databases (2014), to be used for benchmarking, research and quality improvement. While both our study and the one conducted by The Connecticut Human Milk Research Center (Brownell et al., 2014) above predominantly explored HMBANA, other organizations, such as Prolacta Bioscience might be expected to improve transparency for safety and health equity reasons.

The potential need for a database that accounts for all donor human milk, or at this time, a HMBANA-wide database system is immense. Such a system would allow milk banks to gather valuable information that can be used in a number of different ways to promote infant health. However, the feasibility of the system needs further investigation. Whether all milk bank directors maintain continual access to a centralized database or the data are compiled and
reviewed at HMBANA meetings, having the information will permit the organization to assess the status of donor human milk banking issues in a more efficient and organized way.

**Allocation of Milk.** Our study revealed a critical need for codification and transparency in the prioritization of donor human milk distribution and in its use. Milk sharers, sellers, bankers, and prescribers, note the importance of knowing who receives milk and how that is determined. HMBANA Guidelines specify that banked donor milk is to be dispensed for clinical use only by prescription or hospital purchase order. If their milk bank is unable to meet the demand of its recipients, they are to contact other HMBANA milk banks for assistance.

HMBANA Guidelines outline the following suggested priority for dispensing donor human milk.

<table>
<thead>
<tr>
<th>HMBANA Guidelines: Suggested Priority for Dispensing Donor Human Milk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recipient Factors</strong></td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>Projected length of need</td>
</tr>
<tr>
<td>Medical condition</td>
</tr>
<tr>
<td>Prognosis</td>
</tr>
<tr>
<td>Prevention of problems</td>
</tr>
<tr>
<td>Research</td>
</tr>
</tbody>
</table>

HMBANA milk banks are required to have a written plan of how to dispense milk by priority to those with greatest need if unable to provide supply for the entire demand. Still, milk bank directors report varying processes for communicating with hospitals and other customers to determine priority distribution when supply cannot immediately meet the need. Hence, donor
human milk bank staff act as gatekeepers to the supply milk, and together with physicians, must decide who gets the milk, including when there is not enough supply to meet all requests.

When we surveyed HMBANA milk bank directors, only two of the 13 banks reported meeting the demand for donor human milk in all 52 of the past 52 weeks. Some of the milk bank directors indicated that the issue of distribution is not a significant problem because they help each other: When one donor human milk bank cannot meet its demand, it can usually work with another milk bank to ensure the need is met. Nonetheless, the issue warrants further investigation because the need for donor human milk may exceed supply in the years to come.

HMBANA and Prolacta both recommend that hospitals using their products have a policy for use in place, which is partly meant to guide prioritization of use. In interviews with hospital personnel, it became clear that they have various approaches to ensuring that their supply needs are met. Some order in anticipation of normal trends in patient census, presuming that all NICU patients meet the clinical need criterion. The banks subsequently fill requests from NICUs based on anticipated need for a two to four week period without reviewing case-specific details. Many

Until we have every preterm and medically fragile population served with human milk, we [milk banks] have no business sharing our milk with healthy infants.

In the ideal world, every human baby receives human milk through at least 12 months of age. But, in this less-than-ideal world, every medically fragile baby gets donor human milk far before we consider anybody else. It’s not any different than the heart transplant industry and I totally get that if you are famous and rich, you can get a heart transplant before my sick people can. But, for the most part, gatekeepers take care of scarce resources. We are the same in milk banking. So, ideally, national marketing, every healthy lactating mother knows she can donate to the non-profit milk banks and she does so. And, therefore, we’re not limited to taking care of these sick babies in the NICU who are 1500 grams and less, but rather all of the babies in the NICUs and the PICUs and all of the human children up through 12 months who don’t have a biological mother providing milk to them.

In the ideal world, the demand is not what it is today. It’s much less, because far more of these moms are breastfeeding their own infants because they either choose to work and are given ample breaks and ample privacy and an environment conducive to breastfeeding, or they choose not to work and they are supported by a social welfare – a system that allows them to make that choice and care for their family at least through 12 months of age.
NICU staff we interviewed reported that donor human milk is only prescribed for babies at risk for NEC (under 1,750 grams) and by “insistent maternal request.” However, one of the pediatricians in our study reported that since the donor human milk banks “won’t provide milk for the well-baby unit, we order extra from NICU and then use it to avoid supplementation in well-baby when moms really want to succeed with exclusive breastfeeding.” The extent to which NICU orders for donor human milk reflect purposeful overestimates of the need for milk for infants receiving intensive care in order to provide milk for healthier infants is unknown. Clearly, the system of providing donor human milk en masse to NICUs can be improved to ensure that the milk is distributed according to need. Moving forward, donor human milk banks should partner with healthcare professionals, key informant recipients and donors, and ethicists to create an enhanced distribution algorithm. While the development of this algorithm may be controversial, Miracle, Szucs, Torke, and Helft (2011) point out, “increasing awareness for the potential for bias would be a prudent first step.” Further, one respondent in our study cautioned of the risk for over-structuring the distribution algorithm: “Milk banks need infra-structure and freedom to create and meet the needs of the community served.”

**Outreach Efforts.** Over the course of our assessment, key informants indicated that donor human milk banking is “winning the battle of acceptance.” Unfortunately, competitors and misinformation have accompanied increasing clinical and public awareness of donor human milk banking. For example, the perception that donor human milk banking is a transactional, for-profit enterprise likely reduces donations and spurs increased interest in mother-to-mother milk sharing. HMBANA may benefit from developing and implementing a comprehensive marketing strategy that incorporates messages tailored around donor human milk banking motivations that
are distributed utilizing multiple channels, including social media. HMBANA may also benefit from increasing engagement in communities, and expanding its donor and processing network.

**Frame messaging around key themes.** A marketing campaign tailored to the primary motivations of potential human milk bank donors would increase HMBANA’s ability to successfully engage women and thereby increase the availability of donor milk. We found that the most influential themes are the ways in which donor human milk improves the quality of life, not only for vulnerable infants, but also for the mothers and families of those infants. Further, the quality of life of donor may be enhanced through an ‘easy’ way to help. Our study respondents indicated a desire for donor human milk banking language that offers a “mother-to-mother” connection with the mothers and infants benefiting from milk donations. While the donors respect the privacy of recipients, many expressed a desire know where their milk is going and to see the fruits of their labor. They would appreciate “the immediate gratification that comes with milk sharing.” One donor suggested that recipients “could self-select to share information about their babies’ after they go home, or the milk bank could even do a monthly report for donors on how many people got milk and some sort of information about them – like to put a more specific face on the reason we pump.” Some HMBANA milk banks use Facebook to post “thank you” messages to donors with pictures of the donors, their babies, and the milk.
Additionally, the Facebook pages occasionally publicize consented “thank you” messages from recipient families. The posts often show healthy babies and older children who had previously received donor human milk while in the NICU. One donor interviewee said, “I like this because it makes it more personal, and milk is personal. I can just feel the oxytocin, and it makes my milk let down!”

The majority of the donor human milk banks with Facebook pages feature images of NICU babies. This practice is important to consider because human milk donors reported being turned off by some images of babies in intensive care units because the photos could be upsetting. Marketing campaigns may be most effective by promoting the value of donor human milk banking for all who are involved, using non-intimidating imagery.

A final aspect of to address with donor human milk marketing language is the importance of safety of the milk for recipients. This issue requires balance in emphasizing the
safety of donor milk for a lay audience and minimizing potential feelings of judgment regarding human milk sharing. Our interview respondents expressed the need for a standard set of materials and messages on donor human milk banking for use by both medical professionals and milk bank representatives. A recognizable graphic for HMBANA may assist in the development of a more coherent and authoritarian organizational message.

In developing and testing HMBANA marketing strategies, there is a need to permit adaptability to the local context. This flexibility is especially important if strong local branding has already been implemented for donor human milk banks. Tailored messages to various target audiences, such as health care providers, new mothers, pregnant women, etc., is also an area for exploration and testing to increase knowledge about donor human milk banking and thereby increase the pool of human milk donors.

**Increase supply from within: staff education/awareness campaign.** Marketing effectiveness is dependent in part upon its successful execution. HMBANA may wish to consider a systematic staff-training program for medical professionals who use donor human milk and/or interact with potential donors. The milk banks currently offer written guidance and inter-personal consultation with the hospitals they serve, but several health professionals who participated in our study noted a lack of formal training on and/or a limited understanding of the donor human milk banking process. Hospital staff comprise an essential partner in the donor human milk banking process. These individuals have the potential to increase the supply of human milk by recruiting prospective donors, educating donors on collection and distribution requirements, and advocating for donor human milk use in NICUs.

One training approach would be a unilateral, web-based or in-person training module. This program would also address common misperceptions and stigmas about donor human milk
and reinforce HMBANA’s central role as an advocate for breastfeeding. To minimize costs, HMBANA may also wish to consider a “train the trainer” program to expand training within hospitals. Incentives for healthcare professionals to participate in the donor human milk training program include offering continuing education credits and a promotional system that would reward the hospital staff who increase the number of human milk donors.

**Expand community engagement.** The location of human milk banks and donors’ ability to access these sites, is a notable driver of the supply of donor milk. The vast majority of Americans do not have a milk bank in driving distance and therefore these women are less likely to see the physical location, meet its representatives, or meet other human milk bank donors. HMBANA views increasing the number of depots as part of the solution to this problem and HMBANA milk banks have been increasing the partnerships with depots accordingly. In addition, each HMBANA-affiliated depot or distribution site may wish to consider establishing and fostering a local donor-recipient network. The network could foster relationships through maternal support groups (especially for mothers of infants in the NICU, who may be working to establish and build their milk supplies). Additional opportunities could be volunteering at the milk banks and ride-shares to milk donation drop-off sites. Further, human milk banking “alumni ambassadors” could promote the awareness and importance of donor milk within their communities.

Donor human milk banking through HMBANA may also from further promotion of its screening and donation processes. The ease of screening and dropping off or shipping milk is valued as one of HMBANA’s strengths. A centralized marketing strategy could highlight the convenience HMBANA offers while reducing perceived access barriers.
**Recommendation: implement an evaluation strategy for potential marketing efforts.** A key component of evidence-based marketing is strategy monitoring and evaluation (M&E). HMBANA could implement a M&E plan, with a focus on healthcare professionals, donors, and potential donors. Central issues to address are marketing visibility, target audience receptiveness to the marketing strategies, changes in volume of donations under different marketing campaigns, and the attitudes and knowledge about donor human milk banking. The qualitative information can be collected through questions on donor milk intake forms (i.e., which of the following impacted your decision to donate to this milk bank?), surveys, focus groups and interviews with donors and potential donors.

**Donor Recruitment and Engagement.** According to the *HMBANA Guideline* (2011b), donor human milk can only be ordered directly from a hospital for inpatient recipients or with a physician’s prescription for outpatients. Milk banks are gatekeepers of milk and consider themselves to be responsible for meeting the needs of the most vulnerable first (Tully, 2002). In the absence of an adequate supply of donor human milk, bank personnel make decisions about who will receive the milk and who will not. It is therefore significant that only two banks we surveyed reported having been able to meet demand in 52 of the past 52 weeks.

Limitations to potential donations is a barrier to engaging adequate numbers of women to donate their milk. According to HMBANA and Prolacta guidelines, women are eligible to become milk donors if they produce enough human milk to meet and exceed the needs of their own infant and also meet screening criteria for medical and social-behavioral factors. Lactating women are also an inherently difficult population to reach due to the time-sensitive nature of the recruitment period. Mothers must not only be breastfeeding, but they must also be aware of donor milk banking and complete the screening process in pregnancy or soon after giving birth.
Then, mothers create a surplus milk supply that is also properly labeled and stored for hand delivery or shipment to the donor milk bank. This extensive process necessitates reaching women at specific moments in time in order to successfully engage human milk bank donors. For this reason, donor human milk banking stakeholders include not only representatives from the milk banks, but also medical professionals who provide healthcare for women and children, current and former human milk donors, as well as groups that may have contact with women during their reproductive years.

Currently, milk banks actively recruit human milk donors with a variety of marketing strategies. HMBANA milk banks currently use brochures to increase awareness of human milk banking. However, the brochures vary on literacy level, messaging, and graphic design. The majority of the brochures are distributed to doctors or hospitals for patients who express an interest in human milk banking. Only one milk bank we assessed reported that the brochures are handed out to a broader population of women (through designated Women, Infants, Children (WIC) clinics).

Four of the eleven milk banks in our study that responded to this question reported that they attend conferences and other events are used to expand the knowledge of human milk banking. The events target medical providers, volunteers, potential funders, women, and others. One milk bank currently offers seminars for medical providers and lay audiences on human milk banking, while another dedicates a full-time staff member to enhancing donor recruitment and engagement.

Further, donor human milk banks utilize the Internet to increase awareness of their services. Social media websites are considered to be helpful in increasing connections among donors who may enjoy interaction with peers, as well as offering a venue for dialogue between
human milk donors and recipients. While seven of eleven of the milk banks who responded are marketing through the Internet, only six of eleven are using social media marketing (Facebook, Twitter, search engine optimization, etc.).

According to human milk donor participants, providing information about milk banking in childbirth classes may be a successful way to recruit future donors. Two out of the eleven HMBANA milk banks are currently marketing through childbirth classes. TV and radio press are used by three of the eleven HMBANA milk banks to expand awareness of donor human milk banking to a wide audience.

Marketing for HMBANA milk banks has traditionally been performed by the individual milk banks in an effort to deliver tailored message to the particular communities. Centralization of recruitment may decrease potential for collective impact through pooled resourcing in terms of finance and human services. Some of the milk banks have begun tracking the donor motivations for donating milk, but this process has not been standardized. Therefore, evidence-based marketing plan development has not been accessible for a majority of the milk banks.

Several themes about donor human milk banking motivations emerged from our interview and survey responses:

**Donor motivations: easy and convenient.** Many donors preferred to downplay their heroism. Instead, almost all donors were motivated to donate by abundant supply of their milk and not wanted to waste it, which is consistent with previous findings (Arnold & Borman, 1996; Azema & Callahan, 2003). Another donation theme was “simple ease of access.” Many women indicated that their International Board Certified Lactation Consultants made milk donation seem like a straightforward process. For example, a participant recalled being casually informed that “and, if you have extra once you’re all settled, consider donating to the milk bank.”
According to Infant Feeding Practices Survey II results, 85% of breastfeeding moms express milk between 1.5 and 4.5 months postpartum and 92% of those women who are breastfeeding at 7 months postpartum had expressed milk. (Fein SB, Labiner-Wolfe J, Shealy KR, Li R, Chen J, Grummer-Strawn LM. 2008) With so many women breastfeeding, and so many expressing their milk, every effort should be made to enable women to express extra for donation. The following donors report ease of expressing for human milk banking:

**All moms should learn how easy it is to be a donor! The milk bank pays all costs. The milk banks prioritize NICU babies, so you're the difference between life and death. And, everyone gives different amounts, so no one should feel intimidated by the quantity they will have to accumulate.**

"I pump just keeping up with them [two babies], so it's not like I'm putting a lot of extra effort in. I'm just giving what's left over. I'm not that good of a person, like I'm going above and beyond to produce extra. It just happens that way, so I go with it."

"I just know that I'm helping a good cause and it's not really that hard for me to do it... I pump one extra time each day for the bank, then drop it by when the freezer gets too full." [Husband adds] She has to pump at work anyway, so either it's use it for a good cause or throw it out."

"I think calling it donating is one thing. When I started thinking of it as volunteering, I started thinking "Okay, that’s where my time is going... There’s my volunteer hours!"

The presence of the husband during one of the above-mentioned interviews, and his supportive statement, highlights of a predominant theme: the importance of perceived approval in milk donations from partners, friends and other mothers. Social support for breastfeeding is known to be important for breastfeeding initiation, duration and exclusivity, and this assessment supports findings that it is also true for human milk donation (de Alencar & Seidl, 2010; Rempel, 2004).

**Donor motivations: save lives.** The life-saving properties of human milk are one of the strongest motivations identified as a reason for donation by current and former donors. Milk bank donors are driven by the vital role human milk plays in providing the best health outcomes.
for premature and other vulnerable infants.

“It can save lives for the littlest and most fragile babies.”

There actually was somebody up when I was birthing... a little neonatal baby and in the back of my head [I was] thinking of that baby when I was pumping. Born at 22 weeks or something. I also saw on the news that he was there.

“It’s hard to imagine that I might have otherwise discarded this amazing gift.”

All parties involved in donor human milk banking promote the life-saving properties of human milk. Human milk is commonly referenced as “liquid gold” and a valuable gift.

**Donor motivations: personal benefits.** The other significant motivating factors for human milk donation identified by donors was personal benefits. From weight loss to personal empowerment, women offered statements of how the milk donation process enhance their lives:

“It gave me confidence, which in turn, made me a better mother.”

“On a lighter note, pumping burns calories...who doesn't want to get back into their pre-pregnancy shape and SO fast!”

“(1) gets you tested for several diseases free of charge, (2) allows you to become familiar with FedEx schedulers & drivers, (3) empties your freezer regularly”

We strongly suggested to [donors] that this is a partnership deal, that if I can influence you as the biological mother of that child and I can affect positively your ability to lactate successfully for that child, that’s great. But, if I can also say to you, you can feed your child and you can feed ten preterm infants, because they take a very small volume of milk, because you are healthy and able to follow protocols for successful expressing and storage of your milk, you have a power beyond the care of your own child.

**Donor motivations: safety through medicalization.** Our participants identified the “known” safety of donor milk as being important to donors and medical professionals, in contrast to the milk that may be received through mother-to-mother milk sharing.
Information regarding the safety of donor human milk generally employs the use of medical language to describe the elements of donor screening and milk processing. Several milk bank affiliates (directors and neonatologists) reported that they prefer not to deviate from this clinical language “because it shows credibility… it distinguishes us from other well-intended milk providers.” Donor responses suggest that lay comprehension of messages about safety do not require familiarity with clinical vocabulary:

"I feel as a neonatologist I should warn parents against [human milk sharing], saying, 'Make sure that you know this milk is going to be safe for your child. It’s been tested. It’s been pasteurized.' There are risks – making sure they know about that"

"Yeah. I trust [milk banks] when there’s screening and there’s the pasteurizing and everything… I was impressed with how extensive it is... I don't think it's a big deal to go through because it would make me feel better, you know, if I was on the receiving end."

"[Recipients] should know that we are definitely screened. And that we are all healthy. I don't like to feel like a drug dealer because you've got to worry about people like that, but they need to know that people here aren't doing it for the wrong reasons… it's just so natural, and everyone's really good... and clean... and well-screened and everyone has their milk."

One milk bank affiliate recommended that HMBANA provide information in its marketing materials on how HMBANA banks process milk. The purpose of publicizing the safeguards would not only to provide general insight, but also to illustrate the reason for the high fees associated with banked donor human milk. The Mother’s Milk Bank at Austin has already responded to this finding and has established the following: a “Follow the Milk” display in its headquarters, a photographic handout for donors, and a Facebook program called “Follow the Milk Fridays.”
Marketing.

Research on HMBANA and HMBANA Milk Banks’ marketing strategies was a major focus of this assessment. Themes were developed around recommendations for ways to improve milk bank marketing based on current successful strategies and strategies that need to be updated or changed.

**Marketing milk: the need for standardization and/or resource pooling.** In our key informant interviewees, medical professionals and milk bank stakeholders expressed a desire for a standard, centralized HMBANA marketing campaign (Throughout the course of this assessment, HMBANA was able to procure and allocate resources for centralized marketing. Their efforts are in process, and therefore are not the subject of any analysis herein.)

“So, ideally, national marketing, every healthy lactating mother knows she can donate to the non-profit milk banks and she does so.”

“Is there one HMBANA brochure that has all the milk banks listed? I know each of the milk banks has its own, which is fine, but there ought to be one over-arching brochure or piece that has all the appropriate websites and emails on it and the general agreed-upon statement about when you use donor milk and what it is and how safe it is and all of that so it can be a life saver with flexibility to adapt to local offices.”

**Marketing ideas: focus on mother-to-mother and donor community.** Human milk donors desire connections among donors and between donors and recipients. This relationship
approach is suggested instead of rather than focusing on the medical aspects of human milk banking, which was the previous HMBANA focus on in efforts to engage new donors.

“\textit{And in terms of what the impact of the donated milk can do, they're on the side of talking about the impact of the donated milk will be to prevent a baby's death. And I'm posing that they shift into a language that talk about what saving that life means, what kind of happy future that baby will face.}”

The softer language is recommended in addition to social marketing and appreciation events. Six of eleven HMBANA milk banks responding to our survey reported using social media to establish mother-to-mother connections. This is a low-cost method to create a community for donors and recipients.

“\textit{Internet sites are trying to foster this sense of community. It is an identity. The Milk Bank is working on using social marketing to facilitate voluntary interaction between donors, supporters, recipients.}”

Social media also permits donors and recipients to self-select to disclose that they either donated to or received milk from the bank. Self-disclosure is important because milk banks are restricted by HIPPA laws and cannot connect donors and recipients without consent. Finally, appreciation events for donors are perceived to be an approach for fostering a sense of community among donors and to bring donors and recipients together. One donor said that she would like to tour the human milk laboratory, tour the NICU, and attend meet-ups of recipients and/or other donors. Another donor suggested that donors could receive “milk drop pins” after donating a set amount of milk, or at the end of their donation eligibility. The pins would incentivize and acknowledge donation, but also provide a talking point for telling others (especially potential donors) about their experiences.

“\textit{Annually, they have a, sort of like a “thank you” party...this year was at one of the big parks where the donors are invited and former recipients are invited and they get to sort of intermingle. And, there’s a small moment where people give speeches, you know, where they will ask a recipient family to just come and talk for a few minutes.}”
Exception to mother-to-mother. Some NICU situations are an exception to the desire among human milk donation recipients for mother-to-mother connection between themselves and donors:

“I think that the anonymity of it all is not a bad thing, especially since the milk is being all pooled together, and when you’re in the NICU or you’re somewhere knowing that there are mothers with healthy babies that are helping you, it’s great. But, being confronted with that is difficult. It’s difficult when everywhere you go all you see are, you know, healthy, typical babies and you don’t have one.”

In addition to mothers with an infant in the NICU, those women who are having lactation difficulties may or may not wish to meet mothers with an abundant milk supply. After the infant is no longer confined to the NICU and/or once infant feeding issues are resolved, donor human milk recipients may become more interested in establishing connections with human milk donors. The recipient women may appreciate the opportunity to express their gratitude and show off their growing child.

Marketing to Increase Knowledge. Despite the increasing awareness of donor human milk banking in the United States, misconceptions persist among both donors and medical professionals. Three methods emerged from our data to promote understanding of human milk banking practices: (1) expansion of donor human milk banking marketing to obstetricians (OBs), (2) including milk banking education in prenatal classes, and (3) increasing access to comprehensive breastfeeding support.

I think reaching women when they’re pregnant before they’ve had their babies is a great way to kind of prep for it. Because you’re prepping for everything while you’re pregnant — you know, you’re buying all these things and you’re making all these plans that will probably all be like dashed against the rocks. But, if you reach a pregnant woman and you say, “Listen, you don’t have to have excess supply to donate to the milk bank.” You can go into it thinking, “I’ll just have one extra pumping session a day,” and you know, that milk will go aside — like helping them come up with a plan and just saying like, “Maybe try taking, you know, ibuprofen instead of Vicodin the first few days you’re home from the hospital if you’re interested in donating milk,” like, just kind of catching them early and showing them that it’s not that hard.
Expansion to Obstetricians. HMBANA’s ability to reach potential human milk donors before they give birth may be expanded with the provision of information on human milk banking to OBs and others who provide care for pregnant women. Both medical professionals and milk bank affiliates cited OBs as a health care provider who is well placed to provide brochures and other resources about milk banking. In addition to the potential for recruiting donors, education about donor human milk banking from OBs may also help to normalize breastfeeding and human milk. Furthermore, suggesting that a patient may make an excellent milk donor is an inherent expression of confidence that she will be successful in breastfeeding.

“So, it was really good for us to see an OB and to, be able to, you know, kind of understand where they’re coming from and how – have her help her consistency. You know, find out how, how important they are in the milk banking industry. I don’t think we do enough for OBs. We don’t really do a lot with OBs and we need to start doing that.”

Expansion through childbirth education and prenatal breastfeeding classes. Several human milk donors we interviewed said that they were introduced to milk banking through childbirth education and prenatal breastfeeding classes. All of these prenatally prepared donors were living nearby HMBANA milk banks and attended classes at affiliated hospitals. Future studies could assess the prevalence of donor human milk banking information inclusion in prenatal classes at facilities, by HMBANA affiliation and proximity. In circumstances in which potential donors do not the access and familiarity of a local human milk bank, it may be helpful to partner with childbirth education certifying agencies and curriculum providers (including Lamaze, International Childbirth Education Association, and others) to test and implement this donor human milk banking prenatal education.

Expansion through comprehensive breastfeeding support. While awareness of donor human milk banking is a critical issue, more women reaching their breastfeeding goals are
needed. One donor interviewee in our study reported that she had first considered donating milk after her midwife commented on how full her breasts were during her routine postpartum exam.

**Expansion: access, promotion and convenience.** The need to expand the HMBANA reach of was identified as a next step by all of our interviewees and survey participants. The main themes corresponding to expansion are access, promotion, and convenience.

**Access.** HMBANA milk banks often work with milk depots, where families drop their milk donations off. The milk banks provide shipping materials and cover delivery costs. These costs are either generally covered in the fees for milk (paid by hospitals, insurers, and recipients directly) or by the milk banks themselves by using donations. Additionally, volunteer milk bank staffers lower direct costs of the final products. Therefore, to increase the cost-effectiveness and to keep pace with the growing demand for human milk, strong preferences were expressed for expanding the number of milk banks, and/or increasing capacity of existing milk banks by adding depots. Medical professionals and donors frequently expressed a desire for a milk bank to be available in every state and/or a depot in or near virtually all hospitals with Levels III or IV NICUs. (In the United States in 2011, there were 715 Level III and 130 Level IV NICUs (AAP, 2012b). The typical response for access to human milk was: “If you’re going to be part of the demand, you should be part of the supply.” One milk bank affiliate suggested that hospitals could act as their own collection site, ship the milk to centralized regional processing centers, and then have the milk returned for their own use. With this framework, hospitals are responsible for their own supply and may therefore be more likely to increase donor recruitment and breastfeeding support.
The desire for a convenient donation process was a common theme among human milk bank donors. These women with experience donating their milk largely stressed the accessibility, brief time, and minimal cost associated with the donor process.

"If my friend was worried about the time it would take, or the expense to ship it (I shipped mine from South Dakota), I would highlight that it cost me nothing. HMBANA provided all but the milk, and the directions and assistance from HMBANA made the process easy. Goodness! Why not?!"

"It was so easy. Easier than I thought it would be."

In addition to expanding and increasing the number of donor human milk banks, several interviewees suggested multiple benefits of opening additional milk depots. There are currently 156 milk depots working with HMBANA milk banks. These depots are collection sites for local lactating mothers who have been screened and approved by a HMBANA milk bank that might be too distant from the donor to facilitate easy drop-off. According to HMBANA Guidelines (2011b), milk depots have two essential requirements: maintenance of dedicated freezers with controlled temperature and security and detailed recordkeeping that enables the milk bank to trace all milk to the individual donors.

Milk depots are typically opened after coordination between the banks and a hospital. The most common and “best” practice is for the HMBANA milk bank to:
1) Seek out depot locations where there are existing high rates of breastfeeding and ample breastfeeding support.

2) Send information about becoming a HMBANA Donor Human Milk Depot to a hospital that has self-identified, a hospital using milk from the bank, or a hospital identified by others are being a good potential depot.

3) Send a representative to discuss use of donor human milk in-hospital, as well as benefits and responsibilities of becoming a HMBANA-affiliated depot.

4) Support efforts to recruit donors and host a grand opening.

5) Continue to partner to ensure satisfactory donor experience, freezer maintenance, shipping safety and record keeping.

The sixth “best practice” often goes without mention: the prioritization of requests for milk from hospitals that operate affiliated depots.

The practice of distribution prioritization by organizational affiliation creates a mutually beneficial relationship among the participating institutions, by ensuring adequate supply for the hospital and for the bank. However, this practice raises ethical concerns. A fundamental principle of donor human milk banking (as opposed to milk sharing or selling) is the prioritization of milk distribution to the most vulnerable infants. In the case of affiliated hospital prioritization, though, human milk is a consumer commodity. The conflict of interest is this agenda means that infants most in need may not be the ones most likely to receive the milk.
Community-based milk depots serve as convenient local drop-off sites for donors, but interviewees also point out that they are important in spreading the community message about the importance of human milk. The presence of a milk depot sends a message to providers, patients, and community members that human milk is a high public health priority.

Some women offered improvements for the milk donation process. The recommendations include bank had extended drop-off hours, partnership with local resources to coordinate pick-ups, and/or drive-through windows for drop-offs.

**Promotion and staff education.** We found large disparities in the level of awareness and education among medical professionals about donor human milk banking. This lack of education can lead to the proliferation of misinformation, such as a respondent perceiving formula to be superior to donor human milk. Another concern about inadequate medical training related to donor human milk is missed opportunities for donor recruitment. Respondents in our study also cited a preference for research statistics to illustrate the value of donor human milk in promoting infant health.
Prolacta Bioscience, Inc.

Prolacta Bioscience is a privately held, for-profit company that refers to itself as “the pioneer in standardized human milk-based nutritional products for premature infants in the neonatal intensive care unit” (Prolacta Bioscience, 2014b). Founded on the principle that infant nutrition should be human milk-based, Prolacta is responsible for producing the first and currently only human milk-based fortifiers. These fortifiers are designed to complement mothers’ own fresh milk with essential minerals, added calories, and more protein.

Processing Human Milk into Standardized Human Milk Products. Until 2014, all milk donated to Prolacta was processed into nutritional products for preterm infants in NICUs, except for a portion of the milk that was donated to the “International Breast Milk Project.” That project tested, pasteurized, standardized and shipped the milk donations to Africa for infants who do not have safe access to their own mothers’ milk. Prolacta produced four fortifiers, each intended to achieve particular nutritional targets when added to mother’s own milk, and one specifically for trophic feeds. In February of 2014, Prolacta launched three new products: Prolact HM$^\text{TM}$, Prolact CR$^\text{TM}$ and Prolact RTF$^\text{HM}$ (Ready to Feed). These products are standardized, pasteurized donor human milk for use alone or with mother’s milk (Prolacta Bioscience, 2014a).

Prolacta markets the standardization of their products as an important advantage for medical practitioners. According to Prolacta representatives interviewed in this study, providers that prefer to control the caloric and protein contents of their patients’ feeds are able to do so with “unparalleled precision” by using Prolacta’s Human Milk Fortifiers (with added minerals), Human Milk Caloric Fortifiers (no added minerals) and Ready-to-Feed Human Milk-Based Premature Infant Formula (with added minerals). Prolacta products are analyzed and labeled according to AOAC methods. The AOAC Stakeholder Panel on Infant Formula and Adult
Nutritionals is funded by the Infant Nutrition Council of America, previously known as the Infant Formula Council, on behalf of Abbott Nutrition, Fonterra, Mead Johnson, Nestle, and Perrigo. (AOAC, 2014) Prolacta argues that this protocol should be the standard for human milk analysis and labeling. According to Prolacta executives, “AOAC methods for nutritional testing of foods are the standard in the US. However, there are no AOAC methods specific to human milk. Labs typically use cow milk methods. We start with AOAC methods and validate them specifically for use in human milk. Appropriate microbiological methods may be taken from AOAC or the FDA Bacteriologic Analytical Manual. However, again these methods should be demonstrated to be appropriate through validation or method qualification. If other methods are used, they should be appropriately validated to ensure accurate, precise and repeatable results.”

Prolacta Bioscience products are regulated as food (except for RTF, Caloric Fortifier and other Fortifiers, which are regulated as exempt infant formulas), as is donor milk distributed by HMBANA milk banks. Prolacta developed methods of processing human milk that adhere to the FDA’s Pasteurized Milk Ordinance and other “industry-leading safeguards that exceed current industry standards.” Prolacta’s website states that they have conducted four (and published two) studies on the high temperature short time (HTST) pasteurization process they utilized to evaluate the effectiveness in whole pasteurized human milk and versions of their preliminary fortifiers. Furthermore, their website states that they also have data on file to (as part of the same set of experiments) for a vat pasteurization process also used by Prolacta (Prolacta Bioscience, 2014c).

Prolacta products are designed to support “a 100% human milk diet” for babies born weighing less than 1250 grams. While most healthcare professionals refer to all fortifiers as “human milk fortifiers,” it is worth noting that only Prolacta’s fortifiers are actually made from
human milk. All other fortifiers are made of non-human milk proteins, usually bovine or soy. Prolacta staff report that human milk is concentrated to approximately 8-10 times to produce a fortifier. Prolacta’s formulations are fortified with essential minerals (according to Pediatrics Nutrition Handbook, 6th Edition specifications) and offer protein delivery up to 3.7g/100mL of fortified milk\(^1\) and 24 to 30 Cal/fl. oz., in support of adequate growth and neurological development of the preterm infant (AAP, 2009). When added to human milk, Prolact+ H\(^2\)MF\(^\circledast\) was demonstrated to reduce the odds of developing NEC by 77% in premature infants weighing between 500 – 1250g at birth compared to infants receiving human milk fortified with cow’s milk-based HMF or preterm infant formula (Prolacta Bioscience, 2014a; Sullivan, 2010).

**Risk Management Practices.** Prolacta is heavily invested in developing technologies that ensure milk safety, manage product risk, and decrease the burden on human milk donors. Built on the model of the human plasma industry’s work, Prolacta’s systems for processing human milk indicate treating the substance as a biologic (as opposed to a food or medication). Accordingly, their system has a series of unique tests intended to safeguard the quality of the milk. Prolacta performs in-house DNA matching of every donation to the donor, ELISA method testing for illegal drugs, nicotine and caffeine, dilution and adulteration, (at the donor screening point), both nucleic acid and antibody testing (NAT) for all bacterial and viral contagions at the donor screening point, and NAT again for HIV-1, HBV and HCV in the product. While effects of dilution and adulteration may be eliminated in processing, the company typically discards such donations and dismisses the donor because they may not be eliminated, and they prefer to maintain a donor pool of highly ethical and responsible donors. They have also designed and validated a reusable soy-based cooler that consistently holds temperature for 72 hours, eliminating the risk of milk thawing and bacterial growth that may occur in transport. All
Prolacta inventions and acquisitions (minerals, coolers, bags, etc.) are sent for external evaluation and quality assurance prior to full implementation. With these technologies, the Prolacta Senior Administrators intend to minimize the burden of testing and screening donors, and shift the emphasis on 1) testing the milk, and 2) educating, supporting, and incentivizing donors. For example, all accepted donors attest to be non-smokers. Still, Prolacta representatives explained via interview that they test for nicotine in the milk, educate the donor on risks of nicotine contamination for NICU babies, and encourage smoking cessation when nicotine is found in the milk.

The Prolacta Senior Administrative Leaders contend that their technologies build the potential for providing financial incentives for human milk donation. They plan to report on studies designed to assess feasibility of a model that “pays moms and protects babies” in 2014. “This field has always thought it impossible to pay women for their work because it might entice them to degrade the quality of the milk. We’ve developed high through-put tests that put us in a unique position to ensure the quality of the product, minimize the risk to [recipients], and pay women for their time and effort.” The Prolacta pilot tests involved paying women $1 per ounce of milk that passes the adulteration, drug and dilution testing, and Prolacta expects to expand the model at this rate. If the donated milk is found to have unacceptable bacterial counts, Prolacta expects to still pay women for that milk; however, they “reserve the right to stop accepting milk from a mom that is continually high in bacillus cereus.” Prolacta also anticipates paying “for milk from qualified donors that is unacceptable for our use due to medications that mom is taking temporarily... so donors have no financial incentive to hide medicine usage that might hurt [recipients].” In the charitable model, a donation of $1 an ounce is made on behalf of the mom to a charity (e.g. Make-A-Wish Foundation) and they reimburse the woman for her breast
pump. Preliminary testing of this model suggests they can do so without adding to the cost of the product for hospitals.

**Sites and Operations.** Potential Prolacta human milk donors select from twelve milk banks. All of these milk banks are operated solely for recruitment. No Prolacta donor human milk banks screen donors or collects, tests, or processes milk. All milk donations are sent directly to Prolacta headquarters for processing and distribution. Therefore, Prolacta milk banks are fundamentally different than the definition of HMBANA milk banks. The Prolacta milk banks are identified as “affiliated with,” “operated by,” or “in partnership” with the company. Some of the milk banks are independent organizations that recruit donors and receive shares of Prolacta products. An example is the International Breast Milk Project (http://www.breastmilkproject.org), which reports sending 25% of milk contributed to infants suffering from HIV/AIDS, malnourishment, poverty and disease in Africa. Other organizations that work with Prolacta receive financial compensation ($1) for each ounce of milk donated to the banks in their names. Examples of these charity-donation arrangements, to “make your milk go twice as far,” are the Susan G Komen and Make-A-Wish Foundation. Prolacta senior administrative leaders refer to this charity collaboration as “multiplying the good” and report nearing two million dollars of charitable donations to these organizational partners to date. Other Prolacta affiliated milk banks are brands of “virtual milk banks” designed to appeal to donors with different interests. An example of an online milk bank is Milkin’ Mamas (http://www.milkinmamas.com).

**Donor Recruitment and Engagement.** As described above, our key informant interviews revealed that human milk donors are motivated by various reasons. The most common themes for donation are supporting the survival of critically ill infants, volunteerism and
philanthropy, “doing something good,” and participating in a community of “sisterhood.” The Prolacta donor human milk banks respond directly to these maternal motivations to attract and retain donors (see Table 4). While all milk is received by, processed and distributed from Prolacta headquarters, Prolacta “milk banks” are each branded to appeal to donors motivated by various factors. Potential donors can visit Prolacta.com, and click “Find a Milk Bank” or they can go to different sites for each “bank.” Four of the sites are distinguished by being hospital-based, which emphasizes direct service to hospitalized, critically-ill infants. In two of these clinical donation settings, the messages explicitly state that donations to their banks goes towards establishing the human milk supply in their local facilities. According to a Prolacta representative, this branding is designed to appeal to donors that find it “rewarding to make a difference for the families in our own communities.” Four of the sites appeal to potential donors for whom milk donation represents a way of charitable giving which may not be financially possible otherwise. Examples include Helping Hands and Milk for Wishes, and the International Breast Milk Project which appeals to many whose charitable aims may be foreign or African specifically. Two sites are designed to attract potential donors interested in the “sisterhood” of sharing milk, best exemplified by National Milk Bank and Milkin’ Mamas, both of which appear fun and youthful.

Table 4. Human Milk Bank messaging.3

<table>
<thead>
<tr>
<th>Prolacta Sites</th>
<th>Clinical Urgency</th>
<th>Philanthropy or Volunteerism</th>
<th>Sisterhood</th>
<th>Simplicity of Doing Something Good</th>
<th>Local</th>
</tr>
</thead>
<tbody>
<tr>
<td>BayCare Donor Milk Program</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>FirstSteps</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3 Note: Update: Prolacta no longer partners with South Coast or Minnesota. They have added BayCare, Benefis, CHOC, First Steps, Piedmont, Tiny Treasures, University Health System, and Wesley Medical Center.
<table>
<thead>
<tr>
<th>Donor Human Milk Bank</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Helping Hands Milk Bank</td>
<td>1</td>
</tr>
<tr>
<td>International Breast Milk Project</td>
<td>1</td>
</tr>
<tr>
<td>Milk for Wishes Milk Bank</td>
<td>1</td>
</tr>
<tr>
<td>Milkin’ Mamas</td>
<td>1</td>
</tr>
<tr>
<td>National Milk Bank</td>
<td>1</td>
</tr>
<tr>
<td>Palmetto Health</td>
<td>1</td>
</tr>
<tr>
<td>San Gabriel Valley Milk Bank</td>
<td>1</td>
</tr>
<tr>
<td>South Coast Milk Bank</td>
<td>1</td>
</tr>
<tr>
<td>Texas Children’s Hospital</td>
<td>1</td>
</tr>
<tr>
<td>University Health System</td>
<td>1</td>
</tr>
</tbody>
</table>

One of Prolacta’s primary human milk donor recruitment and retention strategies is to “make it easy to get screened and start donating.” For this reason, the company has produced a series of YouTube videos to educate families and health professionals about their products and about the NICU more generally. Through this public outreach, Prolacta puts forward their role as experts in the care of very premature and micro-preemie babies. On YouTube, there are over 14,000 views of the video “What is Human Milk Fortifier and Why Does My Premature Baby Need It?,” nearly 3,500 views of a video explaining “Prolacta Human Milk Fortifier Product and Safety Standards.” In 2013, Prolacta introduced a YouTube video series, “What to Expect in the NICU,” designed for parents and other family members of babies who spend time in the NICU. The video series is designed to demystify the NICU experience by explaining terminology, equipment, medical conditions, optimal infant nutrition, and more. Throughout our key informant interviews, human milk donors and recipients expressed desire for more information about how milk is processed and used. While evaluation of YouTube videos would be useful, it seems that this method of communicating information may empower families in their NICU and human milk experiences.
**Information Management.** Like HMBANA, Prolacta tracks their human milk products by knowing which lots are sent to which hospitals and which donations were pooled into each lot. Prolacta also retains a sample of milk from each donation in case the need arises to trace contamination back to an individual donor. The company also retains samples from the final lots for investigation purposes. The pasteurization methods at Prolacta allow for large lots, often up to 1500 liters (~51,000 ounces) and 400 donors per lot.
Physician Perspectives on Donor Human Milk

Our findings indicate the central role of the providers of healthcare services for promoting human milk use and breastfeeding. We surveyed members of the Academy of Breastfeeding Medicine (ABM). ABM is an international professional organization comprising physicians with a special interest in breastfeeding.

The 71 US-based physicians who took part in our study varied in age, with an average age of 50 and medical school graduation in the 1980s; 94% had had a personal experience with breastfeeding, defined as having breastfed or having had a partner who did so, and 87% were women. The majority were pediatricians (47% pediatricians, 25% neonatologists), with the remainder including the specialties of breastfeeding medicine, family medicine, OB/GYN, and preventive medicine/public health.

ABM physicians with personal breastfeeding experience (94%; n=67) reported sharing milk with a known peer (14%; n=10), with an unknown peer (6%; n=4), and with a non-profit human milk bank (7%; n=5). Among those with a reported “positive breastfeeding experience,” (81%; n=55) had prescribed use of mother’s or donor milk within the last 60 days. The majority (74%; n=53) had prescribed mother’s expressed milk, and more than one third (35%; n=25) had prescribed donor human milk from a milk bank. This last finding is consistent with the findings of Sattari, Levine, Neal, and Serwint (2013), that despite high breastfeeding initiation rates, physician mothers are at risk of early breastfeeding cessation, like many other populations. Eighty physician mothers were interviewed in Gainesville FL and 97% of their infants were breastfed. Only 34/57 (60%) who planned to breastfeed for a year reached their goal, with nearly half stating that cessation was due to employment demands. Physician mothers who reported actively promoting breastfeeding to their patients and housestaff breastfed four months longer
than those who reported not actively promoting breastfeeding (p<0.001). There demonstrates that there is clearly a need to support breastfeeding duration among physician mothers (Sattari et al., 2013), both for their own health and potentially for infant feeding guidance they offer to patients.

**Prescribing Practices.** Prescribing practices among this breastfeeding-supportive cohort varied by specialty, as expected. Among the pediatricians, 8% had prescribed non-pasteurized milk from another mother, 3% from an unknown mother, and 6% prescribed use of a surrogate or wet-nurse. In addition, 11% had prescribed human milk for NICU, 14% for non-NICU, and 32% for outpatients. Not surprisingly 89% of the neonatologists had prescribed for NICU patients, and 17% for non-NICU patients. None of the respondents had prescribed human milk for adolescents or adults. Logically, neonatologists were much more likely to prescribe human milk than pediatricians: 89% and 39%, respectively. Pediatricians were less likely to prescribe donor milk, and among those that did, 56% of reported prescriptions were for outpatients, while all neonatologists reporting prescribed in in-patient NICU settings as well as a minority that also prescribed for non-NICU patients. This breakdown, in all likelihood, is reflective of their practices and patient population served. The most commonly reported reasons for the use of donor milk were prematurity, NEC, maternal medication, delayed lactogenesis, breast pathology or maternal illness, low infant birth weight, and significant infant dehydration that was not improved by skilled support for breastfeeding.

The survey asked providers to report what types of human milk and for which patients they had prescribed in the past 60 days. Not surprisingly, neonatologists reported having prescribed all forms of human milk, but especially banked donor milk, more frequently than other providers (Table 5). Also not surprisingly, providers reported prescribing most frequently for NICU in-patients.
Table 5.

Physician prescriptions of human milk, by pediatrician or neonatology specialization.

<table>
<thead>
<tr>
<th>Types of Human Milk Prescribed</th>
<th>All N=71</th>
<th>Pediatricians N=33</th>
<th>Neonatologists N=18</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expressed mother's own milk</td>
<td>74%</td>
<td>72%</td>
<td>95%</td>
</tr>
<tr>
<td>Donor milk from a milk bank</td>
<td>35%</td>
<td>14%</td>
<td>84%</td>
</tr>
<tr>
<td>Donor milk from known mother</td>
<td>10%</td>
<td>8%</td>
<td>0%</td>
</tr>
<tr>
<td>Donor milk from unknown mother</td>
<td>1%</td>
<td>3%</td>
<td>0%</td>
</tr>
<tr>
<td>Wet-nurse or surrogate</td>
<td>5%</td>
<td>6%</td>
<td>0%</td>
</tr>
<tr>
<td>None</td>
<td>23%</td>
<td>22%</td>
<td>5%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Groups Prescribed Human Milk</th>
<th>All N=71</th>
<th>Pediatricians N=33</th>
<th>Neonatologists N=18</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-patient, NICU</td>
<td>37%</td>
<td>11%</td>
<td>89%</td>
</tr>
<tr>
<td>In-patient, Well-baby</td>
<td>15%</td>
<td>14%</td>
<td>17%</td>
</tr>
<tr>
<td>Out-patient, pediatric</td>
<td>22%</td>
<td>32%</td>
<td>0%</td>
</tr>
<tr>
<td>Out-patient, adolescent / adult</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>None</td>
<td>41%</td>
<td>61%</td>
<td>11%</td>
</tr>
</tbody>
</table>

**Donor Engagement by Physicians.** The respondents estimated that about 80% of mothers in their practices with infants in the NICU provide their own milk, often noting that mother’s milk supply may diminish with long NICU stays. However, even among this human milk-friendly cohort, the physicians report discussing becoming a milk donor with only about 6% of the mothers who are expressing milk or breastfeeding; one reported that it was not their role to do so, and those who had had negative breastfeeding experiences discussed the issue with less than 1%; however, there were only three physicians in this category.

**Physician Attitudes about Human Milk.** The vast majority of respondents indicated on Likert scale with an average score of 4.6 out of 5, where 5 is the highest agreement, that they considered pasteurized donor human milk to be the best supplement when mother’s own milk is unavailable for all babies when compared to commercially available artificial baby formulas. This average was slightly higher (4.8 out of 5) when asked the same, but for the NICU baby. And, this average was only slightly lower (4.36) when asked the same, but for the term baby with
a clinical indication for supplementation. Physicians were notably less supportive of informal/peer-to-peer milk sharing. When asked whether informal/peer-to-peer milk sharing (milk that is given freely by mother to mother and is not pasteurized in a milk bank) is a reasonable practice, the average Likert scale score was 3 of 5. However, when asked whether sharing of non-pasteurized non-banked milk might be a reasonable practice if there were guidelines to follow for testing donors for transmissible diseases and safe collection and transportation of milk, the average score was increased to 3.95 out of 5.

**Provider Report of Donor Human Milk Availability.** In their own practice, 31% of pediatricians (15 of 47), and 47% (12 of 25) of neonatologists reported incidents when they were unable to obtain donor human milk when needed.

**Informed Consent**

Another issue that is increasingly being discussed among clinicians is whether there is need for informed consent for human milk receipt by the adult responsible for the child. HMBANA offers a sample acknowledgement form, which providers may adapt and use in practice. A recent discussion on a ABM physician’s listserv included whether special consent is needed, beyond the overall consent upon hospitalization. The majority felt that the use of banked milk was part of normal care, hence, no special permission is needed. However, this is an issue that merits a formal consent guidelines. A reasonable ethical argument is that there may be a need for informed consent for the use of premature formulas, since these are associated with higher incidence of morbidity and mortality than with the use of donor human milk. In any case, education-empowered, family-centered care would require, minimally, engaging recipient’s caregivers in their infant feeding decisions.
The use of incentives to mothers to encourage milk donation has also been an area of interest in terms of ethics and encouragement of donation. Currently, in some cases, hospitals receive incentives for encouraging donation; in other settings, women may be offered free or reduced price pumps as an incentive to donate. The latter, arguably, may be considered a necessary device for a person to become a donor, however, such practices deserve oversight and consistency, as well as study for any impact on unbiased informed consent.

**Pasteurization Techniques**

All human milk banks process donated milk to eliminate pathogens and the accepted approach is pasteurization. Pasteurization, named after scientist Louis Pasteur, is a process that generally employs heat to destroy pathogens in milk. Earliest pasteurization techniques were methods of scalding or boiling milk. Although pasteurization was originally developed for processing cows’ milk, some of these methods have been adapted for use in the pasteurization of human milk. Today, the predominant pasteurization technique employed by HMBANA-approved facilities is Holder Pasteurization, which calls for milk to be heated to 63°C (143°F) for 30 minutes.

**Holder Pasteurization: Benefits and Risks.** As noted previously, the FDA, in considering control of human milk pasteurization follows the same guidance as for cow’s milk pasteurization. The Holder method reduces or eliminates the pathogen load but the prolonged heating required by this method also reduces the nutritional/biological quality of donor human milk, resulting in excessive inactivation of important bioactive components. For this reason, many experts today are calling for pasteurization techniques that could optimize the composition of the final product. One expert on oligosaccharides commented that the Holder method is used
because “we do not have enough information yet to change” or to convince the FDA that change would be beneficial. Further, if there were a simplified and less expensive pasteurization approach, it might be feasible for large hospitals to maintain their own milk bank, obviating the need for shipping and possibly for the double freezing of donor milk. These changes would both increase availability and may reducing destruction of milk components.

Concerns about the changes that occur through Holder processing include the composition of the possibly hundreds of structurally distinct oligosaccharides, which represent the third most abundant component of human milk (Marx et al., 2014). Oligosaccharides are complex carbohydrates that act as receptor analogs, inhibiting the binding of enteric and respiratory microorganisms and their toxins, and protecting the baby from pathogens by preventing them from binding to receptor sites in the gut – protect against UTIs and diarrhea. One study found that the total human milk oligosaccharides, as well as concentrations of lacto-N-tetraose, lacto-N-neotetraose, lacto-N-fucopentaose 1, and disialyllacto-N-tetraose, were significantly lower in donor milk than in unpasteurized mother’s milk as a result of Holder Pasteurization and related processes, including freezing, refreezing after pasteurization, and defrosting for use. Further, the concentrations of 3'-sialyllactose and 3'-fucosyllactose were significantly higher in donor. Lack of these components is associated with changes in the modulation of mucosal immunity. The potential impact of these differences and other changes that occur with the Holder technique are undergoing more study to better understand the impact on donor human milk recipient gut health, ability to respond to pathogens, and related health outcomes.

There are also bacteriological, biochemical, and immunological modifications that occur when either colostrum or mature milk are pasteurized with the Holder method. In a study
comparing treated colostrum and mature milks, bacterial counts and the concentration of furosine, lactose, myoinositol, glucose, lactulose, cytokines, and immunoglobulins were determined before and after the heat treatment (Espinosa-Martos et al., 2013). Mean bacterial counts in unpasteurized colostrum samples varied between 2.72 and 4.13 log10 colony-forming units per ml in the agar media tested but Holder pasteurization eliminated all bacteria, commensal and pathologic. Furosine was detected in all samples before pasteurization and increased significantly after the heat while lactulose content, below the detection limit in unpasteurized colostrum, was detected in all samples after Holder pasteurization. Lactose, glucose, and myoinositol concentrations did not change after Holder pasteurization. Immunoglobulin content, both in colostrum and in mature milk, was reduced during pasteurization, whereas, among cytokines, only macrophage inflammatory protein-1β, interleukin-7, and granulocyte-macrophage-colony-stimulating factor concentrations were affected by this heat treatment (Espinosa-Martos et al., 2013). In sum, Holder pasteurization modifies the immunological profile of both colostrum and mature milk.

Donor human milk also undergoes freezing and thawing and related handling that changes milk composition including nutrients. Vieira, Soares, Pimenta, Abranches, and Moreira (2011) followed milk through these processes, i.e., from donation through the Holder process and related freezing, thawing and feeding methods, found that the influence of these repeated processes on the mean concentration of macronutrients in donor human milk changed. The researchers found that pasteurization was responsible for the most significant change between the average amounts of fat and protein per sample. While the speed of thawing did not cause a significant change, the continuous infusion feeding delivery system reduced the fat concentration (Vieira et al., 2011). When the influence of repeated processes was analyzed, the fat and protein
concentrations varied significantly (reduction of 56.6% and 10.1% respectively) \((p<0.05)\). Lactose is maintained, but the repeated processes that donor milk undergoes before delivery to newborn infants cause a reduction in the fat and protein concentration. Clearly, these losses merit careful consideration when preterm infant growth is concerned. García-Lara and colleagues (2013) found similar impacts on fat and protein (nitrogen), and also examined the impact of pasteurization and freezing on total energy. In addition to reductions in fat, and a decrease in nitrogen primarily related to freezing, a decrease in lactose with freezing duration. Overall (post-pasteurization with frozen storage), they found a 6.2% and 5% decrease for fat and energy, respectively. From this they concluded that Holder oasteurization decreased fat and energy content of human milk. Frozen storage at -20°C of pasteurized milk significantly reduced fat, lactose, and energy (García-Lara et al., 2013).

Other Approaches

There are several other approaches to pasteurization or pathogen reduction that have been studied with the hope of increasing convenience, lowering costs, and/or reducing the losses in human milk quality. For example, flash heating, which can be carried out in the home, has been examined. Additionally, and more closely aligned with current milk banking approaches, are the possibilities of using high temperature, short time (HTST) pasteurization, UV light, microwave and ultrasound.

Flash heating a mother’s milk has been recommended for women who are HIV positive and are transitioning from exclusive breastfeeding. The weaning period is one of mammary gland tissues apoptosis (breakdown), which results in non-infection-based mastitis. This non-clinical mastitis is associated with increased viral transmission. Therefore, expression and treatment of milk during this weaning period could reduce risk of transmission. Flash heating is
perhaps the most well disseminated approach for HIV+ women and has been tested for efficacy and acceptability (Chantry et al., 2012). Mothers are instructed to wash their hands and then manually express 75-150 mL of their milk into a sterile jar. The jar containing the milk is then heated in an aluminum pan with 450-mL water until the water boiled, then the milk is removed (Israel-Ballard et al., 2007).

Flash heating can easily be carried out in the home so there is an interest in assessing the quality of the outcome in controlled settings and in the home. Research carried out in Durban, South Africa, assessed the impact on vitamins [A, ascorbic acid, riboflavin (B2), pyridoxal-5-phosphate (B6), folate, and B12]. (Israel-Ballard et al., 2008). The findings included no significant impact on Vitamin A while vitamins B12 and C and folate were increased. Vitamins B2 and B6 were decreased to 59% (95% confidence interval 44 to 81) and 96% (95% confidence interval 92 to 99), respectively, of that found in unheated milk. The conclusion of the researchers was that these were not changes of concern and that flash-heat may be a practical and nutritious method to continue feeding mother’s milk in developing countries. Feasibility and adherence to the protocol of this method were tested in Tanzania (Chantry et al., 2012) with peer counselors providing in-home counseling and support from 2-9 months postpartum. Bacterial cultures of unheated and heated milk samples were performed. Among the 37 women who chose to flash-heat, no samples contained bacterial pathogens, however, the authors called for clinical trials on infant health outcomes with flash-heating to assess potential as a convenient, cost-effective approach to pasteurization.

The majority of donor milk use in the US is for infants who are most vulnerable and/or preterm, and therefore this milk must undergo stringent quality control for all pathogens. The method of high-temperature short-time (HTST) pasteurization process (72°C for 16 seconds) was
studied as a possible alternative to Holder pasteurization. Findings suggest that HTST is effective in the elimination of bacteria as well as of certain important pathogenic viruses (Terpstra et al, 2007). Another study compared the impact of Holder and HTST pasteurization on the HM protein profile, and found that the protein patterns of HTST-treated milk and raw milk were similar; the HTST method preserved the integrity of bile salt-stimulated lipase, lactoferrin and, to some extent, of IgAs; they conclude that HTST pasteurization seems to better retain the protein profile and some of the key active components of donor human milk (Baro et al., 2011).

Others have considered how to reduce temperatures or time in order to retain the highest level of immunological proteins and other factors in the pasteurized milk. Czank, Prime, Hartmann, Simmer, and Hartmann (2009) used an experimental pasteurizer to determine the maximum temperature at which at which 90% of secretory IgA, lysozyme, and lactoferrin were retained and whether this temperature was capable of inactivating five common bacterial contaminants (Czank et al., 2009). They found that the retention of all three proteins was at least 90% when human milk was pasteurized at 57°C for 30 min, and that this temperature was also effective at removing 99.9% of all inoculated bacterial species. Goelz and colleagues (2009) assessed outcomes with two heating methods: Short-term (5 sec) pasteurization at 62, 65, and 72 °C, and standard Holder Pasteurization. They found that short heating methods (5 sec, 62-72°C) can preserve the concentrations of peptides such as insulin-like growth factors (IGFs) that support maturation of the gut, whereas Holder does not (Goelz et al., 2009).

Ultraviolet-C (UV) irradiation has also been considered as an alternative pasteurization technique (Christen, Lai, Hartmann, Hartmann, & Geddes, 2013). Samples were inoculated with E. Coli and S. aureus to investigate UV-C’s impact on bacterial growth. The samples were then pasteurized using Holder or UV-C, with an untreated control, and analyzed for bacterial growth,
sIgA, lactoferrin and lysozyme. The bacterial growth rate of untreated and UV-Cof irradiated human milk was not significantly different. The bacterial growth rate of Holder pasteurized human milk was double compared to untreated human milk (p<0.001). The retention of sIgA, lactoferrin and lysozyme after UV-C irradiation was 89%, 87%, and 75% respectively, which were higher than Holder treated with 49%, 9%, and 41% respectively. However, levels of other cellular and non-cellular elements were not measured.

Ultrasound techniques have also been considered as a way to overcome the disadvantages of Holder pasteurization. Power-ultrasound (20-100 kHz) is an emerging technology for the preservation of foods and could be an alternative method for the treatment of human milk (Christen, Lai, and Hartmann, 2012). A recent study concluded that the viability of E. coli could be nearly eliminated with a minimal loss of activity of bile salt stimulated lipase (BSSL). However, this approach necessitates short exposure time or lower power settings that would require a cooling system to ensure the human milk BSSL and related complexes are protected against temperature denaturation.

Another area being considered is a modification of standard microwave treatment. Current technology does not allow for accurate low internal temperature monitoring of liquids, and therefore, its use as a pasteurization technique in its current form is not acceptable (Sigman Burke, Swarner, & Shavlik, 1989). However, because microwaving is as effective as Holder pasteurization in killing bacteria, and because it would be less expensive and is faster, this process merits further investigation.

Finally, irradiation methods currently used in the food industry, based on the use of gamma rays, X-rays and accelerated electrons, have been considered (CDC, 2009). Irradiation has been used on blood and related products and on foods to kill bacteria in order to prolong
shelf life. However, this approach would kill all living elements and should only be used in rare events. It has an advantage over artificial formulations as it retains many of the growth factors, antibacterial factors, cytokines, and other factors that could help to prevent infections, NEC and other gut diseases. However, any living element would be eliminated and at adequate levels it would cause other unwelcomed changes. Dr. David Rechtman of Prolacta noted, as part of our study interviews, that the dose of radiation typically used in irradiated blood is approximately 2500 rd. or 0.025 kGy, which is 2 to 3 orders of magnitude lower than the typical "low" doses used when irradiating food. These doses are too low to be effective in reducing the bio-burden, particularly in the form of viruses and spores, while those high enough to do so are also high enough to cause changes to proteins and other bioactive molecules without special steps being taken to stabilize the solution. Dr. Rechtman concludes there would be no advantage in using irradiation as extant pasteurization approaches are easier and less expensive. However, if the irradiation of human milk is instituted, consumer acceptance as well as standardization such as is required for pasteurization will be required (CDC, 2009).

There has also been consideration of using such low-tech approaches in concert with a system of sensors and mobile phone-based applications for oversight and data gathering across multi-center systems of pasteurization (Chaudhri et al., 2013; Israel-Ballard et al., 2013). The study of this type of system, which would allow central monitoring of milk banking, might inform a national system in the US.
V. Human Milk Sharing

There is evidence to suggest that milk sharing has probably been practiced since the beginning of the human species but has only recently become the subject of intense public and clinical debate. According to the Human Milk 4 Human Babies Informed Milk Sharing Network (HM4HB, http://hm4hb.net), “milk sharing is a vital tradition that has been taken from us, and it is crucial that we regain trust in ourselves, our neighbors, and in our fellow women.” In contrast, the “FDA recommends that if, after consultation with a healthcare provider, you decide to feed a baby with human milk from a source other than the baby’s mother, you should only use milk from a source that has screened its milk donors and taken other precautions to ensure the safety of its milk” (US FDA, 2010). Despite the seemingly growing fervor of the debate, human milk sharing happens every day in the United States, occasionally with tacit clinical oversight. The culture and practices involved in modern American milk sharing is critical to understand.

The visibility of human milk sharing in the United States has increased significantly in the past five years. Growing awareness is fueled by women using the internet to sharing their milk and to provide information about the practice. According to one of our study participants, “Social media made the world seem so much smaller, and made it possible for more women to learn about milk sharing, get to know donors and recipients, and start sharing milk in a really personal way.” One of the most popular human milk sharing websites, Human Milk 4 Human Babies (HM4HB), was started in 2010 as a call to action to launch a global milk sharing network. According to their site, “the announcement of a milk sharing network was received with enthusiasm by parents that could then use the Internet to build local milk sharing communities. Within a very short period of time, those communities flourished and grew with
very little assistance from their administrators… Milk sharing was happening between families making informed choices and this attracted the attention of many media outlets; our Facebook-based network quickly became famous.” HM4HB now has more than 130 active Facebook networks in 52 countries, and over 20,000 community page members.

Another online milk sharing facilitator, the website Eats on Feets (http://www.eatsonfeets.org), uses Facebook connections to “facilitate a world-wide network of parents and professionals who have made the informed choice to share or support the sharing of breast milk.” While encouraging community-development, empowerment and autonomy like other human milk sharing sites, Eats on Feets also espouses a risk-management model that is more similar to donor human milk banking. Specifically, Eats on Feets operates according to their The Four Pillars of Milk Sharing: informed choice, donor screening (through self-exclusion and communication about health and lifestyle), safe handling, and home pasteurization. While the Eats on Feets practices cannot be enforced, the understanding is that that human milk sharers are working with good intentions to ensure healthy outcomes, and are therefore unlikely to misrepresent themselves.

Content analysis of the HM4HB, Eats on Feets, and other milk sharing sites, reveals the use of highly personal language. The discourse features mothers’ empowerment, exertion of informed free-will and autonomy, desire for community among mothers, sisterly solidarity, innovation to combat a perceived scarcity of mother’s milk, and a desire to counter perceived mistrust and suspicion of women and their milk (Gribble, 2012). Much of this online discourse focuses on mothers’ satisfaction, unlike most of the clinical safety messaging currently used by donor human milk banking organizations. Contributors to human milk sharing blogs often write about wanting to “help the babies who need mommy’s milk, but can’t afford to buy it or don’t
qualify for a prescription” to reflect their stance that they are justice and equity based. Human milk banking leadership are concerned with this theme of equity through milk sharing, as one of our participants noted,

[We all have] horror tales of people who feel empowered and entitled and want us to provide the milk when there really isn’t an indication [of need]. So here we are, touting the importance of human milk, but then turning around saying, ‘But not for you.’ How can I blame them for sharing? But, still I’m really nervous about it. I would never accuse a woman of using milk intentionally to get her revenge on the world. But, I would say that most people are shocked to find out they have hepatitis. Now some people get themselves tested before they share and I guess that’s okay.”

Differing underlying reasons for human milk provision drive milk sharers versus milk bank administrators. Among human milk sharers, the issue is often women’s rights and justice. The primary driver among human milk banking staff is recipient infant health. These related but distinct core issues may contribute to misunderstandings and friction between women who share their milk directly with other women and those women who donate to milk banks. However, the interview responses of human milk sharers and milk bank affiliates demonstrated understanding of the various priorities and lack of ill will.

In medical practice and donor human milk banks, guidelines for pasteurization and non-contamination determine the milk donation practices and distribution outcomes. In contrast, milk sharing centers on the relationships among women. According to Walker and Armstrong (2012), milk sharing communities allow people to establish long-term “milk matches,” where donors are empowered by seeing babies grow and heal on their milk and a kin-like relationship is forged. For some mothers, knowing the recipient of her hard-earned milk supply can be a healing and
growing process. Mothers who have lost a child find have found some solace in being able to directly interact and support another mother and child. In Muslim societies, it has been “required” that the family of the recipient knows the donor as religious belief dictates that the donor is considered maternally related to the baby. (Al-Naqqeb NA 2000)

Two concerns regarding human milk sharing emerged from our key informant interviews: the lack of prioritization of milk for the most vulnerable infants and the perceived threat to donor human milk banking supplies. Milk bank donors felt that because milk sharing lacks formal prioritization of need, the milk is therefore less likely to be available for the most vulnerable infants. This theme was most common among women whose infants had spent time in the NICU.

“If they understood that that milk could go to the one pound babies and the two pound babies and that that much milk could feed, you know, hundreds of babies – and it’s, you know, one of the only medications that is going to help prevent certain diseases.”

However, milk bank personnel were less concerned about the allocation of human milk based on the severity of infants’ conditions. They felt that that “there is enough milk to go around” and milk sharers may be ineligible to donate to milk banks. Anticipated reasons for exclusion from human milk banking was because of infant age (a rule had been donations were not accepted after one year postpartum). Additionally, “Use of anti-depressants excludes lots of moms from donating to HMBANA milk banks. But, a lot of moms figure that their anti-depressants are safe for their term baby and safe for others’ term babies. We explain their exclusion and the risks to her or other babies, and I hope they disclose that to their recipients. But, if I can’t take her milk [for the milk bank], then it’s not my place to say much about it [milk sharing].”

Human milk donors may donate to both milk banks and directly to other women. A donor interviewee indicated that she shares her milk through Eats on Feets “in between babies” after
her infants are greater than one year of age. When asked to respond to the assertion that milk sharing depletes the supply of human milk for NICU babies, participant replied, “That’s just it. As women we are trying to tell the world that it is our milk and we will decide who ‘needs’ it as we see fit. Who is anyone to say who ‘deserves’ milk and who doesn’t? I’m not depriving a milk bank of my milk. I’m giving it to someone else!” The general consensus is that if breastfeeding were adequately supported there would be enough human milk for high-risk populations as well as others in need. As one milk bank affiliate said, “Success of breastfeeding and success of human milk banking go hand in glove.”

Recently, a study into human milk sharing on Facebook among 954 participants found that the most common reasons for requesting milk included “lactation problems” and “child health problems” (Perrin, Goodell, Allen, & Fogleman, 2014). Nearly half of donors in this sample were offering 100 ounces or more. This level of donation meets the threshold for milk bank donation. This study suggests that thousands of individuals participate in efforts to directly exchange fresh or frozen unpasteurized human milk.
Buying and Selling Human Milk

As public knowledge about the importance of breastfeeding has increased, so too has the public interest in buying and selling human milk. Laws have yet to catch up with this trend, so sales are unregulated. As such, there is very little information available to characterize the human milk buying and selling practices.

The content of our interviews of human milk bank donors, milk bank affiliates, and physicians reflected a generally negative perception of milk selling. The themes were (1) the potential for corruption; (2) an ethically gray area; and (3) the fear of scams. These all relate to the issue of mothers donating for reasons not perceived to be altruistic, which has arguably occurred since the start of milk banking in the US but still “feels divergent from the way we think about it.”

“I would see corruption and I would see people either keeping milk from their own baby, or denying habits, diseases – I, I see it becoming kind of a very sticky situation.”

Donors, recipients and medical professionals all reported their perception that selling milk on a for-profit exchange, rather than donating to a non-profit organization, can facilitate scams, for the donor, the recipient, and company.

“I tried to sell mine online and got a whole bunch of scams and people trying to send me checks, I got a check for $2,100 and I’m selling it for $200, like it was a big check and it was just like a giant scam, he said that his wife had cancer and he was getting milk for his wife, helping someone who really needed it. But it was a scam.”

The emphasis on milk selling sites is community, empowerment, relationships, fairness and sisterhood, like on milk sharing sites. For example, a popular site for buying and selling milk was started by a “mom who wants the best for [her] baby.” The site is positioned as a place for other mothers like her “to connect.” Onlythebreast.com features a section entitled, “Moms Cry Out,” with quotes from women seeking to sell their milk. Women feel a need for independence
in decision about human milk and demonstrate misunderstanding of not-for-profit milk banking. In one example, “milkmommy says: I completely agree with all of you. I’m a healthy 28 yr. old w/ a thriving 9-mth-old daughter and an abundance of milk in my freezer. I don’t smoke, drink, or do drugs. It is absurd to me that mothers who spend large amounts of their days pumping extra milk can’t be compensated, while the milk banks are making millions!!”

The popular milk selling website Only The Breast was visited on ten occasions about every six weeks during our study period. There was an average of 1479 ads for selling human milk, 134 for buying, 15 for donating, and 22 for wet nurses in the US. The classifieds are presented in the following categories: 0-2 months, 2-6 months, 6-12 months, Discount $1.00 or less, Fat Babies, Fresh Breast Milk on Demand, Milk Bank Certified, Milk Bank Screened Breast Milk, Selling in Bulk, Selling locally / Local Buyers, Special Diet, Willing to Sell to Men / Men Buying Breast Milk, For Premature Birth, Seeking Donations, Sick Babies in Need.

HMBANA and Prolacta will accept milk expressed prior to screening and provide education about safe expression, storage, and shipment. Because they pool milk for medically vulnerable populations, milk bank guidelines exclude women who use medications (such as mega dose vitamins, anti-depressants, etc.), drink more than 2 ounces of hard liquor or equivalent / 24 hour period, use tobacco or nicotine products, , or did so during the time that unexpired milk was collected. Donors may be deferred temporarily due to active infection of temporary use of a prohibited medication. Women are also excluded for reasons such as repeated donations of unacceptably high bacteria counts after they are counseled on hygienic expressing practices. The numerous exclusion criteria for human milk bank donating leaves a substantial number of women who have a strong desire to share their milk without a means for organizational donation. The rigorous screening may account for the findings of Keim and
colleagues (2013), in which human milk samples purchased via popular milk-sharing website had significantly greater amounts of bacteria than human milk donated to milk banks. While high bacteria levels in milk may be tolerated by a relatively healthy recipients, the risk of negative outcomes if and such milk is used with infants born preterm or otherwise medically compromised is unknown.

In an effort to promote the safety of human milk, the classifieds list categories for “Milk Bank Certified” and “Milk Bank Screened Breast Milk.” This categorization is problematic for several reasons. First, there is no “milk bank certification” designed to indicate approval for milk sharing online. Second, proof of “certification” is rarely offered. Even if a woman was at one time eligible to donate her milk to a bank, she may have been subsequently excluded. Throughout each of our repeat visits to the website, there were an average of 44 sellers listing in this category, with few identifying their certifier, an average of 1.5 sellers attesting to be “HMBANA certified” and 11 attesting to be “Prolacta certified.” Several sellers described their screening and certification by reporting that they “have donated to my local hospital.” These claims are unverified. Several “certified sellers” state that they reached the end of their 180-day qualification/donation period for Prolacta and have not re-applied. One donor wrote “I also donate to the breast milk bank located in Kansas City, so I have been screened and this milk is given to NICU infants.” This person’s description indicates that are some women may be choosing to sell milk when it is eligible to donate to a milk bank. Donor human milk banks pay for the cost of screening women with the understanding that the milk donations are to be submitted to their organization. This necessary cost is part of the processing fee charged for the pasteurized donor human milk. Some women who get approved to donate to milk banks never donate, donate once, or only provide some of their available milk. All of these circumstances are
acceptable to the milk banks. Nonetheless, it is a financial loss for the milk banks, and may drive up the processing fees for the milk. The final significant problem with milk selling ads is that since milk banks do not return screened milk or sell it on the free market, the entire category of “Milk Bank Screened Breast Milk” may be fabricated.

**Legal Implications of Milk Selling and Buying.** Participants in our study who had purchased human milk online expressed their need to “trust the honor system.” However, medical professionals suggest that the health of infants, young children, and medically-vulnerable individuals should not depend on an “honor system.” Current state and federal law does not address internet sales of human milk, so neither sellers’ rights or recipients’ well-being are protected. Donor human milk banks products are regulated as foods, but it would be almost impossible to hold a seller legally accountable for the composition of her milk. Some state tort and contract laws may grant restitution to an injured party if s/he can prove that the injury resulted from contaminated, volume-enhanced, or misrepresented milk. There are federal and state laws that could be used to assert criminal liability for the sale of bodily fluids from an individual who has, and is aware of, a disease communicable via human milk (for example, HIV, active tuberculosis, hepatitis C). However, there is currently no precedent for applying such laws to the sale of human milk. Based on liability, sellers may be brought to suit for harm done to recipients of knowingly adulterated products. In such a case, the injured parties would be the one required to provide proof of misrepresentation and adulteration and the fact that it led to harm. Most buyers of human milk likely lack the resources to test the milk for contamination or composition. Further, illness is rarely attributed to any single exposure. Creating a legal precedent would be possible only after someone has been hurt.
An online human milk market is now offering a mechanism to become “Safe to Share Certified.” Members of the site are eligible for a discounted rate on a “Breast Milk Donor Panel Basic.” LabTestPortal will email the user a Lab Requisition for the tests for HIV 1 & 2, Human T-Cell Lymphotrophic Virus I and II, hepatitis C, hepatitis B and syphilis, and provide instructions for how to prepare for the labs. Users are instructed to search the site for their nearest Labcorp location, bring the Lab Requisition, and have the specimen collected by licensed phlebotomists. Usually within 24-48 hours, the user will receive an email indicating that the lab results are ready, and be directed to login to the website to review lab test results. If all tests are negative, LabTestPortal emails the user a dated certificate image that can be added to human milk classified ads on the site. However, only Prolacta is able to confirm by DNA analysis that human milk provided actually belongs to the person who was approved for donation.
Ethical Considerations

Ethical and cultural considerations are essential with any intervention designed to improve the health of a population. Some of the main issues for promoting human milk use are resource allocation, sharing, and selling.

In recent history, medical advancements have enabled the survival of younger and more critically ill infants. The result is a greater prevalence of infants in the NICU, many of whom greatly benefit from donor milk. At the same time, public perception about the importance of human milk for human babies has resulted in a greater demand for donor human milk than is currently available. The shortage of donor human milk necessitates decision-making about distribution by milk banking professionals, healthcare providers, hospital administrators, and insurers (Arnold, 2006b). Prioritization currently occurs within the US without federal oversight or a common, evidence-based. Furthermore, there is no national data management system to determine how much of the demand is being met, and for which populations. Therefore, as previously discussed whether the principle of justice is being upheld is unknown (Miracle et al., 2011).

At its core, debate about human milk involves issues of ownership and who has the appropriate authority to determine what is safe, possible, and desirable. Does the responsibility for milk belong to the federal government, the milk banks, milk sharing sites, and/or donors and recipients acting independently? Further, in this discourse, milk is conceptualized in at least three ways: as “private property,” an entity of business and commerce; as a private component of the intimate world of the family and the dyad; or, specifically, as a part of the woman’s body, broadly considered unacceptable for the marketplace. These different ways of viewing human milk reflect culturally shaped ideas about the safety and appropriateness (Swanson, 2011).
Additionally, donor human milk banks generally view themselves as part of the health team, which dictates a medical model of human milk: it is vital to protect the safety of recipients from pathogens by screening, pasteurizing, and testing the donors and their milk. Others argue that women seeking to donate their milk are altruistic and responsible, and that recipients can be trusted to make informed decisions. Still others, due to cultural considerations that dictate that if they frequently accept milk from a single donor that that donor becomes the infant’s parent, prefer combined donated milk from unknown donors, rather than that of a known individual.

Regarding the sale of human milk, there seems to be general consensus (as there has been since in the early 1900s) that this practice is a slippery slope. The seller’s child may be deprived of mother’s own milk. And/or, sellers may alter their milk by watering it down for greater volume in an effort to increase profit. Still, there are others who argue from a feminist perspective that women are in charge of their bodies and bodily products, and should be at liberty to do with them as they see fit. Historically, wet-nurses were often treated as a commodity and their infants suffered (Wolf, 2001).
VI. The Costs and Benefits of Human Milk Feeding

The basic issue in establishing the costs and benefits of human milk feeding is the understanding and acceptance of the fact that the use of exclusive human milk, versus preterm formula, is associated with several measurable benefits, including a significantly greater duration of parenteral nutrition and higher rate of NEC and surgical NEC in infants receiving preterm formula, especially among extremely premature very low birthweight (VLBW) infants (Cristofalo et al., 2013). While dialogue about human milk has long involved “the benefits of human milk,” it is important to consider that there are measurable risks of exposure to non-human milk, especially for preterm infants. (Abrams, Schanler, Lee, & Rechtman, 2014). For example, one study found that only 50% human milk feeding with 50% preterm formula offered little advantage in cost or length of hospital stay over only preterm formula (Parker, Sullivan, Krueger, Kelechi, & Mueller, 2012).

Mother’s own milk is preferred for infant feeding because it is both infant age- and maternal-specific. However, not all women can successfully express their milk when their child is premature and the shock of a sick newborn can create stress that may mediate milk production. There are many programs and approaches that can facilitate milk expression, however, the infant’s needs may still surpass the capabilities of the mother to produce and express her own milk. The World Health Organization notes that donor human milk is the next best approach for optimizing infant health outcomes, as stated in the background section of this report. Therefore, optimally, breastfeeding, then mother’s expressed milk will be used, and if further supplement is needed, donor milk should be used.

A recent extensive review of the literature by the Committee on Nutrition of the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN)
summarizes the existing evidence of the benefits and common concerns deriving from the use of donor human milk in preterm infants (ESPGHAN, 2013). They categorized their findings under clinical issues -- NEC; Feeding Tolerance; Cardio-vascular; Pulmonary and Allergy – and Concerns and Uncertainties; including Safety, Altered Quality, Potential for Slowed Growth and “Does the Presence of an HMB Compete with Breast-feeding?” A major concern of that discussion is the lack of studies that actually define and compare these important and very common issues. Further, the paper notes that Holder pasteurization, the most commonly used procedure, is safe but reduces the nutritional/biological quality of DHM, and that pasteurization should be optimized to maintain microbiological safety while preserving the highest amount and activity of the bioactive milk components.

The conclusion of the ESPGHAN review is that the limited number of studies, and the resulting limited evidence, only leaves decreased incidence and severity of NEC entirely defensible as an impact of the use of human milk in preterm infants. Although there are probable associations with all of the other clinical areas, these issues have been inadequately studied. Therefore, to create a calculation of costs and benefits of donor human milk use we, perforce, must rely on the more readily measurable costs (skilled maternal support, pasteurization, storage, etc.) and the benefits (decreased NEC and length of infant hospitalization). Additional costs of DHM use, such as mothers’ time, are more difficult to measure. Further benefits of DHM use, such as lifetimes of improved health outcomes and decreases in less frequently occurring illnesses are not fully considered herein. This review of costs and benefits, therefore concentrates on the cost savings from use of DHM among premature infants and the impact on NEC alone. Other costs and other benefits are discussed in brief.
There are about 450,000 US births that are premature each year, and these vulnerable infants cost the American health care system more than $26 billion each year (CDC, 2014). To understand the potential cost savings associated with the use of human milk among premature infants, we need to understand the cost of care with and without human milk feeding, as well as the total need and potential cost of providing adequate quantity and quality of human milk for these infants. For the purposes of this analysis, we are not considering the cost of fortifiers because we assume that they will be used with either formula or human milk, thereby not impacting cost. If however, human milk based fortifiers become the standard of care, this will independently increase the cost of either approach to feeding, and will merit separate analysis.

For this analysis, we further assume that there is minimal current use of human milk in NICUs, despite AAP recommendation that all preterm infants receive human milk. This assumption is based on recent research that found that even in advanced care neonatal units (Level III and above) less than a third of these units regularly provide human milk, and only about 20% of these NICUs provide donor human milk (Perrine & Scanlon, 2013). The issue of human milk scarcity is compounded by the fact that nearly one in four infants who are delivered prematurely are born outside of a level III hospital, where we might assume that even fewer facilities are offering donor banked milk (Freeman, V. 2010). Therefore, for modeling purposes, we will assume in this analysis 1) that there is no use of human milk and, also, 2) that about 25% of the feedings of premature infants is human milk.

There is a great human and fiscal cost when a neonate develops NEC, which can destroy intestines, and, in a fragile newborn, NEC often results in death. Treatment may be medical or surgical. A recent study found that the adjusted incremental costs of medical NEC and surgical NEC over and above the average costs incurred for extremely premature infants without NEC, in
2011 US$, were $74,004 (95% confidence interval, $47,051–$100,957) for medical
treatment, and $198,040 (95% confidence interval, $159,261–$236,819) for surgical treatment
per infant (Ganapathy, Hay, & Kim, 2012). As a result, the economic cost of NEC is high in the
US, accounting for approximately 19% of neonatal expenditures a decade ago, at an estimated $5 billion per year for hospitalizations at that time (Bisquera, Cooper, & Berseth, 2002). Bisquera
and colleagues (2002) emphasize that these numbers reflect hospital charges only, and thus, are
conservative estimates of the true cost of this disease, as they do not include physician charges.

Today, some costs that these researchers used in their calculations may be contained, but we
have experienced inflation and increased use of technologies, so the findings may be a
reasonable estimate for costs today for hospital charges. Clearly, even dismissing the myriad
“costs” of a child death, the economic cost of NEC treatment alone is substantial.

A recent study by Hull and colleagues (2014) examined data from 655 US centers that
prospectively evaluated 188,703 VLBW neonates (born weighing 401 to 1,500 g) between 2006
and 2010. There were 17,159 (9%) patients who had NEC, with mortality of 28%; fifty-two
percent of VLBW neonates with NEC underwent surgery.

<table>
<thead>
<tr>
<th>Calculation Box 1: Calculation of the cost of the national annual cost of treating NEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Given 9-10% of VLBW babies get NEC, or about 2,200 annually, and using the</td>
</tr>
<tr>
<td>estimated costs of $ 74,004 for medical treatment, and $198,040 for surgical treatment, we can</td>
</tr>
<tr>
<td>calculate the approximate cost of treatment to be:</td>
</tr>
<tr>
<td>2,200 X 0.52 (the proportion surgically treated) X $198,040 = $226,557,760</td>
</tr>
<tr>
<td>and</td>
</tr>
<tr>
<td>2,200 X 0.48 (the proportion medically treated) X $74,004 = $78,148,224</td>
</tr>
<tr>
<td>= or a total annual cost of about $304.7 million for NEC alone, beyond the other costs</td>
</tr>
<tr>
<td>of prematurity and related care.</td>
</tr>
<tr>
<td>Conservatively, the use of human milk could reduce the incidence of NEC from about</td>
</tr>
<tr>
<td>3.4% to 1%, reducing the cost from $304.7 million to about $90 million, saving about $215</td>
</tr>
<tr>
<td>million</td>
</tr>
<tr>
<td>The estimated current cost of supplying human milk for these infants approx. $5 cost per</td>
</tr>
<tr>
<td>ounce = $74 million</td>
</tr>
<tr>
<td>Therefore, the Benefit: Cost ration is $2.9 saved for every dollar spent.</td>
</tr>
</tbody>
</table>
Conclusions

This report contributes an external review of the current US donor human milk banking practices, in support of The Surgeon General’s Call to Action to Support Breastfeeding (US DHHS, 2011). The following are our identified issues and proposals:

Issues and Controversies

1. The World Health Organization prioritizes “at-breast” breastfeeding for infant feeding, followed by mother’s own milk via another method, then donated unpasteurized human milk, pasteurized donated human milk and, only after these, formula. If for no other reason, the need for human milk to prevent infant deaths from NEC is undeniable. Nonetheless, often in the US, preterm infants are primarily fed formula. Participant in this study suggested that maternity centers that serve poor populations, rural communities, and/or racial minorities might be least likely to support breastfeeding and to use human milk. This inequity could be due to the perception of low patient interest and facility costs of breastfeeding support and donor human milk use. In sum, recognition of the central role of human milk for health, especially for infants born prematurely, is not as yet the norm.

2. Currently, human milk is used in the NICU when it is available from the mother or from a donor human milk bank. Since milk banks differ in protocols and practices for allocating donor milk, and as human milk pricing varies by location and by processing approaches (primarily preterm preparations v. non-calorie specific formulations), distribution is an issue worthy of much additional consideration. There may be disparities in the use of human milk among NICU patients by race, geographic locales, and NICU levels.
3. Human milk has been shown to reduce incidence and/or severity of many diseases. Currently, donor human milk is systematically allocated to only the most vulnerable or ill infants. The real level of need for human milk for both treatment and prevention is unknown.

4. Health professional groups have policies to promote for breastfeeding and human milk use for all infants. However, the 2011 Surgeon General’s Call for Action has not been answered for the most vulnerable infants. It is not clear that models from other countries have been considered by the federal government in terms of centralized databases, infrastructural support, and reimbursement.

5. Donor human milk banking was historically a local practice. Is long term freezing (and shipping) necessary for centralized pasteurization? Will new pasteurization methods alter the donor human milk banking process? Perhaps more donor human milk pasteurization will occur locally, while calorically modified milks and fortifiers will remain a centralized function.

6. The most appropriate role for federal regulation is unclear. In 2014, the FDA issued an Interim Final Rule that any entity that supplies human milk or human milk products must comply with federal regulations governing the production and labeling of such items as covered by statute in 21 CFR 100-169, and, in particular, parts 105-107 dealing with infant foods. With the increase in the number of donor human milk banks, more products being distributed, and the development of a for-profit human milk banking entity that has proprietary processes, there is concern that the FDA should ensure that all human milk banking and processing meets standards. However, as guidelines are developed, it will be important to ensure that the regulations do not lead to reduced availability of pasteurized
donor human milk. There is also the hope that guidelines will lead to more ready coverage by insurance companies.

7. The ACA does not currently specify coverage for donor human milk, nor does national Medicaid policy require states to cover these costs, and national WIC policy strictly prohibits coverage of DHM. Limited third party payment restricts access to donor human milk, perpetuating inequities in exclusive human milk feeding and associate outcomes.

8. Health Care Providers are not universally trained in the risks of formula use or in the skills to support breastfeeding and the use of human milk in the NICU. Further, cultural humility curriculum and experience remain scarce in medical training. Even among breastfeeding supportive physicians, a large proportion does not achieve their own goals, and personal experience does seem to influence physician practice. The fact that not this entire group agrees that donor human milk should be used instead of formula underscores the importance of this issue. Perhaps the development of Ten Steps (equivalent to the Ten Steps to Successful Breastfeeding that constitute the Baby-Friendly Hospital Initiative) for the NICU would enhance uptake of best practices (Nyquist et al., 2013). There also is an immediate need for marketing/training of clinicians concerning supporting milk banking.

9. The Innocenti Declaration of 1990, signed by a US representative, calls for 4 actions: Development of a national committee for oversight, change hospital practices to break down barriers to breastfeeding, avoidance of formula marketing, and paid maternity leave and workplace accommodation (WHO/UNICEF, 1990). Similarly, or in conjunction with breastfeeding support in the US, the use of human milk would benefit from consideration of the need for these same four elements, designed to ensure rights and justice for all. There is a need for an agreed upon committee to provide oversight of all donor milk use in the US, as
well as the need for health provider training to facilitate collection and use, and to ensure that there is no undue marketing of cow’s milk-based substitutes and that workplaces realize the vital need for mothers of all infants, including the most vulnerable, to be supported in milk expression.

10. Currently, neither HMBANA nor Prolacta track exactly which milk is fed to which recipients. Therefore, these data are not compiled or analyzed to allow descriptive data of the demographics of donors or recipients. This result in 1) a very limited ability of a milk bank to monitor equity in use of the milk they provide, and, 2) inability to ensure that milk is being distributed according to acuity of clinical need. Many see a centralized data management system for all milk banks as a possible solution. However, there is concern that such data collection may be unfeasible, undesirable for healthcare professionals, and/or problematic re: recipients’ rights to privacy.

11. Many research questions remain (see next section), but there are very limited research funds available at this time.

12. Existing evidence and clinical experience reports are conflicting regarding support for calorie-specific milks for long-term development of preterm infants, and there are questions of impact on cost and quality with target pooling. There is a significant increase in the cost of providing a variety of calorie levels of pasteurized human milk over the cost of providing non-calorie-specific pasteurized milk. This topic warrants further exploration using robust, randomized controlled trials using standardized definitions and measurements.

13. The not-for-profit milk banks bill for the cost of processing and associated overhead, while the for-profit model, by definition, sells a product. Both may include advertising and benefits to donors in their pricing structure. However, given women’s stated concerns regarding
others potential for profit from their donations, and costs of milk that may be prohibitive for recipients. Educating the public on the similarities and differences between these two human milk donation approaches may create a better-informed pool of donors.

14. The expressed opinion by those who choose to milk their share is that donor milk banks are all for profit and benefit financially from their donation. Information on the basis for cost setting by for-profits and not-for-profits should be made public to allay these concerns.

15. We must increase the number of donors to adequately address the need for human milk. Development of the social marketing strategy to do so should include the inputs of the target audience. Marketing to increase the donor pool could benefit from using major themes identified in this paper as those that catalyze initial and continued donations.

16. Restrictions, or perception of restrictions, on milk donation that are designed to increase safety have limited availability of milk. Some restrictions may or may not increase safety, and in general, some may be misunderstood by potential donors.

17. With increased centering in pregnancy care, it may be possible to have a group of mutually supportive and screened women who are dedicated to helping each other when donor human milk is needed, as an alternative or supplement to pasteurization, or buying and selling.

18. Alternative pasteurization techniques may increase the quality of the final product, but it is unclear when and how any of these approaches may be integrated into current systems.

19. Cost-benefit analyses are an important tool in informing policy-makers and health administrators on the value of programs to support breastfeeding and human milk expression.

20. The need for donor human milk, which would appear to be higher than previously estimated, is very dependent on the efforts made to support mother’s own milk use as the first choice for all infants. Support for mothers of infants in the NICU or others settings to breastfeed and/or
produce milk for their own child remains inadequate. Furthermore, it is imperative that

equity be considered in improvement programs. Improving such support for all women will
decrease the need for donor human milk, and increase the pool of potential donors.

Proposed Research Needs

Human milk banking and the use of donor human milk may be greatly improved by
defining, implementing and disseminating a national research agenda. Research can be divided
into five primary areas: 1) composition, 2) processing, 3) clinical use, 4) socio-behavioral
factors, and 5) ethics.

Composition. The following research questions address the components and quality of
the milk provided.

- Which components of human milk are most important for infant health, growth and
neurologic development (according to measures of long-term cognitive development, long-
term growth, long-term cardiovascular outcomes, Bayley psychomotor scale, etc.), and in
what amounts and/or ratios?
- What is the appropriate definition of “preterm milk?”
- Is there a duration of lactation (i.e., age of child) at which the milk no longer has sufficient
levels of nutrients and protective factors, such as oligosaccharides, to be of use for the NICU
population?
- Is there a duration of lactation (i.e., age of child) at which the milk no longer has sufficient
levels of nutrients and protective factors, such as oligosaccharides, to be of use for outpatient
use?
- Is there adequate evidence for all of the exclusion criteria that limit that amount of donors
and volume of milk donated?
**Processing.** These research questions address the activities involved in the processes in donor milk banking.

- What is the optimal batch size for pasteurizing donor human milk in terms of quality control and cost-benefit?
- What changes in composition are occurring in processing of human milk that may impact availability and absorption of micronutrients? How can absorption be optimized?
- The immune factors in human milk should be preserved as much as possible. What duration of freezing and storage result in optimal composition, pasteurization and immune support? Are there specific types of pathogens that escape neutralization with current pasteurization techniques?
- Many other countries provide freshly expressed milk from known donors, rather than pasteurizing. There is a need to carry out studies on the safety of this approach in the US.

**Alternative Pasteurization.** It is becoming increasingly evident that there are significant losses in quality with Holder pasteurization and the freezing and shipping associated with its use.

- What other methods of pasteurization may be employed by state-level milk banks to optimize nutrient and immune factor retention, minimize pathogenic risk factors, and offer ideal cost-benefit?
- With new pasteurization techniques, would it be possible to identify a single approach to pasteurization that is optimal in terms of the quality of the final product as delivered to the infant?
- Could this allow increased availability of pasteurization in all hospitals, or enhance hospital use of immediately available donor milks? Would this reduce loss of quality seen with current techniques?
**Donor issues.** It is important to consider the safety of both the donor and the recipient while seeking to increase the supply.

- How frequently should donors be tested to ensure the safety of their donations and cost-benefit?

- Is offer of payment or product incentives to those donating to donor human milk banks associated with their depriving their own children, milk dilution, or other potentially unsafe and unethical behaviors?

- Is offer of payment or product incentives to those donating to donor human milk banks associated with increased enrollment and/or volume of donation?

- Is there a safe approach to human milk sharing that would allow women to help each other with minimizing risk?

- Is there a way to encourage donation to both milk banks and to local sharing? Might physician supervision of local human milk sharing, based on evidence-based screening, allow women to address both their need to share and their need to see their milk in use?

**Clinical Use.** This set of questions addresses the current use, need, and impact of donor human milk.

- Are there disparities by race in the current patterns of donor milk provision within the US? If so, is this cause by availability, clinical decision, region of the country, hospital practices, or other?

- Assuming our calculations to be correct for the NICU, how many additional ounces might be needed to address this entire population as well as well babies with indication, outpatients with indication, etc.?
What is the comparative effectiveness of various combinations of milk use, e.g., mothers own and donor, mothers own and formula, donor and formula, each of these with differing types of fortifiers, etc.? How does this vary by GA, age, weight gain and diagnosis? How is the impact best measured, e.g., weight gain, type of weight gained (lean vs. fat), slower weight gain with indicators of health, etc.

Do we need improved measures of physiological progress? (e.g., timing and frequency of ultrasound to assess gastric physiology, concurrent and later immune functions, later allergy and gut function, current and later cardio-vascular and metabolic status, etc.

A related question would be: What is the lifelong cost-benefit of optimal milk use (including breastfeeding support and donor milk use if needed) in the NICU?

Is there a consistent and measurable clinical benefit to target pooling, caloric standardization, and/or fortification of donor milk? If so, at what level of specificity?

What is the current status of third party reimbursement for banked donor human milk, and how does this vary by state, hospital diagnosis, etc.?

Sociobehavioral Factors. The rationales reported by human milk donors to milk banks and donors through sharing should be considered in increasing our understanding of how to increase the donor population overall.

What are the factors associated with women’s decision to donate or not to donate their milk that might be a focus for social marketing?

Why do women donate to one organization over another?

How much human milk is currently donated to all milk banks and how much is currently being shared and/or sold?
• How can the public awareness about the importance of banked donor human milk be heightened?

**Ethics.** In addition to general concerns about who is receiving donated human milk, there are additional ethical issues.

• Are there inequities in current distribution of banked donor human milk by Region? by hospital, especially among hospitals in the region of a hospital based milk bank? within the community? By ability to pay? By racial or ethnicity within facilities?

• What are the ethical implications of buying and selling human milk as a consumer product? Can issues that arise from research ethics be addressed with alternative analytic techniques?

It is imperative to always consider ethical implications, especially in researching donor human milk use. For example, it is unethical to randomize patients to donor human milk vs. infant formula, as the data are clear that there are increased risks with formula use.

Unfortunately, this means that much of the current evidence base is non-random assignment of recipients, or cohort. Some studies compare between units where banked donor human milk use is standard vs. those where it is not, or compare difference in fortifiers or timing of introduction of milks. It is clear that much additional research is needed to address the questions raised in this paper, alone, and many more if we included fortifiers, different calorie level milks, etc. A research agenda should include recommendations for managing ethical implications while optimizing accuracy and precision of findings.

**Suggested Policy and Practice/Operations Priorities**

1. We recommend that all donor human milk banks cooperate to have a centralized database, not only containing information that milk banks are currently required to document, but also contain the following demographic information on donors and on recipients:
- Age
- Maternal race and ethnicity
- Household income
- Maternal education attainment
- Percent of potential need and actual demand satisfied, and,
- Percent of demand for in-patient and outpatient use that is met.

It is recommended that this information be collected, analyzed, and reported nationally regarding both donors and recipients as a primary need for greater understanding the reach and impact of current practices on specific sub-populations.

2. There is also a need for consistent guidelines with codification and transparency in the prioritization of donor human milk distribution and in its use. Milk sharers, sellers, bankers, and prescribers, alike, note the importance of the issue of who receives milk and how that is determined. Prolacta policies, HMBANA Guidelines and all HMBANA milk banks report that milk is distributed to according to clinical and ethical factors, however, there is no consistent systematic guidance for these decisions. Hence, milk bank staff are forced to act as gatekeepers, and, together with physicians must decide who gets milk when there is not enough to meet all requests.

It is recommended that guidelines be developed for all donor milk distributors and applied nationwide, and that such guidelines be widely disseminated and evaluated, and regularly updated based on best evidence and research. Ideally, stakeholders from non-profit and for-profit organizations and external stakeholders convene to develop guidelines.

3. It may be possible to reduce loss in quality and simplify processing with selected new pasteurization techniques. Further, it may be possible with the new techniques to establish
hospital-based or more local milk banks in more settings reducing the need for shipping and reducing the incidence of inability to meet needs. However, to date, there is not sufficient data on any one method to justify unilateral movement away from the Holder method.

It is recommended that the federal government be encouraged to fund the research needed and the regulatory guidance needed to allow a system with higher quality milk outcomes.

4. The current milk banks and sharing are comprehensively and appropriately regulated by any government entity, although the FDA has demonstrated increased interest and hosted a major national review. It is likely, however, that intensive oversight might result in an improved product or increased cost or reduced volume of donors.

It is recommended that a national committee be developed, such as that called for in the Innocenti Declaration, to provide oversight to enhance the possibility that all of the above research, policy and program suggestions might be addressed.

5. Finally, it is clear that the current level of mothers own milk used in the NICU setting, as well as with term infants, must be -- and can be -- increased. The greater breastfeeding community prioritized national oversight, hospital practice improvement, avoidance of unnecessary use of non-human milks, and accommodation of women’s need to express their milk, in accordance with the Innocenti Declaration of 1990.

It is highly recommended that any effort to increase donor milk availability be linked and mutually supportive with efforts to support maternal decisions to breastfeed, and to empower them to succeed in this relationship.
Recommendations and Next Steps: Building Consensus and Synergy

W.K. Kellogg Foundation Goals: Improve children’s health by ensuring more babies benefit from breastfeeding as their first food experience; Eliminate health disparities by addressing barriers to breastfeeding in communities of color.

This paper addresses the W.K. Kellogg Foundation improving child health and reducing disparity goals through documentation of the availability of human milk may be increased and considering how barriers to human milk feeding might be addressed.

A benefit of utilizing the ETIERS framework, which included continuous vetting with stakeholders, is that some of the suggestions presented here have already been addressed. For example, HMBANA is taking steps to increase data collection, working toward centralized reporting, and considering distribution priority algorithms. We additionally recommend an increased exchange of ideas and collaboration among all who value use of human milk. Further, breastfeeding promotion may be enhanced by incorporating the need for donor human milk into all breastfeeding support efforts. Enabling breastfeeding and facilitating human milk banking can be achieved through federally funded programs, the First Food builders and other First Food organizations, and professional organizations. It may be necessary to establish government oversight of donor human milk banking in order to encourage all of the major actors to share techniques, promote transparency, and improve data collection and sharing.

This report is the result of a multi-method approach to collect data within an interactive framework. Ultimately, we see this effort as aiding work to reduce maternal and child morbidity and mortality. Further, the need for donor human milk banking would not be so great if there were improved quality and ensuring equity in health care across populations and over the
lifespan to reduce occurrence of preterm births and increase the rates and duration of breastfeeding.
References


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, *J Pediatr* 2010; 156:562-7


