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The Creation of a Template for the Incorporation of a Human Milk Analyzer into a Human Milk Bank

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APPROVAL FOR SUCCESSFUL DEFENSE

Sarah Rieber has successfully defended and made the required modifications to the text of the DNP Final Scholarly Project for the Doctor of Nursing Practice during this Fall, 2021

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Dedication

To my husband, Michael Rieber who has tirelessly supported this process from its inception. Always my greatest champion, you have encouraged me through your own (aspirational) example with and without words. Through your love, understanding, kindness and encouragement you have made me better. Thank you for always lifting me up and making me feel treasured.

To my mother who taught me at an early age that education can give you eagle wings. To my father who showed me the power of determination and aspiration. I will be forever grateful for your prolific life lessons.

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Abstract

A milk bank is a nonprofit service that collects, screens, and processes by pasteurization human milk that is donated by mothers not biologically related to the infant in need. Milk is then dispensed to hospitals and private homes to babies with a prescription. A milk bank collects and analyzes human milk, as breast milk is the ideal nutrition source and the gold standard feeding method for infants. Breast milk significantly reduces premature babies' chance of developing necrotizing enterocolitis (NEC) and offers gastrointestinal protection, increases immunity, decreases the likelihood of asthma, allergies, ear infections, obesity, and respiratory ailments. Some mothers are unable to breastfeed their own babies related to a multitude of medical conditions, including; breast surgery, breast cancer, thyroid disease, polycystic ovarian syndrome (PCOS), hypoplasia, medication contraindication, complicated birth, postpartum hemorrhage, or retained placenta. For these mothers and babies, donor milk is a viable option. The use of a milk analyzer when evaluating and processing human milk can provide better insight into the macronutrient content of the donor sample. This process can allow for a more targeted allocation of the sample. Providing the 23-week-old premature infant with milk that has a higher protein count is more suitable than offering that same sample to a full-term nine-pound baby. This quality improvement project will chronicle the initiation of an analyzer into clinical practice, develop a replicable template for that incorporation, and follow the impact of quantified human breast milk in the field. Through the guidance offered by the template, the long-term goal is increased participation of milk banks in macronutrient analysis. Identification of the values available in each sample offers a better product to families in need and has the potential to improve health and growth rates.

Keywords: pasteurized donor human milk, human milk analysis, macronutrient analysis, breastfeeding, template, milk bank

BACKGROUND

The Problem

Not all infants are fortunate enough to receive their mother's breast milk. For a multitude of reasons, this can be a physiologic challenge or impossibility. Breast milk is universally accepted as the ideal nutritional source and the gold standard feeding method for infants. The scope of this problem has existed since the beginning of time. Wet nurses, throughout history, have been used for breastfeeding another person's child not biologically related to them. Accessing macronutrient, content- analyzed and designating appropriate donor milk can provide a targeted bridge to mothers and babies in need. Pasteurized Donor Human Milk (PDHM) is breast milk that has been donated, screened, tested for disease, and pasteurized under the protection, safety, and regulation offered by a milk bank. Breast milk contains antibodies that protect babies from viruses and bacteria and lowers the incidence of asthma and allergies, ear infections, respiratory illnesses, obesity, and diarrhea. The fat in breast milk enhances brain development and aids in the healing of the intestinal tract in premature infants with gastrointestinal diseases, including NEC (Riordan & Wambach, 2010). Many hospitals across the United States are now introducing the prescription use of PDHM on well-baby units and in neonatal intensive care units as an alternative to formula in mothers who wish to exclusively breastfeed but are unable to produce enough milk. Prior to the introduction of PDHM, the only appropriate alternative for mothers with supply issues while in the hospital was to offer formula. The goal is always safe milk for babies. Evidence also suggests that protecting the breastfeeding relationship in the early postpartum period extends the duration of exclusivity. Utilizing donor

milk when there is a medical indication for supplementation is an ideal way to promote continuation without interference. “The most positive maternal and newborn health outcomes from exclusive breastfeeding are realized within a minimum of three months of breastfeeding with a dose-response effect” (American Academy of Pediatrics, 2016, page 1). Additionally, the incentive for the development of this breast milk safety project resulted from a dangerous pattern of mothers bringing in breast milk to the hospital that was donated by other lactating family members or had been purchased from other mothers online. These methods are dangerous as there is no United States Food and Drug Administration (USFDA) oversight of this practice. Milk temperature cannot be assured, and there is no proper testing for viruses and disease outside the protection of a milk bank. Hospitals obtain the PDHM from accredited milk banks compliant with the Human Milk Bank Association of North America (HMBANA) guidelines and standards. Unregulated milk cannot meet the safety standards comparable to milk offered by a human milk bank.

Current Practice

The current trend in milk banking includes the incorporation of pasteurized donor human milk analysis to further understand macronutrient content. As of May 2021, 6 out of 31 nonprofit milk banks in North America are using human milk analyzers, HMA. There are milk banks using other types of analyzers that have not been USFDA approved specifically for human milk analysis. The intent of targeting analyzed donor milk is to translate evidence acquired to guide safe and effective medical and nursing care across a variety of settings. Using a HMA through this process will facilitate the most targeted nutrition for infants (Ray, 2014). “The United States Food and Drug Administration (USFDA) permitted marketing of a HMA, to aid healthcare professionals in measuring nutrients in breast milk, including the concentration of fat,

carbohydrate, protein, total solids, and energy." ("FDA Permits Marketing of a Diagnostic Test to Aid in Measuring Nutrients in Breast Milk" 2018, page 1) In 2018 the USFDA provided approval for use in Clinical Laboratory Improvement Amendments (CLIA) labs only, and in 2019 the use of a HMA was approved universally. The composition of human milk is quite variable and having a baseline nutrient content to aid in the fortification of milk for infants is ideal. The variability of human milk macronutrients is related to many factors such as; the gestation of the pregnancy, the number of times per day that mother is nursing and/or expressing milk, the time of day that milk is expressed, how long she expresses milk, and the return of menstruation. Providers should keep in mind that additional variables such as the preparation and handling of fresh vs. frozen milk, duration of infant feedings, and positioning of feeding syringes during enteral feedings will also impact the delivery of macronutrients, particularly fat.

The collection and analysis of human milk occur, as breast milk is the ideal nutrition source and the gold standard feeding method for infants. Breast milk significantly reduces premature babies' chances of developing NEC. The use of a milk analyzer when evaluating and processing human milk can provide better insight into the macronutrient content of the donors' samples. This process can allow for a more targeted pooling of the samples. The state of the current technology now supports the decision to analyze donor milk for nutritional content. The outcome goal post-implementation includes targeted milk for babies in need, resulting in improved growth rates. Human milk analysis puts milk banks at the forefront of change and progress in an industry whose goal is providing optimal care to infants. To understand human milk analysis, it is essential to know that milk banks throughout North America deliver pasteurized donor human milk (PDHM) to Neonatal Intensive Care Units (NICUs) and well-baby postpartum units to babies in need. PDHM is beneficial when supplementation of mothers'

milk becomes necessary. Using a HMA to assess the macronutrient content of pooled PDHM can provide valuable insight, so that milk may be targeted and allocated appropriately to individual babies based on the specifics of their gestation, growth and medical need.

Project Description

This project includes the development of a procedural template (Appendix E) that other milk banks and NICUs can use to facilitate an easy transition from theory to practice. It accounts this idea's journey, change process, and experiences from the concept introduction, staff education, incorporation, launch, and continuance. The goal of the template is to provide milk banks considering the incorporation of a human milk analyzer into practice with a plan or layout that makes the process uncomplicated. The template will be offered to milk banks throughout North America and to the manufacturer's laboratories. It will be presented to the Human Milk Bank Association (HMBANA) standards committee. While pending approval, there will be a poster presentation of the template at the 2022 HMBANA conference. The template development portion of this project was conducted on a voluntary basis by the doctoral student, and did not incur any additional expense to the milk bank. The project intended to implement a quality improvement program to improve the understanding, acceptance and use of milk analysis in the milk banking community. Using of a logic model, a plan was developed to demonstrate the purpose and objectives within a timeline focusing on the identification of need, process, planning, incorporation of the change model, and its effect on care that will lead to an improvement in nutrition. In the form of a created brochure, poster and PowerPoint, this template will be a guide for other milk banks to use when they incorporate milk analysis into their clinical practice.

Project Recipients

The primary recipients of this template will be the remaining 24 milk banks in North America that are not using this human milk analyzer. The experience of following a milk bank as they navigate the journey of pasteurized donor human milk analysis from inception and purchase of the HMA to the hospital roll-out has provided a solid foundation for the template development. During this time, this author has participated in many meetings, compiled research articles, and become acquainted with a whole world of specialists, scientists, and academics that have provided an all-encompassing understanding and perspective on the incorporating of a human milk analyzer into a milk bank.

Secondarily, hospitals and NICUs will benefit from the introduction of milk analysis at their supporting milk banks. "Milk analysis is a tool available to neonatologists and NICUs. Colleagues in the medical, research, and milk banking community are energized about the new evidence on the accuracy and clinical utility of the analyzers now available." (About Us • Mothers' Milk Bank Northeast, n.d.)

Finally, babies will benefit from this project as breast milk is the ideal nutrition source and the infant's gold standard feeding method. The use of a milk analyzer when evaluating and processing human milk can provide better insight into the macronutrient content of the donor sample with a more targeted allocation to babies. This project places value on optimal health and nutrition for neonates using creative, scientifically advanced modalities to better understand the macronutrient content of donor human milk. Health care providers and scientists are accountable for developing, utilizing, and transforming the delivery of optimal nutrition to transform the universe for families.

Expected Result

The expected result of creating a template to guide the incorporation of a human milk analyzer into a milk bank is a seamless transition from donor milk that has not been analyzed to successful human milk macronutrient analysis. Secondarily, the expected result includes improved growth rates with improved health for neonates receiving PDHM that has been analyzed for macronutrient content. This program will facilitate stronger fortification strategies for our NICUs.

Purpose

The purpose of chronicling the incorporation of a HMA into a milk bank practice is to use the information and experience gained to accurately develop a template for standardization and streamlining of the process. Human milk analysis is a relatively new endeavor in the milk bank community, so the establishment and creating a template can provide an opportunity for standardization following HMBANA guidelines. This process can make navigation safer, easier, and timelier for forthcoming milk banks while reinforcing a quality outcome. The focal point will be on human milk analysis of macronutrient content of PDHM to more specifically allocate appropriate milk to babies. Beginning in November 2020, pooled milk was analyzed for the purposes of machine mastery and laboratory practice. Following analysis of donor pools and several months of practice with the HMA, the process of analyzing PDHM and producing Milk Batch Analysis Reports (MBAR's) will be considered the standard of care. Conscious efforts will also be made during this process to increase the number of donors per pool in an effort to more richly fortify the quality of the milk and provide more antibodies.

Aim of Project

The expected result of creating a template for incorporating of a HMA into a milk bank is to increase the ease and effort involved in analyzing milk and remove the barriers that can present themselves while embracing a change process. Through the process of analyzing PDHM, we are creating the opportunity for infants to receive the most optimal, appropriate, high-energy, and nutrient-dense breast milk available to them, thereby supporting their growth. A template can save other non-profit milk banks precious time and money. Having this guide removes the margin of error that we encounter when developing new modalities to increase productivity and efficiency. The Theory Logic Model will demonstrate how human milk analysis can be a process improvement endeavor. The intention is to describe how and why change happens on this occasion. Increased knowledge that will accompany this transition and change process should result in more targeted, accurate behaviors and outcomes. Identification of the program components and stakeholders will facilitate the process of creating forward-thinking change and produce insightful improvements. The outcomes' goal post-implementation includes targeted milk for babies in need, resulting in improved health and growth rates.

Steps to Implementation

The steps to the successful implementation of the project begin with evidence-based education in the milk banking community, specifically to the remaining milk banks in North America not analyzing milk for the identification of macronutrient content. The forum for this educational plan begins with dispensing information via phone calls, emails, meetings, and presentation at the HMBANA conference in April, 2022. Formal education includes the HMBANA presentation in PowerPoint and posters and the distribution of the created brochure

template detailing the many steps and phases included in the incorporation of a HMA into clinical practice.

Significance for Nursing

Creating a template to incorporate human milk analysis in milk banks is significant to nursing primarily because it offers the opportunity for better patient care with improvements in outcomes. Human milk analyzers can measure the macronutrient content in donor milk, thereby allowing for the targeted allocation of the most appropriate milk. The most vulnerable neonates receive the highest protein and fat milk. This process reduces the risk of postnatal growth restriction while receiving breast milk, mother nature's perfect food. Long-term follow-up of infants who receive targeted PDHM will assuredly demonstrate decreased growth restriction as a measure of the magnitude of the successful treatment effect. This template has the capacity to improve patient care through the positive influence of the health care provider. Its impact and improvement on the current medical practice of offering PDHM that has not been analyzed can be considered practical and prudent. The knowledge imparted to the nurse about caring for infants through milk analysis with the clinical support and milk bank safety assurance of a template advances our profession by advocating for the highest quality mothers' milk alternative. The interventions of this project will assist nurses in promoting newborn health. This template makes human milk analysis easier. Human milk analysis is significant to all the components of healthcare as it improves neonatal health and growth and supports exclusive breastfeeding rates. Improvement in exclusive breastfeeding rates can be translated into economic and healthcare benefits at a global scale while decreasing global healthcare expenditures.

LITERATURE REVIEW

This DNP quality improvement initiative will chronicle the incorporation of the USFDA approved HMA into practice at a non-profit milk bank in the northeast. By chronicling the use of the human milk analyzer, a procedural template for the use of targeted human milk will be developed and established for other milk banks to utilize. “The milk bank’s mission is engagement in the larger landscape of breastfeeding support, in which donor milk plays a critical role. Staff is committed to ensuring that milk donation becomes as widely known to the public as blood donation.” (About Us • Mothers' Milk Bank Northeast, n.d.) The current trend in milk banking includes the incorporation of pasteurized donor human milk analysis to further understand macronutrient content. The intent is to translate evidence acquired to guide safe and effective targeted medical and nursing care across a variety of settings. This literature review examines the elements, barriers, facilitators, and changes involved in the process of incorporating the HMA into practice at a human milk bank.

When a mother is unable to feed her infant, donor milk is recommended as the best alternative. (Radmacher & Adamkin, 2017) Human milk analysis is essential in adapting donor milk for the fortification in preterm neonates, and mid-infrared spectroscopy is an accurate way to measure the macronutrient content of human milk (Billard et al., 2015). Using the Human Milk Analyzer through this process will facilitate the most targeted nutrition for infants (Ray, 2014). Biomolecules in breast milk are challenging and difficult to characterize based on their diversity (Ninnonuevo et al., 2009). Despite this complexity, “HMA can inform health care providers information to more closely match an infant’s diet with nutritional needs for adequate growth and development.” (Radmacher & Adamkin, 2017, p. 34) “The HMA will improve the

ability of human biologists and anthropologists to study human milk in field settings." (Miller et al., 2012, p.1)

Comparisons of human milk samples demonstrate "a significant difference in calorie values between methods. A mean calorie difference of 3.1kcal/ ounce is clinically important for preterm infants, suggesting the need for standardization." (Perrin et al., 2020, p. 1692) "Preterm, small for gestational age (SGA) HDM was significantly higher in protein, fat, and energy content than appropriate for gestational age (AGA) HDM and significantly lower in carbohydrate content than AGA HDM. Prematurity is an important determinant of macronutrient content in human milk." (Mills et al., 2019, p. 1155) "Infrared instruments may be useful tools to help milk banks determine how to combine milk from multiple donors to achieve target fat and protein amounts." (Perrin et al., 2019, p. 6) Research studies have considered the possibility of formulating concentrated human milk and freeze-drying it as an additive to milk to bridge the gap in calorie differences between pools. (Oliveira et al., 2019) There are many elements that affect and influence macronutrient content. Research has told us that it is crucial to ensure the proper measurements of macronutrients in donor milk. (Kwan et al., 2020) These measurements are crucial to neonatal growth and are not directly influenced by the infant's gestational age. However, it has been noted that protein count shows a tendency to decrease with the duration of lactation. (Kreissl et al., 2016) The factors that can influence these macronutrient values are varied. A woman's diet is thought to directly impact the quality and carbohydrate, fat, and protein breakdown of her milk. (Bravi et al., 2016) Milk storage containers can also be impactful. "Our study reveals that fat loss occurred in all the breast milk samples that were stored in the nine containers investigated. The loss of fat was as high as 9%." (Chang et al., 2012., p. 9) The storage and freezing of breast milk can diminish antioxidant activity. "Fresh

human milk has the highest antioxidant capacity, which decreases with storage over time. To preserve antioxidant capacity, milk should only be stored for a short time at refrigerator temperature and not frozen" (Hanna, 2004, p. 519). Milk storage and freezing have also been shown to decrease glutathione (GSH) content. GSH has the capacity to detoxify various types of toxins and carcinogens. (Ankrah, 2000) The method of pasteurization can influence the macronutrient quality of donor milk. Protein content has been noted higher in holder pasteurization samples, as opposed to retort sterilization methods (Meredith-Dennis et al., 2017). Finally, instrument accuracy and poor adherence to calibration guidelines can demonstrate variability in values and inaccurate performance outcomes, further complicating analysis results (Giuffrida et al., 2018). "Knowing the macronutrient content of the breast milk may help the health care team and parents make informed decisions on how to fortify the breast milk based on the individual needs of the infant" ("FDA Permits Marketing of a Diagnostic Test to Aid in Measuring Nutrients in Breast Milk," 2018, p. 1).

"Milk analysis is a relatively new addition to the tools available to neonatologists and NICUs. The state of the current technology now supports the decision to analyze our donor milk for nutritional content" (About Us • Mothers' Milk Bank Northeast, n.d.).

THEORETICAL FRAMEWORK

For this project, the Roy Adaptation Model developed by the theorist Calista Roy was applied. The Roy Model views humans as holistic, adaptive systems. The project goal is to promote adjustments that support health and increase adaptability to the vulnerable states of human babies. By the use of feedback and management plans, goals have been modified throughout the process. The project has been able to prioritize the needs of team members and recipients while creating a quality improvement template in an accurate, thorough, and timely

manner. The principles and assumptions of the Roy Adaptation Model place value on human relationships using creative abilities of awareness. People are described as accountable for deriving, sustaining, and transforming the universe. This project places value on optimal health and nutrition for neonates using creative, scientifically advanced modalities to better understand the macronutrient content of donor human milk. Health care providers and scientists are accountable for developing, utilizing, and transforming the process of the delivery of optimal nutrition to transform the universe of these families in need. “Adaptation is the basis for the fundamental concept of homeostasis which is widely used in the study of biology. Adaptation relates to the way an individual responds to changes in the environment, whereas homeostasis is concerned with the internal environment (Akinsanya, 2015, p. 13). This program places value on the interdependence of human beings, while “deriving, sustaining and transforming” health care.

METHODOLOGY

The process of developing a project connected to breast milk was very organic based on the author’s roles and experience as a nurse practitioner and lactation consultant. The project approval process was initiated and readily accepted on the heels of multiple meetings with the founding director of the milk bank. Together the author and milk bank director established the PDHM program and Milk Depot at the local hospital. The IRB approval was waived based on the quality improvement (QI) nature of the project and template creation. This project does not jeopardize any violation of the Health Insurance Portability and Accountability Act (HIPPA), as the element of concern is connected to donor breast milk and its allocation upon analysis. Donor names are never involved in the milk distribution process. Data collection is centralized around the process, rendering the identification of sample collections referred to as “Batch A, B, C, D, etc.”. In the clinical practice setting, the founding director of the milk bank is credentialed to

approve the process based on her instrumental role at this facility. She has willingly volunteered to serve on the Scholarly Project Committee and is qualified to do so based on her extensive expertise in this field.

Risks and Benefits

Risk analysis involves the evaluation of external opportunities relevant to the incorporation of a human milk analyzer into a milk bank. The most significant opportunities for this project are connected to the unique occasion to improve the quality and measurability of PDHM, in response to new USFDA guidelines. Through macronutrient analysis, NICUs and postpartum units will have the fortuitous opportunity to provide targeted, fortified nutrition as a result of this machine and its incorporation into practice. Using the HMA can enhance growth rates for babies improving their transition from the hospital to home. This project has the opportunity to dispute the claim that “babies don't thrive on donor milk” based on precise, factual data. Through this program, there is an opportunity to reduce the variability in nutritional intake compared to generic fortification. It is essential to educate staff RNs about evidence-based guidelines and thereby improve patient and family education regarding the use of analyzed PDHM. Health care providers and families need to better understand that “Human milk analyzers are increasingly used to rapidly measure the macronutrient content in breast milk for individual target fortification, to reduce the risk of postnatal growth restriction.” (Kwan et al., 2020, p. 2121) Risk Analysis includes a comprehensive understanding of the threats that jeopardize the project's success. Currently, competitors are attempting to develop more effective products as they study the current model, its assets, and its deficits. Due to calibration inconsistencies, there is the potential for USFDA approval to be threatened or removed based on variations in macronutrient analysis. The HMA can provide us with a false sense of security regarding

macronutrient values if not properly calibrated. Operational errors and maintenance errors must always be considered as a threat. The additional cost to a human milk bank can be prohibitive to many non-profit institutions. The final recognizable threat is that long-term studies demonstrate no improvement in growth rates for babies receiving PDHM that has undergone milk analysis, as the concept of using a USFDA-approved modality specific to human milk is still in the neonatal stages.

Despite the risks, the analysis identified many important strengths. The APN compiling this information and writing the template has expertise in breast milk, lactation, and women's health while functioning in a clinical position at a hospital receiving and using PDHM. Additionally, the same APN brought the concept of using donor milk in lieu of formula to the hospital while also establishing the hospital's milk depot. A milk depot is a collection point for milk donors to send their excess supply to milk banks. It is a strength having direct access to the milk bank, NICUs, and postpartum units using donor milk. The project’s strength is also evidenced by the support it has received from experts in the field who are associated with the milk bank and invested in its success. Their support is evidenced by the many emails, insights and perspectives, opinion contributions, phone calls, article advice, and virtual meetings. There is a precise level of strength in being a pioneering milk bank incorporating the analyzer into practice, on the heels of FDA approval.

This DNP quality improvement initiative will chronicle the incorporation of the USFDA-approved human milk analyzer into practice at a milk bank in the northeast. By chronicling the use of the human milk analyzer, a procedural template for the use of targeted human milk will be developed and established for other milk banks and neonatal intensive care units to utilize. This initiative will be followed and developed to provide a comprehensive template or guide for other

facilities interested in incorporating human donor milk macronutrient analysis into their clinical practice. The development of this project includes the use of a framework to identify strengths, weaknesses, opportunities, and threats (SWOT) to the use of a milk analyzer, and the development of a procedural template when processing pasteurized donor human milk. The SWOT analysis will be used by the APN and Executive Director of the milk bank throughout the process of incorporating the HMA into the milk bank's new guidelines and while writing the template. Through this dynamic process, the team hopes to clearly identify the strengths at hand while focusing on methods to minimize weakness. This project is well-aligned with the milk bank mission of engagement in the larger landscape of breastfeeding support, with donor milk playing a critical role. It is the hope and goal of the milk bank to ensure that milk donation becomes as widely accepted and known to the public as blood donation.

The first step in the SWOT analysis identified many important strengths. This author has expertise in breastmilk, lactation, and women's health. Additionally, the author brought the concept of using donor milk in lieu of formula to the hospital while also establishing the hospital's milk depot. Through this journey, a relationship was developed with the collaborating milk bank. It is a strength having direct access to the milk bank. It is a strength having direct access to the milk bank, NICUs, and postpartum units using donor milk.

The second step of the SWOT analysis identified several weaknesses addressing the ethical controversy regarding the analysis of PDHM and universal concerns over a false sense of assuredness to NICUs and postpartum units. The measurements need to be authentic and accurate. "The HMA, based on mid-infrared methodology, is convenient for a unique determination of macronutrients. However, HMA measurements are not totally comparable with reference methods (RMs)." (Billard et al., 2015, p.19) The potential exists that milk analysis

may threaten the breastfeeding model and inspire mothers to then seek to evaluate their own milk for protein, fat, and carbohydrate content. Those results have the potential to negatively affect a breastfeeding dyad. Donor milk that is lower in content may be devalued and discarded. The presence of trepidation regarding the use of donor milk in some institutions exists. Milk analysis is not a universally embraced concept and can be likened to opening a pandora's box. There is a lack of long-term evidence of the effectiveness of the process of human milk analysis related to recent USFDA approval. A weakness includes the lack of universal support and understanding by the milk bank culture.

Many knowledge deficits regarding the use of donor milk exist in hospitals and communities. Clinical staff tends to be more receptive to donor human milk banking than non-clinical health workers who are not familiar with its use. At the same time, many communities have never even heard of milk donation. There is an expense associated with the use of PDHM. With a prescription and a medical indication, insurance is expected to reimburse recipients for the cost; however, without a medical indication PDHM can average $4.50 an ounce. An expense that can accumulate rapidly.

The third step in the SWOT analysis involves the evaluation of opportunities (external) relevant to the incorporation of a human milk analyzer into a milk bank. The most outstanding opportunities for this project are connected to the unique occasion to improve the quality and measurability of PDHM, in response to new USFDA guidelines. Through macronutrient analysis, NICUs and postpartum units will have the fortuitous opportunity to provide targeted, fortified nutrition as a result of this machine and its incorporation into practice. Using the HMA can enhance growth rates for babies improving their transition from the hospital to home. This

project has the opportunity to dispute the claim that “babies don't thrive on donor milk” based on clear, factual data.

The fourth and final step of the SWOT analysis includes a comprehensive understanding of the threats that jeopardize the project's success. Currently, HMA competitors are attempting to develop more effective products as they study the current model, its assets, and its deficits. There exists the potential for FDA approval to be threatened or removed based on variations in macronutrient analysis due to calibration inconsistencies. The final recognizable threat is that are no long-term studies in human milk analysis, as it is a relatively new concept.

Timeline

This project implementation timeline to date starts with months one and two to include identifying of the scholarly project topic, establishing of a mentor, thorough literature review, further research of the topic to ensure understanding, and the creation of an annotated bibliography. Month three to five include; weekly meetings with the mentor via phone, email, text, zoom. There were many conversations with field experts, participation in virtual training sessions with the lab, revision of the milk bank website position statement, development of a charting system using an Excel spreadsheet for lab data and macronutrient content. There were many phone calls with executive directors of various milk banks to discuss their transition to the use of a HMA. All of this information was provided to my mentor regarding the specific knowledge gained. The development of a SWOT analysis and risk management matrix. There were many additional follow-up phone calls with other milk banks for procedural guidance. On November 13, 2020, the incorporation of the HMA into the milk bank was initiated with success. Following this official beginning, this author was tasked with selecting an appropriate related

academic article on the calibration of a HMA, and began preparations to present it to the Board of Directors (BOD).

Month six and seven started with the presentation of the milk analysis article to BOD. It was well-received and many questions ensued. There was an extensive follow-up and continued evaluation of HMA reports, including a very informative virtual meeting with nutritional experts to understand the results of milk analysis more effectively. At this time, we had to revise the Excel worksheet to reflect our new understanding. In an effort to improve fortification, the bank attempts to increase donors to 3 per batch, despite barriers with lactobacillus infection rates. In response to this, there were multiple meetings to discuss research-related articles to troubleshoot the bacillus outbreak. Additionally, there were several meetings with the operations team to change HMA spreadsheet. A letter was composed to inform hospital recipients of the use of HMA and its effect on their practice and relevance to babies. Together with the milk bank director, the Nutritional Standards Committee (NUTS) HMBANA guidelines were reviewed, and modifications were made to the hospital letter based on the updates.

Month eight through eleven included a continued collection of data and evaluation of MBA reports, milk pooling, and bacillus rates. Data was compiled on the projected sustainability of the project. Using the information acquired to this point, the template is choreographed. Month twelve takes us to the anticipated official roll-out of our HMA to hospitals and the presentation of the template. There is a delay in the official roll-out in response to covid related staffing deficits. The projected roll-out is established as fall 2022. A graphics company is contracted and the develop a beautiful poster and pamphlet.

Budget

Developing a budget imparts important questions and analysis to the agency at hand. "Once management has decided on a business plan, they need to determine a) if they can afford those goals b) if the plan will make a profit and c) if the plan will meet the goals set by management" (Siciliano, 2015, p. 177). Over the course of many months, extensive discussion and collaboration between the milk bank and their BOD led to the mutually agreed upon establishment of a business plan that included the incorporation of a human milk analyzer into practice.

As a non-profit, this milk bank attempted to offset the cost of an analyzer by applying for a grant for the $50,000 project. The grant was denied as the organization offering the assistance did not support the concept of payment for donor milk. The business plan was strategic, and the milk bank was able to safely afford the established goals by tapping into their capital budget. The milk bank's proper planning and financial management provided a cushion of funds from the revenues acquired and secured the milk analyzer. The incorporation of the HMA was never intended to make a profit for the company. The acquisition provided an opportunity for additional human milk research, data, and macronutrient content evidence to dispute the theory that babies do not grow successfully on donor milk. Using an analyzer keeps the milk bank at the forefront of change and innovation in milk banking. "The purpose of healthcare professional education is to educate learners to a high standard and keep them up to date-not make a profit." (Managing a Budget in Healthcare Professional Education, n.d., p. 72) The return on investment is anticipated to equal the upfront cost but not generate any profound change or growth in the financial direction of this nonprofit organization. The operational budget will cover the monthly cost associated with maintaining the human milk analyzer.

The cost of the analyzer is $50,000, annual service and extraneous expenses averaged approximately $7,800. (Appendix C) The expense for HMA supplies and disposables is based on last year's processing estimates of 522,000 ounces of milk.

The chronicling of this process and the choreography of an instructional template to guide other milk banks through the incorporation of a human milk analyzer into their practice will not incur any additional expense to the institution, as it is a voluntary, academic endeavor. The template is now available and offered to milk banks throughout North America. It has been submitted to the product manufacturer laboratories and has been forwarded to the HMBANA standards committee for their review. The template development portion of this project is on a voluntary basis by the doctoral student, and did not incur any additional expense to the bank. Labor hours have been spent on research, observation, education, the choreography of the proposed template, and presentation of the finished product to interested milk banks and HMBANA.

The budget is a planning tool. “A nonprofit budget is a planning document used to predict expenses and allocate resources for your organization.” (Nonprofit Budgeting: Understand the Basics, 2020, p. 1) Through strategic planning, effective allocation, and earmarking, the milk bank was able to format a successful budget to guide their non-profit milk bank to the forefront of change and progress in this industry. Macronutrient analysis of human milk provides targeted milk for vulnerable neonates to enhance their growth and development and reduce their risks of medical complications associated with prematurity.

Marketing

“As the philosophy and marketing techniques in other fields cannot find applicability in the healthcare services, healthcare needs its own approach to present certain features that are not

found in other industries." (The Impact of Marketing Strategies in Healthcare systems, n.d., p. 93) Marketing a project in the confines of the milk bank, hospital dynamic is much less complex than marketing a product in the business world to consumers. Buy-in already exists based on the nature of the established, trusting relationships, and the mutual goal of delivering quality healthcare. The Human Milk Analyzer project is research-based, with an educational tool designed to improve the process of allocation of human milk-based on its macronutrient content and the nutritional needs of NICU babies. Marketing includes the preparation of an informative letter notifying the participating hospital's NICUs' of the change process, the inclusion of estimated milk batch analysis reports with each batch of donor milk delivered, and finally an update to the milk banks' website informing the public about the analyzer. The financials of the marketing plan included 20 hours of time divided by three people to create materials to roll out the program, at an average of $30 an hour for twenty hours, or $600. The key stakeholders include; the milk bank, the participating hospitals, the recipients of the donor milk, and the breastfeeding community at large. The critical focus of marketing is directed towards the ninety hospitals participating in the allocation of milk from this milk bank, and the letter addressing the change process (Appendix A) describing what it means to their patients and families. A great deal of focus and attention was also given to the website position statement on milk analysis (Appendix B)

Needs Assessment, Phase 1

The needs assessment for this project includes the systematic process for determining and addressing the gaps that exist when a hospital is trying to support breastfeeding and the use of donor milk as the current alternative condition. There exists a more accurate modality to target

PDHM through human milk analysis that has prompted the use of an analyzer. Milk analysis bridges the gap and provides the most allocated nutrition for babies.

The identification of a better way to provide PDHM to babies, improve their growth and the desire to be at the forefront of progressive change in milk banking prompted this milk bank to invest in an analyzer. The serendipitous timing of this author's interest in a project involving human milk banking made this an ideal and mutually beneficial collaboration.

Stakeholder Support, Phase 2

The milk bank research and the advisory board did not previously support the use of human milk analyzers as there was not one USFDA approved. The sentiment was that cow analyzers, being used by many milk banks, were not wholly accurate on human milk. Following USFDA approval, the advisory board and milk bank staff were eager to partake in a venture that could improve health and growth rates. Other stakeholders included hospitals, health care providers, and NICUs. NICUs want an analysis of milk to account for individual variation when fortifying donor human milk, the HMA measures that individual variation accurately. With the hospital, providers, and the milk bank on board, stakeholder buy-in was complete. Communication was essential in ensuring this phase and bringing human milk analysis to the forefront of the milk bank mission.

Implementation, Phase 3

The initial implementation of the project, following the purchase of the HMA, included a plethora of meetings with field experts familiar with the process of milk analysis; milk bank directors using this analyzer; neonatologists, scientists, dieticians, pediatricians, nurses, and IBCLCs. Phone calls, emails, meetings, text messages, in-services, reading, and research built a solid foundation for the program. Following the establishment of a strong initial structure,

training with the manufacturer began, Since the company is based in Upsala, Sweden the training included many early mornings meetings. In these meetings, we were educated and in-serviced on the details of operation and calibration. Other phases of the initial implementation included the composition and revision of the milk bank position statement regarding the introduction of human milk analysis into the distribution of PDHM to NICUs (Appendix B). This author was responsible for writing the letter to hospital recipients (Appendix A) regarding analysis of PDHM and its potential effect on their practice and relevance to babies in their care. Together with the milk bank director, the NUTS guidelines were evaluated and the hospital letter was modified based on the updates. Tireless efforts were applied to the development of a charting system using the Excel spreadsheet for lab data, and macronutrient content including the compilation of charting for laboratory data.

The next step included selecting an appropriate related academic article on the calibration of a HMA, and this author began preparations to present it to the BOD. It was well-received and many questions ensued all connected to this endeavor. There was an extensive follow-up and continued evaluation of HMA reports, including a very informative meeting with an experienced dietician to understand the results of milk analysis more effectively. At this time, we had to revise the Excel worksheet to reflect our new understanding. In an effort to improve fortification, the bank must attempt to increase donors to 3 per batch, despite barriers with lactobacillus infection rates. There were multiple meetings to discuss related research articles to troubleshoot the bacillus outbreak in response to this. Additionally, there were several meetings with the operations team to change HMA spreadsheet. On November 13, 2020, the incorporation of the HMA into the milk bank was initiated with success.

Ongoing Implementation, Phase 4

As the implementation and roll-out came closer to fruition, the efforts to increase fortification by increasing pool donors to three per batch continued. This increased number of donors is associated with high rates of bacillus in milk, thereby bringing the production of HMA to an abrupt halt and reflexively delaying roll-out. In response to the bacillus identification, milk is wasted. Field experts, assembly line specialists, milk scientists, and manufacturing engineers are consulted and offer a plethora of advice and guidance.

Additionally, the milk bank sustained a great hit during the Covid-19 pandemic. Many staff changes ensued. The director of the milk bank stepped down, the lab director, the director of hospital relations, and many laboratory technicians resigned unable to perform their functions in the face of the pandemic. These principal staff and directorial changes put the HMA roll-out on the lower end of the priority list. The HMA manufacturing company was asked to return to the bank, assist with the new staffing changes and assume responsibility for operations orientation. During the delay in production, this author was able to reflect on the experiences of the last year and create the template (Appendix E) for the incorporation of an HMA into practice, as the foundation for this project had been thoroughly established by this time. Ongoing implementation includes paying close attention to the budgeting and marketing components throughout. The most incredible opportunities for this project are connected to the unique occasion to improve the quality and measurability of PDHM, in response to new FDA guidelines. “A wide variety of bacteria contaminate human milk from donor mothers” (Landers & Upgrove, 2010, p. 121).

Project Evaluation, Phase 5

The observational and participatory experiences can measure this project evaluation over the past year and create a change process procedural template for the incorporating a human milk analyzer into a milk bank. The long-term implications of the effectiveness of the template are yet to be measured, based on the composition of this quality improvement initiative. The project outcome can be clearly evaluated and considered in the forthcoming years, as we ascertain the level of participation in human milk analysis and the utilization of our template as a procedural guideline meant to augment the process. If the majority of milk banks in North America are analyzing donor milk in one year, with success and ease, then we will consider this project and template to be successful.

Data Collection and Analysis

The outcome measurements for data collection and analysis of this long-term study will include the quantitative results captured to measure the change process in milk banks. How many milk banks have incorporated the use of the template into their practice? Ascertaining the number of banks is a simple process that does not require complex statistical analysis; however, it will take time to be measured over the period of approximately twelve months. To enhance the efficacy of findings and usefulness of the template, a follow-up survey has been developed to be distributed to milk banks with the template to measure and assure that the template was obliging (Appendix F). Additionally, a post implementation feedback survey was created for hospitals to complete so that we may better measure the effectiveness of milk analysis from health care providers perspectives (Appendix G).

Conclusions and Summary

A milk bank is a non-profit service that collects, screens, and processes by pasteurization human milk that is donated by mothers not biologically related to the infant in need. Milk is then dispensed to hospitals and private homes to babies with a prescription. Breast milk is collected and analyzed, as it is the ideal nutrition source and the gold standard feeding method for infants. In January 2019, the HMA became the first USFDA-approved analyzer for use with human milk in clinical and milk bank settings. The HMA uses mid-range infrared transmission spectroscopy and patented innovation to analyze the macronutrients, energy, and total solids in human breast milk. This milk bank has been utilizing the HMA to strategically pool and prepare optimal batches of PDHM since November 2020. The analyzer is calibrated once a day and validated every 10 samples, per the manufacturer and USFDA guidelines. The composition of human milk is quite variable and having a baseline nutrient content to aid in the fortification of milk for infants is ideal.

Through this process, under the guidance of the milk bank, this author has developed a procedural template that other milk banks and NICUs can use to facilitate an easy transition from theory to practice. The template chronicles this idea's journey, change process, and experiences from the concept introduction, staff education, incorporation, launch, and continuance. The goal of the template is to provide milk banks considering the incorporation of a human milk analyzer into practice with a plan that makes the process uncomplicated. Simplification of macronutrient analysis enhances targeted nutrition while improving health and growth.

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APPENDICIES

Appendix A

Letter to Hospitals

In January 2019, the MIRIS Human Milk Analyzer (HMA) became the first FDA-approved analyzer for use with human milk in clinical and milk bank settings. The MIRIS HMA uses mid-range infrared transmission spectroscopy and a patented innovation to analyze the macronutrients, energy, and total solids in human breast milk. Mothers' Milk Bank Northeast has been utilizing the MIRIS HMA to strategically pool and prepare optimal batches of pasteurized donor human milk (PDHM) for the last 3 months. The analyzer is calibrated once a day and validated every 10 samples at MMBNE, per the manufacturer and FDA guidelines.

The composition of human milk (donor or mother's own milk) is quite variable and having a baseline nutrient content to aid in the fortification of milk for infants is ideal. The variability of human milk macronutrients is related to many factors such as the gestation of the pregnancy, the number of times per day that mother is nursing and/or expressing milk, the time of day that milk is expressed, how long she expresses milk, and the return of menstruation. Providers should keep in mind that additional variables such as the preparation and handling of fresh vs. frozen milk, duration of infant feedings (bolus vs. continuous) and positioning of feeding syringes during enteral feedings (vertical vs. horizontal) will also impact the delivery of macronutrients, particularly fat.

In an attempt to facilitate stronger fortification strategies for our NICU's, Mothers' Milk Bank Northeast will provide each facility with a *Milk Batch Analysis Report (MBAR)* with each shipment. The MBAR will provide the HMA results for fat, carbohydrates, true protein, crude protein, total solids, and energy counts. We will continue to make it our priority to send our highest fat and protein count batches to NICU's at no additional cost.Our focus will be to follow the new HMBANA (Human Milk Bank Association of North America Guidelines) that encourage the "pooling" or combining of three or more donors in each batch and to move away from an emphasis on calories and towards an emphasis on fat and protein. As a reference milk batch analysis reports (MBAR's) may look similar to the model below.

Standard Milk: 3.2-4.2 g/dL total fat, .9-1.2g/dl crude protein (19-21 k cal)

Protein Plus Milk : *3.2-4.2 g/dl total fat, 1.3 g/dl crude protein (19-21 k cal)*

Energy Plus Milk: >4.3 g/dl total fat, .9-1.2 g/dl crude protein (>22 k cal)

Community Milk: 2.2 g/dl total fat, .8 g/dl crude protein (16-18 k cal)

Reduced Fat Milk: <1 g/dl total fat, >.9 g/dl crude protein (16-18 k cal)

The move away from calorie-named based products is a reflection of the accuracy of the milk analyzers that are most efficient at measuring fat and crude protein, and not precise enough to distinguish between 19 and 20 kcal/oz milk. On these reports a range for calories will be provided with the focus on the fat and crude protein. It is critical to note that the MIRIS HMA results reported by Mothers Milk Bank should not be the sole basis for the management of the infant's nutrition care. The HMA device provides the range of energy and macronutrients in PDHM but cannot determine the bioavailability of any nutrient. The results of human milk analysis will not alone predict infant growth. Multidisciplinary monitoring of the infant's weight, growth, and labs will remain the gold standard for assessing the infant's nutrition needs.

Please feel free to reach out with any questions via email at info@milkbankne.org

Appendix B

Statement on Analysis of Donor Human Milk

Staff Medical Alerts

We often answer questions from health care providers about our detailed and evidence-based safety protocols, including donor screening modeled after blood banking and milk storage, and testing and pasteurization techniques compliant with FDA food preparation regulations and the Human Milk Banking Association of North America (HMBANA).

Recently, we have received a number of queries about milk analysis. Milk analysis is a relatively new addition to the tools available to neonatologists and NICUs. As a new technology, it takes time to conduct research and to determine best practices.

The Mothers' Milk Bank Northeast (MMBNE) Medical and Research Advisory Boards have considered this issue carefully. The state of the current technology now supports the decision to analyze our donor milk for nutritional content. We and other colleagues in the medical, research, and milk banking community are energized about the new evidence on the accuracy and clinical utility of the analyzers now available and in use.

In 2018 the FDA permitted (for the first time) marketing of the infrared spectroscopy system (MIRIS Human Milk Analyzer) to analyze human milk and determine the concentrations of fat, carbohydrate, protein, solids, and energy. "Knowing the macronutrient content of the breast milk may help the health care team and parents make informed decisions on how to fortify the breast milk based on the individual needs of the infant." ("FDA Permits Marketing of a Diagnostic Test to Aid in Measuring Nutrients in Breast Milk," 2018)

Neonatal Intensive Care Units (NICUs) want analysis of milk to account for individual variation when fortifying donor human milk, the Miris Human Milk Analyzer measures that individual variation accurately. HMBANA guidelines require milk banks to pool milk from multiple donors to achieve a good mix, an average of the components of mothers' milk. This reduces the variation among batches of pasteurized donor milk. This is designed to make each batch of donor milk as close to the literature values for mature milk (milk produced from one month parturition onward) as is feasible.

MMBNE's new policy (in response to the FDA regulations) is that it is efficacious to provide representative (averaged) milk while providing additional nutritional information obtained through the use of the MIRIS Human Milk Analyzer. The nutritional content (energy, fat, protein, carbohydrate values) of human milk changes over time; fortification without knowledge of macronutrient breakdown has the potential to miss nutritional targets for infants at risk. The Miris HMA can measure these components effectively, enabling adapted, targeted fortification as appropriate.

It is our belief, inspired by science and research (and supported by the FDA), that this approach to analysis of donor human milk stands to reduce the variability in nutritional intake, providing the greatest opportunities for sustained physical growth for infants in need.

FDA permits marketing of a diagnostic test to aid in measuring nutrients in breast milk. (2018). *Case Medical Research*. https://doi.org/10.31525/fda2-ucm629089.htm

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Appendix C

Table 1

Proposed Budget
The Incorporation of a Human Milk Analyzer into a Milk Bank, With the Creation of a Template to Streamline the Process for Other Milk Banks.

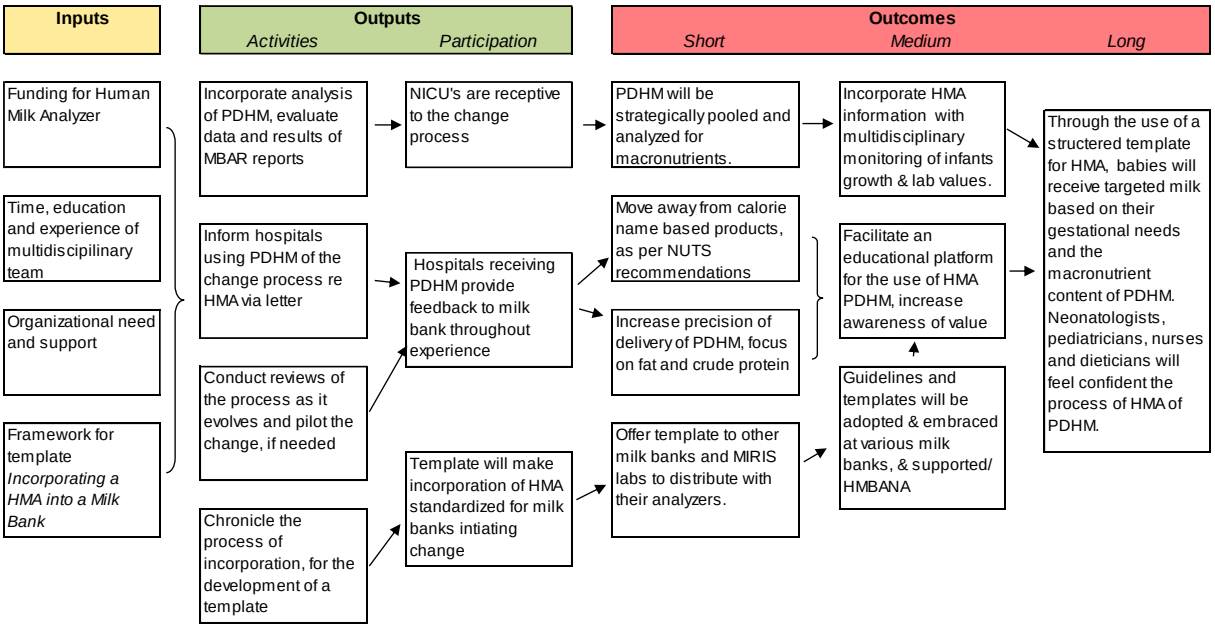
Resources	**Estimated Expense**	**Actual Expense**
MIRIS Human Milk Analyzer	$50,000	$50,000
Annual expense for HMA supplies/ disposables	$7,000	$6,437
Principal investigator, author of template. Estimated 100 hours	volunteer	$0
Expense of laboratory staff training	$0 Incorporated in cost of HMA	$0 Incorporated in cost of analyzer
Marketing (Communication to hospitals via letters, emails and web updates) 20 hours of time divided by three people to create marketing materials to roll out the program, at an average of 30$ an hour.	20 hours x $30/ hour= $600	$600
Printer paper and paper for labeling bottles annually	$200	$200
Platinum Service Contract with MIRIS Labs	$500 annually	$500 annually
Total	**$58,300**	**$57,737**

Appendix D

Theory Logic Model

Program: **The Incorporation of a Human Milk Analyzer (HMA), and the Development of a Template for the Processing of Pasteurized Donor Human Milk (PDHM) in a Milk Bank**

Situation: PDHM has traditionally been distributed to NICU's, from milk banks without maacronutrient content breakdown as part of the sample. The FDA has recently approved the use of the MIRIS Human Milk Analyzer (HMA) for identification of that content. This project seeks to chronicle one milk banks journey of incorporation and establish a template for other milk banks to use, as they incorporate human milk analysis fro a seamless and successful transition.



Assumptions= The program resources are adequate and available to support the incorporation of a HMA into practice. The HMA will provide macronutrient content of PDHMto NICU's through milk batch analysis reports. A template will provide guidance, resources and support in accordance with HMBANA standards to other milk banks.

External Factors = Bacillus infection rates (bacterial contamination of milk) are propogated when we try to increase the number of donors in a pool for donation. Pooling is ideal and essential , as it increases the macronutrient fortification value of the product. Combining three or more donors is recomended when using HMA.

Rev. 7/09

Appendix E

Template for the Incorporation of a Human Milk Analyzer into Your Milk Bank

Procedures for Milk Analysis in your Milk Bank

The intent of this template is to translate evidence acquired to guide safe and effective nursing care across a variety of settings. Through this process, I have been developing a procedural template that other milk banks, and NICUs can use to facilitate an easy transition from theory to practice. The Human Milk Analyzer (HMA) is currently the only FDA approved modality (of any sort) to measure energy, fat, carbohydrate, and protein content in human milk. It does so within minutes, using a small volume of supply. These measurements of pasteurized donor human milk (PDHM) are conducted in an effort to provide targeted, individualized nutrition for babies due to the high macronutrient variability in human milk throughout the lactation period (nutrient content of full term donor milk is different than that of preemie donor milk) This process assures that the neediest babies receive the densest milk available to them. The template chronicles the journey, change process, and experiences of this idea from the concept introduction, staff education (in servicing), incorporation, launch and continuance.

7. Introduction

The current trend in milk banking includes the incorporation of pasteurized donor human milk analysis to further understand macronutrient content (As of May 2021, 6 out of 30 nonprofit milk banks in North America are using a HMA. There are milk banks using other types of analyzers that have not been FDA approved specifically for human milk analysis). The intent is to translate evidence acquired to guide safe and effective targeted medical and nursing care across a variety of settings.

Using the Human Milk Analyzer through this process will facilitate the most targeted nutrition for infants (Ray, 2014).

"The U.S. Food and Drug Administration permitted marketing of the Human Milk Analyzer, a new diagnostic test to aid healthcare professionals in measuring nutrients in breast milk, including the concentration of fat, carbohydrate, protein, total solids, and energy. The test provides healthcare professionals with a new tool to aid in the nutritional management of newborns and young infants at risk for growth failure due to prematurity or other medical conditions." ("FDA Permits Marketing of a Diagnostic Test to Aid in Measuring Nutrients in Breast Milk,"2018) In 2018 the FDA provided approval for use in CLIA labs only, and in 2019 the use of MIRIS HMA was approved universally.

Why collect and analyze human milk? Breast milk is the ideal nutrition source and the gold standard feeding method for infants. Breast milk significantly reduces premature babies' chances of developing NEC (necrotizing enterocolitis is a disease associated with prematurity that affects

the lining of the small intestine. The intestine becomes damaged, necrotic and dies resulting in surgery. Infants who are exclusively formula fed are at higher risk for NEC.) Human milk, including donor milk, also offers gastrointestinal protection, strengthens immunity, decreases the likelihood of asthma, allergies, ear infections, obesity, and respiratory ailments. Some mothers are unable to breastfeed their own babies due to a multitude of medical conditions (breast surgery, breast cancer, thyroid disease, PCOS, hypoplasia, medication contraindication, complicated birth/ postpartum hemorrhage, or retained placenta). For these mothers and babies, donor milk is a viable option. The use of a milk analyzer when evaluating and processing human milk can provide better insight into the macronutrient content of the donors' samples. This process can allow for a more targeted pooling of the samples.

II. Goal

The state of the current technology now supports the decision to analyze donor milk for nutritional content.

The outcome goal post-implementation includes targeted milk for babies in need, resulting in improved growth rates.

"We and other colleagues in the medical, research, and milk banking community are energized about the new evidence on the accuracy and clinical utility of the analyzers now available and in use."(*About Us • Mothers' Milk Bank Northeast*, n.d.)

III. Analyzer Use

What is the need you have identified for analysis of donor human milk? Why do you want to better understand PDHM nutritional content?

Which hospital neonatal intensive care units are requesting this service? Why do they want it?

Understand the current state of technology and research that supports macronutrient analysis of human milk. What are the drawbacks?

Consult with your milk bank's medical and research advisory boards for their perspectives.

Seek consensus among the Board of Directors, employees, and hospitals receiving donor milk

VI. Develop a Budget

The budgeting portion is critical to ensure that adequate resources are set aside prior to project implementation.

Through strategic planning, effective allocation, and earmarking, the milk bank can develop a successful budget to guide their non-profit milk bank to the forefront of change and progress in this industry.

Allocating funds for the capital purchase of the analyzer can come from the milk bank (or hospital) revenue, fund raising, or application for acceptance of a non-profit grant.

Resources	**Estimated Expense**	**Actual Expense**
Human Milk Analyzer	$50,000	
Annual expense for HMA supplies/ disposables	$7,000	
Extras		
Expense of laboratory staff training	$0 Incorporated in cost of HMA by MIRIS Labs	
Marketing (Communication to hospitals via letters, emails and web updates) 20 hours of time	20 hours x approximate -ly $30/ hour= $600	
Printer paper and paper for labeling bottles annually	$200	
Platinum Service Contract with MIRIS Labs	$500 annually	

$58,300

V. Develop a Timeline

Once the team has committed to the investment in the HMA, develop a project timeline with a roll out in approximately 6-10 months. Decide where analyzer fits in other strategic and operational priorities.

Leave time for staff education, and troubleshooting associated with learning to use new equipment, increased donor pooling and potential rise in bacillus rates.

VI. Develop a Marketing Plan

Marketing a project in the confines of the milk bank hospital dynamics is much less complex than marketing a product in the business world to consumers. Buy in already exists based on the nature of the established, trusting relationships, and the mutual goal of delivering quality healthcare.

The Human Milk Analyzer project is research based, with an educational tool designed to improve the process of allocation of human milk based on its macronutrient content and the nutritional needs of NICU babies.

Marketing includes the preparation of an informative letter notifying the participating hospitals' NICUs of the change process, the inclusion of estimated milk batch analysis reports (or specified bottle labels) with each batch of donor milk delivered, and finally an update to the milk bank website informing the public about the analyzer. (letters attached)

The estimated financials of the marketing plan include communication with hospitals via letters, emails and web updates, 20 hours of time divided by three people to create materials to roll out the program, at an average of $30 an hour for twenty hours, or $600. The key stakeholders include; the milk bank, the participating hospitals, the recipients of the donor milk (neonates), parents of premature babies and the breastfeeding community at large.

VII. Training

MIRIS has built extensive knowhow and expertise on coaching their customers in setting up the best solutions for their specific needs.

MIRIS assumes full responsibility for staff and laboratory training tailored to your milk bank needs.

Online demonstrations in the Miris Studio™ give you the opportunity to discover everything from set up, walk-through the different sequences in the daily use of Miris HMA™ and the process of human milk analysis.

VIII. Available Supporting Resources

Included as a supplement to this template, for your reference, exists an Annotated Bibliography, SWOT Analysis, Theory Logic Model and Risk Management Profile. (will provide upon request)

IX. Access to Experts

Who are the experts in your organization (neonatologists, dieticians, scientists, pediatricians, nurses, lactation consultants, feeding specialists) or on your Board of Directors? Who are the hospital experts in the NICUs' receiving your donor milk?

Access the knowledge of your experts to help the organization achieve implementation and sustainability.

Provide an online platform for accessing experts via zoom, email, chat group, Facebook page, etc to improve and fortify the human milk analysis experience. Tap into their knowledge throughout the journey of milk analysis and after the roll-out is complete.

Take advantage of the experiences of other milk banks that have incorporated an analyzer in their practice. Set up meetings, access protocols and tap into the knowledge of those using the MIRIS HMA.

X. Evaluate and Practice HMA on Small Samples

In an effort to increase laboratory staff proficiency and productivity, test small samples as often as possible over a sufficient period of time prior to the official roll-out to ensure a successful transition to milk analysis, and to implement efficiencies and improvements before roll out.

Conscious efforts should be made during this process to increase the number of donors per pool (recommended 3-5) in an effort to more richly fortify the milk. Bacillus rates should be monitored continually through this process as there is an increased propensity with increase in number of donors in a pool. (Troubleshooting this process can delay the roll-out timeline.) Through the incorporation of modified, targeted educational plans to donors (pump cleaning, milk storage), and through the consultation of milk experts and product line experts additional (specified) modifications can be made with regard to milk processing, resulting in improvements in bacterial rates.

Evaluate and modify (as needed for your bank) the excel spreadsheet that comes with the MIRIS HMA. This spreadsheet will be directly connected to the milk batch analysis reports and bottle labels you attach to the donor milk, so ensure that the spreadsheet is appropriate to your needs.

XI. Roll-Out

Develop a formal launch plan that includes; schedule, milestones, alignment and communication with the hospital.

Make certain that all components are aligned prior to launch; marketing, customer service, clinical experts, administration, laboratory staff, etc.

Establish a plan to track progress of the use of human milk analyzer once received by NICUs

Seek feedback on an established schedule from NICUs.

Ensure the oversight and ongoing evaluation-processes are rigorous, regular, compliant with regulations and standards and documented.

Follow carefully the manufacturers recommendations and the Human Milk Bank Association of North America (HMBANA) standards and requirements regarding upkeep, calibration and validation of the HMA.

The greatest opportunities for this project are connected to the unique occasion to improve the quality and measurability of PDHM, in response to new FDA guidelines. Through macronutrient analysis, NICUs and postpartum units will have the fortuitous opportunity to provide targeted, fortified nutrition as a result of this machine and its incorporation into practice. Using the MIRIS HMA can enhance growth rates for babies improving their transition out of the hospital to home. This project has the opportunity to dispute the claim that “babies don’t thrive on donor milk” based on clear, factual data.

Appendix F

Follow up Survey
Follow Up Survey, Post Template Implementation
Procedures for Milk Analysis at a Milk Bank

1.How likely is it that you would recommend the use of this template to another milk bank?

a. Extremely likely
b. Very likely
c. Likely
d. Not likely
e. Definitely not

2. Overall how would you rate this template?

a. Excellent
b. Very good
c. Good
d. Fair
e. Poor

3. What do you like about this template?

What did you dislike about this template?

5. How organized was this template?

a. Extremely organized
b. Very organized
c. Somewhat organized
d. Not so organized
e. Not at all organized

6. How helpful was the template?

a. Extremely helpful
b. Very helpful
c. Somewhat helpful
d. Not so helpful]
e. Not at all helpful

7. Is there anything else you would like to share about the template?

Appendix G

Follow Up Survey, Post Implementation
Procedures for Milk Analysis at a Milk Bank

The composition of human milk (donor or mother's own milk) is quite variable and having a baseline nutrient content to aid in the fortification of milk for infants is ideal. The variability of human milk macronutrients is related to many factors. The state of the current technology supports the decision to analyze our donor milk for nutritional content. Please take some time to complete this survey and let us know how your hospital is embracing PDHM Analysis.

1. When did your facility start using PDHM that has been analyzed for macronutrient content?

2. How was this change process received by health care professionals?

3. Please describe your hospital-based protocol for allocation of milk that has been analyzed. Is there a direct connection to the MBAR reports?

4. Is there a conversation with parents about the use of PDHM that has been analyzed?

5. How do the bottle labels and milk batch analysis reports influence allocation?

6. Is there anything we can do to make this process easier for you?

7. How are you tracking the outcomes from use of analyzed milk? What have you found thus far?