Procurement and Use of Pasteurized Donor Human Milk in the Outpatient Setting: Retrospective Analysis and Case Study

by

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Background/Significance: Due to the importance of human milk for infant health, organizations including the American Academy of Pediatrics recommend the use of pasteurized donor human milk (PDHM) if parents' milk supply is unavailable for low birthweight infants. PDHM, like parental milk, contains macro- and micronutrients and other factors (hormones, immune components) that are essential for infant growth, development, and optimal physiologic functioning. Human milk banks screen and pasteurize raw, donated milk from milk donors to ensure safety and preserve nutritional quality. The use of PDHM has been linked to the reduction of serious neonate conditions, such as necrotizing enterocolitis (NEC). For this reason, hospitalized infants with critical illness and/or prematurity who are at risk of NEC, have been prioritized for PDHM, with infrastructure to support cost coverage. Outpatient PDHM use for other infants with medical conditions who could potentially benefit from PDHM is constrained by the associated costs of procurement and processing and insurance coverage barriers, but there is a growing interest in PDHM beyond the hospital setting. Infants discharged from pediatric hospital settings often have ongoing serious health issues and could benefit from continued PDHM until they can transition to human milk substitutes (e.g., commercial infant formula) or solid foods. Currently, patterns of procurement and distribution of PDHM and familial experiences with PDHM in the outpatient setting are understudied.

Purpose: To describe patterns and experiences with outpatient PDHM distribution/use, including indications for dispensation, cost coverage, volumes, periods of use, and perceived value and barriers to use and procurement.

Methods: This study was a retrospective analysis conducted on de-identified data from infants receiving outpatient PDHM provided by a single milk bank over a period of 5 years. In addition, we interviewed and reviewed health records of a mother whose infant had received outpatient PDHM as a case study. For the retrospective analysis, summary statistics were computed.

Results: The analytic sample for the retrospective analysis included 423 infants who received outpatient PDHM from the milk bank. On average, outpatient PDHM was dispensed for under a month (n=57; 42%) with most families not having any of the costs covered by insurance. Families paid a mean of $1,571 for outpatient PDHM (SD: $4,386, Range: $0- $49,515). The most common type of PDHM prescribed was term infant milk (n=400; mean=23,970 mL) followed by dairy-free milk (n=42; mean=43,646 mL) and low dairy milk (n=26; mean=9,627 mL). The case study illustrated that there was poor awareness of outpatient PDHM as an infant feeding within the healthcare community, and that a major barrier to the procurement of outpatient PDHM was advocating for and coordinating insurance coverage. The case study highlighted that a high level of organization and commitment was needed from the parent to obtain insurance approval and that there were significant delays in obtaining the milk. The case study highlighted the financial and time costs that accessing outpatient PDHM places on the recipient family.

Conclusion: PDHM is a lifesaving intervention that can be critical to infant/child health in the inpatient setting, with limited current evidence to support use in outpatient settings. However, families who access and utilize PDHM in the outpatient setting with a $1,500 average cost for a

month's supply of PDHM access are largely limited to those who have high incomes, private insurance that covers PDHM, or residents of Pennsylvania under the Medicaid program. Finally, there are a lack of federal public healthcare programs and policies that enable access to PDHM on an outpatient basis. Further research needs to be conducted into the benefits of and access to outpatient PDHM use in different racial, ethnic, and socioeconomic groups.

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Preface

I would like to thank all those who helped, supported, and inspired me along the way. Firstly, many thanks to my Undergraduate Research Mentorship Program advisor and thesis advisor Jill Demirci, PhD, RN, IBCLC, for her never-ending guidance, support, and resilience in inspiring and helping me conduct my research. I would like to thank the Mid-Atlantic Mothers' Milk Bank for their support through the countless questions I had throughout the process. My gratitude extends to the University of Pittsburgh for supporting students who want to research and providing them with opportunities. A thank you to my thesis defense committee for taking the time to listen to my research and help me throughout the process. The case study would not be possible without our case study participant who graciously took time to participate in an interview, email with follow and respond to emails, and review multiple drafts of their narrative to ensure accuracy. Lastly and most importantly, I would like to thank my family and friends for their unwavering support and encouragement in the pursuit of research.

1.0 Introduction: Pasteurized Human Donor Milk

The World Health Organization (WHO), American Association of Pediatrics (AAP), the American College of Obstetricians and Gynecologists, and the American Academy of Family Physicians recommend that young children breastfeed exclusively for the first six months of their life (Meek & Noble, 2022). This recommendation is based on rigorous science demonstrating significant, dose-dependent health benefits of breastfeeding for infants (Victoria et al., 2016). Breastfed infants exhibit decreased rates of lower respiratory tract infections, severe diarrhea, and obesity, gastroenteritis, respiratory tract infections, childhood leukemia, and feeding intolerances (Bartick et al., 2017; Victora et al., 2016). For preterm and other vulnerable infants, breastfeeding and human milk are especially important. Exclusive human milk diets have been demonstrated to reduce the occurrence and severity of a deadly intestinal condition called necrotizing enterocolitis for which preterm infants are at particular risk (Victoria et al., 2016). Additionally, in vulnerable infant populations, exclusive human milk diets have been shown to improve infant growth, reduce the use of total parenteral nutrition (TPN), shorten hospitalization, decrease complications of bronchopulmonary dysplasia, retinopathy, feeding intolerance, and sepsis (Goldstein, 2020). Many of these benefits are linked to the constitution of human milk, which includes "macronutrients and micronutrients as well as active biological components, including immunoglobulins, cytokines, growth factors, hormones, antimicrobial agents, immune cells, stem cells, and prebiotic oligosaccharides" (Ballard & Morrow, 2013). The composition of human milk is constantly changing throughout the postpartum period and has been found to change depending on the time of day and other environmental exposures—all to provide the optimal benefit to the infant and

their development (Wu, et al., 2018). Infant formula, although providing nutrition, does not have the same immunity and health benefits as human milk.

While parent's/mother's milk is considered the gold standard for infant nutrition, when this is not available or breastfeeding is contraindicating, the AAP recommends the use of pasteurized donor human milk (PDHM) as the next best alternative in the low birth weight neonate population, rather than commercial infant formula (Meek & Noble, 2022). The American Academy of Pediatrics and the Academy of Breastfeeding Medicine recommend PDHM as the first-line feeding alternative or supplement to a mother's milk, particularly for low-birth-weight infants (Kellams et al., 2017). Thus, PDHM has become an important medical intervention for medically vulnerable infants. Although a parent's milk is individually tailored to the unique characteristics of their infant—such as gestational age, chronological age, and environmental exposures— even after pasteurization, PDHM retains many important immune components and is a viable replacement for parents' milk, especially in comparison to formula, according to the AAP (Meek & Noble, 2022).

1.1 Milk Banks

PDHM undergoes rigorous screening and processing according to guidelines set forth by the Human Milk Banking Association of North America (HMBANA). HMBANA guidelines published in their *HMBANA Standards for Donor Human Milk Banking: An Overview* (September 2020) outline the process from screening of donors through packaging. In screening, donors undergo serological testing for excluded diseases like HIV-1 and -2, HTLV-1 and -2, Hepatitis C, Hepatitis B, and Syphilis. After donors are screened and accepted by the milk bank, donors are

given instructions on milk care, handling, storage, labeling, transporting, and other pertinent instructions. Once the screening process is complete, donated milk follows strict guidelines set forth by HMBANA. Once received by an HMBANA milk bank, raw milk is logged which allows for an inventory to be tracked. If needed, raw frozen milk is thawed per Food and Drug Association (FDA) Food Code guidelines. Following the thawing process, raw milk is pooled together from multiple donors using an aseptic technique to form a uniform batch. Then the milk is strained and bottled into a glass or food-grade plastic bottle. Once packaged, the milk is pasteurized at 62.5 degrees Celsius for 30 min, then rapidly chilled. This process does not affect the macronutrients of the milk and maintains some immunological components, such as oligosaccharides and IgA (Wesolowska, et. al, 2019). Additionally, some milk banks can customize the calorie count of the milk to 17 calories/ounce, 20 calories/ounce, and 22+ calories/ounce. Each batch is labeled with a serial number in cases of contamination or other issues to facilitate recalls. Lastly, the bottles undergo bacteriology testing by a third-party accredited lab. Some HMBANA milk banks can offer customized milk needed for different medical conditions, including defatted milk or milk from donors practicing a restricted diet (e.g. dairy-free, soy-free).

1.2 Pricing

The health benefits of PDHM in the inpatient NICU are widely supported and therefore costs are typically covered by the hospital for infants meeting medical eligibility criteria for PDHM. However, access to PDHM in the outpatient setting is limited by high prices or confined to those with adequate insurance or higher income. It has been estimated that PDHM costs the patient between $3-$5 per ounce (Furman, 2018). For infants meeting eligibility criteria with a

prescription in the inpatient setting, the cost is typically either covered by the hospital or the patient's insurance. Eligibility criteria are set by the health system and health payors/insurers. Hospitals that receive PDHM pay about $4 an oz (Harris, 2022). This cost per oz is higher than the cost of formula, which is often given for free or at a reduced price so that hospitals will promote the product (Harris, 2022). Due to the price difference, hospitals are incentivized to reserve PDHM for the most vulnerable infants—typically those with certain risk factors like low birth weight or NEC. Even for these infants, PDHM is typically only used for short periods. A study conducted by Carroll and Herman in 2013, found that the price of using PDHM in hospitals varied between $27-$590 per infant per hospital stay based on whether PDHM was the primary or supplemental form of nutrition; infants who were provided milk from their parents only used an average of $27 of PDHM. Infants who did not receive any milk from their parents during their NICU stay cost $590.

1.3 Outpatient versus Inpatient Access

Inpatient access compared to outpatient access to PDHM can vary because of multiple factors. In a hospital, care is managed by a team of experts who can collectively or individually decide that the infant should receive PDHM and prescribe it immediately from PDHM already available within the hospital. In the outpatient setting, care and insurance coverage are more fragmented, and coverage of a PDHM prescription may require multiple layers of approvals. In addition, the costs of outpatient donor milk may be on average higher, because the infant consumes more as they grow. A newborn infant is expected to consume about 1-2 oz about 8-12 times a day.

When they are about a month old, a baby is expected to consume between 3-4 oz about 8-10 times a day (Furman, 2018).

In the outpatient setting, infants need to meet prerequisites and have a medical prescription to qualify for donor milk. Fifteen states (CA, CT, DC, IL, KS, KY, LA, MO, NJ, NY, OH, OR, PA, TX, UT) have state legislation and/or policies about the totality of insurance coverage for outpatient use and access to PDHM (Medicaid or commercial insurance) (Rose, et al., 2022). Since 2000, The Special Supplemental Nutrition Program for Women Infants, and Children (WIC) has stated that they will not cover the cost of PDHM, as milk banking operations have less stringent federal health and safety standards compared to the regulations imposed of WIC-eligible formula companies (U.S. Food and Nutritional Services, 2020). However, many opinions at the federal level are changing following the formula shortage, which has led to an increase in investigation into PDHM as an alternative source of nutrition. This shift in opinion may lead to the FDA overseeing regulations of donor milk banks and their products.

2.0 Methods

The growing use and interest in outpatient PDHM warrants further research in infant health outcomes with PDHM, current practices of outpatient PDHM in milk banks, and families' experiences accessing PDHM. The purpose of this study was to examine past five years outpatient PDHM dispensation practices in one HMBANA milk bank and describe at an individual level one family's experience with accessing and using PDHM.

2.1 Design

We conducted a retrospective analysis of de-identified data collected from families receiving PDHM for their infant after hospital discharge over a 5-year period from a single HMBANA-accredited milk bank. To illustrate the process of accessing PDHM for an outpatient infant, we also describe a representative case. This study was approved by the University of Pittsburgh Human Research Protection Office (expedited approval; STUDY19010256: "MAMMB Outpatient Use of Donor Human Milk").

2.2 Recruitment and Sample

The Mid-Atlantic Milk Bank (MAMMB) is a community-based HMBANA-accredited milk bank founded in 2016 to serve the tri-state area (serves PA, OH, WV) with physician prescribed PDHM. The MAMMB provided de-identified data to the study team from their

database of all infants/families receiving outpatient donor milk from MAMMB over the past five years. MAMMB also provided a short description of families who had recently used outpatient donor milk, and the study team selected families for a potential case profile through dialogue with MAMMB. In these discussions, we prioritized case selection based on the recency of PDHM receipt and experiences that highlighted a common/representative trajectory with outpatient PDHM. We selected three potential families, and MAMMB contacted each family to ascertain interest in participation. One family responded and was selected for a case profile.

2.3 Data Collection and Management

For the retrospective analysis, data abstracted from the MAMMB database included medical diagnoses or conditions that qualified the infant for PDHM, volume and duration of PDHM prescription, start and end date for PDHM dispensation, PDHM milk type (e.g., term milk, preterm milk, dairy-free, low dairy), total PDHM volume dispensed, payment method (e.g., insurance, self-pay), and estimated total out-of-pocket payments to MAMMB from the families. For the case study, the participant was interviewed through Zoom by the thesis advisor (Demirci) and thesis student (Hayden-Vazquez). Verbal consent was obtained from the participant to conduct the interview and review the participant's and her infant's medical records. The interview was audio recorded, and we used a semi-structured interview script that addressed the infant's medical trajectory, the process of obtaining PDHM, and the perceived importance and impact of PDHM. Following the interview, field notes (including the interview conditions and summary) were written by the thesis student. Following the interview, we continued to follow up with the participant with more questions about the timeline specifics and other pertinent information via

email. Additional data was collected about the participant and her infant through the review of MAMMB records including infant birth details, MAMMB and PDHM timeline, and insurance coverage timeline. No medical chart review was conducted, due to the transparency of the participant and the extensive records available through the MAMMB.

2.4 Analysis

For the retrospective analysis, data were transferred from the Excel document provided by MAMMB into SPSS (IBM Corp, V.29, 2023). The MAMMB database included individual-level data (e.g., one line per family) rather than summary data. Data were collapsed into meaningful categories where pertinent (e.g., duration of PDHM dispensation) and summary statistics were calculated.

For the case analysis, we reviewed interview audio, fieldnotes, and email communications with the participant and the MAMMB to develop a chronological history of her and her infants' experiences with acquiring and using PDHM. The participant reviewed the developed timeline and text of the case for accuracy and to add additional thoughts and ensure the accuracy of information.

3.0 Results

3.1 Retrospective Analysis

3.1.1 Data Set

In total, 423 infants received outpatient PDHM in the past five years through the MAMMB and comprised the analytic sample. No demographic data were available for this sample.

3.1.2 Duration of Use

Duration of dispensation of PDHM was available for 136 infants (n=287 missing, 68%). Approximately 42% (n=57) of infants with duration data available received PDHM from the MAMMB for under a month (0-4 weeks), and most infants received PDHM for less than 3 months (mean=12.4 weeks, SD: 12.6 weeks). However, 26% (n=35) continued to receive PDHM for 21-24 weeks (about 5-6 months; Table 1).

Table 1 Duration of Use

Weeks Receiving PDHM	Number of Infants	Percent
0-4 weeks	57	41.9
5-8 weeks	18	13.2
9-12 weeks	11	8.1
13-16 weeks	5	3.7
17-20 weeks	3	2.2
21-24 weeks	35	25.7
45-48 weeks	5	3.7
49-52 weeks	2	1.5
Total	136	100

This data set excludes 287 infants who had no data collected in these categories

3.1.3 Types of Prescribed Milk

There were four main categories of PDHM prescribed (Table 2): dairy-free, low-dairy, colostrum, term milk, and other (cream, preterm, defatted). Of these types of milk, the most commonly dispensed milk was term milk (~82%, n=400 infants), followed by dairy-free and low dairy (~13.9%, n=68 infants). Dairy-free milk had the highest average quantity prescribed, with a mean dispensation of over 40,000 mL, while colostrum had the lowest average quantity prescribed. The high mean in prescribed milk is due to 21 outliers (total that fell outside of the 75th percentile) who received large quantities of milk compared to other infants (maximum volume provided to a single infant 336,000 mL).

Table 2: Types of Prescribed Milk (mL)

Type of Milk	Number of Infants	Minimum Volume (mL)	Maximum Volume (mL)	Mean Volume (mL)	Std. Deviation Volume (mL)
Dairy Free Milk	42	200	242,450	43,646.4	67,472.1
Low Dairy Milk	26	200	65,000	9,626.9	13,684.1
Colostrum Milk	12	50	1,600	566.7	567.4
Term Milk	400	100	336,000	23,969.9	51,663.1
Other Milks	8	50	65,600	22,968.8	27,185.5

3.1.4 Payment of Milk

Figure 1 shows the distribution of how outpatient PDHM was paid for by recipient families of infants. Payment types were divided into four main categories: Out-of-Pocket, Insurance, Discounted, and Other. Out-of-pocket indicates the PDHM was paid 100% out-of-pocket for a family, while discounted indicates that the patient received a total discount ranging from 30-75% off the total price and then paid the remaining total out-of-pocket. “Other” indicates infants for whom PDHM was donated, billed to another bank, was partially covered by insurance and the remainder covered by another organization, etc.

As illustrated in Table 3, the mean out-of-pocket expense for families using outpatient PDHM was $1,571 (SD: $4,386, Range: $0- $49,515). This number is for those only paid out-of-pocket and does not include any who received discounted PDHM. Out-of-pocket costs accounted for about 81% of the total methods of payment, while insurance was only used to cover the cost of milk in 13% of the cases. Payment cost did not include shipping cost. All term milk costs $15.00/100mL bottle, specialty milk costs more per mL (Table 4).

Table 3: Estimated Total Payment

	Number of Infants	Minimum payment	Maximum Payment	Mean
Estimated Total Payment	423	$0	$49,515	$1,571

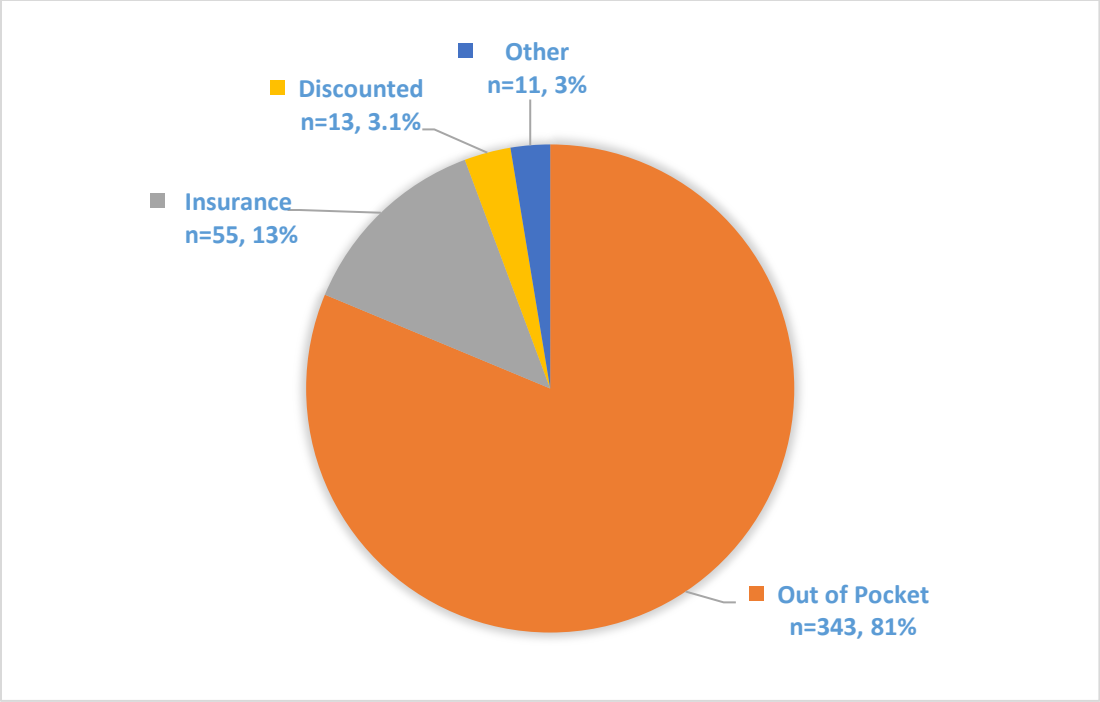


Figure 1: % of Payment Types

One infant is missing from the data set. There are only 422 infants depicted in this pie graph.

Table 4: Cost of Each Types of Milk Provided by MAMMB 2023

Description	Price per Bottle (shipping not included)
Term Milk 20 kcal/oz 100mL Bottle	$15.00
Term Milk 22 kcal/oz 100mL Bottle	$15.00
Term Milk 24 kcal/oz 100mL Bottle	$15.00
Term Milk 20 kcal/oz 200mL Bottle	$30.00
Term Milk 22 kcal/oz 200mL Bottle	$30.00
Term Milk 24 kcal/oz 200mL Bottle	$30.00
Preterm Milk 50mL Bottle	$10.00
Defatted Milk 90mL Bottle	$15.30
Cream Milk 90mL Bottle	$13.33
Colostrum 50mL Bottle	$10.00
Term Milk Specialty Diet 200mL Bottle	$30.00

The price indicated is for the cost of each bottle

3.1.5 Indications for Prescription

Not all infants receiving outpatient PDHM had a coded diagnosis/indication for PDHM. A diagnosis was available for 230 infants in the database (64%). The most common indication was "other" (n=79; 19%), followed by multiple indications (n=37; 8%) and maternal indications (n=35; 8%). "Other" is a term used by the MAMMB and is undefined for this study—a catch-all for several diagnoses. Healthy is a term defined by MAMMB that indicates the infant was healthy and had no genetic conditions, but the family chose to purchase PDHM. Maternal indications included cancer, Polycystic Ovarian Syndrome (PCOS), low milk supply, and disorders of lactation. The most common diagnoses that qualified infants for outpatient PDHM included bridge milk (supplementation of parental supply with PDHM), poor infant weight gain, excessive weight loss, surrogacy, and prematurity. It is important to acknowledge that a large percentage of the infants did not have an indication available for PDHM.

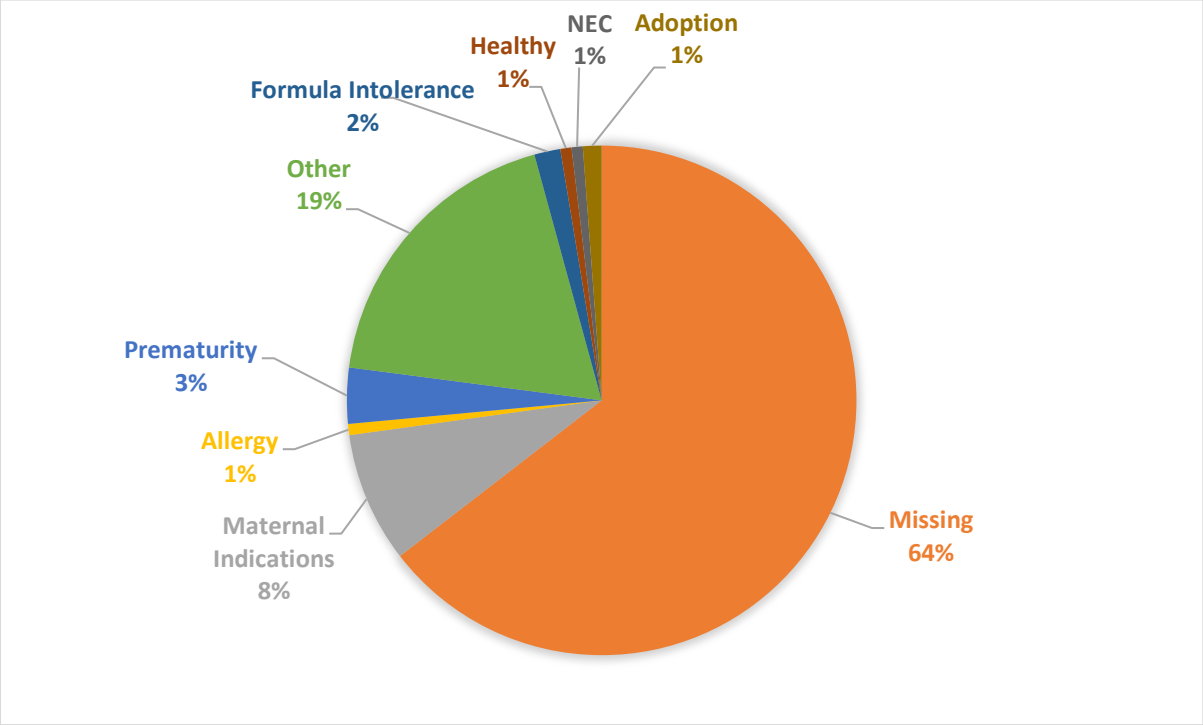


Figure 2: Indications for PDHM Based on Outpatient Diagnosis

3.2 Case Study

3.2.1 Birth and Hospitalization Course

A case study interview was conducted with the mother (MP) of a medically complex special needs child (IP) who received outpatient donor human milk from the Mid-Atlantic Milk Bank. MP's pregnancy was considered higher risk due to advanced maternal age; however genetic testing was not covered by health insurance. Her pregnancy with IP was her first. All pregnancy ultrasounds were unremarkable. MP was diagnosed with gestational diabetes in the second trimester and gestational hypertension around week 38 of pregnancy. Induction was scheduled for

39.1 weeks given these pregnancy complications. MP gave birth to IP (2.98kg, female) at a high-volume birth hospital in March 2022 at 39.1 weeks gestation, following a failed induction of 48 hours that led to an emergency Cesarean section. The uterus was ruptured, and MP lost approximately 1.5 liters of blood but did not require a blood transfusion. At birth, MP's infant (IP) experienced respiratory distress and was transferred to the hospital's level III neonatal intensive care unit (NICU). IP was intubated, with improvement in respiratory function over nine days. IP was then transferred to the NICU at the nearby regional pediatric hospital. IP was hospitalized at the pediatric hospital NICU for a total of 79 days following IP's birth. During this period, IP was diagnosed with three different genetic mutations, linked to her high palate, small jaw, and complicated feeding and respiratory function. IP was also diagnosed with failure to thrive (FTT), and a gastrostomy tube (G-tube) was placed during her hospitalization. Subsequently, IP was transferred to a step-down pediatric rehabilitation center for two weeks, before being discharged to home.

3.2.2 Breastfeeding and Use of PDHM

Beginning in the birth hospital's NICU, IP experienced difficulties breastfeeding, including being unable to latch; unable to coordinate an organized suck, swallow, and breathe sequence; severe reflux; and vomiting attributed to oral aversion. MP began expressing colostrum with an electric breast pump at 24 hours postpartum and continued to pump for 356 days postpartum; because of her plentiful supply in the hospital and IP's term gestational age, IP did not need or qualify for PDHM during hospitalization (per hospital guidelines). IP developed FTT due to her oral feeding difficulties and concomitant intolerance of supplemental commercial infant formula feeds. Formula was trialed due to infants feeding intolerances, and FTT. During IP's inpatient stay,

she was trialed on a variety of commercial infant formulas to see if they could resolve her FTT and feeding intolerances. The only type of nutrient that IP could tolerate was MP's milk, however. Direct breastfeeding was deemed unsafe at that time due to the infant's genetic conditions and increased risk of aspiration.

To address FTT, formula and human milk feeds were given three times a day (TID) via NG, and a G-tube was later placed on day of life (DOL) 39 to ensure adequate nutrition and growth. Feeds were fortified with human milk fortifier (HMF) (human vs. bovine unknown) with volume determined daily in rounds by the dietician on call. IP was cleared to attempt to latch and breastfeed again on DOL 59 safely. Initially, MP had an overabundant milk supply and used a hospital-provided double electric milk pump while at the hospital (Medela Symphony). She was able to express milk at the hospital regularly. MP was at the bedside in the NICU daily from approximately 7 am to 9 pm, pumping every three hours with the hospital breast pump. At home, she pumped three times overnight using a Spectra 2 double electric pump.

After 79 combined days in the birth and pediatric hospital NICUs, IP was transferred to a pediatric inpatient specialty step-down hospital. At this facility, MP and IP's father were trained to be primary caregivers. A Medela Symphony pump was provided at this facility as well, and MP pumped every three hours, in addition to direct breastfeeding *ad-lib*. At this time, IP had transitioned to only MP's milk (no infant formula). MP therefore developed a robust backup supply, which was sufficient for IP's first 6 months of life.

Upon return to work in the service industry at 14 weeks postpartum, MP noted a decrease in milk supply, despite continuing to pump three times per day. She attributed this supply drop to the stress of balancing work demands (50+ hour work weeks) with being the primary caregiver at home for her medically complex child, as well as fitting in pumping when time allowed at work

and within a busy work environment not conducive to milk production. During this time, MP was able to secure a loaner Medela Symphony pump in an attempt to help boost her supply from the Special Supplemental Program for Women, Infants, and Children (WIC). While MP had sufficient frozen milk that she began using for feedings, she became worried about continuing to provide enough milk for IP into the future, particularly given that human milk was the only nutrition IP tolerated. MP began investigating ways to increase her supply and initially explored obtaining unpasteurized, unscreened human milk through peer-to-peer milk-sharing groups on Facebook. Ultimately, however, she felt that due to the medical fragility of her child, this was not a safe option. Through the same research, MP found the Mid-Atlantic Mothers Milk Bank (MAMMB).

3.2.3 Acquisition of PDHM

For MP and her family, the acquisition of PDHM was a complicated, lengthy, and frustrating process that required considerable time, paperwork, and self-advocacy from MP to navigate the insurance coverage of PDHM. IP was covered by two insurances: MP's primary employer-based plan and secondary coverage through Medicaid (given her medical diagnosis). In the Commonwealth of Pennsylvania, Medicaid policy allowed coverage of the full cost of PDHM for as long as medically indicated, but only after the primary insurance denied or exhausted coverage. However, the employer-based plan did not recognize PDHM as a medical intervention and as such, the verbiage caused issues and delays between the two insurers. Finally at 10.5 months post-birth and after about 6 months of trying to obtain PDHM with a rapidly dwindling supply of frozen milk, IP obtained a prescription for PDHM from Medicaid. To gain a prescription for PDHM, MP had to get approval from IP's various specialty doctors and finally from IP's primary doctor. MP recalled the insurance approval process for PDHM took "months and hours on the

phone" and many email exchanges, some of which were facilitated by the Mid-Atlantic Milk Bank (MAMMB), whose staff she expressed gratitude toward. Delays and an unclear process to obtain insurance coverage of PDHM created unnecessary stress during an already difficult time. She remembered feeling extremely frustrated and constantly debating whether she should remove IP from her primary insurance to accelerate the PDHM coverage through Medicaid. However, she worried that IP would need the primary insurance for other exorbitant medical expenses. MP mentioned there was a point when her milk supply was extremely low, and the insurance still had not provided coverage. She reconsidered the option of "buying [human] milk" from an online peer-to-peer milk-sharing group. Her hesitation, was again, due to the medical frailty of her child and the lack of screening and treatment of this milk to ensure safety and quality. With the out-of-pocket costs of PDHM surpassing $1,500 per month, paying out of pocket was not a viable option.

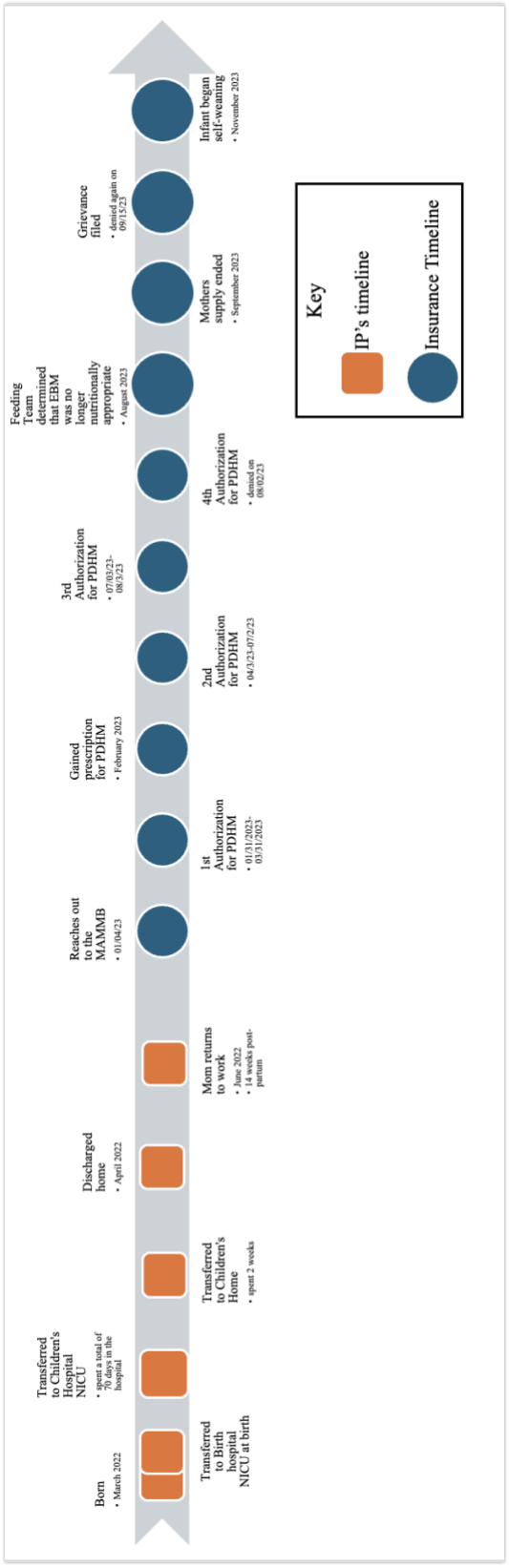
Once MP had obtained insurance coverage for PDHM through Medicaid, she described the process of acquiring PDHM as extremely easy. She reported that MAMMB was easy to communicate with and was willing to set up mutually beneficial pick-up points for the PDHM. Once she had coverage, she had no concerns with her own milk supply, as she was always supplied with enough and sometimes more than enough PDHM as a backup option. After the initial authorization for PDHM in January, MP received authorization for PDHM another three times (coverage until August of that same year). MP attempted to gain a fourth authorization but was denied. Following their denial, they filed for a grievance and were denied. MP continued to pump until August of 2023 (when IP was 17 months old) when the feeding clinic that was part of IP's healthcare team determined expressed breast milk (EBM) was no longer nutritionally required. At this point, IP was meeting, and even exceeding, her growth and developmental milestones as they settled into the feeding routine of ad-lib breastfeeding plus scheduled bolus PDHM feeding

through her G-tube three times a day throughout the day. At about 20 months, IP began to self-wean from direct breastfeeding to varied solids and has tolerated well the change in diet.

3.2.4 Participant's Overall Impressions and Experience

MP expressed a myriad of feelings throughout the interview process. She described the stress of having a child in the NICU and the exhaustion of having to advocate for her child and her best interests constantly. She expressed disbelief and panic when her child's primary insurance would not acknowledge PDHM as a medical intervention and stressed about being able to feed her child when she had no other safe options. She expressed appreciation for the support and help she received from MAMMB in helping her collect the necessary paperwork for the insurance and troubleshooting the different problems with insurance coverage. Finally, MP described intense relief when she was able to gain access to PDHM, and her child began to thrive and surpass all development milestones. Throughout the interview, she highlighted that she could not have persevered if she had not had the support of her husband and the MAMMB. Because of her difficult and life-changing experience, she has now begun to work as an advocate for PDHM with the MAMMB. She shares her story in the hope that she can inspire other parents to not give up on doing what is best for their child, but also with the hope that her and her child's story will help make the case for legislative changes in coverage for and access to PDHM.

Figure 3: Case Study Timeline



4.0 Discussion

PDHM is a relatively new medical intervention, which is regulated as food instead of medicine by the FDA. Because of this, there is limited guidance and oversight of the insurance coverage and qualifications standards that apply to a patient receiving PDHM. It is important to understand the impact that PDHM and milk banks can have on an infant and their family, as well as the federal and state legislation that protects or hinders their access to this medical intervention. The last main stakeholders are the insurance companies, each has their own coverage or policy as it relates to the coverage of PDHM. Each of these aspects needs to be examined to fully comprehend the scope of PDHM in the US healthcare system.

4.1 Equity and PDHM

A retrospective cohort study conducted by Palmquist and colleagues (2022) looked at in-patient infant EMR data between 2014-2016 to determine rates of different types of nutrition: their mother's own milk (MOM), PDHM, or formula. This study found that infants of non-Hispanic Black and Hispanic mothers had lower rates of PDHM use. They concluded that there are inequalities that exist in exclusive human milk feedings, and the use of PDHM and that anti-racist interventions are needed to provide and promote equitable access to lactation consultants by certified providers and counseling for PDHM. This inequality is further exacerbated in the outpatient setting where the cost of PDHM becomes a major barrier to many.

Although our analysis did not distinguish PDHM recipients by race or ethnicity, we did uncover a likely socioeconomic disparity, in that the main demographic who can afford PDHM in the outpatient study are those with disposable income who can afford unanticipated out-of-pocket costs exceeding $1500 over an average 3-month period. According to the US Census Bureau (2023), in 2022 the median household income in Pennsylvania was $72,210, slightly below the U.S. median of $74,580. Due to Owen's law (in PA) recently enacted in 2024, Medical Assistance will now cover the cost of PDHM in the outpatient setting if an infant meets standards. However, it is unclear what the standards will be and who will assess/enforce the standards. As illustrated in our case study, different insurances have different qualification standards and willingness to cover PDHM costs.

4.2 Further Action

Small steps are being made to reduce inequalities in access to PDHM in healthcare systems, but as highlighted previously, there is currently only a small portion of the population who can afford PDHM and limited research on infant health outcomes related to PDHM use in populations beyond the preterm infant. Other potential barriers to PDHM access include resources, time, support, and literacy level. Barriers are being reduced through laws like Owen's Law in PA, but federal legislation would better protect infants' right to access lifesaving human milk without placing their families at a significant financial disadvantage. Policy changes in organizations like WIC giving preference to PDHM before formula would be incredibly beneficial in the reduction of access barriers.

More research needs to be conducted to understand the impact of PDHM on other populations in other states and/or countries. It would also be imperative to understand PDHM infant eligibility criteria at other milk banks and in other countries and compare and contrast their patient populations. By understanding the populations served through other milk banks, researchers, policymakers, and insurance companies can create inclusive policies and comprehensive and representative criteria for accessing PDHM. Additionally, more research is needed to understand the efficacy and benefit of PDHM in the reduction of other medical conditions (besides NEC), especially conditions that impact outpatient infants (e.g., FTT). Other situations that need further investigation would include benefits of PDHM for older outpatient infants, the costs vs. benefits of long-term use due to long-term medical conditions, and disparities in access to outpatient PDHM for different demographics.

4.3 Legislation

4.3.1 Owen's Law in Pennsylvania

Owen's Law or Senate Bill 500 (S. 500) was signed into legislation on November 17th, 2023. This law is the first in the Commonwealth that would provide insurance coverage for outpatient donor human milk for medically necessary infants. SB 500, among other things, provides children who are less than a year old with access to medically prescribed PHDM by requiring Medical Assistance coverage in both the inpatient and outpatient setting (*Brooks Bill Providing Life-saving Care for Babies Set for Enactment*, 2023).

The Hospital and Healthsystem Association of Pennsylvania (HAP) breaks down the impact of this legislation into two main parts for easier understanding: the key components and specific details for coverage. The key components, as it relates to PDHM, include the increased access to medically prescribed PDHM for medically fragile infants who do not have access to their mothers' own milk. The bill requires coverage and reimbursement for inpatient and outpatient infants and their families. This coverage and reimbursement increase accessibility for all patients regardless of their socioeconomic status. Specific details for coverage include that PDHM must be obtained from a licensed milk bank in the Commonwealth of Pennsylvania or through a state-monitored hospital licensure process. Additionally, to qualify for coverage, the lactating parent must be medically or physically unable to produce sufficient milk to provide for their child's needs.

4.3.2 Federal Legislation

Currently, at the federal level, there are two bills in progress S. 2819 and H.R. 5486, both known as Access to Donor Milk Act of 2023 (Congress.gov, 2023)**.** Both bills would establish programs and requirements for PDHM (through the FDA and HHS), allow WIC funding to be used towards nonprofit milk banks, establish a grant program to expand the emergency capacity of nonprofit milk banks and create and promote a donor milk awareness program. This bill would provide $3 million in emergency capacity funding in case of a rapid increase in demand, as was seen during the 2022 formula shortage (*HMBANA Applauds Introduction of Legislation Which Would Increase Access to Donor Milk,* 2023). It would also require the HHS to create standards for the collecting, processing, handling, transferring, and storage of PDHM (*HMBANA Applauds Introduction of Legislation Which Would Increase Access to Donor Milk,* 2023). Both bills were introduced on September 14th, 2023, and the House bill has 13 co-sponsors, and the Senate bill has

1 co-sponsor. Both bills have been sitting in the subcommittee since their introduction. Congressional representatives worked closely with HMBANA in the creation of this legislation.

4.4 Specialty Milks

Due to their large volume of donors and community need, MAMMB has made available specialty milk (dairy-free, low-dairy, colostrum, cream, preterm, and defatted milk) to those patients who need it for a variety of reasons including a diet trial or a dairy/soy intolerance. In our retrospective data analysis, a total of 400 (~82% of the total sample) of the patients used the term milk (infant may have also been prescribed another type of milk alongside term milk). Another 88 infants (18%) received another type of specialty milk (e.g., dairy-free, low-dairy, colostrum, cream, preterm, and defatted). Some patients received multiple types of milk throughout the 5 years that the data were collected.

Currently, PDHM goes to those with an evidence-based need, which includes preterm infants where research has shown that PDHM will drastically improve and/or resolve their condition (such as with NEC). These include conditions common in prematurity (NEC and FTT) and prematurity overall. Priority of milk goes to those in the prematurity and at-risk category while ideally, any surplus supply would go to infants with need. MAMMB has rarely had shortages of PDHM, making second-priority infants often eligible for PDHM. By allowing others outside of the priority set categories to have access to milk, broader access is improved.

4.5 Ethical Challenges

An important aspect of the expansion of policy is the creation of equitable access, but also protection for those at risk of being taken advantage of. There is the fear that lactating individuals of lower socioeconomic status will or have begun to sell their milk, to the detriment of their child, to those of higher socioeconomic standing. Groups such as the Ethox Centre of the University of Oxford and the Oxford-PATH Human Milk Working Group have begun conducting studies that "identified cross-cutting ethical considerations and key actions that should be addressed as part of global and regional responses to donor milk policy and guideline development (panel)" (Israel-Ballard, et al., 2019). Results from this investigation are to be used by policymakers to enact legislation for the safe and ethical use of PDHM while continuing to promote, protect, and support breastfeeding (Israel-Ballard, et al., 2019). This research-informed legislation will help establish guidelines for the safe and ethical use of human-origin medical products such as human milk (Israel-Ballard, et al., 2019). Note that HMBANA-accredited milk banks prohibit compensation of milk donors to avoid these ethical issues.

4.6 Increasing Access

During the infant formula shortage of 2022, many parents turned to milk banks as an alternative to infant formula. Milk banks across the U.S. saw a surge in inquiries and demands for PDHM in 2022 leading to almost 10 million ounces of donor human milk being donated across the country (*Nonprofit Milk Banks Step Up During Formula Crisis, Dispensing Nearly 10 Million Ounces in 2022,* 2023). Following the formula shortage and the pandemic, milk banks across the

U.S. saw an increase in demand leading to expansions and the creation of more banks (*Nonprofit Milk Banks Step Up During Formula Crisis, Dispensing Nearly 10 Million Ounces in 2022*, 2023).

The creation of more milk banks would ostensibly increase the accessibility of PDHM to many communities that previously were unable to procure donor human milk easily. HMBANA currently has 33 milk banks in its network (including the USA and Canada), which is an increase from 27 in 2017 (*Nonprofit Donor Human Milk Distribution Reaches Record High in 2017*, 2018).

4.7 Limitations

The data collected by the MAMMB on outpatient PDHM recipients did not distinguish infants by race, ethnicity, or socioeconomic status and medical information was not consistently available within MAMMB records for PDHM indication. The dataset was also missing the duration of PDHM use for about 68% of the study sample, and there was no diagnosis code for about 54% of the sample. Additionally, the MAMMB data reflects a sample who come in largely through a referral network in Pennsylvania and the Tri-State area, which may not be representative of the U.S. population. No contact was made with insurance providers to understand their policies and coverage. Finally, the case study was a self-reported story of a participant who opted to share their story; thus, self-selection bias and inclusion of a single case limits generalizability.

4.8 Interconnectedness and Further Research

Changes and updates in legislation would allow more equitable access to PDHM for all who need it. Organizations like MAMMB are limited by the scope and extent of federal and state laws and insurance policies. Increasing investigation, research, and advocacy on PDHM will allow for the expansion of PDHM use where medically relevant.

Additionally, research needs to be conducted to observe the effect and the usage of PDHM in different ethnic and racial groups, in different common preterm conditions such as failure to thrive, and barriers to access in different socioeconomic groups. Additional information is also needed on different insurance providers' policies on access and coverage to PDHM. Although more research needs to occur there is also a need for reform at the insurance level, hospital level, and policy level. These changes would allow access to PDHM to other infants for non-medical or non-qualifying reasons if the local/state milk bank has an abundant supply (with those who demonstrate greater medical need gaining first access).

5.0 Conclusion

In the absence of a parent's own milk, PDHM can provide an infant with nutrients and some important immunological protection they need to grow and thrive. The World Health Organization, the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the American Academy of Family Physicians, and the Academy of Breastfeeding Medicine all endorse the use of PDHM as the preferred alternative feeding source in the small and vulnerable newborn when a parent's own milk is not available.

Currently, many outpatient barriers exist to accessing this evidence-based medical intervention that has improved infant health outcomes in the NICU/hospital setting. Barriers such as insurance provider coverage, coordination of payment, access to PDHM as a limited resource, lack of research on health outcomes in populations other than the hospitalized newborn, and qualification for PDHM by infant condition are all hurdles any parent must face if they wish for their infant to access PDHM in the outpatient setting. It is important to raise awareness about these barriers and increase research on the topic to allow for an expansion of protection for all infants who currently need and may benefit from PDHM in their infancy. Policymakers, researchers, healthcare workers, and parents must advocate for and facilitate the creation of more comprehensive and expansive insurance and legislative policies for PDHM access.

Appendix A

Interview Consent Document

Members of the Mid-Atlantic Mothers' Milk Bank Medical Advisory Board, who are also researchers at the University of Pittsburgh, are interested in learning more about the outpatient use of donor human milk. The researchers from the University of Pittsburgh are conducting a research study to find out the impact of donor human milk on short term health outcomes based on both medical record review and parental perception, and the cost of donor human milk for outpatient use.

We are asking parents of children who received donor milk from the Mid-Atlantic Mothers' Milk Bank to participate in a research study if they are at least 18 years of age. If you agree, we will ask you to allow the research team from the University of Pittsburgh to call you and interview you about your reasons for seeking donor milk for your child, your experience with the process, and how you think the donor milk had on your child's health. The interview will take 20-30 min and will be audio recorded.

We are also asking that parents allow the research team to access their child's medical record. We will collect information about your child's growth, feeding history, health conditions that led to need for donor milk, and impact of donor milk on health. To obtain your child's medical records, we need to have you complete a HIPPA Authorization. The way this is done depends on where you receive your medical care at. Is your child at patient at the University of Pittsburgh Medical Center (UPMC)?

If no/unknown:

To obtain this access, we will ask you to sign a HIPAA Authorization to release your child's medical records. Once you sign that form and return it to the research team, the research team will send the signed form to your child's healthcare provider along with a form for the doctor to fill out that asks about your child's diagnosis, birth, and reasons for needing human donor milk. This authorization is valid for a year from sign of consent but you can always withdraw your authorization to allow the research team to review your child's records by contacting the investigator by phone or mail. Any information obtained from the record up to that point will continue to be used by the research team.

There is no direct benefit for participation. The possible risks for this study are: first, that you might feel uncomfortable answering questions in the interview and a possible breach of confidentiality. To protect confidentiality, we will remove names and personal identifying information and use a study code. We will keep your and your child's information private. Only the researchers and their staff and the Milk Bank Staff will have access to the data collected. Authorized representatives from the University of Pittsburgh Office of Research Protections may review your data solely for the purpose of monitoring the conduct of this study. You will not receive any payment for taking part.

Participation in this study is voluntary, and you have the right to withdraw at any time. If you would like to withdraw, please call Dr. Demirci at 724-622-6371 or send an email to her at jvr5@pit.edu. Data already collected will be retained but no additional data will be obtained. If you have any questions about your rights as a research subject, please contact the Human Subjects Protection Advocate at the University of Pittsburgh IRB Office at 1-866-212-2668.

This study is being conducted by Dr. Jill Demirci, a researcher the University of Pittsburgh School of Nursing. Dr. Demirci can be reached at 724-622-6371, if you have any questions.

Are you willing to participate in this research by completing an interview and provide written authorization the research team to access your child's medical information?

If Yes:

Members of the study team are part of UPMC and have the ability to access your child's medical record electronically. To obtain this access, we ask that you provide a verbal HIPPA authorization.

This authorization is valid for a minimum of seven years. The research team will look at information including diagnosis, birth, and reasons for needing human donor milk. The identifiable medical record information will be available to members of the research team for an indefinite time period. You can always withdraw your authorization to allow the research team to review your child's records. You can do this by contacting the study team. If you do withdraw authorization, any information obtained from the electronic medical record up to that point will continue to be used by the research team.

There is no direct benefit for participation. The possible risks for this study are: first, that you might feel uncomfortable answering questions in the interview and a possible breach of confidentiality. To protect confidentiality, we will remove names and personal identifying information and use a study code. We will keep your and your child's information private. Only the researchers and their staff and the Milk Bank Staff will have access to the data collected. Authorized representatives from the University of Pittsburgh Office of Research Protections may review your data solely for the purpose of monitoring the conduct of this study. You will not receive any payment for taking part.

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This study is being conducted by Dr. Jill Demirci, a researcher the University of Pittsburgh School of Nursing. Dr. Demirci can be reached at 724-622-6371, if you have any questions.

Are you willing to participate in this research by completing an interview and provide your verbal authorization to the research team to access your child's medical information?

Appendix B

MAMMB Qualitative Interview Script

Experiences from the Mid-Atlantic Mothers' Milk Bank Regarding Outpatient Use of Donor Human Milk: A Case Series

Thank you for agreeing to participate in this interview about your experience using donor milk from the Mid-Atlantic Mothers' Milk Bank. Our goal is to understand ways in which donor milk is used/valued by families outside the hospital or NICU setting; currently, there is a lack of evidence or precedent for using donor milk in the outpatient setting. Your participation will help us to fill this information gap and address access issues to donor milk for infants beyond their NICU hospitalization.

This interview should take less than one hour. The interview will be audio-recorded and later transcribed so that we can remember what was said without writing down every word. I will also be taking brief notes about our conversation, in case the audio-recorder fails. We will not transcribe any identifying information about you, such as your name or your child's name. Both the transcripts and audio recordings will be stored in a password-protected electronic file, accessible only to those involved in the study. These files will be labeled with a study ID, rather than your real name. If we use your words in a presentation or publication, we will change or remove any information that could potentially be used to identify you. Do you have any questions before we begin?

INTRODUCTION TO AND VALUATION OF DONOR MILK

1. I'd like to begin by hearing your story about how you came to seek out and/or use donor milk for your child.

Probes if needed: **Note: Please ensure you specifically ask the bolded feeding history question in item #3 below if the topic doesn't come up organically in conversation*

1. How did you first hear about donor milk and the Mid-Atlantic Mothers' Milk Bank? What are the reasons you wanted/needed to use donor milk?

2. Did you have any reservations about donor milk before you used it? What did you see as the benefits to using donor milk? What and/or who influenced how you viewed donor milk (e.g., family, partner, friends, online community, medical staff)? In what ways, if any, have your views on donor milk changed since you began using it for your child?

3. What type(s) of nutrition did your child receive prior to or in addition to donor milk—**can you walk me through a brief history of how your child has been fed, as well as how they are currently being fed (for example, any of your own breast milk, formula: types/brands, solids)?*** How do you think these sources compared to donor milk (nutritional quality, tolerance/side effects, ease of use, cost, etc.)?

4. Did you perceive that your child had a reaction, positive or negative, to the taste or consistency of donor milk? Did this change over the course of time that donor milk was used?

EXPERIENCE WITH PROCESS OF ACQUIRING DONOR MILK IN OUTPATIENT SETTING

2. Tell me about your experience with the process of acquiring donor milk outside of the hospital setting.

Probes if needed:

1. How did the process compare with getting donor milk while your baby was hospitalized/in NICU if applicable? How did/has the process changed in the outpatient setting, if at all, as your baby got older?

2. Had you tried to acquire outpatient donor milk from other sources prior to getting donor milk from MAMMB? How did the processes compare?

3. What kinds of barriers did you encounter in getting donor milk outside of the hospital setting? How did you navigate/overcome these barriers? How did these barriers affect

you and your family? What would have made the process easier/better for you personally? If you could, what kinds of changes would you make at a systems-level to help families like yours get donor milk when and where they need it?

4. What things went right/most smoothly for you in getting donor milk in the outpatient setting?

5. Given the limited supply and costs of donor milk, how do you think milk banks and medical professionals should decide who gets donor milk? And backing up on this point, WHO should be in charge of making the decisions about who gets donor milk, at what cost, and for how long?

PERCEIVED IMPACT OF DONOR MILK

3. What kind of effect(s), if any, do you think donor milk has had your child's overall health?

Probes if needed:

1. What changes in your baby's behavior or health did you notice after/when using donor milk as compared to other nutrition? Were these changes immediate or gradual? Did they sustain if/when you had to use of forms of nutrition?

2. As you may be aware, some medical professionals, insurance carriers, and even milk banks are skeptical of continuing to provide donor milk once a baby leaves the NICU. Given your experiences with donor milk, what would you like these individuals to know/be aware of when making decisions about which families receive donor milk outside of the hospital?

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