Development, Implementation and Evaluation of a Pilot Intervention: Promoting Breast Milk Expression in a Neonatal Intensive Care Unit

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Dedication

To Mom and Dad.

I love you more than the moon!

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Abstract

Background: Very preterm infants receiving breast milk experience better health outcomes compared to formula fed infants. However, these infants often lack the ability to coordinate sucking and swallowing and are unable to breastfeed at delivery. Consequently, mothers of very preterm infants must initiate milk expression. While these mothers demonstrate high milk expression initiation rates, continuation of this behavior until infant discharge from the Neonatal Intensive Care Unit (NICU) is a significant challenge. Therefore, the primary aim of this study was to gain an understanding of mothers' experiences expressing milk for their very preterm infants in a Level III NICU and to develop, implement and evaluate a pilot intervention to promote milk expression. **Methods:** This study was conducted in three phases: 1) using a phenomenological approach, mothers were interviewed about their experiences expressing milk, 2) PumpMed, a web-based application, was developed in response to these interviews and a developmental evaluation (DE) was conducted to assess usability and acceptability by members of the target population, 3) PumpMed was piloted using a randomized design in a Level III NICU, with mothers of very preterm infants to assess feasibility and efficacy. Mothers of very preterm infants were randomized to one of three study groups: 1) Control Group (Resources), 2) Partial Intervention (Resources + Logs), and 3) Full Intervention (Resources + Logs + Questions + Feedback). **Results:** Five global themes emerged, which informed the prototype of PumpMed. PumpMed scored significantly above the benchmark average in

usability and the majority of participants reported they would have used PumpMed. Recruitment and retention rates for the pilot intervention were high. However, actual usage of PumpMed among participants was low. There were no significant differences between groups and milk expression outcomes, however the small sample size was a limitation. **Conclusions:** This study provides insight into the complex experience mothers undergo when expressing milk for their preterm infants. A DE of PumpMed demonstrated it was useable and allowed for iterative changes to further tailor PumpMed to the unique needs of the target population. Future iterations of PumpMed may benefit from alternative strategies to increase usage.

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Chapter I: Literature Review

Prematurity

Preterm Birth & Low Birth Weight: Definitions and Trends

Prematurity, a leading cause of infant morbidity and mortality in the United States (US), has been identified as a Leading Health Indicator by the Healthy People 2020 initiative targeting the Nation's health (**Table 1.1**).[1] Although the etiology of prematurity is not well understood, some identified risk factors include prior preterm delivery, multifetal pregnancy, incompetence of the uterus or cervix, greater maternal age, maternal hypertension, low or high maternal BMI, low maternal socioeconomic status (SES), maternal race, delayed utilization of prenatal care, and smoking.[2] The World Health Organization (WHO) and the US Centers for Disease Control and Prevention (CDC) categorize "premature" or "preterm" infants as those born at less than 37 weeks gestation.[3, 4] Prematurity is further segmented into late preterm birth (34-36 weeks gestation), early preterm birth (< 34 or 32 to 33 weeks gestation), and very preterm birth (<32 weeks).[1, 3, 4]

Table 1.1 Healthy People 2020 Objectives Targeting Preterm Birth[1]

Objective MICH-9 Reduce preterm births	**Baseline 2007**	**Target 2020**
Sub-objective	**Baseline 2007**	**Target 2020**
MICH-9.1 Reduce total preterm births	12.7%	11.4%
MICH-9.2 Reduce late preterm or live births at 34 to 36 weeks of gestation, from	9.0%	8.1%
MICH-9.3 Reduce [early preterm] live births at 32 to 33 weeks of gestation	1.6%	1.4%
MICH-9.4 Reduce very preterm live births less than 32 weeks of gestation	2.0%	1.8%

Compared to infants born full term, infants born preterm have an increased risk of lower birth weights.[5] When combined with gestational age, infant birth weight is indicative of intrauterine growth and development.[4] Infants who are born smaller are more likely to be less mature, and consequently have an increased risk of morbidity and mortality.[3, 4] Infants who are born low birth weight (LBW), defined by the WHO as infants weighing less than 2500 grams (5 pounds 9 ounces), are at a higher risk of infant morbidity and mortality than infants who are born at a healthy, birth weight (2500 (5 pounds 9 ounces) to 4000 grams (8 pounds 14 ounces)).[3, 4, 6, 7] Low birth weight is further categorized into very low birth weight (VLBW), infants weighing less than 1500 grams (3 pounds 5 ounces), and extremely low birth weight (ELBW), infants weighing less than 1000 grams (2 pounds 4 ounces).[7] For infants, the risk of morbidity and mortality is inversely related to birth weight.[3, 4, 7] Healthy People 2020 objectives, targeting infant birth weight, are shown in **Table 1.2**.[1]

Because of the prematurity of most VLBW infants (frequently <32 weeks gestation), they experience high rates of morbidity and mortality due to their underdeveloped organ systems and inability to survive independently outside of the uterine environment.[8, 9] The brain, lungs, immune system, kidneys, skin, eyes, and gastrointestinal system are underdeveloped when an infant is born preterm.[3] This can

Table 1.2 Healthy People 2020 Objectives Targeting Birth Weight[1]

Objective MICH-8 Reduce low birth weight & very low birth weight	**Baseline**	**Target**
Sub-objective		
MICH-8.1 Reduce low birth weight	8.2%	7.8%
MICH-8.2 Reduce very low birth weight	1.5%	1.4%

result in both immediate and long-term medical complications.[3] Examples of these complications include late onset sepsis and necrotizing enterocolitis (NEC).[3] Consequently, preterm infants often require life support and alternative feeding methods (i.e. parenteral and enteral nutrition) provided in a neonatal intensive care unit (NICU).[3]

The rate of preterm delivery in the US rapidly increased by 30% between 1981 and 2006.[2, 7, 10-12] In 2014, the National Center for Health Statistics transitioned from using maternal report of the last menstrual period (LMP) to the obstetric estimate of gestation at delivery (OE) because of its increased validity when measuring gestational age.[13] Collection of data using OE began in 2007.[13] When comparing births classified as preterm using both the LMP and the OE, fewer births were classified as preterm when using the OE.[13] For example in 2013, when using the LMP, 11.39% of births were classified as preterm, as compared to 9.62% of births when using the OE.[13] This amounted to a difference of 70,000 fewer infants identified as preterm when using the OE.[13] The difference between the LMP and the OE for early and very preterm infants is not as large, at less than one-half of a percentage point.[13] Despite these differences, the Healthy People 2020 objectives for preterm birth continue to be based on LMP rather than OE.[1]

Though Healthy People 2020 objectives (**Table 1.1**) are designed to report data based on last menstrual period (LMP) and not obstetric estimate of gestational age at delivery (OE), data presented in this paper are based on data published using the OE.[1, 13] However, the LMP, when available, is also reported in parentheses. Over the past decade, preterm delivery has gradually declined, based on both the OE and the LMP

measure.[2, 7, 10-13] The rate of preterm birth was 9.57% (11.32%) in 2014, an 8% (10%) reduction from 10.44% (12.68%) in 2007.[7, 13, 14] Most recent available data show only a slight decline for preterm deliveries, moving from 9.62% (11.39%) in 2013 to 9.57% (11.32%) in 2014.[7, 13, 14] Further assessment by categories of preterm delivery showed late preterm deliveries stabilized at 6.82% using the OE measure and decreased slightly using the LMP measure (7.99 →7.96%).[7, 13, 14] Early and very preterm deliveries both declined slightly during this same time period, from 2.79% (3.40%) to 2.75% (3.36%) and 1.62% (1.92%) to 1.60% (1.90%), respectively.[7, 13, 14]

As with rates of preterm birth, rates of LBW birth have been gradually declining since 2006.[1, 2, 12] The most recent data indicate a minimal decrease from 8.02% in 2013 to 8.00% in 2014.[7] Very low birth weight has experienced only a minor decline over this same time period, and is currently at 1.40% of total births, after declining from 1.41% of total births in 2013.[7]

Importantly, prematurity is considered a prevalent health disparity in the US, as substantial differences are seen when evaluating rates of prematurity by race and ethnicity.[2, 7, 11] The 2013 CDC *Health Disparities and Inequalities Report* (CHDIR), using birth certificate data from the 2006 to 2010 National Vital Statistics System (NVSS), found preterm birth rates differed by as much as 60% between non-Hispanic white and non-Hispanic black mothers.[11] This disparity has persisted, and in 2014, 13.23% of infants born to non-Hispanic black mothers were born preterm compared to 8.91% of infants born to non-Hispanic white mothers.[7] The disparity was the greatest among very preterm infants.[7, 11-13] For example, in 2014, 3.08% of non-Hispanic black infants were

delivered very preterm, whereas the rate for non-Hispanic white infants was only 1.29%.[7, 11, 12] Though non-Hispanic black mothers continue to be more likely to experience preterm birth, as compared to non-Hispanic white mothers, rates in both groups similarly declined from 2013 to 2014 for preterm, early, and very preterm births.[2, 11, 12]

A similar relationship is found when comparing birth weight by race and ethnicity.[7, 11, 12] Though LBW is decreasing at a similar rate for infants born to non-Hispanic white mothers and non-Hispanic black mothers, overall rates remain higher in non-Hispanic black mothers (13.15% in 2014) as compared to non-Hispanic white mothers (6.96% in 2014).[7] There were no significant differences in the rate of decline for VLBW between non-Hispanic black mothers (2.90% → 2.86%) and non-Hispanic white mothers (1.11% → 1.10%) from 2013 to 2014.[7] However, infants born to non-Hispanic black mothers are still nearly three times more likely than infants born to non-Hispanic white mothers to be VLBW.[7] The higher rates of short gestation and LBW among non-Hispanic black mothers is reflected in higher rates of infant mortality.[7, 15] Despite these slight improvements, short gestation and LBW continue to be a leading public health concern as these infants have a high risk of morbidity and mortality, and contribute importantly to health disparities.[1]

Infant Morbidity & Mortality: Definitions and Trends

The Infant Mortality Rate (IMR), defined as the number of infant deaths in the first year of life per 1000 live births in a specified population over the course of a year, is a measurement commonly used to compare the health of different populations.[16] The total

IMR includes the early and late neonatal periods defined as less than 7 days postpartum and between the 7th and 28th day postpartum respectively.[15] The postneonatal period is defined as between the 28th and 364th day postpartum, or after the neonatal period and before the infant reaches one year of age.[15]

The Central Intelligence Agency (CIA) uses data collected by the US Census Bureau's International Programs Center's (IPC) International Database to compute and compare the IMR of different countries, from highest IMR (1st) to lowest IMR (224th).[17] Globally, the US is ranked 167th among both developed and underdeveloped nations.[17] This means that 57 countries in the world have lower IMRs than the US.[17] The current total IMR reported by the CIA in the World Fact Book in the US is 5.87 per 1000 live births.[17] This is comparable to the most recent NVSS report on infant mortality statistics from 2013 with 5.96 infant deaths per 1000 live births.[15, 17] The US is more closely comparable to underdeveloped nations rather than to other developed nations.[17] For example, the US has only a slightly lower IMR than Serbia (6.05), which has a Gross Domestic Product (GDP) of $97.27 billion ($13,600 per capita) compared to the US GDP of $17.97 trillion ($56,300 per capita).[17] Monaco is currently ranked the highest globally at 224th with the lowest IMR with 1.82 per 1000 live births.[17] Currently there are 34 countries which are recognized as developed nations by the CIA.[17] Select examples of other developed nations with lower IMRs than the US include Sweden (2.60), France (3.28), Italy (3.29), Belgium (3.41), Germany (3.43), and the Netherlands (3.62).[17] The CIA's World Fact Book only reports the IMR, without further analysis by maternal and

infant characteristics, therefore understanding the differences in IMRs between countries cannot be determined using the CIA's World Fact Book.[17]

Reports published by the CDC attribute the low US ranking to the higher rates of preterm deliveries, as compared to other developed nations.[17, 18] A 2014 NVSS report comparing the US IMR to developed European nations found that when compared to Sweden, approximately 39% of the US IMR was due to a higher rate of preterm deliveries.[18] Therefore, countries with lower rates of preterm delivery, consequently have lower IMRs compared to countries with higher rates of preterm delivery.[18] In simple terms, if the US were to lower their preterm delivery rates then IMR should decrease at a similar rate.[18] This is supported by recent national trends with declines in both preterm delivery and IMRs.[7, 14, 15]

The most recent data available on infant mortality in the US were published in 2013, therefore reports were made using gestational age from LMP data rather than OE data.[15] Comparisons between the OE and LMP as a measure of gestation, illustrate that previous estimates of infant mortality risk may have underestimated preterm infants risk of death in the neonatal and postneonatal period because of the misclassification of term infants as preterm.[13, 15] While infants who are born preterm accounted for only 11.4% (LMP) of the birth population in 2013, these infants made up 67% of total infant deaths.[15] The most vulnerable infants are those who are born less than 32 weeks gestation (very preterm), contributing to more than 50% of infant deaths annually.[15] Deaths attributed to preterm-related causes accounted for 36% of total infant deaths in 2013.[15] Infant deaths are classified as preterm-related when 75% of deaths due to that

cause occur among infants who are born preterm.[15] The leading causes of infant mortality in the US for all infants are: 1) congenital malformations, **2) disorders associated with short gestation and low birth weight**, **3) maternal complications from pregnancy**, 4) SIDS, and 5) accidents.[15, 19] Of the five leading causes of infant death, disorders associated with short gestation and low birth weight as well as most maternal complications from pregnancy are classified as preterm-related causes.[15]

Geographical analyses indicate that infants born in the South and Midwest have a higher risk of infant mortality compared to infants born in other regions of the US.[15] For example, in Tennessee the IMR is 7.16 per 1000 live births, the 13th highest IMR in the US, which includes Puerto Rico and Guam.[15] Risk of infant death increases with both decreasing gestation and birth weight.[3, 15] When compared to infants born term and at a normal birth weight, those born preterm and/or with a LBW are more likely to die in either the neonatal or postneonatal period, as well as the neonatal and postneonatal periods combined.[3, 7, 15] The following measures refer to the combined neonatal and postneonatal period for IMR.[15] In 2013, infants born early preterm were 9 times (16.02 deaths per 1000 live births) more likely to die than infants born at term (1.85 deaths per 1000 live births).[15] Very preterm infants (<32 weeks) were 88 times more likely to die (163.71 deaths per 1000 live births) than infants who were born at term (1.85 deaths per 1000 live births).[15] Linked infant birth and death certificate data from 2013 indicate the highest IMR occurs among VLBW infants (219.56 per 1000 live births), as compared to LBW infants (50.26 per 1000 live births), and normal birth weight infants (2.05 per 1000).[15] For example, VLBW infants (<1500 grams) were 100

times more likely to die than normal birth weight infants and LBW infants were 25 times more likely to die than normal birth weight infants.[15]

Infants born to non-Hispanic black mothers had the highest IMR for infants of all gestational ages.[15] It is likely not surprising that IMR differs by race as these infants are more likely to be smaller and more likely to be preterm.[15] In 2013, infants born to non-Hispanic black mothers were 2.2 times (11.11 per 1000 live births) more likely to die in the first year of life, as compared to infants born to non-Hispanic white mothers (5.06 per 1000 live births).[15] NVSS infant mortality data from 2013 revealed a higher IMR among infants born to non-Hispanic black mothers, compared to infants born to non-Hispanic white mothers, regardless of gestation or birth weight (with the exception of early preterm IMR) (**Table 1.3)**.[15] The difference in IMR for late and early preterm infants born to non-Hispanic black and non-Hispanic white mothers is minimal and may be representative of the higher likelihood of these infants surviving when born at these gestational ages compared to infants who are born very preterm.[15] The IMR disparity between non-Hispanic black and non-Hispanic white mothers is driven by the disparity

Table 1.3 2013 comparison birth outcomes, per 1000 live births, experienced by non-Hispanic black and non-Hispanic white mothers[15]

	Non-Hispanic Black Mothers (n=584,834)	Non-Hispanic White Mothers (n=2,129,196)
Length of Gestation	Per 1000 live births	Per 1000 live births
Preterm	50.01	30.50
Late Preterm	8.45	7.23
Early Preterm	15.36	16.85
Very Preterm	186.41	150.92
Birth weight	Per 1000 live births	Per 1000 live births
Low Birth Weight	63.00	45.11
Very Low Birth Weight	233.77	208.58

in IMR for very preterm infants.[15] Infants who are very preterm, have the highest IMR, which can be explained by these infants being the least mature and the smallest of infants.[15] For example, in 2014, 75.2% of infants born very preterm (<32 weeks) were born at a VLBW, and 98.7% of infants born less than 28 weeks were VLBW.[15]

While the root causes of disparities in rates of preterm birth and lower birth weights are not fully understood, it has been suggested that delayed utilization or lack of prenatal care may play a role.[20] Using 2007 data from the NVSS, Mathews and MacDorman found that approximately 76.1% of non-Hispanic white mothers accessed prenatal care services in the first trimester, compared to only 59.1% of non-Hispanic black mothers.[20] Approximately 11.6% of non-Hispanic black mothers delayed utilization of prenatal care services until the 3rd trimester or simply never accessed prenatal care services, compared to 5.0% of non-Hispanic white mothers.[20] In 2001, the Surgeon General's office published findings that indicated, even when access to health services are available, non-Hispanic black women are less likely to access services than non-Hispanic white women.[21] Decreased use of prenatal services among non-Hispanic black mothers may be due to the lack of culturally relevant services available to non-Hispanic black women.[20] The underutilization of healthcare services is associated with lower incomes, lack of health care coverage, as well as issues surrounding cultural norms and personal histories.[21] This suggests that, even if services were available, non-Hispanic black women may not be comfortable accessing these services if they are not culturally relevant.[21] In a review of hospital services as contributing factors to preterm delivery, the IMRs for non-Hispanic black infants were significantly higher than for non-Hispanic

white infants when non-Hispanic black infants were born in hospitals that provided labor and delivery services to a higher proportion of non-Hispanic black women than non-Hispanic white women.[22] However, when VLBW non-Hispanic black infants were delivered at hospitals more likely to be providing services to VLBW non-Hispanic white infants, survival rates were better in these non-Hispanic black infants.[22] The researchers estimated that there would be a 10% decrease in the IMR racial disparity, if black infants were delivered at a higher proportion in hospitals that predominantly serve non-Hispanic white women.[22] Unequal access to medical technology is consistent with higher rates of infant mortality seen in non-Hispanic black populations.[23] Hospitals frequented by non-Hispanic black women, compared to those frequented by non-Hispanic white women, had less medical technology available.[22, 23] These findings imply a gap in the quality of care available to non-Hispanic black mothers and infants.[22, 23]

Consequently, there are variations in the order of the leading causes of death between infants born to non-Hispanic black or non-Hispanic white mothers.[15] In 2013, infants born to non-Hispanic black mothers were more likely to die from preterm-related causes (44% of infant deaths), compared to infants born to non-Hispanic white mothers (31.5% of infant deaths).[15] The five leading causes of infant death for infants born to non-Hispanic black mothers, listed from highest to lowest are: **1) disorders associated with short gestation and low birth weight**, 2) congenital malformations, **3) maternal complications from the pregnancy**, 4) sudden infant death syndrome (SIDS), and 5) accidents.[15, 19] In contrast, the 5 leading causes of infant death for infants born to non-Hispanic white mothers in order from highest to lowest are: 1) congenital malformations,

2) disorders associated with short gestation and low birth weight, 3) SIDS, **4) maternal complications from pregnancy**, and 5) accidents.[15, 19]

Explanations for the disparity in IMR seen in non-Hispanic black infants have emerged from a complex framework and interaction of social, behavioral, genetic, medical, political, and health care factors that continue to be explored and interpreted.[24] Social determinants for increased risk of infant mortality include delayed utilization of or no prenatal care, behavioral and environmental risks, and maternal demographics.[15, 19] For example, women of all races, falling below 185% of the federally poverty level have a higher risk of delivering preterm and/or lower birth weight infants compared to women with higher incomes.[3, 12, 25] In summary, preterm delivery and lower than normal birth weights differ by social determinants and increase the risk of infant morbidity and mortality.[3, 12, 15, 19, 25] Evidence supports the use of human milk as protective against negative health outcomes among preterm infants, in spite of social determinants.[26-29]

Nutrition for Preterm Infants

Human Milk

Use of human milk has been associated with improved health outcomes and is the recommended form of nourishment for most infants.[30-32] Human milk is a unique biological substance, with a composition that can change through the course of a feed, a day, and an entire period of lactation, in order to meet the growing needs of the infant.[33, 34] In addition, human milk is made up of numerous immunologic factors such

as hormones, growth factors, enzymes, antibodies, and live cells that are nearly impossible to replicate in infant formula.[26, 33] Milk produced by mothers of term infants differs in its composition when compared to milk produced by mothers of preterm infants.[35] Therefore, the AAP Section on Breastfeeding recommends preterm infants receive milk from their own mothers whenever possible.[30, 31] When mother's milk is not available, the AAP then recommends using donor milk if available and, lastly, preterm formula.[30] The composition of term and preterm milk are presented separately in the next two sections.

Term Milk

Term human milk, refers to milk produced by mothers of infants born at greater than 37 weeks gestation.[3, 4] In this section, when referring to an infant, the infant is a healthy, term infant. Over the course of the first month of an infant's life, the composition of human milk is highly variable, transitioning from colostrum, to transitional milk, to mostly mature milk, and then to completely mature milk.[33] During the first few days postpartum, colostrum is produced in very small amounts (~ 1 teaspoon).[33] While minimal in volume, colostrum is relatively high in protein and low in fat and lactose compared to milk at later stages.[35] Colostrum is recognized for its bioactive factors, for example, secretory IgA, lactoferrin, and Heparin-binding epidermal growth factors (Hb-EGF).[33] Colostrum has lower levels of lactose, potassium, and calcium, but higher levels of sodium, chloride, and magnesium, compared to milk produced in later lactation stages.[33, 36, 37]

Around 5 days postpartum, colostrum becomes transitional milk and this is produced until the infant is approximately 2 weeks of age.[33] By two weeks postpartum, human milk is recognized as being mostly "mature".[33] However, it is not until 4 to 6 weeks when human milk is considered to be completely "mature".[33] Human milk produced prior to the first 4-6 weeks postpartum (transitional and mostly mature milk) contains higher protein levels than completely mature milk.[33, 38] Mature milk is lowest in protein compared to milk at other lactation stages and is highest in lactose and energy due to increased fat content.[35] Once human milk is completely mature, it will remain relatively stable in composition, experiencing only minor changes in composition during a discreet feed.[33] The maturation of human milk from colostrum to "mature" milk matches the maturation of an infant's nutritional needs.[33]

The nutritional composition of human milk is dependent upon synthesis of nutrients in lactocytes, the cells responsible for producing milk in the mammary gland.[33] Specifically, maternal intake of certain vitamins (D, K, B6) and fatty acids may influence the micronutrient composition of human milk, however macronutrient composition remains relatively unchanged regardless of maternal diet.[33, 39-41] Despite slight variations during a feed, macronutrient composition is surprisingly consistent between mothers, regardless of maternal nutritional status and diet.[33] Typically, mature, term milk contains between 0.9 and 1.2 g/dL of protein, 3.2 to 3.6 g/dL of lipid, and 6.7 to 7.8 g/dL of lactose.[33, 35] Kilocalorie content varies from 65 to 70 kcal/dL.[33, 35] In contrast to protein and fat, the lactose and oligiosaccharide content found in human milk remains relatively

stable over the course of lactation, with the exception of lower levels found in colostrum.[33]

Preterm Milk

The nutritional composition of milk varies drastically depending on the infant's age of gestation at delivery.[35] Compared to milk present at a term birth, milk initially produced by mothers of preterm infants tends to be higher in protein and fat (**Table 1.4**).[33, 35] Subsequently, protein and fat content decreases at a similar rate for both term and preterm milk as each progresses through the stages of maturation and the infant grows.[33, 35] Gidrewicz and Fenton conducted a meta-analysis comparing the macro- and micronutrient composition of preterm and term milk.[35] At days 1 to 3 postpartum, preterm milk was 35% higher in protein than term milk (2.7 $\pm$ 1.5 vs. 2.0 $\pm$ 0.9 g/dL; p<.00001).[35] This difference remained significant through week 9 postpartum.[35]

Table 1.4 Macronutrient (g/dL) and energy (kcal/dL) composition of human milk[33, 39]

Author (year), n	**Protein (g/dL) M (+/- 2 SD)**	**Fat (g/dL) M (+/- 2 SD)**	**Lactose (g/dL) M (+/- 2 SD)**	**Energy (kcal/dL) M (+/- 2 SD)**
Preterm, 24-hour collection, first 8 weeks of life				
Bauer & Gress (2011) Born <29 weeks, n=52	2.2 (1.3, 3.3)	4.4 (2.6, 6.2)	7.6 (6.4, 8.8)	78 (61, 94)
Born 32-33 weeks, n=20	1.9 (1.3, 2.5)	4.8 (2.8, 6.8)	7.5 (6.5, 8.5)	77 (64, 89)
Term infants, 24-hour collection, mature milk				
Nommsen et al (1991), n=58	1.2 (0.9, 1.5)	3.6 (2.2, 5.0)	7.4 (7.2, 7.7)	70 (57, 83)
Representative values of mature milk, term infants				
Reference standard	0.9	3.5	6.7	65 to 70

However, true protein difference showed that protein in preterm milk post day 3 was only higher by 0.1 to 0.3 g/dL.[35] Preterm milk was 23% higher in fat than term milk at days 1 to 3 postpartum (2.2 ± 0.9 vs. 1.8 ± 0.7; p=0.002).[35] The difference in fat content between preterm and term milk only remained significant through week 2.[35] Preterm milk was lower than term milk in lactose content, except for days 4 to 7 where it was significantly higher by 4% (6.3 ± 1.1 vs. 6.0 ± 1.0, p=0.009).[35]

Milk from an infant's mother is typically adequate at meeting the preterm infant's needs for growth during the first month postpartum.[33, 35, 42] However, protein content decreases during the course of lactation, therefore it is standard practice to supplement with a human milk fortifier in order to provide the preterm infant with adequate protein, minerals and vitamins for optimal growth.[33, 35, 42] Despite the need to fortify human milk, it remains the best nutritional option for preterm infants because of its immunologic and antimicrobial properties.[30, 31]

Donor Milk

Because human milk is recognized for its medicinal properties, in addition to nutritional value, when an infant's biological mother is unable to provide her own milk then donor milk is recommended.[33] The use of donor milk in NICUs across the United States is increasing, as the benefits of human milk are becoming better understood.[43] The costs associated with donor milk procured from an accredited human milk bank include, packaging, transportation, and pasteurization.[43] On average, one ounce of donor milk costs $4.00.[44, 45] Many hospitals are choosing to cover these costs and

provide donor milk to preterm infants during their hospitalization.[43] Typically, NICUs that provide donor milk during hospitalization will discontinue it prior to the infants' discharge.[44, 46, 47]

In studies examining the benefits of donor milk the results have been mixed and vary based on the level of prematurity.[43, 48, 49] It is important to note that donor milk oftentimes comes from women who have delivered at term, which is initially lower in protein and fat than milk initially produced by women delivering prematurely (**Table 1.5**).[48] Donor milk, which has been highly processed, has been linked with positive health outcomes in LBW infants, but not necessarily in VLBW infants.[43] These mixed findings may be somewhat explained when noting that most research exploring the impact of human milk on NEC risk in VLBW infants has been conducted using unprocessed milk that has been obtained directly from the biological mother, and donor milk may not provide the same protective effects.[30, 31, 50-52]

Table 1.5 Macronutrient (g/dL) and energy (kcal/dL) composition of preterm and term donor milk[33, 39]

Author (year), n	**Protein (g/dL) M (+/- 2 SD)**	**Fat (g/dL) M (+/- 2 SD)**	**Lactose (g/dL) M (+/- 2 SD)**	**Energy (kcal/dL) M (+/- 2 SD)**
Preterm donor milk				
Hartmann (2012), n=47	1.4 (0.8, 1.9)	4.2 (2.4, 5.9)	6.7 (5.5, 7.9)	70 (53, 87)
Term donor milk				
Wojcik et al (2009), n=415	1.2 (0.7, 1.7)	3.2 (1.2, 5.2)	7.8 (6.0, 9.6)	65 (43, 87)
Michaelsen et al (1990), n=2553	[a] 0.9 (0.6, 1.4)	[a] 3.6 (1.8, 8.9)	[a] 7.2 (6.4, 7.6)	[a] 67 (50,115)
Representative values of mature milk, term infants				
Reference standard	0.9	3.5	6.7	65 to 70
[a]Median (lower bound)				

In fact, a recent randomized trial, comparing donor milk to formula, found no significant differences between groups in the rates of NEC in a group of VLBW infants.[48, 53] Because of the limited and inconclusive research specifically exploring the effect of milk collected from the infant's mother versus donor milk on NEC risk among VLBW infants, provision of milk directly from the infant's mother remains the preferred feeding choice.[30, 31, 50, 51] In addition donor milk, like mother's milk, has to be fortified to adequately meet a preterm infant's nutritional needs.[54, 55]

Infant Formula

Standard Infant Formula for Term Infants

Human milk is recognized as containing medicinal properties, making it the ideal choice for infants, both term and preterm.[33] Because of its variability and unique properties, it is difficult to replicate the composition of human milk.[56] When milk from the infant's mother or donor milk is not available or is medically contraindicated, then infant formula becomes a necessity.[30] The American Academy of Pediatrics (AAP) recommends using an iron-fortified infant formula when human milk is not available or is medically contraindicated.[30] Infant formula is modeled after human milk, however, it is not possible to replicate the composition of human milk.[30] Because of the difficulty in replicating the composition of human milk, current research is focused on developing formulas that allow for a formula fed infant to grow and develop comparably to a breastfed infant, rather than being focused on replicating the composition of human milk.[30]

Infant formula composition must meet the standards set forth by *Codex Alimentarius* or *"Food Code"*, published by the Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations (FAO) and WHO.[56] The US has been a member of the Codex Alimentarius Commission since 1963.[56] The US also implemented the Infant Formula Act of 1980, to provide further regulation of infant formula.[57] This act was amended in 1986 and now addresses the minimum and maximum nutrient requirements for infant formula.[57, 58] The requirements set forth by the *Codex Alimentarius* and the amended Infant Formula Act of 1980 are comparable.[56, 57] Therefore, all infant formulas available on the market in the US are composed of macro and micronutrients that address the nutrient and energy needs of infants through 4 to 6 months postpartum.[56-58] Minimum and maximum allowable values of macronutrients per 100 kcal, published by the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) International Expert Group and followed by US manufacturers are listed in **Table 1.6**.[56] Most formula companies produce infant formulas with nutrient amounts that exceed the minimum standard.[56] The recognized standard calorie content of infant formula in the US States is 20 kilocalories per ounce or 67.7 kilocalories per 100 ml, for a healthy, term infant.[56]

Preterm Infant Formula

Preterm infants' nutritional needs differ from those of term, healthy infants.[59-62] For example, whereas it is recommended that a term infant consume formula that is concentrated at 20 kcal/oz, more energy dense formulas (24 kcal/oz), when tolerated,

Table 1.6 ESPGHAN proposed macronutrient requirements of standard infant formula for healthy, term infants[56]

Component	Unit	Minimum	Maximum
Energy	Kcal/100ml	60	70
Protein			
Cows' milk protein	g/100kcal	1.8	3
Soy protein isolates	g/100kcal	2.25	3
Hydrolyzed cows' milk protein	g/100kcal	1.8	3
Lipid			
Total fat	g/100 kcal	4.4	6.0
Linoleic acid	g/100 kcal	0.3	1.2
Alpha-linolenic acid	mg/100 kcal	50	NS
Docosahexaenoic acid*	% of fat	0	0.5
Carbohydrate			
Total Carbohydrates	g/100 kcal	9.0	14.0

NS: not specified
*optional ingredient

are favored for preterm infants (**Table 1.7**).[56, 62, 63] Formulas with a higher energy-density are beneficial for preterm infants because they allow for their energy needs to be met with a smaller volume of formula.[56, 62] Formulas with a higher energy density are often a necessity, when trying to promote growth in preterm infants with a limited stomach capacity due to prematurity.[56, 62] Consequently, infant formula companies have developed infant formulas specifically for preterm infants.[64] Infant formulas designed to meet the nutritional needs of preterm infants are higher in protein and minerals, and contain easier to digest forms of carbohydrates and fats compared to those found in standard formulas developed for term, healthy infants.[64]

In addition to having varied nutritional needs, compared to healthy, term infants, preterm infants have an increased susceptibility to illnesses and infections such as those caused by *Cronobacter sakazakii* (previously known as *Enterobacter sakazakii*).[65] Preterm infants are at an increased risk for developing the infection due to having an

Table 1.7 ESPGHAN proposed macronutrient requirements of preterm infant formula for preterm infants[63]

Component	Unit	Minimum	Maximum
Energy	kcal/kg/day	110	150
Protein*	g/100kcal	3.2	4.1
Lipid			
Linoleic acid	mg/100kcal	350	1400
Alpha-linolenic acid	mg/100kcal	>50	NS
Docosahexaenoic acid*	mg/100kcal	11	27
Medium chain triglycerides	% of fat	40	50
Carbohydrate	g/kg/day	10.5	12

NS: not specified
*varies by infant weight

underdeveloped immune system as a result of prematurity.[65] In 2002, the Food and Drug Administration (FDA) made the recommendation to feed preterm infants only ready-to-feed preterm infant formulas.[65, 66] The FDA recommendation was the result of cases of *Cronobacter sakazakii* infection, traced back to contaminated powdered infant formula.[65, 66] In fact, all powdered infant formula is not sterile and improper handling and preparation of powdered infant formula may lead to *Cronobacter sakazakii* infection.[65, 66] Preterm infants should be fed ready-to-feed preterm infant formulas to meet their nutritional needs because these have been sterilized during the manufacturing process.[65, 66]

Human Milk Benefits

Preterm Infant Health Outcomes

Infants who are born preterm, especially those who are very preterm are at an increased risk for experiencing medical complications during their NICU hospitalization

secondary to the vulnerability from having immature organ systems.[3] Milk from the infant's biological mother has been found to be protective against medical complications such as late onset sepsis and NEC, two of the leading causes of morbidity and mortality in preterm infants.[5, 26, 67-73] Lower risk of late onset sepsis and NEC have been linked to infants receiving enteral feedings earlier and reaching full enteral feeds faster.[74, 75] Infants who receive expressed milk from their own mothers have been found to experience better feeding tolerance compared to infants receiving infant formula.[74, 75] Similarly, receipt of human milk by preterm infants is associated with lower rates of late onset sepsis and NEC and consequently shorter hospital stays.[72, 76] Therefore, provision of human milk from the infant's biological mother is a primary goal for NICUs worldwide.[30] The role human milk plays in timing of enteral feedings, late onset sepsis, NEC, and length of hospital stay will be discussed.

Enteral Feeding

Infants who are born very preterm initially lack the ability to coordinate sucking and swallowing, therefore these infants are unable to be fed orally by breast or bottle.[69, 77] To meet nutrient needs to ensure adequate growth, infants are fed intravenously with parenteral solutions, advancing to enteral feedings as tolerated.[69] Enteral nutrition (EN) for infants includes; milk from the mother, donor milk and infant formulas.[69] EN bypasses the need for the infant to suck or swallow, by delivering the milk or formula directly into the stomach or the small bowel.[69] EN can be administered using either a tube, catheter or stoma depending on the duration of the intervention.[69] Short-term EN

is delivered using a feeding tube inserted through either the nose (naso-) or mouth (oro-) and with the tip of the tube located in the stomach (-gastric) or small bowel (-duodenal and –jejunal).[69] Long-term EN is delivered using a stoma that is surgically created so that the feeding tube can be inserted through the abdominal wall directly into the stomach (gastrostomy) or small bowel (jejunostomy).[69]

Historically, EN has been delayed in very preterm, VLBW infants due to the concern that these feedings may not be well tolerated and could increase the risk of NEC.[78, 79] Recent research has focused on the benefit of minimal enteral feedings (MEF), also referred to as 'early trophic feedings' (up to 24 ml/kg/day or 1 ml/kg/hour, in preparing the gut for advancement to full feeds and therefore, theoretically, reducing the risk for NEC.[78] This is especially important when those feeds consist of human milk.[78] Researchers hypothesize administration of MEF of human milk will enable infants to reach full enteral feedings sooner and lower the risk of negative consequences such as NEC and late onset sepsis.[78] Current recommendations from the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N) recommend beginning MEF in very preterm, VLBW infants within 2 days postpartum and to advance to nutritive feedings by increasing the rate by 10-20 mL/kg/day.[69] Infants receive parenteral nutrition (PN) and EN simultaneously, until they achieve full enteral feedings.[69] Infants have been found to have better feeding tolerance and advance to full feeds sooner when fed human milk compared to infant formula.[75] Infants fed formula exclusively were significantly less likely to achieve full enteral feedings (defined as 150 ml/kg/day) sooner compared to infants fed human milk (in this study both milk from the infant's mother and donor milk)

by 1.4 days ((SE 0.556); p<.010).[75] Despite being a relatively short period of time, 1.4 days has clinical importance in an infant's risk for diagnosis of late onset sepsis and/or NEC.[75] A 2014 Cochrane review found that delaying enteral feeds in very preterm, VLBW infants beyond 5 to 7 days postpartum resulted in a longer time to achieve full enteral feedings (median 2-4 days) compared to infants who received progressive feedings prior to 4 days postpartum.[79] Research has continued to focus on the role of MEF and its impact for VLBW infants as initiation of MEF has become common practice across NICUs.[79] The working group for the "Evaluation of the evidence to support guidelines for nutritional care of preterm infants: The Pre-B Project" has identified MEF of human milk as one of the topic areas for systematic review in addition to a more broad focus on the role of human milk.[80, 81] The Pre-B project was initiated in response to the need for guidelines for preterm infant's nutritional care, following initiation of the "Evaluation of the evidence to support the inclusion of infants and children from birth to 24 months: B-24 project".[80, 81] The B-24 project is focused on inclusion of infant feeding guidelines within the Dietary Guidelines for Americans, which will be included in future publications beginning in 2020.[80, 81] In contrast, the Pre-B Project, while following much of the same procedures for developing evidence-based guidelines is separate from the B-24 project and will not be included in the DGA.[80, 81]

Late Onset Sepsis

Late onset sepsis refers to infections that occur on or after day 3 postpartum and is linked to longer hospital stays and higher rates of infant morbidity and mortality.[5]

Preterm and VLBW infants have a higher risk of being diagnosed with late onset sepsis compared to term infants, due to having an immature immune system, and this risk increases with decreasing gestational age and birth weight.[5] In 2002, the National Institute of Child Health and Human Development (NICHD) Neonatal Research Network reviewed 6215 VLBW infant cases for late onset sepsis occurring between 1998 and 2000.[5] The majority of infants in this prospective cohort were very preterm (93.5%).[5] Stoll and colleagues found that approximately 21% of these very preterm infants had at least one positive result on a blood culture for late onset sepsis.[5] Infants diagnosed with late onset sepsis were significantly more likely to remain hospitalized for a longer period of time compared to infants without positive blood cultures (79 days vs. 60 days; P<.001).[5] Infants who developed late onset sepsis were significantly more likely to die when compared to infants who did not develop late onset sepsis (18% vs 7%; p<.001).[5] The likelihood of an increasing number of episodes of late onset sepsis was positively associated with shorter gestation and smaller size.[5] For example, 9.8% of infants born between 29 and 32 weeks gestation developed late onset sepsis compared to 28% of infants born between 25 and 28 weeks and 45.7% of infants born less than 24 weeks gestation.[5] In contrast, a study examining late onset sepsis in late preterm (34-36 weeks) infants, only 6.2% developed late onset sepsis.[72] Therefore, infants who are born preterm have a higher risk of late onset sepsis, compared to not only term infants but to other preterm infants who have a higher gestational age and higher birth weight.[5, 72]

It appears that timing of enteral feeds may affect the risk of infection, possibly due to the reduced exposure via activities related to PN (i.e., central line placement). The earlier an infant received enteral feeds and progressed to full enteral feeds the lower his risk of developing an infection.[5] The link between earlier full enteral feedings and lower risk of late onset sepsis is explained by the decreased duration of placement of a central catheter or other intravenous access routes for administration of parenteral nutrition.[5] Infants receiving parenteral nutrition for greater than 22 days have a significantly increased odds of having a positive blood culture for late onset sepsis compared to infants receiving PN for 0 to 7 days (aOR:1.0 vs. aOR:22.3, 95% CI:16.2-30.5), p<.001).[5] Among infants receiving their first enteral feed between 0 and 7 days postpartum, only 17% of infants were diagnosed with late onset sepsis compared to more than half (56%) of infants not receiving their first feed until 22 or greater days postpartum (aOR:4.0, 95% CI:2.8-5.7, p<.001).[5] Achievement of full feeds results in discontinuation of PN and typically removal of the intravenous access route in most infants.[5] Therefore, infants reaching full feeds sooner will have a lower likelihood of being diagnosed with late onset sepsis.[5] Only 3% of infants reaching full feeds between 0 to 7 days postpartum were diagnosed with late onset sepsis compared to 42% of infants who did not receive full feedings until 22 or more days postpartum (aOR:4.3,95% CI: 3.5-5.3, p<.001).[5]

In a subsequent report, examining trends in cases of late onset sepsis for 34,636 extremely preterm, VLBW infants (<28 weeks gestation, 400-1500 grams) from the prospective cohort between 1993 and 2012.[82] In the past decade, the rate of late onset

sepsis has been declining for extremely low birth weight infants.[82] From 1998 to 2002, 35% of the Neonatal Research Networks cohort was diagnosed with late onset sepsis, compared to only 24% of the cohort born between 2008 and 2012.[82] The rate of decline is consistent across infants of all gestational ages within the extremely preterm infant category (data were not presented for infants born greater than 28 weeks gestation).[82] However, infants with shorter gestation and lower birth weights continue to be at a higher risk of late onset sepsis compared to older and heavier infants.[82] The decline in diagnosis of late onset sepsis has been linked to improved hygienic practices (i.e. washing hands) as well increased efforts in the provision of human milk in quality improvement initiatives implemented across the US.[82-84]

Research has focused on the effects of human milk compared to infant formula on diagnosis of late onset sepsis.[76, 84] Patel and colleagues conducted a prospective cohort study examining the dose response relationship of human milk on the incidence of late onset sepsis and the associated NICU costs among 175 preterm infants (28.1 $\pm$ 2.4 weeks gestation).[76] The majority (97.7%) of the sample received at least some human milk over the course of the study.[76] Infants in this study received human milk expressed by their mothers when available; if human milk was not available they received preterm formula.[76] In this sample, 13% of infants developed late onset sepsis (n=23) and these infants received significantly less human milk than infants not developing late onset sepsis (57 ml/kg/day $\pm$ 31 vs. 31 $\pm$ 33 ml/kg/day; p=0.001).[76] Over the course of the first 28 days postpartum, increasing the average daily dose of human milk by 10ml/kg/day decreased the odds of infants developing late onset sepsis by

19%.[76] When compared to infants receiving less than 25ml/kg/day of human milk, the cost of care for infants receiving more than 50ml/kg/day and 25-49.99ml/kg/day over the first 28 days post birth were $31,514 and $20,384 lower in sepsis costs, respectively.[76] Providing infants with more than or equal to 50 ml/kg/day of human milk rather than preterm formula could result in reducing hospital costs by $1.8 million for the infants included in their study.[76] In an earlier study, late onset sepsis was associated with an increase in hospital costs of $10,055 per case.[85] Infants who receive human milk have a lower risk of late onset sepsis and consequently shorter hospital stays and lower medical costs.[76, 85] The use of human milk as the primary form of EN for preterm infants has substantial financial benefits and plays an important role in reducing infant morbidity and mortality.[76, 84, 85]

Necrotizing Enterocolitis

NEC is the leading cause of gastrointestinal disease and infant mortality among preterm infants.[4, 5, 48] This condition results in the death of patches of intestinal tissue, greatly increasing the risk of morbidity and mortality in these infants.[86] Technological advances in neonatology have increased the survival rates of those with younger gestational ages and lower birth weights, and have consequently increased the incidence of NEC in the US.[48, 71, 87] Preterm infants account for 90% of NEC cases, and infants born at a VLBW or at less than 30 weeks are especially susceptible to NEC, due to their immature gastrointestinal systems.[26, 27, 48, 88] Approximately 12% of VLBW infants will be diagnosed with NEC and subsequently 30% of those cases will result in

death.[26, 88] In the US, those infants who survive experience significantly increased length of hospital stays and account for 19% of annual neonatal expenditures ($5 billion).[26, 68] Prevention of NEC is a primary concern in NICUs across the United States.[26, 68]

Though differentiation of the human gut has been largely achieved by about 20 weeks gestation, infants born at less than 29 weeks gestation have not fully developed organized peristalsis, which increases their risk of developing NEC.[8, 9] In addition, the ability to coordinate sucking and swallowing does not fully develop before 32 weeks gestation, decreasing the ability to receive nutrition via breast or bottle, and increasing the risk of infection resulting from placement of a feeding tube.[8, 9] In term infants, the gut has been colonized by bacteria from amniotic fluid consumed while in utero, beginning during the last trimester of pregnancy, from early feeds and possibly from exposure during vaginal delivery. [8, 9, 89]

In contrast, preterm infants are more likely to experience a consistently nearly sterile environment, from cesarean delivery to being fed sterile formula, which can result in abnormal bacterial colonization of the intestinal microbiota.[8, 9, 89] In 2014, more than half (50.4%) of preterm infants were delivered by cesarean delivery compared to 26.1% of term deliveries.[7] Very preterm infants often do not receive a full enteral feeding until at least 2 weeks post-delivery and VLBW infants are among those experiencing the highest rates of feeding intolerance.[8, 9, 90] Because of prematurity, VLBW infants often present with reflux, gastric residuals, and constipation associated with delayed gastric emptying, prolonged intestinal transit, abdominal distension, and delayed passage of

meconium, resulting in delayed advancement to enteral feeds and consequently feeding intolerance and NEC. [8, 9, 89] At the time of diagnosis approximately 90% of NEC cases have received enteral feeds.[26, 88] Because of the high infant mortality rate associated with it, NEC prevention is a primary goal for NICUs across the US.[67] Expressed, unprocessed milk, from the mother of the preterm infant, has been linked to decreased rates of NEC and therefore is a target for prevention efforts in NICUs worldwide. [8, 9] ASPEN recommends the use of milk from the infant's mother when available for the prevention of NEC.[69]

In both animal and human models, the use of colostrum ('first milk') and human milk have been associated with decreased rates of NEC.[26-28, 74, 91-93] Higher levels of bile acids have been found in the intestines of formula fed infants, as compared to infants fed human milk.[26, 94, 95] It is theorized that high levels of bile acids can lead to development of NEC by causing ileal damage.[26, 94, 95] It is thought that epidermal growth factor, found only in human milk, protects against the ileal damage caused by bile acids, and has a trophic effect on the intestine.[26, 48, 94, 96] Lucas and Cole conducted a large prospective trial comparing VLBW infants receiving human milk to those receiving formula.[28] VLBW infants fed only formula developed NEC six to ten times more frequently than infants fed human milk exclusively, and exclusively formula fed infants developed NEC three times more frequently, as compared to infants fed a combination of human milk and formula.[28] Additionally, the severity of NEC appears to be reduced significantly in infants exclusively receiving human milk.[26, 28] Feeding infants human milk, exclusively, is projected to prevent one case of NEC in every ten infants and one

case of surgical NEC or death in every eight VLBW infants.[26, 97] The use of human milk has a protective effect against NEC and consequently shortening the length of an infant's hospitalization.[98]

Breast Milk Expression in the NICU

Human Milk Feeding Rates

Published reports on breastfeeding rates at the national level do not include data collected about length of infant gestation or birth weight.[99] Therefore, current data on national breastfeeding rates include both term and preterm infants, but do not differentiate between them.[99] Consequently, it is difficult to establish what the current rate of breastfeeding is for the preterm population independent of the general infant population in the US.[99] Each year the Centers for Disease Control and Prevention (CDC) publish the *Breastfeeding Report Card* using data from the National Immunization Survey (NIS), which illustrates the current breastfeeding rate for infants in the US, regardless of gestational age.[99] Families with infants between 17 and 37 months of age are surveyed and retrospective inquiries are made regarding breastfeeding behaviors.[99] Specifically, questions are posed to elicit data on whether the infant was ever breastfed, breastfed at 6 months, breastfed at 1 year, breastfed exclusively at 3 months, and/or breastfed exclusively at 6 months.[99] These questions parallel the Healthy People 2020 objectives allowing for comparisons to be made over time.[99] For example, to measure whether an infant was ever breastfed caregivers are

asked, “Was [child] ever breastfed or fed breast milk?” It is important to note that due to the question structure (close-ended), data are not available to differentiate whether infants were fed directly at the breast or fed expressed breast milk.[99] Therefore, when describing breastfeeding rates using this dataset, it is important to be aware of this distinction as this includes human milk that is fed by breast and/or bottle.[99] In addition, based on this question structure, it is possible that responses include infants that are receiving milk that was previously expressed and stored for later use. **Table 1.8** compares the Healthy People 2020 breastfeeding objectives to National and Tennessee State breastfeeding rates from the 2014 *Breastfeeding Report Card*, which is the latest available report (2011 NIS data).[1, 99] While breastfeeding rates for preterm infants may be captured as part of the *Breastfeeding Report Card*, the lack of data collected on infant gestation make it impossible to differentiate between the breastfeeding rates for term and preterm infants.[99] Understanding the breastfeeding rates for the preterm population is important, especially in the NICU setting because of the critical role breast milk plays on infant health outcomes.

Table 1.8 Comparisons of Healthy People 2020 Objectives to National and Tennessee State Breastfeeding Rates, from the 2014 Breastfeeding Report Card[1, 99]

	Ever Breastfed	**Breastfed at 6 months**	**Breastfed at 1 year**	**Exclusively breastfed 3 months**	**Exclusively breastfed at 6 months**
Healthy People 2020	81.9%	60.6%	34.1%	46.2%	25.5%
US 2014	79.2%	49.4%	26.7%	40.7%	18.8%
TN 2014	74.9%	40.7%	20.9%	39.1%	15.4%

While breastfeeding rates are not available at this time on a national level for preterm infants, studies have begun to look these rates in NICU settings, with a primary focus on receipt of human milk at NICU discharge.[46, 100-105] The studies included in this section focus on very preterm (<32 weeks) and/or VLBW infants as this is the primary population of interest. Infant receipt of some amount of human milk (biological mother's milk and/or donor milk) at infant discharge ranges between 37% and 61% of feeds.[46, 100, 101, 104, 105] Most of the studies measuring human milk receipt at NICU discharge are retrospective cohort studies that use data from NICUs that are collaborating with the Vermont Oxford Network (VON).[46, 100, 101, 104, 105] VON is global collaborative of NICUs, including NICUs from the US, which maintains a database on data collected related to infant health outcomes for VLBW infants.[101] Only one categorical measure of human milk use is included in the VON database, "enteral feeding at discharge," possible responses include "Human milk only," "Human milk in combination with either fortifier or formula," and "Formula."[101] It is important to note that this variable does not differentiate between milk expressed by the infant's own mother and that of donor milk.[101]

Brownell and colleagues used data collected for VON to assess what percentage of infants were receiving their own mother's milk at discharge at one urban, level IV NICU between 2002 and 2012, in relationship to independent predictors.[46] At this NICU, donor milk had been available since 2010, however, donor milk was discontinued after 10 weeks, or once infants reached 50% full oral feedings.[46] Infants are not discharged until they achieve 100% full oral feedings, therefore, infants in this sample would not have been receiving donor milk at discharge.[46] Brownell and colleagues found that of

the 660 infants included in the analyses, 399 (60.4%) were receiving some milk at discharge, over the course of the study period.[46] The researchers did not report on infants receiving exclusive human milk at discharge.[46]

Similarly, Lake and colleagues conducted a retrospective study of 98 NICUs from the VON database.[101] Between 2007 and 2008, a total of 6,964 VLBW infants were discharged from the NICU on enteral feedings and included in data analyses.[101] Human milk use was only assessed at discharge, as this was the only variable available from the VON database.[101] From this sample, 44.1% of infants were receiving at least some human milk at discharge.[101] In a secondary study, Hallowell and colleagues were able to determine that only 6% of these infants (from Lake and colleagues) were receiving human milk exclusively (including donor milk) at NICU discharge.[100] Meaning, without the addition of fortifiers or supplementation with infant formula.[100] There was a high degree of variability in the percentage of infants discharged on *any* human milk, with most NICUs having between 25 and 65% of their infant populations discharged on *any* human milk.[100] A small number of NICUs had less than 15% (n=3) and 100% (n=2) of infants discharged on *any human milk*.[100] Unfortunately, these studies do not capture maternal breastfeeding behaviors (whether or not mothers were still expressing breast milk or breastfeeding) at the time data were submitted to the VON database.[100, 101] In addition, these studies are unable to capture the intensity of human milk feedings for infants who are fed partial human milk.[100, 101] For example, there is no differentiation between infants who receive 90% of enteral feeds as human milk and infants who receive only 10% of enteral feeds as human milk.[100] Lastly, “enteral feeding at

discharge" is only a snapshot at one time point and does not fully capture the complexity of infant feeding. For example, if a mother develops mastitis at the time her infant is being discharged from the NICU, she would temporarily be unable to nurse or provide her infant with expressed milk. So using data from the VON database can result in both an underestimation and overestimation of what amount of expressed milk infants receive from their own mothers. The low rates of providing exclusive human milk at NICU discharge and the limited information available about maternal breastfeeding behaviors among mothers of preterm and LBW infants, both in the NICU setting and post-discharge, indicate a need for further investigation into the facilitators and barriers to milk expression in the NICU and supporting mothers to continue this behavior post-discharge.

Factors Influencing Milk Expression in the NICU

Mothers of very preterm infants must initiate milk expression in order for their infants to receive their milk.[106] For these mothers, this involves pumping for an extended period of time before their infant is able to attempt latching on to breastfeed.[106] Previous research has focused on factors associated with an infant receiving or not receiving *any* breast milk in the NICU setting, rather than factors associated specifically with *early pumping cessation* among mothers, which is considered to be an important barrier to provision of this source of nutrition.[46, 100-103] Findings on the influence of maternal factors and infants' receipt of human milk from their own mothers are mixed and vary depending on the support available in the NICU being studied.[46, 102] For example, black

maternal race has been associated with lower rates of infants receiving human milk from their own mothers over the course of the NICU stay and at discharge, however, when a peer support program is implemented this relationship appears to be reversed.[46, 102] Mothers who are engaged in a peer support program interact with trained peer counselors, who had experience expressing milk for their own preterm infant.[29, 46, 107]

Pineda and colleagues examined the role of maternal and infant factors on breast milk feeding initiation, duration, and continuation at discharge of expressed milk as well as direct breastfeeding.[102] Medical charts were retrospectively reviewed in a convenience sample of 135 VLBW infants admitted to the NICU between 2004 and 2005.[102, 103] The relationship between demographic factors and breastfeeding outcomes, following education of staff on breastfeeding, was analyzed.[102, 103] In the sample studied, 78% of infants ever received breast milk.[5, 102] This was slightly higher than national initiation rates in 2004 and 2005, at 73.1% and 74.1%, respectively.[1, 102] At discharge, infants were significantly more likely to still be receiving breast milk if their mothers were white (black 13% vs. white 50%; $p<0.01$) and older (30.4 years $\pm$ 7.7 vs. 24.1 years $\pm$ 5.7; $p<0.01$).[102] A lower socioeconomic status was defined as being eligible for Medicaid.[102] Whether or not an infant was ever fed at the breast while in the NICU was significantly associated with a higher socioeconomic status (Medicaid eligible 37% vs. not Medicaid eligible 90%; $p<0.01$), being white (black 33% vs. white 68%; $p=0.01$), and having an infant with a higher infant birth weight (1122 grams $\pm$ 250.5 vs. 913.3 grams $\pm$ 253; $p=0.01$).[102] When looked at as a full sample, only 37% of infants

were receiving any breast milk at discharge.[102] In contrast, Brownell and colleagues found, VLBW infants of black mothers, were significantly more likely to receive human milk feedings at discharge, compared to infants of white mothers.[46] The authors attributed this difference to having a well-established lactation program, which included peer support.[46]

Research has primarily focused on how factors that are not modifiable influence the receipt of human milk, such as race, socioeconomic status and maternal education level.[46, 102] Few studies have explored, from the maternal perspective, concerns related to infants receiving human milk.[108] In a secondary, longitudinal analysis of a randomized controlled trial, Callen and colleagues examined a research lactation consultant's notes from consults with mothers of VLBW infants randomized to an intervention group in Canada.[108] These notes were analyzed using content analysis methodology to identify barriers to breastfeeding throughout the first year of life.[108] The original sample consisted of 64 mothers; 3 mothers dropped out and 2 infants passed away, leaving a sample of 59 for analysis.[108] At infant discharge from the NICU (but remaining in the hospital) 85% (n=50) of mothers were breastfeeding.[108] Among this subsample, the most prevalent concerns mothers shared with the IBCLC included; "low milk supply" and "mother emotionally compromised."[108] At infant discharge from the hospital, mothers continuing to breastfeed further declined to 69% (n=41) of the original sample.[108] Again, the most prevalent concerns mothers shared with the IBCLC included; "low milk supply" being cited as a concern among 11 mothers and "mother emotionally compromised" cited as a concern among 20 mothers.[108] The number of mothers still breastfeeding

continued to decline to 59% (n=35), 46% (n=27), 36% (n=21), and 12% (n=7) at 1 month, 3 months, 6 months, and 12 months respectively.[108] It is important to note that without establishing an adequate milk supply, a successful breastfeeding relationship between mother and infant can be compromised before an infant is ever discharged from the hospital.[108] Mothers with preterm infants must establish and maintain their milk supply using a breast pump until their infant is physically capable of latching on for nutritive sucking.[108] Thus, understanding the maternal experience of breast pumping and how a low milk supply may develop could provide important guidance on how to better support mothers during this period.

Efforts to Improve Provision of Mother's Milk in NICUs

The health benefits of human milk are well understood for very preterm, VLBW infants.[30] Though many mothers are able to successfully provide human milk during part of their infant's hospitalization, provision of breast milk from the infant's mother is often discontinued prior to infant discharge, indicating that breast pumping has been stopped.[46, 100-103] Quality improvement efforts in NICUs across the United States have included various programs targeting improvement of breastfeeding rates among very preterm, VLBW infants.[107, 109-111] Interventions are often delivered in bundles, components of which vary across NICUs.[29] Examples of best practices for lactation support for mothers of preterm infants that can be found in most NICUS include; maintenance of maternal breastfeeding diaries to keep track of breast milk expression,

access to lactation and peer support, and dissemination of educational pamphlets and videos.[29]

One example of a NICU lactation program, supporting mothers to provide their milk, is the Rush Mother's Milk Club initiated by Meier and colleagues.[107, 110, 111] The Rush Mother's Milk Club offers peer support to mothers with infants in the NICU as well as resources to facilitate mothers continuing to provide their milk.[107, 110] These include, but are not limited to, providing taxi services to and from the NICU, electrical breast pumps, and social contact via activities such as weekly luncheons.[107, 110] Like Brownell and colleagues, Meier and colleagues have found that with a well-established lactation program, racial disparities in providing human milk were minimized.[46, 107, 110, 111] Both of these programs were implemented at NICUs in urban settings that served predominantly black mothers.[46, 107, 110, 111] Miracle and colleagues further demonstrated that a predominantly black, low-income sample was able to successfully provide their milk when support and guidance through the Rush Mother's Milk Club was available.[111]

These researchers conducted qualitative interviews with 21 mothers, of VLBW, preterm infants, who had initially planned to formula feed their infants.[111] The purpose of these interviews was to identify what motivated mothers to decide to provide their infants with breast milk.[111] Mothers reported that explanations of the health benefits of human milk for their preterm infants greatly influenced their decision to change feeding mode.[111] Previous research has found that health professionals want to avoid making mothers feel guilty or coerced to express milk.[111, 112] Rodriguez and colleagues found that mothers wanted to know the benefits of human milk and did not feel pressured to

feed their infant a certain way when the benefits of human milk were explained.[111, 112] This research led to widespread recommendations to "share the science" on the benefits of human milk with mothers of preterm infants.[112] Today, explanation of the benefits of mother's milk specific for a preterm infant is a common practice in NICUs across the US, including East Tennessee.[29]

Despite many lactation support practices being widely implemented across NICUs in the US, the evidence to support these practices is limited.[29] In a recent integrative review, Lucas and colleagues rated the evidence available for lactation support based on the quality of research.[29] Peer support was found to have evidence from only one well-designed randomized control trial (RCT).[29, 113] Whereas, other best practices for lactation support were rated as Level IV (case-control and cohort studies), Level V (systematic reviews of descriptive and qualitative studies), Level VI (single descriptive or qualitative study), and Level VII (opinion and expert committees).[29] Based on the current level of evidence available for lactation support in NICUs, additional research is needed to better meet the needs of mothers of preterm infants.[29] Prior to implementing interventions, it is important to identify the needs of lactating mothers to facilitate continued and successful breast milk expression.[29] Limited research has investigated what influences a mother's decision to continue or discontinue expressing breast milk for her very preterm or VLBW infant.[114] Research is needed to capture both facilitators and barriers to this behavior and to comprehend, from the maternal perspective, how NICUs can tailor support for women to provide their milk, both in the NICU and post-discharge.

Conclusion

Regardless of gestational age and/or birth weight, mother's milk is recognized as the preferred form of infant nutrition.[4, 30, 31] Mother's milk, shown to reduce the risk of respiratory and gastrointestinal infections in healthy, term, normal birth weight infants (compared to similar infants receiving infant formula), becomes increasingly important when considering preterm and VLBW infants.[4, 30, 31, 50, 51, 115, 116] Provision of mother's milk for very preterm infants is of high priority due to a reduced risk for severe medical complications such as late onset sepsis and NEC.[26, 74, 109, 117, 118] Very preterm infants often lack the ability to coordinate sucking and swallowing, and human milk must be acquired via breast pump and then provided via feeding tube.[3, 77, 119] Though motivation to express breast milk is high in the NICU population, even the most motivated mother can be impacted by the stress of a preterm birth and this can be a tremendous barrier to the ability to successfully express human milk.[111, 112, 120, 121] Moreover, many mothers who successfully provide expressed human milk while in the NICU often experience barriers to continuing this behavior for the duration of the NICU stay and post discharge, despite the recommendation to provide human milk until the infant is at least one year of age.[119, 122] Further research is needed to better understand the experiences of mothers who express human milk for their preterm infant from the perspective of mothers with infants in the NICU, in an effort to provide effective and appropriate support services to this population.[114]

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Chapter II: “I Had One Job and That Was to Make Milk”: Mothers’ Experiences Expressing Breast Milk for Their Very Low Birth Weight Infants

A version of this chapter is currently under review by the Journal of Human Lactation by Katherine Bower, Tara Burnette, Daniel Lewis, Courtney Wright, and Katie Kavanagh.

My contributions to the paper were i) study design, ii) preparation and submission of the study protocol to the University of Tennessee at Knoxville and University of Tennessee Medical Center Institutional Review Boards (IRB), ii) participant management, iii) participant interviews, iv) first interview transcription (n=13) and transcription verification (n=4), v) data analysis, vi) manuscript preparation, editing based on co-author feedback, and submission for publication. T. Burnette contributed to i) study design, ii) provided feedback on the study protocol and approved submission to the IRBs, iii) participant recruitment; D. Lewis contributed to i) interview transcription (n=4), ii) data analysis; C. Wright contributed to i) verification of interview transcription (n=13), ii) data analysis; K. Kavanagh contributed to i) study design, ii) provided feedback on study protocol and approved submission to the IRBs. All co-authors read and approved the final manuscript.

Abstract

Background: For very low birth weight (VLBW) infants, breastfeeding may no longer be an immediate option. Mothers often turn to mechanically expressing their breast milk with a breast pump to provide their infants breast milk.

Objective: To gain an understanding of mothers' experiences expressing breast milk for their VLBW infants in a Level III Neonatal Intensive Care Unit (NICU).

Methods: Qualitative, phenomenological methods were used to better understand the breast milk expression experiences of 17 mothers of VLBW infants. In-depth interviews were recorded and transcribed verbatim. Transcripts were analyzed using Colaizzi's seven-step protocol and themes were identified to illustrate the lived experience of the mothers.

Results: The global theme, "I had one job and that was to make milk" is supported by three subthemes; 1) "I was heartbroken;" 2) "Pumping is a full time thing" and; 3) "I literally sacrificed nights."

Conclusion: This study provides insight into the complex experience mothers in the Southeastern United States undergo when expressing breast milk for their VLBW infants.

Well Established: Breast milk is recommended for infants worldwide regardless of their birth weight. Prior research shows mothers often start breast milk expression for their very low birth weight infants (VLBW), but have difficulty continuing this behavior.

Newly Expressed: Mothers choosing to express breast milk for their VLBW infant place pressure on themselves to be successful. This pressure may interfere with their ability to meet breast milk expression recommendations to sustain and maintain their milk supply.

Background

The American Academy of Pediatrics recommends breastfeeding regardless of infant birth weight or gestational age.[1] Compared to formula, breast milk, when fed to very low birth weight (VLBW) infants, has been associated with improved health outcomes, such as decreased risk of necrotizing enterocolitis (NEC) and nosocomial infections.[2, 3] Lower risk of NEC and nosocomial infections have been linked to infants receiving enteral feedings earlier and reaching full enteral feeds faster.[3,4] Infants who receive expressed breast milk from their own mothers have been found to experience better feeding tolerance compared to infants receiving infant formula.[3,4] Similarly, receipt of breast milk by VLBW infants is associated with lower rates of NEC and nosocomial infections and consequently shorter hospital stays.[5,6] Provision of breast milk from the infant's biological mother is a primary goal for Neonatal Intensive Care Units in the United States (US).[1]For VLBW infants, the ability to coordinate sucking and swallowing is often underdeveloped.[7-9] Consequently, breast milk must initially be acquired via a breast pump and delivered enterally prior to the infant being able to feed at the breast.[7-9]

Although research shows high rates of breast milk expression initiation among mothers who deliver VLBW infants, continuation of this behavior until infant discharge from the NICU is less common.[10-12] Though research has been conducted, exploring non-modifiable influences on breast milk expression behaviors, such as race, socioeconomic status and maternal education level, limited research has investigated what modifiable factors influence a mother's decision to continue or discontinue breast milk expression for her VLBW infant. [10, 13-15] Identifying the needs of lactating mothers is important in order to tailor support for mothers to continue breast milk expression.[14] The objective of this study was to gain an understanding of mothers' experiences expressing breast milk for their VLBW infants in a Level III NICU in the Southeastern US.

Methods

This qualitative study focused on mothers' experiences expressing breast milk for their VLBW infants, using phenomenological methods.[16] A phenomenological framework is often used in the health sciences to better understand the experiences of patients in order to ultimately improve those experiences, making it an appropriate method for this study (Appendix A).[17, 18] The University of Tennessee at Knoxville and the University of Tennessee Medical Center Institutional Review Boards approved the research protocol. Recruitment took place from June 2014 to February 2015 and continued until data saturation was achieved, defined as the point at which participants shared no new information.[17, 18]

The methods followed were consistent with ensuring that the four criteria for trustworthiness in qualitative studies were addressed and followed; 1) transferability, 2) dependability, 3) credibility, and 4) confirmability. Using purposeful sampling, mothers of infants from a local Level III NICU in the Southeastern US were invited to participate in the study if they met the following eligibility criteria: were at least 18 years of age and English-speaking; breast milk was not contraindicated by a medical issue or illicit drug use; custody of their infants would be maintained post-discharge; breast milk expression had been initiated; and infant birth weight was equal to or less than 1500 grams. Infant charts were screened by a neonatologist (TB) and the nursing staff delivered a study invitation to eligible mothers, no other methods were used to recruit participants. Interested mothers could contact the primary researcher (KB) to set up an interview date and time. Mothers were interviewed in a private room at the NICU or over the phone, per maternal preference. This allowed for participation by mothers who were not able to visit the NICU regularly. Prior to each interview, study activities were reviewed, informed consent was obtained, and mothers completed a brief demographic questionnaire. Demographic data were collected to allow for the assessment of the transferability of study findings.

To maintain consistency in interview methods throughout data collection, and to ensure dependability of the study findings, the primary researcher (KB) conducted all interviews. There was no relationship between KB and the participants. Consistent with phenomenological methods, interviews began with a general statement regarding the experience of interest.[7] In this study, this statement was: “Tell me about your

experience pumping breast milk for your baby." Additional prompting questions were asked and assisted with better capturing of the mothers' experiences. The open-ended structure of the questions allowed mothers to elaborate on what was most significant about their experiences. All interviews were audio-recorded, transcribed verbatim, and checked for accuracy. Data analyses were ongoing and concurrent with data collection, allowing researchers to identify, as early as possible, when saturation was achieved. Data were analyzed independently by two researchers (KB and DL) using the seven procedural steps outlined by Colaizzi:[16]

1) Complete transcripts were read and re-read by two independent researchers (KB and DL) to grasp a general understanding of the experience for each mother.
2) Significant Statements-These are defined as phrases or sentences that related directly to the experience of expressing breast milk.[7] To increase the credibility of the study, two researchers (KB and DL) independently extracted significant statements from each transcript. When there were discrepancies in selection of significant statements by the two researchers a third researcher (CW) was involved to increase credibility. The research team then discussed these discrepancies until consensus was reached (e.g. peer debriefing).[10]
3) Formulated Meanings- The research team derived meanings from each significant statement to allow for further interpretation of the results. This is akin to 'coding', in other qualitative methods.[7, 10]
4) KB and DL then independently categorized formulated meanings into clusters of subthemes and further grouped subthemes into larger global themes. At each stage

of data analysis components were compared and any discrepancies were addressed through peer debriefing, further increasing the credibility of the study findings.

5) The formulated meanings, as well as clusters of subthemes and global themes, were integrated into an exhaustive description of the mothers' experiences as interpreted by the research team.
6) The fundamental structure of the phenomenon was produced from the exhaustive description and is presented in the results section.
7) Member Checking- Consistent with Colaizzi's methodology, whenever possible, the exhaustive description of the phenomenon was presented to participating mothers during a follow-up phone interview. This allowed the research team to confirm the consistency of their interpretation with the mothers' actual experiences. In addition, member-checking potentially identifies the need for further phenomenological exploration should new concepts be introduced at this time, thus strengthening the confirmability and dependability of the findings.[7]

In addition, the fundamental structure of the phenomenon was brought to the Phenomenological Research Group at the University of Tennessee at Knoxville to increase the confirmability and dependability of the study findings. This multidisciplinary group was invited to provide comments to support or contradict the presented analyses.

Results

Seventeen mothers enrolled in the study and were interviewed during their infants' hospitalization in the NICU. Demographic characteristics of the full maternal and

infant sample are presented in Table 2.1 and Table 2.2. Comparisons between the two independent researchers showed minimal variability in selection of significant statements and in organization of formulated meanings into clusters of subthemes and global themes. From the interviews, five global themes emerged (Appendix B). In this paper the global theme *"I had one job and that was to make milk"*, and how it captures the experience of breast milk expression among mothers of VLBW infants, is discussed. This theme and subthemes are presented in the mothers' language, to be most authentically reflective of their experiences. Mothers participating in member checking (n=11) are in agreement with the research team's interpretation of their experience.

Table 2.1 Descriptive Statistics for Mothers (n=17)

Characteristics	**n (%)**	**Characteristics**	**n (%)**
Race		Education	
Caucasian	11 (65)	High school or less	7 (41)
African American	2 (12)	Some college	6 (35)
Asian	3 (18)	College degree	2 (12)
Hispanic	1 (6)	Graduate degree	2 (12)
Marital status		Parity	
Married	11 (65)	1st time mother	12 (71)
Unmarried	6 (35)	2 or more children	5 (29)
Income status		Planned feeding type	
WIC eligible	13 (76)	Breast milk	13 (76)
Non-WIC eligible	4 (24)	Infant formula	4 (24)
Age (years)		Breast milk expression at time of interview	
18-25	6 (35)	Yes	13 (76)
26-30	5 (29)	No	4 (24)
31-35	6 (35)		

Abbreviation: WIC, Special Supplemental Nutrition Program for Women, Infants, and Children.

Table 2.2 Descriptive Statistics for Infants (n=18)

Characteristics	M (SD)
Gestational age, weeks	28 (2.0)
Birth weight, grams	952 (251.1)
Infant age at interview, weeks since birth	8 (2.5)

Global Theme: "I Had One Job and That Was to Make Milk"

While the majority of mothers had planned to breastfeed, those who had initially planned to formula feed changed these plans when their infants were born preterm. Education by medical staff regarding the added benefits of breast milk for their preterm infant, as compared to infant formula, prompted these mothers to initiate breast milk expression because breast milk is seen as the 'best medicine' that mothers can provide for their infants. Despite being educated on the benefits of receiving any amount of breast milk, mothers put pressure on themselves to provide enough breast milk to meet their infants' full nutritional needs. When mothers are unable to keep up with their infants' needs they become 'heartbroken' because this results in their infants receiving supplemental infant formula feeds. Mothers view breast milk expression as a uniquely critical role they can play in their infants' care, while simultaneously struggling with the time required to express breast milk for an infant that is not always physically present. The essential structure of this theme, along with supporting significant statements from mothers, is presented three subthemes; 1) *"I was heartbroken;"* 2) *"Pumping is a fulltime thing"* and; 3) *"I literally sacrificed nights."*

Subtheme 1: "I Was Heartbroken"

Mothers put pressure on themselves to provide for their infants, stating they are 'moms'. Mothers describe wanting to produce enough breast milk to meet their infants' nutritional needs because this is the one way they are able to participate in their infants' care. While the majority of mothers were still expressing breast milk at the time of the interview, almost every mother voiced concerns about her milk supply and feelings of inadequacy when unable to provide for her infant's full needs. In spite of knowing the benefits of 'small amounts' of breast milk, mothers report experiencing feelings of 'disappointment,' 'defeat,' 'embarrassment,' and 'depression' when they are unable to fully keep up with their infants' needs as they grew and the volume of their feeds increased. As one mother said; *"I would come in with maybe a couple of drops in each bottle and be really embarrassed and depressed about it."*

Mothers reported experiencing conflicting burdens on their time, with one mother talking about how making the choice between spending time expressing breast milk or seeing her infant was a source of 'emotional stress' and contributed to low milk production; *"…there was that decision to make…do I want to be with my son or do I want to feel terrible and make a little bit more milk...and then the emotional stress of that would affect how much I made."* The stress of having an infant in the NICU led mothers to put more pressure on themselves to express breast milk, despite not feeling emotionally stable. As one mother described; *"[Pumping]…is hard to do, and then the stress of having a sick child and putting that added stress on yourself…basically, you*

know that it's something you have to do but you're not necessarily in a good place, mentally, emotionally, physically."

Four mothers were no longer expressing breast milk at the time of the interview, and their experiences capture the 'heartbreak' they felt from not being able to provide for their infants. Despite following the advice of lactation consultants, one mother emphasized the lack of control she had over her milk supply; "*I would do everything she told me to do and- nothing… and … I was like, my back was against the wall, cause all she could tell me was, you know, "make sure you're eating right, getting rest, pumping every three hours, faithfully, plenty of water, no stressing." …Besides the stressing part, cause I had no control over it, I was doing everything, and nothing."*

Underlying mothers' concern for their infants' general health was the fear of their infants dying. Mothers put pressure on themselves to keep their infants alive with their breast milk. As one mother who had originally planned to formula feed emphasized; *"I felt like if I wasn't gonna get him breast milk, he was gonna die."* She describes how she continued to express breast milk for 6 weeks despite never having fully established her milk supply; *"I was trying to breastfeed until he was released from the NICU. That was the goal. At least until he was released. But I couldn't, it was painful. It wasn't coming out how it was supposed to…I was stressing my body out, stressing myself out, and I was like, that's it. I can't. It's like, I can't. There's nothing producing. That's when I decided to stop."* For these mothers, the emotional aspect of expressing breast milk for their infants could be either motivating and/or the cause of stress.

Subtheme 2: "Pumping is a Fulltime Thing"

Time-management is a focal point of breast milk expression described by mothers as 'time-consuming' and 'inconvenient', because of the frequency required to establish and maintain their milk supply. For many mothers, the time spent expressing breast milk is 'stressful' and 'overwhelming.' Mothers describe breast milk expression as 'taking time away' from being with family, friends, and their infants. The time it takes to express breast milk adds to the stress of the experience for many mothers. However, when mothers spend less time expressing breast milk this often leads to a lower milk supply and stress from not being able to provide for their infants. As one mother describes; *"With family, I have to take my time away from them to go somewhere to be able to pump or if I don't take my pump with me that just makes me lose more milk. The longer you go without pumping the less milk you produce so it just takes a lot of time away from people."* For her this experience was stressful; *"Just having to stop what you're doing…then my son always, like, wants to play with me and stuff when I'm pumping and I have to tell him no so that can be very stressful."*

Finding the time to express breast milk is often difficult. As one mother emphasizes; *"Pumping is the pits. I'll be honest, it is not fun. Three hours…it seems like a long time but it's not, so there's always the stress of, oh my god it's almost time…I've gotta pump."* Mothers schedule daily activities in between pumping sessions, even delaying visits to the NICU to see their infants, to ensure they have adequate time to express breast milk. As one mother said; *"It's just uncomfortable and I mean it interferes with your schedule cause like every three hours you have to stop whatever you're doing*

or hurry home…so you can pump." Despite the time breast milk expression consumes, mothers are driven by their need to provide breast milk for their infants. Mothers view the time spent expressing breast milk as 'minor' compared to the 'major problems' their infants are facing. One mother stating; *"Sometimes like I have to skip something for pumping and I have to skip pumping like that and that is minor challenges but having baby here is stressful..."*

Subtheme 3: "I Literally Sacrificed Nights"

To establish and maintain a breast milk supply, mothers are advised to express breast milk eight to ten times per day or every two to three hours. For these mothers the 'frequency' required to establish and maintain their milk supply can lead to 'exhaustion'. At first, for many mothers, the frequency needed to establish their breast milk supply was achievable. Over time, continuing to express breast milk at this frequency becomes more 'difficult.' As one mother describes; *"When I first started again I was tired but I wasn't as tired, so I would literally get up at first every three hours and pump. Which, when you do that you think, oh well, that's great, I'll get three hours of sleep and I'll get up to pump and I'll get three hours of sleep. Well it doesn't work that way."* For some mothers, being 'tired' from the frequency of expressing breast milk every two to three hours sometimes leads to 'oversleeping' and missing a breast milk expression session. In these scenarios, mothers often attribute a low milk supply to not pumping frequently enough. As one mother said, *"Sometimes I skip 'cause I just oversleep and be so tired. I*

think that's why my milk supply has gotten a little lower, but I'm trying to not do that anymore."

Not having their infants at home can make the task of remembering to express breast milk more difficult because mothers don't have their infants there to wake them up at night. As one mother said; *"Thirty minutes, every two to three hours a day…if he was home it would be a lot easier…it doesn't always take as long to breastfeed him…so with him not being home it, sometimes I often forget, like, exactly to pump on time because he's not there to feed."* Mothers sometimes find waking up at night more difficult knowing that, rather than getting up to breastfeed their infants, they had to get up to have an 'intimate moment with a machine.' Breast milk expression becomes increasingly 'harder' for mothers the longer their infants are in the NICU. As one mother describes; *"It does get harder though, because he's not with me, so you kind of have to have a scheduled time, sit down, and pump milk and still go on do your day. It takes a lot of dedication."* Despite the difficulties mothers face expressing breast milk they are willing to make 'sacrifices' in order to do their part to in the hope that their infants' health will improve, so that they can come home.

Discussion

Research shows establishing and maintaining milk supply to achieve adequate breast milk feeds is challenging for mothers with infants in the NICU as they learn to incorporate breast milk expression into their daily lives.[20] Many mothers are unable to sustain this behavior, thus reducing their ability to continue to provide breast milk for

their hospitalized infants.[20] As evidenced by earlier studies, despite high initiation rates, significant declines in rates of breast milk feeds at infant discharge have been widely observed.[13, 20, 21] Factors previously found to contribute to this early cessation in preterm infant populations are often non-modifiable, and include maternal race, education, maternal age, socioeconomic status, marital status, parity, previous breastfeeding experience, infant birth weight, and gestational age.[10, 13, 21, 22] However, while providing valuable insight in identifying populations that may be at risk for early lactation cessation, these identified relationships are not always consistent between studies.[10, 13, 21, 22] The findings from this study illustrate the unique experience mothers of VLBW infants face when taking on the added task of breast milk expression.

Findings on the effects of potentially modifiable factors that may contribute to early lactation cessation, such as stress, are conflicting.[23, 24] While we did not include an objective measure of stress in our study, mothers' self-reported 'stress' and its effects on their milk supply is supported by previous research in this area.[23] In a longitudinal, observational study of mothers of infants born between 26 and 29 weeks gestational age, increased levels of stress, secondary to the perceived inability to serve in a parental role, were associated with an increased likelihood of discontinuing breast milk expression.[23] In contrast, Hill and colleagues found that while perceived stress, sleep difficulty, and fatigue levels remained elevated at 6 weeks postpartum in a sample of mothers of preterm infants, none of these factors appeared to be significantly related to lactation success.[24] Despite mixed findings on the relationship between stress and lactation success, it is important to recognize that mothers of preterm infants are facing

a great number of challenges that could have negative implications for their ability to sustain breast milk expression.

Phenomenological studies from Taiwan and Australia uncovered similar themes to those that emerged in our sample.[25, 26] In an Australian sample, with mothers and fathers of VLBW infants, mothers felt an 'innate pressure to succeed' with breast milk expression in order to ultimately transition to breastfeeding.[25] Mothers equated providing sufficient breast milk for their infants as their 'only tangible mothering role' and consequently mothers placed pressure on themselves to be successful.[25] Participants interviewed spoke of breastfeeding being a 'mother's job'.[25] Like these mothers, our sample frequently addressed breast milk expression as a 'job.' In contrast, our sample felt 'pressure to pump' in order to establish an adequate breast milk supply to meet their infants' needs regardless of delivery mode, whether it be by bottle or breast. While some mothers envisioned they would be able to transition to feeding at the breast, this was not a primary concern for the majority of our sample, despite prenatal or postnatal goals to breastfeed. This contrast may be reflective of variations in cultural breastfeeding norms between Australia and the US.[25]

Inability of mothers to maintain breast milk expression is a concern as there is a direct relationship between frequency of breast milk expression and milk supply.[27] Mothers emphasize concerns with being able to keep up with their infants' feeds as their infants grow and begin to tolerate an increased feeding volume. This experience coincides with earlier quantitative studies examining milk production patterns in mothers of VLBW, infants and extremely preterm infants.[27, 28] Hill and colleagues found that

mothers of VLBW infants expressed breast milk on average five to six times per day compared to mothers of term infants who fed at the breast on average eight times per day.[27] Current recommendations for supporting optimal breast milk volume production for mothers of preterm, VLBW, infants are to express breast milk eight to ten times per day.[27, 29] In our sample, mothers describe difficulty keeping up with a demanding breast milk expression schedule and they often miss sessions at night due to 'exhaustion'. This is important to consider, as milk production is optimal at night due to higher levels of prolactin.[27, 30]

Conclusion

Our sample was limited to English-speaking mothers from one NICU. Therefore, our findings may not be generalizable to other NICUs. Interviews were conducted both in-person and over-the-phone until saturation was achieved, minimizing the likelihood of variability in global themes due to interview mode. The primary researcher (KB) performed bracketing prior to conducting interviews and throughout data analysis to minimize inherent biases. Researcher bias was further minimized through inclusion of two independent co-coders, peer debriefing, member-checking, and presentation of final results to the Phenomenological Research Group. We conclude that the experience mothers face when making the decision to express breast milk for their VLBW is a challenging one, both physically and emotionally. The pressure mothers place on themselves can become overwhelming and may in some cases interfere with their ability to maintain the frequency of breast milk expression needed to sustain milk

supply. The difficulty mothers have with establishing and maintaining an adequate breast milk supply coupled with meeting breast milk frequency recommendations is of concern. Focusing on the benefits of any amount of breast milk, rather than providing 'all' nutrition as breast milk, is especially important for those mothers who have difficulties establishing and maintaining their breast milk supply. This study provides insight into the complex experience mothers in the Southeastern US undergo when expressing breast milk for their VLBW infants.

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Conflict of interest

The authors declare no conflict of interest.

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Chapter III: Development of PumpMed: An Interactive Web-Based Application Designed to Promote Breast Milk Expression Among Mothers of Preterm Infants

This article hasn't been published anywhere, nor will it be before I turn in the final version of my ETD, so I didn't include a publication statement.

Abstract

Background: PumpMed was developed in response to formative qualitative interviews (phase 1). Themes from these interviews shaped the development of the PumpMed prototype, with the goal of designing an intervention targeting breast milk expression.

Purpose: To conduct a developmental evaluation (DE) of PumpMed to assess any issues prior to implementation of a pilot intervention and to make iterative changes as needed.

Methods: Mothers of preterm infants with any experience pumping and International Board Certified Lactation Consultants (IBCLCs) with any experience working with mothers of preterm infants were invited to provide feedback on PumpMed. Once enrolled, participants were given access to a PumpMed account. The usability and acceptability of PumpMed was assessed using the Systems Usability Scale (SUS) and open-ended exploratory questions.

Results: Twelve mothers and 8 IBCLCs completed the study. PumpMed scores for both mothers and IBCLCs, were significantly above the benchmark average. The majority of mothers and IBCLCs reported they would have used PumpMed or recommended PumpMed to mothers, respectively.

Conclusion: A DE of PumpMed demonstrated it was useable and allowed for iterative changes to further tailor PumpMed to the unique needs of the target population. A

randomized pilot design will be used to test the feasibility and efficacy of PumpMed on breast milk expression outcomes.

Well Established: Although the use of paper logs to track breast milk expression is common practice in NICUs, no studies have assessed using electronic logs in this setting. Before implementation, it is important to assess the usability and acceptability of this method.

Newly Expressed: In this study a web-based application, designed to promote breast milk expression, proved to be usable and accepted among the target population. PumpMed may be an appropriate alternative to the traditional paper breastfeeding diaries among mothers of preterm infants.

Background

Regardless of gestational age and/or birth weight, breastfeeding is recognized as the optimal infant-feeding mode, unless contraindicated by certain medical reasons or illicit drug use.[1, 2] Breast milk, shown to reduce the risk of respiratory and gastrointestinal infections in healthy, term, normal birth weight infants, becomes increasingly important when considering preterm infants.[1-5] For example, research indicates that preterm infants receiving breast milk are at a lower risk of developing necrotizing enterocolitis, a costly, devastating and often deadly diagnosis, than similar infants who are formula-fed.[3, 6-8] The protective effect of breast milk may be largely due

to immunologic factors that are present in breast milk but absent in infant formula.[9-11] For this reason, providing breast milk for these particular infants is of high priority in most Neonatal Intensive Care Units (NICUs).[12, 13] However, because preterm infants may lack the ability to coordinate sucking and swallowing, in most situations breast milk must be acquired via breast-pump and delivered via feeding tube.[14-16] Though motivation to provide breast milk is generally high among mothers of infants in the NICU, the stress of a preterm birth can be a tremendous barrier to the ability to successfully express breast milk or to breastfeed directly when possible.[17-19] Moreover, many mothers who successfully provide expressed breast milk while in the NICU often experience barriers to continuing this behavior for the entire duration of the NICU stay, and then post-discharge, despite the recommendation to breastfeed until the infant is at least one year of age.[15, 20]

While the long-term goal is to achieve infant breast milk feeding recommendations, short term and primary outcomes should be to help these mothers continue to express breast milk and maintain their milk supply until infant discharge or the infant is able to successfully breastfeed.[1, 2] A predominant issue facing many mothers of preterm infants is achieving an adequate milk supply to fulfill their infants' nutritional needs.[21, 22] While healthcare access remains an issue for many Americans, internet access is widely available and utilized by the majority of Americans, often regardless of socioeconomic differences.[23, 24] Accessibility to health resources through an internet avenue may be one way to address healthcare barriers prevalent among lower-income populations and low breast milk provision rates among mothers of

preterm infants.[23] The use of the internet to provide supplemental lactation support in the NICU setting remains largely unexplored.[23] To date, no studies targeting mothers of preterm infants to promote breast milk expression via a web-based application have been identified. The purpose of this study was to conduct a developmental evaluation of PumpMed in preparation for its use in a pilot randomized controlled trial targeting increased breast milk supply. The objectives of this study were to:

1. Determine the usability of PumpMed from the perspective of members of the target population: a) mothers of preterm infants with prior experience pumping and/or b) International Board Certified Lactation Consultants (IBCLCs) with experience working with mothers of preterm infants.
2. Determine the acceptability of PumpMed from the perspective of members of the target population: a) mothers of preterm infants with prior experience pumping and b) IBCLCs with experience working with mothers of preterm infants.

Methods

Development of PumpMed

Our research team conducted a qualitative study (phase 1) with the aim of gaining a better understanding of mothers' experiences pumping for their preterm infant. Following purposive sampling, seventeen mothers with preterm, very low birth weight infants, who had initiated pumping, were interviewed. Among our sample, fifteen mothers expressed concerns with their milk supply. Of these mothers, four were no

longer pumping at the time of the interview, citing low milk supply as their reason for discontinuation. Five global themes emerged from these interviews; 1) “I had one job and that was to make milk;” 2) “Why keep pumping?;” 3) “In the end pumping was worth it;” 4) “You think of your situation as different;” and 5) “It’s not your baby, it’s cold plastic.” Detailed descriptions of each theme are presented separately (Chapter II and Appendix B). These themes informed the prototype of PumpMed, with the goal of designing an intervention that meets the unique needs of mothers of preterm infants. For example, mothers discussed how they struggled with establishing and maintaining their milk supply and that staff did not always recognize the effort they put into expressing their breast milk. PumpMed is designed to validate the work that mothers are doing to provide breast milk for their infants. The name “PumpMed” comes from mothers frequently describing their milk as the “best medicine” for their infants. Therefore, mothers were essentially pumping medicine for their infants, which led to the name “PumpMed.”

Developmental Evaluation Framework (phase 2)

PumpMed was developed to provide supplemental lactation support to mothers of preterm infants, using an iterative development process. Developmental Evaluation (DE) allows for adaptations to be made as feedback is obtained.[25, 26] A DE framework was applied to allow for iterative changes to be made to PumpMed to increase usability and acceptability among the target population: 1) mothers of preterm infants who had experience pumping, and 2) IBCLCs with experience working with mothers of preterm

infants.[25] DE has also been referred to as “real-time,” “emergent,” “action,” and “adaptive” evaluation.[27] A DE framework was chosen because the purpose was to develop an innovative intervention to support breast milk expression among mothers of preterm infants.[26-28] DE is utilization-focused, which allows for the involvement of the target population in making iterative changes prior to implementation of the intervention.[26-28] Taking an iterative approach within the context of a DE, allowed for the customization and modification of PumpMed features in response to feedback from the target population.

PumpMed Platform

Self-monitoring is often the first approach when targeting maintenance or modification of specific behaviors and is recommended for mothers of preterm infants who are pumping their breast milk.[29] Therefore, an interactive web-based application, PumpMed, was developed as a mechanism through which mothers can receive timely encouragement regarding their milk supply. In addition, the platform allows mothers to log their pumping sessions electronically instead of using the traditional mechanism of paper breastfeeding diaries.[29] The targeted behavior for this intervention will be increased and continued pumping to establish and maintain breast milk supply (up to 8-10 times per day).[29, 30] Once logged in to PumpMed, participants from the target population were able to view the Dashboard which includes three primary components:

1) Logs, where mothers can enter their pumping sessions and receive immediate feedback from a customized graphing feature;

2) Questions, where mothers may post pumping-related questions and receive evidence-based responses and;
3) Resources, which is a compilation of resources developed in response to feedback from the target population.

Participants were able to navigate PumpMed through use of colored tabs available on the Dashboard and pull-down menus. PumpMed is accessible and compatible on any device that can connect to the internet at: http://www.pumpmed.org (i.e. smart phones, tablets, laptop computers, desktop computers, etc.). This allows PumpMed to function like a smart-phone application or "app," which allows participants to view and use on a variety of devices (**Figure 3.1**). Measures taken to protect the security of participants accessing PumpMed are detailed in the PumpMed Security Statement (Appendix C).

Study Design

A descriptive, cross-sectional, online survey was conducted to assess the usability and acceptability of PumpMed. Feedback collected was incorporated into PumpMed prior to implementation of the pilot intervention (i.e. Resources, Frequently Asked Questions).

Participants and Setting

The study samples included two distinct study groups 1) mothers with previous experience pumping for their preterm infant, and 2) IBCLCs with experience working with mothers of preterm infants. Mothers who had completed the first phase of the stud

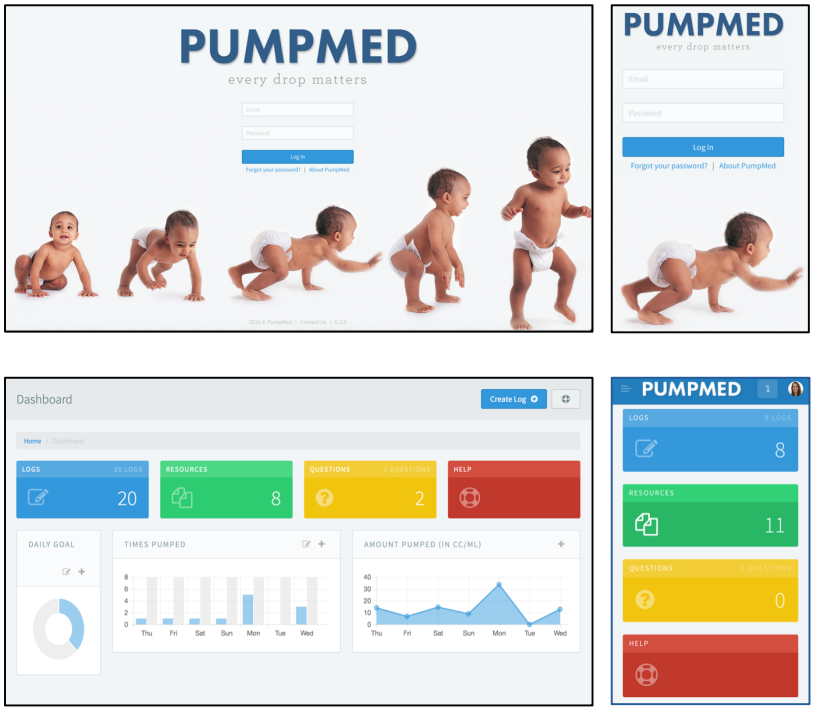

Figure 3.1 Side by side comparisons of Laptop and Smart Phone Views of PumpMed Login and Dashboard pages

(qualitative) and had previously indicated interest in participating in this phase of the project were invited to participate in the present study. This was a proof of concept study, therefore, a theoretical sample was used because actual usage of PumpMed was not being assessed. To achieve feedback saturation, additional participants, mothers and IBCLCs, were recruited through state and local breastfeeding coalitions, via social media and by word of mouth. English-speaking mothers of preterm infants (<37 week's gestation), whose infant had since been discharged from the hospital, who had access to the internet (with a valid e-mail address), who were 18 years of age or older, and had any experience pumping for their preterm infant (mothers did not have to be currently pumping) who was less than 2 years of age, were eligible to participate. English-

speaking IBCLCs with access to the internet (with a valid e-mail address), and who were 18 years of age or older with any experience working with the target population (i.e. mothers of preterm infants), were eligible to participate. The University of Tennessee at Knoxville Institutional Review Board approved the study protocol prior to the initiation of recruitment.

Procedures

Potential interested participants completed an online screen via Qualtrics. Individuals meeting the eligibility criteria based on responses to the screening questions were directed to a page explaining study activities, which was followed by informed consent and potential participants were given the option to select “I do not consent to participate” or “I consent to participate”. Potential participants selecting “I consent to participate” were considered eligible and enrolled in the study and were then directed to a brief demographic questionnaire. Study activities included completion of the demographic questionnaire, logging into and exploring PumpMed, and completion of the Systems Usability Scale (SUS) and exploratory questions to assess acceptability (referred to as the “Usability and Acceptability Questionnaire”). Data were collected using the online survey tool, Qualtrics. All communication between the participants and the research team was electronic (i.e. e-mail and the PumpMed Questions feature). Participants completing all study activities received a $25 gift card to Target as a thank you for taking the time to participate in the study.

Providing Log-in Information to PumpMed

Following completion of the demographic questionnaire, participants were e-mailed login information for their PumpMed account and instructions for logging into PumpMed, followed by an activation e-mail to activate their PumpMed account and create an individualized password (**Figure 3.2**). Participants were instructed to freely explore PumpMed and were provided information on how to request access to the Usability and Acceptability Questionnaire in the initial e-mail. Participants were given two weeks to access and explore PumpMed and could request access to the Usability and Acceptability Questionnaire at any point during their two-week access period. The instructions provided were brief and straightforward allowing the research team to assess whether or not more detailed instructions were needed for navigating PumpMed when implemented as an intervention. Only a participant who had logged into PumpMed

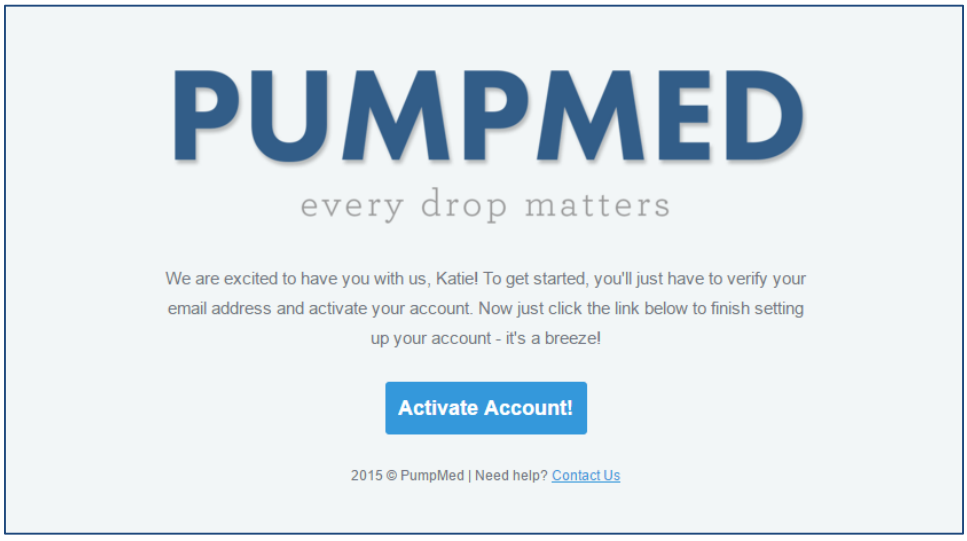

Figure 3.2 Screenshot of PumpMed Activation E-mail

was able to request access to the Usability and Acceptability Questionnaire. The first author (KB) monitored PumpMed daily for account activity (i.e. web analytics such as type of device the participant accessed the site from, whether or not the participant logged into the site, whether or not the participant interacted with the site such as logging a pumping session or downloading a resource). The purpose of monitoring whether or not participants logged in was to ensure that they were able to meaningfully complete the Usability and Acceptability Questionnaire.

Measures

System Usability Scale (SUS): The SUS was developed by John Brooke and has been widely used to assess the usability of various systems, including web-based application development.[31-33] The SUS has shown consistent measures of reliability and validity across different systems.[31-33] It is important to complete this process at the beginning of development in order to ensure that the web-based application has input from and is usable by the targeted population.[31-33] The 10-item SUS is scored on a 5-point Likert scale, from 1 being strongly disagree to 5 being strongly agree.[31-33] When participants responded to items indicating low usability, an open-ended question was posed to solicit more information. For example, if a participant responded with “strongly disagree,” to the item “I think that I would like to use this system frequently;” the follow-up question; “what would make you more likely to use it?” was asked. The measured usability of a system, such as a web-based application, when using the SUS can be reached with between 8 and 12 participants.[31, 33-35] This is a sufficient sample size to

determine whether or not major issues with usability are present in the system.[31, 33-35]

Exploratory Questions: Open-ended exploratory questions were administered to assess the general acceptability of PumpMed from the perspective of the target population. For example, participants were asked: “How likely would you have been to use PumpMed if it had been available to you? Please describe why or why not.” Mothers were also asked to suggest resources that they believed they would have found beneficial both when they first started pumping and throughout their pumping experience. Similarly, IBCLCs were asked to suggest resources as well. In addition, participants were prompted to provide general advice for future mothers who would be pumping for their preterm infants. Feedback and responses were used to “build out” the resources available on PumpMed.

Scoring the SUS

Composite SUS scores range from 0 to 100, with 100 being the highest score possible.[31, 33] However, the composite SUS score was not interpreted as a percentage.[31, 33] To calculate the SUS score, for even-numbered items, the raw score was subtracted from 5.[31, 33] For example, if a participant responded with “strongly agree” to an even-numbered item, their score on that item would be 0 (5-5=0).[31, 33] In contrast, odd-numbered items were scored by subtracting one from the raw score.[31, 33] For example, if a participant responded with “strongly agree” to an odd-numbered item, their score on that item would be 4 (5-1=4).[31, 33] Once all item scores are converted from their

raw values these are summed and then multiplied by 2.5 for the final composite score ranging from 0 to 100.[31, 33]

There are multiple, acceptable ways to interpret a SUS score.[31-33, 36] In general, the higher the SUS score the greater the likelihood of someone using the system themselves or recommending the system to someone else.[31, 33, 36] One method for interpreting a SUS score is to compare the average SUS composite score of all participants to the benchmark '68.'[31-33, 36] The benchmark of '68' is the overall average SUS score found when measuring usability from 446 studies of various systems, therefore, a score above '68' is recognized as 'above average.'[31-33, 36] Another method of interpreting SUS is by using the *Adjective Rating Scale* developed by Bangor and colleagues, with scores in the acceptable range falling as follows; 90-100 (Grade: A; Adjective: Best Imaginable), 80-90 (Grade: B; Adjective: Excellent), and 70-80 (Grade: C; Adjective: Good).[31, 33, 36] Sauro and Lewis modified the Bangor adjective rating scale to grade scores on a curve, by converting SUS scores to a percentile rank.[31, 33, 36] Using the Bangor method, achieving a grade of an "A," Lewis and Sauro found to be "virtually impossible."[32, 33] When grading on a curve, the grade ranges make achieving an "A" on the SUS realistic.[32, 33, 36] For example, to achieve an "A," the SUS score would fall between 80.8 to 84.0 with a percentile rank of 90 to 95, whereas with the Bangor method this would be a "B".[32, 33, 36] We calculated the average composite SUS score for both mothers and IBCLCs and interpreted each score using all three methods.

Statistical Analyses

We analyzed the sample characteristics and the data collected from the SUS for both individual item scores and composite scores using descriptive statistics. We treated individual item scores and composite scores for the SUS as continuous variables and the mean and standard deviation were calculated. The results for continuous data (i.e. age) and categorical data (i.e. education) are presented as means and standard deviations and frequencies and percentages, respectively. The average composite SUS score for both mothers and IBCLCs was compared to the benchmark '68' using a one-tailed level of significance set to $p<0.05$. A one-tailed level of significance was sufficient because we wanted to know if the average composite score for both groups was significantly above the benchmark. We did not compare SUS composite scores between mothers and IBCLCs because the purpose was to assess the general usability of PumpMed. The reliability of the SUS was determined by measuring internal consistency with Cronbach's alpha, with values above 0.7 indicating good internal consistency.[37] All quantitative measures were performed using SPSS version 22.0.

Responses from participants to the open-ended exploratory questions were analyzed using qualitative content analysis.[38] Qualitative content analysis allowed for the data gathered from participants to be organized in a meaningful manner that is manageable as well as flexible.[38] For example, this was especially useful when identifying what resources to include in future iterations of PumpMed by helping to narrow down what was most important to the majority of participants. By asking the

open-ended exploratory questions we wanted to answer four key questions, 1) how likely mothers would be to use PumpMed and why or why not or how likely IBCLCs would be to recommend PumpMed and why or why not, 2) what resources would be useful, 3) what are the most frequently asked questions, and 4) what advice would be given to a mother who had just started pumping. Responses to these inquiries allowed the research team to further tailor PumpMed to the needs of the target population.

Results

Participants

Of the original 17 mothers who were interviewed during phase 1, 9 were interested and 7 responded to the follow-up invitation to be enrolled in the present study. These 7 mothers provided feedback on PumpMed. An additional 5 mothers and 7 IBCLCs were recruited via local and state breastfeeding coalitions to achieve feedback saturation.[38, 39] All mothers who completed the informed consent completed all study activities, whereas 3 IBCLCs were lost to follow-up for unknown reasons. Participants were predominantly white, with some degree of higher education (i.e. associate's degree, some undergraduate schooling, bachelor's degree, master's degree).

The majority of infants were male (9/14). Infants were on average born at 30.5 (SD 3.5) weeks gestation, weighing 1234.8 (SD 791.2) grams, and were 11.1 (SD 5.8) months of age at the time of study participation. Most mothers were no longer pumping at the time of study completion (n=10) but had pumped for an average of 18 weeks (SD 17.74), ranging from 3 weeks to 1 year. Reasons provided for discontinuing pumping

included having a low milk supply (n=4), returning to work and lacking time to maintain milk supply (n=1), infant allergy (n=1), subsequent pregnancy (n=1), difficulty balancing taking care of infant and pumping (n=1), infant age (n=1) and transitioning to feeding the infant at the breast (n=1). The two mothers who were still pumping at the time of study completion planned to continue to pump for their infants for 9 months (infant 7 months of age at time of study completion) and 2 years of age (infant 8 months of age at time of study completion). Of the 12 mothers, 7 had attempted to feed their infant at the breast at least once. Only one mother, who had discontinued pumping when her infant was 3 months of age, was still breastfeeding and had plans to breastfeed her infant until he was 3 years of age (infant gestation=34 weeks). Reasons given for no longer breastfeeding varied between mothers. Three mothers had difficulty getting their infant to latch on. One mother breastfed and pumped until 7 months postpartum and then exclusively pumped until her infant was 11 months of age because her infant's teeth erupted. One mother discontinued pumping and breastfeeding due to her infant's milk allergy.

All IBCLCs were currently working with mothers of preterm infants and worked in both community and hospital settings. IBCLCS working in a community setting worked at a birth and breastfeeding center (n=1), private practice (n=1), and/or the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) (n=3). IBCLCs working in a hospital setting worked on multiple units including; the mother baby unit, labor and delivery, and/or in the NICU (n=3). IBCLCs working at WIC primarily worked indirectly with mothers by assisting with obtaining a breast pump, whereas IBCLCs

working in a hospital setting worked directly with mothers through consults and assisting with establishing milk supply and using the pump. IBCLCs who reported working in private practice or at a breastfeeding center had experience working with mothers once their infants were discharged. Experience of IBCLCs in practice was on average 8.8 years (± 8.2), ranging from 2 to 24 years, with a combined total of 70 years. Additional participant characteristics for mothers and IBCLCs are presented in **Table 3.1.**

Table 3.1 Demographic Characteristics of Participants

Characteristics	**Mothers (n=12) No. (%)**	**IBCLCs (n=8) No. (%)**
Race		
Caucasian	11 (92%)	8 (100%)
Other	1 (8%)	0 (0%)
Marital status		
Married	11 (92%)	-
Unmarried	1 (8%)	-
Income status		
WIC eligible	7	-
Non WIC eligible	5	-
Age (years)	26.5 ± 4.4	42.38 ± 10.03
Education		
Less than High School	1 (8%)	0 (0%)
High School Diploma or GED	2 (17%)	0 (0%)
Some College	3 (25%)	1 (12.5%)
Associate Degree	2 (17%)	2 (25.0%)
Bachelor's Degree	4 (33%)	4 (50.0%)
Master's Degree	0 (0%)	1 (12.5%)
Number of Children		
One	8 (67%)	-
Two	1 (8%)	-
Three	3 (25%)	-
Parity		
Singleton	10 (83%)	-
Twins	2 (17%)	-
"-" Data not collected		

Usability

The SUS assessed the usability of PumpMed from the perspective of mothers and IBCLCs. Participants scored each item from 1 (strongly disagree) to 5 (strongly agree).[31-33] Individual item responses are presented in **Table 3.2**. Both mothers and IBCLCs scored PumpMed significantly above the benchmark of "68", with scores of 83.96 $\pm$ 9.85 (p=0.00) and 80.31 $\pm$ 17.45 (p=0.04), respectively. Mothers' SUS composite scores ranged from 72.5 to 100, with all mothers scoring PumpMed above the benchmark for usability. In contrast, there was more variability in SUS composite *scores for IBCLCs ranging from 52.5 to 100, with 2 IBCLCs scoring PumpMed below the benchmark for usability. The mean composite SUS score for both mothers and IBCLCs was excellent and graded as a "B" on the* Adjective Rating Scale.

Table 3.2 SUS Raw Scores by Individual Items (Mothers n=12; IBCLCs n=8)

1 Strongly Disagree → 5 Strongly Agree	Mother's SUS M (SD)	IBCLCs SUS M (SD)
I think that I would like to use this system frequently.	4.00 (0.74)	3.88 (0.99)
I found this system unnecessarily complex.	1.42 (0.51)	1.63 (0.52)
I thought the system was easy to use.	4.42 (0.51)	4.13 (0.99)
I think that I would need the support of a technical person to be able to use this system.	1.25 (0.45)	1.63 (0.74)
I found the various functions in this system were well integrated.	4.33 (0.49)	3.88 (0.83)
I thought there was too much inconsistency in this system.	1.83 (0.58)	1.75 (0.71)
I would imagine that most people would learn to use this system very quickly.	4.42 (0.51)	4.50 (0.53)
I found the system very cumbersome to use.	1.50 (0.52)	1.63 (0.74)
I felt very confident using the system.	4.25 (0.75)	4.00 (1.20)
I needed to learn a lot of things before I could get going with this system.	1.83 (0.71)	1.63 (1.06)

When converting the raw mean score to a percentile, the percentile rank for mothers was 95.9% and the grade on a curve was an "A".[31, 36] In contrast, the percentile rank for IBCLCs was slightly lower, at 88.9% and the grade on a curve was an "A-".[31, 36] SUS as a measure of usability had good internal reliability for both mothers and IBCLCs with a Cronbach's Alpha of 0.86 and 0.94, respectively.

Exploratory Questions

PumpMed design and content modifications are presented in **Table 3.3**. On the Resources page, no actual resources were included accept a blank template of a downloadable resource with the PumpMed logo and a message as a prompt for

Table 3.3 PumpMed Design and Content Modifications Following Participant Feedback

	Issue	**PumpMed Modifications**
Design	Simplicity of accessing resources	When possible resources were embedded onto the page rather than having to be downloaded as a PDF
	Simplification of logging	A "Mark Now" button was added to the logs to mark the pumping session end time Reordered required and optional fields to simplify process Addition of total amounts calculations Simplified
Content	Inclusion of resources that were most relevant to the target population	Resources were developed based on maternal and IBCLC feedback
	Inclusion of an orientation video	Orientation video included how to navigate PumpMed and basic pumping recommendations

participants to think of what resources they would like to see included. The following resources were developed by the lead author (KB) in response to participant feedback; 1) Frequently Asked questions, 2) Advice from Moms, 3) How Does My Body Make Milk, 4) Tips for Increasing Your Milk Supply, 5) Hands Free Pumping Bra, 6) Safe Storage of Breast Milk, 7) Understanding Engorgement, Plugged Ducts, & Mastitis, and 8) Mom's Nutrition Matters too. Additional resources, based on participant feedback, included a local community breastfeeding resource guide developed by the local health department, information on a local breastfeeding in-person and online support group, and a handout on Kangaroo Care developed for the NICU. In addition, the state of Tennessee Breastfeeding Hotline and contact information for the NICU and hospital lactation consultants were included, as well as links to the hospitals' website with information on lactation support. When possible, per participant feedback, resources were embedded onto the page rather than having to be downloaded as a PDF.

Acceptability

Overall, the feedback on PumpMed was positive. The majority of mothers reported they would have used PumpMed if it had been available to them when they were actively pumping (n=11). Mothers found the *Logs* to be the most helpful feature in PumpMed because it would have allowed them to keep track of their milk supply. A first time, 36-year-old, mother of a singleton boy born at 27 weeks wrote;

> *"Very likely. I had a lot of questions about pumping that were eventually answered, but if I had this area to go to with collected info I think it would have*

helped me even more. I also wish that I had documented in some way how much I pumped. I think it would have eased my mind and helped the lactation consultants to better understand and help me to pump more efficiently."

A 21-year-old mother of twin boys born at 24 weeks, with previous experience breastfeeding wrote;

"I would use it! I loved being organized and when you pump 8 to 12 times a day, it's sometimes gets a little stressful. PumpMed would have helped reach my goals to provide the best nutrition for my baby."

Similarly, the majority of IBCLCs reported they would recommend PumpMed to a mother who was pumping and found the *Logs* most helpful. IBCLCs working with mothers in the NICU wrote;

- *"I love this! I would love to give this resource to our NICU moms."*
- *"Very likely. Most mothers have smart phones and this helps to draw a picture of their hard work!"*
- *"The way the new mothers are into the apps, etc, this would be available on their phones, which are always with them nowadays, so can be an easy way to keep up with pumping instead of paper."*

In contrast, one mother and two IBCLCs would not use PumpMed or recommend it to mothers, respectively. A 31-year-old mother of a male infant born at 34 weeks, who had previous experience breastfeeding and pumping, found the focus on the amount pumped to be unhelpful, writing;

"Stress decreases milk supply. So if it is all about how much you pumped that is not beneficial. And while having a child in the NICU you don't have much time to login to a website. Pumping and being at the hospital is most important."

These two IBCLCs were working in a community setting with indirect contact with mothers of preterm infants (i.e. issuance of breast pumps), had similar attitudes, one wrote;

"Tracking anything can be very stressful for some breastfeeding mothers. Often when they are asked to keep logs of amounts of breast milk pumped, etc. They tend to focus on the amount that they are NOT seeing and begin to stress about that, which can further affect their breast milk supply. We often encourage mom to do her best to pump at least every 2-3 hours and not worry about how much milk she is getting. Some moms don't let down well to a pump although they have plenty of milk. This could be perceived that her body is not making adequate milk."

To address the issue of the focus on the amount pumped leading to stress, PumpMed graphing features include the following graphs; *Daily Goal*, *Times Pumped* (in the past week), and *Amount Pumped* (total per day in the past week) (**Figure 3.3)**. The *Daily Goal* refers to the times pumped rather than the amount pumped, therefore emphasizing the importance of frequently pumping. When a mother has completed a pumping session this will be illustrated by the *Daily Goal* graph being partially filled with blue. Therefore, the emphasis for the graphs is on the frequency of pumping rather than the amount pumped. Further, the *Amount Pumped* graph is based on what an individual

mother has expressed, and is not compared to a standard amount. This allows a mother to be able to track her milk supply and to see if it is going up or down. For example, if the most a mother has expressed in one day is 30 milliliters (ml), the maximum amount on the Y-axis of the graph will be 30 ml. In **Figure 3.3**, the *Daily Goal,* illustrates how the graph will appear for a mother who has pumped 6 times over a 24-hour period. The *Daily Goal* can be adjusted based on an individual mother. The intent is to emphasize the importance of providing *any* amount of breast milk.

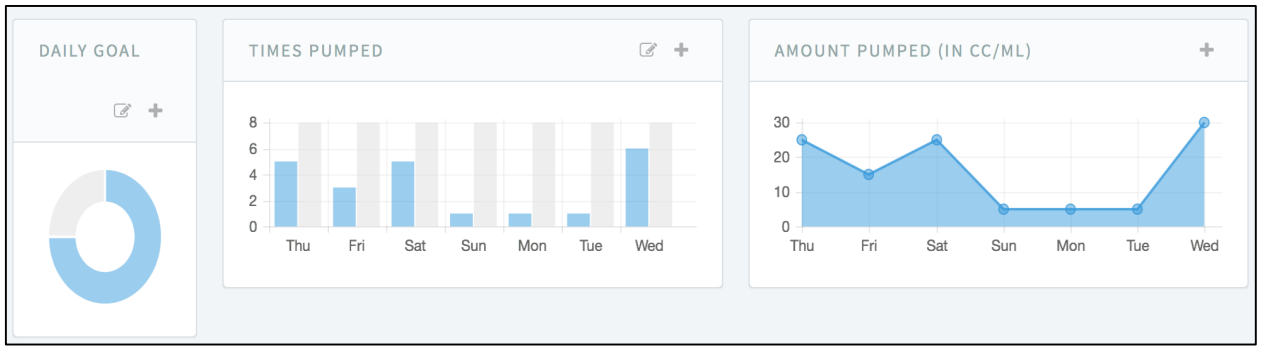

Figure 3.3 Screenshot of PumpMed Graphing Features

Discussion

This is the first study to assess the usability and acceptability of PumpMed, a web-based application designed to support breast milk expression among mothers of preterm infants, by both mothers with experience expressing breast milk for preterm infants and IBCLCs who interacted with mothers of preterm infants. Because PumpMed was developed using formative work from completion of a qualitative study (phase 1), the positive feedback from participants is not surprising, as it was specifically designed

based on the pumping experiences of mothers of preterm infants. PumpMed provides an alternative approach to implementation of a traditional breastfeeding diary, with the added components of a Questions and Resources page. The creation of online records rather than paper records may be more accepted among younger participants.[40] This may partially explain the discrepancy in SUS scores seen between mothers and IBCLCS as IBCLCs tended to be older than mothers. In addition, the variability between mothers' and IBCLCs' scores are important to note as this may be an opportunity for workforce development and educating IBCLCs not working directly with mothers of preterm infants on the unique challenges these mothers face due to the necessity of manual or mechanical breast milk expression.

Today, women of childbearing age (16-49) were born between the years 1967-2000.[41] This generation of women would have had access to the internet from birth or at the latest from age 20 and up.[42] Accessibility to the internet is increasing even among lower income populations [43, 44]. While accessibility to the internet can be an appropriate and innovative tool for delivering health information, it also may be overwhelming and lead to delivery of incorrect information because of the ability for anyone to post their thoughts via social networks such as Facebook and Twitter.[43, 44] Therefore, it is important for mothers to be able to easily identify and access helpful and accurate evidence-based information about pumping and breastfeeding. While interventions promoting breastfeeding via use of electronic technologies are becoming increasingly popular, the focus of these interventions remains predominantly on mothers of healthy, term infants and does not meet the unique needs of mothers with preterm infants.[23, 45, 46]

PumpMed uniquely provides mothers of very preterm infants with evidence-based health information related to breast milk expression and the ability to log breast milk sessions on any device, which can connect to the internet. PumpMed is the first web-based application that is specifically designed to meet the needs of mothers of very preterm infants.

By using a developmental evaluation framework, PumpMed was modified in response to participant feedback prior to implementation. For example, the *Daily Goal* graph focuses on the frequency rather than the amount of milk expressed, in response to feedback related to mothers feeling stress from perceiving a low milk supply. Future work to further tailor PumpMed may benefit from focus groups specifically focused on the acceptability of the name and color schemes used. For example, while blue was chosen as the primary color because it was perceived by the authors to be a calm and cooling color, the other colors were chosen to differentiate the sections from one another and not based on maternal preference. This study was primarily focused on the general user-friendliness of PumpMed and therefore participants were not specifically probed on what they thought of these specific components of the web-application. Focus groups may help to identify whether the target population would prefer a different color scheme or name, which may increase the user-friendliness of PumpMed.

Low milk supply is a common concern among mothers of preterm infants.[21, 47] Self-monitoring pumping sessions may help mothers to stay on track. Experts recommend the use of a paper breastfeeding diary to keep track of breast milk expression sessions.[29] Novel approaches to support mothers in providing expressed

breast milk for their preterm infants are needed in NICUs.[22] Next steps include piloting PumpMed using a randomized design in a level III NICU in the southeastern United States to assess feasibility and efficacy in improving breast milk expression duration among mothers of very preterm infants. This will allow the researchers to assess the actual usage of PumpMed and whether or not additional modifications need to be made.

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Conflict of Interest

No conflict of interest exists.

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Chapter IV: A Pilot Randomized Control Trial of PumpMed: A Web-based Intervention Designed to Promote Pumping in a Neonatal Intensive Care Unit

This article hasn't been published anywhere, nor will it be before I turn in the final version of my ETD, so I didn't include a publication statement.

Abstract

Background: Breastfeeding is recognized as the ideal form of nourishment for infants worldwide. However, for premature infants, the ability to coordinate sucking and swallowing may be underdeveloped, making breastfeeding difficult. In these instances, mothers often turn to mechanically expressing their breast milk with a breast pump. Motivation to pump is generally higher in the NICU population compared to the general population. Despite positive initiation rates, continuation of pumping and/or breastfeeding until infant discharge falls below recommendations.

Purpose: 1) Assess the feasibility of implementing a web-based application, PumpMed, in a NICU setting and 2) compare, between three study groups, the duration and intensity of breast feeds (for example: partial vs. exclusive breast milk feeds) at the conclusion of a 6-week monitored access period to PumpMed.

Methods: PumpMed was piloted using a randomized design in a Level III NICU, with mothers of very preterm infants to assess feasibility and efficacy. Mothers were randomized to one of three study groups: 1) Control Group (Resources), 2) Partial Intervention (Resources + Logs), and 3) Full Intervention (Resources + Logs + Questions + Feedback).

Results: Recruitment and retention methods proved to be feasible; however, actual usage of PumpMed among participants was low. There were no significant differences

between groups and breast milk outcomes (i.e. partial vs. exclusive breast milk feeds); however, the small sample size was a limitation.

Conclusions: PumpMed is the first web-based application built to provide breastfeeding support for mothers of very preterm infants. While response to it has been positive, future iterations of PumpMed may benefit from alternative strategies to increase actual usage.

Background

Very preterm infants (those born at <32 weeks gestational age) who receive breast milk experience better health outcomes and shorter lengths of hospital stay, as compared to those receiving any infant formula.[1-3] Infants born prior to 32 weeks' gestational age, often lack the ability to coordinate sucking and swallowing.[4, 5] Consequently, mothers of very preterm infants must initiate breast milk expression via a breast pump.[5] In many cases this behavior must continue for weeks or months before the infant is capable of latching on to the breast.[5] While mothers of very preterm infants demonstrate high breast milk expression initiation rates, continuation of these behaviors until infant discharge from the NICU is a significant challenge.[1, 4-7]

One issue that mothers of very preterm infants often encounter is establishing and maintaining their milk supply using a breast pump.[8] An adequate milk supply is recognized as approximately 750 mL or 25 ounces of breast milk expressed over the course of 24 hours.[9-11] In order to achieve and maintain this threshold, it is recommended that mothers express breast milk up to 8 to 10 times per day for 15 to 20

minutes or at 2-3 hour intervals.[8-11] However, Hill and colleagues found that mothers of very preterm infants struggle with maintaining the frequency of breast milk expression needed to sustain their milk supply, when compared to mothers of healthy, term infants who are feeding at the breast.[8]

One recommendation to assist mothers with maintaining the frequency needed to establish and sustain their milk supply is maintenance of a breastfeeding diary.[9-12] Distribution of paper breastfeeding diaries is common practice in Neonatal Intensive Care Units (NICUs) across the United States.[9-12] However, research assessing the effectiveness of self-monitoring in improving breast milk expression outcomes is limited.[12] There is an increasing demand for web-based interventions focused on improving breastfeeding outcomes.[13-17] However, current web-based interventions focused on improving breastfeeding outcomes target mothers of healthy, term infants and not mothers of very preterm infants.[13, 18, 19] For example, Ahmed and colleagues assessed the feasibility of using a web-based breastfeeding monitoring system among mothers of healthy, term infants who were feeding their infants directly at the breast.[18] This study illustrated that implementation of this mode of monitoring was feasible and well accepted in their target population.[18] However, to date, no studies have assessed the feasibility of translating the traditional breastfeeding diary to an electronic platform, while specifically targeting mothers of very preterm infants who are pumping. Therefore, the aims of this study were to: 1) assess the feasibility of implementing a web-based application, PumpMed, in a NICU setting and 2) compare, between three study groups,

the duration and intensity of breast milk feeds (for example: partial vs. exclusive breast milk feeds) at the conclusion of a 6-week monitored access period to PumpMed.

Methods

Study Design

PumpMed was designed to support mothers of preterm infants to express their breast milk ('pump') via resource delivery, asynchronous interaction with trained breastfeeding specialists, and access to a self-monitoring component. Using a randomized controlled design, PumpMed was piloted and evaluated for feasibility, acceptability, and usability among three study groups: 1) Control Group (Resources only), 2) Partial Intervention (Resources + Logs), and 3) Full Intervention (Resources + Logs + Questions + Feedback). By providing mothers with the ability to interact remotely, PumpMed allows for milk supply issues to potentially be identified earlier and appropriate and timely guidance to be delivered. Through formative work, we showed that adequacy of milk supply is a sensitive issue and many mothers are acutely aware of whether or not they produce enough breast milk to meet their infants' needs. These mothers reported feeling 'blamed' or 'judged' when their milk supply was not sufficient to meet their infants' nutritional needs. Therefore, the goal of PumpMed is to minimize mothers' expressed feelings of blame and guilt by providing a simplified system for logging their milk production and potentially improving communication between mothers and healthcare providers. While pumping is often described as 'stressful,' the overarching goal of this proposed research is to improve pumping and/or breastfeeding

duration rates among mothers of very preterm infants. By improving pumping and/or breastfeeding duration rates infants may receive optimal nutrition and experience better health outcomes, for example, shorter length of stay in the NICU.

Setting and Sample

The pilot project was granted approval from the University of Tennessee and the University of Tennessee Medical Center (UTMC) Institutional Review Boards. Recruitment took place at the UTMC Neonatal Intensive Care Unit (NICU), a 65-bed level III NICU, from December 2015 to March 2016. Mothers, who were pumping, 18 years of age or older, English speaking, and who had given birth to an infant born at or before 32 weeks' gestation were eligible to participate. Mothers were excluded from participating if they had not initiated breast milk expression, were not English speaking, the infant was not believed to be viable, and/or if they were less than 18 years of age. Dr. Tara Burnette, a neonatologist at the UTMC, NICU and a co-author on this study, identified potentially eligible participants based on a brief pre-screen following review of infant medical charts. She then notified the first author, Katie Bower of the eligibility of potential participants. Katie Bower then approached potential participants and provided study information using the study invitation as a guide. If the potential participant was unavailable, the first author left the invitation by the infant's bedside. Potential participants were invited within one-week of delivery. The first author obtained informed consent from interested and eligible potential participants prior to study enrollment and the initiation of study activities.

Randomization

Participants were stratified by income and parity using computerized blocked permutated randomization to assign mothers to the Control, Partial or Full Intervention study groups.

Blinding

Due the nature of the intervention, both participants and the research team who delivered the intervention were aware of the allocated group.

Interventions

In all three groups, participants had access to the standard of lactation care available at the NICU, which included provision of a paper breastfeeding diary and the ability to consult with an International Board Certified Lactation Consultant (IBCLC) as needed. A personal PumpMed account was created for all participants, using their personal e-mail addresses. Participants could login to PumpMed from any electronic device with access to the Internet. When first logging in to PumpMed participants were directed to view an orientation video on how to navigate PumpMed. This video varied based on group assignment. For example, participants randomized to the Control group only had access to the Resources page. Therefore, they received instructions specific to just this page. In contrast, participants randomized to the Full Intervention group, received instructions on how to use the Logs and the Questions pages, in addition to

the Resources page. The Dashboard viewed by participants in the Full Intervention group is shown in **Figure 4.1**.

Participants randomized to the Control group received access to the Resources page when logging into PumpMed. In addition to the Resources page, participants randomized to the Partial Intervention group received access to the Logging feature page to track their breast milk expression sessions.

Self-monitoring is the first approach when targeting maintenance or modification of specific behaviors. The targeted behavior for this intervention is increased and continued pumping to establish and maintain breast milk supply (up to 8-10 times per day). Self-monitoring involves systematically recording the targeted

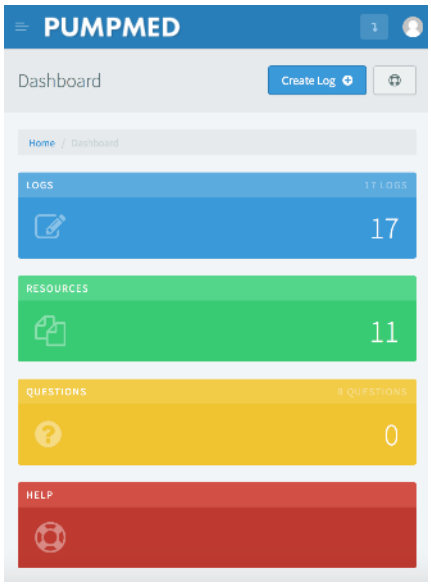

Figure 4.1 Screenshot of Full Intervention Smart Phone Dashboard View

behavior. Therefore, participants randomized to either intervention group had access to the Logs page to document their pumping sessions (**Figure 4.2**).

Participants in the Partial Intervention group were able to share their progress with IBCLCs if desired, however IBCLCs were not able to access participants' logs. Participants had the ability to download their logs and track their progress using a visual graphing tool embedded in PumpMed. Participants were encouraged, but not required, to log the date, time of day, amount expressed from both breasts, and to indicate if the breast milk was delivered to the NICU. These logs were permanent, but modifiable, allowing participants to develop an accurate history of their pumping sessions. For example, if a mother pumped at home and then delivered the breast milk to the NICU on a different day, she could go back in to PumpMed and revise the entry to indicate that the milk was dropped off on the later date.

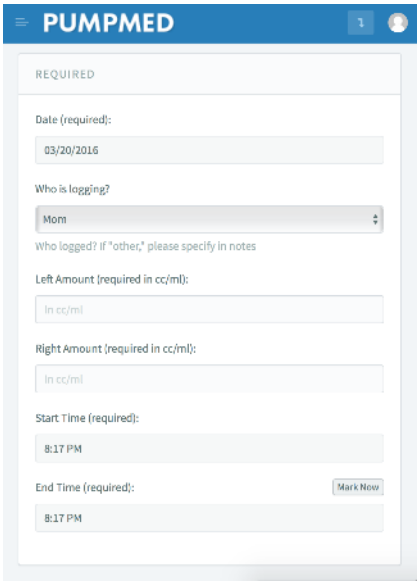

Figure 4.2 Screenshot of Smart Phone View of Logs Page

In addition to the Resources and Logs page, participants randomized to the Full Intervention group received access to the Questions page and received weekly feedback e-mails. For the 6-week monitored access period, participants randomized to the Full Intervention group received individualized feedback on reported pumping activities which was delivered via e-mail. The Questions page is a communication portal where participants may ask questions regarding their breast milk expression experience and receive responses to their questions within 48 hours. Commonly asked questions were added to the Frequently Asked Questions (FAQs) page available to all groups under the Resources page.

Measures

In all groups, participants were asked to complete a demographic survey, activate their PumpMed account and log in. Completion of the demographic survey allowed for stratification of the sample prior to randomization. Participants not logging into their PumpMed account within 2 weeks of enrollment were considered lost to follow-up and excluded from subsequent analyses. During the informed consent process, the three different study groups were described in detail to participants. However, participants did not become aware of which group they had been randomized to until they logged into their PumpMed account for the first time. Participants were informed that the first 6 weeks of activity on their account would be monitored. At the conclusion of participants' 6-week monitored access to PumpMed, infant medical records were reviewed to collect data on infant nutrition. Data collected on infant

nutrition included; percentage of breast milk received while in the NICU and if the infant was exclusively or partially fed breast milk throughout the 6-weeks monitored access period. In addition, participants were asked to report whether or not they were pumping at the conclusion of the 6-week monitored access to PumpMed.

Definitions

Exclusive breast milk (EBM): Infants were identified as receiving EBM, when all enteral feeds included breast milk. This included both breast milk with and without fortification.
Partial breast milk (PBM): Infants were identified as receiving PBM, when enteral feeds were both breast milk (with and without fortification) and infant formula.
Exclusive formula (EF): Infants were identified as receiving EF, when all enteral feeds included infant formula.

Statistical Analyses

Continuous variables were examined for normality and equality of variance, using Shapiro-Wilk and Levene's tests, respectively. Due to the small sample size, comparisons between the three study groups' expression outcomes were unable to be performed. Baseline characteristics of the participants are presented using frequencies and percentages and means and standard deviations when appropriate. Statistical analyses were completed using IBM SPSS 22.0.

Results

Enrollment Rate

Medical charts of 130 infants were reviewed to assess maternal eligibility. One hundred fourteen (including 4 sets of twins) mothers did not meet inclusion criteria. Reasons for ineligibility included; 1) infants exceeding gestational age requirement (n=78), 2) exposure to maternal drug use in utero (n=22), 3) mothers not initiating pumping (n=6). Of the 16 eligible mothers, 81% (13/16) agreed to participate in the pilot study. Three potential participants were not interested in participating in the study, the reason provided by all three of these mothers was that they had too much going on at the time. The thirteen consenting participants were randomly assigned to the Control (n=4), Partial (n=6) and Full Intervention (n=3).

Retention Rate

The retention rate of the study was 77% (10/13). The reason for attrition was participants never logging into and activating the PumpMed account (n=3). The three participants who did not log into their accounts appeared to be younger (21.67 years $\pm$ 2.08) than participants who did log in (30.6 years $\pm$ 2.13). Of these participants, one had attended some college, but had no degree, and was married. The other two participants had a high school diploma and were single. All three participants participated in the Special Supplemental Nutrition Program for Women, Infants and Children (WIC). Two of the participants had a singleton birth delivered by caesarean section and were white. The other mother was black and had delivered twins vaginally. She was also the only

mother of these three participants with an older child and had previous pumping experience. Infants born to these three participants appeared to have a higher gestational age compared to participants remaining in the study (GA 31.7 ± 0.7). Participants were unaware of the group they were randomly allocated to until they activated their PumpMed account. Of the participants who did not activate their accounts they had been randomly allocated to the Control (n=1) and Partial Intervention (n=2); however, they were never aware of their group assignment. Therefore, the final sample used in the analyses were the 10 participants who activated their PumpMed accounts.

The baseline demographic characteristics by group are presented in **Table 4.1** All of the participants were non-Hispanic white and had at least a high school diploma or equivalent (GED) and most participants had at least some college. Participants were on average 30.6 ± 2.13 years of age with an infant born at 29.3 ± .62 weeks of gestation weighing on average 1221.36 ±109.84 grams at birth. In all three groups, most participants were primiparous and had a singleton birth, delivered via caesarean section and initiated pumping within 6-hours of infant delivery. Most participants planned to feed their infants at the breast once their infants were able; however, when asked how long participants planned to pump or breastfeed, the majority of participants (n=7) responded by saying “as long as I can” rather than giving an actual duration.

Table 4.1 Demographic Characteristics of Mothers and Infants at Baseline

	Control n=3	**Partial Intervention n=4**	**Full Intervention n=3**
Age, yrs. (M ± SD)	28.7 ± 8.5	35.4 ± 5.6	26.3 ± 3.1
Education (n (%))			
High school diploma	2 (67)	1 (25)	0 (0)
Some college, no degree	0 (0)	0 (0)	2 (67)
Associate's degree	0 (0%)	1 (25)	1 (33)
Bachelor's degree	1 (33)	1 (25)	0 (0)
Doctoral degree	0 (0)	1 (25)	0 (0)
Marital status (n (%))			
Married	2 (67)	3 (75)	3 (100)
Single	1 (33)	1 (25)	0 (0)
Income (n (%))			
High	2 (67)	2 (50)	2 (67)
Low	1 (33)	2 (50)	1 (33)
1st time mother (n (%))			
Yes	2 (67)	3 (75)	2 (67)
No	1 (33)	1 (25)	1 (33)
Pregnant Plan (n (%))			
Breastfeed only	1 (33)	3 (75)	2 (67)
Pumping only	1 (0)	0 (0)	0 (0)
Breastfeeding/Pumping	0 (0)	1 (25)	1 (33)
Formula only	1 (33)	0 (0)	0 (0)
Decide to pump (n (%))			
Pregnancy	1 (33)	1 (25)	1 (33)
After delivery	2 (67)	3 (75)	2 (67)
Delivery (n (%))			
Caesarean-section	2 (67)	4 (100)	3 (100)
Vaginal	1 (33)	0 (0)	0 (0)
Started Pumping (n (%))			
Less than 6 hours	2 (67)	2 (50)	3 (100)
Greater than 6 hours	1 (33)	2 (50)	0 (0)
Gestation (M ± SD)	29.4 ± 2.4	29.4 ± 2.5	29.2 ± 1.4
Infant Birth weight	1133.5 ± 157.4	1317.7 ± 549.1	1180.7 ± 182.4
Infant Gender (n (%))			
Male	1 (33)	2 (50)	2 (67)
Female	2 (67)	2 (50)	1 (33)
M ± SD= mean ± standard deviation			

Feasibility

Assessing the feasibility of an intervention can be accomplished by answering the question "can this study be done?"[20] Recruitment of mothers of very preterm infants to participate within one-week of infant delivery proved to be feasible with a high retention rate. However, despite most mothers logging into and activating their PumpMed accounts, actual continued usage was low. The trend among most mothers was to start logging pumping sessions in the first day or two following account activation and then completely stop logging. Only one mother demonstrated a different pattern, as she began consistently logging her pumping sessions after being inactive for the first 3 weeks after account activation. Mothers randomized to the full intervention did not utilize the "Questions" communication portal and only one mother viewed 3 of the first 6 weekly feedback e-mails. However, this mother did not log any pumping sessions after the first two days of account activation.

Breast Milk Outcomes

At 6-weeks post account activation, 80% (n=8) of infants were receiving breast milk in some quantity. Mothers of these 8 infants were continuing to pump at this 6-week mark, and 7 of these infants were receiving exclusive breast milk. Receipt of enteral feeds as breast milk ranged from 20% to 100% over the course of the 6-week study period. Infant receipt of EBM, PBM, and EF are presented by study group assignment and week of the monitored access period (**Table 4.2).**

Table 4.2 Number of infants receiving any breast milk by group assigned during 6-week monitored access period

PumpMed Account Activated	Control (n=3)			Partial Intervention (n=4)			Full Intervention (n=3)		
	EBM	*PBM*	*EF*	*EBM*	*PBM*	*EF*	*EBM*	*PBM*	*EF*
Week 1	1	2	-	4	-	-	2	1	-
Week 2	2	1	-	4	-	-	2	1	-
Week 3	2	1	-	4	-	-	2	1	-
Week 4	2	-	1	4	-	-	2	1	-
Week 5	2	-	1	4	-	-	-	1	-
Week 6	2	-	1	4	-	-	1	1	1

EBM: Exclusive breast milk feeds; PBM: Partial breast milk feeds; EF: Exclusive formula feeds; "-": indicates no participants fell into this category during this week

Discussion

This was the first study to assess the feasibility of implementing PumpMed, a web-based application designed to support breast milk expression among mothers of very preterm infants. PumpMed takes a traditional approach to monitoring breast milk expression and translates it for the millennial generation using electronic logging. [9-11] Over 80% of eligible mothers consented to participate in the study and 77% of these mothers logged in and activated their PumpMed account. The attrition rate was 23% which is consistent with other web-based studies.[18, 21] For example, in a study conducted by Ahmed and colleagues, assessing the feasibility of a web-based breastfeeding monitoring system among mothers of healthy, term infants, 28% of their sample never logged into their system.[18] Mothers of preterm infants may be more likely

to initially utilize a monitoring system such as PumpMed compared to mothers of healthy, term infants, as self-monitoring, using a paper breastfeeding diary, is often included in standard care.[9-11] In addition, these mothers are highly motivated to provide breast milk for their infants because of the health benefits.[7] Unfortunately, data on reasons for attrition were unable to be collected for this study. A mechanism to contact participants via phone when collecting subsequent measures would have been beneficial. In the future, identifying reasons mothers do not log into PumpMed would allow for modifications to be made to PumpMed to make it more accessible to these mothers.

Because this was a feasibility study to determine how participants would interact with PumpMed within a natural environment mothers were encouraged, but not required, as part of their participation, to keep track of their breast milk expression sessions. Therefore, low usage of the Logs component of PumpMed was not a surprise. Even when mothers received weekly feedback e-mails based on the sessions they logged, usage did not increase. Other methods of feedback for this population may prove to be more effective and should be assessed such as feedback over the phone, via texting, or in-person. In their study of electronic breastfeeding monitoring, Ahmed and colleagues called mothers when there was insufficient data entered, for example, mothers were called when data were missing for more than 24 hours or mothers entered data for less than 6 feeding sessions over 24 hours.[18] Mothers who did not enter data or stopped breastfeeding were excluded from their final data analyses.[18] Approximately, a quarter of their sample were excluded from analyses due to missing

data.[18] Similarly, Héon and colleagues called mothers to remind them to keep a breastfeeding diary as part of their study participation.[22] In these studies, phone calls as reminders to complete a breastfeeding diary appeared to improve compliance.[18, 22] Future assessment of PumpMed may benefit from including a mechanism to encourage logging breast milk expression sessions, such as phone call reminders to complete logs. This may be most beneficial during the first two weeks postpartum, when establishment of milk supply so that it can be maintained for an extended duration is most important.[9-11, 18]

While it was feasible to recruit and retain participants from the target population, implementation of PumpMed as an independent intervention did not show improvements of breast milk expression outcomes when comparing between the three study groups. However, a small sample size and low usage among participants may help to explain the similarities between the three study groups. Alternative strategies to increase usage should be explored. Future iterations of PumpMed may benefit from additional interaction, such as phone, texting, or in-person contact from a breastfeeding specialist (i.e. IBCLCs).[23] PumpMed is built so that a "Consultant" account can be created, allowing a breastfeeding specialist to view participants "logs." Therefore, transitioning to another mode of feedback would be feasible. However, it would be important to engage IBCLCs when designing future studies to ensure they play an active role in the intervention.

The most frequently used components of PumpMed were the Resources and Logs pages. While usage on these pages was minimal among the majority of

participants, they may be the most appropriate components of PumpMed to include in future iterations as there were select participants who demonstrated high usage. Future research may benefit from exploring what influences a mothers' decision to manually or electronically keep track of her pumping sessions. For example, are these mothers more or less likely to sustain breast milk expression compared to mothers who do not keep track of their pumping sessions? Next steps would include validating PumpMed as a measurement tool, such as verifying that the frequency and amount recorded match the amount of breast milk received by the infant in the NICU. In conclusion, further research is needed to identify how to increase PumpMed usage in order to be able to assess whether or not breast milk expression outcomes can be improved.

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Conflict of Interest

No conflict of interest exists.

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Chapter V: Conclusion

The primary aim of this study was to gain an understanding of mothers' experiences expressing breast milk ('pumping') for their very preterm infants in a Level III NICU and to develop, implement and evaluate a pilot intervention to promote pumping. This study was conducted in three phases:

1) The first phase of this study provided the foundation for the development of PumpMed, a web-based application designed to promote pumping. In-depth interviews using a phenomenological approach provided insight into the complexities of the maternal pumping experience. The focus for many mothers was on the milk they were not producing rather than the breast milk they were able to provide for their infants. The difficulty mothers experienced with establishing and maintaining an adequate breast milk supply coupled with meeting pumping frequency recommendations is of concern. Balancing pumping with everyday tasks and the stress of having an infant in the NICU could be overwhelming for mothers, making it easy to not have time to pump.
2) The second phase of this study was the development and initial evaluation of PumpMed. PumpMed was built in response to the challenges mothers experienced with maintaining the frequency of pumping needed to sustain their breast milk supply. Self-monitoring pumping sessions can help mothers meet frequency recommendations as well as identify issues with milk supply early. PumpMed takes a traditional method, the paper breastfeeding diary, to a web-based platform. Through conducting a developmental evaluation, PumpMed was found to be usable and accepted by mothers of preterm

infants and International Board Certified Lactation Consultants. Findings from the developmental evaluation resulted in iterative changes to PumpMed that improved usability prior to implementation. The final prototype of PumpMed included three primary components: 1) Resources, compilation of resources developed in response to feedback from the target population, 2) Logs, where mothers can enter their pumping sessions and receive immediate feedback from a customized graphing feature, and 3) Questions, where mothers may post pumping-related questions and receive evidence-based responses.

3) The third phase of this study was the implementation of PumpMed in a Level III NICU. Using a pilot randomized design, the feasibility and efficacy of PumpMed was assessed. Participants were randomized to one of three groups: 1) Control (Resources), 2) Partial Intervention (Resources + Logs), and 3) Full Intervention (Resources + Logs + Questions + Weekly Feedback). Recruitment and retention methods proved to be feasible, however there were no significant differences between group assignment and breast milk outcomes (i.e. partial vs. exclusive breast milk feeds), which may be due to the small sample size and low usage. Future iterations of PumpMed will assess alternative strategies to increase usage.

PumpMed is the first web-based application built to promote pumping among mothers of very preterm infants and provides insight into how mothers interact with a fully online intervention. In conclusion, further research is needed to identify how to

increase PumpMed usage in order to assess whether or not breast milk expression outcomes can be improved.

Appendices

Appendix A: Expanded Phenomenological Methods

Although efforts have been made to provide support for mothers of preterm infants to provide their breast milk in the NICU setting, little is known about the maternal breast milk expression experience from the target group's perspective.[1] Further research is needed to identify facilitators and barriers to these behaviors and to understand, from the perspective of mothers with infants in the NICU, how to better support them to provide expressed breast milk.[1, 2] Therefore, the purpose of phase 1 was to gain an understanding of mothers' experiences expressing breast milk for their VLBW infants in a Level III Neonatal Intensive Care Unit (NICU). This was achieved using phenomenological methods.[3-7]

Methodology: Phenomenological Framework

A phenomenological framework is often used in the health sciences to better understand the experiences of patients, making it an appropriate method for the topic of maternal breastfeeding experiences in the NICU setting.[3, 4] In contrast to other qualitative methods, a phenomenological approach focuses on the participant experience and the meaning of these experiences, rather than focusing on participant actions and behaviors.[5-7] Because of the variability seen in NICUs across the United States in the rates of breast milk expression, it is likely that there is not a standard NICU environment and maternal experiences may vary greatly depending on the location.[2, 8] Therefore the qualitative component of this study allowed the research team as noted by Merriam "research focused on discovery, insight, and understanding from the

perspectives of those being studied offers the greatest promise of making significant contributions to the knowledge base."[9]

In order to maintain methodological rigor, strategies of verification, validation, and validity were employed throughout the data collection and analysis process.[3, 10] The first step in achieving validity in qualitative research is verification.[3, 10] To accomplish verification a literature review was conducted, a recognized qualitative methodology (i.e. phenomenology) was used, field notes were taken, and qualitative data was collected until saturation was reached, defined as the point when no new information was shared by participants.[3, 10] Validation was accomplished by using multiple methods of data collection.[3, 10] These included interviews during phase 1 followed by subsequent member-checking interviews. Validity of the project findings was achieved through the process of peer-debriefing and through presenting select interview transcripts and final results to an interdisciplinary Phenomenology Research Group at the University of Tennessee.[3, 10] Reliability was achieved by engaging a co-coder for data analysis and interpretation.[11] When approaching phenomenological research, the major procedural steps outlined by Moustakas[7] include: 1) identifying the phenomenon, 2) bracketing, 3) data collection from individuals who have experienced the phenomenon, and 4) data analysis. How each of these steps was approached is outlined as follows:

Identifying the phenomenon

The phenomenon identified for this study is the maternal experience of providing breast-milk for a VLBW infant, hospitalized in the UTMC-NICU.

Bracketing

Bracketing, or “epoche,” is the process of the researcher recognizing their own inherent biases, understanding how these biases may influence the study outcomes, and employing strategies to reduce these biases as much as possible.[3, 4, 7] To accomplish bracketing the primary researcher (KB) kept a research diary for the duration of data collection and analysis in which potential biases were acknowledged. In addition, prior to the initiation of interviews, KB performed a bracketing exercise.

Recruitment method

Utilizing ***purposeful sampling[3],*** mothers of VLBW infants, who initiated breast-milk expression at some point during their infant’s stay in the UTMC-NICU, who were preparing for discharge, and who met additional inclusion criteria (defined below) were recruited to participate in this study. Purposeful sampling was used because participants must have all experienced the shared phenomenon in order to participate in the study.[3] Both those who were expressing breast milk at the time of infant discharge and those who had discontinued breast milk expression prior to infant discharge were included. For this reason, only biological mothers were eligible to participate in this study. Mothers who had never expressed breast milk for their VLBW infant were excluded from participation. Any mothers, who had been identified, as potentially losing some or all-custodial rights post-discharge, were excluded secondary to the significantly reduced likelihood that breast milk expression would continue upon discharge. Additionally, mothers whose milk was contraindicated by drug abuse or a diagnosed

medical problem were excluded from participation in this study, because the barrier to providing human milk is already well defined. Therefore, the inclusion and exclusion criteria were as follows:

Inclusion criteria:

- English speaking, mothers, 18 years of age or older, who had expressed breast milk at some point during the NICU stay and who were expected to maintain custody of infant post discharge.
- Infants were slated for discharge within the next 1-2 weeks.

Exclusion criteria:

- Mothers whose breast-milk had been identified by NICU staff as contraindicated (i.e. illicit drug use, relevant medical issue, etc.)
- Mothers who had never expressed breast-milk while infant is a patient in the NICU
- Legal guardians, other than the biological mother
- Mothers identified as losing custodial rights

Participants were pre-screened by a neonatologist, who then provided an invitation to potentially eligible mothers infant's nurses. Participants were 'self-selected,' in that they can choose to contact or not contact KB to complete either an audio-recorded in-person or phone interview. Participants were interviewed as soon as possible, upon receipt of informed consent.

Interviews were conducted until saturation was achieved. In phenomenological studies there are various recommendations for the number of participants to interview.[3,

[12] Polkinghorne recommends interviewing 5 to 25 participants, while Dukes recommends interviewing 3 to 10 participants, and Riemen recommends interviewing 10 participants.[6, 13, 14] The general recommendation is to interview participants until saturation is reached, which typically occurs between 15-20 participants.[13, 15] Eligible mothers who chose to complete the in-depth interview in-person were compensated with a $20 gift card to a local retailer and UTMC parking pass (worth ~$5). Mothers who chose to complete the interview over the telephone received a $25 gift card to a local retailer. This is considered appropriate compensation for the time spent completing the interview, which was estimated to last up to one hour. Actual interviews ranged from fifteen minutes to one hour and were on average half an hour long.

Participant Interviews

Consistent with phenomenological methods, interviews began with a general statement regarding the experience of interest.[5] In this study, this statement was: “Tell me about your experience pumping breast milk for your baby.” Additional prompting questions were asked and assisted with better capturing of the mothers’ experiences. The open-ended structure of the questions allowed mothers to elaborate on what was most significant about their experiences. Interviews were tape-recorded using digital recording devices, and transcribed using InqScribe software, in preparation for data analysis. All interviews were verified for accuracy.

Demographic Information

Demographic information, including; infant gender, gestational age, date of birth, and birth-weight, and maternal age, years of education, parity and socioeconomic status were collected for each participant. This allowed for a general description of the sample in phase 1, and allowed for the assessment of the transferability of study findings.

Field Notes

Field notes were recorded as soon as possible following each interview. This included documentation of nonverbal behavior exhibited by the participant (if in-person interview), the environment where the interview took place, any distractions or interruptions occurring during the course of the interview, and self-reflection by the researcher on her thoughts regarding the interview.

Data Analysis

Transcriptions were analyzed using Colaizzi's phenomenological method.[5] This method involves reading transcripts numerous times to gain an overall sense of the data.[5] Each transcript was carefully read and significant statements were coded using the highlight feature of Microsoft Word.[5] Significant statements were phrases or sentences that related directly to the experience of expressing breast milk.[5] Statements not related to this experience were be coded.[5] These significant statements were then categorized to form clusters of meaning and were then organized into global themes and subthemes.[5] For example if two statements were related to working with a lactation

consultant to improve breast milk expression, they were clustered together. Another example is if three statements were related to traveling to and from the NICU making it difficult to express breast milk, these were clustered together. Ultimately, lactation consultation support could be identified as a facilitator and traveling could be identified as a barrier. Subsequently, global themes were used to develop an exhaustive description of participant experiences, this was then used to complete the fundamental structure of the phenomenon.[5] Select significant statements were used to illustrate these themes.[5]

In order to ensure the data analysis was both reliable and valid and to increase the creditability of the study, KB employed multiple methods of reliability and validity; these were engaging a co-coder and conducting peer-debriefing sessions, respectively and presenting select transcripts and final results to an interdisciplinary Phenomenology Research Group. To measure the reliability of the data analysis, KB trained a co-coder on the Colaizzi data analysis methodology.[5] Each transcription was analyzed for significant statements and formulated meanings were derived from each significant statement.[5] Formulated meanings were then categorized and clustered into subthemes and larger global themes.[5] Following the completion of identifying significant statements for the first transcription, inter-coder agreement was calculated.[11] Inter-coder agreement was determined using the following calculation by the KB prior to each meeting:

$$\text{Inter-coder agreement} = A/n^{11}$$

A= total agreements between the two coders

n= total number of units coded by the coders

In order to move forward to analyzing the next transcript, inter-coder reliability must reach 80%.[11] KB and the co-coder discussed and resolved any disagreements regarding significant statements coded.[11] Following completion of the discussion, significant statements were recoded and post-discussion inter-coder reliability was calculated. Once the first transcription reached an inter-coder agreement equal to or greater than 80%, three transcriptions were coded prior to the next meeting and the same procedures were followed until all transcriptions were coded and data saturation had been achieved. If there was any disagreement that could not be resolved by KB and the co-coder, a peer-debriefer (described below) assisted in the process.[11]

Throughout the data analysis process, KB employed peer-debriefing of the interviews in order to enhance internal validity and minimize the influence of the researchers' biases.[11, 16] Peer debriefing occurs when a peer, not directly involved in the research project, assists in examining the primary researcher's thought process during interpretation and analysis of the data.[11, 16] By employing an external peer to play the "devil's advocate," the validity of the project's findings were strengthened by minimizing the effect of KB and the co-coder's biases on the final interpretations of the data.[11, 16] The peer-debriefer's role was to keep KB and the co-coder honest in their analysis and interpretation of the data, by asking questions about the methodology and how KB and the co-coder came to their interpretations.[11, 16] When comparing to quantitative research, peer-debriefing is equivalent to internal validity.[11, 16] A peer-debriefer should be someone who has knowledge of the phenomenon being explored and experience with qualitative methodology.[11, 16] For the present study, the peer-debriefer had personal

experience with expressing breast milk for an extended duration. There are no standard guidelines for conducting debriefing sessions.[11, 16]However, it is recommended for debriefing sessions to occur on a regular basis throughout the research process, these took place every three interviews after coding had been completed by KB and the co-coder.[11, 16] If there was disagreement during meetings between the PD and co-coder, the peer-debriefer's presence was requested to help resolve these issues.[11, 16] For example, if KB and co-coder disagreed on whether or not a significant statement was related to breast milk expression the peer-debriefer acted as the tie-breaker. Throughout the course of data analysis disagreement of KB and the co-coder was minimal and decreased as the process continued.

Member-Checking

Following data analysis, participants were re-contacted via telephone to validate the maternal experience of breast milk expression identified by the researchers during data analysis. This is known as member-checking, and is often used to validate findings in qualitative research.[3, 5, 10] In phenomenological methodology, validation is typically achieved by presenting back to participants the description of their experiences and discussing the accuracy of the researchers' interpretations.[3, 5, 10] This allowed the research team to confirm the consistency of their interpretation with the mothers' actual experiences. In addition, member-checking potentially identifies the need for further phenomenological exploration should new concepts be introduced at this time, thus strengthening the confirmability and dependability of the findings.[5] Participants

completing a member-checking interview were in agreement with the research team's interpretation of their experiences and therefore no changes were made to the results.

Phenomenology Research Group

Select interview transcripts and the fundamental structure of the phenomenon were brought to the Phenomenology Research Group at the University of Tennessee to increase the confirmability and dependability of the study findings. This multidisciplinary group was invited to provide comments to support or contradict the presented analyses. This further aided in the research team minimizing their own inherent biases. The Phenomenology Research Group assisted in ensuring that the interpretation of the maternal breast milk expression experience stayed true to what was shared by participants. For example, when writing up the results KB originally used the word "innate" to describe the pressure mothers felt to produce enough breast milk to meet their infant's needs. However, the Phenomenology Research Group assisted KB in realizing that as the researcher she could not identify the "innate" feelings of the participants unless the participants had voiced these during the interview. Therefore, the wording of the results was changed to "mothers put pressure on themselves…," which was true to how the experience was described by participants.

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Appendix B: Expanded Phenomenological Findings

Participants (Aliases)

Participant (Alias)	Age (years)	Highest Level of Education	Race	First time mother	Currently Pumping
Allie	24	Associate's degree	Black	Yes	Yes
Cassie	29	Associate's degree	Asian	Yes	Yes
Emily	20	High school diploma	White	No	Yes
Christina	34	Some college, no degree	White	Yes	Yes
Olivia	29	Associate's degree	White	Yes	Yes
Anna	24	GED	White	Yes	No
Josie	31	High school diploma	White	Yes	Yes
Cassidy	21	10th grade	White	No	Yes
Tiffany	24	Bachelor's degree	White	Yes	No
Alicia	33	Associate's degree	White	No	Yes
Erica	21	High school diploma	Black	Yes	Yes
Sarah	28	11th grade	Hispanic	No	No
Lizzie	26	Master's degree	Asian	Yes	Yes
Jessie	33	Some college, no degree	White	No	No
Vanessa	35	Bachelor's degree	White	Yes	Yes
Andrea	26	10th Grade	White	Yes	Yes
Miranda	34	Master's Degree	Asian	Yes	Yes

Global Theme: "Why Keep Pumping?"

The global theme *"Why keep pumping?"* encompasses the pumping experience. This includes mothers learning how to pump and manage the daily tasks of pumping, struggling to find an emotional connection to an inanimate object, and making the decision to continue or discontinue pumping. The shared experiences of pumping for an infant born too soon revealed the reciprocal nature of pumping. Through pumping, mothers were able to provide breast milk for their infants and see their infants respond positively. This experience was positive and lead to feelings of empowerment. For these mothers, pumping provided an opportunity to gain some control in a situation where they were otherwise reliant on others to care for their infant, while at the same time providing a connection to their infants. However, the paradox of pumping revealed itself as mothers struggled to continue pumping and felt defeated when their milk supply fluctuated and they once again felt a loss of control over their own bodies. This theme is supported by three subthemes: 1) "This is all new to me"; 2) "An intimate moment with a machine"; and 3) "Not even a drop".

Subtheme 1: "This is All New to Me"

For the majority of the mothers interviewed, this was their first experience pumping. For twelve of the seventeen mothers, this was also their first child. Of the five mothers with older children, only one had pumped for her older child who had also been born preterm, and only two others had any experience breastfeeding their older children. Mothers felt 'nervous' because pumping was something they had no prior

experience with. Vanessa, a first time mother of a baby boy born at 27 weeks, just "didn't know" what to expect;

> *"I'm thirty-five years old, you think I would know these things but I don't. Just the fact it's going to be slow and at first you're going to think you're not getting it, but it's okay, it will come in. It's not all supposed to come in the beginning and your colostrum is going to be a different color than all the other stuff and I mean it's just basics. I didn't know basics. And I'm not an uneducated person. I just didn't know."*

For mothers who decide to nurse their healthy, term infants, it is typical for their milk to come in 2 to 3 days after delivery.[1] In contrast, a mother who delivers prematurely may experience delayed lactogenesis and her milk may not come in until up to 8 days after her infant was delivered.[1] In Vanessa's case, despite being college educated, knowing what to expect when pumping was something she had to learn as she went through the experience.

Mothers often found pumping was difficult in the beginning, because it took time for milk to come in and for their supply to become established. For some mothers, pumping became less challenging over time as they 'got used to it,' and began producing more milk. Pumping more often helped mothers to see progress. Emily, a mother of a baby girl born at 26 weeks, with a toddler at home, emphasized pumping was especially hard when her baby was first born;

> *"It was harder at first, but they saved it and it's a lot better for him. The lactation nurse talked with me and explained how to do it [pumping] and at first I*

didn't get hardly any. I wasn't even getting a half ounce and then it just progressed the more that I pumped."

Like Emily, many mothers found it helpful to have someone show them how to use the pump. Mothers are given the recommendation to pump between 8 and 10 times per day, or every 2 to 3 hours, in order to establish and maintain their milk supply.[2-5] For Emily, being able to see her milk supply improve the more she pumped, reinforced the importance of pumping frequently.

Pumping was not intuitive or natural, and time was required to learn how to use the pump. Miranda, a first time mother of a baby girl born at 27 weeks, describes learning how to pump;

"*I just remember my first time [pumping] the nurse explained how we use the pumping machine and how to pump, but at that time, I don't have good understanding about that stuff. But after one weeks and two weeks, I just learning, learned about the process of pumping. After that point I can manage my schedules and other things."*

With time and experience, most mothers were able to manage use of the pump. However, in spite of becoming more comfortable with the act of pumping, it was never 'easy.' Many mothers reported experiencing a low milk supply, but did not 'give up' easily, even up when giving up would have been the easy thing to do. 'Knowing that every little bit counts,' and that one day their infants would benefit from their breast milk is what kept mothers pumping.

Subtheme 2: "An Intimate Moment with A Machine"

Mothers pumped to provide for their infants and to play a role in their care. Not being able to take their infants home with them because of their prematurity was 'stressful.' Mothers attributed having a low milk supply to the 'stress' of being away from their infant. The experience of having to leave their infant in the care of someone else was unique to their role as a mother of an infant in the NICU. Christina, a first time mother of a baby girl born at 24 weeks, said;

> *"I mean, I think pumping would be hard anyway, but just even if the baby was term, but I mean it's a lot harder doing it knowing that she's not with us."*

Mothers found affirmation when being with their infant was accompanied by an improved milk supply. Vanessa experienced this first hand when she figured out how to hold her baby and pump at the same time;

> *"Well, I love pumping in the NICU because I figured out how to pump while he's sitting on me. And yeah, that's like great, I can spend time with my kid and get something done, and he's on me, which is helping me, I feel, produce more."*

Vanessa was the only mother who described pumping while simultaneously holding her infant. In contrast, when mothers had to spend time away from their infants, or were unable to hold their infants, they noticed their milk supply deteriorated. As Andrea, a first time mother of a baby girl born at 30 weeks, described;

> *"I just haven't been able to see her as much. So I think being around her more, actually helps my milk supply. […] I got sick and wasn't able to come in, so my milk supply went down a lot."*

Research supports these mothers' perceptions of their milk supply improving when they are able to be with their infants.[5] Kangaroo care, also known as skin-to-skin care, is promoted with both healthy, term deliveries and in NICUs to improve a mother's milk supply.[5]

Despite the sense that being away from their infants decreased pumping success, knowing that breast milk could lead to their infants becoming healthier and coming home sooner, seemed to provide a buffer that helped mothers cope with pumping even when they were unable to be with their infants. Mothers talked about how their infants were constantly on their mind, which helped them to remember to pump. Mothers used various techniques to try to improve their milk supply, most often using reminders of their infant. Cassandra described how she used sensory cues and reminders of her son to help her milk supply;

> *"I kept thinking of him and looking at pictures, sniffing blankets, all that stuff, his burp rags I would take home and that kind of helped a lot."*

These personal items from their infants helped mothers to negate the mechanical reality of pumping. Christina found having an "intimate moment" was difficult;

> *"It was hard for me to have kind of that intimate moment, with a machine. Essentially I tried taking articles of his clothing and smelling [them], I tried looking at pictures, I took videos on my phone."*

Mothers used surrogates, such as sensory reminders of their infants, to humanize pumping when they were unable to be with their infants.

Subtheme 3: "Not Even a Drop"

As mothers waited for their milk to come in and worked to establish their milk supply, they questioned; 'why keep pumping' when their infants were unable to eat. Infants who are born very preterm (<32 weeks' gestational age) lack the ability to coordinate sucking and swallowing, making oral feeds at birth improbable.[6] These infants are unable to latch on to the breast or take a bottle until they have matured.[6] In addition, premature infants often cannot tolerate full enteral feeds immediately after birth. Allie, a first time mother of a baby boy born at 27 weeks, questioned why she should pump when her son was unable to eat;

> *"At first my son couldn't eat so then comes the questions well why keep pumping? He's not eating it. He was too small to even have anything on his stomach, and I'm producing all this milk, and he isn't even drinking it. He can't even take it, so you know, why do it?"*

At times, being able to fully grasp the necessity of pumping during the present to provide an infant with breast milk in the future was outweighed by infants' immediate needs.

Allie, like most mothers that were interviewed, pumped because she knew that one day her son would need her milk, and she viewed breast milk as the 'best medicine' that she could provide for her son. For Allie, and other mothers, knowing that they were able to provide their infants with something that no one else could, is what helped them to keep pumping. For some mothers, struggling to fully establish their milk supply led them to questioning again, 'why keep pumping?' In some cases, pumping became

overwhelming, and having formula available meant their infants were not going to starve. Alicia, a mother of twins born at 30-weeks' gestation, had prior experience breastfeeding her older child for a few months, planned to pump until it became 'too stressful,' and was grateful that formula was available for when she was no longer able to pump.

> *"When my supply is running low, they're able to give them the formula. So, I don't feel as bad- I feel good that I've got to pump this far and I'm glad that the formula is able to supplement when I can't be there."*

Alicia had recently returned to work. Finding time at work to pump was becoming increasingly difficult and her milk supply was declining. The combination of returning to work and experiencing a dwindling milk supply was 'too stressful' for her to continue to pump. At the time of the interview, she was pumping, but did not anticipate being able to maintain pumping for much longer. During the follow-up interview, she reported continuing to pump for a few days after the initial interview.

For the 4 mothers who were not pumping at the time of the interview, the decision to discontinue pumping often came after days or weeks of not producing enough milk for their infants' feedings. For these mothers, over time, the few drops that they were able to produce were no longer worth the stress or time spent trying to produce more. Sarah, a mother of a baby boy born at 28 weeks, had not breastfed for her 3 older children because she was uncomfortable with the idea of 'having a baby sucking on your stuff.' When her son was born early, her 'whole attitude about breastfeeding' changed to *"I think it should be a law. Every woman should-must*

breastfeed a premature baby!" She not only struggled with her milk supply, but with being able to visit her baby in the NICU, she commented,

> *"If it wasn't pumping enough milk, it was that we didn't have enough money to pay for –to get out [parking]. And if it wasn't that, we just didn't have gas money to come. It was hard."*

Despite struggling with her milk supply and facing obstacles getting to and from the NICU, Sarah persevered and pumped for her baby for 6 weeks. She revisits the last day she pumped;

> *"I was up at like 7 o'clock in the morning that day, and nothing. When I tell you, not even a drop. And I stood there, in fact, for thirty minutes to see, and nothing would come out."*

Like Sarah, Tiffany decided to stop pumping when she was not producing more than a few drops of breast milk;

> *"When you sit there and pump for over fifteen minutes, and you get maybe three drops, and it's not anything that we'd actually feed her. It just, slowly, like every time you do it, you get less and less milk. And then it got to where basically it's not even worth pumping for fifteen minutes or twenty minutes to only get two drops of breast milk that's not even gonna feed her."*

The decision to no longer pump was not easy for mothers, however, knowing their infants were *'not going to starve,'* along with not having to worry about pumping any more brought some 'relief.'

Global Theme: "In the End Pumping was Worth It"

The global theme *"In the end pumping was worth it,"* answers the question: 'why do it?'… 'why keep pumping?' Pumping, frequently described as a negative and impersonal act, was the only way for mothers to provide breast milk for their infants. Breast milk was viewed as the 'best medicine' and could help their infant's health improve and consequently their infants may be able to come home sooner. Whether mothers were pumping or not at the time of the interview, for them, what they had been able to provide for their infants was 'worth it.' In spite of the struggles and time lost to pumping, mothers would 'do it all over again' if it meant it could provide their child with breast milk. This theme is supported by two subthemes: 1) *"Every little bit counts"*; 2) *"You know what's best for your child."*

Subtheme 1: "Every Little Bit Counts"

The value of breast milk increases in importance when infants are born preterm, as it minimizes an infant's risk of NEC and late onset sepsis.[7-12] Infants who are born before 32 weeks have yet to develop the ability to coordinate sucking and swallowing, which allows them to latch on and nurse at their mother's breast.[6] For mothers of very preterm infants the only option for providing breast milk to their infants is by mechanically expressing breast milk with a pump.[1, 13] Many mothers in our sample made the decision to pump, not because they wanted to, but because it was the 'only option.' Allie who had been on the fence about breastfeeding when she was pregnant, ultimately decided to pump for her son because he was born thirteen weeks early. Like

many mothers, Allie struggled with being tired from pumping, but she continued to wake up and pump because her son needed her:

> *"I have to get up and I have to do this for him and it's not what I want to do no more. It's what I need to do for my son and that made it easier."*

Many mothers echoed Allie's words that pumping was not something they 'wanted' to do, but it was something they 'needed' to do to help their infants grow and become healthy enough to come home. Like all of the other mothers interviewed, Alicia and Miranda pumped because their infants needed them:

> *"Just knowing that the babies needed me. And that it was making them healthy and strong." (Alicia, 30-week twins)*

> *"I'm a mom honestly. I'm a mom! If he needs some milk and breastfed milk is better than the formula and I can make him milk so yeah let's do it! [Baby] needs my milk. That's the motivation." (Miranda, 27-week baby boy)*

Breast milk was described as what was 'best for the infant at the time' because their infants were born early. Olivia, a first time mother of a baby girl born at 29 weeks, explains why she pumps in the context of her daughter being premature:

> *"It's kind of one of those things you do. What you have to do to keep your baby as healthy as possible…mine was born early, eleven weeks early, so you do what's best for the baby at the time."*

Jessie, a mom of a baby boy born at 26 weeks, had previous experience for her older child who had also been born preterm. She viewed taking the time to pump as minor compared to what her son was having to go through:

"[Baby] has had a lot of problems; I mean it's been one challenge after another, after another and it just taken that ten twenty minutes out of every three hours compared to what he's going through just seemed minor… I mean the fact that, you know, he was having to be poked and pushed on and surgeries and this and that and the other it just that seemed, pumping seemed insignificant you know like whoopee I gotta take twenty minutes every three hours and go do this because it's gonna be better for him when he does get it. It just it just didn't seem like it was a big deal it's the least I can do."

Like Jessie, Lizzie, a first time mother of a baby boy born at 28 weeks, viewed challenges she faced with pumping as less significant than the setbacks her baby had to face and found comfort when her son was fed her breast milk:

"Sometimes, like I have to skip something for pumping and I have to skip pumping [for something else] like that and that is minor challenges, but having baby here is stressful and when he's got some problem it really hurt us..."

Mothers wanted to do whatever they could to help their infant's health improve even if it meant having to do something they did not enjoy, like pumping. For these mothers, it was no longer about meeting their own needs, but making sure their infants got what they needed, breast milk. While the majority of mothers had planned to breastfeed, mothers who had intended to formula feed described changing their minds when their infants were born early. Learning about the added benefits of breast milk, compared to formula, led to these mothers deciding to pump. As Erica, a first time mother of a baby girl born at 24 weeks, who had planned to formula feed her daughter, described; *"I*

wanted to do whatever would help her out. It wasn't about me. It was about her." Sarah put her own discomfort with breastfeeding aside to provide breast milk for her son:

> *"Knowing his position- knowing my body's producing something that is gonna benefit him 100%, why not give it to him? Especially him that he's in a NICU like, at 28 weeks, two days, helpless, just fighting for his life, like, why why not?"*

Mothers felt it was their responsibility to pump and it was something *'you have to do to keep your infant as healthy as possible.'* For many mothers this answered the question '*why keep pumping?*

Subtheme 2: "You Know What's Best for Your Child"

Mothers recognized breast milk as the best option for their infants, especially because they were born preterm. Mothers wanted to provide breast milk for their infants because they wanted to 'help' in any way they could. Not only was providing breast milk a way to provide nourishment for their infants, pumping allowed mothers to gain back some control and play a role in their infant's care. For the majority of mothers, pumping made them feel connected to their infants, by giving them an opportunity to contribute to their infant becoming healthier. Allie found comfort in knowing that she had control over what her son was eating:

> *"…You're doing this because you know he's going to be eating, you know what's going to be in it and you know what's best for your child…what's best for him is the breast milk… I was like when he gets old enough and eventually when*

he does start eating, I'll have the control over what he gets so that kind of brought me comfort into knowing that okay, I know that this is what I'm pushing into my son."

When mothers were able to pump successfully they found 'gratification' from pumping, knowing that they were providing something for their infant that nobody else could. Pumping was repeatedly described as 'rewarding' and 'worth it' because it enabled mothers to take part in their infants' care and mothers found comfort in having control. In spite of pumping being 'challenging' and 'exhausting,' Christina found pumping 'rewarding':

"It was rewarding. Knowing I was doing something for him that no one else was capable of, it was very comforting just feeling like I had a part to do with his care. It was very challenging, very exhausting and not as easy as I thought it was going to be, definitely a lot of work involved but what I think is what I was able to do so far was definitely worth it."

For mothers who had wanted to nurse their infants, pumping was the means to an end. Pumping became worth it when they were able to successfully nurse their infants. Cassie reflects on how she felt the first time she was able to nurse her son for a full feeding;

"Nursing was such a relief, the first time I fed him the full feeding was so rewarding. I remember thinking this is so much better than pumping like a billion times. Just knowing that your body made a little person and your body can feed that little person is a pretty amazing feeling and if I hadn't pumped all those days,

months before, [then] trying to nurse him for an entire feeding, I might not have been able to produce that much and so I guess in the end pumping was worth it."

Pumping was 'easy to give up' and 'hard' to maintain, yet most mothers kept pumping because it would help their infants become healthier. Mothers believed in their breast milk when they saw their infants becoming stronger and healthier. Lizzie reflected on how she had 'faith in her heart' that one day her son would be able to have her breast milk and it would help him to get better:

"I knew that he would get that [breast milk] later and it's better to start pumping earlier and that [breast milk] is the best milk for baby. I knew everything, but also at the same time I pumped he was not getting [breast milk] and that was like, oh he's not getting [breast milk]. If he could suck or not, I had to pump. I had other faith in my heart mind that he'll do better one day and he can get everything, every milk [he would get] that would be helpful for him, so I have to wait for the time like that."

Many continued to pump, despite continuing to have a low milk supply, because they did not want their infants to 'be any more uncomfortable' than they already were, as Olivia describes;

"Since she's in the NICU and has to have [an] NG tube, I don't want her to have to go on [formula…] I don't want to see her have to be any more uncomfortable than she already has to be."

By providing their infants with breast milk, mothers hoped their infants would be able to 'come home sooner.' As Sarah emphasized;

"Just try it. What do you have to lose, you have nothing to lose. You gain as a matter of fact. You gain getting your son home earlier, him fighting all those infections, and being sick."

Mothers often shared that, without their breast milk, they did not think their infants would be doing as well. In spite of no longer pumping, Tiffany a first time mother of a baby girl born at 27 weeks, attributed her daughter's health improving to the breast milk she was able to provide;

"She had a really hard time with the surgery, and I don't think, if she hadn't had the breast milk in her. I don't think that she would have be, like she wouldn't be doing as good as she is right now. So, I think the breast milk was the best thing."

In spite of not enjoying pumping, Tiffany would 'do it all over again' because:

"Knowing that it was helping her, it gave me a sense of doing something right."

Erica echoed her feelings;

"She's doing very good and she's growing good. And it makes me feel good. Even though she can't really- it just makes me feel good that she is doing well with the breast milk and is likin' it and stuff."

Pumping for their infants provided mothers with control in an environment in which they had minimal control. Pumping and being able to provide their infants with breast milk not only gave mothers the strength and power to continue pumping, but provided strength and nourishment for their infants. In contrast, not being able to produce breast milk to meet their baby's needs was 'depressing' for mothers and they attributed their infants'

setbacks to being switched to formula. Jessie broke down crying when talking about what it was like for her when her milk dried up:

> *"Horrible, very very horrible, cause like I said I mean I know I'm a great mom and knowing that I couldn't feed him and couldn't do that for him was just horrible. I mean it was horrible… When he ran out of breast milk it was another whole challenge for him because he didn't do well with the formula and it was just it was like the emotion all over again. Cause, it's like man, if I my milk hadn't dried up then he'd still be getting breast milk and he'd be doing so much better and it just, it was it was very hard… when you're determined to do it and you just can't, it's hard."*

When pumping allows mothers to provide breast milk to their infants it can be empowering and 'worth it.' Giving mothers a sense of 'doing something right' and regaining control in their role as a mother. However, when pumping no longer results in mothers being able to provide their infants with nourishing amounts of breast milk, mothers question 'why keep pumping?' This can result in discontinuing pumping and feelings of 'depression and 'defeat.'

Global Theme: "You Think of Your Situation as Different"

Societal pressures to breastfeed often led mothers to put pressure on themselves to pump. Higher value was placed on NICU staff than on family or friends for pumping support and information. Mothers were concerned with how others perceived the effort they put in to expressing breast milk. The global theme *"You think of*

your situation as different" is supported by three subthemes: 1) "Are you pumping still?;" 2) "I knew they had too many things to worry about;" and 3) "He's never been judgmental."

Subtheme 1: "Are You Pumping Still?"

Whether coming from the NICU staff, or family and friends, 'words of encouragement' helped many mothers to continue pumping in spite of a low milk supply. When a mother's family and friends had experience nursing, it helped her become more comfortable with pumping. Erica became more comfortable with pumping when her friends and family decided to breastfeed their own children after she started pumping:

> *"My sister she's gonna be breastfeeding. My best friend's breastfeeding. My little cousin, she's gonna be breastfeeding. I guess me doin it made them wanna do it even more…It actually helps me out too by them wanting to do it, it makes me feel more comfortable with doing it."*

Having people who were supportive of pumping helped mothers to continue pumping even when they were worn out. Allie's mother and sister were her cheering squad who reminded her to pump even when they were unable to be with her physically;

> *"My mom actually breastfed my sister and my sister breastfed her first son. So they were kind of my support group with the whole breastfeeding things. Cause like I said it's, it does wear you out and it's easy to give up, but you know*

when you got strong people to motivate you, like "okay it's time for you to go pump that milk out," you know, you just do what you have to do."

Christina worked with other mothers who breastfed their children and were supportive of her decision to pump, but for her it was hard to relate to their experiences because her baby was in the NICU:

"It's just taken a lot of work and a lot of dedication, every three hours, so but it hasn't been easy. Talking to mothers that I work with, and no one has ever had a premature baby and everything seems to come naturally for them. Having a baby in the NICU one that you can't you know touch and bond with and you know you're trying to pump to support its life, it's very difficult and stressful. It's been hard for me, I'm about seventy-five miles away from home staying here alone and that add, just adds stress to it so it has been a very difficult process for me."

In our sample, mothers' decisions to pump were supported by family and friends as well as NICU staff because it was best for the baby. Receiving recognition for pumping from the NICU made mothers feel valued for what they were doing for their infants. Allie was thinking of stopping pumping when she saw the sign 'My Mommy Pumped Me Breast Milk" above her son's bed;

"That made me feel good which helps motivate me to keep doing it. Cause it's like, well somebody is noticing what I'm doing for my son. Just the little small things."

Where most mothers expected to feel pressure from staff to pump, they felt encouraged to continue pumping when they were reminded that ‘every little bit helps.’ Cassie had expected to feel pressure from the NICU staff but felt encouraged instead;

> *“I thought there would be a lot of pressure especially since they’re with [baby] all the time. They were probably thinking “hey this is really good for him.” They were all really sweet and kind and informative and encouraging me to keep going and even a little bit matters.”*

Christina saw the nurses and her husband as her two most important supporters when it came to pumping for her baby:

> *“The nurses at the NICU; they have been wonderful. I've never felt any judgment from them. They've always been very supportive and just like oh you're doing great and just very encouraging, so those are probably my two biggest supporters there, the nurses in general and my husband.”*

Sarah talked about how the nurses did not try to pressure her to pump. Rather the nurses made sure she understood the importance of breast milk for a premature baby and played a pivotal role in her deciding to give pumping a try:

> *“I think the consistency of them explaining to me and making sure that I- I've got that idea, like I understood. I felt more like they were trying- not that they were trying to pressure me to do it. But they wanted me to understand the role it plays for a newborn- for a premature baby.”*

NICU staff, family and friends also served a role in reminding mothers that they also needed to keep their own health in mind in order to be able to take care of their infants. Vanessa was reminded to take care of herself by doctors and nurses;

> *"Words of encouragement. Like if I'm, they're very encouraging. And telling me to take care of myself and the doctors and the nurses and everybody else has been pushing that very much. You can't take care of him, if you can't or if you don't take care of yourself."*

None of the mothers interviewed encountered individuals who were not supportive of their decision to pump. Vanessa spoke of how she viewed some of the NICU staff as her advocates for when she started to nurse her infant;

> *"Oh they have been very, if this is what you want to do this what we're gonna do. Now there's some nurses like the night shift nurses who love to give bottles, cause the night shift is more like oh the fun stuff. But they have been very adamant, the doctors and the lactation consultants specifically and a few of the nurses about if you want to breastfeed, that's what you're gonna do. We're not gonna do bottles, we'll PO feed, but it will only be breastfeeding."*

In contrast to experiencing support for pumping, when mothers began to talk about switching to fully formula-feeding, family encouraged continuing to pump, which for some mothers was not seen as supportive. Mothers reported societal pressures to only breastfeed [or formula-feed] because family and friends did not understand the medical barriers to directly breastfeeding. Shortly after her son was born, Cassie encountered

friends who were encouraging her to try nursing right away while her son was still on enteral feeds;

> *"[Baby] was born at 29 weeks and he was maybe a week old and he still he really wasn't on a breathing tube he was on a cannula for a little bit of pressure and he was eating with a feeding tube and at one week out of the womb people were like so you should try to nurse him and I'm like he's too little you know he needs to be able to regulate his body a little more and grow a little more and I got a lot of comments like that."*

For Cassie, she felt pressure from these stereotypes of either breastfeeding or formula feeding;

> *"There are stereotypes of you only have to breastfeed or you only have to give formula or do this or do that that kind of put a lot of pressure on."*

Because mothers viewed their experience as 'unique and different,' they often turned to NICU staff for advice, rather than family or friends. Most mothers found 'words of encouragement' and reminders of the benefits of breast milk to be supportive of pumping. However, Anna, a first time mother of a baby boy born at 31 weeks and no longer pumping at the time of the interview, reported feeling 'judged' and 'blamed' by staff when she did not have enough milk to feed her baby:

> *"Whenever I called up here to check on him not telling me every time that they didn't have enough breast milk to feed him so they had to use formula like I, I knew how much breast milk they had because it was I was givin it to them but they didn't have to remind me every time that they didn't have enough and a*

couple of times I just kinda felt judged because I would give them some and they would just look at me like this is all you've got are you, are you pumping still?"

In the beginning, Anna appreciated the advice given by staff, but over time this became repetitive which was frustrating for her. Tiffany experienced similar frustrations, when given advice by NICU staff to help her milk supply, because it was unrealistic for her to follow in her present circumstances. Tiffany and her husband were staying at temporary housing away from their own home while their daughter was in the NICU. At the time of the interview they had not stayed at home for eleven weeks;

"I mean, they have a couple nurses that's our favorite and, they was always saying', "are you doing' okay with your breast milk? Do you need to talk to somebody about lactation," and all that. Then you talk to lactation, they just basically tell you exactly what you already know. They tell you to stay hydrated and to eat right, and, that's kinda hard when you're down here. But, that's, that was it."

These mothers wanted staff to understand that they were doing all that they could to pump and provide breast milk to their infants in their current situations.

Subtheme 2: "I Knew They Had Too Many Things to Worry About"

While not expressed by as many mothers as verbal support, some mothers talked about the tangible support they received for pumping from NICU staff, family and friends. Most mothers reported receiving a pump to use from NICU staff, which made it

easier for them. Cassidy talked about how someone from the NICU staff took her through how to use the pump;

> *"Oh they've all been great… they've set down. Like the woman that brought my pump in she sat down, showed us where this goes and where that goes and all that and the people from the NICU they've all sat down with us and said how we were doing and step by step they've all explained everything to us."*

In addition, the ability to come into the NICU during shift change was helpful for mothers. Tiffany was the only mother who experienced difficulties with obtaining a pump for use at home, which meant she had to go longer without pumping when she first started;

> *"Cause I know my insurance, like the Sympathy, the Sympathy pump that they use, it's paid for through my insurance. Like, they pay for the rental of it because she was born premature. And they pay 100%. So, if they'd had one here and, that they could have gave and billed the insurance then they pay 100%. And the doctor here could have wrote the order. But a doctor here wouldn't even, when we asked the, I think it was a social worker or something? She said that, no they don't even do anything like that. So, if a doctor here could have wrote the prescription and then, you know, sent it and got me a pump here, it would have also been a lot quicker than. I was having to go five or six hours, sometimes ten hours without even getting to pump. So that made it a lot more difficult too."*

A more common issue was mothers not wanting to bother NICU staff to use the hospital grade pump when they were in the NICU. Alicia did not want to bother the nurses to use the pump;

> *"I think they actually offer a pump. I just never really wanted to bother them about it, cause I knew they had too many things to worry about."*

Mothers often talked about how watching the hospital video, *"A Preemie Needs His Mommy,"* was helpful with preparing them for pumping when NICU staff was not available. Vanessa gave birth when lactation was short-staffed;

> *"At first I had no idea what I was doing but I did start at [hospital] like a day after he was born or something like that and the lactation people came and saw me, but it wasn't until a few days later. I actually watched all the videos that they told me to watch like you know on the [hospital] TV and they were actually very helpful so by the time the lactation consultants got there I didn't have any questions that I knew of at the time cause I was so new to it."*

Tangible support varied between mothers, from a nurse going to get a cream to help with soreness, to family members providing gas money, or employers providing a space to pump. Each mother's experience differed in what form of tangible support was available to her from family, friends, and even NICU staff. Christina worked with other mothers who had breastfed their children and had a supportive environment for pumping;

"I've had to go back to work part-time and my employer, they give me a place to pump, give me all the time that I need in there so they too have been supportive. I really haven't ran across any negative comments or negative opinions."

Whereas Alicia, who had just gone back to work as a dental hygienist, had difficulty finding the time to pump:

"When I went back to work, if I had a patient- I worked at- I'm a dental assistant- if I had, a patient, I wasn't able to- I'd have to delay the pumping. And, therefore, it started making my milk supply a little less and less because I was prolonging the amount of time that I was able to do it."

Vanessa experienced hands on support from her husband, parents and in-laws when she first started pumping and was too tired to hold the pump herself;

"I mean my husband, my mom, my dad, my father-in-law, they were all, it's kind of funny when I first, I just have to tell you this on a side note. When I first started pumping, again I have no idea what I'm doing I don't know how to hold everything on make the machine work. So I've got my mom holding one on, my father-in-law holding the other one on and I'm just sitting there. Trying to not fall asleep. It was quite hilarious."

While support varied between mothers, having some external support from family, friends, and/or NICU staff helped to minimize the isolation they experienced from having to express breast milk.

Subtheme 3: "He's Never Been Judgmental"

Spousal support stood out for most mothers and was different than support received from other family or friends, as well as NICU staff. For most mothers, it was her decision to pump rather than a mutual decision with her partner. Allie emphasized that it was her body, so it was her decision; *"My husband was very supportive of he wanted me to breastfeed from the very beginning but I was like them are not your nipples those are mine they're tender."* However, spouses (husbands or boyfriends) were supportive of mothers' decisions to pump because it was best for the infant. The majority of mothers were married or living with their partner. Christina's husband was sympathetic;

> *"He's been very sympathetic and very encouraging. It's like "don't give up and try" and "we can try this and I was reading this and you could try that." He's never been judgmental. I've definitely been my worst critic as far as this is concerned, he's been wonderful."*

All but one mother focused on the support received from her spouse. In addition to 'words of encouragement,' spouses provided support for pumping in more tangible ways, such as labeling bottles, putting bottles in the freezer, cleaning pump parts, setting up the pump, even helping mothers with let down by massaging their breasts. As Lizzie experienced with her husband;

> *"My husband supported me a lot…initially it was not coming [in] good and I feel like tender over the breast, but it was not pumping good. He did some massage to support to flow the breast milk and there is equipment he cleaned*

and washed that he transport breast milk to the NICU. I was not able to come every time when I pumped, so he used to bring that [milk].”

Cassie’s husband was supportive with tangible tasks;

“He tried to be supportive and patient by just washing the pump or having it ready for me or you know making sure I was eating enough and drinking enough and not being so wrapped up in [Baby] that I wasn't taking care of myself so that was really that was really sweet.”

Mothers reported this tangible support with pumping helped take some of the burden of pumping off of them. Christina’s husband’s set her up a space to pump when she was able to be at home;

“He agreed with my decision to breast he was all for it. That was kind of our plan. We thought that would be best for the child, especially after he was born prematurely. He's very understanding when I'm at home…he made me a little breast pumping area in the nursery. So when I'm home just somewhere to be able to [pump], a nice comfy chair and somewhere to kick my feet up and have a little radio there to just kind of tune everything out. He just tried to make it as easy for me as possible.”

Allie describes how her husband assisting with pumping tasks helped her from becoming too overwhelmed;

“He stays on me, he'll be like, “hey babe, you know you gotta ready to pump.” Like I said…after I pump he'll take the bottles and label them for me and put them in the freezer so I can freeze them. So I can bring them back, so he's

very supportive in that way. Just to take the load off me, so I won't get overwhelmed with doing everything and then having to try to pump and label them and everything else."

Beyond helping with the pumping tasks, many mothers talked about how their spouse made sure mothers took care of their own needs so that they were able to pump and visit their infant in the NICU (i.e. eating, sleeping). Andrea describes how her husband took care of her so she would be able to keep pumping;

"Just making sure I get enough sleep and just that eating right and all that so I can continue."

Spouses played a key role in making sure mothers took care of themselves so that they would be able to continue to pump. They found ways to alleviate some of the work that came with pumping, by assisting mothers with setting up the pump, labeling bottles, washing the pump parts, and taking the bottles to the NICU.

Global Theme "It's Not Your Baby, It's Cold Plastic."

Pumping was 'frustrating' because it was not nursing and having to wash pump parts and set up the machine added to the exhaustion of pumping. The theme "It's not your baby, it's cold plastic" is supported by three subthemes: 1) "Plugged in to the wall" and 2) "Once he could nurse it would make things easier."

Subtheme 1: "Plugged in to The Wall"

Pumping was 'frustrating' because it was not the same as nursing. Mothers had to 'take time away' from holding their infant to pump. Mothers wanted to stay by their infants' bedside, which for some mothers meant not pumping while in the NICU, because of concerns with privacy.

- *"I find it very frustrating, cause it's not a baby and it's not your baby, it's cold plastic." (Cassie)*
- *"It takes time away from him or even if I'm here and I have to pump before I go [see him] that takes time away from being able to hold him." (Emily)*
- *"It [was] just whenever he was back there, I didn't wanna leave his side. Cause he was still on an incubator and so whenever I would come up here, I wanted to stay with him." (Anna)*

When mothers were near their infant, they described an improved milk supply. However, many mothers reported being uncomfortable pumping by their infants' bedside due to a lack of privacy. While privacy screens are available for use in the NICU and there is a private pumping room, mothers reported not wanting to bother NICU staff to get one for them. Low milk supply was often attributed to being away from their infant and a lack of sensory cues to pump when at home. Alicia describes how pumping at home away from her twins was hard;

"*It's been hard. Because when you're- when you don't have them at home and you don't have anything to go by besides just a machine to pump, when you*

can't see them or smell them or hear them cry, it's a little bit difficult, because, that doesn't really get your milk flowing when you're just at home thinking about them."

Alicia found pumping near her infants helped her milk supply;

"I pumped in the NICU a few times, and when I did I seemed to get a better output. Lots of more milk as a result of being able to be up there and see 'em and feel 'em and smell 'em."

Mothers experienced difficulties with milk flow at home because they weren't able to 'hear' or 'smell' their infants. Cassidy describes this;

"It might just be where I'm not up there every day seeing him neither so I mean it might come back when he gets home or something."

Mothers frequently described pumping as painful and uncomfortable. Olivia describes why pumping was uncomfortable and painful for her; *"It's uncomfortable, it's painful. Your breasts either get, well they're sore and they kind of get dried out just from how the breast shield has to pull."* Allie describes how the discomfort of pumping can make it easy to give up on;

"The hardest thing about breast pumping is it actually hurts your nipple and it gets tender and it's easy to quit so kinda have to have your mindset that you're actually going to do that because it's very easy to give up on."

Mothers overcame the pain or found solutions, such as finding the right sized breast flange in order to continue pumping and provide breast milk for their infants. Cassidy became accustomed to the discomfort of pumping; *"I mean I got used to it after a while."*

Tiffany struggled with not feeling like she had an infant and her only role was to pump and provide breast milk;

> *"I honestly felt like I was coming here to donate my time to give them breast milk. Like, I didn't even felt like I have a baby in here. Like, I would go pump and then I would give them the milk, and I wouldn't see it. It would go to a freezer and then she would get it, like, you don't even feel like you're actually feeding her."*

Pumping proved to be empowering at times by providing a connection for mothers to their infants, but could also make mothers feel disconnected from being 'plugged in all the time'.

Subtheme 2: "Once He Could Nurse It Would Make Things Easier"

Mothers understood the benefits of providing breast milk for their infants. However, many viewed nursing as the 'ideal.' Mothers often planned to pump until they would be able to transition to nursing. Christina imagined nursing would be less work than pumping;

> *"I was gonna pump until he was able to nurse I thought once he got to the point where he could actually nurse it would probably make things easier for me."*

She also describes how pumping is time consuming and how nursing would be more convenient;

> *"It is very time consuming, a little more so than what I would imagine breastfeeding. Cause breastfeeding, if you have your infant, it's just kind of like*

milk on the go. You can do it wherever, whenever. With a pump, it's like I said, there's a whole set-up process and then you gotta pump and then you gotta clean all your pump parts and next thing you know it's like two hours have gone by."

With pumping, mothers found the additional task of washing the pump parts and setting up the machine 'time consuming' and 'annoying,' adding to the exhaustion of pumping. Similar to Christina, Olivia found pumping to be time consuming;

"It takes a lot of time and, haven't really gotten to where I can nurse her yet so it's just been the most annoying thing about it is you have to wash pump parts all the time."

In contrast, nursing was viewed positively because it allowed mothers to 'bond' with their infants and didn't involve the added tasks of washing and setting up the pump parts.

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Appendix C: PumpMed Security Statement

Server

To access the hosting provider online panel, both a 16 character, highly secure password and device multi factor authentication (MFA) are needed. The server itself is a virtual private server, so no other customers are co-located on the server.

To access the server, a Secure Shell (SSH) tunnel is required. Instead of a password, an SSH key is used that requires a matching private and public portion in order to allow. In order to directly access the server, one needs the server's IP address, the correct username along with the private portion of the SSH key. The public portion resides on the server, to be matched to the provided private SSH key.

SSH keys are significantly more secure than even a highly complex password as it is encrypted and thousands of characters long. The private key is only stored on the developer's working computer, which is secured using a password as well. If the laptop is ever lost or stolen, the SSH key can be disabled using the aforementioned hosting provider.

Code updates are deployed using a deployment manager. To access this panel, a 16 character, highly secure password, unique from the previously mentioned password and an additional device MFA.

Database

Direct database access is strictly controlled and secured. The schema the database is stored in requires a separate username password, which is a unique 20-

character password. Additionally, direct access to the database requires the SSH tunnel mentioned above to be established first.

Within the code, database access is done over a PHP Data Objects connection, which secures against SQL injection. All code that accesses the database is stored outside of the web root, and thus not directly accessible outside of specifically established and secured routes. By using unique and validated tokens for every submitted request, the website is completely secured against cross website scripted attacks as well.

Passwords are hashed using the bcrypt algorithm, which currently is the most secure encryption algorithm available and has the ability to scale with Moore's Law.

Users

Access to the website is end to end over Transport Layer Security (TLS) 256 bit encryption, using a Secure Sockets Layer (SSL) certificate. This is also known as HTTPS. The SSL certificate has been refreshed and secured against all currently known vulnerabilities, including Heartbleed.

Every aspect of the website except for the login, account activation and password reset pages are secured behind a roles-based authentication structure the user needs to log into first.

Vita

Katherine (Katie) Bower was born in Rochester, New York to Shirley and Chris Bower. She is the older sister to Anna, an environmental consultant in Arlington, VA. She attended preschool at the Rochester Institute of Technology, where Shirley recently retired from her position as the Library Director. She went on to attend elementary, middle and high school in Pittsford, New York, graduating from Pittsford Mendon High School in 2006. In the fall of 2006, Katie, began her education in Nutrition at Syracuse University in Syracuse, New York. In 2010 she graduated from Syracuse University with a Bachelor of Science in Nutrition and Dietetics and a Minor in Child and Family Studies. After college, Katie moved to Knoxville, Tennessee to begin her graduate studies at the University of Tennessee, Knoxville. Here, she completed her Dietetic Internship and received her Registered Dietitian credential and Masters of Public Health prior to her Doctorate of Philosophy in Nutrition Science.