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IMPLEMENTATION OF DONOR HUMAN MILK IN A NEWBORN NURSERY: A QUALITY IMPROVEMENT INITIATIVE TO INCREASE EXCLUSIVE BREAST MILK FEEDING

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IMPLEMENTATION OF DONOR HUMAN MILK IN A NEWBORN NURSERY:
A QUALITY IMPROVEMENT INITIATIVE TO INCREASE

EXCLUSIVE BREAST MILK FEEDING

BY

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QUALITY IMPROVEMENT PROJECT

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Doctor of Nursing Practice

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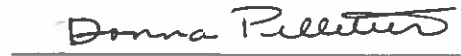


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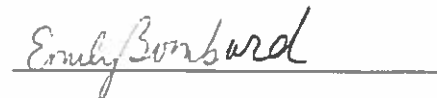


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Abstract

Background: At the site of this quality improvement project, exclusive breast milk feeding rates before discharge from a newborn nursery were behind benchmark goals. The aim of this project was to improve exclusive breast milk feeding rates by implementing a Pasteurized Donor Human Milk (PDHM) Program for breastfeeding newborns requiring medically indicated supplementation. The study site was a Level I newborn nursery of a 20-bed, labor, delivery, recovery, and postpartum unit within a 100-bed community hospital (i.e., the agency).

Methods: This retrospective pre-post cohort study used the Plan, Do, Study, Act (PDSA) framework for rapid cycle change to assess the impact of the program on breast milk feeding exclusivity on discharge. The primary outcomes of interest were on the change in exclusivity among the full-term population according to the Joint Commission's Perinatal Care Core Measures PC-05 and PC-05a (retired). Variables of interest included the hour of newborn age at first supplementation, indications for supplementation, and formula use in the breastfeeding population within the first two days of life. Data were collected by abstraction and medical record review for 3 months pre- and 3 months post- PDHM Program implementation.

Interventions: A multi-disciplinary team was developed to plan and implement the PDHM Program. The process began by developing necessary documents and workflows and ended with staff training and safe provision of PDHM.

Results: Three months after implementation, exclusive breast milk feeding rates increased 3% (pre- 68%, post- 71%) in the full-term population and 11% (pre- 77%, post- 88%) within the full-term, breastfeeding population.

Conclusions: The implementation of a PDHM Program was successful in improving exclusive breast milk feeding rates. Exclusive breast milk feeding rates exceeded the intended 10%

increase based on the PC-05a metric. While many successes were realized in this quality improvement project, further work is needed to better grasp the impact of a PDHM Program at the agency and the implications of using PDHM in the full-term population.

Keywords: baby-friendly, baby-friendly hospital initiative, breastfeed, breast feed, breastfed, donor, donor milk, donor human milk, exclusive, exclusive breastfeeding, formula, human, human milk, infant formula, milk

Implementation of Donor Human Milk in a Newborn Nursery:
A Quality Improvement Initiative to Increase
Exclusive Breast Milk Feeding

Problem Description

Based on extensive empirical evidence, many leading health organizations including the World Health Organization (WHO, 2017), American Academy of Pediatrics (AAP, 2012), and Academy of Breastfeeding Medicine (ABM, 2017) recommend exclusive breastfeeding for the first 6 months of life with continued breastfeeding for a minimum of 1-2 years. The Centers for Disease Control and Prevention (CDC) report exclusive breastfeeding rates based on data from the National Immunization Survey (NIS) which also informs the Maternal, Infant, and Child Health metrics on exclusive breastfeeding for HealthyPeople 2020 (2017). Breastfeeding initiation and exclusive breastfeeding rates at 3 months and 6 months were reported in 2014 as 82.5%, 46.6% and 24.9% respectively (CDC, 2017). This significant drop in exclusive breastfeeding rates over the first 6 months of life may indicate that women are not receiving the education or support needed to achieve the recommended duration of exclusive breastfeeding (CDC, 2017).

Available Knowledge

Breastfeeding Support

Evidence-based strategies to support breastfeeding are broad. Examples include prenatal education, limiting infant formula marketing, and family, professional, peer, and workplace postpartum support. While each strategy plays a role in breastfeeding success, what follows is a discussion of available knowledge focused on the role of breastfeeding support in the inpatient setting.

The WHO and United Nations International Children’s Emergency Fund (UNICEF) have been gathering evidence and promoting best practices in breastfeeding support for decades. In 1981 (UNICEF & WHO) the International Code of Marketing of Breast-Milk Substitutes (The Code) was released representing one of the first global strategies to support breastfeeding. The Code prohibits purveyors of breastmilk substitutes from public advertising, provision of samples, or direct contact with pregnant women or mothers with young children (UNICEF & WHO, 1981). In 1990, UNICEF established the Innocenti Declaration calling for organizations and governments to recognize, protect, promote, and support breastfeeding. Subsequently, in 1998 the WHO published evidence-based maternity practices that support breastfeeding called the “Ten Steps to Successful Breastfeeding” (Ten Steps) which are presented in Table 1.

Table 1

The Ten Steps to Successful Breastfeeding

-
1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
 2. Train all health care staff in the skills necessary to implement this policy.
 3. Inform all pregnant women about the benefits and management of breastfeeding.
 4. Help mothers initiate breastfeeding within one hour of birth.
 5. Show mothers how to breastfeed and how to maintain lactation, even if they are separated from their newborns.
 6. Give newborns no food or drink other than breast-milk, unless medically indicated.
 7. Practice rooming in - allow mothers and newborns to remain together 24 hours a day.
 8. Encourage breastfeeding on demand.
 9. Give no pacifiers or artificial nipples to breastfeeding newborns.
 10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or birth center.

Note. Table information is from Baby-Friendly USA (n.d.).

The Ten Steps focus on the importance of maternity care practices in improving breastfeeding outcomes and are widely accepted as the best evidence-based practices to support breastfeeding. The Ten Steps continue to be well supported by organizations including the AAP and ABM, among many others (Baby-Friendly USA, n.d.). In 2009, UNICEF and WHO released The Baby-Friendly Hospital Initiative (BFHI) to encourage, and recognize through designation, birthing facilities that follow the Ten Steps to Successful Breastfeeding (UNICEF & WHO, 1998) and The Code (UNICEF & WHO, 1981) globally.

Positive outcomes of the BFHI are repeatedly reported in the literature. The PROBIT study was a hallmark cluster-randomized trial of over 17,000 subjects concluding that BFHI practices and the Ten Steps had a positive impact on exclusive breastfeeding rates in the first year of life (Kramer et al, 2001). While BFHI designation does not appear to effect breastfeeding outcomes (Patnode, Henninger, Senger, Perdue & Whitlock, 2016), evidence shows that implementing some or all of the Ten Steps has a positive, dose-response on breastfeeding (Kramer et al., 2001; Perez-Escamilla, Martinez, Segura-Perez, 2016). In other words, implementation of only a portion of the Ten Steps may still translate into positive patient breastfeeding outcomes. The goal of this project, at what will heretofore be referred to as the study agency, was to address Step 6, “Give no food or drink other than breast milk,” (Baby-Friendly USA, n.d.) and improve exclusive breastfeeding before discharge by implementing a Pasteurized Donor Human Milk (PDHM) program.

Exclusive Breast Milk Feeding

While the general definition of breastfeeding is inconsistent or lacking in some evidence, the AAP, WHO, and Joint Commission (JC) broadly agree on definitions of exclusive breastfeeding defined as: the provision of only breastmilk from birth and allows for vitamins,

minerals and medicines as needed (JC, 2017; National Institute of Child Health and Human Development [NICHD], 2017). By this definition, newborns are still considered exclusively breastfed whether they feed directly at breast, receive their expressed mother's own milk, or donor human milk. Breastfed newborns who receive infant formulas, glucose water, water, or solid food are no longer considered exclusively breastfed regardless of the medical indication, or lack thereof. The early use of formula supplementation in the breastfed newborn increases the newborn's risk of infection (Kramer & Kakuma, 2012), early cessation of breastfeeding (Chantry, Dewey, Pearson, Wagner, & Nommsen-Rivers, 2014; Demirci & Bogen, 2017; Parry, Ip, Chau, Wu, & Tarrant, 2013), and alters the newborn gut microbiome with the potential to impact long term metabolic health outcomes (Azad et al., 2013; Bokulich et al., 2016; Johnson & Versalovic, 2012; Luerou-Luron, Blat & Boudry, 2010; Madan et al., 2016; Wampach et al., 2017).

The literature strongly supports that the lack of breastfeeding in the newborn and infant populations leads to morbidity and mortality in infancy through adulthood. The AAP (2012) reported dose-response risk reductions for breastfed newborns for the following conditions: otitis media, respiratory tract infections, asthma, atopic dermatitis, gastroenteritis, inflammatory bowel disease, cardiovascular disease in adulthood, obesity in adolescence and adulthood, celiac disease, type I and type II diabetes, leukemia, sudden infant death syndrome (SIDS), and necrotizing enterocolitis (NEC) in preterm infants. Mixed results in some outcomes have been identified, such as for asthma and allergies, yet the evidence clearly supports improved health outcomes overall (AAP, 2017; Dietrich et al., 2013; Ip et al., 2007). Dietrich et al. (2013) report outcomes from a 1999 study by Ball and Wright indicating that for 1,000 infants who exclusively breastfed for 3 months vs 1,000 infants who never breastfed, the healthcare system would see a

reduction of 2,033 office visits, 212 hospital days, and 609 prescriptions in the first year of life alone. Equally as important, are the negative outcomes in a dose-response relationship for mothers who do not breastfeed. These mothers have an increased risk of type II diabetes, postpartum depression, breast cancer, ovarian cancer, and cardiovascular disease (Ip et al., 2007; Chowdhury et al, 2015; Dietrich et al., 2013).

To reduce the risk of morbidity and mortality, one approach to supporting early exclusive breastfeeding is to avoid supplementation of breastfed newborns unless medically indicated (AAP, 2012; ABM, 2017; International Lactation Consultant Association [ILCA], 2014). The ABM (2017) lists possible medical indications for supplementation: hypoglycemia, signs and symptoms of insufficient milk intake (i.e., dehydration, weight loss, insufficient voids and stools), hyperbilirubinemia, inborn errors of metabolism, delayed onset of maternal milk supply, glandular insufficiency of the breast, breast pathology or past surgery, contraindicated maternal medication use, temporary separation of the dyad, or intolerable maternal pain during feeding unresolved by intervention. When supplementation of a breastfed newborn is medically necessary, and the mother's milk is insufficient or unavailable, donor human milk is the preferred alternative (WHO, 2017). Most organizations, have made the further distinction to recommend pasteurized donor human milk (PDHM) to reduce potential exposure of newborns to diseases and contaminants (ABM, 2017; AAP, 2017; Association of Women's Health, Obstetrics and Neonatal Nurses [AWHONN], 2015; ILCA, 2014). Rates of early formula use in breastfed newborns are decreasing nationally; however, rates in the agency under study remain high (CDC, 2017).

A divide exists among leading organizations that promote the use of PDHM as the next best alternative to a mother's own milk when supplementation is necessary. Some organizations

and statements, such as the AWHONN statement (2015), and Surgeon General's Call to Action to Support Breastfeeding (U.S. Department of Health and Human Services [U.S. DHHS], 2011), recommend PDHM as the next best alternative to a mother's own milk specifically for fragile newborns (e.g., premature, low birth weight, critically ill) while not making exclusionary comments on its use for other newborn populations. However, other organizations, such as the AAP (2012), ABM (2017), and ILCA (2014) support PDHM as the next best alternative to a mother's own milk without distinction to population. The dichotomy stems in part from a historically limited supply for the existing demand thus to preserve the supply for those in greatest need. In 2008 milk banks in the U.S. distributed 1.4 million ounces of PDHM yet the need for just the low birth weight newborn population (<1,500 g) at that time was approximately 9 million ounces (U.S. DHHS, 2011). However, PDHM availability and use is at a record high. In 2018, Human Milk Banking Association of North America (HMBANA) reported nearly 6 million ounces, from 10,000 donors, were distributed from 27 HMBANA member milk banks in the U.S. and Canada in 2017 (Groff, 2018). These increases are also reflected in Perrin's (2018) report of a 74% increase in the use of PDHM among Level II to Level IV neonatal care hospitals since 2011 when the Surgeon General's Call to Action was released. While the inequality of supply and demand for PDMH exists, so does a lack of clinician and payor knowledge about PDMH and a lack of policies to regulate and support the use of PDHM (U.S. DHHS, 2011). Despite the reported disparity in access to PDHM, local hospitals that are obtaining PDHM through a regional milk bank accredited by HMBANA, called Mothers' Milk Bank Northeast (MMBNE), have found an abundant supply and have begun offering PDHM to healthy newborn populations.

Donor Milk's Impact on Exclusivity

At the time of this project, 10 hospitals in NH were using PDHM from Level I nurseries to Level III NICU's (New Hampshire Breastfeeding Task Force [NHBFTF], 2017). There is strong evidence and wide-spread support for the use of PDHM in the NICU setting due to its significant reduction in certain morbidities, such as necrotizing enterocolitis (NEC), which are almost exclusively experienced by the preterm population (AAP, 2012; ABM, 2017; AWHONN, 2015; U.S. DHHS, 2011). Additionally, the preterm population is at higher risk of experiencing several breastfeeding challenges such as low maternal milk supply, inability to directly breastfeed, and the potential for multiple comorbidities and interventions all which may negatively impact exclusive breastfeeding. Therefore, the results of these prior studies may not be generalizable to the full-term newborn population.

The body of evidence on the impact of PDHM on exclusive breastfeeding rates in the late-preterm and full-term newborn population is extremely limited. The use of PDHM in the healthy newborn population is a more recent development driven in part by statements from the AAP and ABM that PDHM is the best alternative to a mother's own milk. Additionally, quality metrics such as the JC's (PC-05) Exclusive Breast Milk Feeding, which does not discretely account for PDHM in establishing exclusivity and applies only to the full-term population, are driving birthing facility decisions and policies related to newborn feeding. The University of Iowa's Children's Hospital has been offering PDHM to term and late-preterm populations for over a decade and report that provision of PDHM may promote exclusive breastfeeding (Kair, Colaizy & Hubbard, 2014; Kair & Flaherman, 2017). A 2018 survey of northeastern hospitals, found that 32% of hospitals provided PDHM to healthy newborns (Belfort, 2018). Based on the JC's Exclusive Breast Milk Feeding (PC-05) metric, hospitals that provided PDHM to healthy

newborns had a 77% exclusive breast milk feeding rate at discharge compared to only a 56% at hospitals who do not offer this option (Belfort, 2018).

Sen et al. (2018) at Brigham and Women's Hospital in Boston, MA examined the trends in PDHM use in their hospital for the healthy newborn population and found increasing utilization over a 3 year period. The authors advise caution as there is little known about the benefits and risks of PDHM use in this population (Sen et al., 2018). It is well documented that early formula supplementation has a negative effect on maternal breastfeeding confidence and maternal milk supply which create a cycle of increasing supplementation which continues to negatively impact confidence and supply and ultimately results in early breastfeeding cessation (Sen et al., 2018). The concern has been raised whether the provision of PDHM may establish a similar cycle. One study in the preterm population concluded that the use of PDHM may decrease the provision of a mother's own milk which would have implications for the duration of exclusive or any breastfeeding (Williams, Nair, Simpson & Embelton, 2016). However, multiple studies found positive outcomes regarding PDHM use on exclusivity before discharge in the preterm population (Marinelli, Lussier, Brownell, Herson, & Hagadorn, 2014; Utrera Torres, 2010).

Based on available supply and significant costs, PDHM in the healthy newborn is often seen as a "bridge" to support short-term medically indicated nutritional needs of a breastfed newborn until the onset of lactogenesis II and copious milk supply. In a qualitative study by Kair and Flaherman (2017), mothers viewed PDHM as temporary whereas formula was viewed as an ongoing plan. This paradigm for the temporary use of PDHM when supplementation is medically necessary may help decrease the risk of mothers experiencing the negative cycle

leading to early breastfeeding cessation, as seen with early formula supplementation; and may be a contributing factor to the ultimate return to exclusively providing a mother's own milk.

Benchmark Reporting

Benchmark reports exist related to exclusive breast milk feeding in the inpatient setting. Differences in how data are collected, measured, and reported are evident among organizations that benchmark and report exclusive breast milk feeding including HealthyPeople 2020, the JC, mPINC, the Breastfeeding Report Card, and the BFHI. This can make comparing exclusive breastfeeding rates and practices among birthing facilities challenging for both laypeople and staff.

HealthyPeople 2020 (2017) set a goal to reduce the proportion of breastfed newborns who receive formula supplementation in the first 2 days of life from the current 17.1% to 14.2% (CDC, 2016). Alternatively, the JC developed quality metrics in perinatal care to support improvements in patient safety and effectiveness of care called the "Perinatal Care Core Measure Set" (JC, 2017). The PC-05 metric is related to newborn feeding and measures the proportion of full-term inpatient newborns fed only breast milk before discharge (JC, 2017). The JC reported a 2016 national rate of exclusive breast milk feeding of 52.9% (JC, 2017). Unlike the HealthyPeople 2020 goal, the PC-05 measure includes newborns of families who have chosen to formula feed and newborns for whom breastfeeding is contraindicated based on maternal factors. Historically, the JC attempted to collect breast milk feeding data based on feeding choice (PC-05a) and excluded patients for whom breastfeeding was contraindicated by maternal factors. These subsets and exclusions were deemed too difficult for hospital data abstractors and were ultimately retired. In a 2015 publication the JC acknowledges the impact of family preference and states that they, "...expect that performance on PC-05 will remain well below

100%...Available evidence suggests that a performance rate of 70% on PC-05 is an achievable target for hospitals to strive to achieve” (JC, 2015).

The CDC (2015) reports state and national survey data on maternity practice measures in a report called “Maternity Practices in Newborn Nutrition and Care” (mPINC). In the mPINC survey, hospitals are asked “what percent of healthy breastfed newborns receive non-breast milk feedings” (CDC, 2015). The CDC reports that nationally, 27% of hospitals replied <10%, 53.7% of hospitals replied 10-49%, 17.1% replied 50-89%, and 2.2% of hospitals replied 90% or more. In NH, 55.6% of hospitals replied that <10% of healthy breastfed newborns receive non-breast milk feedings and the remainder fall into the 10-49% category, including the study agency (CDC, 2015). The CDC ranks states on the overall mPINC findings with NH ranking 2nd nationally. With the state providing some of the highest quality inpatient practices in maternity care and newborn feeding nationally, the study agency must meet high standards to remain competitive.

The CDC (2016) also produces the Breastfeeding Report Card which reports state-based data according to HealthyPeople 2020 goals. In 2014, NH’s rates of breastfeeding initiation and exclusive breastfeeding at 3 months and 6 months were 82.5%, 46.6% and 24.9% respectively (CDC, 2017). Of particular interest were the national and NH state specific rates of breastfed newborns receiving formula before 2 days of age which were 17.1% and 6.6% respectively (CDC, 2016).

Hospitals designated through the Baby-Friendly Hospital Initiative, or that are aiming to follow the “Ten Steps to Successful Breastfeeding”, follow the “Guidelines and Evaluation Criteria” (2016) set forth by the Baby-Friendly Hospital Initiative. Criteria for Step 6, “give newborns no food or drink other than breast milk, unless medically indicated”, advises facilities

to reach for the HealthyPeople 2020 goals related to exclusivity (Baby-Friendly USA, 2016). The Guidelines also advise facilities to compare the rate of non-medically indicated supplementation to the annual supplementation rate reported by the CDC's NIS data in the facility's region (Baby-Friendly USA, 2016). The BFHI (2016) requires at least 80% of breastfeeding mothers report exclusive breastfeeding at discharge, supplementation for a medically acceptable reason based on current evidence, or supplementation by parental request. If a parent requests supplementation, at least 80% should have documented education on the negative impact of non-breast milk feedings, and the facility's rate of non-medically indicated supplementation is required to decrease annually (Baby-Friendly USA, 2016).

Rationale

The rationale behind the use of PDHM in the healthy newborn population is multifaceted. PDHM is the recommended alternative to a mother's own milk when supplementation is medically necessary (AAP, 2012; ABM, 2017; ILCA, 2014; WHO, 2003) and its use aligns with Step 6 of the BFHI (Baby-Friendly, USA, n.d.). Evidence strongly suggests that protecting the breastfeeding relationship through early maternity practices that support exclusive breastfeeding improves breastfeeding related outcomes such as duration and exclusivity of breastfeeding (BFHI, 2016; DiGirolamo, 2008; WHO, 2009). This is exceptionally important as suboptimal breastfeeding increases the risks of morbidity and early mortality for both mothers and children (Bartick, 2017).

Second, it has been shown that early formula supplementation results in a nearly three-fold increased risk of breastfeeding cessation by 2 months of age (Chantry et al, 2014). However, most positive maternal and newborn health outcomes from breastfeeding are realized with a minimum of 3 months of breastfeeding with a dose-response effect (AAP, 2012; Bartick et al,

2017; Stube et al, 2017). Focused initiatives to improve maternity practices in support of breastfeeding may have a direct impact on the health benefits to both mothers and children.

Third, data have been available for decades on the impacts of breastfeeding and formula feeding on the health and development of the newborn gut (Le Huerou-Luron, Blat & Boudry, 2010; Wang, 2016; Wampach et al., 2017). More recent studies are finding that human milk is composed of beneficial bacteria and human milk oligosaccharides (HMO's). HMO's, the third largest component of human milk, are prebiotics to promote beneficial flora while inhibiting pathogenic bacterial binding (Davis, 2016). Formula use decreases bacterial diversity and increases the proportion of potentially pathogenic bacteria such as *C.difficile* (Davis, 2016; Wang, 2016). The resulting dysbiosis, also impacted by other variables such as mode of delivery and antibiotic use, has the potential for negative long-term outcomes via immune-modulated and metabolic diseases (Wang, 2016).

Finally, quality improvement measures, such as the JC's PC-05 on Exclusive Breast Milk Feeding and mPINC, are driving birthing facilities to examine their current practices and strive to make evidence-based improvements that support breastfeeding (CDC, 2015; JC, 2017). These types of benchmarks and reports related to exclusive breast milk feeding may also have a financial impact on birthing facilities. Patient satisfaction related to breastfeeding policies and care, ability to achieve BFHI designation, and the impact of suboptimal breastfeeding on morbidity and mortality each play a financial role for birthing facilities.

Specific Aim

The specific aim of this quality improvement initiative was to implement a PDHM program at a single, community hospital with the goal of improving exclusive breastfeeding rates

by 10% according to the JC's Exclusive Breast Milk Feeding measure (PC-05) within 3 months of implementation (JC, 2017).

Methods

Context

The agency is a 100-bed, Magnet designated hospital serving the NH seacoast community and is affiliated with other local healthcare services such as a visiting nurse association and multiple outpatient providers. The agency's Family Center is a 20-bed labor, delivery, postpartum, recovery, and pediatric unit with a designated operating room, antenatal room, and Level I nursery. The nursery supports stable newborns of 35 completed weeks of age and older. The Family Center has approximately 650 births per year and is staffed with Registered Nurses, Clinical Practice Leaders, Obstetrical Technicians, and Lactation Consultants. Additional routine clinical providers include: obstetricians, midwives, pediatricians, and family practice physicians. Currently, approximately one-half of births in NH occur in a BHFI designated facility (NHBFTF, 2017). Notably, the agency is neither designated as a BFHI facility nor on the path toward designation. However, it is the agency's goal at the time of this report to align with nine of the Ten Steps.

Intervention

Process.

The intervention was to develop and implement a PDHM Program in a Level I newborn nursery aimed to positively impact exclusive breastfeeding rates in the healthy newborn population. Stakeholder buy-in and an environment to support the use of PDHM was established over 1 year prior to the renewed efforts to implement the program. The delay was related to a change in leadership, lengthy process to procure and install a freezer for PDHM, and lack of

available time by staff to maintain project momentum. In September 2017 a multidisciplinary team was established to implement the project. The Donor Milk Team (Team), was formed to have a broad range of perspective in the planning and actualization of the project and included the Team Leader, Pediatric Medical Director, Obstetric Medical Director, maternal-child Clinical Practice Leader, inpatient Lactation Coordinator, midwife, day-shift staff nurse, night-shift staff nurse, and Quality Coordinator. The Team met face-to-face initially, then collaborated electronically and via smaller face-to-face meetings periodically. The purpose of the Team's collaboration was to plan the steps, develop and approve documents, develop and provide education to staff, and ultimately bring the PDHM project from initial stakeholder approval to post-intervention sustainability.

Agency groups outside of the core Team were also part of the process: the Maternal-Child unit Director for approval of all documents and workflows, the Patient Care Standards Committee for policy approval, the Legal Department for informed consent final approval, the Document Control team for processing all forms to be available electronically to staff, and Information Technology for private folder creation to facilitate the Team's communication and accessibility to the most current documents. The Director of Client Relations at MMBNE, the regional milk bank accredited by HMBANA, was also integral in the planning stage of the project to ensure all necessary guidelines and procedures were met to comply with the safe management of PDHM in the hospital setting. MMBNE also enrolled the Team Leader in a ListServ of hospitals who offer, or are in the process of implementing, PDHM as an outside source of support for the project.

The Plan, Do, Study, Act (PDSA) framework for rapid cycle change was used in this quality improvement project (Institute for Healthcare Improvement, 2018). One full cycle was completed at the time of this report as follows.

Plan.

The Team began by meeting and planning the necessary steps and gathering key stakeholders for the project. The first goals were to create and obtain approval for the necessary documents to support a PDHM program including a policy, consent form, and patient education handout. Six hospitals in the region that already used PDHM were contacted and asked if they would share their existing documents related to PDHM. All hospitals willingly shared information which helped guide the Team's creation and approval processes.

Do.

Establishing a Milk Bank Account.

The Team assisted the agency in establishing an account with MMBNE. Workflows were developed in coordination with MMBNE for ordering, maintaining, feeding, and tracking the use of PDHM. An additional program offered by MMBNE for patients who are using PDHM at discharge and wish to purchase a supply for home use was implemented concurrently with the use of PDHM on the unit. This Replacement Agreement program required the use of additional documents from MMBNE and a workflow for sending patients home with a small supply of PDHM from the stock at the agency and a means of reimbursement from the patient to the agency for that PDHM.

Creating the Environment.

A hardwired, alarming freezer and refrigerator were installed and designated solely for PDHM prior to the start of this project. During the project, Facilities staff assisted in calibrating

the freezer to meet HMBANA specifications and calibrating tap water temperatures to facilitate milk thawing and warming in the PDHM area. Containers to hold water for the warming of PDHM, as well as oral syringes, spoons, cups, finger feeders, and supplemental nursing systems (SNS) for individual feedings, were already available on the unit. A resource binder with all PDHM related documents, a log for the receipt and delivery of PDHM, and packets of patient documents necessary to initiate PDHM were stocked in the PDHM area to streamline workflow for staff.

Educating Staff.

The Team Leader developed staff education which was provided electronically and through face-to-face poster presentation training sessions. Four live sessions were executed at various times within the 2 weeks prior to the implementation date. All staff received the training: nurses, Lactation Consultants, pediatricians, obstetricians, midwives, family practice providers, Obstetrical Technicians, and Unit Coordinators. The education included the policy, workflow, related documents, and resources for families and staff. The Lactation staff required deeper understanding as they would become resources to all staff and responsible for maintaining the supply of PDHM and processing Replacement Agreements. Targeted education was provided directly to all Lactation staff.

PDHM Tracking Process.

An account was established with MMBNE, in conjunction with the agency's Purchasing Department, to establish a standing purchase order enabling the Team Leader and Lactation staff to place orders directly with MMBNE. The initial stock of PDHM was ordered by the Team Leader and subsequently maintained by the Lactation staff. The initial order of seven 100 ml bottles and three 50 ml bottles was based on MMBNE's recommendation. Subsequent orders

were based on actual usage by the inpatient families and families sent home with PDHM. Upon receipt of PDHM, it was logged with receipt date, volume, batch numbers, and expiration date. Any PDHM received as a Replacement Agreement for PDHM previously sent home with a family was also logged with receipt date, volume, name and medical record number of the newborn associated with that order.

Provision of PDHM.

The Team developed the following criteria for PDHM supplementation eligibility.

1. The mother must have chosen to breastfeed with the absence of contraindications to breastfeeding.
2. The newborn must have at least one medical indication for supplementation: preterm or late preterm gestation, large or small for gestational age, hypoglycemia, hyperbilirubinemia, excessive weight loss, implementation of a Lactation Feeding Plan, a medically compromised mother (e.g., the mother was in the intensive care unit [ICU] or experienced a postpartum hemorrhage), or at the newborn's provider's discretion.
3. Maternal milk must be unavailable or insufficient to meet the newborn's need.
4. An order for PDHM must be obtained from the newborn's provider. Volumes of any supplement given to a breastfed newborn, including PDHM, are based on the average newborn intake volumes established by the ABM (2017).

Four months after the team's first meeting, in January 2018, PDHM was first ordered and became available to the patients. The Team Leader was on-site frequently in the first 3 weeks to assist staff and answer questions. Small improvements to workflow were made on an ongoing basis guided by direct feedback from nursing and lactation staff.

Families of newborns who met criterion to receive PDHM were educated verbally and in writing about the use of PDHM and its alternative, formula, to facilitate informed decision making. Parents had the opportunity to have all their questions answered to their satisfaction. Regardless of the type of supplement chosen, families continued to receive the standard level of care. Families who chose to use PDHM received the PDHM Patient Education sheet and signed the PDHM Informed Consent prior to supplementation. Details about the feeding, including batch number and signed consent, were documented in the electronic medical record (EMR). Hard copy documents were placed in the newborn's chart.

Study.

The Team Leader was responsible for data collection. Pre- and post- quantitative data were collected using a retrospective medical record review for the 3 months prior to PDHM implementation and 3 months after implementation. With the guidance of a graduate student statistician approved by the agency's IRB, data were analyzed. Ongoing data collection on exclusive breast milk feeding rates by the agency will continue and help to inform future quality improvements. Details about the measures, analysis and results of the study are detailed in the following sections.

Act.

The Team Leader assisted staff during the first 3 months post-implementation. This allowed for opportunities to reinforce staff teaching and better understand challenges in the process. Small changes in the workflow were made based on feedback from the staff. For example, RN's were required to manually log each PDHM feeding and document it in the EMR. This was a failsafe to ensure the batch number of each feeding was being captured which is critical in the event of a recall. However, after confirmation of consistently appropriate

electronic documentation by staff, the written log was discontinued. Also, RN's and Lactation Consultants who work directly with the process of thawing, warming and feeding PDHM expressed a lack of efficiency in the time and attention required in the thawing and warming processes. Discussions with the Director of the unit to obtain a commercial grade warmer were ongoing, though the unit's budget did not allow for the purchase of a warmer until the next budget cycle in late 2018. As a result, renewed efforts for outside funding were explored and ultimately secured. At the time of this report, the unit is awaiting receipt of the milk warmer. Education and new workflows will be put in place with the aim of streamlining the process for staff and improving access to PDHM for those in need.

Study of the Intervention

The metrics established by the JC in their Perinatal Core Measure of Exclusive Breast Milk Feeding measures (PC-05 & PC-05a) were used to assess the impact of the intervention on the primary variable of interest, exclusive breast milk feeding. Descriptive statistics were used to express clinical trends of interest among additional variables including: hour of age at first supplementation, indications for supplementation, and formula supplementation of breastfed newborns in the first 2 days of life. Pearson's chi-square was used to determine whether an association existed between implementation of PDHM and exclusive breast milk feeding with statistical significance established at $p = \leq 0.05$.

Measures

Breastfeeding exclusivity was measured based on the Joint Commission's (JC) Perinatal Core Measure on Exclusive Breast Milk Feeding (PC-05) and Exclusive Breast Milk Feeding Considering Mother's Initial Feeding Plan (PC-05a) (JC, 2017; Milton, 2015). Medical records of all newborns born at the study agency during the study period were included in data

abstraction. The JC (2017) provides definitions and data requirements for population inclusion, exclusion, data collection elements, and proper calculations for PC-05. While PC-05a is a retired metric, it was used by the JC to calculate exclusive breast milk feeding metrics based on the mother's feeding choice on admission. Notably, at the time that PC-05a was retired, exclusion criteria included maternal indications for contraindications to breastfeeding along with those currently used for PC-05 calculations. For the purposes of this report, exclusions for calculating PC-05a were based on the same exclusions currently used for PC-05 which do not exclude maternal contraindications to breastfeeding. Exclusion criteria included gestational age less than 37 completed weeks, multiple gestation, transfer to another hospital, diagnosis of galactosemia, receipt of parenteral nutrition, death, or length of stay greater than 120 days. The validity and reliability of the measure tools (PC-05 & PC-05a) are not documented. Despite this, the PC-05 tool is used by JC accredited facilities, the Centers for Medicare and Medicaid Services (CMS9v6), insurers, and among others.

Data were abstracted and manually collected from the medical records. Patient identifiers were removed from the aggregate data. Aggregate data were entered and managed in Excel 16.12 (Excel). Analyses via descriptive statistics in Excel and Pearson's chi-square in OpenEpi 3.01 (Dean, Sullivan & Soe, 2006) for exclusive breast milk feeding outcomes before and after project implementation were completed. Promotion of data accuracy was based on redundancies in data collection from multiple locations, spot checks, and comparisons of data with the agency's Quality department. Data were initially abstracted from Midas (Conduent Health Analytics Solutions, 2012), the agency's reporting system. Additional data were collected from the agency's electronic medical records system called Meditech (Medical Information Technology, Inc., 2015), hard copy delivery log for the unit, and hard copy lactation

department documentation. Spot checks of data were compared among available data sources for accuracy. Completeness was ensured by the Team Leader's review of data to ensure no missing values were present.

Analysis

Pre-intervention and post-intervention cohorts were analyzed using a Pearson's chi-square with $p = \leq 0.05$ set for statistical significance. Descriptive statistics describe the outcomes of clinical interest. A Master's student statistician from the University of New Hampshire was consulted as needed for guidance on analysis.

Ethical Considerations

The agency's Institutional Review Board (IRB) approval and University of New Hampshire (UNH) IRB waiver were obtained prior to initiating the project. All data were handled in accordance with Health Insurance Portability and Accountability Act of 1996 (HIPAA) to protect the privacy of patients' health information (DHHS, 2003). Data were collected, maintained, and analyzed via Excel and OpenEpi (Dean, Sullivan & Soe, 2006). Aggregate data did not include potential patient identifiers. All electronic medical records containing identifiable information, as well as de-identified data collected and maintained in Excel, were password protected to prevent access by unauthorized users. Hard copy medical record information was accessed and maintained in accordance with the policies and procedures of the agency. Electronic and hard copy medical records were only accessed by the Team Leader or agency employees who already had access to the data during the normal course of business for their role. The statistician had access to the de-identified aggregate data only for the purposes of this project. Protected health information (PHI) was not reused or disclosed to any other person or entity. De-identified data will be maintained for 1 year after study completion,

then destroyed in accordance with the Department of Health and Human Services' Guidelines for Responsible Data Management in Scientific Research (Coulehan & Wells, n.d.). This research and quality improvement project posed no more than minimal risk to the subjects.

A conflict of interest form and waiver of informed consent were submitted to the agency with the IRB application. No conflicts of interest were identified. This research could not be practicably conducted without a waiver as no identifiable patient information was maintained; and as a retrospective medical record review there was no direct contact with subjects.

Clinical ethical considerations involve the use of PDHM in the healthy newborn based on clinical recommendations and inferred benefits from the literature despite extremely limited evidence on the risks and benefits of PDHM in this population. However, to the knowledge of the Team Leader, no evidence exists of direct harm to a newborn, regardless of gestational age, through the use of PDHM.

Results

Evolution of the Intervention and Details of Process Measures

The steps involved in establishing a PDHM Program are outlined in Table 2. While some portions of the project were completed in the expected timeline, most were completed 1 month behind schedule. This was mainly due to lagging response times of individuals outside of the Team from whom approvals were required. Despite the minor delays, the project was planned, implemented, studied, and initial improvement actions were taken (i.e., PDSA cycle) within the established timeframe of September 2017 to May 2018. PDSA cycles will continue for quality improvement related to PDHM.

Table 2

Intervention Timeline

Task	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
Multidisciplinary Team Meetings	X O	X O	X O	X O	X O	X O	X O		
IRB Submission & Approval - Exeter	X O	X O	X O						
IRB Submission & Approval/Waiver - UNH			X O	X					
Develop & Approve PDHM Policy, Patient Education & Workflow	X O	X O	X O						
Develop & Approve Patient Consent	X O	X O	X O	O					
Collaborate with MMBNE on Policy & Workflow	X O	X O	O	O					
Develop Staff Education	X	X O	O						
Cost Analysis to Obtain PDHM		X	X O						
Train Staff			X	O					
Order & Set Up of First PDHM			X		O				
Implementation				X	O				
Data Collection				X	X O	X O	X O	O	
Data Analysis							X	O	
Attempt to Receive Funding for Milk Warmer	X O	X O					O	O	
Results Presented to Clinical Agency								X	O

Note: X – Projected Timeline
 O – Actual Timeline

Primary Measures

Exclusive Breast Milk Feeding According to PC-05 & PC-05a.

Over the 6 month pre- and post-implementation period, a total of 325 births (pre-implementation N=169, post-implementation N=156) occurred at the study agency. Of those, 287 newborns (88%) met inclusion criteria (pre- n=154, post- n=133) based on the JC’s PC-05 metrics. In the pre-implementation cohort, 104 out of 154 newborns (68%) were exclusively

breast milk fed. Comparatively, 95 out of 133 newborns (71%) were exclusively breast milk fed in post-implementation. Pearson's chi-square analysis of the PC-05 metric, and resulting 3% rate increase, was not statistically significant ($p = 0.47$). Of the families who chose breastfeeding on admission, 77% ($n = 104/135$) of the pre-implementation and 88% ($n = 95/108$) of the post-implementation cohorts were considered exclusively breast milk fed using the JC's retired metric PC-05a. Pearson's chi-square analysis revealed a statistically significant increase in exclusive breast milk feeding ($p = 0.03$).

Two likely explanations exist for the modest improvement in the PC-05 and PC-05a outcomes. First, the short timeframe for data collection and analysis resulted in small sample sizes thus potentially skewing results. Second, the 3 month timeframe for post-implementation data collection also coincided with the staff acclimating to the new PDHM processes. As staff were learning the PDHM processes, there was the potential that patient eligibility for PDHM was mistaken thus potentially impacting the number of families who were offered or used PDHM. Longer pre- and post-implementation timelines for data collection would increase the sample sizes, and the inclusion of a washout period for staff acclimation, together may have further improved the results.

Variables of Interest

Hours of Age at First Supplementation.

The hours of newborn age at the time the first supplementation was received was calculated for each supplemented breastfed newborn (pre- $n = 31$, post $n = 23$). Supplementation with both formula and PDHM were included in the calculation. Figure 1 shows a comparison of the number of supplemented newborns between 0 – 72 hours of age, grouped into 12-hour blocks. Variables that may have impacted this change in newborn age when first supplemented

are unknown though this warrants further investigation to better understand when mother-newborn couplets are most vulnerable to the need or request for supplementation.

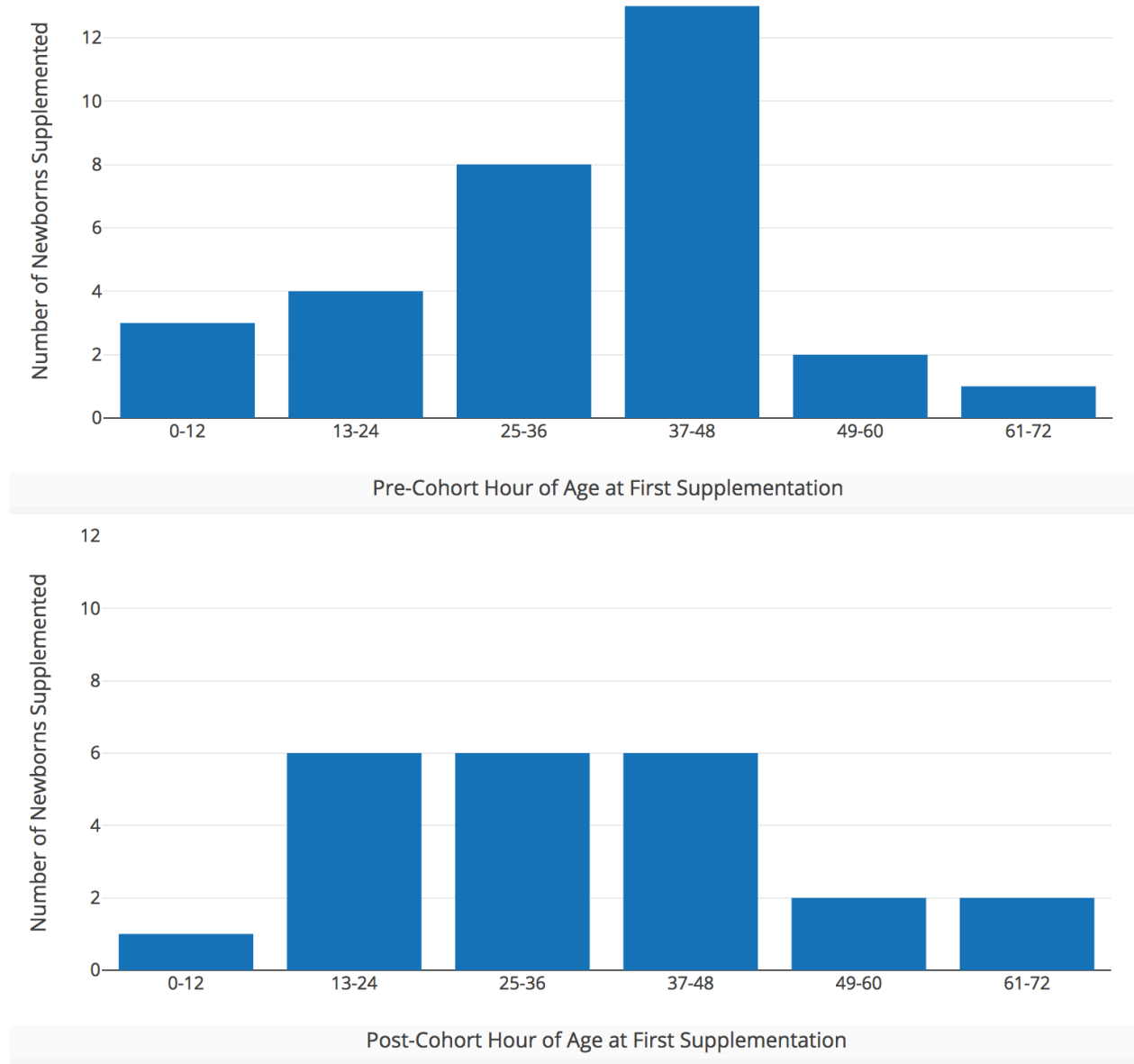


Figure 1. Newborn age at the time the first supplement was received in the pre- and post-implementation cohorts. Graphs were produced in Plot.ly (2017).

Indications for Supplementation.

Table 3 captures the indications for supplementation data. During pre-implementation there was a 65% medical indication rate, a 47% rate of parent request for supplementation, and 6% were unable to be determined. Outcomes do not total 100% as several newborns had multiple indications for supplementation documented. Four newborns of the pre-implementation cohort had both parent request and medical indications documented. Ideally, newborn documentation would indicate supplementation based on either medical indications or non-medical indications (i.e. parent request) but not both. The post-implementation cohort had 65%, 35%, and 0% rates respectively. While the percent of medical indications for supplementation didn't change, the results represent a relative decrease in parent requests (-12%) between the pre- and post- cohorts. These outcomes could potentially be the result of targeted and repeated staff education regarding indications for supplementation which improved accuracy of documentation or potential evidence of a workaround.

Table 3

Indications for Supplementation

Indication	Pre-	Post-	Percent Change
Medical	20/31 (65%)	15/23 (65%)	0%
Contraindicated	1	1	
Dehydration	3	0	
Hyperbilirubinemia	3	4	
Hypoglycemia	1	3	
Low Supply as Only Indication	3	1	
Maternal Nipple Damage	3	1	
Mom Unavailable	1	0	
Poor Newborn Feeding	0	3	
Newborn Weight Loss	4	7	
Non-Medical			
Parent Request	13/31 (47%)	8/23 (35%)	-12%
Unable to Determine	2/31 (6%)	0 (0%)	-6%

Note: Percentages may not total 100% as some newborns had more than one indication for supplementation.

Formula Supplementation of Breastfed Newborns in the First Two Days of Life.

The pre- and post-implementation cohorts were compared on the breastfed newborns' use of formula in the first two days of life. These outcomes are based on HealthyPeople2020 benchmarks which include the total population who was ever breastfed or fed breastmilk without exclusions. For this project, all mothers who were undecided or chose breast or mixed feeding on admission without a contraindication to breastfeeding were included. Newborns who were transferred were excluded from the calculation based on limited feeding data for this population. The pre-implementation cohort had a 23.2% rate of formula use in the first 2 days of life ($n = 33/142$). The post-implementation cohort had a 16.9% ($n = 21/124$) rate of formula use among breastfed newborns in the first two days of life. The CDC's Breastfeeding Report Card for 2016 presented data on this metric, which was obtained from mPINC survey data, and reported a rate of formula use with breastfed newborns in the first two days of life of 17.1% nationally and 6.6% in the state of NH. The HealthyPeople 2020 goal for this metric is 14.2% (HealthyPeople 2020, 2017). Although the change in the rate of formula use from pre- to post-implementation was not statistically significant ($p = 0.20$), the agency's post-implementation rate of 16.9% nearly reached the HealthyPeople2020 goal for 2020 of 14.2% and surpassed the national rate of 17.1% (CDC, 2016; HealthyPeople 2020, 2017). However, the agency has more work to do to reach the 2020 goal and approach the average rate of formula use in the state of 6.6% which has implications in patient satisfaction and in remaining competitive in the marketplace.

Contextual Elements and Unexpected Consequences

Figure 2 shows the proportion of feedings by supplement type. Nine patients received PDHM in the post-implementation cohort and one patient received both PDHM and formula. This means an additional 7% ($n = 9/133$) of the post- PC-05 population were able to continue

exclusive breast milk feeding until discharge which would not have been possible before PDHM implementation.

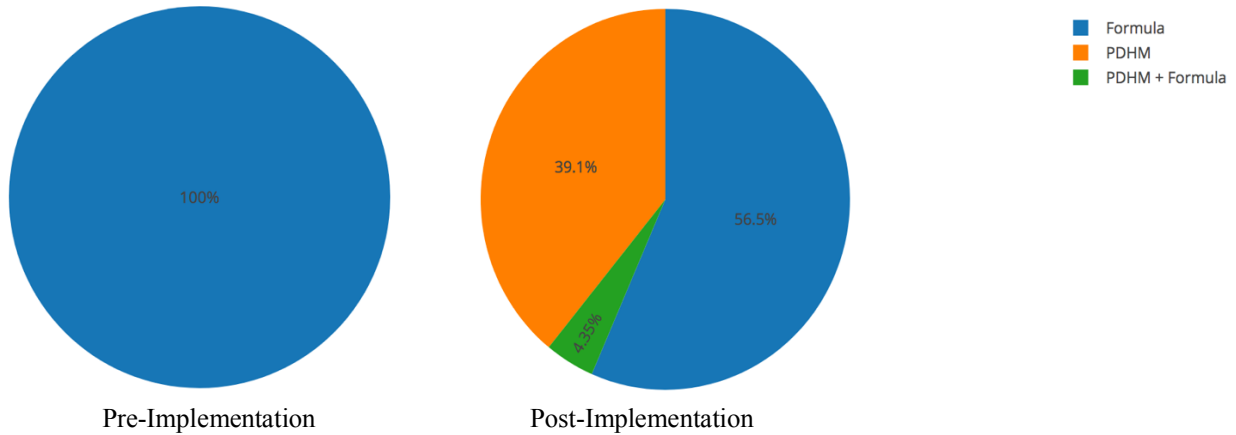


Figure 2. Proportion of newborns supplemented by type in each cohort. Graphs were produced in Plot.ly (2017).

Feeding choices on admission of families in the pre- and post-cohorts are displayed in Table 4. Historically, the agency experienced a near 90% breastfeeding initiation rate, therefore the drop in rate for the PDHM group (pre- = 88%, post- = 81%) is unexpected and of interest. The reason families chose each feeding type was not collected; however, there is an increasing rate of maternal substance use which may be influencing this rate. This is an area for future investigation in subsequent PDSA cycles.

Table 4

Feeding Choices on Admission in Pre- and Post- Cohorts

Feeding Choice	Pre-Implementation	Post-Implementation
Breast	88%	81%
Formula	8%	13%
Mixed	4%	5%
Undecided	0%	1%

Of the JC defined breastfed newborn population, 23% in the pre-implementation cohort (n = 31/135) and 21% of the post-implementation cohort (n = 23/108) received supplementation of any type representing an interesting clinical trend. Despite staff education regarding the risks of providing any supplement to breastfed newborns, such as negative impacts to maternal milk supply and the newborn's latch at breast, a minimal change in the rate of supplementation was observed. This highlights the need to assess staff and patients' understanding, practices, and potential biases regarding supplementation of any type.

Missing Data

Despite attempts to retrieve missing data, there were a few occasions when the data were unavailable from any source. These were labeled "Unable to Determine" (UTD) per JC guidelines. UTD data were calculated separately. The missing data did not impact the calculation of PC-05 or PC-05a, however they are addressed in the section on indications for supplementation.

Discussion

Summary

The primary aim of this quality improvement project was to implement a PDHM Program in a Level I nursery between September 2017 and May 2018 which was achieved. The measured goal was to have an absolute increase of 10% in exclusive breastmilk feeding according to the JC's Perinatal Core Measure for that outcome (PC-05). With an absolute increase of 3%, this goal was not achieved. However, when the data were measured according to the JC's retired metric on exclusive breast milk feeding among the breastfeeding population (PC-05a), an 11% increase was achieved with statistical significance (p=0.04).

Interpretation

The desired outcome of increasing exclusive breast milk feeding by 10% according to the JC's PC-05 was not realized; although, a modest yet positive increase of 3% was observed. However, the post-implementation exclusive breast milk feeding rate of 71%, not only meets the JC's suggested target for hospitals to strive to achieve but far exceeds the JC's national average of 52.9% (JC, 2015). Another successful outcome was the achievement of a statistically significant, 11% increase in exclusive breast milk feeding rates among breastfed newborns (PC-05a). The PC-05a measure allows for assessment of exclusive breast milk feeding while considering the feeding choices of the population. Results of both PC-05 and PC-05a at the agency represent a positive trend that will continue to be monitored. Increases in exclusive breast milk feeding in a well-baby population after implementation of PDHM were also reported by Belfort (2018) and Kair (2014).

The tight project timeline included the immediate post-implementation period which was a time of continued and significant learning for the staff. These post-implementation data may not be representative of the longer-term success of the program. Marinelli et al (2014) and Utrera-Torres et al (2010) both completed before and after studies using PDHM in a NICU; and used data from 6 months pre-implementation and 6 months post-implementation with a washout period between (6 months and 8 months respectively) for implementation, education, and acclimation. A prolonged data collection period may have resulted in different reporting outcomes.

Staff reported that PDHM was well received by the patients; however, this is anecdotal and collecting data on staff and patient perceptions regarding PDHM is a recommendation for future exploration. Kair and Flaherman (2017) found that mothers see PDHM as healthier and

temporary when compared to formula. PDHM was also seen as unfamiliar, costly and logistically challenging (Kair & Flaherman, 2017). When used before discharge, PDHM is covered 100% for patients by the agency thus removing the cost barrier in this setting. The agency's cost coverage also aligns with current regional practice as 95% of hospitals in the Northeast that provide PDHM to healthy newborns pay for it through the hospital budget (Belfort et al, 2018).

Table 5 reflects the financial impact of the program; costs for implementation and the first 3 months of PDHM purchases are reflected. The calculation does not account for the cost of time for project related work from the remainder of the Team or for staff to become educated. The Team experienced a greater than anticipated usage of PDHM in the 3 months following implementation. Actual usage costs for PDHM in 3 months of \$1,396.25 equates to an estimated annual expense of \$5,585. While these costs may not be offset directly, indirect savings to the hospital will likely be realized through increased patient satisfaction and decreased maternal and child morbidity and mortality. At the end of 3 months post-implementation, the agency had a positive net balance of approximately \$6,000 which is in excess of the estimated cost to purchase PDHM for 1 year. Usage, costs to purchase milk and maintain the milk warmer, and outcomes data will continue to be collected by the Lactation Department.

Table 5

Approximate Costs of PDHM Implementation

Item/Service	Projected Cost/Savings	Actual Cost/Savings	Comment
Professional Time for DNP QI Project Management	\$10,500.00	\$10,500.00	Financial savings based on 300 hours of unpaid service
Equipment & Supply Cost: Commercial Grade Freezer	-\$3,000.00	-\$2,478.60	This was obtained and paid for in a prior budget cycle
Equipment & Supply Cost: Commercial Grade Milk Warmer	-\$1,300.00	\$0	Charitable funding obtained through Community Relations Department
Cost of PDHM + Shipping for First 3 Months	-\$650.00	-\$1,396.25	This does not include milk sent and received via Replacement Agreements
TOTAL SAVINGS	\$5,650	\$6,103.75	

National economic cost analyses of suboptimal breastfeeding can be found in the literature. Bartick et al (2017) modeled lifetime costs of suboptimal breastfeeding (i.e. for maternal ages 15 to 70 and from birth to 20 years of age for children) for a cohort of 1.9 million women and 3.75 million children including direct and indirect medical costs, non-medical costs, and premature death in 2014 U.S. dollars for the top 5 maternal and 9 childhood diseases impacted by breastfeeding which are listed in Table 6. In this 2017 study, Bartick et al reported maternal and child costs totaling \$18.5 billion. It was also estimated that the number of women needed to breastfeed optimally to prevent 1 incidence of disease were 0.8 for gastrointestinal illness, 3 for acute otitis media, 95 for lower respiratory tract infection hospitalization, 55 for maternal hypertension, 162 for diabetes, and 235 for myocardial infarction (Bartick et al., 2017).

Table 6

Top Diseases Impacted by Breastfeeding Reported by Bartick et al.

Pediatric
Acute lymphoblastic leukemia
Acute otitis media
Crohn's disease
Ulcerative colitis
Gastrointestinal infection
Lower respiratory tract infection requiring hospitalization
Necrotizing enterocolitis
Obesity in non-Hispanic whites
Sudden Newborn Death Syndrome
Maternal
Breast cancer
Pre-menopausal ovarian cancer
Type II diabetes mellitus
Hypertension
Myocardial infarction

Note: As reported in the study by Bartick et al. (2016)

Based on the same simulation reported by Bartick et al. (2017), Stube et al (2017) go on to estimate that an absolute increase of 5% in any and exclusive breastfeeding would result in a \$44 million lifetime savings for the medical costs of childhood otitis media and gastrointestinal illness alone. A 5% absolute increase in breastfeeding rates would result in a total savings of \$1.9 billion when considering direct and indirect medical, non-medical, and premature death costs for mothers and children (Stube et al, 2017). Therefore, investing in effective practices supporting breastfeeding, such as the BFHI and the Ten Steps, is considered a cost-effective strategy (Stube et al, 2017).

Limitations

Strong leadership support for PDHM was in place before the Team Leader assumed responsibility for this project. Barriers to PDHM implementation were primarily the lack of staff and provider knowledge about the benefits of, and workflow for, PDHM. Through impromptu conversations with staff, there appears to be a small cluster of staff who are not supportive of PDHM for fear of infection transmission to the newborn despite evidence to the contrary.

Additionally, there is a culture of nonchalance in formula supplementation of breastfed newborns among a portion of both nurses and physicians despite the evidence against this practice unless medically necessary. Both of these barriers will need to be addressed to better understand the culture related to formula supplementation of breastfed newborns and any barriers to the use of PDHM.

Based on new reporting requirements at the study agency that coincided with this project implementation, PC-05 data abstraction will be ongoing. This will continue to inform practices related to exclusive breast milk feeding and the success or failure of the PDHM Program.

Anecdotally, patients and staff have shared primarily positive feedback on the availability and use of PDHM. Surveying staff and patients about feelings and experiences regarding supplementation and the use of PDHM would provide data to establish a more global understanding of the success or failure of the program and areas for future quality improvement efforts. Additionally, patient satisfaction measured through Press Ganey data may begin to reflect patients' experience with PDHM.

Quality improvement data is not intended to be generalizable outside of the study agency. The generalizability of this report to the agency is limited by the small sample size, specific population of interest, and limited statistical analysis. Potential threats to internal validity were also identified. The short timeline of post-implementation data collection meant that staff were still learning how and when to use PDHM. Other studies of PDHM and exclusivity use a total of 12 months of data, rather than 6 months, and a washout period to staff acclimation to the new process. Increasing the length of pre- and post-implementation with a washout period may increase the internal validity and statistical significance of the outcome.

It is also possible that the staff education about PDHM and supplementation prior to implementation may have skewed the pre-implementation data as staff became more knowledgeable and conscientious about the risks of supplementing breastfed newborns. Additionally, human manipulation of data, the necessity of using multiple data sources and system limitations all present the possibility of errors. Efforts to minimize errors involved spot checks in redundant systems, and comparison of data with the Quality department for accuracy. Confounding variables were not adjusted for and may include primiparity, use of glucose-gel in hypoglycemic newborns, staff attitudes, and patient attitudes. Time constraints limited the ability to collect associated data and adjust for these variables.

Conclusions

Despite overwhelming evidence on the benefits of exclusive breastfeeding, national rates of exclusivity and those within the agency, require improvement to meet benchmarks. The “Ten Steps to Successful Breastfeeding”, promoted through The Baby-Friendly Hospital Initiative (BFHI), are evidence-based maternity care practices that support breastfeeding. Step 6 of the Ten Steps is to “give newborns no food or drink other than breast-milk unless medically indicated,” (BFHI, n.d.; WHO/UNICEF, 2009). Likewise, HealthyPeople 2020 (2017) established a goal to reduce formula use in the first two days of life to 14.2% in 2020. Based on improved health outcomes for mothers and newborns who breastfeed, among other rationales, the agency aimed to increase exclusive breastfeeding rates by 10%, as calculated by the JC reporting requirements of PC-05 (2017), within 3 months after implementation of a PDHM program. Based on PC-05 metrics, the agency experienced a 3% increase in exclusive breast milk feeding which was modest and not statistically significant; however, indicates a positive trend toward the initial goal. Success was realized in the breastfeeding population who

experienced a statistically significant 11% increase in exclusive breast milk feeding and the overall exclusive breast milk feeding rate of 71% which exceeds the JC's recommended goal.

When birthing facilities support exclusive breastfeeding in the inpatient setting; they are also promoting breastfeeding success for patients beyond their hospitalization. In the face of medically necessary supplementation and an insufficient maternal milk supply, families now have an option to meet their newborn's nutritional needs while maintaining exclusive breast milk feeding at the agency. This practice has the potential for long-term, positive outcomes for both mothers and newborns.

Funding

No funding was obtained to implement this quality improvement project; however, several avenues were explored to obtain funding for the purchase of a milk warmer to improve the nursing workflow in the preparation of PDHM. Initial efforts to obtain grant funding were unsuccessful; however, charitable funding was secured in April 2018 through the agency's Community Relations Department which covered the exact purchase price of a milk warmer and necessary accessories.

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