



# Availability of Donor Human Milk Decreases the Incidence of Necrotizing Enterocolitis in VLBW Infants

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## ABSTRACT

**Background:** Human milk feeding is associated with decreased risk of necrotizing enterocolitis (NEC).

**Purpose:** To determine whether a quality improvement project in New Jersey neonatal intensive care units (NICUs) to promote human milk (HM) feedings would be associated with a decrease in NEC.

**Methods:** Fourteen New Jersey NICUs engaged in efforts to reduce infection and promote HM feeding in very low birth-weight (VLBW) infants. Donor human milk (DHM) availability and NEC rates were assessed.

**Results:** From 2009 to 2016, NICUs with DHM increased from 0 to 7. VLBW infants discharged on any HM increased from 35% in 2007 before the formation of the New Jersey NICU Collaborative to more than 55% in 2016. Time to first oropharyngeal colostrum decreased from 37 to 30 hours from 2014 to 2016. HM at first feeding increased from 71% in 2013 to 82% in 2016. There was an increase in the percentage of feeds that were HM over the first 7 days of feeding. Analyses of data from 9400 VLBW infants born between 2009 and 2016 showed that the incidence of NEC when DHM was not available was 5.1% (367/7182) whereas the incidence when DHM was available (64/2218) was significantly lower (2.9%;  $P < .0001$ ).

**Implications for Practice:** These findings show advantages of feeding HM and effectiveness of forming an NICU collaborative for improving care for preterm infants.

**Implications for Research:** New research projects should measure the quantity of HM consumed daily during the entire NICU stay and assess the timing and amount of HM consumption in relationship to incidence of NEC and infection in neonates.

**Key words:** donor human milk, human milk, mother's own milk, necrotizing enterocolitis, preterm, quality improvement, very low birth weight

## PROBLEM DESCRIPTION

Human milk feedings have many health advantages for both infants and mothers.<sup>1</sup> There are also considerable data showing that preterm infants experience at least some of these benefits.<sup>2</sup> Based on such findings, the American Academy of Pediatrics now holds

the position that preterm infants should receive human milk (HM), with pasteurized donor milk a preferred alternative when feeding with their mother's own milk (MOM) is not possible.<sup>3</sup> In 2008, a review of data from the 14 neonatal intensive care units (NICUs) in New Jersey showed that the percentage of very low birth-weight (VLBW) infants being discharged on some HM had been at a relatively constant level of approximately 35% since 2002 and was below the national average of approximately 40%. In addition, at that time, there were no NICUs in New Jersey that offered pasteurized donor human milk (DHM).

## AVAILABLE KNOWLEDGE

Quality improvement (QI) programs are an essential component of furthering advances in hospital-based healthcare. Such initiatives, using various methodologies, are now common place in departments of pediatrics throughout the nation.<sup>4</sup> An essential foundation for any QI program is establishment of comprehensive clinical databases. The Vermont Oxford Network (VON) provides a nationwide clinical database that

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facilitates tracking of trends in mortality and morbidity of VLBW infants (<1500 g) and enables testing the effectiveness of QI initiatives.<sup>5</sup> While individual hospital and department-level programs are the mainstay of QI programs, another strategy has been to create local networks of NICUs.<sup>6</sup> Such networks work to (1) identify specific issues on which to focus, (2) develop plans to address these issues, and (3) share and combine data from the participating centers to evaluate success or failure of these plans. Formation of such collaboratives has been shown to be of value in bringing about change in clinical care.<sup>4</sup>

## RATIONALE

In New Jersey, there are 14 level III or IV NICUs. In 2008, directors of these NICUs agreed to form a state-wide collaborative to focus on improving outcomes of VLBW infants in the state. Early on, the members of the New Jersey NICU Collaborative (NJNC) recognized the opportunity to pool data across centers to evaluate the progress of our QI efforts. One of the early targets of this collaborative was to reduce rates of infection, an inherent part of which was to promote early feedings with a preference for MOM or DHM. One of the proximal health outcome benefits of HM for preterm infants is a reduction in necrotizing enterocolitis (NEC).<sup>7-9</sup> The collaborative saw an additional opportunity to examine effects of their QI project on the incidence of NEC.

## SPECIFIC AIMS

1. To promote early and ongoing feeding of HM to VLBW newborns (birth weight <1500 g).
2. To encourage and support mothers to either hand express or express milk as soon after delivery as possible.
3. To provide early colostrum oropharyngeal care (COC).
4. To encourage the adoption and provision of DHM.
5. To evaluate whether these efforts to change HM feeding practices were effective in decreasing the incidence of NEC.

### What This Study Adds

- It is difficult if not impossible to conduct RCTs to test the efficacy of HM in preventing NEC. Therefore, convergent observational studies are critical to establishing this relationship.
- The current study provides a new data set in support of the efficacy of using donor bank milk in preventing NEC.

## METHODS

### Context

The 14 centers that participated in this QI project are spread across the state and vary in size from 20

to 56 beds. They also vary in their location, with 8 being suburban and 6 urban. Four are academic centers and 9 are regional perinatal centers. Eleven centers have achieved Magnet designation. A requirement for joining the NJNC was that centers would participate in the VON database. In addition, participating NICUs agreed to submit data to Children's Hospital of New Jersey (CHoNJ) as the collaborative's central repository. Projects are selected by consensus. All 14 centers participated in the initial infection prevention project (2009-2012) and 13 in the human milk feeding project (2013-2016).

### Interventions

The collaborative held monthly meetings, alternating between in-person meetings and Web meetings. During the first phase of the project (2009-2012), many best practices for decreasing infection were reviewed including the promotion of early feedings (<24 to 48 hours of life) with specific emphasis on human milk feedings. During phase 2 (2013-2016), we not only continued to actively address infection reduction but also focused specifically on best practices to promote human milk feeding and early colostrum.

A steering committee was formed in 2013 to review and recommend best practices to increase the volume of HM fed to VLBW infants. They coordinated an all-day off-site conference focused on breast and human milk feeding including participation of external speakers. They also developed a webinar education series. Both programs included the following topics: (1) The Science of Human Milk and sharing the science with families; (2) Human Milk Basics including the science, physiology, and nutritional aspects of MOM and DHM; (3) Colostrum oral care; (4) Pumping basics, collection, and storage of human milk; (5) Donor human milk; (6) Human milk fortification; (7) IUGR/SGA infants and nutritional needs; and (8) Human milk and NEC.

The list of best practices was adapted from the California Perinatal Quality Care Collaborative (CPQCC) Nutritional Support of the VLBW Infant Toolkit (revised December 2008)<sup>10</sup> and presented to all centers. Each center completed a self-assessment against the best practices and implemented practices to meet the needs of their individual center. Each center formed a multidisciplinary team including combinations of physicians, residents, nurses, nurse practitioners, physician assistants, lactation consultants, social workers, and parents. Some of the approaches used to encourage HM feeding included scripted presentations, discussion on daily rounds, family support groups, and mothers maintaining a milk expression log.

The NJNC discussed strategies to implement these practices and process measures. Process measures were agreed upon. Centers were guided to

utilize the PDSA (Plan-Do-Study-Act) methodology as they executed these strategies. We developed a data collection template, and the centers submitted their data monthly. These data were shared during the monthly collaborative meetings. The centers that had previously implemented some of these best practices shared their experiences, protocols, policies, and data results with the rest of the collaborative.

### Study of the Intervention

The NJNC recognized that the promotion of MOM and DHM afforded an opportunity to document changes in preterm infant morbidities associated with the feeding human milk. Accordingly, trends during the study period as well as before and after the formation of the collaborative were compared as a means of demonstrating effectiveness of the recommended changes in care practices.

### Process Measures

#### *Phase 1 (2009-2012)*

During phase 1, we used 2 process measures to determine whether the NJNC efforts were having a positive impact: (1) discharged home on any HM and (2) availability of DHM. To evaluate human milk feeding trends of the collaborative, we examined the percentage of infants discharged home on any HM and compared this with national averages. For this, we accessed multiyear data from the VON database. The VON database used in these analyses comprises data pertaining to VLBW infants with birth weights from 401 to 1500 g, or a gestational age between 22 and 29 weeks, provided to the VON database by approximately 1000 participating national and international NICUs. Access to the database is provided to the participating NICUs via the Nightingale Internet Reporting System. The second process measure used was the availability of DHM in centers and the date initiated.

#### *Phase 2 (2013-2016)*

An analysis of the baseline data in 2012 showed that the rate of NEC at the 3 centers utilizing donor milk was about half that of the other centers (2.7% vs 5.7%). With this knowledge, the group decided to undertake a QI project to encourage early and consistent feedings with any HM. The process measures used to track this part of the project were as follows: (1) the timing of first oropharyngeal colostrum (hours of life); (2) the percentage of infants receiving HM at first feeding; and (3) the percentage of total feeding that was HM during the first 7 days of enteral feeding.

### Primary Clinical Outcome Measure

The primary outcome measure used to evaluate success of the NJNC project was the incidence of NEC

in VLBW infants born during the period from January 1, 2009, through December 31, 2016. Standardization of data collected was accomplished by using the data sent by the participating centers to the VON. Each of the 14 centers forwarded these de-identified data to investigators at the CHoNJ for analyses. From the combined New Jersey data set, we generated the rates of NEC for NICUs when there was DHM available and when there was no DHM available. In total, information was obtained for 9400 infants.

### Analyses

Descriptive statistics are presented as bar graphs for each participating center. Results for the process measures of time to COC and the percentage of infants discharged on some human milk are presented as trends over time, which were analyzed by linear regression analyses. In addition, significant tests of differences in slopes of national and the collaborative averages were performed. The effectiveness of our project on the clinical outcome of NEC before and after the formation of the collaborative and with or without donor milk was evaluated using  $\chi^2$  analyses.

### Ethical Considerations

All aspects of the collaborative's efforts were consistent with recommended best practices, and all data collection and analyses were performed on de-identified data. Accordingly, institutional review board (IRB) approval was not required. The NJNC's project presented no conflict of interests for the participating centers, clinicians, and researchers.

## RESULTS

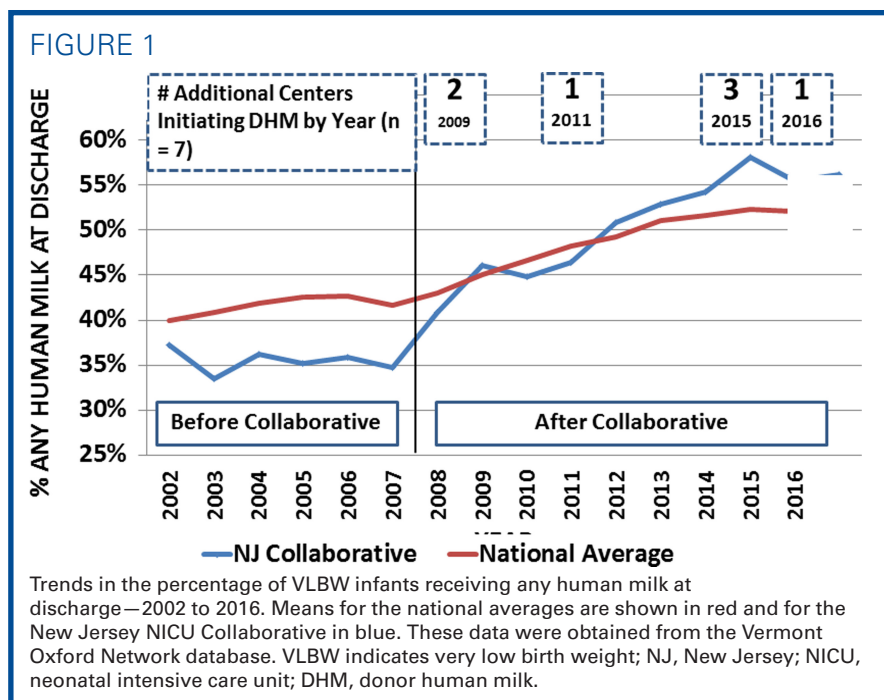
### Interventions

During the initial phase from 2009 to 2012, centers promoted early feedings with MOM and DHM as a fundamental part of their infection prevention measures. The second phase, initiated in 2013, focused on increasing efforts to provide HM earlier and to sustain its use longer. Advocacy for DHM usage was encouraged throughout the 8-year period.

### Process Measures Outcomes

#### *Human Milk at Discharge*

Figure 1 depicts trends in the percentage of infants discharged home from the NICU receiving HM as any portion of their feedings from 2002 to 2016. These means for both the national averages (red line) and the averages for the NJNC (blue line) were obtained from the VON database. The national averages show a steady increase from about 38% in 2002 to just above 50% in 2016. In the years before



the formation of the NJNC (2002-2007), the percentage of infants in New Jersey receiving some HM at discharge changed little and was between 32% and 35%. However, in the years after the collaborative was formed (starting in 2008), the averages for NJ NICUs increased at a steeper rate than the national rate (slope for national =  $1.26 \pm 0.10$ ; slope for NJ =  $2.29 \pm 0.25$ ;  $P < .002$ ). From 2012 to 2016, the NJ annual rates were above 50%, which were above the national averages.

#### Donor Human Milk

From 2009 through 2016, the number of centers with DHM among the NJNC's 14 NICUs increased from 0 to 7. DHM availability was initiated at 2 centers in 2009, a third in 2011, 3 more in 2015, and one in 2016.

#### Colostrum Oropharyngeal Care

Ten centers submitted data on 1850 VLBW infants of the time to first COC from January 2014 to December 2016. We computed the mean time to COC within each center for each month during this 3-year period. We then calculated the median of these means for each month. A linear regression analysis of the medians over the 36 months showed a significant decrease. The y-intercept of 37.8 hours represents an estimated value in January 2014, which decreased by 0.23 hours per month to an estimated time of 29.7 hours in December 2016 ( $y = -0.23x + 37.8$ ;  $r = 0.39$ ;  $P < .001$ ).

#### Human Milk at First Feeding

The percentage of infants across all centers who received MOM or DHM as their first feeding in

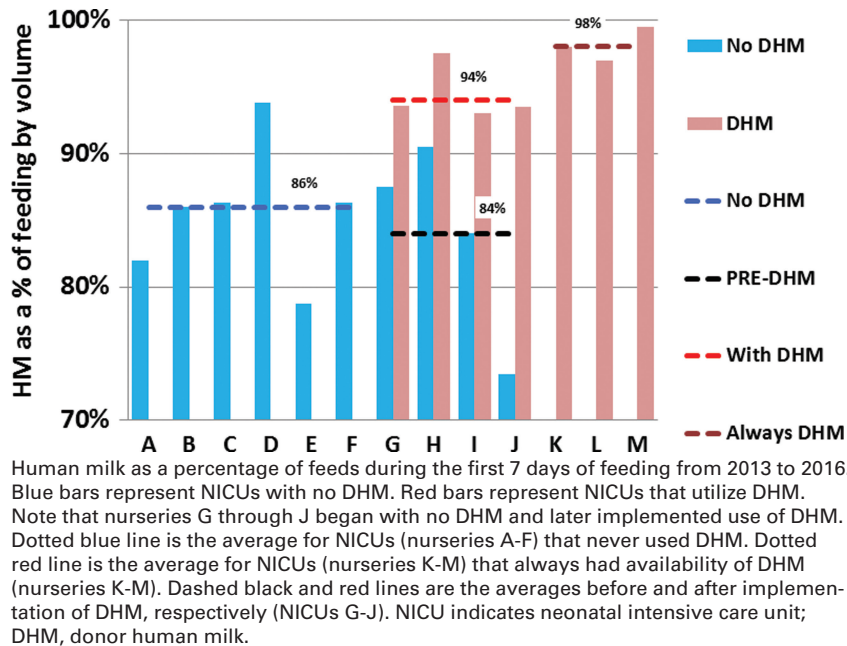
2013, when only 3 centers provided DHM, was 71%. Four additional centers provided DHM in the period 2013-2016. As a result of DHM availability, VLBW infants could receive HM feedings sooner while waiting for availability of MOM from the infants' mothers. During this period, efforts were made to ensure that the first feeding occurred between 12 and 24 hours after birth. This effort resulted in a decrease in MOM from 82% to 63%. Over this period, the percentage of infants who received DHM increased from 18% to 37%. The net result was that the overall percentage of infants, at all centers, receiving HM (MOM or DHM) at their first feeding increased from 71% to 82%.

#### Human Milk During the First 7 Days of Feeding

Twelve of the 14 centers submitted data regarding feeding practices during the first 7 days of enteral feeding. Ninety-one percent (2354/2589) of infants received HM over the first 7 days of feedings. The percentage of this HM that was MOM increased from 85% in 2013 to 95% in 2016. Figure 2 shows HM as a percentage of feeding by volume over the first 7 days in 3 groups of centers. Centers A through F had no DHM available, and the percentage of feedings over the first 7 days for these centers was 86%. Four centers (G-J) initiated the use of DHM during the 4-year period. The percentage of HM given during the period prior to the initiation of DHM usage was 84%, similar to the centers that never had donor milk availability. After implementation of DHM in centers G through J, the percentage of HM fed increased to 94% and was similar to the



FIGURE 2



98% at centers K, L, and M, which provided DHM throughout this period.

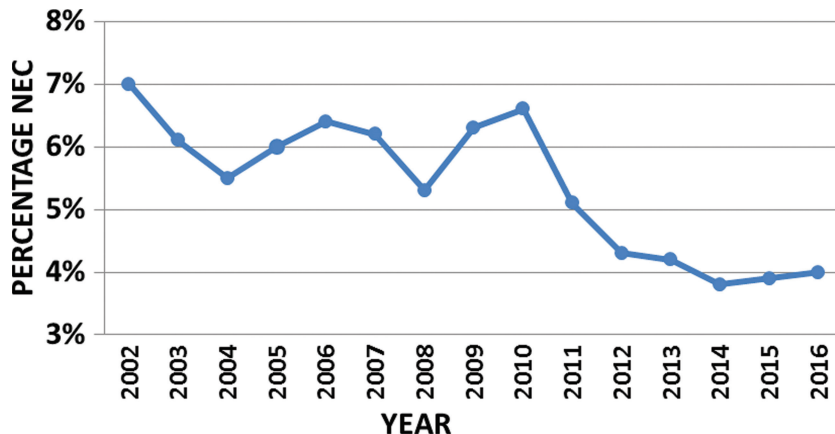
### Primary Clinical Outcome

Figure 3 shows the NEC rate in the NJNC's NICUs between 2002 and 2016. Rates fluctuated from 5% to 7% between 2002 and 2010. From 2010 until 2014, the rates decreased steadily and thereafter remained at approximately 4%.

When data were pooled across all centers from 2009 to 2016, the incidence of NEC when DHM was not available was 5.1% (367 of 7182 infants) compared with 2.9% (64 of 2218 infants) when DHM was

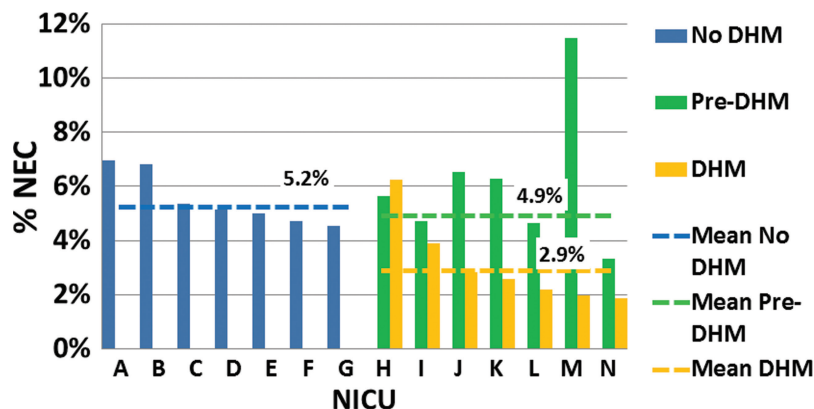
available ( $\chi^2 = 19.17, P < .001$ ). The incidence of NEC for each center in the NJNC as a function of DHM availability is shown in Figure 4. The incidence of NEC in NICUs that never instituted use of DHM was 5.2% (238 cases in 4554 infants), which was not significantly different from the incidence in the 7 NICUs (H-N) prior to their instituting donor milk (4.9%; 129 cases in 2628 infants;  $\chi^2 = 0.35, P = .56$ ). The incidence of NEC in these NICUs (H-N) after implementing DHM was 2.9% (64 cases in 2218 infants), which was significantly lower than the 4.9% for the same centers prior to their instituting DHM ( $\chi^2 = 12.89, P < .001$ ). One center (center M) had a very high

FIGURE 3



Percentage of NEC in VLBW infants in NJNC NICUs from 2002 to 2016. NEC indicates necrotizing enterocolitis; VLBW, very low birth weight; NJNC, New Jersey NICU Collaborative; NICU, neonatal intensive care unit.

FIGURE 4



The mean incidences of NEC (%) in VLBW from 2009 until 2016 for the 7 NICUs that did not have a DHM (blue bars). The average across these units was 5.2% (dashed horizontal line). Green bars show the % NEC for 7 NICUs before implementing DHM (4.9%, dashed green horizontal line); yellow bars show % NEC for these 7 units after they adopted donor milk (2.9%, dashed yellow horizontal line). The incidence of NEC before and after DM was available was statistically different (4.9% vs 2.9%,  $P < .001$ ). NEC indicates necrotizing enterocolitis; VLBW, very low birth weight; NJNC, New Jersey NICU Collaborative; NICU, neonatal intensive care unit; DHM, donor human milk; DM, donor milk.

percentage before implementing use of DHM. However, even after excluding this center, the rate of NEC across all centers remained significantly lower in centers when using DHM (3.1%; 57 of 1865) than at all centers (A-G) that never had DHM available plus (H-N) before they had availability of DHM (5.1%; 360 of 7121;  $\chi^2 = 13.35$ ,  $P < .001$ ). All centers, except for one (center H) that implemented DHM, showed a decrease in the percentage of NEC after implementation.

## DISCUSSION

### Summary

With the advocacy by the NJNC and the forum for shared learning, VLBW infants received increased amounts of HM and the number of centers with DHM increased from 0 to 7 over an 8-year period. Over this period, the percentage of VLBW infants discharged home on feedings with some HM increased steadily. With this change in practice, the incidence of NEC decreased. When donor milk was available, NEC was reduced by approximately 40%.

### Interpretation

The advantages of feeding newborn infants HM are well documented. There is considerable evidence that feeding HM, including donor milk, is a protective agent against NEC and decreases the incidence of NEC.<sup>7,8</sup> A study by the CPQCC linked the data over 7 years from varying levels of NICUs that participated in the CPQCC and utilized DHM from the Mother's Milk Bank of San Jose. They showed that

with an increase in DHM availability from 38.2% to 81.3%, there was a concomitant decrease in the NEC rate from 5.7% to 2.9%.<sup>8</sup> Our results are similar. When our data were pooled across all centers from 2009 to 2016, the incidence of NEC when no DHM was available was 5.1% compared with 2.9% when DHM was available.

The average time to COC was 37.8 hours in 2014. Even with the decrease over the 3 years to an estimated time of 29.7 hours, this remains significantly longer than the 6- to 12- or 24-hour goal that many centers strive for. This time frame is similar to the mean time of 32 hours among 48 VLBW infants reported by Maffei et al.<sup>11</sup> Furthermore, they reported that only 15 (31%) received COC by 24 hours. They also reported that 16 of 48 (33%) received it at greater than 72 hours. A high percentage of mothers who deliver prematurely have difficulty producing colostrum/MOM soon after birth. In addition, they are often not able to produce enough to provide an adequate feeding volume. DHM plays a vital role in bridging the gap until MOM is available and ensuring that the VLBW infants are fed an exclusive HM diet.

In our sample of 2218 VLBW infants cared for in units with DHM, we would have expected to see 113 cases of NEC (5.1%) if DHM was not available. We actually saw 64 cases in this group, 49 fewer than the expected number. At a savings of \$43,818 per case, these 49 patients represent a possible total savings for the New Jersey NICUs of \$2,147,082.<sup>12</sup>

A decrease in the incidence of NEC associated with feeding DHM occurred, although immunological benefits of MOM would have been eliminated

because of pasteurization. If immunological features of human milk are important for these effects, our results could be explained by the observation that the major portion of these feedings were of MOM. Over the first 7 days, the percentage of MOM was more than 85%, and for many infants, mothers continued to provide a significant amount of the feedings. In addition, the availability of DHM would decrease exposure to formula and its potentially harmful inflammatory effects.<sup>13</sup> Regardless of the pathophysiology, this study is convergent with others showing the health advantages of human milk.

We made an effort to ensure that the gains achieved in this project were sustained. While we encouraged centers to continue to collect data on their process measures, this was only done consistently at 7 centers since 2017. Nonetheless, we have continued to present these data and to encourage MOM and DHM at each of our monthly meetings. VLBW infants who received HM for their first feeding remain above 80%. The percentage of total feeds during the first 7 days of feeding that is MOM remains at more than 90%. Based on data from 11 centers for years 2017 and 2018, discharge home on any human milk remains high at 58.9% and 60.0%, respectively. However, the incidence of NEC in 2017 increased to 4.9%. In 2018, it appears to have decreased to 4.1% similar to prior years. Of particular note, since 2017, an additional 3 centers have DHM available, with one center poised to begin as soon as the COVID-19 crisis is stabilized.

### Implications for Practice

These findings show the advantages of feeding HM and the effectiveness of forming NICU collaboratives as a QI strategy for improving healthcare for preterm infants.

### Implications for Research

New research projects should measure the quantity of HM consumed daily during the entire NICU stay and assess the timing and amount of HM in relationship to NEC and incidence of infection in VLBW neonates.

### Limitations

Although these results are supportive of the value of human milk feeding and the formation of local networks as a mechanism of change, we were limited in the collection of more comprehensive process measures due to limitations of resources at some centers. For example, for our goal of establishing and maintaining maternal milk supply, we were only able to measure volume of HM feedings for the first 7 days of feedings.

With regard to established effects of HM on NEC, a weakness of this study is that it was not a controlled trial. NICUs instituted the utilization of donor milk when it was advocated for and found to be financially feasible. Trials comparing effects of DHM and formula on a variety of outcomes including NEC were recently reviewed.<sup>9</sup> These trials were of mixed quality but did show higher rates of NEC in infants fed formula. However, a randomized controlled trial (RCT) in which HM was withheld from some infants would never be approved by IRBs, making any future, high-quality RCTs impossible. In addition, our results would be strengthened if the presence of NEC and total HM exposure for each individual patient were available. This, however, would require a more extensive collection of data.

### CONCLUSIONS

Even with the aforementioned limitations, the findings from our analyses add to the growing evidence that HM is the best food for VLBW infants. The results provide strong evidence for the value of creating local networks to facilitate QI programs and evaluate their effectiveness. Such networks make it possible to collect and utilize larger amounts of data than that are possible from a single site. Recognition of the variation in practice and outcomes among participants in the network affords individual centers a new window on what they could achieve. Finally, the collaborative learning and competition inherent to network activities provide driving forces for change not possible within a single center.

#### Summary of Recommendations

<b>What we know:</b>	<ul style="list-style-type: none"> <li>• There are many benefits of feeding infants human milk.</li> <li>• Among these, studies indicate that human milk feeding decreases the risk of NEC.</li> <li>• Prior studies have shown that DHM availability may be protective against the development of NEC.</li> </ul>
<b>What needs to be studied:</b>	<ul style="list-style-type: none"> <li>• The quantity of HM consumed daily during the entire NICU stay.</li> <li>• Multiyear tracking of the incidence of NEC.</li> <li>• Multisite assessments of the timing and amount of HM in relationship to NEC.</li> </ul>
<b>What can we do today:</b>	<ul style="list-style-type: none"> <li>• Establish local NICU networks for QI projects.</li> <li>• Encourage local networks to track NEC incidence and HM ingestion.</li> <li>• Encourage adoption of DHM.</li> </ul>

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