Impact of Donor Milk Availability on Breast Milk Use and Necrotizing Enterocolitis Rates

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abstract

OBJECTIVES: To examine the availability of donor human milk (DHM) in a population-based cohort and assess whether the availability of DHM was associated with rates of breast milk feeding at NICU discharge and rates of necrotizing enterocolitis (NEC).

METHODS: Individual patient clinical data for very low birth weight infants from the California Perinatal Quality Care Collaborative were linked to hospital-level data on DHM availability from the Mothers' Milk Bank of San José for 2007 to 2013. Trends of DHM availability were examined by level of NICU care. Hospitals that transitioned from not having DHM to having DHM availability during the study period were examined to assess changes in rates of breast milk feeding at NICU discharge and NEC.

RESULTS: The availability of DHM increased from 27 to 55 hospitals during the study period. The availability increased for all levels of care including regional, community, and intermediate NICUs, with the highest increase occurring in regional NICUs. By 2013, 81.3% of premature infants cared for in regional NICUs had access to DHM. Of the 22 hospitals that had a clear transition to having availability of DHM, there was a 10% increase in breast milk feeding at NICU discharge and a concomitant 2.6% decrease in NEC rates.

CONCLUSIONS: The availability of DHM has increased over time and has been associated with positive changes including increased breast milk feeding at NICU discharge and decrease in NEC rates.

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Ms Kantorowska conceptualized and designed the study and drafted the initial manuscript; Ms Wei contributed to the study design, developed statistical models for the study, coordinated and supervised data analyses, and critically reviewed the manuscript; Dr Cohen conceptualized and designed the study, supervised data collection at the Mothers' Milk Bank of San José, and critically reviewed the manuscript; Dr Lawrence contributed to the study conceptualization, participated in data interpretation and presentation, and critically reviewed the manuscript; Dr Gould contributed to the study conceptualization and study design, supervised data collection and other operations at the California Perinatal Quality Care Collaborative, and critically reviewed the manuscript; Dr Lee supervised the study design, led the overall execution of the data analyses and manuscript writing, and critically reviewed the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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WHAT'S KNOWN ON THIS SUBJECT: Human milk is the preferred nutrition for premature infants in the NICU, but mothers may face challenges in having an adequate supply during the hospital course. Donor milk banks can provide supplemental human milk for this purpose.

WHAT THIS STUDY ADDS: Donor milk availability via a human milk bank has increased over time. Donor milk availability is associated with increased likelihood of breast milk feeding at discharge for very low birth weight infants and lower rates of necrotizing enterocolitis.

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Human milk is considered the optimal form of nutrition for all infants, but it is especially important for infants born prematurely. In preterm infants, human milk feeding is associated with lower risks of necrotizing enterocolitis (NEC), retinopathy of prematurity, and sepsis.[1–4] Human milk has been established as a protective agent against NEC.[5] Enteral feeding containing at least 50% human milk in the first 14 days of life is associated with a sixfold decrease in the odds of NEC.[1] Unfortunately, breastfeeding can be quite challenging within the NICU.[6] Mothers of very low birth weight (VLBW) infants are less likely to initiate milk expression, and a significant proportion of them wean their infants off of breast milk relatively soon after birth.[6,7] Practices such as lactation counseling can influence breastfeeding rates in the NICU.[8] Ultimately, when challenges prevent exclusive feedings of mothers' own milk for preterm infants in the NICU, donor human milk (DHM) is the recommended substitute.[9,10]

Although DHM banks have become more prevalent in the United States, we do not yet have a clear picture of the implications of this availability for VLBW infant outcomes.[9–11] Some of our current knowledge on DHM and NEC rates in preterm infants come from studies conducted >30 years ago.[12] There has been debate about whether access to DHM could lead to decreased breastfeeding, the idea being that the availability of an alternate human milk source could lead to attenuated efforts to promote lactation among mothers of preterm infants.[13] A study by the Italian Association of Human Milk Banks showed that access to DHM was actually associated with an increased rate of exclusive breastfeeding in VLBW infants,[13] but data from US NICUs have been lacking. Data from human milk banks in the United States are not standardized, and there is a lack of a central depository.[9] The Human Milk Banking Association of North American (HMBANA) has stated that this situation could be hindering research, quality improvement initiatives, and implementation of NICU donor milk programs.[9]

The California Perinatal Quality Care Collaborative (CPQCC) gathers information on the care of >90% of California's NICU admissions of VLBW infants. The Mothers' Milk Bank of San José (MMB) is the largest HMBANA human milk bank in the United States in terms of distribution and supplies DHM to California NICUs. We linked data from these 2 organizations to get a clear picture of DHM availability and its impact on VLBW infants. Our goal was to examine whether DHM availability affects breastfeeding rates among VLBW infants and rates of NEC. Although interest is growing in evaluating DHM usage and its effects on breastfeeding, previous studies have given only a partial picture of the current status of DHM in US NICUs, examining either NICUs of only a certain level or DHM effects in a few hospitals.[10,14] According to the final birth data collected by the Centers for Disease Control and Prevention in 2012, California is currently the state with the highest number of births per year.[15] We used data from 2007 to 2013 to examine if and how DHM availability has been changing across NICUs and the clinical implications for VLBW infants.

METHODS

Data for this study were obtained from the CPQCC and the MMB. We used data collected between 2007 and 2013. This study was approved by the Stanford University Institutional Review Board.

The CPQCC collects detailed clinical data for infants born at 132 member hospitals, representing >90% of all VLBW infants cared for in California NICUs. We used individual-level data from CPQCC and hospital-level data from the MMB.

The MMB is currently serves 94 hospitals across several states in the western United States. It is also the only HMBANA milk bank that supplies California hospitals. Any NICU that was receiving DHM from an HMBANA milk bank and was a CPQCC member during the study period would have received DHM from the MMB.

Our first analysis was a descriptive analysis of DHM usage in California during the 7 years from 2007 to 2013. Data from the MMB reported which California hospitals were receiving DHM during this time. These data were linked to the CPQCC database, which contains clinical data on all NICU admissions weighing ≤1.5 kg at birth from their member hospitals. By using these 2 data sets in combination, we were able to identify the percentage of NICU VLBW admissions that were occurring in a hospital where DHM was available. To track DHM availability over time, we plotted this percentage over the course of 2007 to 2013. This plot was stratified according to NICU level. In California, regional NICUs take care of the sickest patients who may require subspecialty and/or surgical care, community NICUs can care for VLBW infants who may require prolonged respiratory support, and intermediate NICUs care for infants who do not require long-term intensive respiratory support.

Next, we identified 22 California NICUs that underwent a clear transition from not having DHM to having DHM available at some point during the course of 2007–2013. We evaluated hospitals that underwent only 1 transition in DHM status. For

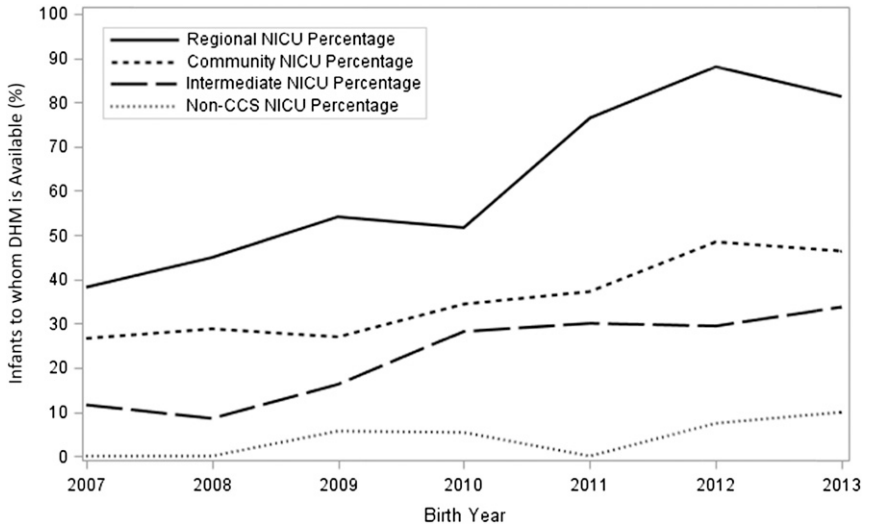

FIGURE 1
Overall DHM availability trends: the percentage of mother-infant pairs who had donor milk available to them over the course of 2007–2013 stratified by NICU level.

example, hospitals that acquired DHM, then stopped offering it, and then restarted offering DHM would be counted as having 2 DHM status transitions and were excluded from this analysis.

To examine the effect of a hospital's DHM status on the rate of breastfeeding among its VLBW infants, we performed paired *t* test analysis for these 22 hospitals, comparing rates of breastfeeding at discharge before and after each hospital acquired DHM. Feeding type at discharge was recorded in the CPQCC database as (1) human milk, (2) human milk with fortifier or formula, or (3) formula only. We combined (1) and (2) for this analysis, considering any human milk in an infant's dietary regimen as a positive outcome for "breastfeeding at discharge." Generally, we would presume that few infants are sent home with DHM, so the presence of human milk in an infant's dietary regimen at discharge signifies a high probability of at least partial feeding with mother's milk. The calculation of the rate of breastfeeding at discharge for infants in each hospital was restricted to VLBW infants only (<1500 g at birth).

We also performed a paired *t* test analysis of the 22 identified hospitals to evaluate changes in NEC rate with change in DHM status. The diagnosis of NEC was dependent on having both clinical and radiographic criteria, as follows: ≥1 bilious gastric aspirate or emesis, abdominal distension, occult or gross blood in stool with no apparent rectal fissure, and ≥1 pneumatosis intestinalis, hepatobiliary gas, or pneumoperitoneum. These criteria were consistent with the definition used by the Vermont Oxford Network. The analysis of NEC rate at each hospital was restricted to VLBW infants only. We compared the percentage of VLBW infants who had NEC before and after DHM was available at those hospitals.

Across all CPQCC hospitals, we used multivariable logistic regression models to examine which hospital, obstetric, and sociodemographic factors were independently associated with breastfeeding at discharge and the occurrence of NEC among VLBW infants. The primary predictor variable of interest examined was the availability of DHM at the NICU of care. Because birth weight and gestational age are highly correlated, we included birth weight but not gestational age as a predictor variable. Adjusted odds ratios (ORs) were calculated with 95% confidence intervals (CIs) for risk factors that were associated with breastfeeding at discharge and the development of NEC.

An α level of $P < .05$ was used as the cutoff for statistical significance. Statistical analyses were computed by using SAS version 9.4 (SAS Institute, Cary, NC).

RESULTS

Accounting for 42 532 VLBW infant records, DHM availability increased during the study period. In 2007, only 27 of 126 NICUs were receiving DHM. By 2013, the number of NICUs receiving DHM had increased to 55 of 133. This upward trend in DHM availability was seen across all NICU levels (Fig 1).

Although the increased DHM availability was seen across all levels, regional NICUs saw the most dramatic increase. In 2007, 38.2% of premature infants were admitted to regional NICUs with DHM availability. By 2013, 81.3% of premature infants were cared for in regional NICUs with DHM availability.

In hospitals in which there was no DHM available throughout the study period, caring for 16 992 infants during that time, there was an overall trend of increasing breastfeeding at discharge from 44.6% in 2007 to 53.3% in 2013. During that time period, the observed rate of NEC decreased from 5.7% to 2.9%.

In the context of these trends, the availability of DHM in a hospital was associated with both an increased rate of breastfeeding at discharge and a decreased incidence of NEC. Figure 2 shows individual hospital rates of breastfeeding at discharge for VLBW infants before and after the

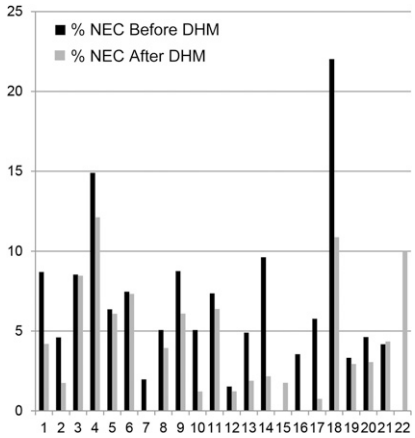

FIGURE 3

Paired NEC rates: comparison of hospital rates of NEC among VLBW infants before/after the transition to having DHM available. Each point on this graph's x-axis represents one of the 22 hospitals that underwent a clear change from not having DHM to having DHM available.

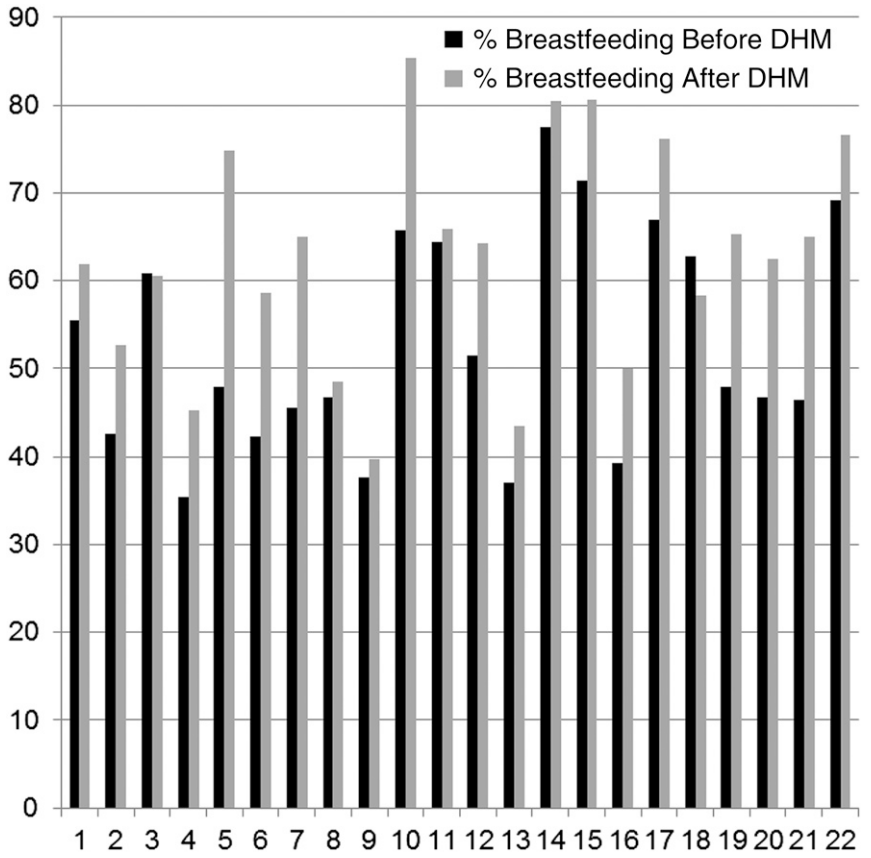

FIGURE 2

Paired breastfeeding rates: comparison of hospital rates of breastfeeding at discharge among VLBW infants before/after the transition to having DHM available. Each point on this graph's x-axis represents one of the 22 hospitals that underwent a clear change from not having DHM to having DHM available.

transition to having DHM available. There were 22 hospitals caring for 10 823 infants that underwent a clear transition over the course of 2007–2013 from not having DHM available to having DHM available. These included 10 community, 3 regional, 2 intermediate, 2 nonclassified NICUs, and 5 NICUs that underwent a transition of levels (typically from community to regional). Among these hospitals, the mean difference at each hospital before/after DHM was a +10.0% increase in the rate of breastfeeding at discharge (95% CI: 6.5–13.5%; $P < .0001$). Figure 3 shows individual hospital rates of NEC among VLBW infants before and after the transition to having DHM available. Among the 22 hospitals that underwent a clear transition in the availability of DHM, the mean difference before/after DHM was a −2.6% decrease in the hospital rate of NEC (95% CI: −3.9% to −1.3%; $P = .0006$).

We evaluated the impact of acquiring DHM on the combined rate of breastfeeding at discharge and the combined rate of NEC. Before acquiring DHM, the combined rate of breastfeeding at discharge among VLBW infants for these hospitals was 52.8%. After obtaining DHM, the combined rate of breastfeeding at discharge was 61.7%. Before acquiring DHM, the combined rate of NEC among VLBW infants for these hospitals was 6.6%. After making DHM available to their NICU infants, the combined NEC rate among these hospitals dropped to 4.3%.

These associations of DHM availability with a higher likelihood of breastfeeding at discharge and a lower likelihood of NEC were seen when considering the whole cohort of CPQCC hospitals (Tables 1 and 2). After risk adjustment for clinical factors with the use of multivariable logistic regression, not having DHM available in a hospital was a negative predictor for breastfeeding at discharge (OR: 0.70; 95% CI: 0.66–0.73). Intermediate and community NICUs had less breastfeeding at discharge than regional and non-California Children's Services (CCS) NICUs.

After risk adjustment, the lack of DHM in a hospital was a positive predictor of NEC (OR: 1.15; 95% CI: 1.03–1.28). Community, intermediate, and non-CCS NICUs all had less NEC than regional NICUs.

DISCUSSION

From 2007 to 2013, DHM availability increased substantially in California across all NICU levels. Regional NICUs saw the largest increase in DHM use, and went from having DHM available to 38.2%

TABLE 1 Multivariable Logistic Regression Model for Breastfeeding at Discharge

	Birth Weight	
	OR	(95% CI)
Birth weight (100-g increase)	1.20	(1.18–1.20)*
No DHM	0.70	(0.66–0.73)*
Maternal age		
<20 years	0.60	(0.55–0.65)*
20–29 years	1.00 (ref)	
30–39 years	1.47	(1.40–1.55)*
≥40 years	1.41	(1.28–1.55)*
No prenatal care	0.34	(0.30–0.38)*
Multiple versus singleton birth	0.98	(0.93–1.03)
Outborn versus inborn location	0.72	(0.67–0.78)*
NICU level		
Regional	1.00 (ref)	
Community	0.80	(0.76–0.85)*
Intermediate	0.50	(0.44–0.56)*
Non-CCS	0.90	(0.80–1.01)
Cesarean versus vaginal delivery	0.98	(0.93–1.03)
Race		
White	1.00 (ref)	
Native American	1.08	(0.81–1.46)
Asian/Pacific Islander	1.08	(0.99–1.18)
African American	0.51	(0.47–0.55)*
Other	0.90	(0.76–1.07)
Ethnicity		
Non-Hispanic	1.00 (ref)	
Hispanic	0.84	(0.79–0.89)*
Apgar score (5 minute)		
0–3	1.00 (ref)	
4–6	1.40	(1.25–1.57)*
7–10	2.14	(1.92–2.37)*
Female versus male	1.09	(1.04–1.15)*
Major birth defect	0.54	(0.50–0.59)*
Normal weight for gestational age	0.79	(0.74–0.84)*

* $P < .05$.

of VLBW infants born in regional NICUs in 2007 to coverage of 81.3% of VLBW infants born in regional NICUs in 2013. There was a slight reduction in DHM availability from 2012 to 2013 in regional and community NICUs (Fig 1), which will need to be monitored, because there may be factors, such as cost, that could influence availability.

Our study gives a broad picture of trends in DHM availability because it covers a large population base of all NICU types. One study limited to level-3 NICUs found increasing DHM use, with larger hospitals and those located in the West and Midwest being more likely to use DHM.[10] A study of 2 level-3 NICUs in Cincinnati examining 650 very preterm infants found increased DHM usage from 8% to 77% from 2006 to 2011, without a change in the provision of maternal milk.[14] Our study goes beyond these previous studies by including NICUs of varying levels of care. The lack of a centralized data depository for the milk banks associated with HMBANA makes it challenging to obtain data on a comprehensive sample of milk banks and their associated NICUs.[9] Because the MMB provided DHM to California NICUs during the study period and we were able to link to data from the CPQCC, we were in a unique position to evaluate trends in DHM availability and its impact on VLBW infants.

Regional NICUs saw the greatest increase in DHM use over the study period. Because regional NICUs take care of the sickest premature infants in California, these infants are more likely to develop NEC than infants at any other NICU level (see Table 2). This environment is also likely one in which it is hardest for mothers to provide their own milk; previous research has shown that infant health factors have a significant influence on the transition from expressed milk feedings to direct breastfeeding.[6] Due to the increased risk of NEC in their patients, regional NICUs may stand to benefit the most from the health benefits that DHM provides to VLBW infants.

The benefits of human milk feeding for premature infants have been well established. Although DHM is often used as a stand-in when mothers' own milk is not available, existing data about the effects of DHM in the United States on VLBW infant outcomes are not very comprehensive. A study of 83 NICUs in Italy found that breastfeeding at discharge tended to be higher in NICUs that had DHM available to them (60.4% vs 52.8%).[13] A single-center study conducted in the Connecticut Children's Medical Center's level-4 NICU that examined data from 154 infants found that the introduction of a DHM policy was associated with a significant increase in the proportion of human milk in the infants' diet.[16]

A systematic review and meta-analysis conducted in 2003 based on 4 small trials that are now >30 years old found that infants who received DHM were 3 times less likely to develop NEC than infants who received formula.[12] The authors of that study cautioned the clinical applicability of those results due to the publication dates of the included trials.[12] A recent multicenter randomized controlled trial examined the effects of formula versus exclusive DHM feeding on 53 infants in 6 centers in the United States and 1 in Austria and found a significant decrease in NEC incidence with DHM.[17]

TABLE 2 Multivariable Logistic Regression Model for NEC

	Birth Weight	
	OR	(95% CI)
Birth weight (100-g increase)	0.84	(0.82–0.86)*
No DHM	1.15	(1.03–1.28)*
Maternal age		
<20 years	1.13	(0.96–1.33)
20–29 years	1.00 (ref)	
30–39 years	0.86	(0.77–0.97)*
≥40 years	0.83	(0.66–1.03)
No prenatal care	0.99	(0.77–1.28)
Multiple versus singleton birth	0.97	(0.86–1.10)
Outborn versus inborn location	1.05	(0.91–1.21)
NICU level		
Regional	1.00 (ref)	
Community	0.67	(0.60–0.75)*
Intermediate	0.41	(0.30–0.56)*
Non-CCS	0.54	(0.41–0.73)*
Cesarean versus vaginal delivery	0.88	(0.79–0.99)*
Race		
White	1.00 (ref)	
Native American	1.43	(0.78–2.60)
Asian/Pacific Islander	1.18	(0.97–1.44)
African American	1.32	(1.12–1.57)*
Other	1.48	(1.05–2.09)*
Ethnicity		
Non-Hispanic	1.00 (ref)	
Hispanic	1.28	(1.12–1.47)*
Apgar score (5 minute)		
0–3	1.00 (ref)	
4–6	1.36	(1.09–1.69)*
7–10	1.47	(1.19–1.80)*
Female versus male	0.82	(0.74–0.91)*
Major birth defect	1.19	(1.02–1.40)*
Normal weight for gestational age	1.57	(1.33, 1.84)*

* $P < .05$.

We found a significant association between a hospital's DHM status and increased breastfeeding and decreased NEC rates among VLBW infants. Specifically, access to DHM was associated with an absolute increase in the breastfeeding rate of 10% and an absolute decrease in the NEC rate of −2.6%. In multivariable logistic regression analyses, access to DHM remained a significant predictor of an infant's status regarding the likelihood of breastfeeding at discharge and decreased risk of NEC. The association of a lower risk of NEC and DHM availability is perhaps not unexpected, because human milk has been shown to be protective against NEC.[4,5] There was a similar absolute decrease in NEC in NICUs that did not acquire DHM. However, after risk adjustment, the lack of DHM in an NICU was associated with a higher risk of NEC.

Hypothetically, DHM could potentially give mothers an alternative avenue to obtain the benefits of human milk feedings without the duress of attempting to provide one's own breast milk as the only enteral nutrition for an infant in the NICU. However, as the investigators of the Italian study suggested,[13] DHM availability could foster a breastfeeding-friendly environment in which mothers may be more encouraged to attempt to provide their own milk. This situation appeared to be the case in the current cohort, with an increase in breastfeeding at discharge among the California NICUs that had DHM available.

A limitation of our study was our lack of information on individual hospital practices and policies on DHM. We do not know if, in NICUs using DHM, whether DHM was used primarily as a back-up feeding if mother's milk was unavailable, or used in another way, or in conjunction with human milk–derived fortifiers. We also do not know the proportion within each NICU of VLBW infants receiving DHM or the length of time that any individual infant would have received DHM. Our main predictor was DHM availability to infants in the NICU. Other interventions in NICUs could have contributed to the findings on NEC, including antibiotic stewardship programs, standardized feeding protocols, and restriction of antireflux medications; we did not have data on those practices.

Although our results are significant, it is important to realize that other factors are contributing to the changes in breastfeeding and NEC rates witnessed from 2007 to 2013. Indeed, there was also an increased rate of breastfeeding and a similar decreasing rate of NEC in hospitals that did not transition to using DHM during the study period. Societal attitudes toward breastfeeding are likely influencing mothers' attempts to provide breast milk to their VLBW infants. According to data from the Centers for Disease Control and Prevention, breastfeeding rates in general in the United States have been on the rise.[18] Early manual expression of colostrum has been encouraged in the NICU. The introduction of human milk–based fortifier created the option for a truly exclusively human milk diet, which has been shown to be associated with decreased NEC risk.[19] There has also been a steady increase in the number of International Board-Certified Lactation Consultants since 2006, from 2.1 per 1000 live

births in 2006 to 3.5 in 2013.[18] It is possible that NICUs with a DHM program may have greater lactation support than those that do not. The NICU battle against NEC is ongoing, and other advances in care that occurred from 2007 to 2013 could be contributing to the observed decrease in NEC rate in hospitals that acquired DHM.

CONCLUSIONS

Our results suggest that the availability of DHM in a hospital is linked to better outcomes for the VLBW infants treated at that NICU. The acquisition of DHM should be considered a worthwhile quality improvement initiative that NICUs can undertake as part of broad strategies to improve nutrition for preterm neonates.

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ABBREVIATIONS

CCS: California Children's Services
CI: confidence interval
CPQCC: California Perinatal Quality Care Collaborative
DHM: donor human milk
HMBANA: Human Milk Banking Association of North America
MMB: Mothers' Milk Bank of San José
NEC: necrotizing enterocolitis
OR: odds ratio
VLBW: very low birth weight

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Impact of Donor Milk Availability on Breast Milk Use and Necrotizing Enterocolitis Rates

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