

## Donor human milk and fortifier use in United States level 2, 3, and 4 neonatal care hospitals

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### **Abstract:**

**Objective:** In 2011, the United States Surgeon General issued a call to action to “identify and address obstacles to greater availability of safe banked donor milk for fragile infants.” The purpose of the present study is to analyze patterns in donor human milk (DHM) and fortifier use in level 2, 3, and 4 neonatal facilities in 2015 and to identify factors associated with nonuse. **Methods:** Data from the 2015 Maternity Practices in Infant Nutrition and Care survey, conducted by the Center for Disease Control and Prevention, were analyzed for questions about feeding practices within neonatal hospitals. **Results:** The percentage of neonatal facilities that reported using DHM in 2015 was 38.3%, up 74% from 2011. The majority of level 3 and level 4 facilities reported using DHM (65.7% and 73.3%, respectively) and fortifiers (96.1% and 91.9%, respectively). Within DHM-using facilities, a wide range of DHM feeding patterns was reported. The prevalence of DHM use was higher in facilities that had the highest rates of mother's own milk feedings ( $P < 0.001$ ), in facilities that were participating in the Baby Friendly Hospital Initiative ( $P < 0.001$ ), and in facilities that were in a state with an operating milk bank ( $P < 0.001$ ). **Conclusions:** DHM use continues to increase in advanced care neonatal settings, with significant difference based on acuity level, facility size, breast-feeding culture, and proximity to a milk bank. Geographic gaps in DHM use provide the opportunity for targeted efforts to improve access.

**Keywords:** donor milk | fortifier | human milk | neonatal feeding

**Article:**

**What Is Known**

- Pasteurized donor human milk is the recommended feeding alternative for preterm infants who do not have access to their mother's milk.
- In 2011, less than one-fourth of advanced care neonatal facilities in the United States reported using donor human milk.

**What Is New**

- The percentage of neonatal care facilities using donor human milk increased 74% between 2011 and 2015.
- Donor human milk use was more likely in facilities with higher breast-feeding rates, participating in the Baby Friendly Hospital Initiative, and in a state with a milk bank.

In 2011, the United States Surgeon General issued a call to “identify and address obstacles to greater availability of safe banked donor milk for fragile infants” as part of the Call to Action to Support Breastfeeding <sup>(1)</sup>. The American Academy of Pediatrics recommends the use of pasteurized donor human milk (DHM), appropriately fortified, for preterm infants when their mother's own milk (MOM) is unavailable or contraindicated, with specific priority for infants weighing <1500 g at birth <sup>(2,3)</sup>. The use of DHM is primarily supported by evidence of reduced rates of necrotizing enterocolitis in very-low-birth-weight infants fed pasteurized DHM compared to preterm formula, although slower growth in these infants was also observed <sup>(4)</sup>. Recent research showed no difference in growth at discharge and continued protection against NEC when DHM was regularly fortified with commercial bovine-based fortifiers <sup>(5)</sup>. Protein and mineral requirements for the preterm infant suggest that human milk typically requires fortification <sup>(6)</sup>. Currently, there are commercially available human milk fortifiers derived from both bovine milk and from human milk. In vitro studies suggest that bovine-derived fortifiers may disrupt antimicrobial properties of human milk <sup>(7)</sup>. Clinical trials of bovine-derived versus human-derived fortifiers have been confounded by supplementation with infant formula, making it difficult to attribute effects to fortifiers versus supplemental formula <sup>(8)</sup>. Limited information is available regarding the prevalence of fortifier use in advanced care neonatal facilities.

At the time of the Surgeon General's Call to Action, the use of DHM in advanced care maternity settings was limited. Perrine and Scanlon reported increasing percentages of advanced care maternity hospitals providing DHM between 2007 and 2011 using data from the Centers for Disease Control and Prevention's (CDC) Maternity Practices in Infant Nutrition and Care (mPINC) survey, with 22.0% of all neonatal hospitals (levels 2 and 3) using DHM and 45.2% of intensive care units (level 3 only) reporting DHM use in 2011 <sup>(9)</sup>. Similarly, a survey administered in 2012 by Parker et al <sup>(10)</sup> reported that 42% of level 3 intensive care units were using DHM. Since 1985, the Human Milk Banking Association of North America (HMBANA) has operated donor milk banks that screen, collect, process, and distribute Holder pasteurized DHM <sup>(11)</sup>. In 2011, there were 10 HMBANA milk banks distributing milk in the United States. By the close of 2016 there were 23 HMBANA milk banks distributing Holder pasteurized DHM in the United States, and also several for-profit companies offering different forms of screened and processed human milk <sup>(12,13)</sup>. The primary purpose of this study is to analyze patterns in DHM and fortifier use in level 2, 3, and 4 neonatal hospitals using data from the 2015 mPINC survey. A secondary objective is to identify gaps in DHM use to inform efforts to support the Surgeon General's Call to Action to remove barriers to DHM use.

**METHODS**

Survey methodology for CDC's biannual mPINC survey has been described in detail elsewhere <sup>(9)</sup>. Briefly, beginning in 2007, all health care facilities providing routine maternity care were invited to participate in a biannual survey about practices related to breast-feeding. The 2015 survey included 60 questions and was intended to be completed in approximately 30 minutes by a key hospital informant knowledgeable about infant nutrition. Hospitals who participate in the mPINC survey receive a Benchmarking Report comparing them to other hospitals nationally and within their state, which is likely an incentive for participation. The response rate for the 2015 mPINC survey was 82%. Data from the 2015 mPINC survey for facilities designated as neonatal level 2, 3, and 4 were included in the analysis. Level 2 facilities are capable of providing care for infants >32 weeks gestation and weighing more than 1500 g, whereas levels 3 and 4 facilities have the capabilities to care for infants weighing <1500 g <sup>(14)</sup>. Two questions from the 2015 mPINC survey informed this analysis: “Approximately what percentage of infants in the special care or intensive care unit regularly receive the following: Mother's own breast milk, Banked donor milk, Formula” (question A35); “Does your special care or intensive care unit use human milk fortifier (HMF)? Commercial bovine-based human-milk fortifier, non-bovine human milk–based fortifier (eg, Prolacta)” (question A36). Surveys were excluded from analysis for the following reasons: if they provided no information about feeding types (2.9%); if they indicated zero for all feeding types (0.7%); or if the combined feedings reported were below 50% (0.3%). A total of 3.9% of surveys were excluded from the analysis.

Using survey data, a facility was classified as a DHM user when they reported a percentage of infants regularly receiving DHM >0%. Facilities were also classified by their level of MOM feedings based on distribution of the population data, with quartile 1 (<55%) and quartile 3 (> 85%) used as cut-off values for defining low-MOM and high-MOM facilities, respectively, and mid-MOM representing the middle 50% of the population. Summary statistics for numerical data on feeding patterns are reported as medians and quartiles due to a non-normal distribution of the data. Differences in feeding patterns between subgroups in the dataset were evaluated using a Chi-square test for categorical variables and a Kruskal-Wallis test for numerical variables. Summary mPINC data by state was combined with preterm birth data and milk bank location data to probe for geographic gaps in which preterm births are high and donor milk utilization is low. Data were analyzed using SAS Enterprise Edition 9.4 (SAS Corporation, Cary, NC). This research received an exempt status from the University of North Carolina Greensboro Institutional Review Board (protocol 16-0464).

## RESULTS

**Table 1.** Number (%) of specialty and intensive care hospitals responding to the 2015 Maternity Practices in Infant Nutrition and Care survey question by facility characteristics

	Number (%)
Hospitals (total level 2, 3, and 4)	1379
Hospitals (%) by level of care	
Level 2	754 (54.7)
Level 3	539 (39.1)
Level 4	86 (6.2)
Hospitals (%) by annual births	
<250	31 (2.3)

	Number (%)
250-499	145 (10.5)
500-999	279 (20.2)
1000-1999	446 (32.3)
2000-4999	428 (31.0)
5000+	50 (3.6)

A summary of the neonatal hospitals included in the mPINC survey analysis by level of care and number of annual births is presented in Table 1.

### Prevalence of Facilities Using Donor Human Milk and Fortifiers

In 2015, 38.3% of level 2, 3, and 4 neonatal hospitals reported using DHM. There was a significant difference in use by level of care ( $P < 0.001$ ) and annual births ( $P < 0.001$ ). The majority of level 3 (65.7%) and level 4 (73.3%) hospitals, which are the facilities tasked with caring for infants weighing <1500 g, reported using DHM. Most facilities (82.2%) reported using a fortifier for human milk, with 67.2% using a bovine-based fortifier and 18.4% using a human milk-based fortifier. Any fortifier use, and human milk-based fortifier use were more prevalent in level 3 facilities (96.1% and 30.4%, respectively) and in level 4 facilities (91.9% and 33.7%, respectively) than in level 2 facilities (71.2% and 8.1%, respectively). Facilities with more than 5000 births annually had the highest prevalence of DHM use (82.0%), fortifier use (98.0%), and human milk-based fortifier use (36.0%). Table 2 provides a summary of DHM and fortifier use by facility type and size.

**Table 2.** Percentage of neonatal facilities using donor human milk and fortifiers in 2015 by level of care and facility size

	Neonatal facilities using donor human milk		Neonatal facilities using human milk fortifiers*					
	%	$P^\dagger$	% Any	Any- $P^\dagger$	% Bov	Bov- $P^\dagger$	% HM	HM- $P^\dagger$
All facilities	38.3		82.2		67.2		18.4	
By care level		<0.001		<0.001		<0.001		<0.001
Level 2	14.7		71.2		60.5		8.1	
Level 3	65.7		96.1		75.9		30.4	
Level 4	73.3		91.9		72.1		33.7	
By annual births		<0.001		<0.001		<0.001		<0.001
<250	6.5		22.6		9.7		12.9	
250-499	7.6		40.0		33.1		4.8	
500-999	13.6		78.5		63.8		12.9	
1000-1999	35.7		89.2		76.0		15.3	
2000-4999	64.7		94.2		74.5		28.3	
5000+	82.0		98.0		80.0		36.0	

Any = any fortifier use; Bov = bovine milk-derived fortifier use; HM = human milk-derived fortifier use.

\* Some facilities reported using both bovine-derived and human milk-derived fortifiers; therefore, the sum of Bov and HM may exceed Any.

$^\dagger$  Using Chi-square test.

### Feeding Patterns in Neonatal Facilities Using Donor Human Milk

Infants in neonatal settings can receive a mix of feeding types including MOM, infant formula, and DHM. Within facilities that reported using DHM in 2015 (N = 528) there was a wide variety

of DHM exposure as defined by the percentage of infants who regularly received DHM feedings. The median percent of infants routinely receiving DHM within all DHM using facilities was 15.0, with a range of 0.8 to 100 and an intraquartile range (Q3–Q1) of 23.0. The distribution of the percentage of infants who routinely received DHM did not vary significantly by facility level ( $P = 0.11$ ) or by number of annual births ( $P = 0.55$ ).

#### Facility Attributes Associated With Donor Milk Use

When comparing hospitals based on the level of regular exposure to MOM's milk, there was a significant difference in the proportion of facilities using DHM based on high-MOM, mid-MOM, and low-MOM use (45.0%, 41.8%, and 25.2%, respectively;  $P < 0.001$ ). Similarly, there was a significant difference in the distribution (median, interquartile range) of percent of infants regularly receiving DHM in high-MOM (0.0, 10.0), mid-MOM (0.0, 10.0), and low-MOM (0.0, 5.0) facilities ( $P < 0.001$ ). When limiting the analysis to level 3 and level 4 facilities, there was no difference in the proportion of facilities using DHM ( $P = 0.35$ ) or in the distribution of the percentage of infants regularly receiving DHM feedings ( $P = 0.67$ ) based on level of MOM feeding. Significant differences in facility use of DHM ( $P < 0.001$ ) and the distribution of the percentage of infant receiving DHM ( $P < 0.001$ ) were observed based on whether a facility was designated as Baby Friendly, in the Baby Friendly certification pathway, or not in the Baby-Friendly pathway, but these differences were not significant when limiting analysis to hospitals with the highest acuity level (level 3 and level 4). Findings are summarized in Table 3.

**Table 3.** Prevalence of facilities using any donor human milk and the percentage of infants regularly receiving donor human milk feedings in 2015 by different factors

	N	Facilities using DHM		% Infants regularly receiving DHM	
		Percentage	$P^*$	Median (IRQ)	$P^\dagger$
Level of exposure to MOM (all facilities)			<0.001		<0.001
Low MOM (<55%)	357	25.2		0.0 (5.0)	
Mid MOM (55%-85%)	682	41.8		0.0 (10.0)	
High MOM(>85%)	340	45.0		0.0 (10.0)	
Level of exposure to MOM (level 3 and 4)			0.35		0.67
Low MOM (<55%)	113	61.1		10.0 (25.0)	
Mid MOM (55%-85%)	345	67.5		10.0 (20.0)	
High MOM(>85%)	167	68.9		5.0 (25.0)	
Baby friendly hospital initiative (BFHI)			<0.001		<0.001
Baby-friendly facility	191	55.5		5.0 (20.0)	
In BFHI pathway	364	44.0		0.0 (15.0)	
Not in BFHI pathway	711	34.3		0.0 (10.0)	
Baby-friendly hospital initiative (level 3 and 4)			0.73		0.64
Baby-friendly facility	123	70.7		10.0 (25.0)	
In BFHI pathway	187	68.5		9.5 (20.0)	
Not in BFHI pathway	283	66.8		10.0 (20.0)	
Geographic location to milk bank (all facilities)			<0.001		<0.001
Milk bank in state	595	46.9		0.0 (20.0)	
No milk bank in state	784	31.8		0.0 (5.0)	
Geographic location to milk bank (level 3 and 4)			<0.001		<0.001
Milk bank in state	282	79.1		12.0 (25.0)	
No milk bank in state	343	56.6		5.0 (15.0)	

BFHI = baby-friendly hospital initiative; DHM = donor human milk; IQR = interquartile range; MOM = mother's own milk.

\* Computed using Chi-square test.

† Computed using Kruskal-Wallis test to evaluate differences in distributions between groups.

### Geographic Differences in Donor Milk Use

Between 2011 and 2015, 6 new HMBANA milk banks began dispensing DHM in the United States, bringing the total number of states with an operating nonprofit or commercial milk bank to 15: California, Colorado, Iowa, Indiana, Massachusetts, Michigan, Missouri, Montana, North Carolina, Ohio, Oklahoma, Oregon, South Carolina, Texas, and Virginia. In 2015, the percentage of neonatal facilities using DHM in states with a milk bank (Table 3) was 46.9% compared to 31.8% in states without a milk bank ( $P < 0.001$ ). Similarly, the distribution (median, interquartile range) of the percentage of infants regularly receiving DHM feedings was significantly different ( $P < 0.001$ ) in milk-bank states (0.0, 20.0) compared to nonmilk bank states (0.0, 5.0). When limiting analysis to levels 3 and 4 facilities, a significant difference continued to be observed in the percentage of facilities using DHM ( $P < 0.001$ ) and the distribution of the percentage of infants regularly receiving DHM ( $P < 0.001$ ) based on the presence of a state milk bank. The states with the lowest percentage of neonatal facilities using DHM are summarized in Table 4, along with the preterm birth rate<sup>(15)</sup> and milk bank status for each state.

**Table 4.** States with the lowest percentage of neonatal facilities that reported using donor human milk in 2015

All level 2, 3, and 4 neonatal facilities				Level 3 and 4 neonatal facilities only			
State	% Using DHM	Preterm births (15) (%)	Milk bank in state?	State	% Using DHM	Preterm births (15) (%)	Milk bank in state?
<b>WV</b>	11.1	11.3	No	CT	25.0	9.4	No
NM	13.3	9.5	No	NY	26.5	8.7	No*
ME	14.3	8.5	No	<b>NJ</b>	29.4	9.8	No
<b>NJ</b>	14.7	9.8	No	<b>AL</b>	40.0	11.7	No*
NY	16.1	8.7	No*	<b>NV</b>	40.0	9.9	No
<b>TN</b>	19.4	11.0	No†	<b>LA</b>	43.5	12.3	No†
<b>AL</b>	21.4	11.7	No*	<b>KY</b>	50.0	10.8	No
<b>NE</b>	21.4	9.9	No	NM	50.0	9.5	No
<b>IL</b>	22.2	10.2	No*	<b>TN</b>	50.0	11.0	No†
CT	25.0	9.4	No	<b>FL</b>	54.5	10.0	No*

**Bold**—state with preterm birth rate greater than national average of 9.6%.

DHM = donor human milk.

\* Milk bank has opened since 2015.

† Milk bank under development in 2017.

## DISCUSSIONS

The use of DHM in neonatal facilities in the United States is increasing according to data from the CDC's biannual mPINC survey. Results from the 2011 mPINC survey reported 22.0% of neonatal facilities using DHM<sup>(9)</sup>, compared to 38.3% in the 2015 survey, which represents a 74% increase over 4 years. Parker et al<sup>(10)</sup> described a rapid adoption of DHM programs in 2012, with 85% of DHM using facilities reporting that their DHM programs were <5 years old. Findings from the most recent mPINC survey suggest that hospital DHM programs continue to rapidly expand. The majority of level 3 (65.7%) and level 4 (73.3%) facilities, in which infants weighing <1500 g are routinely cared for, reported using DHM in 2015. With an increased

demand for DHM, concern exists regarding potential shortages<sup>(16)</sup>. Evidence of national human milk shortages is limited. A 2012 survey of level 3 facilities reported only 1% dissatisfaction with the turnaround time of receiving DHM<sup>(10)</sup>, and HMBANA has reported steady growth in the volume of milk dispensed and new milk banks opened<sup>(16)</sup>. In addition, peer-to-peer milk sharing is prevalent in the United States<sup>(17,18)</sup> and lactating women have reported receiving limited information about donation from their physicians<sup>(19,20)</sup>, suggesting that donation rates may be improved by integrating donation discussions into the perinatal care process. Nonetheless, the availability of DHM for neonatal facilities is an important metric to monitor given limited regulation of human milk exchange in the United States and the public health call to prioritize access for medically fragile infants<sup>(1,3)</sup>.

Within facilities that reported using DHM, there was a wide range of DHM feeding patterns, with the interquartile range of infants regularly receiving DHM ranging from 7.0% to 30.0%. Wide variations in DHM initiation and discontinuation patterns have been reported by others<sup>(10,21)</sup>, suggesting this is an important area of research in the context of developing evidence for the use of DHM to improve health outcomes. Fortifier use was the norm in neonatal facilities, with more than 90% of level 3 and level 4 facilities fortifying human milk, and almost one third of these facilities using a human milk–derived fortifier. While both the AAP and ESPGHAN recommend human milk fortification for preterm infants to attain target growth, hospital level data regarding fortifier use in the United States is scarce. Findings from this study of high, but not universal, fortifier use in level 3 and 4 NICUs (96.1% and 91.9%, respectively), raises questions about data integrity given consensus among professional organizations regarding the need for fortification. Studies published in the last 10 years in other developed countries have reported fortifier use at the hospital level ranging from 84% to 100%, which is line with findings from this study<sup>(22–24)</sup>. The significant relationship between facility size and fortifier use reported in this study warrants further investigation regarding potential barriers in smaller facilities.

Facilities with a high percentage of infants receiving MOM feedings (>85%), and facilities that were participating in the Baby Friendly Hospital Initiative reported significantly higher utilization of DHM, suggesting that a strong breast-feeding culture is associated with DHM use. Others have reported a symbiotic relationship between MOM feedings and the use of DHM. In retrospective reviews, Parker et al<sup>(25)</sup> and Kantorowska et al<sup>(26)</sup> described increased rates of MOM feedings in facilities after implementation of a DHM program. Similarly, a study conducted in Italy found significantly higher exclusive breast-feeding rates at discharge in intensive care facilities with a human milk bank compared to facilities without a milk bank<sup>(27)</sup>. Interestingly, differences in MOM feedings and baby-friendly status were not significant when limiting analysis to level 3 and 4 neonatal facilities, suggesting that facilities with higher patient acuity may prioritize access to DHM independent of breast-feeding culture. Future research should explore barriers to DHM use within neonatal facilities. There is evidence of racial differences in consent to use DHM<sup>(28,29)</sup>. A 5-year longitudinal study showed a significant decline in nonconsent across races, with an overall nonconsent rate in 2015 of 8.0%, suggesting that DHM is becoming more acceptable to many families<sup>(29)</sup>. These studies were done regionally, so findings may not be applicable to other geographic areas. Other barriers to DHM use that have been reported include costs, and lack of knowledge among health care providers<sup>(10)</sup>.

Geographic differences in DHM use have previously been reported, with a higher percentage of facilities using DHM in the West and Midwest<sup>(10)</sup>, and in hospitals in close proximity to a human milk bank<sup>(9)</sup>. In this analysis, geographic proximity to a milk bank continued to be associated with significantly higher DHM use in 2015, even when limiting analysis to high acuity facilities. In addition, the 10 states with the lowest percentage of neonatal facilities using DHM were all states that did not have an operating milk bank. It is unclear whether the presence of a milk bank increases general awareness of donor milk, or whether outreach efforts of local milk bank staff contribute to the increased prevalence of use. Since the administration of the 2015 mPINC survey, 7 new HMBANA milk banks have opened in the United States, 4 others are under development, and additional commercial entities have entered the human milk market, suggesting ongoing growth in the availability and use of DHM.

Although there were multiple factors in the present study that were significantly associated with increased prevalence of DHM use across all level 2, 3, and 4 facilities, geographic proximity to a milk bank was the only factor that was significantly associated with DHM utilization when limiting analysis to level 3 and 4 hospitals. The prevalence odds ratio<sup>(30)</sup> for DHM use within levels 3 and 4 facilities based on the presence or absence of a state milk bank was 2.90. Currently, the strongest evidence of the need and benefit for DHM is within populations served at these high acuity facilities<sup>(3,4)</sup>. This research suggests that milk banking organizations play an important role in driving acceptance and utilization of DHM within high-acuity facilities. Further research into effective models for scaling milk banking services is warranted, with a priority on reaching states with low rates of DHM use and high preterm birth rates.

A strength of this study is the high participation rate in the biannual mPINC survey. In addition, revisions to the mPINC survey now provide more detailed information about DHM feeding patterns and fortifier use within each facility. There are several weaknesses to this study: the survey is completed by 1 individual and is thus dependent on their knowledge of feeding patterns in the neonatal care setting; the survey did not define what “regularly receives” means when asking about infant feeding exposure which may be interpreted differently by survey participants; the survey is expected to be completed in 30 minutes or less; therefore, the infant feeding data may be based on estimates instead of actual data; the survey is limited to maternity centers so neonatal facilities at nonbirth centers are not included in the analysis; and demographic information on DHM recipients and health outcome information is not assessed. Although there was lack of specificity to the survey question regarding what “regularly receives” means, findings from the analysis of this question were similar to findings from the analysis of baby-friendly status, a highly specific question that also serves as a proxy for evaluating breast-feeding culture. Findings from both questions suggest that the role of breast-feeding culture on DHM use may be more impactful in lower acuity environments than in levels 3 and 4 facilities.

Data presented in the present study describe growing utilization of DHM within advanced care neonatal settings, with significant differences based on facility size, acuity level, breast-feeding culture, and geographic proximity to a milk bank. Future research is needed to identify patterns of DHM use by infant demographic characteristics including race, income, birth weight, and gestational age; identify effective strategies for scaling milk banking services in target geographies; and develop evidence regarding the effectiveness of using existing and emerging DHM products in preterm infants and other populations.

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