

# Clinical and Sociodemographic Factors Associated With Human Donor Milk Supplementation in Term Newborns

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## ABSTRACT

**OBJECTIVES:** To identify differences between healthy term newborns supplemented with human donor milk (HDM) and those supplemented with infant formula. We hypothesized that sociodemographic and clinical distinctions exist between newborns receiving different milk types.

**METHODS:** This retrospective study included term newborns admitted to the postpartum unit between March 2017 and April 2019 with  $\geq 1$  supplemental feeding with HDM or formula for indications other than hypoglycemia. Maternal and newborn data were abstracted from the electronic medical record.

**RESULTS:** Five hundred eighty-four dyads met inclusion criteria. More newborns received supplementation with formula than with HDM (57.7% vs 42.3%;  $P < .001$ ). Infants undergoing phototherapy who required supplementation were more likely to receive HDM ( $P < .001$ ). Newborns born to white and non-Hispanic mothers were more likely to receive HDM than those born to African American (adjusted odds ratio [aOR] 5.6;  $P = .007$ ), Hispanic (aOR 3.0;  $P = .001$ ), or Asian American mothers (aOR 2.7;  $P = .007$ ). Newborns born to primiparous women (aOR 1.6;  $P = .03$ ), those born to women with private insurance (aOR 3.7;  $P < .001$ ), and those born via cesarean delivery (aOR 2.0;  $P < .001$ ) were more likely to receive HDM. HDM use was more likely in primary English- or Spanish-speaking households (aOR 8.5;  $P = .009$ ). Newborns receiving their first supplemental feeding during the day (aOR 1.9;  $P = .001$ ) were more likely to be supplemented with HDM.

**CONCLUSIONS:** There are clinical and sociodemographic differences between healthy term newborns supplemented with HDM and formula. These findings reveal that there are disparities in current supplementation practices for healthy newborns.

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Ms McKittrick performed data abstraction for all participants, conducted the initial analyses, and drafted the initial manuscript; Drs Khaki and Gievers conceptualized and designed the study, designed the data collection instrument, coordinated the final analyses, and reviewed and revised the manuscript; Dr Larson conceptualized and designed the study, designed and oversaw the data collection instrument and data abstraction, coordinated the final analyses, and critically reviewed the manuscript; and all authors approved the final manuscript as submitted.

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Extensive literature exists revealing the medical and socioeconomic benefits of exclusive breastfeeding.<sup>1</sup> To this point, the American Academy of Pediatrics (AAP) recommends exclusive breastfeeding for the first 6 months of life.<sup>2</sup> During the birth hospitalization, some newborns of mothers intending to breastfeed experience excessive weight loss, hyperbilirubinemia, or mother-infant separation and ultimately receive supplementation. Historically, pasteurized human donor milk (HDM) has been used for supplementation of very low birth weight, premature, or critically ill infants in the NICU.

In recent years, HDM has become more widely available, with some hospitals in the United States now offering HDM for supplementation in healthy term newborns. Although there is a clear medical benefit of HDM as opposed to formula for preterm newborns who are critically ill,<sup>3,4,5</sup> the literature on term newborns is more limited. There is evidence that formula feeding in the first 2 years of life is associated with significant changes in the intestinal microbiome of term newborns, including those who receive concurrent breast milk.<sup>4,6</sup> Although this suggests a possible benefit of HDM, there have been no additional investigations of clinical outcomes in healthy newborns supplemented with HDM. Despite this, the use of HDM in term newborns has increased rapidly.<sup>7,8</sup> The Academy of Breastfeeding Medicine, the AAP, and the World Health Organization all recommend supplementation with HDM when expressed mother's milk is not available and supplementation is required.<sup>9,10,11</sup>

Multiple studies have revealed demographic patterns of nonconsent for HDM in the NICU.<sup>12,13</sup> These important studies reveal a disparity gap in the receipt of HDM for preterm neonates, but equivalent studies in healthy newborns are lacking. In several qualitative studies, parental knowledge and attitudes toward HDM in parents of term newborns have been examined.<sup>14,15</sup> However, little is known about the sociodemographic characteristics of term newborns who receive supplementation with HDM. Given the increasing availability of HDM as a

supplement option for term newborns, it is important to understand how multiple factors contribute to HDM use. The purpose of this study is to examine the characteristics of healthy term newborns receiving supplementation with HDM compared with infant formula and identify differences between these groups.

## METHODS

In this retrospective study, we investigated supplementation in newborns in the Mother Baby Unit (MBU) at a single quaternary academic medical center in the Pacific Northwest. There are ~2250 deliveries annually, with a cesarean delivery rate of 30%. The patients admitted to the MBU were primarily white (77%) and non-Hispanic (81%). Most patients had a primary language of English (92%), with 6% of patients primarily Spanish speaking. Phone translation services were available around the clock for assistance with assent in families with limited English proficiency. Sixty-three percent of patients admitted to the MBU in 2019 had commercial insurance. The center's institutional review board approved this study.

Eligibility criteria for this study included term newborns  $\geq 37$  weeks' gestation admitted to the MBU between March 1, 2017, and April 30, 2019, with a maternal intent to breastfeed and at least one supplemental feeding with either HDM or infant formula. Exclusion criteria included birth weight  $< 2500$  g, maternal or newborn contraindications to breastfeeding, supplementation for hypoglycemia (defined as blood glucose level  $< 40$  mg/dL within the first 4 hours after birth or  $< 45$  mg/dL at  $\geq 4$  hours of age), exclusive formula feeding, and nonviable newborns. The electronic medical record (EMR) query used to identify eligible patients was originally designed for a quality-improvement project to decrease supplementation in healthy newborns; as such, hypoglycemic newborns were excluded from the build and subsequently excluded from this subanalysis.

During the study period, our center was working toward Baby-Friendly Hospital Initiative designation. The institutional breastfeeding-initiation rate was ~80%.

HDM had been available in the MBU since October 2013. Supplemental feeding required a physician order; families could choose pasteurized HDM purchased by the hospital from a local Human Milk Banking Association of North America milk bank or infant formula. Use of HDM required signed assent obtained by a nurse or physician. Term newborns were eligible to receive HDM if there was a plan to provide breast milk after discharge and if they had either a medical indication for supplementation (per hospital policy, potential indications include temporary separation from their mother, hypoglycemia, jaundice, dehydration, excessive weight loss, or prematurity) or a recommendation for supplementation from a lactation specialist or physician. HDM was not available to families without intention to breastfeed or those requesting supplementation for personal preference. Both milk options were available to families without charge and were kept accessible to unit staff in the same location within the MBU.

## Data Collection

Eligible dyads were identified through a custom EMR query, and select newborn and maternal fields were abstracted into the study database. Abstracted data included newborn feeding data (time of first supplementation and supplemental milk type); newborn medical data, including factors that increase the likelihood of supplementation (birth weight, gestational age at birth, and receipt of phototherapy during birth hospitalization); NICU transfer; 30-day readmission; and maternal data (delivery method, parity, age, race and/or ethnicity, insurance coverage, and primary language). Birth weight was transformed into an ordinal variable and categorized into 4 groups. Gestational age was categorized as early term (37 + 0/7–38 + 6/7 weeks), term (39 + 0/7–40 + 6/7 weeks), or late term (41 + 0/7–42 + 6/7 weeks). Method of delivery was dichotomously split into vaginal (including operative vaginal delivery and vaginal birth after cesarean delivery) or cesarean delivery. Maternal age was separated into 4 categories determined by quartile. Time of first supplementation was coded

dichotomously as day shift (7:00 AM–6:59 PM) or night shift (7:00 PM–6:59 AM).

### Statistical Analyses

Descriptive statistics were calculated for each variable. The 2 groups of subjects were compared by using  $\chi^2$  tests for association. A univariate analysis was performed for each independent variable to determine which to include in the final regression model. Only variables with a  $P$  value  $\leq .2$  were included in the pooled logistic regression model. Binomial logistic regression was used to evaluate the relationships between clinical and sociodemographic factors and the type of supplementation received. All statistical analyses were conducted by using SPSS Statistics for Macintosh software, version 25 (IBM SPSS Statistics, IBM Corporation), with a significance level of  $P < .05$ .

## RESULTS

### Participant Characteristics

Six hundred two dyads were identified through the EMR query (Fig 1). Of these, 18 received supplementation with both HDM and formula; the maternal and newborn characteristics of this group were similar to those of the overall cohort. Given the small size of this group, they were excluded from further analysis. In the final cohort of 584 dyads, the average maternal age was 31.3 years (SD = 6.1). The majority of women were white (73.3%) and non-Hispanic (75.8%). A slight majority held private insurance at the time of delivery (51.0%). Fifty-three percent of mothers were multiparous, and 54.8% delivered vaginally (Table 1).

### Supplementation Practices

Supplementation with infant formula was more frequent than supplementation with HDM and was provided to 337 newborns (57.7%) in this cohort. Most patients received their first supplemental feeding during a night shift (55.5%), and 26.3% received supplementation within 12 hours of delivery.

Multiple demographic characteristics were associated with HDM supplementation compared with formula supplementation. In the univariate analysis, there were

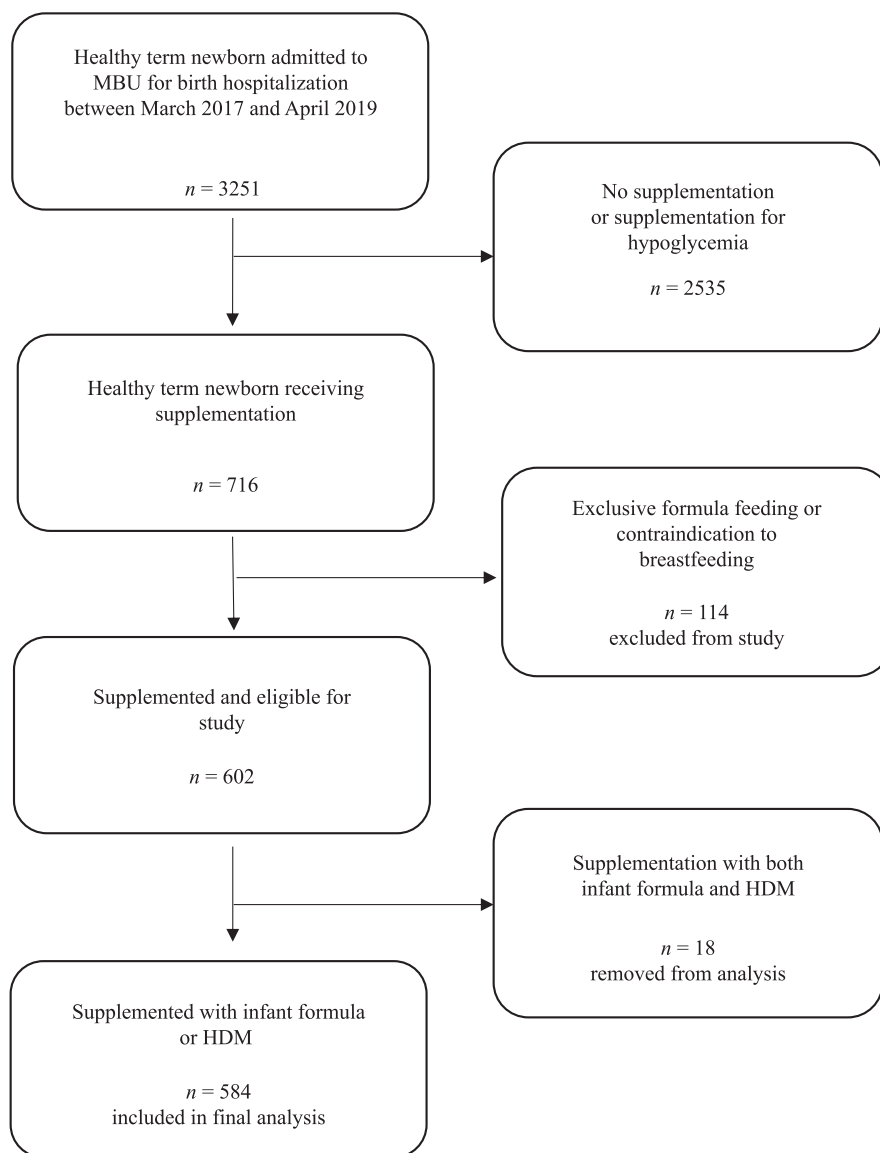


FIGURE 1 Diagram of study participants.

associations with receipt of HDM and multiple factors, including timing of the newborn's first supplementation, gestational age, delivery mode, maternal parity, insurance type, ethnicity, race, receipt of phototherapy, and transfer to the NICU (Table 1). These factors were combined to build the final multivariate logistic regression model. Birth weight category, supplementation within 12 hours of delivery, and 30-day readmission status were not significant in the univariate analysis and were not included in the multivariate model. On the basis of multivariate analysis, there were multiple newborn characteristics that

were associated with receipt of HDM (Table 2). Newborns receiving their first supplemental feeding during the day shift were twice as likely to receive HDM compared with those first supplemented during the night shift (adjusted odds ratio [aOR] 1.9;  $P = .001$ ). Of newborns receiving phototherapy during their birth hospitalization, HDM was used more frequently than formula (81.3% vs 18.6%;  $P < .001$ ). After controlling for potential interactions, gestational age and NICU transfers were no longer statistically significant predictors of supplement type.

**TABLE 1** Characteristics of Participants by Supplement Type

	HDM ( <i>N</i> = 247), <i>n</i> (%)	Infant Formula ( <i>N</i> = 337), <i>n</i> (%)	<i>P</i>
<b>Maternal characteristics</b>			
Age, y			<.001
27	28 (11.3)	98 (29.1)	—
27–32	86 (34.8)	104 (30.9)	—
33–36	79 (32.0)	69 (20.5)	—
36	54 (21.9)	66 (19.6)	—
Ethnicity			<.001
Hispanic	22 (8.9)	104 (30.7)	—
Non-Hispanic	219 (88.7)	223 (66.2)	—
Declined	6 (2.4)	10 (3.0)	—
Race			<.001
White	202 (81.8)	228 (67.7)	—
African American	4 (1.6)	23 (6.8)	—
Asian American	21 (8.5)	27 (8.0)	—
Other	10 (4.0)	25 (7.4)	—
Declined	10 (4.0)	34 (10.1)	—
Language			<.001
English	236 (95.5)	252 (74.8)	—
Spanish	7 (2.8)	54 (16.0)	—
Other	3 (1.2)	28 (8.3)	—
Insurance type			<.001
Public	57 (22.9)	214 (63.1)	—
Private	187 (75.1)	114 (33.6)	—
None	3 (1.6)	9 (2.9)	—
Parity, primiparous	154 (62.3)	122 (36.2)	<.001
Delivery method, vaginal	112 (45.3)	211 (62.6)	<.001
<b>Newborn characteristics</b>			
Birth wt, kg			.35
367	71 (28.7)	75 (22.3)	—
3067–3350	60 (24.3)	87 (25.8)	—
3351–3660	58 (23.5)	90 (26.7)	—
366	58 (23.5)	85 (25.2)	—
Completed gestational age (wk)			.01
Early term (37 + 0/7–38 + 6/7)	83 (33.6)	119 (35.3)	—
Term (39 + 0/7–40 + 6/7)	138 (55.9)	192 (57.0)	—
Late or post term (41 + 0/7–42 + 6/7)	26 (10.5)	26 (7.7)	—
Supplement within 12 h	65 (26.3)	79 (23.4)	.48
Timing of first supplement, day shift	132 (53.4)	128 (38.0)	<.001
Receipt of phototherapy	35 (14.2)	8 (2.4)	<.001
Required transfer to NICU	5 (2.0)	1 (0.3)	.04
30-d readmission	3 (1.2)	5 (1.5)	.66

—, not applicable.

receive HDM ( $P < .001$ ). Newborns born to women who self-identified as white and non-Hispanic were also more likely to receive HDM when compared with newborns born to African American (aOR 5.6;  $P = .007$ ), Asian American (aOR 2.7;  $P = .007$ ), and Hispanic (aOR 2.9;  $P = .001$ ) mothers. HDM supplementation was more likely in families who spoke primarily English or Spanish compared with families with a different primary language (aOR 8.5;  $P = .009$ ). Maternal age did not have a significant impact on supplement type.

## DISCUSSION

There are numerous factors associated with a newborn receiving HDM compared with formula for supplementation during the birth hospitalization. Among demographic variables, newborns of white and non-Hispanic mothers had the greatest likelihood of receiving HDM. Private insurance coverage and a primary language of either English or Spanish also correlated with increased odds of HDM supplementation, although not to the degrees of race and ethnicity. Although these data do not provide evidence of causation, the disparities in supplement type could result from differences in parental attitudes, differences in provider counseling (which may be impacted by ease of counseling in families with limited English proficiency), systems-based differences, or a combination of factors. The literature has revealed that parents selecting a supplement are more likely to choose what is most familiar.<sup>10</sup> Given these findings, it is possible that multiparous mothers and/or mothers from specific sociodemographic backgrounds are more familiar with infant formula and therefore prefer this option. However, drawing a firm conclusion as to the basis of this relationship is beyond the scope of this study. There is also evidence that providers counsel African American and Hispanic mothers and mothers with limited English proficiency differently than white, English-proficient mothers when discussing breastfeeding, which may contribute to parental selection of supplement type.<sup>16,17,18</sup>

Clinically, multiple factors predicted supplementation with HDM. Our data

Multiple maternal characteristics were associated with HDM supplementation. Newborns of primiparous women were more likely to receive HDM supplementation

(aOR 1.6;  $P = .03$ ). Cesarean delivery doubled the odds of a newborn receiving HDM (aOR 2.3;  $P < .001$ ). Dyads with private insurance were 3.7 times more likely to

**TABLE 2** Significance and aOR Describing Relationships Between Maternal and Newborn Characteristics and Supplementation With HDM After Multivariate Logistic Regression

	<i>P</i>	aOR (95% Confidence Interval)
Maternal characteristics		
Age	.24	1.14 (0.92–1.42)
Ethnicity		
Non-Hispanic	Reference	—
Hispanic	.001	0.34 (0.18–0.63)
Race		
White	Reference	—
African American	.007	0.18 (0.05–0.63)
Asian American	.007	0.37 (0.18–0.77)
Other or unknown	.47	0.72 (0.30–1.75)
Language		
English	Reference	—
Spanish	.78	0.86 (0.29–2.51)
Other	.009	0.12 (0.02–0.58)
Insurance type		
Private	Reference	—
Public	<.001	0.27 (0.17–0.44)
Parity		
Primiparous	Reference	—
Multiparous	.03	0.61 (0.39–0.94)
Delivery method		
Vaginal	Reference	—
Cesarean	<.001	2.27 (1.49–3.45)
Newborn characteristics		
Completed gestational age	.14	1.14 (0.96–1.36)
First supplement		
Day shift	Reference	—
Night shift	.001	0.52 (0.34–0.77)
Phototherapy		
No	Reference	—
Yes	<.001	10.25 (3.97–26.47)
NICU transfer		
No	Reference	—
Yes	.29	3.34 (0.36–30.99)

—, not applicable.

Additionally, both cesarean delivery and phototherapy during admission were associated with a greater likelihood of supplementation with HDM. Although the exact cause of these associations remains unclear, both factors are associated with an increased potential medical need for supplementation. There is evidence that newborns delivered via cesarean delivery have greater weight loss than those delivered vaginally.<sup>19</sup> A newborn requiring phototherapy may benefit from supplementation. In these cases, it is possible that a provider is the one initiating the conversation about supplementation, in contrast to a situation in which a parent is requesting supplementation or assistance for low supply, fatigue, or other concerns. This study was conducted at an academic center moving toward Baby-Friendly Hospital Initiative designation, so it is possible that providers would advocate for HDM when initiating a discussion about the need for supplementation with a family.

Although clinical guidelines from the AAP, World Health Organization, and Academy of Breastfeeding Medicine<sup>9–11</sup> recommend supplementation with HDM when possible, there is currently no literature in which the medical benefit of HDM over formula for supplementation of healthy term newborns is directly compared. The absence of clinical superiority makes it challenging to advocate for one supplement type over the other in this situation. There is good evidence that certain sociodemographic factors, such as race and ethnicity, contribute to differences in the supplement type provided to preterm newborns in the NICU.<sup>20</sup> Our findings suggest that similar sociodemographic disparities exist in supplementation of healthy term newborns. Therefore, it is crucial for clinicians to remain mindful of their biases and the complex social dynamics contributing to a dyad's experience with newborn feeding.

The strengths of this study are twofold. There are no previous reports in which the characteristics of term newborns who receive HDM are described, and therefore this study helps to narrow an

revealed an association between timing of first supplementation and milk type, with newborns first supplemented during the day shift more likely to receive HDM. It is possible that the more frequent use of HDM as initial supplementation during the day shift reflects increased time for counseling and assent and, conversely, a hesitation to engage in the assent process at night. Additionally, this disparity may reflect a misconception in the perceived ease of

access to formula during night-shift hours. Both HDM and formula are readily accessible within the unit at all times, but training on the availability and steps for obtaining each milk type may vary between day and night shift and may influence provider-parent counseling. To our knowledge, there is no previous literature in which a relationship between time of first supplementation and milk type is discussed, and further investigation is warranted.



important knowledge gap. The large sample size of this study affords precision to these results and offers confidence in applying these results to similar populations. Our study has several limitations. The retrospective nature limited our ability to understand the indications for supplementation as well as parental and provider preferences toward supplementation type. Additionally, the use requirements of infant formula and HDM differ within our hospital setting. Families may use formula for supplementation for personal preference after education, even in the absence of a medical indication. In contrast, hospital policy limits the use of HDM in healthy term newborns to those with an intention to breastfeed and an identified medical indication for supplementation. It is possible that our results reflect different milk use due to the different requirements for the milk options; however, it is likely that the medical indications for supplementation would be equal across sociodemographic groups. Because of the retrospective methodology, we are unable to limit this analysis to only those infants with a medical indication for supplementation.

Additionally, newborns with hypoglycemia were not included in this analysis. This study was a subanalysis of a quality-improvement effort to decrease supplementation in term newborns in the MBU. Because hypoglycemia nearly always requires supplementation, the EMR query was designed to exclude any newborn with hypoglycemia. Lastly, this study was performed within a predominantly white, non-Hispanic population, which may limit generalizability to more diverse patient populations.

The trend of increasing HDM use in well-infant nurseries offers a myriad of future research directions. The clinical impact of HDM supplementation in term newborns has not been well described, and researchers of future studies should investigate the clinical outcomes of healthy term newborns receiving supplementation with HDM compared with infant formula. Given the paucity of literature examining the clinical and

social factors contributing to supplementation type in term newborns, we believe these findings offer an important perspective on supplementation practices. Future studies are warranted to prospectively examine the indications and decision-making processes surrounding supplementation.

## CONCLUSIONS

There are multiple clinical and sociodemographic differences in newborns receiving HDM compared with infant formula for supplementation. These findings highlight the continued need for awareness of the disparities that exist, especially as HDM supplementation becomes more widely available for healthy term newborns.

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