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TECHNIQUES AND PROCEDURES

Perceptions of the impact of a multidose human-milk fortifier on human-milk preparation practices in United States neonatal intensive care units: A survey of nutrition care team members

Amy Gates PhD, RDN[1,2] | **Heather V. Evans MS, RDN**[1,2] | **Alayne M. Gatto MS, RDN**[1,2] | **Jodee Le Vin MS, RDN**[1,2] | **Jessica L. Thornton MS, RDN**[1,2] | **Katina Langley MS, RDN**[1,2] | **Bethany S. Hodges MS, RDN**[1,2] | **Christina Valentine MD, RD**[3]

[1]Reckitt/Mead Johnson Nutrition, Evansville, Indiana, USA

[2]Department of Pediatrics, Medical College of Georgia, Augusta University, Augusta, Georgia, USA

[3]University Medical Center, College of Medicine, University of Arizona, Tucson, Arizona, USA

Correspondence
Amy Gates, PhD, RDN, Reckitt/Mead Johnson Nutrition, Medical Science Liaison, Medical & Scientific Affairs, 112 Deer Springs Road, Clarks Hill, SC 29821, USA.
Email: amy.gates@reckitt.com

Abstract

Background: In 2020, a multidose human-milk fortifier (MDHMF) was designed to improve the process of human-milk (HM) fortification. The bottle of MDHMF (5.5 oz, 163 ml) allows aseptic removal of HMF in a precise measure. This survey aimed to examine the experience of nutrition care team (NCT) members who used the MDHMF in a hospital setting.

Methods: A survey link (Qualtrics XM) was sent to NCT leaders ($N = 108$) at hospitals who participated in an evaluation of the MDHMF from June 1, 2020, through April 30, 2021. The NCT leaders sent the survey to members at their prospective hospitals ($n = 344$). The investigators did not know the identities of the recipients of the survey and collected no identifying information on respondents. Respondents were asked to evaluate their experience with the MDHMF compared with their previous practice.

Results: The majority of respondents ($n = 63$, 72%) reported that the MDHMF improved their HM preparation practices and was better than their previous practice for reducing the time to prepare ($n = 33$, 71.7%), ensuring the accuracy of fortified HM ($n = 32$, 69.6%), ensuring aseptic preparation ($n = 24$,

Abbreviations: AND, Academy of Nutrition and Dietetics; DHM, donor human milk; EHMF1, Enfamil acidified human-milk fortifier; EHMF2, Enfamil human-milk fortifier powder; HM, human milk; HMBANA, the Human Milk Banking Association of North America; HMF, human-milk fortifier; IRB, internal review board; MT, formula or milk room technician; mPINC, Maternity Practices in Infant Nutrition and Care; MOM, mother's own milk; NCT, nutrition care team; NHMF, novel human-milk fortifier; NICU, neonatal intensive care unit; NNP, neonatal nurse practitioner; PHMF, Prolacta human-milk fortifier; RD, registered dietitian; RN, registered nurse; SHMF1, Similac human-milk fortifier concentrated liquid; SHMF2, Similac human-milk fortifier hydrolyzed protein concentrate liquid; SHMF3, Similac human-milk fortifier powder.

52.2%), reducing HM waste ($n = 27$, 58.7%), and being easy to use ($n = 30$, 65.2%). Those responsible for evaluating nutrition status answered that the MDHMF was the same for feeding tolerance ($n = 41$, 58.6%), weight gain ($n = 47$, 67.1%), head growth ($n = 56$, 81.2%), and length growth ($n = 53$, 76.8%).

Conclusion: US neonatal intensive care unit NCT members perceived that the MDHMF resulted in improved HM preparation practices while maintaining growth and tolerance.

KEYWORDS
human milk, human milk fortifier, neonatal intensive care unit, premature infant

BACKGROUND

Human milk (HM) is the preferred source of nutrition for all infants and supplies unique benefits for the preterm infant.[1–4] The hospitalized infant's dependence on expressed mother's own milk (MOM), or donor HM (DHM) when maternal milk is unavailable, presents challenges for neonatal intensive care units (NICUs) that may not be equipped to prepare this milk safely.[5–8] In addition to the complexity of HM collection and delivery in the hospital setting, preterm and high-risk infants have increased nutrient needs that require the supplementation of micro- and macronutrients. Fortification of HM with a multinutrient HM fortifier (HMF) is a necessary step in processing HM for the hospitalized preterm infant.[9] Data from the Centers for Disease Control and Prevention's Maternity Practices in Infant Nutrition and Care survey showed that 92% of level III and IV NICUs consistently use HMF to fortify HM.[10]

The responsibility of ensuring that HM is delivered safely and accurately to the hospitalized infant falls to members of the multidisciplinary nutrition care team (NCT).[11,12] The NCT typically consists of neonatologists, nurses, nursing leadership, registered dietitians (RDs), neonatal nurse practitioners, lactation consultants, and formula or milk room technicians (MTs). Each member of the NCT has a unique responsibility for HM safety as the milk passes through the multistep process that begins with milk expression and ends with feeding the infant. The process of HM preparation includes milk expression, labeling, refrigeration, freezing, moving milk from its original bottle, adjusting expiration times, adding HMF, and dosing for individual feedings. The multistep HM preparation process creates opportunities for waste, cross-contamination, mixing errors, and misadministration.[5] The Academy of Nutrition and Dietetics (AND) and the HM Banking Association of North America (HMBANA) have published best practices for HM handling in hospital settings. The overarching recommendations include aseptic preparation of HM in a designated space.[5,7]

Procedures for the preparation of fortified HM vary between NICUs. Preparation occurs at the bedside, in a designated space for milk preparation within the NICU space, or in a separate milk preparation room. For an individual infant, fortified HM may be prepared in bulk (prepared once and dosed for 12 or 24 h) or for individual feedings (6–8 per day). The preparer of the fortified HM may prepare for a single infant, several infants in their care, or all the infants receiving HM in the hospital.[12,13]

Manufacturers recommend a ratio of one packet or vial (5 ml) of HMF to 25 ml of HM to achieve 30 ml of 24 calories/ounce prepared HM.[14–16] Unlike DHM, MOM is typically expressed and stored in varying volumes and NICU patients may not receive enteral volumes that match predetermined recipes.

Given the complexity of fortified HM preparation, clinicians have requested flexible HMF measuring options. The currently available 5 ml single-serve vials or sachets of HMF provide less ease and flexibility in mixing variable volumes of MOM or DM. In addition, for those who prepare fortified milk in bulk or for many infants, the milk preparer will open several hundred vials or sachets each day. This milk preparation process creates opportunity for error, cross-contamination, leftover HM, and worker fatigue.[11,12,17]

In 2020, a multidose HMF (MDHMF) bottle was designed by neonatal practitioners to improve the process of HM fortification. Unlike 5 ml vials or sachets of HMF, the multidose bottle (5.5 oz, 163 ml) allows aseptic removal of HMF in the desired volume and is not dependent on 25 ml increments of HM. The multidose bottle allows for the preparation of fortified milk for a single infant or several infants, individual feedings or bulk feedings, and all feeding volumes. According to the manufacturer, a variety of aseptic preparation methods

can be used to prepare the MDHMF, including the use of sterile mixing bottles; sterile transfer lids; and sterile, single-use enteral syringes. The liquid HMF may also be poured from the bottle using aseptic technique.

In a controlled laboratory setting, the MDHMF showed an improvement in the number of steps needed to prepare fortified HM, the amount of time needed to prepare fortified HM, and the amount of HM wasted because of the inflexibility of the set HMF to HM ratios.[17] The MDHMF was made available to NICUs in the United States in 2020. This follow-up study aimed to examine the experience of NCT members who used the MDHMF in a NICU setting.

METHODS

A survey (Qualtrics XM) was designed to determine the impact of an MDHMF on HM preparation practices in US NICUs. An anonymous survey link was sent to the NCT leader at all US hospitals that had evaluated the MDHMF from June 1, 2020, through April 30, 2021 ($n = 108$). The leader of the NCT sent the survey to the relevant members of the NCT in their hospital. Investigators did not know who completed the survey and collected no identifying information from respondents. After obtaining consent, survey respondents were asked 29 questions about their NICU, the make up of the NCT, HM preparation practices, and their perception of growth, feeding tolerance, and nutrition status of infants who received the MDHMF. The survey design was adaptive based on responses to bypass questions that were not relevant to the participant based upon the answers provided, and respondents were permitted to skip questions. The questions were designed to measure the experience of the individual clinician, not compliance with the manufacturer's recommendations or recommendations for safe milk preparation in a hospital setting. The protocol was deemed exempt by the Advarra Institutional Review Board #PRO00054789/Exempt. Survey responses were evaluated and tabulated with Qualtrics XM 2021.

The survey asked respondents to evaluate their experience with the MDHMF (Enfamil liquid HMF, high or standard protein, Mead Johnson Nutrition) compared with their previous practice. Products included in the survey for comparison were Enfamil HMF powder (EHMF1) and Enfamil acidified HMF liquid (EHMF2) produced by Mead Johnson Nutrition; Prolacta HMF (PHMF) Prolacta+ H2MF, which includes all calorie options produced by Prolacta Bioscience; and Similac HMF concentrated liquid (SHMF1), Similac HMF hydrolyzed protein concentrate liquid (SHMF2), and Similac HMF powder (SHMF3) (Abbott Nutrition).

RESULTS

Demographics

The NCT leaders ($n = 108$) sent the survey to 344 members of the NCT at their prospective hospitals. The response rate was 36% ($n = 124$), with 99.2% of that number consenting to the survey ($n = 123$). Of those that consented, 91.9% ($n = 113$) responded that they had used the MDHMF for at least one patient and were allowed to continue the survey (Figure 1). Most of the respondents were RDs ($n = 36$, 32.4%), nurses with direct patient care responsibilities ($n = 29$, 26.1%), or MTs ($n = 19$, 17.1%) (Figure 2). The NICU characteristics provided by the survey respondents indicated that most NICUs were designated level III or IV NICUs ($n = 102$, 95.3%), had at least one RD ($n = 70$, 95.9%), and had 41–70 beds ($n = 50$, 46.7%) (Table 1).

Preparation practices

Most respondents prepared HM in a milk-preparation room ($n = 82$, 76.6%) or in a designated space in the NICU ($n = 20$, 18.7%). HM was prepared most often by MTs ($n = 63$, 58.9%) or nurses, nursing assistants, or care technicians assigned to the patient ($n = 37$, 34.6%). Most prepared fortified HM for 24 h ($n = 62$, 57.9%) or for 12 h

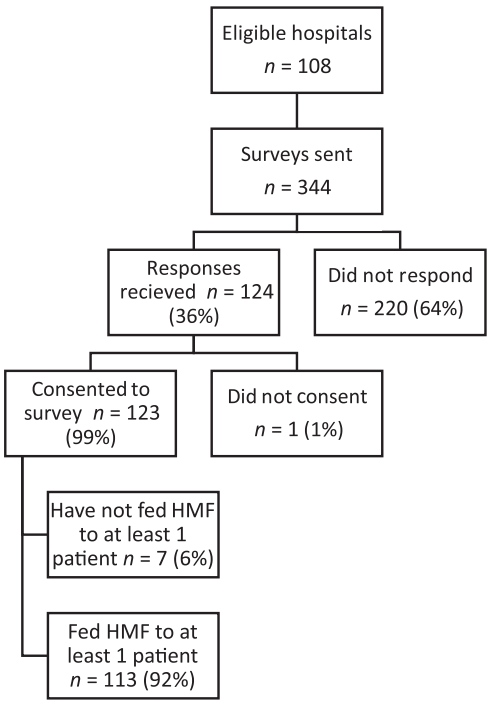

FIGURE 1 Survey participant flow diagram. HMF, human-milk fortifier.

FIGURE 2 Survey respondents by profession

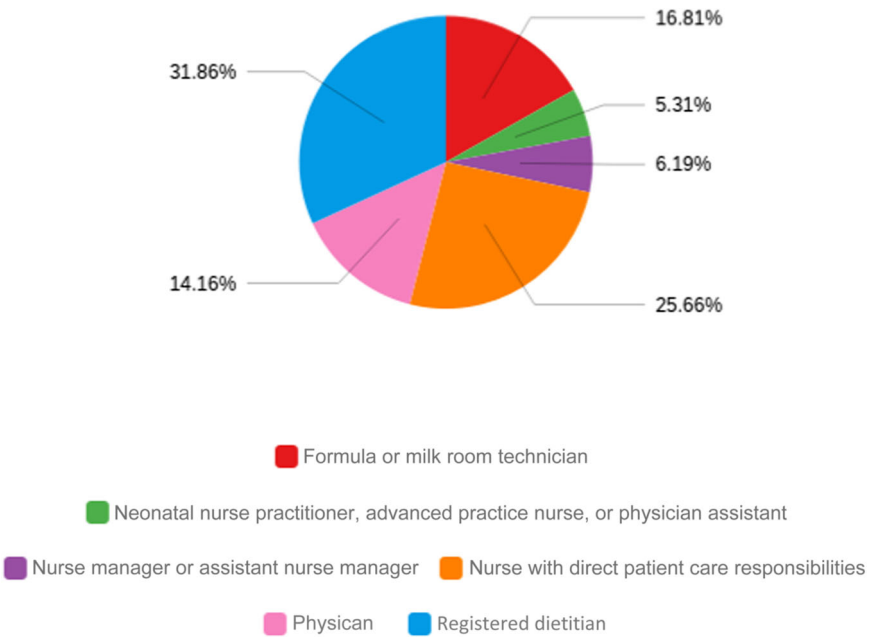

TABLE 1 NICU characteristics

	n	%
NICU level of care		
Level I or II	5	4.7
Level III or IV	102	95.3
NICU has at least one registered dietitian	70	95.90
NICU beds		
≤9	1	0.9
10–20	15	14.0
21–40	23	21.5
41–70	50	46.7
>70	18	16.8

Abbreviation: NICU, neonatal intensive care unit.

($n = 4$, 37.4%). Most respondents used DM when MOM was not available ($n = 106$, 99.1%). Various aseptic methods may be used to safely remove the HMF from the MDHMF bottle. Respondents used a transfer lid and syringe ($n = 25$, 43.1%), the pour method ($n = 17$, 29.3%), or a straw or syringe directly into the bottle of HMF ($n = 16$, 27.6%) (Table 2).

Respondents were asked to compare the MDHMF with the HMFs they had previously used. A variety of products were in use before the survey, with EHMF2 (31.1%) used most often, followed by SHMF2 (15.8%), PHMF (15.3%), and EHMF (15.3%). SHMF3 was used by only 5.6% of respondents (Figure 3). The rating selections "better than," "the same," or "worse than" compared with previous practice. When compared with previous

TABLE 2 Breastmilk fortification practices

	n	%
Where is fortified breastmilk prepared in your NICU?		
At the patient's bedside	5	4.7
At a designated space in the NICU	20	18.7
In a separate milk preparation or formula room	82	76.6
Who prepares fortified breastmilk for the NICU patients?		
The nurse, nursing assistant, or patient care technician assigned to the patient	37	34.6
Formula/breastmilk technician	63	58.9
Pharmacy technician	4	3.7
Other	3	2.8
How often is fortified breastmilk prepared for the patients in your NICU?		
One feed at a time	1	0.9
For each 12-h shift	40	37.4
For 24 h worth of feeds	62	57.9
Each nurse decides when to prepare for the individual patient	4	3.7
Does your NICU use donor human milk?		
Yes	106	99.1
No	1	0.9
How do you remove the fortifier from the bottle?		
Pour method	17	29.3
Transfer lid	25	43.1
Syringe or straw directly into the fortifier bottle	16	27.6

Abbreviation: NICU, neonatal intensive care unit.

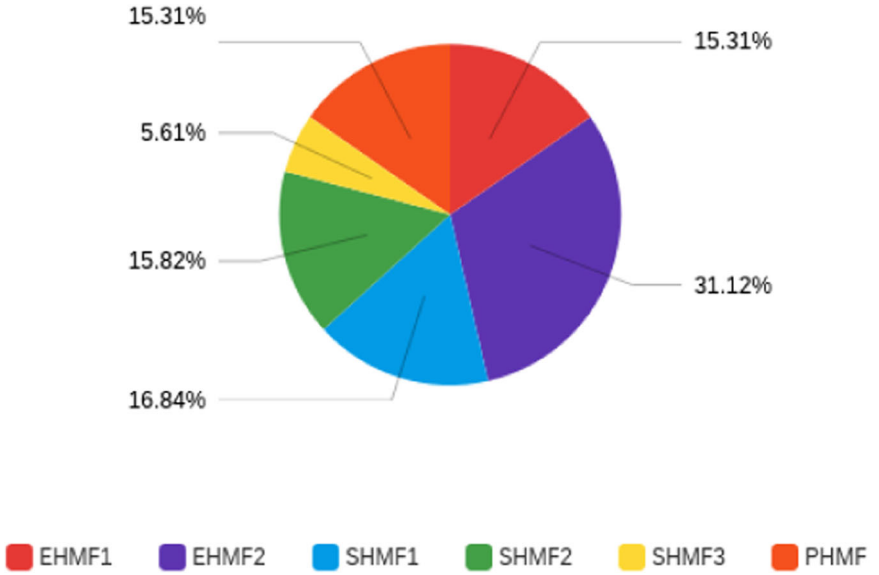

FIGURE 3 Human-milk fortifier used prior to the multidose HMF. Respondents could choose more than one HMF. EHMF1, Enfamil acidified human-milk fortifier; EHMF2, Enfamil human-milk fortifier powder; HMF, human-milk fortifier; PHMF, Prolacta human-milk fortifier; SHMF1, Similac human-milk fortifier concentrated liquid; SHMF2, Similac human-milk fortifier hydrolyzed protein concentrate liquid; SHMF3, Similac human-milk fortifier powder.

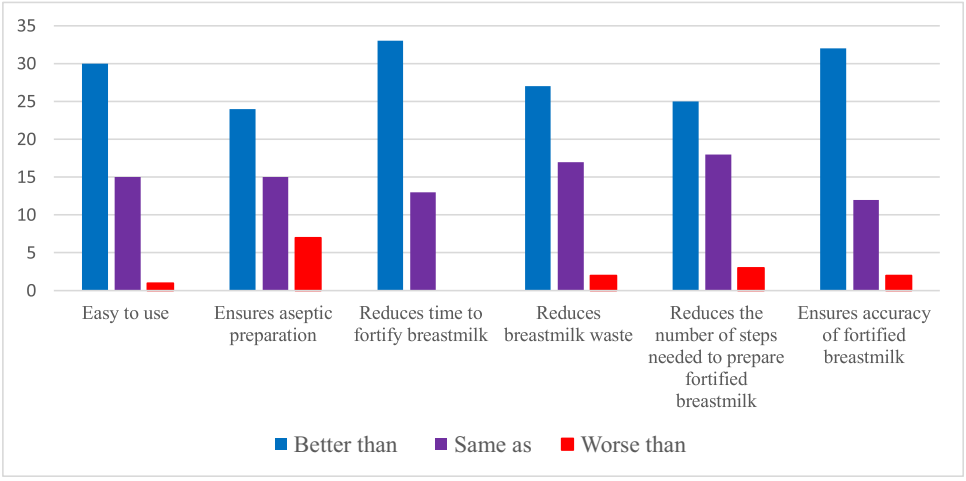

FIGURE 4 Compared with the human-milk fortifier(s) you have used before, how does the multidose human-milk fortifier compare?

products used, respondents answered that the MDHMF was better than their previous practice for ensuring ease of use ($n = 30$, 65.2%), ensuring aseptic preparation ($n = 24$, 52.2%), reducing the time to fortify HM ($n = 33$, 71.7%), reducing the waste of HM ($n = 27$, 58.7%), reducing the number of steps needed to prepare fortified HM ($n = 33$, 71.7%), and ensuring the accuracy of fortified HM ($n = 32$, 69.6%) (Figure 4). Of those that used PHMF before evaluation ($n = 20$), 68.4% ($n = 13$) indicated that the MDHMF was better for ensuring the accuracy of HM preparation. Of those that used SHMF2 ($n = 17$) previously, 69.3% ($n = 13$) answered that the MDHMF was better for ease of use and 69.3% ($n = 9$) for reducing the time to fortify. Responses from those that used any single-use 5 ml vial/sachet or powder sachet of HMF (EHMF1, EHMF2, SHMF1, or SHMF2) comprised 99% ($n = 43$), of those, 62.8% ($n = 27$) indicated that ease of use was better. When asked about HM waste, 59% ($n = 25$) of all product users responded that the MDHMF was better for reducing the waste of HM.

HM was prepared most often by MTs ($n = 63$, 58.9%). When asked to compare the MDHMF with products they had used before, the MTs ($n = 19$, 30%) responded that the MDHMF was better than the previous product for ease of use ($n = 16$, 84.2%), ensuring aseptic technique ($n = 13$, 68.4%), reducing the time to fortify ($n = 15$, 63.2%), and ensuring the accuracy of fortified HM ($n = 15$, 79.1%). Nurses responsible for HM preparation ($n = 18$, 66.1%) responded that the MDHMF was better than the previous product for reducing the time to fortify

($n = 12$, 66.7%), reducing HM waste ($n = 9$, 50%), and ensuring the accuracy of fortified HM ($n = 14$, 77.8%). Those that prepared HM at the bedside or in a designated space ($n = 11$, 44%) responded that the MDHMF was better than their previous practice for ensuring the accuracy of fortified HM ($n = 8$, 72.7%). Of those that prepare fortified milk in a milk-preparation room, 68.6% ($n = 24$) indicated the MDHMF was better than their previous practice for ensuring the accuracy of fortified HM (Table 3).

TABLE 3 Compared with the human-milk fortifier(s) you have used before, how does the MDHMF compare? Listed by profession

	Better than	The same	Worse than	*N*
Easy to use				
Formula or milk room technician	84.2%	15.8%	0%	19
Nurse	44.4%	50%	5.6%	18
Registered dietitian	100%	0%	0%	6
Ensures aseptic preparation				
Formula or milk room technician	68.4%	26.3%	5.3%	19
Nurse	27.8%	44.4%	27.8%	18
Registered dietitian	100%	0%	0%	6
Reduces time to fortify				
Formula or milk room technician	79%	21.1%	0%	19
Nurse	66.7%	33.3%	0%	18
Registered dietitian	100%	0%	0%	6
Reduces breastmilk waste				
Formula or milk room technician	63.2%	36.8%	0%	19
Nurse	50%	45.4%	5.6%	18
Registered dietitian	66.7%	16.7%	16.7%	6
Reduces the number of steps to prepare fortified breastmilk				
Formula or milk room technician	63.2%	36.8%	0%	19
Nurse	38.9%	50%	11.1%	18
Registered dietitian	83.3%	16.7%	0%	6
Ensures accuracy of fortified breastmilk				
Formula or milk room technician	79%	21.1%	0%	19
Nurse	77.8%	22.2%	0%	18
Registered dietitian	50%	33.3%	16.7%	6

Growth, feeding tolerance, and nutrition status

Of those responsible for evaluating growth, feeding tolerance, and nutrition status ($n = 79$, 73%), most respondents answered that feeding tolerance with the MDHMF was better ($n = 27$, 38.5%) or the same ($n = 45$, 58.6%) when compared with products they had used before. Of those that used PHMF ($n = 20$), most responded that feeding tolerance was better ($n = 8$, 40%) or the same ($n = 12$, 60%) as products they had used before. Similarly, for those that used SHMF2 ($n = 17$), 38.9% ($n = 7$) responded that feeding tolerance was better or the same ($n = 10$, 55.6%) as the MDHMF. Respondents who used SHMF1, SHMF2, or SHMF3 ($n = 32$) used less additional protein supplementation with the MDHMF ($n = 18$, 56.3%).

Respondents were asked to compare their perception of growth with the MDHMF compared with growth from previous products. Most answered that growth was the same as before for weight ($n = 47$, 67.1%), head circumference ($n = 56$, 81.2%), and length ($n = 53$, 76.8%) (Figure 5).

Practice change

Respondents were asked if their use of the MDHMF resulted in a practice change and if they would recommend the product to their peers. Most respondents ($n = 63$, 71.6%) answered that the MDHMF improved their HM mixing practices. Most ($n = 49$, 94.2%) will continue to use the MDHMF and would recommend the product to other healthcare providers ($n = 88$, 91.7%). When broken down by preparation space, those with a designated space for mixing ($n = 3$, 60%) or a separate preparation space ($n = 15$, 93.8%) would recommend the MDHMF to their peers, compared with 60% ($n = 3$) of those who mix at the bedside.

DISCUSSION

Unlike infant formula, HM is a biological fluid that cannot be prepared in the hospital kitchen.[7] NICU NCTs must design feeding preparation policies for HM that are separate from those designed for meal preparation for patients in other areas of the hospital. Premature and hospitalized infants are susceptible to foodborne illness, mixing errors, and nosocomial infections related to cross-contamination.[8] The recent pandemic, supply chain issues, staffing shortages, and infant formula recall highlight the need for hospitals to take a careful look at the products and procedures used for this vulnerable population.[18–20]

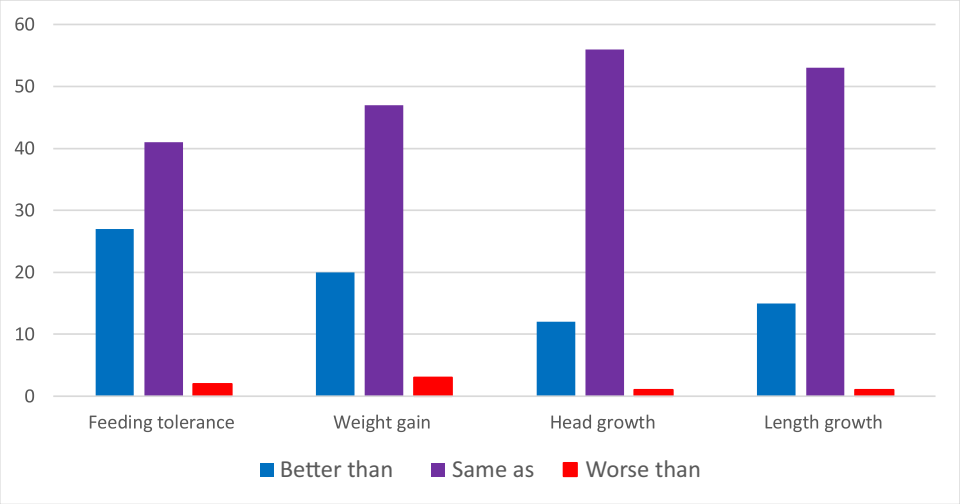

FIGURE 5 Compared with the human-milk fortifier(s) you have used before, how does the multidose human-milk fortifier compare?

Strengths

The survey had a strong response rate (36%), consistent with previous reports.[21,22] Researchers did not know the identities of respondents, and the survey was distributed to all hospitals that had ordered the MDHMF, thereby limiting selection bias. The anonymity of the survey minimized response bias. All members of the NCT were invited to participate, adding strength to the responses with the variety of viewpoints possible from the different professions represented. With the nine professional roles included in the survey, the representation by survey respondents is similar to the makeup of many NICUs. Lastly, the diversity of NCT member professions is representative proportionally to typical NICU staff based on the combined clinical experiences of the authors.

Limitations

Most respondents represent US level III or IV NICUs, have at least one designated RD on staff, and have access to a formula- or milk-preparation room. The experiences expressed in this survey may not be generalizable to smaller level II units that may not conform to this profile. Although the invitations were sent to hospitals representing a variety of geographic locations throughout the United States, the investigators did not collect exact hospital locations, so geographic representation cannot be confirmed. Lastly, the evaluation of growth parameters captures the experience of the NCT. The survey responses do not have the same quality of evidence as outcomes studies in which anthropometrics are measured and compared.

Tolerance and safety

The experiences shared by the survey respondents regarding feeding tolerance compared with previous products, whether bovine milk or HM-based, indicated the same or better tolerance with the bovine-based MDHMF. This finding aligns with those in O'Connor et al., which showed no difference in clinical outcomes for premature infants fed an HM-based fortifier compared with a bovine-based fortifier.[23] As outlined in the recent expert guidelines, HM-based fortifiers are not preferentially recommended over bovine-based fortifiers. The results of this survey demonstrate that the clinician experience aligns with recent guidance.[9,24–27]

Practice implications

A 2019 time-motion study compared the MDHMF with two individually (5 ml) dosed HMFs.[17] The study compared the time to prepare, waste of HM, and steps needed to prepare fortified HM. The study compared SHMF1 and EHMF2 with MDHMF. The multisite study took place at two centers with three milk preparers at each site. The HMFs were prepared in three different volumes (10, 200, and 500 ml) to 24 calories per ounce according to manufacturers' instructions: 162 samples in total. The researchers concluded that the MDHMF reduced milk waste by 97%, time to prepare by 37%, and steps taken by 61%.[17] The result of the present survey aligns with these findings. The practice implications for NICUs include time savings for those preparing fortified milk, with 63.2% of survey respondents agreeing that the MDHMF saves time. A time savings of 37%, as seen in

the time-motion study, could translate into half an hour for an 8-h shift or as much as 4 h for a 12-h shift. The reduction in time spent on the task of milk preparation would allow bedside nurses to devote more time to clinical care and reduce the workload of milk preparation technicians. The reduction in time could also reduce costs related to inefficient milk preparation practices, such as overtime pay.[28–33]

In addition to time savings, the respondents of this survey agree with Gates et al.[17] that the MDHMF reduces the waste of HM. Fortification strategies that depend on rigid ratios of HM to HMF are often unrealistic. The amount of MOM in a particular bottle varies, as does the feeding volume for each infant. Predetermined ratios are less flexible and often require preparing more fortified milk than the infant needs to adhere to the recipe. The surplus fortified milk must be used within 24 h, which is unlikely considering the limited enteral volumes consumed by this population.[7,34] MOM is more nutrient-dense than the alternative of DHM and therefore promotes better growth and long-term outcomes.[35–39] Mothers of preterm infants are dependent on breast pumps; they may experience delayed lactogenesis and may see their milk supply dwindle over the course of their infant's hospitalization.[40–42] The higher the proportion of the preterm infant's diet that comes from MOM, the better the clinical outcomes.[43] Preserving every drop of MOM should be a priority for the NCT. Minimizing waste by targeting the volume of available MOM and preparing the exact amount of fortified milk needed could help achieve this.

Providing safe, effective, and efficient patient care solutions while improving staff satisfaction is difficult to achieve in the hospital setting. In the present survey, healthcare providers responded that the MDHMF met or exceeded goals for patient tolerance and growth while also saving time and improving their workflow. When used according to the manufacturer's instructions, the MDHMF aligns with recommendations for an aseptic, no-touch technique described in the HMBANA and AND guidelines.[5,7] Additionally, the MDHMF prioritizes MOM by reducing the waste of HM through using a precise mixing technique.

CONCLUSIONS

The benefits of an HM diet for the preterm infant are broadly acknowledged, and the fortification of HM is commonplace. Fortification of the expressed HM adds complexity to the feeding process for the hospitalized infant with implications for staffing, safety, feeding tolerance, environmental waste, and cost. Members of NCTs in NICUs across the United States provided valuable feedback regarding the benefits of a multidose bottle of HMF. The data from this survey add a practical perspective to clinical outcome studies and expert recommendations. NICU NCT members perceived that the MDHMF may reduce the preparation time of fortified HM and reduce the waste of HM while maintaining growth and tolerance.

AUTHOR CONTRIBUTIONS

Amy Gates, Heather V. Evans, Alayne M. Gatto, Jodee Le Vin, Jessica L. Thornton, Katina Langley, and Christina Valentine equally contributed to the conception and design of the research. Amy Gates, Heather V. Evans, Alayne M. Gatto, Jodee Le Vin, Jessica L. Thornton, and Katina Langley equally contributed to the acquisition and analysis of the data. Amy Gates, Heather V. Evans, Alayne M. Gatto, Jodee Le Vin, Jessica L. Thornton, Katina Langley, and Bethany S. Hodges equally contributed to the interpretation of the data. Amy Gates and Heather V. Evans drafted the manuscript. All authors critically revised the manuscript, agree to be fully accountable for ensuring the integrity and accuracy of the work, and read and approved the final manuscript.

CONFLICTS OF INTEREST

All authors are employees of Reckitt, Mead Johnson Nutrition, the maker of the novel human-milk fortifier. At the time of the study, Christina Valentine was working as a neonatologist at the University Medical Center at the University of Arizona. The authors did not know the identities of the respondents of the survey, no identifying information on the respondents was collected, and all users of the novel human-milk fortifier received the survey.

ORCID

Amy Gates http://orcid.org/0000-0001-5500-543X
Heather V. Evans http://orcid.org/0000-0002-1727-2024

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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