



Original Article

Necessity of human milk banking in Japan: Questionnaire survey of neonatologists

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Abstract **Background:** If their own mother's milk (OMM) is not available, another mother's milk may be used for extremely low-birthweight (ELBW) infants. Human milk is a bodily fluid, however, therefore we have assumed that other mother's milk is currently seldom given to infants despite its superiority to formula. Although the World Health Organization and the American Academy of Pediatrics have recommended using donor human milk (DHM) from a human milk bank (HMB) in the case that OMM is not available, there is no HMB in Japan. To assess whether other mother's milk is used for ELBW infants and whether an HMB is necessary in Japan, we surveyed neonatal intensive care units (NICU) via questionnaire.

Methods: The questionnaire was sent by email to members of the Japanese Neonatologist Association who are responsible for NICU.

Results: In total, 126 completed questionnaires (70.7%) were returned and analyzed. One-fourth of NICU give other mother's milk to ELBW infants. The first choice of nutrition is OMM, but other mother's milk or formula is given to infants at 19% of NICU if OMM is unavailable. Approximately three-fourths of NICU would like an HMB.

Conclusion: Although human milk contains contagious agents and authorities do not recommend giving other mother's milk as a substitute for OMM, other mother's milk is still a choice in NICU in Japan. Many neonatologists, however, would prefer a safer alternative, that is, DHM obtained from an accredited HMB. A well-regulated HMB should be established and safe DHM should be available for all preterm infants if necessary.

Key words donor human milk, human milk bank, other mother's milk, own mother's milk.

In Japan, for extremely low-birthweight (ELBW) infants, if their own mother's milk (OMM) is not available, another mother's milk used to be given without hesitation. Human milk is a bodily fluid, however, and may contain contagious agents, therefore we have assumed that other mother's milk is not readily given to infants these days, although other women's milk is superior to formula, especially for very immature infants.

The World Health Organization recommends that "LBW infants, including those with very low birthweight, who cannot be fed mother's own milk should be fed donor human milk. This recommendation is relevant for settings where safe and affordable milk-banking facilities are available or can be set up."¹ The American Academy of Pediatrics and European Society of Paediatric Gastroenterology, Hepatology and Nutrition also recommend donor human milk (DHM) provided from an accredited human milk bank (HMB) when OMM is not available.^{2,3} There is no accredited HMB, however, in Japan.

Currently, there is much evidence showing that early aggressive nutrition results not only in better growth but also in better neurological development.^{4,5} In addition, adequate nutrition results in less retinopathy of prematurity, chronic lung disease (CLD), and extrauterine growth restriction.⁶ Early enteral nutrition is one of the main strategies for early aggressive nutrition,⁷ because longer parenteral nutrition without enteral nutrition has been shown to cause deterioration of bowel conditions in an animal model.⁸

Early enteral feeding, that is, initiation of enteral feeding within 24 h of birth, was shown to result in better growth, shorter length of stay in the neonatal intensive care unit (NICU), and lower incidence of serious diseases such as necrotizing enterocolitis (NEC) and CLD.⁹ Delay of enteral feeding could diminish the functional adaptation of the gastrointestinal tract and prolong the need for parenteral nutrition with its attendant infectious and metabolic risks. Because we know formula feeding early postnatally increases the risk of NEC,¹⁰ to initiate enteral feeding within 24 h of birth, we sometimes need to use DHM. That is one of the reasons why the early enteral nutrition strategy has not become established in Japan. In Scandinavian countries, enteral feeding is introduced within 24 h in all NICU, because DHM is available from HMB, mostly belonging to each NICU.¹¹

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As already described, enteral feeding is better if introduced early along with high-quality nutrition such as OMM (first choice) and DHM (second choice). Knowing that there are no authorized HMB in Japan, we wondered how enteral feeding was managed in the first few days of life for ELBW infants in Japan. To discover whether other women's milk is still commonly used for ELBW infants and whether other women's milk is considered desirable for ELBW infants, we surveyed via questionnaire NICU that provide care for ELBW infants, asking for information regarding the use of human milk for ELBW infants.

Methods

A questionnaire (Appendix S1) was sent to the 283 members of the Japanese Neonatologist Association by email. Of 179 members relevant to the present study 126 members returned satisfactory responses to the questionnaire, corresponding to 70.7% of NICU that provide care for ELBW infants.

At the top of the questionnaire form, we defined the terms related to HMB as follows: (i) HMB is responsible for donor selection, storage of donated human milk, bacterial culture, pasteurization of donated human milk, and management of individual data; (ii) other women's milk is human milk that is freeze-thawed but not pasteurized; (iii) donated human milk is human milk that is provided by the HMB.

Results

Use of other mother's milk

In answer to the question of whether other mother's milk was given to infants, 32 of 126 respondents (25%) replied "yes" (Fig. 1). Only two institutes, however, received approval from

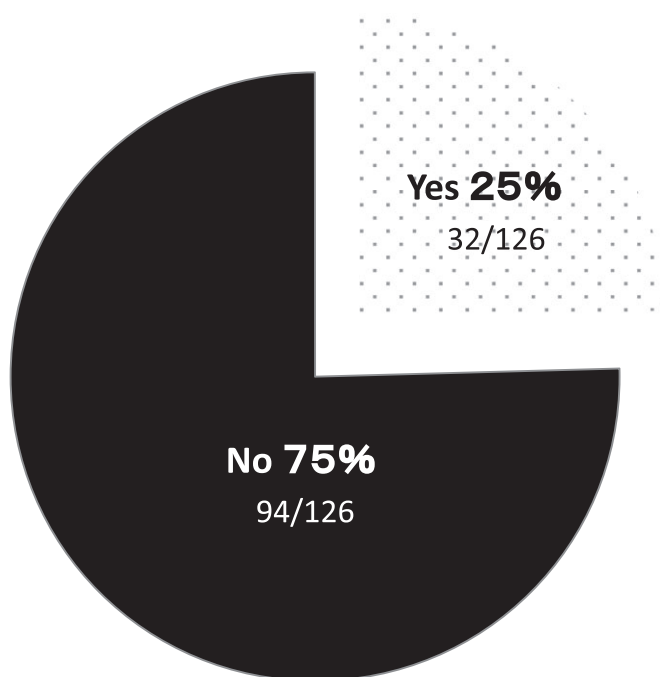


Fig. 1 Proportion of respondents giving other mother's milk to infants.

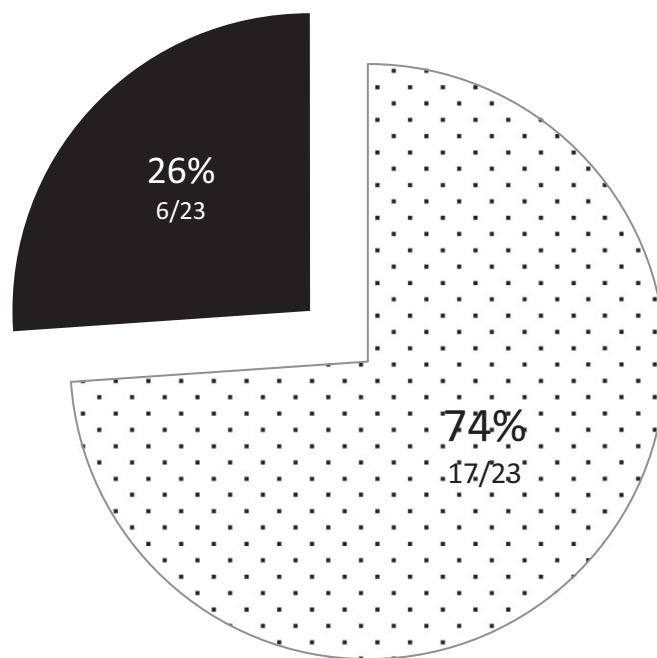


Fig. 2 Selection criteria for other mother's milk: 23 neonatal intensive care units had selection criteria for the other mother's milk: (□) being free of contagious disease was considered the most important factor by three-fourths of the institutes; the other one-fourth considered (■) abundant milk production and/or gestational age of donor as the most important issue.

their research ethics committee to give other mother's milk to infants. Of the 32 institutes that use other women's milk, 23 (72%) have selection criteria for the donor mother to determine whether the breast milk is adequate to be given to other infants. Being free of contagious disease was considered the most important factor by three-fourths of the institutes; the other one-fourth considered "abundant milk production and/or gestational age of donor" as the most important issue (Fig. 2).

Although 37% of NICU (12/32) obtained written informed consent from the donor mothers, 13% of NICU (4/32) used other mother's milk without informed consent (Fig. 3a). All NICU obtained informed consent from the caregivers of the recipient infants (written consent, 20/32, 62.5%; oral consent, 12/20, 37.5%; Fig. 3b).

Infection via other mother's milk

Two institutes replied "yes" to the question, "Have you experienced infections in infants that were related to donor mother's milk?" One was human cytomegalovirus, and the other was extended-spectrum β -lactamase-producing *Escherichia coli*.

First enteral feeding

More than one-third of NICU initiate the first enteral feeding by 24 h of age, and 80% of NICU initiate enteral feeding by 72 h of age (Fig. 4). One-sixth of NICU start enteral feeding whenever OMM is available. In terms of the first feeding, 80% of NICU use

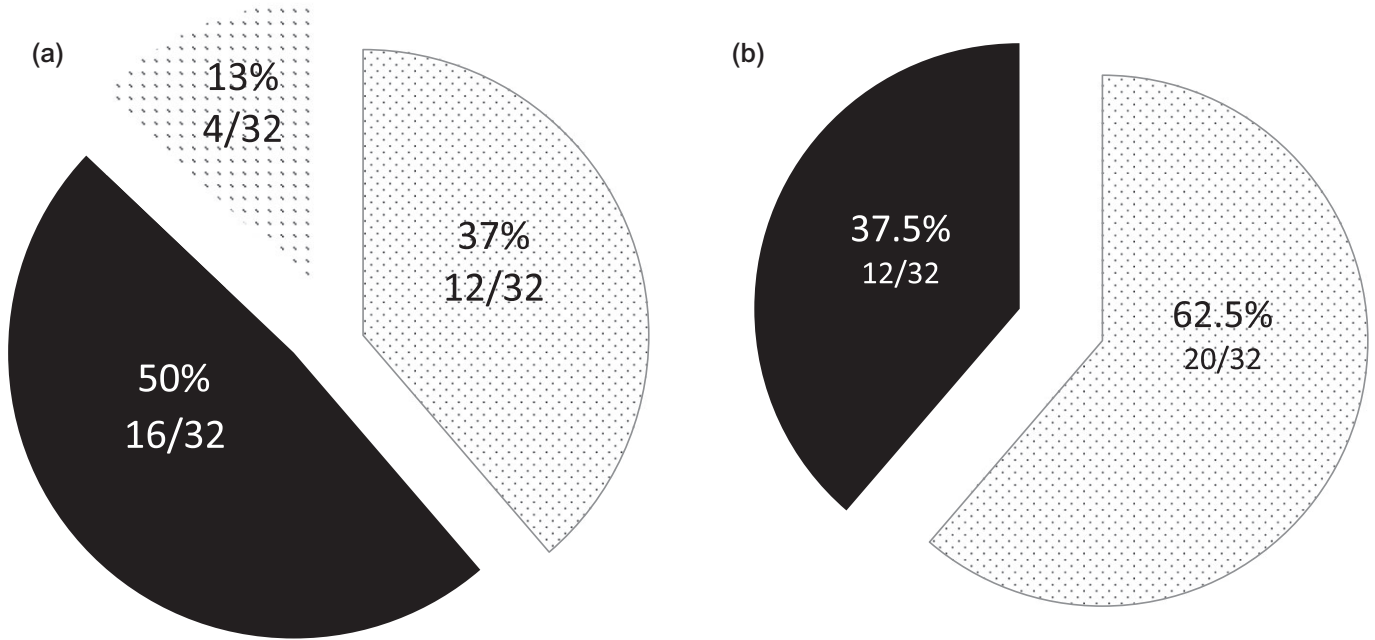


Fig. 3 (a) Type of informed consent for donors: although 37% of neonatal intensive care units (NICU) obtained (◻) written informed consent from the other mother’s milk, 13% of NICU used other mother’s milk (◻) without informed consent; (■) oral informed consent. (b) Type of informed consent for recipients: all NICU obtained informed consent from the caregivers of the recipient infants. (◻) Written informed consent; (■) oral informed consent.

OMM, but 8% and 10% of NICU may use other mother’s milk and formula, respectively.

Is an HMB necessary in Japan?

Approximately three-fourths of NICU responded that an HMB is necessary in Japan (Fig. 5a). Thirty NICU (24%) denied the need

for an HMB, with 55% responding that an HMB is not necessary because “formula is acceptable” or “other mother’s milk is available” (Fig. 5b). Five NICU responded strongly that an HMB is unnecessary because “formula is acceptable” (2 NICU), “we can obtain OMM” (2 NICU), and “other women’s milk is available”(1 NICU).

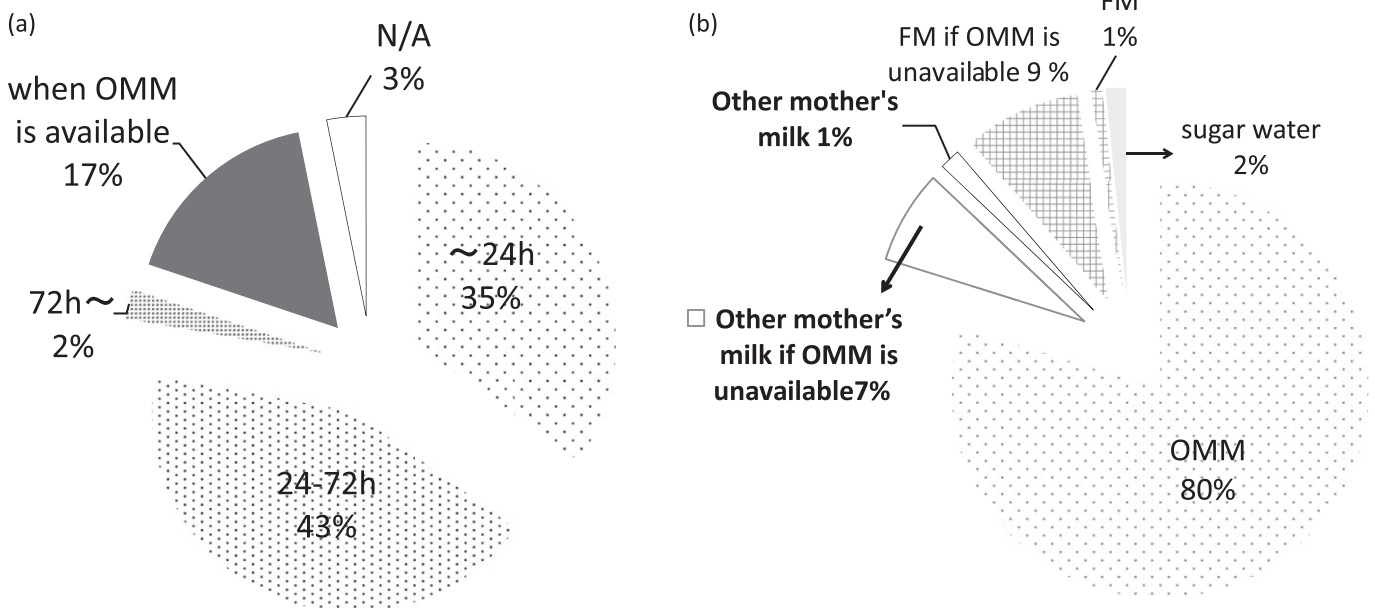


Fig. 4 (a) Timing of first enteral feed. A total of 44 neonatal intensive care units (NICU; 35%) initiate the first enteral feeding by 24 h of age, and 98 NICU (78%) initiate enteral feeding by 72 h of age. A total of 21 (17%) start enteral feeding when own mother’s milk (OMM) is available. (b) Milk used for first enteral feed: 101 NICU (80%) use OMM, but 8% and 10% of NICU may use other mother’s milk and formula (FM), respectively.

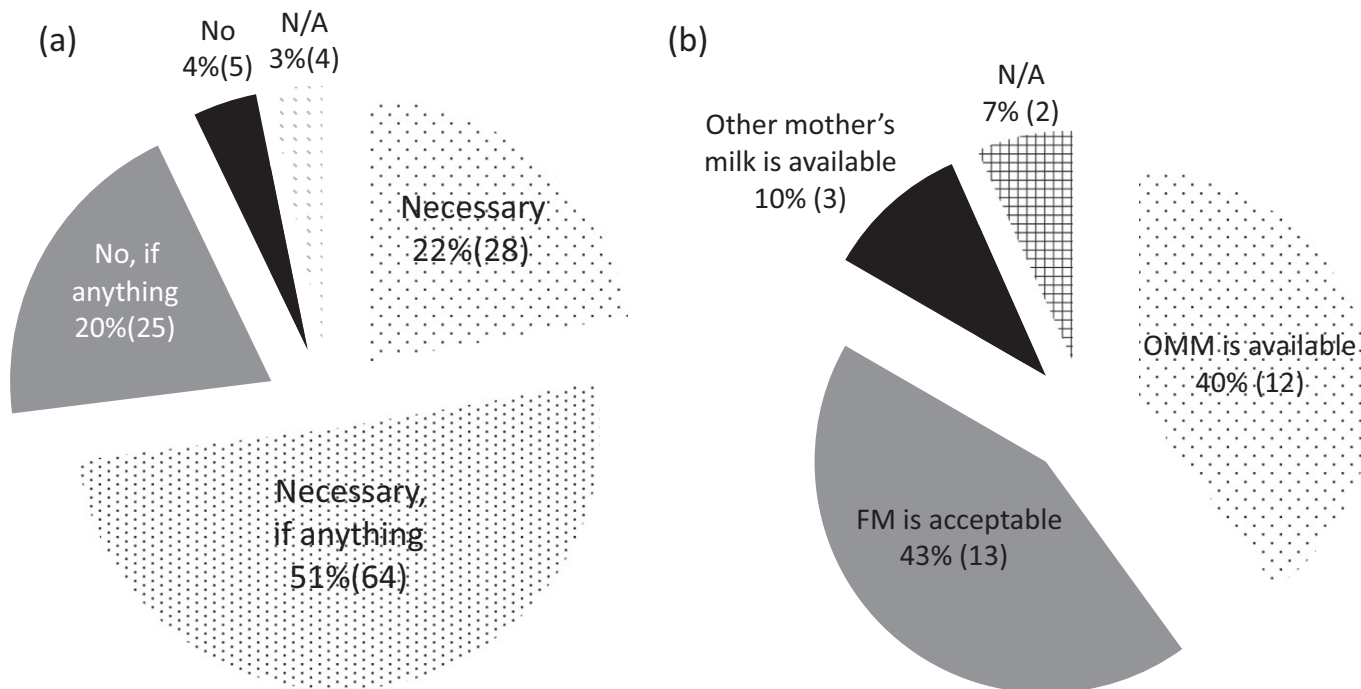


Fig. 5 (a) Need for human milk bank (HMB) in Japan. A total of 92 neonatal intensive care units (73%) responded that an HMB is necessary in Japan. A total of 30 (24%) denied the need for an HMB. (b) Reasons why HMB is not necessary. FM, formula; OMM, own mother's milk.

The next question for the neonatologists who admitted the necessity of an HMB in Japan was regarding where the HMB should be established. Twenty-nine percent responded that the HMB should be established together with their own NICU, 31% responded that the HMB should be independent from the hospital, and 19% responded the HMB should be located in a maternal perinatal care center (Fig. 6).

Donor and recipient selection

Sixty-seven neonatologists responded that the HMB donor candidates can be either mothers of preterm delivery or mothers of term delivery. A total of 21 neonatologists selected "mothers of preterm delivery" and 22 neonatologists selected "mothers of term delivery".

Indications for DHM

Respondents were asked what the indications for DHM were at their NICU and could choose more than one item (number of neonatologists choosing the item is given in parentheses): very low-birthweight (VLBW; $n = 90$); gastrointestinal tract surgery ($n = 71$); risk of NEC ($n = 93$); food protein-induced enterocolitis syndrome ($n = 44$); maternal difficulty in producing OMM (e.g. Human T-cell Leukemia Virus (HTLV) positivity; $n = 46$); and maternal wish for OMM despite inability to produce it ($n = 34$).

In a free answer section of the questionnaire, some neonatologists described gestation <24 weeks or severe small for gestational age as indications for DHM. Furthermore, indications for DHM may depend on the amount of available DHM, because

more than one-fourth of neonatologists considered insufficient human milk itself as an indication for DHM. In consideration of this, we need to collect as much donor milk as possible, independent of preterm or term delivery.

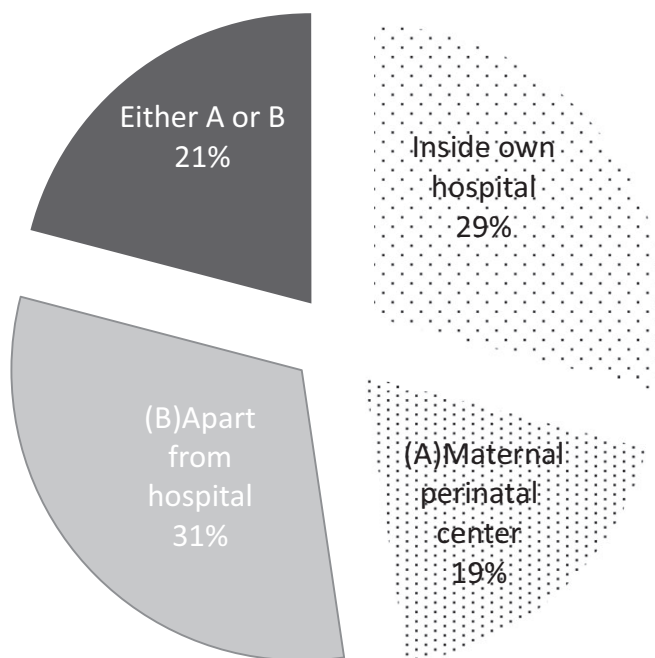


Fig. 6 Preferred location of human milk bank. A total of 87 neonatal intensive care units responded to the question "where is a human milk bank is best established?".

Plans to establish an HMB

Approximately half of the neonatologists surveyed were interested in the establishment of an HMB. One NICU already had a plan to establish an HMB at its own institution, but establishment of an HMB is challenging due to staff shortages, space, and financial resources.

Discussion

This questionnaire survey showed that one-fourth of NICU in Japan use other mother's milk. In addition, most institutes do not obtain approval from their research ethics committee. Because human milk is known to carry a risk of infection, human milk with less infectious risk, that is, DHM obtained from an accredited HMB, should be adopted.

Regarding the initiation of enteral feeding, approximately one-third of the NICU initiate enteral feedings within 24 h of birth, and OMM is the first choice. In the case that OMM is not available, other mother's milk or formula is given to ELBW infants. Some neonatologists (17%) do not initiate enteral feeding until OMM is available, probably because OMM is superior to formula; waiting too long to start enteral feeding, however, may cause serious problems. DHM could be an option in such a situation and is available in other countries. With respect to donor selection, we assumed that neonatologists would prefer mothers who deliver preterm infants. Most neonatologists, however, think either mothers of preterm delivery or of term delivery are acceptable, therefore indicating that it would be easy to find donors for HMB.

Formula has been known to increase the incidence of NEC and feeding intolerance compared with DHM.¹² We assume, therefore, that neonatologists choose other mother's milk for the enteral feeds early on for ELBW infants if OMM is not available. How long to wait before the first enteral feeding is dependent on the institute's policy, although the initiation of enteral feeding by 24 h of age has been shown to be beneficial to growth and to decrease the period of parenteral nutrition required, among other benefits.¹⁴

Many of the free comments regarding HMB in Japan suggest that the matter is one of "lots of pain and not much gain". For example, waiting for OMM for 72 h after delivery often means that DHM is not needed. If enteral feeding is initiated by 24 h of age, however, DHM becomes more important. Recently, Butler *et al.* reported on the benefits of standard practice for nutrition support in VLBW infants.^{9,13} In this standard practice, enteral feeding is initiated by 24 h of age. Currently, the nutrition for VLBW infants is receiving a lot of attention. An HMB would support the early initiation of enteral feeding and early aggressive nutrition as well.

Regarding barriers to the establishment of an HMB, some neonatologists expressed the concern that "if we can use DHM, health-care providers or mothers are less motivated in expression of OMM." That is a frequently expressed concern regarding the establishment of an HMB. Simmer, however, reviewed the breast-feeding rate in an NICU before and after establishment of an HMB.¹⁴ The breast-feeding rate on discharge actually increased from 61% to 75%. She speculates that increased aware-

ness of the benefits of human milk may be a contributing factor to the increased breast-feeding rates of mothers of preterm infants. We, of course, recommend and support mothers to express their own breast milk for their infants.

Regarding establishment and regulation of an HMB, we received comments from neonatologists such as "an association for HMB should be established to regulate (control) the safety of DHM" and "a government agency is desirable to be involved in some way in regulation of HMB". Another respondent commented that "we used to use other mother's milk, but it is outdated from the point of infectious issue and informed consent of donor/recipient." Furthermore, indications for DHM may depend on the amount of available DHM.

From this questionnaire survey, we confirmed that an HMB should be established with government involvement in the regulation of DHM. The lack of accessibility to DHM is a disadvantage to some ELBW infants if enteral feeding cannot be initiated with human milk. It is challenging to establish an HMB at one's own institute because of financial issues, lack of space, and/or staff shortages. It might be best to establish an HMB in a general maternal-perinatal center under regulation by an association of HMB with government involvement. Either mothers of preterm or term delivery would be acceptable and indications for donor milk would be up to the institute. Another issue would be the costs for running the HMB, which may be offset by receiving payment (either from the institute or the caregiver) for the DHM. Such issues need to be resolved in the near future.

Acknowledgments

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Appendix S1 Questionnaire.