Standards for donor human milk banking



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Cover photo: Mother providing continuous kangaroo care to her, preterm infant whilst giving expressed breastmilk by nasogastric tube © Born on the Edge

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Abbreviations

CMV	cytomegalovirus
DHM	donor human milk
HPP	high-pressure processing
HTLV-1	human T-lymphotropic virus 1
HTST	high-temperature short-time
IgA	immunoglobulin A
MOM	mother's own milk
PICO	participant-intervention-comparison-outcome
WHO	World Health Organization

Executive summary

Background

Donor human milk (DHM) is a critical intervention recommended by WHO for the care of preterm and low-birthweight infants when their mother's own milk (MOM) is not available. It is used as a bridge to establish breastfeeding and optimal feeding practices, providing essential nutrition and immunological protection during the most vulnerable period of life. By providing clinical stability and growth, donor milk gives mothers time to initiate or restore lactation, in line with WHO's guidance that breastfeeding is the cornerstone of infant survival, health and development.

Purpose of the standards

The WHO Standards for Donor Human Milk Banking provide global evidence-based guidance to ensure the safety, quality and ethical management of DHM. The standards were developed by the WHO Department of Nutrition and Food Safety and the Standards Development Group. The purpose of the standards is to ensure that policymakers, health systems and milk bank operators use best practices in the collection, processing and distribution of DHM.

Standards development

The standards were formulated by conducting systematic reviews, a narrative synthesis on ethical considerations and expert consensus using a modified "evidence-to-decision" framework. Procedures of the WHO methods for guideline development were largely adhered to, although adaptations were made to bring together evidence from multiple evidence streams, including impacts of milk banking procedures on milk safety and quality, donors and donors' infants in addition to health impacts on the recipients of the milk itself.

To develop the recommendations, WHO convened a Standards Development Group with expertise in related disciplines, including infectious disease, blood banking, food safety, lactation care, and milk banking operations. The process was comprehensive, transparent and evidence-based, utilizing systematic reviews to address critical questions in banking of DHM. The recommendations were agreed by consensus after careful consideration of the evidence, most of which, however, was of low certainty, indicating that further research should be conducted.

Recommended practices

1 Donor recruitment



- ☑ Human milk banks may recruit donors at all stages of lactation, regardless of the gestational age of the infant at birth. Recruitment strategies should be inclusive of all potential donors.
- ☑ Human milk banks should recruit only mothers who can express more milk than their infant needs or who have stored surplus milk.
- ☑ Human milk banks should provide support to bereaved mothers who wish to donate their milk.

Remarks

- Recruitment of donors at early stages of lactation may ensure that the nutritional composition of their milk is better aligned with the recipients' nutritional needs. Milk from donors early in lactation has higher contents of protein, zinc, copper, selenium and vitamins A, B12 and E.
- Donors may be recruited early in lactation to donate surplus expressed milk that would otherwise be discarded. Bereaved mothers may experience unique benefits from donating their milk.
- Recruitment of human milk donors should be based on eligibility criteria and the demand for donor milk.
- Any limitation placed on recruitment should avoid creating the perception that the breast milk produced by women who do not meet the eligibility criteria is unsafe or nutritionally incomplete, as such perceptions could discourage them from breastfeeding their own child.

2 Remuneration of donors



- Financial incentives should not be offered to milk donors.
- Human milk banks may choose to reimburse donors for actual costs incurred in donating milk (e.g. milk expression supplies).

Remarks

- Reimbursement may take the form of financial, non-financial or in-kind support.
- Reimbursement of actual costs incurred by donors should maintain financial neutrality and not create a financial incentive.
- Examples of actual costs are those for travel, transport, equipment or consumables required to express and store milk safely.

3 Donor screening



- Screening of potential donors should include a risk questionnaire and serological screening.
- Donors who test positive for HIV or human T-lymphotropic virus 1 (HTLV-1) should be excluded.
- The risk questionnaire should exclude donors who take recreational drugs, alcohol or medications that are known to be passed into the milk and which are contraindicated in breastfeeding.

Remarks

- Considerations for screening in the risk questionnaire may be aligned with WHO recommendations for blood banking screening.
- Potential donors should be screened before donation and at a designated frequency during the donation period.
- Individuals who do not pass screening to become eligible donors should be encouraged to continue to breastfeed their own infant, unless there are contraindications.

4 Donor education and support



- Human milk banks should protect and support continued breastfeeding by donor mothers, ensuring that the donor's infant is receiving their mother's milk.
- Human milk banks should support the donor's health, including by preventing excessive milk donation and hyperlactation.
- Donors should be asked to report any changes in their health or behaviours that might affect the safety of their donor milk.
- Human milk banks should train mothers in expressing their milk with techniques and equipment that are safe and acceptable, while encouraging them to use their preferred method of expression.
- Human milk banks should train mothers in adhering to hygiene practices, including hand hygiene and cleaning and disinfection of equipment and/or supplies for milk expression when expressing milk.

Remarks

- Support for donors may include provision of skilled lactation care and the supplies necessary for milk collection and storage.
- Human milk banks should adopt the WHO Guidelines on hand hygiene in health care *(1)*.
- Both manual and electric breast pumps and hand expression are all acceptable. Devices designed for individuals or several users are acceptable.
- Human milk banks may accept milk expressed before the donor receives support and education on expression if the donors report that they use storage and hygiene practices consistent with milk bank requirements.

5 Containers for milk expression and processing



- Expressed milk may be stored and transported in any clean, food-grade container that can be sealed effectively and resists breakage.
- Containers for handling and processing milk at a human milk bank should be easy to clean, disinfect and label, resistant to breakage, have an effective closure and be of approved food grade quality.

Remarks

- Approved food-grade containers made of glass, plastic or stainless steel or any other food-grade approved material may be used to collect, store and transport expressed breast milk to a human milk bank.
- The local supply chain should inform the choice of container.

6 Storage and handling of donor milk



- Human milk expressed for donation should be refrigerated or frozen as soon as possible, within a maximum of 4 hours after it is expressed.
- Raw human milk should not be stored for more than 4 days in a refrigerator (at 4 ± 2°C).
- Raw human milk may be stored in a freezer (< –18°C) for up to 6 months before donation.
- Pasteurized milk may be kept frozen before use for up to 6 months from the day of pasteurization, in frozen storage (< –18°C).
- Human milk banks should maintain reliable refrigeration (4 ± 2°C) and freezer conditions (< 18°C) for safe storage of donor milk from the time of receipt of donation until delivery to the recipient, including maintaining the cold chain during transport.
- All cold storage temperatures should be monitored regularly (manually or digitally) and recorded at least twice per day with reliable instruments.

Remarks

- In settings with high ambient temperatures, expressed human milk might have to be refrigerated or frozen sooner than in the recommendation.
- If refrigeration temperatures cannot be maintained reliably at 4 ± 2°C, expressed milk should not be stored for more than 12 h before it is either transferred to frozen storage or transported to a milk bank.
- The criteria for the reliability of a human milk bank include the possibility of maintaining refrigeration conditions at 4 ± 2°C and freezer conditions < –18°C, with use of back-up electricity if necessary.
- Storage temperature conditions should be monitored regularly to ensure proper maintenance of temperatures and the cold chain.

7 Pooling, mixing, and tracking and tracing of donor milk



- Where culturally appropriate, human milk banks may pool milk from several donors to improve its nutritional adequacy and consistency.
- Single and multi-donor pools may be mixed effectively either mechanically or manually.
- Human milk banks should have track-and-trace systems to track donor milk from donor to recipient and to trace donor milk from recipient to donor in case of an adverse event.

Remarks

- If resources and infrastructure allow, human milk banks should prioritize digital track-and-trace systems, although paper-based systems are acceptable in settings in which digital solutions are not feasible.

8 Treatment of donor milk



- To ensure microbiological safety, donor milk from screened healthy women should be heat-treated by holder pasteurization or high-temperature short-time to reduce or eliminate any pathogen (viral or bacteriological).
- Heat treatment may be avoided if each container of raw milk is tested to ensure that it remains within safety limits determined locally to be acceptable.
- Retort methods of heat treatment are not recommended.

Remarks

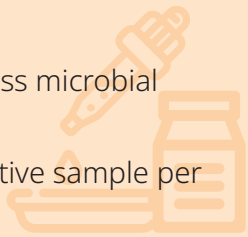
- Several alternative non-thermal processing procedures are being investigated and have been shown to retain heat-sensitive nutrients and bioactive components in donor milk more effectively. High-pressure processing is used widely in the food industry, and the available data suggest that its use may result in a microbiologically safe product comparable to that of heat-treated milk. These newer technologies are probably most suitable for large regional milk banks that have the necessary capital and infrastructure.
- When donor milk is not pasteurized, donors must be screened more carefully, perhaps more frequently, to limit any risk of viral transmission.

9 Testing donor milk



- ☑ When donor milk is pasteurized, post-pasteurization testing for microbial content is recommended.
- ☑ Nutritional testing of donor milk is not recommended.

Remarks



- Pre-pasteurization testing may also be considered, in order to assess microbial contamination, but should not replace post-pasteurization testing.
- Sampling techniques should include a minimum of one representative sample per batch of pasteurized donor milk.



Breastfeeding specialist supporting a mother of a term infant to feed her infant expressed breastmilk with a cup and spoon © Born on the Edge

1. Introduction and scope

1.1 Background

In 2022, WHO published Recommendations for care of the preterm or low-birthweight infant *(2)*, which recommend that preterm or low-birthweight infants, including those with a very low birthweight, who cannot be fed their mother's own milk (MOM) should be fed donor human milk (DHM). This recommendation was qualified as being relevant only for settings in which safe and affordable milk-banking facilities are available or can be set up.

The WHO and UNICEF Implementation guidance on the Baby-friendly Hospital Initiative *(3)* similarly stated that "infants who cannot be fed their mother's own milk, or who need to be supplemented, especially low-birthweight infants, including those with very low birthweight and other vulnerable infants, should be fed donor human milk" *(3)*. The American Academy of Pediatrics, the European Society for Paediatric Gastroenterology, Hepatology and Nutrition Committee on Nutrition, and other national and global policy groups also call for use of DHM as the feeding of choice if the MOM is insufficient, unavailable or contraindicated.

There is growing interest in creating and sustaining HMBs globally to fulfil the need for DHM. HMBs have now been established in over 60 countries, with a small but increasing number of milk banks opening in low- and middle-income countries.

WHO and the University of Zurich co-sponsored an international expert meeting in 2019 to examine the implementation, operation and regulation of HMBs *(4)*. The participants concluded that global guidance was required on the quality and safety of human milk banking *(5)*.

1.2 Purpose and target audience

These standards for banking donor human milk provide global, evidence-based guidance for ensuring the safety, quality and ethical management of DHM. Their purpose is to guide policymakers, health systems and milk bank operators in using best practices for DHM collection, processing and distribution.

1.3 Objective

The objective of these standards is to provide globally harmonized, evidence-based guidance for ensuring safe, ethical, high-quality collection, processing and distribution of DHM. The standards are intended to help Member States, United Nations agencies, nongovernmental organizations and other stakeholders to protect vulnerable infants by adhering to standards that preserve the nutritional and immunological integrity of human milk while safeguarding donor health and well-being. The standards are aligned with the WHO recommendations for the care of preterm



Very preterm baby learning to transition from nasogastric tube feeding to cup and spoon feeding © Born on the Edge

or low-birthweight infants *(6)*, which promote use of MOM as a priority as the optimal diet and first choice for infants. If MOM is insufficient (such as during the first hours or days after birth, when the mother's milk is still coming in and the preterm newborn requires higher volumes of their mother's milk than are available), DHM is indicated as the next best alternative.

The goals of these standards are to strengthen equitable access to safe, high-quality donor milk (when maternal lactation and breastfeeding are optimally supported and prioritized), improve neonatal survival and health outcomes and align with WHO's broader strategies for maternal, newborn and child health and nutrition.

1.4 Population of interest

The population of interest includes preterm and low-birthweight infants, who are at the greatest risk of morbidity and mortality and benefit most from DHM when MOM is unavailable or insufficient. The standards also address the needs of vulnerable newborns in low- and middle-income countries, where safe donor milk can significantly improve their survival and development. The standards also address the health and well-being of lactating donors, ensuring that donation practices do not compromise their own health or their infant's nutritional needs.

1.5 Scope

This document is intended to provide guidance for establishing and implementing safe, high-quality HMBs. It includes minimum standards and considerations of human milk donors, the recipients and product pathways, in direct alignment with guidance to protect, promote and support breastfeeding. This document does not address requirements for implementing the standards.

1.6 Justification

WHO recommends DHM for preterm and low-birthweight infants when their mother's milk is not available, as reflected in the Recommendations for care of the preterm or low-birthweight infant *(2)*. These standards do not, however, address the standards for safe collection, processing and distribution of donor milk. Establishment of WHO standards for banking of donor human milk is essential to ensure its safety, quality and equitable access, to harmonize global best practices and to support countries in integrating milk banking into public health systems, ultimately improving the outcomes of the most vulnerable infants.

1.7 Related WHO guidance

These standards are aligned with other WHO guidelines for safe, ethical, evidence-based use of donor milk for vulnerable infants. The Baby-friendly hospital initiative for small, sick and preterm newborns *(6)* explicitly calls for systems to ensure timely access to donor milk, to reduce neonatal morbidity and mortality. The WHO recommendations for care of the preterm or low birth weight infant *(2)* also emphasize that donor milk is a critical intervention when breastfeeding is not possible. The ethical and safety principles outlined in WHO's Principles on the donation and management of blood, blood components and other medical products of human origin *(7)* provide a framework for donor milk as a medical product of human origin, including informed consent, traceability and rigorous quality standards. Even in specific contexts, such as those addressed in the Clinical management of COVID-19: living guideline *(8)*, WHO maintains prioritization of DHM to safeguard infant nutrition during disruptions. Collectively, these recommendations are the basis for DHM banking standards, ensuring equitable access, clinical safety and alignment with global best practices, while protecting, promoting and supporting breastfeeding.

2. Methods

2.1 Standards Development Group

Members of the Group were identified according to their technical expertise in various disciplines related to human milk banking, including infectious disease, blood banking, food safety, lactation care, and milk banking operations. Candidates were identified from human milk banking associations, hospitals, academic institutions, ministries of health and nongovernmental organizations. Care was taken to ensure representation from different WHO regions and differing viewpoints on the topics covered. A total of 16 candidates was identified and asked to provide documentation relating to any potential conflict of interest. Members of the Group are listed in the Annex.

Potential conflicts of interests were managed by the steering committee, in collaboration with the WHO Office of Compliance and Risk Management and Ethics. All potential Group members, the first authors of the systematic reviews and observers also completed the standard WHO form for declaration of interests and signed forms ensuring confidentiality. Searches were conducted to identify any public statements made or positions held by potential Group members with respect to breastfeeding and complementary feeding. Any concerns were discussed with the Office of Compliance, Risk Management and Ethics and managed case by case.

Meetings of the Group were held both virtually and in-person from 2022–2024 to formulate the questions, to review the evidence and develop recommendations. To manage development of the current evidence-based recommendations, the Group adhered to the procedures outlined in the WHO handbook for guideline development *(9)*, with modifications to consider broader evidence, including impacts on safety and quality of milk and on donors and donors' infants. The steps in the process were: (i) identification of priority questions and critical outcomes, (ii) retrieval of evidence, (iii) assessment and synthesis of the evidence and (iv) formulation of recommendations. Group members reviewed multiple drafts of materials and recommendations online.

2.2 Formulation of priority questions

At first meeting of the Group in 2022, a review of existing WHO reference materials, as well as globally available HMB guidelines, were presented for background and discussion to inform the current context of milk banking globally. This built on the international expert meeting in 2019 and all documents were shared with the members electronically.

In October 2022, the WHO coordinating committee convened two virtual global stakeholder meetings to identify top issues that needed to be addressed in the Standards. The consultations included nominated representatives from major global and regional human milk banking associations, – the Human Milk Banking Network of Southeast Asia, the European Milk Banking

Association, the Global Alliance of Milk Banks and Associations, the Human Milk Banking Alliance of North America, the Programa Iberoamericano de Bancos de Leche Humano, and the Human Milk Banking Association of India – as well as senior milk banking leaders from each WHO Region. Participants reviewed and provided feedback on a proposed set of priority technical questions to assess their relevance to the global HMB community and to differentiate issues appropriate for normative HMB Standards versus those better addressed through implementation guidance.

Based on this feedback from stakeholders, the Standards Development Group consolidated a list of ten priority questions to be addressed, spanning donor recruitment and screening, milk expression, donor human milk (DHM) handling, treatment, and testing (Table 1).

Table 1. Priority questions to be addressed in the Standards

1. How do recruitment practices optimize donation efforts and prevent harm to the donor mother, her infant, the milk, and the recipient?
2. What selection criteria optimizes donation efforts and prevents harm to the donor mother, her infant, the recipient infant, and the donor milk?
3. What are the minimum requirements for providing donors with education and support on best practices for milk expression?
4. What are the minimum requirements for supporting human milk expression in order to achieve safe and quality donated human milk?
5. What are the minimum requirements for storage of expressed milk from expression until processing?
6. What are the minimum requirements for handling DHM, including DHM storage (temperature and time) pre- and post-pasteurization, containers used, and thawing practices to ensure safety and quality?
7. What are the minimum requirements for pooling, and track and trace of DHM to ensure safety and quality?
8. What are the minimum requirements for DHM safety and quality to ensure positive infant health outcomes?
9. What are the minimum requirements for treatment of DHM to ensure optimal safety and quality?
10. What are the minimum requirements for DHM testing to ensure safety and quality?



Human milk bank technician carefully aliquots pooled donated milk into individual containers for preparation for heat-treatment © Hearts Milk Bank

2.3 Collection and review of evidence

2.3.1 Systematic reviews

To compile relevant evidence on these priority questions, the Standards Development Group used the traditional participant-intervention-comparison-outcome (PICO) format for defining systematic reviews, considering that multiple types of evidence would be relevant for each question. Different PICO reviews were mapped to the priority questions.

The Group made two significant modifications. First, the concept of "population" (or subject) of interest was broadened to refer to the object of study, which included the milk itself, donors and their own babies, and recipients of donor milk. Secondly, the "comparison" was not explicitly specified a priori in order to include studies that addressed the extent of implementation, comparisons of several options or simply the absence of an intervention. WHO commissioned seven systematic reviews as described in the Table 2.

Table 2. PICO questions used for systematic literature reviews

PICO question	Population or subject details	Intervention/exposure details	Outcome details
1. What is the impact of storage, handling and treatment on the nutritional quality and safety of animal milk?	**Animal milk**: includes that from cows and other mammals (non-human)	**Storage**: refrigeration, freezing, length of time, containers for storage **Handling**: freeze–thaw number of times and methods, exposure to light **Treatment**: containers used during processing, treatment (high-pressure processing (HPP), ultraviolet C irradiation, high-temperature short-time (HTST) (*11*), holder pasteurization (HP) (milk is held at a temperature of 62.5°C for 30 min), other heat treatment (defined by time and temperature) or thermoultrasonic)	**Quality**: nutritional composition, bioactivity retention **Safety**: contamination–microbial load (count and type–pathogen); viral load What are the effects of maternal characteristics, expression practices or techniques, storage practices, mixing and pooling methods or treatment+ on the nutritional quality and safety of human milk?
2. What is the impact of maternal characteristics, expression practices or techniques, storage practices, mixing and pooling methods or treatment+ on the nutritional quality and safety of human milk?	**Human milk**: comprises both MOM and donor milk. Note whether the intervention includes only donor milk	**Maternal characteristics**: lactation stage, disease/health status, birth outcome, drug/medicine exposure, diet (restricted diet or diet quality index), lifestyle factors (smoking, drinking, factors related to increased risk of certain communicable diseases, such as multiple sexual partners) **Expression practices and techniques:** type of expression method (hand, with a (electric or manual, multi or single-user) breast pump, or other collection devices or methods such as drip milk collectors); hygiene practices during expression (hand washing, cleaning or sanitizing supplies, setting of expression)	**Quality**: nutritional composition, bioactivity retention **Safety**: contamination – microbial load (count and type, pathogen); viral load; presence of drugs; environmental toxins

PICO question	Population or subject details	Intervention/exposure details	Outcome details
		Storage practices: container (material, construction and shape) used for collection, number of container transfers, temperature, time and duration (by storage location in or out of facility, commercial or non-commercial storage equipment), lighting exposure (type and time), maintenance/cleaning of equipment and containers, freeze–thaw method and number of cycles **Mixing**: manual mixing, automatic mixing (donor milk only) **Pooling**: pooling milk from several donors with various selection criteria (e.g. early versus late term, time of day of expression) (donor milk only) **Treatments**: HPP, ultraviolet C irradiation, HTST, HP, other heat treatment (defined by time and temperature) or thermoultrasonic, container used during processing	
3. What is the impact of donating milk on the health, lactation and well-being of donors?	**Donors**: includes those donating their milk who have health concerns **Note**: Authors should report findings broken down by information on donor health (such as suboptimal birth outcome, including preterm birth, bereavement, low birth weight), body mass index outside healthy limit, acute or chronic illness)	**Donating milk** **Note**: Authors should report findings by time after birth	**Health**: includes nutritional and psychosocial outcomes **Lactation**: includes milk supply, feeding pumped milk, exclusive breastfeeding, duration of breastfeeding, mastitis **Well-being**: includes prevention of harm

PICO question	Population or subject details	Intervention/exposure details	Outcome details
4. What is the impact of providing milk from donors at various stages of lactation or with a suboptimal birth outcome on health and growth and maternal milk supply of the donor's infant?		**Stage of lactation**: various times after birth **Suboptimal birth outcomes**: include stillbirth, preterm birth, low birthweight and infant death.	**Health**: includes morbidity, mortality, tolerance, adverse events or effects, infections, developmental outcomes **Growth**: includes weight, height, head circumference **Supply** of MOM
5. What is the impact of feeding breast milk expressed by different practices and techniques or with treated or pasteurized milk on the health and growth outcomes of infants fed their MOM?		**Expression practices and techniques:** type of expression method (hand, with a (electric or manual, multi or single-user) breast pump, or other collection devices or methods such as drip milk collectors); hygiene practices during expression (hand washing, cleaning or sanitizing supplies, setting of expression) **Milk treatment:** any heat treatment before milk is fed to an infant	**Health:** includes morbidity, mortality, tolerance, adverse events or effects, infections, deficiencies in micronutrients (e.g. B12, vitamin A, iron), developmental outcomes **Growth**: includes weight, height, head circumference
6. What is the impact of breastfeeding on health and growth outcomes among infants of mothers with health concerns? [limited to evidence from systematic reviews]	**Health concerns**: include disease or health status, birth outcome, exposure to drugs and medicines, diet (restricted diet or diet quality index), lifestyle factors (smoking, drinking, factors related to increased risk of certain communicable diseases), body mass index beyond healthy limits, acute or chronic illness	**Breastfeeding**: feeding directly at the breast or with expressed MOM	**Health:** includes morbidity, mortality, tolerance, adverse events or effects, infections, deficiencies in micronutrients (e.g. B12, vitamin A, iron), developmental outcomes **Growth**: includes weight, height, head circumference

PICO question	Population or subject details	Intervention/exposure details	Outcome details
7. What is the impact of feeding milk from donors at various lactation stages, health concerns, various expression practices and techniques or with various treatment or testing methods on health and growth outcomes of infants fed donor milk?		**Lactation stages**: various times after birth **Health concerns**: disease or health status, birth outcome, exposure to drugs or medicines, diet (restricted or diet quality index), lifestyle factors (smoking, drinking, factors related to increased risk of certain communicable diseases), body mass index outside healthy limits, acute or chronic illness **Expression practices and techniques:** type of expression method (hand, with a (electric or manual, multi or single-user) breast pump, or other collection devices or methods such as drip milk collectors); hygiene practices during expression (hand washing, cleaning or sanitizing supplies, setting of expression) **Treatment**: HPP, ultraviolet C irradiation, HTST, HP, other heat treatment (defined by time and temperature), or thermoultrasonic **Testing**: pre-pasteurization or post-pasteurization testing of milk	**Health**: includes morbidity, mortality, tolerance, adverse events or effects, infections, developmental outcomes **Growth**: includes weight, height, head circumference

2.3.2 Narrative review on remuneration of donors

For the question of whether and how to remunerate donors of human milk, the Standards Development Group recognized that the PICO format for gathering evidence on specific outcomes would not adequately address the important ethical considerations. Therefore, WHO commissioned a narrative review of literature on the subject. The review considered themes of commodification of human milk, exploitation of donors, equity of access, donors' motivation, incentives to adulterate the milk or withhold disclosures, overproduction of milk, impacts on supply, and valuation of women's labour.

2.4 Decision-making

The WHO Evidence-to-Decision Framework *(12)* was adapted for deliberations and for achieving consensus on decisions. The framework is designed for use by committees to make recommendations on health care by moving from evidence to decisions and providing a concise summary of the available evidence for use in making decisions. The tool was modified to include the following considerations: the benefits and harms assessed relative to safety and quality of the milk and effects on donors, their infants, and recipients; the overall balance of benefits and harms; resource implications; the desirability of the intervention by key stakeholders; and impacts of the intervention on supply of DHM.

The Standards Development Group discussed the findings of the systematic reviews and supplementary evidence according to the evidence-to-decision framework. The Group reached consensus on the direction, strength and wording of the recommendation using a sociocracy process *(13)*, whereby members first expressed their agreement or disagreement on the details of each recommendation. When the members did not fully concur, suggested revisions were presented, and another round of voting was held, until the Group unanimously approved the wording of the recommendation. The Group provided further remarks on each recommendation to clarify and provide guidance on application of the recommendation.

For most recommendations, almost all the evidence was considered to be of low or very low certainty, because of limited sample size, limited description, a high risk of bias in the method or inconsistent results. For some questions, their were no or few robust studies available to guide a decision.

When drafting the standards, the Group considered each recommendation from the point of view of equity to ensure fair access to donor milk for all infants, especially those who are most medically vulnerable or in resource-poor settings. Considerations included inclusive access, non-discrimination, ethical sourcing and distribution, community engagement and empowerment, and sustainability and adaptability to local contexts.

3. Recommended practices

3.1 Donor recruitment

3.1.1 Recommended practice

1 Donor recruitment



- Human milk banks may recruit donors at all stages of lactation, regardless of the gestational age of the infant at birth. Recruitment strategies should be inclusive of all potential donors.
- Human milk banks should recruit only mothers who can express more milk than their infant needs or who have stored surplus milk.
- Human milk banks should provide support to bereaved mothers who wish to donate their milk.

Remarks

- Recruitment of donors at early stages of lactation may ensure that the nutritional composition of their milk is better aligned with the recipients' nutritional needs. Milk from donors early in lactation has higher contents of protein, zinc, copper, selenium and vitamins A, B12 and E.
- Donors may be recruited early in lactation to donate surplus expressed milk that would otherwise be discarded. Bereaved mothers may experience unique benefits from donating their milk.
- Recruitment of human milk donors should be based on eligibility criteria and the demand for donor milk.
- Any limitation placed on recruitment should avoid creating the perception that the breast milk produced by women who do not meet the eligibility criteria is unsafe or nutritionally incomplete, as such perceptions could discourage them from breastfeeding their own child.

3.1.2 Background

HMBs are responsible for identifying, recruiting and supporting potential milk donors. They raise awareness about the importance of milk donation and provide the necessary information and support to encourage mothers to donate their excess milk. This involves educating the public

about the benefits of DHM, the donation process and the impact of their contributions on the lives of infants in need. Recruitment strategies should be designed to maximize the donor pool, while ensuring the safety and quality of the milk and the well-being of donors, donors' infants and recipients of donor milk.

3.1.3 Evidence for benefits and for harms

Safety and quality of donor milk

The characteristics of donors may influence the safety and quality of donor milk. The second systematic review found that the quantities of protein, vitamins A and E, and some minerals and trace elements (e.g. sodium, zinc, copper and selenium) decrease over the course of lactation, while those of other nutrients, including lactose and some B vitamins, increase. This review found no consistent results for vitamin C but indicated that the quantity of vitamin B12 may decrease during lactation. Thus, the lactation stage of a donor influences the composition of donor milk. Additional evidence was found in a study on donor milk in five countries, in which the composition of milk from milk banks that collected mainly early milk (< 2 weeks postpartum) was different from that in milk banks that collected predominantly mature milk (> 1 month postpartum) with respect to many nutrients and bioactive compounds, such as immunoglobulin A (IgA) and lactoferrin *(14)*.

Benefits and harms to recipient infants

The systematic reviews found no evidence of benefit or harm to recipient infants of limiting donors to those early postpartum. As the micronutrient composition of donor milk may differ, the Group expressed concern about potential micronutrient deficiency with prolonged use of donor milk without micronutrient supplementation.

Benefits and harms to donors

The evidence from the systematic reviews indicates that donating milk is not detrimental to the health, lactation or well-being of donors. The third systematic review found no difference between milk bank donors and non-donors in body mass index, postpartum depression, postpartum anxiety, risk of pumped milk feedings, mastitis, cracked nipples or breast engorgement. More recent evidence has since been published that the act of donating milk has a generally positive impact on maternal well-being *(15)*.

The certainty of the evidence for all outcomes was, however, very low because of observational study designs, high risk of bias and imprecision of the summary estimates. The systematic reviews did not specifically examine recruitment strategies or practices; however, the relationships between donor characteristics and the quality of donor milk and impact of donation itself on donors were addressed.

3.1.4 Balance of benefits and harms

While the systematic reviews did not indicate any negative impact on donors, members of the Group raised concern that encouraging expression of milk by recruiting donors early in lactation,

before breastfeeding is fully established, may interfere with mothers providing milk to their own infants or could lead to hyperlactation, breast engorgement or plugged ducts. Excessive milk production may be influenced by the volume of milk donation, and expressing milk or breastfeeding one's own infant may put a donor at risk of anaemia or osteoporosis.

The Group agreed that inclusion of bereaved mothers and mothers with birth trauma in donor recruitment can provide psychosocial support during grieving and healing.

3.1.5 Resource implications

The costs of donor recruitment include that of identifying and engaging with lactating mothers to provide information about becoming a milk bank donor. Donor recruitment costs are also influenced by the timing and location of recruitment and the minimum donation requirements. No direct evidence was found on recruitment costs, and, therefore, the comments are based on expert opinion.

Recruitment strategies that target subgroups of donors with certain characteristics may increase donor recruitment costs, as the number of eligible donors is limited. Recruitment in hospitals during the perinatal period – ideally by health-care providers – may be more cost-effective, as the potential donors are all in the same place (rather than having to locate them once they have left the hospital). Recruitment of donors during the perinatal period could also reduce screening costs, if recent perinatal screening results are available. Recruitment costs are probably influenced by minimum donation requirements, as low-volume donors will increase average donor management costs.

3.1.6 Desirability

Drawing donors from among mothers of infants born preterm may improve awareness and the acceptability of DHM among recipient families. However, restriction of donor eligibility to specific groups, such as those who are breastfeeding infants < 6 or 12 months could create the impression that the quality of breast milk decreases over time and that breastfeeding beyond this age is not beneficial for their own infant. Such a restriction may also increase the burden of recruitment.

3.1.7 Impact on access to DHM

Proactive and inclusive donor recruitment can increase access to DHM by increasing the donor pool and improving the overall effectiveness of HMBs. Exclusive recruitment of certain sub-populations, such as mothers of preterm infants or in early lactation, may limit the availability of donor milk. It may also inadvertently negatively affect the experience of mothers who are unable to donate, resulting in feelings of rejection, frustration and exclusion.

3.1.8 Rationale

The Standards Development Group determined that the available evidence indicated that recruitment of donors in early lactation stages might ensure that the composition of donor milk

is more closely aligned with needs of the recipient population. However, there was insufficient evidence to make a clear recommendation. The Group agreed that recruitment practices should never undermine perceptions of the safety or quality of feeding MOM to their own infants. A more inclusive recruitment strategy could mitigate such concerns while maximizing the amount of donor milk for equitable access.

3.2 Remuneration of donors

3.2.1 Recommended practice

2 Remuneration of donors



- ☑ Financial incentives should not be offered to milk donors.
- ☑ Human milk banks may choose to reimburse donors for actual costs incurred in donating milk (e.g. milk expression supplies).

Remarks

- Reimbursement may take the form of financial, non-financial or in-kind support.
- Reimbursement of actual costs incurred by donors should maintain financial neutrality and not create a financial incentive.
- Examples of actual costs are those for travel, transport, equipment or consumables required to express and store milk safely.

3.2.2 Background

The remuneration of donors, particularly in the context of HMBs, is a topic of significant debate. Various models are used globally, ranging from non-financial support to direct financial incentives. The primary goal is to ensure a safe, steady supply of donor milk while maintaining ethical standards and avoiding exploitation. In 2017, the WHO secretariat reported to the World Health Assembly on the Principles on the donation and management of blood, blood components and other medical products of human origin *(7)*. The document highlights the importance of voluntary, non-remunerated donations to ensure the safety and quality of the product. While this helps to protect donors from exploitation, the principle also states that reasonable costs associated with donation should be covered or reimbursed. Additionally, the WHO Global framework for 100% voluntary blood donation *(16)* outlines steps to strengthen voluntary donor programmes, which may be weakened by donor remuneration and payments.

The narrative literature review on remuneration of donors identified a variety of harms resulting from remuneration of donations, but also pointed out a number of ways in which donation of human milk is distinct from the donation of other medical products of human origin. The frequency of milk expression is much greater, supplies required are distinct, and donors need to increase their nutritional intake to produce additional milk. The review discussed literature on the ethical considerations of not compensating women for their time and effort. It also pointed out potential benefits in increasing the supply of donors milk and economic empowerment of donors.

The Standards Development Group discussed the need to balance support to donors while mitigating concern about safety, quality and conflicts of interest introduced by incentives for donation.

3.2.3 Evidence on benefits and harms

Safety and quality of donor milk

The evidence on the impact of remuneration on donor behaviour and the quality of milk is mixed. Remuneration may negatively influence donor behaviour in ways that compromise milk quality. When donors are motivated primarily by financial gain, it has been shown that quantity is prioritized over quality. The narrative literature review on remuneration identified concerns over milk adulteration, such as dilution with water or the addition of cow's milk, to increase volume. In one study, bovine DNA was found in samples sold as human milk *(17)*, which raises serious concerns about safety, particularly for infants allergic to cow's milk protein.

Some donors who are seeking financial gain might withhold information that would make them ineligible to donate or would result in their milk being rejected, such as information about their health or lifestyle, neglected hygiene practices, failures in cold chain or storage requirements and/or adulteration or dilution of their milk to increase the volume of donation *(18)*.

The review also indicates that milk banks may find it difficult to maintain rigorous screening and infection control standards as donation volumes increase. If compensation leads to a rapid increase in donations without proportional investment in donor screening, testing and pasteurization, the risk of contamination or disease transmission to recipient infants increases.

Benefits and harms to donors

Monetizing milk donations can exploit women in difficult financial situations *(19,20)*. Financial pressure to produce large quantities of milk can lead to hyperlactation, maternal exhaustion, dehydration or mastitis, all of which can impair safe milk expression and storage. These risks are heightened for women in low-income contexts if they feel compelled to continue donating despite the health consequences.

Non-financial support to donors, however, could decrease the cost of donation, thus maintaining financial neutrality for donors while avoiding remuneration, which may increase the risk of exploitation. In Brazil and the United Kingdom of Great Britain and Northern Ireland *(19,20)*, donors do not receive financial payments for their milk, but milk banks offer support in the form of the free use of breast pumps, milk storage containers and reimbursement of transport costs

to facilitate donation and reduce the financial burden on donors *(21)*. Such non-financial support also ensures that more mothers can donate milk.

3.2.4 Balance of benefits and harms

Non-financial support, such as providing milk expression devices and supplies, milk storage containers and reimbursement for transport, alleviates the financial burden on donors without compromising the altruistic nature of donation. Financial compensation may affect the quality and safety of donor milk and lead to exploitation, particularly in low-income settings.

3.2.5 Resource implications

Remunerating donors, whether financially or with non-financial support, has significant implications for HMBs, depending on the types of remuneration and support provided to donors.

The Standards Development Group also noted that remuneration (financial or non-financial) may be an additional burden for HMBs in low-resource settings.

- Remuneration transfers the actual cost of donation (e.g. related to supplies) from the mother fully or partially to the HMB.
- Remuneration may increase the cost of processing or providing donor human milk.
- Remuneration is an extra expense for HMBs.
- Remunerating donors is cost-effective only if its impact on the volume of milk donated is large enough to offset the increased cost of collecting milk.

3.2.6 Desirability

Reimbursement of actual costs incurred can mitigate the risks of exploitation and maintain the integrity of donation while alleviating an undue burden on the donor. While financial remuneration may increase the availability of donor milk, it may undermine voluntary donation programmes and increase the cost of donor milk collection and processing. Non-financial support maintains the financial neutrality of donors and obviates the ethical issues associated with direct payments.

3.2.7 Impact on access to DHM

Reimbursing donors (financially or non-financially) for the costs associated with donating milk may reduce barriers (time, logistics) to donating milk and therefore potentially increase the number of donors, the length and frequency of donation and the overall availability of DHM.

Financial compensation can encourage donation of more milk, particularly in clinical settings with higher demand, such as neonatal intensive care units. Studies cited in the review of studies on remuneration indicate that compensation can attract donors and help to sustain donation over time, potentially improving access for vulnerable infants. Nevertheless, increased volume

can significantly strain systems for screening, pasteurization and quality control, especially in for-profit milk banks that process large quantities of paid donations.

Indirect evidence from the WHO Global framework for 100% voluntary blood donation *(16)*, however, indicates that well-informed voluntary donors are more likely than remunerated donors to report that they are no longer eligible to donate, thus reducing wastage with its associated costs, as fewer donations have to be discarded.

3.2.8 Rationale

The Group concluded that, where appropriate, reimbursement or remuneration for the costs incurred by milk donors costs would be appropriate to prevent an undue burden on the donor, who is already contributing her time and expressed milk. There was concern that provision of financial incentives would add to the cost of the donation process and potentially increase the requirement for testing or screening when necessary to validate the safety and quality of donor milk (such as to rule out contamination).

3.3 Donor screening

3.3.1 Recommended practice

3 Donor screening



- ☑ Screening of potential donors should include a risk questionnaire and serological screening.
- ☑ Donors who test positive for HIV or human T-lymphotropic virus 1 (HTLV-1) should be excluded.
- ☑ The risk questionnaire should exclude donors who take recreational drugs, alcohol or medications that are known to be passed into the milk and which are contraindicated in breastfeeding.

Remarks

- Considerations for screening in the risk questionnaire may be aligned with WHO recommendations for blood banking screening.
- Potential donors should be screened before donation and at a designated frequency during the donation period.
- Individuals who do not pass screening to become eligible donors should be encouraged to continue to breastfeed their own infant, unless there are contraindications.



3.3.2 Background

Screening procedures help to minimize any potential risk of transmitting infectious diseases or harmful substances to the recipient infant, who may be particularly vulnerable due to illness or prematurity.

Risk questionnaires are commonly used to collect information on the donor's health and on the dose and timing of the latest exposure to harmful substances. Careful evaluation of the responses allows health-care providers to identify individuals who may pose a risk and to exclude them from the donor pool. Recreational drug use, including smoking tobacco, heavy alcohol consumption and certain medications, can introduce harmful substances into the milk, which may adversely affect the health of the recipient infant. The Group discussed exclusion of donors with these risk factors in order to prevent contamination of DHM.

3.3.3 Evidence on benefits and harms

Safety and quality of donor milk

The second systematic review examined the literature on use of recreational drugs and exposure of infants through milk. The evidence indicates that lactating women who smoke tobacco, consume alcohol and/or use other recreational drugs (e.g. cannabinoids) transmit these drugs into their milk and that heavier exposure results in higher concentrations in breast milk.

The Group also discussed screening donors for those on a vegetarian or vegan diet. The second systematic review indicated that restriction or elimination of animal-source foods has no significant effect on the nutritional profile of milk, with the possible exceptions of vitamin B12 and iodine.

Benefits and harms to recipients

No evidence was available on the impact of milk from donors with known diseases on recipients; therefore, the evidence reviewed was derived from guidance on breastfeeding more broadly. A review of studies on mother-to-child transmission through breastfeeding indicated that mothers with HIV or HTLV-1 can transmit the diseases to their infant in their milk *(22)*. For this reason, the Group considered that HIV and HTLV-1 are priority viruses for screening to prevent transmission through donor milk, even if the potential for transmission can be mitigated by heat-treatment and processing.

A sub-group of experts from the Group discussed the other diseases for which to potentially screen, including hepatitis B and C, cytomegalovirus (CMV) and syphilis. The live virus that causes hepatitis B is not, however, transmitted through milk but rather through other contacts such as open sores on the breast. The subgroup therefore considered that there was insufficient evidence to recommend screening for all the viruses. They discussed an ideal scenario in which the end product (i.e. DHM ready for dispatch) could be tested instead of screening the mother. They considered, however, that this was not yet a viable option with current diagnostics for human milk, or for alignment with milk banking practices and costing mechanisms.

Benefits and harms to the donor and her infant

The third and fourth systematic reviews were of a limited number of studies that indicated that donation of milk caused no harm to either the donor or her infant.

Serological screening of donors can provide valuable health information and lead to improved healthcare and support. The benefits for potential donors and their families include identification of unknown health conditions and guidance on caring for themselves and their families.

The Group discussed concern that screening might discourage some mothers from breastfeeding their own infants. Furthermore, exclusion of potential donors from the donor pool because of their lifestyle choices or medical treatments could lead to feelings of rejection and could discourage breastfeeding altogether. Recent evidence on the effect of donating milk on maternal well-being (published after the systematic reviews were conducted) indicates that women who were unable to donate reported feelings of rejection, frustration with not receiving a response or feeling that the restrictions were unfair *(23)*.

The Group also investigated the impact of a mother donating her milk on the health and growth of her own child. The fourth systematic provided evidence that donating human milk has no effect on the health or growth outcomes of donors' infants (very low certainty evidence). There was no evidence of effects of continued breastfeeding during donation.

3.3.4 Balance of benefits and harms

While screening can be a negative or positive experience for potential donors, the Group concluded that inclusion of serological tests for HIV and HTLV-1 is crucial for identifying potential donors who carry these pathogens, thereby reducing the risk of transmitting infections through donor milk. The Group concluded that serological screening is effective in detecting these infections, which can pose significant risks to recipient infants.

3.3.5 Resource implications

Moderate costs are associated with increasing screening requirements, including staff training and serological testing. The Group prioritized the most impactful screening tests for inclusion in the recommendation but also affirmed that additional serological screening could be conducted in accordance with local disease prevalence (e.g. to align with WHO blood banking guidelines adapted for local use and transmission through human milk), if the resources required are offset by the reduction in risk of transmission. There are minimal resource implications of factors that can be assessed from a questionnaire or from verbal screening.

3.3.6 Desirability

The Group considered that recipient families and health-care providers are likely to prefer DHM from mothers who have been screened and found to be healthy, do not smoke, do not drink alcohol, do not take medication and are free from certain environmental exposures. The Group

agreed that potential donors would not wish to be screened for unfounded concerns. When prospective donors are rejected during screening, it is desirable and appropriate to provide reinforcement and education on continuing to feed their own infant.

3.3.7 Impact on access to DHM

The Group considered that exclusion of potential donors because of their lifestyle choices, exposure or medical treatments that have no effect on the quality of their milk would restrict the pool of available donors and limit access to DHM. Additionally, if transmission is unlikely, the cost of additional tests would probably increase the cost of DHM, which could reduce the equity of access. Excessive serological screening may decrease the number of donors who can be screened and thus restrict the pool of donors and available DHM.

3.3.8 Rationale

The Standards Development Group recommended serological screening of potential donors for HIV and HTLV-1 and administration of a risk questionnaire that includes questions on use of recreational drugs (including tobacco), alcohol or medications to potential donors of human milk due to concern about transmission of or exposure to harmful substances. The Group did not recommend testing for CMV, hepatitis B or C or syphilis for at least one of the following reasons: difficulty in interpreting seropositivity, low risk of transmission through breast milk, inactivation through heat treatment and a reduction in donor eligibility. The prioritized set of testing recommendations was considered to balance cost and the ability of milk banks to screen donors to maintain a safe supply of donor milk.

3.4 Donor education and support

3.4.1 Recommended practice

4 Donor education and support



- Human milk banks should protect and support continued breastfeeding by donor mothers, ensuring that the donor's infant is receiving their mother's milk.
- Human milk banks should support the donor's health, including by preventing excessive milk donation and hyperlactation.
- Donors should be asked to report any changes in their health or behaviours that might affect the safety of their donor milk.
- Human milk banks should train mothers in expressing their milk with techniques and equipment that are safe and acceptable, while encouraging them to use their preferred method of expression.
- Human milk banks should train mothers in adhering to hygiene practices, including hand hygiene and cleaning and disinfection of equipment and/or supplies for milk expression when expressing milk.

Remarks

- Support for donors may include provision of skilled lactation care and the supplies necessary for milk collection and storage.
- Human milk banks should adopt the WHO Guidelines on hand hygiene in health care *(1)*.
- Both manual and electric breast pumps and hand expression are all acceptable. Devices designed for individuals or several users are acceptable.
- Human milk banks may accept milk expressed before the donor receives support and education on expression if the donors report that they use storage and hygiene practices consistent with milk bank requirements.

3.4.2 Background

Proper education ensures that donors are well informed about the importance of their contribution and the impact it has on the health of recipient infants. It also helps donors to understand the procedures and practices involved in milk donation, including hygiene practices, milk expression techniques and storage and handling standards, which are crucial for maintaining the safety and quality of donor milk.

Support for donors is equally important. Provision of emotional and practical support can enhance the donor's experience and encourage continued participation in milk donation programmes. The support can include lactation counselling, access to milk expression equipment and guidance on managing lactation and milk supply. By addressing the needs and concerns of donors, HMBs can foster a positive and supportive environment to promote successful donation of safe, high-quality milk.

3.4.3 Evidence on benefits and harms

Benefits and harms to the donor

No direct evidence was available from systematic reviews that education of donors in expressing milk prevents harm to the donor, their infant or the quality and safety of the donated product. There is also no evidence that donors have higher rates of injury or poor lactation outcomes according to their expression practices, such as use of a certain type of breast pump. The Group nevertheless considered that lack of support and education could result in poor breastfeeding outcomes and perhaps even early cessation of breastfeeding. The Group discussed the possibility that teaching milk expression and donation practices to prevent oversupply or hyperlactation might also have a positive impact on the donor or her infant and prevent mastitis and/or trauma to the breast.

Safety and quality of donor milk

The Group agreed on the importance of providing counselling on milk expression practices that result in safe, high-quality donor milk. With respect to expression techniques, the seventh systematic review indicated that use of different methods, equipment and/or containers can affect the protein and fat content of donor milk. The fifth systematic review indicated that expressing milk by hand or with a large electric pump may increase the protein content, while hand expression may increase the sodium content. The Group did not, however, consider this evidence sufficient to change milk donation instructions. The fourth systematic review included a single study that showed no difference in the contamination of DHM according to the method of expression.

Direct evidence from the second and fifth systematic reviews indicates that proper hygiene practices and maintenance and cleaning of milk expression equipment have no impact on the nutritional composition or bioactivity of the milk, nor was any difference found when milk was expressed manually or with an electric pump, as also indicated in the fourth systematic review.

Benefits and harms to the recipient

No direct evidence was available on the benefit or harm of donor counselling to infants receiving donor milk. It may be possible, however, to extrapolate from evidence on maternal lactation practices that affect their own infants. For example, the fifth systematic review provides low-certainty evidence that feeding MOM that has been expressed at the latter end of an expression session (at least 3 min after the starting, known as "hindmilk") to very-low-birthweight, preterm infants with slow growth improved growth relative to feeding of milk expressed in the first few minutes of an expression session. Although this evidence was compelling, the Group did not consider it sufficient to change instructions on donor milk expression and collection practices.

The fifth systematic review also found that hand expression of milk results in infant growth similar to that with milk expressed with a breast pump. No direct evidence was found that the use or non-use of any breast pump increases the risk of harm to recipient infants or increases the risk of contamination, nor was there evidence that specific hygiene practices affect the health or growth of infants fed MOM. Similarly, with respect to the type of pump used, the fifth systematic review indicated no difference in infant outcomes (including necrotizing enterocolitis) according to the type of breast pump that mothers used to expressed milk to feed to their very low-birthweight infant.

While no direct evidence was available, the Group discussed the importance of counselling donors to report any change in their health status (such as a change in medication intake) during donation, to ensure the safety of donated products.

3.4.4 Balance of benefits and harms

Educating donors about hygienic milk expression, safe milk storage and safe practices (e.g. reporting any new medications after starting milk donation) probably mitigates the risk of contamination at the site of milk expression. Proper training in expression and support can prevent negative health outcomes for both donors and recipients by ensuring the safety and quality of donor milk. Donors may also benefit from education on nutrition and diet during lactation and donation.

The Group agreed that education and support for milk donors should also emphasize the safety and value of directly breastfeeding the donor's own child, to avoid confusion and disruption to the breastfeeding relationship.

3.4.5 Resource implications

Costs associated with donor education and support include HMB staff time and teaching resources to train and educate donors. These costs can be offset by a reduction in the volume of discarded milk due to improved hygiene practices, leading e.g. to less wastage of DHM after microbiological testing. Cleaning and disinfection of breast milk expression equipment and supplies should be considered, as hand expression is the least costly means of milk expression, requiring no equipment and minimal supplies.

3.4.6 Desirability

Education to improve and guide the donation experience, protect the donor dyad's breastfeeding relationship and enhance the safety of the product is desirable for donors, recipient families and health-care workers. Skilled lactation support may prevent contamination in DHM, increasing its desirability for recipients and health-care workers. Recruitment strategies that include comprehensive information and education about donation and the benefits of human milk donation were considered by the Group to be desirable for potential donors with no previous knowledge of milk banking.

3.4.7 Impact on access to DHM

Lactation support with an emphasis on safety and efficiency was considered by the Group to be the most significant action for ensuring a high volume of donor milk that passes screening. The expression technique used was considered to have no impact on the total volume of milk donated.

Donor education and support potentially increase access to DHM due to less wastage (because of the decrease in discard rate after testing DHM for microbial growth). Increased support for optimal breastfeeding may also increase donor retention, as it may increase the length and frequency of donation and also provide connection, support, trust and a relationship with the HMB.

3.4.8 Rationale

The Standards Development Group agreed broadly to recommend provision of lactation support and education, primarily on safety in milk handling, with broad recommendations on the method of and equipment for milk expression according to the donors' preference.

3.5 Containers for expressed milk and processing

3.5.1 Recommended practice

5 | Containers for milk expression and processing



- ☑ Expressed milk may be stored and transported in any clean, food-grade container that can be sealed effectively and resists breakage.
- ☑ Containers for handling and processing milk at a human milk bank should be easy to clean, disinfect and label, resistant to breakage, have an effective closure and be of approved food grade quality.

Remarks

- Approved food-grade containers made of glass, plastic or stainless steel or any other food-grade approved material may be used to collect, store and transport expressed breast milk to a human milk bank.
- The local supply chain should inform the choice of container.

3.5.2 Background

The containers used for milk expression and processing require special consideration to ensure their safety and quality and the accessibility of DHM. The choice of container requires consideration of various factors, including environmental and clinical safety, cost, availability and the efficiency of milk processing and storage.

3.5.3 Evidence on benefits and harms

Safety and quality of donor milk

The evidence on the impact of container type on the safety and quality of expressed milk is varied. Most of the studies included in the second systematic review suggest no difference in macronutrient loss according to container type – plastic, glass, or stainless steel or by type of plastic, such as hard rather than soft polypropylene. The findings on the impact of container type on retention of bioactive proteins and nutrients such as vitamin C and E were, however, conflicting, as the content of these elements decreased to varying degrees across container types.

The second systematic review indicated no change in bioactivity (IgA, lysozyme*)* in glass versus plastic and glass versus stainless steel containers, although comparisons of glass versus polyethylene bags showed conflicting findings. Limited evidence indicated no difference in bacterial load according to container type and no change in bacterial load between sterile and clean storage containers.

The authors of the second systematic review found no studies on the impact of storage container material on viral load, drug transfer or environmental contaminants or toxins.

The Group was concerned about potential harm with use of plastic containers, noting that some plastics crack at low temperatures, and microplastics could contaminate DHM during heating and cooling.

Benefits and harms to the recipient

The authors of the seventh systematic review also found no studies on the effect of the type of container used in donor milk processing on the health outcomes of the recipients.

3.5.4 Balance of benefits and harms

The overall certainty of evidence on the benefits of different container types for milk expression and processing is low, as there were few studies. While some reported no significant difference in bacterial load or nutrient composition, the Group noted the potential risks associated with certain container materials, such as bisphenol A plastics and microplastics, which should be considered in selecting food-grade containers.

3.5.5 Resource implications

The cost of containers differs significantly according to local availability and the choice between single- and multi-use containers. Single-use containers may be associated with disposal costs, while multi-use containers require ongoing cleaning and sterilization. The choice of container (e.g. glass versus plastic storage bottles) may also have resource implications due to shipping costs.

3.5.6 Desirability

Containers for milk expression and processing should be easy to use, clean and label. They should be compatible with the selected milk expression method and with storage conditions before processing. Donors and milk banking systems may prefer glass to polypropylene food-grade plastic containers due to their lower cost, safety, durability and ease of use.

3.5.7 Impact on access to DHM

Provision of containers for donation or recommending use of containers that are easily available and low cost may help facilitate donation and therefore increase access to donor milk. Containers that are resilient to transport, storage and processing conditions will also reduce wastage of donor milk.

3.5.8 Rationale

After discussing various safe options for DHM containers (from expression through processing and storage), the Group based its recommendations on the safety, ease of use and cost-effectiveness of containers. The prioritized containers that facilitate milk banking practices, are easy to clean, disinfect and label, are resistant to breakage, have an effective closure and are food-grade approved.

3.6 Storage and handling of donor milk

3.6.1 Recommended practice

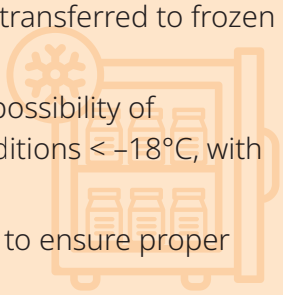
6 Storage and handling of donor milk



- Human milk expressed for donation should be refrigerated or frozen as soon as possible, within a maximum of 4 hours after it is expressed.
- Raw human milk should not be stored for more than 4 days in a refrigerator (at 4 ± 2°C).
- Raw human milk may be stored in a freezer (< –18°C) for up to 6 months before donation.
- Pasteurized milk may be kept frozen before use for up to 6 months from the day of pasteurization, in frozen storage (< –18°C).
- Human milk banks should maintain reliable refrigeration (4 ± 2°C) and freezer conditions (< 18°C) for safe storage of donor milk from the time of receipt of donation until delivery to the recipient, including maintaining the cold chain during transport.
- All cold storage temperatures should be monitored regularly (manually or digitally) and recorded at least twice per day with reliable instruments.

Remarks

- In settings with high ambient temperatures, expressed human milk might have to be refrigerated or frozen sooner than in the recommendation.
- If refrigeration temperatures cannot be maintained reliably at 4 ± 2°C, expressed milk should not be stored for more than 12 h before it is either transferred to frozen storage or transported to a milk bank.
- The criteria for the reliability of a human milk bank include the possibility of maintaining refrigeration conditions at 4 ± 2°C and freezer conditions < –18°C, with use of back-up electricity if necessary.
- Storage temperature conditions should be monitored regularly to ensure proper maintenance of temperatures and the cold chain.



3.6.2 Background

Proper storage of donor milk is essential to maintain its nutritional quality and safety. Storage conditions can significantly affect the bacterial and viral loads and nutrient composition of the

milk. Reliable cold-chain storage is commonplace in high-income settings but it may be less feasible in resource-limited settings because of the high cost of setting up and maintaining a cold chain with consistent electricity for refrigeration and freezers.

Proper handling of DHM requires a coordinated approach at all stages of donation: collection, processing, transport, storage and administration. Maintenance of the cold chain during transport, using evidence-based freezing and thawing methods and ensuring optimal storage conditions are essential to safeguard the quality of donor milk. Adherence to such protocols not only preserves the unique immunological and nutritional benefits of human milk but is also vital to protect the health of the most vulnerable infants.

3.6.3 Evidence on benefits and harms

Safety and quality of donor milk

The evidence indicates that appropriate storage conditions, from expression until use, of donor milk are essential to maintain its safety and quality.

Raw human milk

The second systematic review indicated that the bacterial load of expressed milk increases after 24 hours of storage at room temperature. It was, however, not clear when the increase begins. Storage of milk at room temperature, especially > 30°C, can significantly increase the bacterial load.

The review indicated that unpasteurized human milk stored in a refrigerator (4°C) for less than 1 week generally maintains its nutritional content and bacterial load. Additionally, the activity of IgA remains intact during storage at 4°C for 1 week, while the loads of viruses (CMV, Zika) are usually reduced at this temperature. Longer storage at 4°C, however, can increase the bacterial load and decrease the amounts of certain nutrients, such as vitamin C.

The review indicated that the bacterial load of unpasteurized human milk in a freezer (– 20°C), remains constant for 3 months and then decreases *(24)*. Most but not all essential nutrients were reported to remain at stable levels for up to 3–6 months at – 20°C.

Pasteurized human milk

No bacterial growth was found in Holder-pasteurized DHM after 9 days of refrigeration (4°C).

DHM that was Holder pasteurized within 3 months of expression can be stored at – 20°C for up to 8 months without compromising its macronutrient or energy content *(25)*.

Freeze–thaw cycles

The Group was also interested in freeze–thaw practices and their impact on the safety and quality of donor milk. The second systematic review indicated that freeze–thaw cycles did not affect the bacterial load or nutritional composition of DHM; more specifically, no significant differences in macronutrients were found after quick and after slow thawing. The review found no difference

in bacterial load between warming in tepid water and without water or between use of and automatic freezer and manual defrosting (very low-quality evidence). The review indicated that retention of bioactivity was unclear, as there were insufficient studies that found a clear impact of thawing practices.

Benefits and harms to the recipient

The evidence for an impact of storage temperatures on infant outcomes was inconclusive; however, the fifth systematic review provided indirect evidence of a lower rate of CMV transmission when infants were fed MOM that had been freeze–thawed rather than fresh MOM.

The second systematic review indicated that exposure to light has a minimal effect on the composition of milk (including carotenoids, triglycerides and antioxidant activity); however, thiamine and riboflavin degraded in light. No studies were found of the effect of exposure to light on the presence of environmental contaminants (organic and inorganic) or drug contamination. The Group considered this limited evidence to be insufficient for making a recommendation.

3.6.4 Balance of benefits and harms

The evidence indicates that cold-chain storage and standard handling practices for DHM are effective in preserving microbiological safety and nutritional quality, although evidence on direct links to infant health outcomes is limited. For raw human milk, ambient storage should be minimized because of rapid bacterial growth in these conditions, while refrigeration at 4°C for up to 1 week maintains bacterial stability, preserves IgA and is associated with reductions in the load of certain viruses; freezer storage at – 20°C maintains a stable bacterial load and most nutrients for up to 3 months. For pasteurized DHM, refrigeration at 4°C prevents bacterial growth for at least 9 days after thawing, and frozen storage at 20°C allows safe storage for up to 8 months without compromising the macronutrient or energy content when milk is Holder-pasteurized within 3 months of expression.

3.6.5 Resource implications

Implementation of the recommendations of the Standards Development Group may require HMBs to invest in additional infrastructure, equipment and procedures. The cost of initial procurement and installation of equipment and maintenance costs should be considered. Back-up generators or solar power may be necessary to maintain storage conditions during power outages.

3.6.6 Desirability

Donors, recipients and health-care workers want to know that DHM is safely and optimally stored at all steps in the HMB process for product quality. Appropriate storage conditions with verification and monitoring increase trust in the safety and desirability of donor milk for both recipients and health-care workers.

Impact on access to DHM

The capacity of cold chain storage must be adapted to higher donation volumes. Freezer and refrigeration capacity also allow longer storage between donation and use, which may ensure access to larger volumes of donor milk to meet fluctuating demand.

If many potential donors do not have access to the recommended storage conditions, access to DHM could be decreased, limiting the methods for donation and, potentially, the number of eligible donors.

Inappropriate freezing and thawing and inadequate monitoring of such conditions can result in unsafe conditions, with higher fail rates in DHM microbiology screening, thus reducing access to safe, high-quality DHM for recipients.

Rationale

The Group recognized that overly long storage of milk reduces its safety and quality; however, requiring that milk be discarded if it is not processed or is used after only a short time in storage wastes excessive amounts of donor milk. To balance these considerations, the Group decided to align its recommendations on milk storage with the guidelines of the Academy of Breastfeeding Medicine *(26)*.

3.7 Pooling, mixing, tracking and tracing donor milk

3.7.1 Recommended practice

7 | Pooling, mixing, and tracking and tracing of donor milk



- ☑ Where culturally appropriate, human milk banks may pool milk from several donors to improve its nutritional adequacy and consistency.
- ☑ Single and multi-donor pools may be mixed effectively either mechanically or manually.
- ☑ Human milk banks should have track-and-trace systems to track donor milk from donor to recipient and to trace donor milk from recipient to donor in case of an adverse event.

Remarks

- If resources and infrastructure allow, human milk banks should prioritize digital track-and-trace systems, although paper-based systems are acceptable in settings in which digital solutions are not feasible.

3.7.2 Background

"Pooling" refers to combining milk donated by several donors. Pooling is practised by many HMBs worldwide. "Mixing" is agitating donor milk to prevent separation during bottling. The purpose of mixing is to improve the nutritional consistency and adequacy of DHM.

Track-and-trace systems are used to record the movement, processing and distribution of donor milk from the point of donation to delivery to the recipient. Such systems often include bar-coding, electronic records and integrated databases, which have important advantages, including greater data accuracy, easier retrieval of records and greater capacity for scaling and reporting. Well-designed paper-based systems nevertheless remain acceptable and widely used in resource-limited settings, provided that the records are consistently maintained, securely stored and regularly reviewed.

These systems not only streamline workflows and increase operational efficiency but are also "pillars" of safety, nutritional assurance and trust, increasing the confidence of donors, recipients, health-care providers and regulatory bodies.

3.7.3 Evidence on benefits and harms

Safety and quality of donor milk

The evidence included in the second systematic review was limited to the effects of pooling and mixing donor milk on its nutritional content. It was found that combining donated milk decreases nutritional variability, specifically in the amounts of protein and fat. One study reviewed reported that pooling reduced variability in the activity of IgA *(27)*. None of the studies reviewed addressed the impact of pooling on bacterial load, viral load, drugs or environmental toxins. Both manual and mechanical mixing improved the nutritional content of bottles of donor milk over that with no mixing, indicating that regular mixing during production is important. Evidence that mechanical mixing results in less variation in fat content was inconsistent.

Benefits and harms to the recipient

None of the studies in the seventh systematic review addressed infant health outcomes with use of multi-donor pooled milk rather than single-donor milk.

3.7.4 Balance of benefits and harms

The reviews showed that both pooling and mixing result in greater consistency in the nutritional content of milk. As the number of donors pooled increases, however, the risks of contamination increase, and some batches do not pass screening. The Standards Development Group also discussed the potential problem that pooling milk from several donors could increase the complexity of track-and-trace systems.

While no studies on this possibility were identified, the Group considered that track-and-trace systems can help to ensure that any issues with milk are quickly identified and addressed, thus enhancing the overall safety of DHM.

3.7.5 Resource implications

Processing larger volumes of milk generally reduces costs due to economies of scale. Pooling management, however, may require more space for processing and storage, which may increase costs. Additionally, it is more costly to discard a large batch of pooled donor milk that does not pass microbial screening than a smaller volume.

The Group was confident that simple, low-cost track-and-trace systems could be used in low-resource settings with no additional expenses. Simple, paper-based systems can be used if digital system integration is not cost-effective.

3.7.6 Desirability

Pooling milk from one donor is common globally; however, pooling milk from different donors is conducted in various ways. In some countries, pooling of milk from several donors might conflict with certain cultural or religious beliefs. Recipients and health-care workers, however, may prefer the more consistent nutritional content of DHM that can be achieved by pooling and mixing.

The Group recognized that track-and-trace systems provide confidence for policy, regulatory monitoring, clinical providers and families.

3.7.7 Impact on access to DHM

Pooling of blood from several donors as opposed to pooling milk from a single donor has a negligible direct effect on access to DHM. The additional time and staff labour costs associated with managing multi-donor pooling and/or added track-and-trace steps may reduce access in some settings. Pooling milk from several donors may results in higher volumes of discarded milk, such as when one donation in a multi-donor pool introduces contamination, and the entire batch must be discarded.

3.7.8 Rationale

The Group agreed on the nutritional benefits of pooling donor milk from several donors to increase the likelihood of a more consistent nutritional product. In view of the lack of evidence on the clinical impact on recipients, especially for when a low volume of donor milk is given (when used as a short bridge to feeding MOM), feeding of pooled DHM is recommended where feasible but is not mandatory. The findings on methods used for mixing were not strong, and the Group recommended that either mechanical or manual mixing could be used. The Group unanimously agreed on the necessity of a track-and-trace system to facilitate investigation of adverse events.

3.8 Treatment of donor milk

3.8.1 Recommended practice

8 Treatment of donor milk



- ☑ To ensure microbiological safety, donor milk from screened healthy women should be heat-treated by holder pasteurization or high-temperature short-time to reduce or eliminate any pathogen (viral or bacteriological).
- ☑ Heat treatment may be avoided if each container of raw milk is tested to ensure that it remains within safety limits determined locally to be acceptable.
- ☑ Retort methods of heat treatment are not recommended.

Remarks

- Several alternative non-thermal processing procedures are being investigated and have been shown to retain heat-sensitive nutrients and bioactive components in donor milk more effectively. High-pressure processing is used widely in the food industry, and the available data suggest that its use may result in a microbiologically safe product comparable to that of heat-treated milk. These newer technologies are probably most suitable for large regional milk banks that have the necessary capital and infrastructure.
- When donor milk is not pasteurized, donors must be screened more carefully, perhaps more frequently, to limit any risk of viral transmission.

3.8.2 Background

Most HMBs use some form of heat treatment as an added safety mechanism for destroying pathogenic microorganisms that may have resulted from contamination or due to viral conditions that were missed during donor screening. Maintenance of the bioactivity and nutritional composition of the milk is also critically important, especially for vulnerable infants who are at higher risk of infection. Heat treatment standardizes safety across batches, providing reassurance to both health-care providers and recipients. On the other hand, raw, untreated donor milk may be considered to be of higher quality as it retains its bioactive properties for supporting immunity and the health of the recipient, but this requires enhanced donor screening and greater scrutiny of milk handling.

3.8.3 Evidence on benefits and harms

Safety and quality of donor milk

Heat treatment

The second systematic review indicated that heat treatment methods, such as Holder pasteurization (HP) HTST or flash heating, are effective in reducing the microbial load of human milk to below detectable levels. Some studies, however, showed less reduction in microbial load, with viable cells still present after processing. Spores of *Bacillus* species are not destroyed by heat treatment *(28,29)*. The second systematic review also found that HP was sufficient to inactivate most non-thermally resistant viruses; however, heat treatment at < 62.5°C for 30 min did not consistently inactivate viruses.

Heat treatment such as pasteurization can reduce the levels of some nutrients in DHM. The second systematic review indicated that the levels of heat-sensitive vitamins such as folate and vitamin C are consistently reduced by HP but that pasteurization does not appear to reduce the concentrations of macronutrients (carbohydrate, fat, protein). HTST was shown to have a minimal impact on folate and vitamin C, with better retention than with HP. While few studies have addressed the impact of HP on trace minerals, most reported no change as a result of processing. There was limited evidence for slight reductions in the levels of calcium, iron and phosphorus.

The second systematic review also indicated that HP of human milk impaired its immunological properties, specifically, a reduction in bioactive properties, including IgA, IgM, IgG, lysozyme and others, HTST preserved more bioactive components in human milk than HP, although it slightly reduced the concentrations of certain components, such as IgA and lactoferrin.

High-pressure processing

The second systematic review indicated that high-pressure processing[1] was effective at reducing bacterial loads to below detectable levels in most studies *(27,29)*. The review indicated that non-thermal processing generally preserves the nutrients and bioactive components better than HP. No studies were found that addressed the impact of HPP on minerals and trace elements.

Alternative processing

The second systematic review indicated large effects of the retort method.[2] The lactoferrin content decreased to 16%, the IgA content dropped by 10–80% and that of lysozyme by 0–100% of the content present before treatment.

The review included very few studies of the effects of alternative processing methods (e.g. UV-C irradiation, thermoultrasonic treatment) on inactivation of viruses.

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[1] High-pressure processing involves application of 400–800 MPa for < 5–10 min.

[2] In the retort method, human milk is exposed to high temperature (115 to 145°C) under pressure for several minutes to sterilize human milk *(28)*.

Benefits and harms to the recipient

The impact of pasteurization of DHM fed to a recipient was not clear, as indicated in the seventh systematic review. Feeding MOM that had been processed had various effects on health. Some studies in the fifth systematic review found that feeding pasteurized rather than raw MOM did not significantly affect feeding tolerance or growth; however, mixed results were reported for an effect on time to full enteral feeds, one study favouring untreated MOM. Conflicting evidence was found on the impact of feeding pasteurized rather than thawed MOM on bronchopulmonary dysplasia, although one study in the same review showed that oxygen therapy was required for a significantly shorter time for infants receiving Holder-pasteurized MOM than those receiving frozen–thawed MOM. The systematic review included limited evidence that feeding raw rather than pasteurized MOM appeared to prevent clinical bronchopulmonary dysplasia. The systematic review also indicated mixed results for the effect of feeding pasteurized MOM on infant growth, some studies indicating no effect and others favouring fresh MOM with respect to time to regain birth weight, length and head circumference as compared with Holder-pasteurized MOM. The review also indicated that feeding pasteurized rather than raw MOM did not change the occurrence of necrotizing enterocolitis or retinopathy of prematurity.

Only one randomized controlled trial was found for the seventh systematic review that addressed the effects of DHM subjected to different treatment methods. Although the sample size was limited, no difference in nosocomial sepsis or additional secondary health outcomes was found between infants who received HP-treated rather than HTST-treated DHM. Furthermore, no direct evidence was found on the safety or harm of unpasteurized DHM versus pasteurized DHM on infant outcomes. The Group made note of the safety of systems used currently in Germany and Norway in which unpasteurized donor milk is used, with additional screening of the donors and the donor milk. The Group agreed that the practice might be appropriate in some settings.

3.8.4 Balance of benefits and harms

There is insufficient evidence to determine the effects of alternative processing technologies on the nutritional composition of donor milk. Overall, the balance of benefits and harms in the evidence suggests that, while pasteurization increases the safety of DHM by reducing its microbial load, it also reduces some nutritional and bioactive properties. The evidence on the impact on health outcomes is mixed, some studies showing benefits of raw over pasteurized human milk.

3.8.5 Resource implications

There were insufficient studies to determine the time and cost of milk banking models with raw and with pasteurized human milk. HP and HTST can be conducted with low-cost, manual or semi-automated systems, although each requires personnel resources for safe operation, handling of donor milk and monitoring. Although the energy cost can be high for automated systems, the costs of alternative treatments (such as HPP, microwave) can be even higher, as they include high upfront costs for startup, regulatory compliance and operation. There is limited market availability of equipment offering alternative treatment (e.g. UV-C irradiation, thermoultrasonic treatment).

3.8.6 Desirability

The Group considered that treatment of DHM to reduce its microbial load may increase the perceived safety of DHM among recipient families and health-care professionals; however, in some settings, raw milk may be the preferred option. Potential recipient families may prefer DHM that retains its bioactive properties, including beneficial microbes.

3.8.7 Impact on access to DHM

A requirement that DHM be treated may reduce access to DHM in contexts where laboratory resources are limited. Alternatively, the increased costs of enhanced screening required for use of raw donor milk may be prohibitive in some settings, reducing access to donor milk.

3.8.8 Rationale

The Group acknowledged that use of raw DHM could be feasible if there is enhanced donor and milk screening, as raw milk preserves the full spectrum of bioactive components. Heat treatment (usually HP and, in some contexts, HTST) was considered to be the generally recommended method, as established protocols and evidence provide a balance between safety and preservation of milk quality. The Group considered there was inadequate evidence about use of other treatment methods and they could not currently be recommended.

3.9 Testing of donor milk

3.9.1 Recommended practice

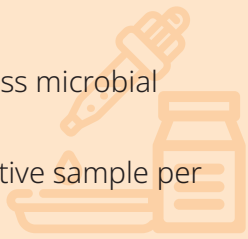
9 Testing donor milk



- ☑ When donor milk is pasteurized, post-pasteurization testing for microbial content is recommended.
- ☑ Nutritional testing of donor milk is not recommended.

Remarks

- Pre-pasteurization testing may also be considered, in order to assess microbial contamination, but should not replace post-pasteurization testing.
- Sampling techniques should include a minimum of one representative sample per batch of pasteurized donor milk.



3.9.2 Background

Processing of DHM includes various types of testing, including microbial and sometimes nutritional testing, to identify potential contaminants and to ensure that the milk meets nutritional and safety standards. Pre-pasteurization testing is used to identify microbial growth before pasteurization, which can obviate pooling and pasteurization of contaminated milk. Post-pasteurization testing ensures that pasteurization was successful and that the microbial content did not exceed a safe threshold at the time of testing. Contamination with *Bacillus* is of particular concern, as it can release toxins that bypass heat treatment *(29)*.

3.9.3 Evidence on benefits and harms

No specific evidence was found in the systematic reviews on testing of DHM for effects on the milk, donor or recipient. The Group discussed the benefits of post-pasteurization screening (as compared with pre-pasteurization screening), as it is a useful approach for validating pasteurization and testing milk for subsequent microbial growth.

No evidence was found in the systematic reviews on the impact of testing of nutritional elements in donor milk on the health outcomes of recipients. The Group noted that the available equipment and methods for nutritional testing of donor milk are not sufficiently reliable and are infeasible in many DHM settings.

3.9.4 Balance of benefits and harms

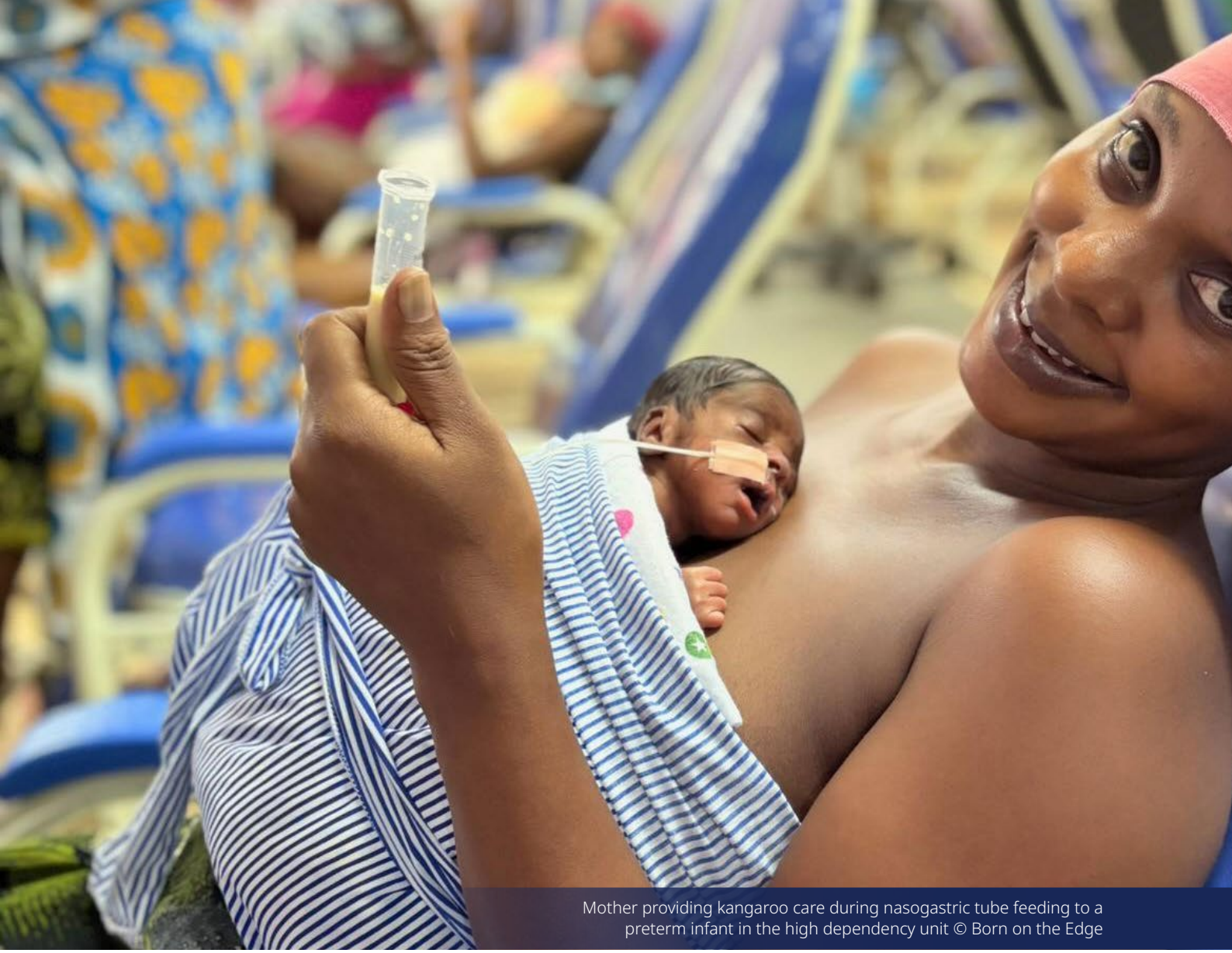
The Group concluded that microbial testing can increase confidence in the safety of DHM and potentially improve tolerance. The Group proposed a cutoff of ≥ 10 coliform forming units (CFU)/mL for discarding of pasteurized milk. Below this threshold, microbial growth is unlikely *(20)*. The cutoff can be assessed by culturing of 0.1 mL of milk, which is feasible in most settings.

3.9.5 Resource implications

The resource implications of testing DHM are substantial. Pre-pasteurization of donor milk would probably be unsustainable in low- and middle-income countries. Nutritional testing can be expensive and unreliable, and the equipment is often not available or not validated for use for human milk in many settings.

3.9.6 Desirability

The desirability of testing DHM (microbially and nutritionally) depends on the view of stakeholders. While some may perceive microbial testing as a safety measure, others may consider the high cost and potential loss of milk as significant drawbacks. Nutritional testing is desirable for clinicians and those prescribing donor milk but may be less desirable for milk bank staff, given the complexity of nutritional testing.



Mother providing kangaroo care during nasogastric tube feeding to a preterm infant in the high dependency unit © Born on the Edge

3.9.7 Impact on access to DHM

Excessive microbial testing can reduce access to donor milk because of a higher rate of discard than may be required. Nutritional testing can also decrease access to sufficient donor milk if only a certain nutritional quality of milk is accepted for use.

3.9.8 Rationale

The Standards Development Group determined that post-pasteurization testing should be prioritized for DHM to verify the efficacy of processing and confirm microbiological safety before distribution. This approach was identified as the most cost-efficient strategy for safeguarding the quality of donor milk. Given the high costs associated with nutritional analysis and the limited evidence of better infant health outcomes, however, the Group decided to recommend against nutritional analysis of donor milk.

4. Conclusion

These standards for donor human milk banking provide evidence-based guidance on the specific technical and operational steps required to ensure safe, ethical, high-quality collection, processing, storage and distribution of DHM. They emphasize the importance of alignment with WHO principles to protect, promote and support breastfeeding and to prioritize MOM whenever possible. By setting minimum standards and key considerations for diverse settings, these standards are intended to ensure consistency, safety and equity in the provision of DHM for vulnerable infants worldwide.

To assist countries with implementing new or improved systems for human milk banking, WHO and UNICEF are releasing implementation guidance on donor human milk banking to address organizational characteristics and regulatory classification *(30).* The companion document addresses practical considerations for adapting and operationalizing the standards in different health systems and provides guidance on determining appropriate models of milk banking for different settings and considerations for determining classification of donor milk and regulatory implications.

Development of these standards has revealed important gaps in evidence. The certainty of the available evidence was low in many domains, including donor characteristics and experience, donor milk processing and handling practices, and the short- and long-term impacts of DHM use on infant health and growth. Additional research is required to find technologies and resources for simplifying and strengthening HMB practices (especially in low- and middle-income countries).

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Annex. WHO standards development group, steering committee, and systematic review teams

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Systematic/Narrative Review Teams

Systematic Review 1: The impact of different treatment, handling, and storage practices on the nutritional quality and safety of animal milk
Roba A Alwasila, Mohammed Amish-Malik, Joy C Edeh, Abigail Smith, Mohammad Hassan Murad, Tarah Colaizy, Zulfiqar Ahmed Bhutta, and Aamer Imdad

Systematic Review 2: Impact of maternal characteristics, expression practices/ techniques, storage practices, mixing and pooling methods, or treatment on the nutritional quality and safety of human milk
Megan R. Beggs, Michael Pitino, Maryam Razaghi, Jo-Anna Baxter, Alison Mildon, Jessie Cunningham, Meghan B. Azad, David C. Dallas

Systematic Review 3: The impact of donating human milk on the health, lactation, and well-being of the human milk donor: A systematic review and meta-analysis.
Alaina Berg, Kendall E Cornick, Jaimie Rogner, Abigail Smith, Mohammad Hassan Murad, Tarah Colaizy, and Zulfiqar Ahmed Bhutta, Aamer Imdad

Systematic Review 4: The Impact of donating human milk on the health and growth outcomes of the donor's infant
Kendall E Cornick, Alaina Berg, Tarah Colaizy, Abigail Smith, Mohammad Hassan Murad, Zulfiqar Ahmed Bhutta, Aamer Imdad

Systematic Review 5: Impact of Feeding Expressed Mother's Own Milk Using Varying Expression Practices or Treatments on Health and Growth Outcomes of Recipient Infants
Serena Gandino, Agnieszka Bzikowska-Jura, Tanya Cassidy, Laura Cavallarin, Karolina Karcz, Daniel Klotz, Marzia Giribaldi, Chiara Peila, Carolyn Smith, Bartłomiej Walczak, Aleksandra Wesolowska

Systematic Review 6: Impact of feeding mother's own milk on health and growth outcomes among infants of mothers with health concerns (overview of systematic reviews)
Megan R. Beggs, Jessie Cunningham, Maryam Razaghi, Michael Pitino

Systematic Review 7: Impact of Donor Characteristics and Donor Milk Handling on Infant Health and Growth Outcomes
Daniel Klotz, Agnieszka Bzikowska-Jura, Tanya Cassidy, Laura Cavallarin, Karolina Karcz, Serena Gandino, Marzia Giribaldi, Chiara Peila, Carolyn Smith, Bartłomiej Walczak, Aleksandra Wesolowska

Narrative Review: Remuneration of Donors in context of Donor Human Milk Banking: Guiding Principles and Perspectives
Antonia Bezoni

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