S2k guideline

Use and treatment of human milk in healthcare facilities

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Society of Neonatology and Pediatric Intensive Care Medicine (GNPI)

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Society of Neonatology and Pediatric Intensive Care Medicine (GNPI)
German Society of Pediatrics and Adolescent Medicine (DGKJ)
German Society of Gynecology and Obstetrics (DGGG)
German Society of Perinatal Medicine (DGPM)
German Society of Hygiene and Microbiology (DGHM)
German Society of Hospital Hygiene (DGKH)
German Society of Midwifery Science (DGHWi)

Participation of other groups:
Human Milk Bank Initiative (FMBI)
German Midwives Association (DHV)
Federal Association "The Premature Infant" (BVDfK)

Coordination
Dr. med. Monika Berns (GNPI, in charge)

Further authors
PD Dr. med. Daniel Klotz (FMBI)
Dr. med. Corinna Gebauer (GNPI)
PD Dr. med. Frank Jochum (DGKJ)
Prof. Micheal Abou-Dakn (DGGG/DGPM)
Dr. med. Friederike Lemm (DGKH)
Dr. med. vet. Nina Parohl (DGKH)
Aleyd von Gartzen (DHV/DGHWi)
Katarina Eglin (BVDfK)

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List of abbreviations

Human milk	HM
Mother's own milk	MOM
Donor human milk	DHM
Donor milk bank	DMB
Milk kitchen	MK
World Health Organization	WHO
American Academy of Pediatrics	AAP
European Society of Pediatric Gastroenterology, Hepatology and Nutrition	ESPGHAN
Necrotizing enterocolitis	NEC
European Community	EC
European Union	EU
Hazard Analysis and Critical Control Points	HACCP
Cytomegalovirus	CMV
Human immunodeficiency virus	HIV
Human T-cell lymphotropic virus type 1	HTLV-1
Hepatitis B virus	HBV
Hepatitis C virus	HCV
Birth weight	BW
Holder pasteurization	HoP
Gestational Age	GA
German Neonatal Network	GNN
European Milk Bank Association	EMBA
Human Milk Bank Association of North America	HMBANA
Colony forming units	CFU
Methicillin-resistant *Staphlycoccus* aureus	MRSA
Multi-resistant gram-negative bacteria	MRGN
Severe combined immunodeficiency	SCID

Methodology

Dealing with conflicts of interest

Conflicts of interest are defined as circumstances creating a risk that a professional judgment relating to a primary interest may be unduly influenced by a secondary interest. A distinction is made between direct financial interests and indirect interests, which should be assessed to determine whether there is a conflict with the primary interest. Direct financial interests are understood to be financial, personal or institutional benefits. Indirect interests include clinical, academic and personal interests. Before initiating guideline development, all the authors declared their potential conflicts of interest to the AWMF Guidelines Officer. For this purpose, conflicts of interest were disclosed in writing using an AWMF form that includes material and immaterial interests. In the further course of processing and especially before the first consensus vote, all authors were again asked to disclose their conflicts of interest in the AWMF online portal on June 2, 2022. This allowed the expertise of all authors to be incorporated into the guideline development process and individual questions to be excluded after the conflicts of interest had been assessed. Exclusions are clearly shown in the individual recommendations.

Implementation

The development of the guideline is described in a separately published guideline report. This guideline is based on the best available evidence, which was carefully compiled and evaluated by the members of the author group. In view of the AWMF's requirements for a uniform structure of the different guideline types (S1, S2e, S2k, S3) made while completing this guideline, the recommendation grades are not explicitly stated in this S2k guideline, but are expressed linguistically by "must”, should", and "can" (Table A).

Table A. Strength of recommendation

Recommendation strengths	Formulation
Strong recommendation	must
Recommendation	should
Weak recommendation	can
Negative recommendations are formulated accordingly	

The content was repeatedly revised and commented on by the working group and finally voted on by the team of authors in a consensus vote on December 13, 2023. Authors considering themselves to be outside their professional expertise on a particular topic concerning individual recommendations were able to indicate this and were excluded from the consensus evaluation as "not agreed". Furthermore, individual authors were excluded from voting on individual questions following an assessment by the GNPI guidelines officer if there were potential conflicts of interest. The consensus strength results from all yes, no and abstention votes and is found in Table B.

Table B. Consensus strength

Consensus strength	Formulation
Strong consensus	Approval by > 95% of the participants
Consensus	Agreement from > 75 - 95% of the participants
Majority consensus	Agreement from > 50 - 75% of the participants
No consensus	Agreement < 50% of the participants

Preamble

1. Aim of the guideline

The aim of this guideline is to provide recommendations for the use of human milk for newborns requiring inpatient treatment. This guideline addresses the collection, transportation, storage, processing and dispensing of human milk in healthcare facilities.

The guideline is divided into three parts. Part I deals with the general handling of human milk. In Parts II and III, the use of breast milk is deliberately addressed separately from the use and handling of human milk. This distinction means that chapters on pasteurization, for example, deal with the technical implementation in Part I and are explained in Parts II and III in terms of the specific indication, taking into account the respective use.

2. Definitions of terms

The terms frequently used in this guideline and others relating to human milk and women's milk banks are listed below.

Table 1. Definitions of terms

Term	Definition of	Comment
Human milk (HM)	Milk of human origin	German expresssion: Humanmilch, humane Milch
Mother's own milk (MOM)	Milk from a lactating woman for her child	German expression: Muttermilch
Donor human milk (DHM)	Donated human milk, intended for consumption by a child other than the donor's own child.	German expression: Frauenmilch, Spendemilch
Donor milk bank (DMB)	A breast milk bank is a facility for the collection, transportation, storage, processing and distribution of donated breast milk under defined minimum requirements to defined recipients without or without sufficient breast milk of their own.	German expression: Frauenmilchbank. The superordinate term human milk banks is used primarily in Austria and in addition to the processing of DHM usually also includes the processing of MOM
Milk kitchen (MK)	As a facility of a children's hospital, a milk kitchen provides the daily prescribed and required nutrition for newborns and infants.	This may involve the provision of MOM, DHM, formula, or special foods.

Colostrum	Colostrum is the first milk produced during pregnancy and in the first few days after birth.	
Pasteurized milk	Heat-treated milk without measurable residual alkaline phosphatase activity	Usually treated at 62.5°C for 30 min (Holder pasteurization)
Raw milk	Milk that has not been frozen or heat-treated, but only chilled (not below 4°C)	
Frozen milk	Milk (regardless of pasteurization) that has fallen below the specific freezing point at least once	Storage usually at -20°C

3. Human milk for newborn infants

Recommendations 1

- The mother's own milk should be used to feed newborn infants.
- If mother's own milk is not available, the use of donor human milk from a donor milk bank should be considered (see Chapter 15. Prioritization).

Strong consensus
7/ 0/ 0 - 0/ 2
(yes/no/abstention - not voted/exclusion)

Breastfeeding and mother's own milk (MOM) feeding are considered the best nutrition for all newborns. Given the known short- and long-term medical benefits for the baby (and its mother), breastfeeding or MOM is recommended for all newborns. The WHO recommends exclusive breastfeeding during the first 6 months of life. Thereafter, appropriate complementary foods should be introduced and breastfeeding may be continued to 2 years of age and beyond.[1] The American Academy of Pediatrics (AAP) and European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) as well as other international specialist societies agree with these recommendations.[2-5] Depending on the readiness of the infant and the family history of allergies, supplementary foods can be started from the beginning of the 5th month of life at the earliest.[2-4,6] The S3 guideline "Duration of breastfeeding and interventions to promote breastfeeding" (AWMF No. 027-072) will comment on the duration of exclusive breastfeeding.

Donor human milk (DHM) should come from an institutional donor milk bank (DMB) and not from an informal donation outside a healthcare facility. Both individual in-clinic donations and

regular donations by internal or external donors are subject to the requirements set out in this guideline.

Premature infants benefit particularly from being fed with their own mother's milk. If this is not available or not available in sufficient quantities, or if one of the rare contraindications for the use of breast milk is present, DHM from a DMB should be used.[7-10] A meta-analysis of numerous observational studies reveals that the administration of human milk instead of formula has a major effect on the prevention of NEC and in reducing infections, and thus contributes to lower mortality in premature infants.[11] Other meta-analyses of randomized studies show that pasteurized DHM reduces the NEC rate.[12,13] This was also demonstrated in the randomized MILK study published in 2024 with a NEC rate of 4.2% in premature infants (birth weight < 1000 g) fed DHM versus a 9.0% NEC rate in the formula-fed group.[14]

In addition, goals such as faster gastric emptying, achieving full enteral nutrition and improved intestinal growth and maturation appear to be favorably influenced by DHM.[15] There is preliminary low level of evidence that diseases associated with prematurity such as retinopathy of prematurity, bronchopulmonary dysplasia, and sepsis may also be reduced by the administration of human milk.[16-19] There is also an association between MOM feeding and better psychomotor development at two years of age compared to formula feeding,[20-22] but not of DHM compared to formula feeding.[14,23] Premature infants who are discharged breastfed have a lower risk of later developmental deficits than those who are formula-fed.[22,24]

Regarding the administration of unpasteurized DHM there is a lack of data from randomized studies.[12]

Part I - Handling human milk

4. Legal basis

A donor milk bank is a facility for the collection, storage, processing and distribution of donated milk. Donor human milk is classified as food product in Germany (personal communication from the Federal Ministry of Food and Agriculture, Berlin, 25.02.2016), but there are different classifications across Europe.[25] In Germany, establishments that process DHM are therefore required to notify the local food control authorities, but are not subject to

approval. They are generally subject to the basic provisions of food law and general hygiene regulations.[26,27] In addition to an obligatory notification requirement, a registration requirement is handled differently in individual federal states.

Medical facilities that obtain DHM from external donor milk banks and use it exclusively in their own facilities are not considered as operating a DMB, as no donated milk is processed into DHM in those facilities.

As a sui generis substance, MOM is not yet subject to regulation for use in the private, domestic sphere. This also includes the handling of MOM in healthcare facilities.

Human milk is processed in a large number of healthcare facilities. There are various models with different terminology, degrees of organization and processes.[28-31] Due to this inhomogeneity, a facility's name (human, breast or women's milk bank, milk kitchen, collection point) does not clearly indicate the products processed there (breast milk, women's milk, artificial substitute foods, special foods).

5. Organizational requirements for human milk processing facilities

Irrespective of the special requirements for donor milk banks, every facility handling human milk must meet the organizational, spatial, personnel and equipment requirements for safe operations.

5.1. Quality assurance

Recommendations 2

For quality assurance purposes

- a quality management system should be implemented to optimize and standardize processes and structures to ensure the safety and quality of human milk in all processing facilities.
- a concept for hazard analysis and critical control points (HACCP) should be implemented for a donor milk bank.

Strong consensus
9/ 0/ 0 - 0/ 0
(yes/ no/ abstention - not voted on/exclusion)

The organization of a milk processing facility includes the clarification of responsibilities and a precise description of work processes. With the help of a quality management system, all work steps should be optimized, from obtaining a suitable donor, processing the milk and to dispensing the milk to infants in need. In this way, all hygienic and medical requirements for the milk can be met to deliver a high-quality product. Each facility must adapt its quality management system to the specific requirements of its own specific needs.
As food processing companies, donor milk banks are obliged to submit a concept for hazard analysis and critical control points (HACCP).[27,32]

Quality management includes procedural instructions on the following topics, and involves the expertise of various specialist departments:

- Necessary maintenance and the appropriate operation of technical devices according to the manufacturer's instructions
- Familiarization program and hygiene training for staff
- Handling of all collection and processing materials (bottles, syringes, lids, spoons, etc.) in accordance with the manufacturer's instructions and EU regulations[33]
- Unique labeling of all milk bottles with a name or donor ID, date, pumping time, raw/pasteurized, expiry date
- Ensuring the traceability of the recipient and donor
- Suitable, easy-to-clean transport containers for maintaining the cold chain
- Carrying out regular microbiological environmental tests
- Temperature monitoring of refrigerators and freezers

To ensure the necessary medical advice and accountability, the DMB management is in the hands of physicians, as the Austrian and Swiss guidelines also require. A joint leadership of medical and nursing professions or a nursing leadership with a medical advisory board or a division of management into organizational and medical management is also possible.[34,35]

The operation of a DMB in a hospital setting is appropriate because, in addition to the aforementioned requirements as a food business, the specific requirements of hospital hygiene also apply. This ensures qualified professional advice and monitoring. Hospitals work in a highly standardized manner in the areas of food supply and sterilization. This results in many synergies making it possible to implement the processes with regard to HACCP concepts

and quality assurance in a well-structured manner. At present, European accreditation institutes do not offer certification for DMBs. Certification according to DIN EN ISO 9001 is recommended.[36] ISO 9001 is the most widely used ISO standard ensuring, process quality and it can contribute to the continuous improvement in processes.[36]

5.2. Space requirements

Recommendation 3

- The space requirements result from the corresponding regulatory requirements and requirements for a donor milk bank.

Strong consensus

9/ 0/ 0 - 0/ 0

(yes/ no/ abstention - not voted/ exclusion)

The required minimum size of individual areas depends on the requirements of the each milk processing facility. As raw milk generally contains bacteria, it must be strictly separated from the preparation of substitute foods while it is being processed.

From a hospital hygiene and infectiology perspective, the space requirements for a human milk processing unit rely on the general requirements of the Food Hygiene Ordinance and hospital-specific regulations.[27,37] It is possible to integrate a donor milk bank within an existing milk kitchen. Individual areas must be adapted to individual processing steps. The strict spatial/physical separation of clean and unclean areas must always be guaranteed.

Table 2. Minimum space requirements

Clean area*	**Unclean area**
Processing and dispensing area (pasteurization, supplementation and filling)	Receiving area
Storage area (frozen storage, refrigeration)	Cleaning area (utensils)
Area for taking samples (e.g., for microbiological testing, measuring nutrients)	Discharge area (consumables, milk residues)
Office workstation	

*(Access for authorized personnel only)

5.3. Personnel requirements

Recommendation 4

- Staff in facilities that process human milk may come from different professional groups and should be trained accordingly.

Strong consensus
9/ 0/ 0 - 0/ 0
(yes/ no/ abstention - not voted on/ exclusion)

The job description of a specialized "milk technician" has not yet been established in Germany.[38] In principle, working with human milk places high demands on staff. Employees can come from various professional groups, including members of the nursing professions as well as nutrition and food technology, lactation consultants, dietitians, medical/pharmaceutical technical assistants, medical assistants and other related professions.

The prerequisite is eligibility to work in a food business. Staff must be suitably qualified and trained in accordance with the hygiene requirements of the Infection Protection Act (IfSG) §42.[39] Standardized training on the specific topics relating to the handling of human milk and regular additional training are required as part of quality assurance.

5.4. Apparative equipment

Recommendation 5

- All equipment and utensils used for processing human milk must be suitable for processing food products.

Strong consensus
9/ 0/ 0 - 0/ 0
(yes/ no/ abstention - not voted/ exclusion)

All equipment and utensils used must be suitable for the storage and processing of food and for cleaning at a temperature of at least +85°C. The equipment used depends on each facility's requirements. The equipment is subject to regular maintenance and inspection, for example by the (medical) technical service of a hospital. Emergency plans must be kept ready in writing

in the event of a failure of refrigerators and freezers. The refrigerators and freezers used are intended exclusively for the processing and storage of human milk.

Table 3. Recommended equipment for handling human milk

Technical equipment	Comments
Freezer (target temperature -20°C)	At least two appliances or separate compartments in a single appliance for untreated and pasteurized milk; automated, central temperature monitoring, emergency power supply
Refrigerator (target temperature +4°C)	At least two appliances or separate compartments in a single appliance for untreated and pasteurized milk, respectively
Pasteurizer	For the administration of pasteurized milk
Cleaning and disinfection device (target temperature +85°C)	For reusable utensils

6. Collection and handling of human milk

6.1. Hygienic aspects during milk expression

Strict adherence to hygiene guidelines for the collection and storage of human milk is essential to minimize the risk of bacterial contamination (Table 4). The hygienic handling of milk can be improved by providing oral and written instructions to milk donors for expressing milk in the clinic and at home.[40] Written instructions can be provided in the form of a leaflet or an educational video, possibly in different languages.

Giving mothers and, if necessary, fathers precise instruction, which includes recommendations for hand, body, and breast hygiene, can prevent increased bacterial contamination during home milk collection and transportation compared to milk expressed in a clinical setting.[40,41] Initial milk amounts during pumping need not be discarded, as higher contamination is extremely unlikely.[42,43]

Table 4. Recommendations for personal hygiene during milk production

Measure	Comment	Reference
Wash hands with liquid detergent for 20 seconds before pumping	Careful drying hands with a daily fresh towel or disposable paper towels	[44,45]
Hygienic hand disinfection	Recommended in the hospital setting due to the increased risk of transmitting pathogenic bacteria	[44-46]
Daily showering as a general hygiene measure	Alternatively, clean the breast daily with clear water and dry with a separate towel	[43,47]
Use of soap-free hygiene products and disinfectants	To keep the skin from drying out	[42,48]

6.2. Containers for milk collection

Recommendations 6

- Food-grade disposable plastic containers or glass containers should be used.
- Each container should be clearly labeled with the donor's identification data and the time (date and hour of day) of milk collection.

Strong consensus
9/ 0/ 0 - 0/ 0
(yes/ no/ abstention - not voted on/ exclusion)

All materials must be designed for the purpose of milk collection and storage and be suitable for food products. Ideally, the consumables provided by the respective department or DMB should be used.

Materials made of glass or plastic having the properties listed in Table 5 are used. However, glass containers must be checked regularly for breakage and chipping, and are unsuitable for freezing milk. Stainless steel containers should not be used for storing human milk (as they reduce the cell count and fat content). All available storage containers change the composition of human milk, especially the macronutrients, in particular the fat content.[49] Polyethylene bags are likewise not very suitable for clinical use (leaky, difficult storage).

Table 5. Properties of containers for milk expression

Consumables	Comment	Reference
Plastic containers (polypropylene or polycarbonate)	free from bisphenol A and plasticizers (phthalates), should be suitable for use in the temperature range -20°C to +64°C	[50-52]
Glass container	must be checked regularly for breakage and chipping, unsuitable for freezing	[53,54]
Locking mechanism	Leak-proof and airtight (e.g. screw cap)	

Clinics recommend the use of disposable containers.. The use of ethylene oxide-sterilized bottles should be avoided due to their toxicity; preference should be given to bottles manufactured in clean rooms or after gamma sterilization, however the use of sterile containers is not mandatory.

If reusable bottles are used, they must be properly cleaned and disinfected in a validated washer-disinfector or commercial dishwasher that is regularly microbiologically monitored. Containers must be clearly and labeled waterproof with the name or an identification number of the donor and the time of milk expression (date and hour of day) for identification purposes. Unmarked containers must be discarded.

6.3. Breast pumps and pump sets

Recommendations 7

- Breast pumps can be used by several mothers in compliance with the hospital hygiene regulations.
- Both disposable and reusable pump sets are permitted, but may only be used in accordance with the manufacturer's instructions.

Consensus
5/ 1/ 0 - 0/ 3
(yes/ no/ abstention - not voted on/ exclusion)

In the hospital, breast pumps can be used by several mothers in strict compliance with the relevant hygiene reprocessing regulations.[55] As with all equipment used in hospitals, breast pumps are also included in the hygiene plan. They must be cleaned after each pumping process in accordance with the manufacturer's instructions. Verbal instructions on handling

and disinfecting the pump and pump sets, including written instructions (e.g., directly on the pump), are recommended.

To be able to provide a sufficient amount of milk for her own child, every mother needs an electric pump with a double pump set for use at home.[56] Oral and written instructions are also recommended here, and a pumping diary can support the mother. In the hospital, pumping can take place in a specially designed breastfeeding and milk expression room, or preferably at the bedside with a view of the child.[57]

Every mother should use her own pumping set. In the hospital, disposable sets are used which, depending on the manufacturer, can be used for 24 hours with intermediate cleaning after each use. Such pumping sets are cleaned with sterile, filtered drinking water (sterile water filters) promptly after each pumping.[58] Avoid contact with the sink, drain, and siphon or with splash water as a contamination source. To completely remove milk residues (lactose, protein, and fat), all pump elements are disassembled according to the manufacturer's instructions and cleaned with hot water and a few drops of detergent. The parts are rinsed in clean drinking water and stored in a clean towel or paper towels to protect them from dust and keep them dry. After drying, the parts are reassembled and visually inspected for contamination before use.

Reusable pump sets that can be thermally disinfected according to the manufacturer's instructions are suitable for pumping at home. Reusable pump sets with clear signs of use (e.g., deep scratches) should be replaced regularly.

6.4. Transportation of human milk

Recommendation 8

- Human milk should be transported using food-grade materials in compliance with the cooling and freezing chain.

Strong consensus
9/ 0/ 0 - 0/ 0

(yes/ no/ abstention - not voted on/ exclusion)

Human milk should be transported as quickly as possible, and standing times should be avoided at all costs. To minimize bacterial proliferation, the cold chain must not be interrupted

while milk is being transported. All transport materials must be suitable for food transport, washable, and easy to clean, and should be disinfected after each use.[59]

Well-insulated cool boxes or bags with frozen cooling elements are suitable for transporting chilled milk. Fresh milk is transported at a target temperature of +4°C; note that a transport temperature of +8°C must not be exceeded.[60] This can be achieved by using cooler bags or polystyrene boxes with frozen cooling elements inside. Styrofoam boxes with a built-in thermometer are available.

Styrofoam boxes with adequate coolants, i.e., with dry ice, are suitable for transporting frozen milk, provided the employees are trained in handling dry ice. Frozen milk is transported at -20°C. Higher temperatures up to -15 °C and lower temperatures, e.g. on dry ice, are safe for short durations during transport.[61] Ice cubes must not be used because the ice's temperature exceeds that of the frozen milk. The temperature of milk arriving frozen should be measured and documented without contact using a (HACCP) infrared thermometer for food monitoring.[62]

Incoming containers are wipe-disinfected upon receipt before further storage or processing.[59] On arrival at the station, the containers must be transferred to the refrigerator or freezer as soon as possible. The correct labeling must be checked again; unlabeled or incorrectly labeled bottles must be discarded.

6.5. Storage and shelf life of human milk

Recommendations 9

- Chilled milk (+4 °C) that is not used within 24 hours should be frozen as soon as possible.
- Freeze storage should take place under controlled conditions at -20°C.
- Frozen milk can be stored for a maximum 12 months.

Strong consensus
9/ 0/ 0 - 0/ 0
(yes/ no/ abstention - not voted on/ exclusion)

The *American Academy of Pediatrics* recently redefined the storage times for fresh, frozen and pasteurized milk for sick and premature infants. Compliance with these times ensures safe handling of the milk after thawing.[9] These times are not the same as the times for storing breast milk at home for healthy infants. When determining the maximum storage times for human milk, a balance must be struck between the best possible nutritional and antibacterial properties, and the desire to minimize waste.

Human milk should be stored in a cool place immediately after pumping. For milk expressed at home, it is recommended to store the milk at the back of the fridge. This is where the temperature is most consistent at a temperature setting of 4°C. Food kept in the refrigerator door, on the other hand, is subject to continuous temperature fluctuations when the door is opened. Milk from several expression processes can be collected in one container within 24 hours, provided it is stored at a maximum temperature of 4°C. The shelf life of pooled milk is determined by the time of expression the first portion. Chilled milk (4°C) that is not used within 24 hours should be frozen as soon as possible. Storage at 4°C triggers a reduction in antioxidant, immunologically, enzymatically and hormonally active peptides compared to storage at -20°C or -80°C.[63] Milk should be refrigerated at 4°C and delivered to the facility either daily or within a specific period of time, or transported frozen at -20°C. Due to expansion during freezing, air space must be left in each bottle. To avoid the reduction of photosensitive components (e.g. ascorbic acid and pyridoxine), human milk should be stored in the dark.[51]

A continuous temperature indication on the outside the refrigerator/freezer is required in the hospital setting. To verify the correct storage of food in accordance with the HACCP concept, at least one temperature monitoring log must be kept that is checked daily. Depending on the hospital's own quality management system, a continuous temperature log can be used. Ideally, the appliances are connected to a central alarm system and emergency power supply.

Table 6. Recommendations on storage conditions for human milk (modified according to [9])

Surroundings	Temperature (°C)	Freshness HM	Frozen HM	Pasteurized HM
Room temperature[a]	16-25	4 h	4 h[b]	4 h[b]
Refrigerator	≤ 4[f]	96 h[d]	48 h[bc]	48 h[bc]
Freezer	≤ -20	6-12 months[e]	6-12 months[e]	6-12 months[e]

[a]as short as possible, max. 4 h
[b]after defrosting
[c]expert opinion
[d]if not consumed within 24 h, freeze as soon as possible
[e]Varies depending on the facility and storage conditions
[f]Germination of *Bacillus cereus spores* possible at refrigerator temperatures exceeding 4°C[62,63]

6.6. Defrosting human milk

Recommendation 10

- Milk should be thawed under controlled conditions (in the refrigerator).

Strong consensus

9/ 0/ 0 - 0/ 0

(yes/ no/ abstention - not voted on/ exclusion)

Frozen human milk should be thawed in the refrigerator at +4°C.[59] If the milk is thawed at room temperature, the milk's temperature must be monitored and kept in the refrigerator while ice crystals are still present.

For reasons of practicability, it can prove useful to employ validated defrosting appliances for a controlled and precisely timed defrosting.[59,64] However, in these defrosting appliances, stronger heating in peripheral zones cannot be prevented. Achieving a result equivalent to defrosting in a refrigerator is therefore impossible and defrosting in a refrigerator is to be preferred.[65]

Some pasteurizers have an automatic defrosting function for frozen milk bottles, here, dry defrosting methods are preferable as they are less of a bacteria source than hot water baths. Defrosting in the microwave or uncontrolled thawing in hot water bath is not suitable.

6.7. Pooling of human milk

Recommendations 11

- Milk portions from one or more donors can be pooled.

Strong consensus

8 / 0/ 0 - 1/ 0

(yes/ no/ abstention - not voted on/ exclusion)

Pooling milk portions from one or more donors is a widely used procedure.[66] Pooling can compensate for intra- and inter-individual fluctuations in macronutrient content and lead to a more uniform nutrient intake.[67] Both random pooling and target pooling after determining the nutrient concentrations have been described.[68] Single donor pooling over 24h reduces variations in circadian energy.[69] In milk from various donors (random pooling), the variability of macronutrients decreases with higher numbers of donors and the range of macronutrients in *target pooling* falls more often within the recommended target range variations.[68,70-72]

In contrast, different pooling practices can lead to greater variability in the fat concentration of individual samples.[73] Exposure to a larger number of donors for individual recipients must also be taken into account. As there are no data on the influence of human milk pooling on clinical parameters, the significance of this measure cannot be conclusively assessed.

6.8. Fortification and dispensing of human milk

Recommendations 12

- Human milk should be fortified shortly before being given to the child.
- Fortified milk should be administered within 24 hours, any unused portions should be discarded.
- The milk should be heated to drinking temperature in suitable bottle warmers.

Strong consensus

9/ 0/ 0 - 0/ 0

(yes/ no/ abstention - not voted/ exclusion)

Supplementation steps must be adapted to the individual circumstances of each facility. Fortification of MOM and DHM with a supplement immediately before consumption has advantages, as the milk's osmolarity increases over time due to enzymatic activity in human milk.[74,75] Osmolarity increases during the first 6 hours after fortification, and remains stable and safe for up to 72 hours.[76] Depending on the fortifier, osmolality increases up to 5-20 mosm/l within 24 hours.[77]

The change in lipids (enlargement of milk fat globules) after supplementing thawed milk seems to be more significant than that of carbohydrates.[78] Furthermore, the addition of supplements reduces the antibacterial properties of human milk.[75] However, these observed effects are minimal.

Human milk fortification should be performed in a donor milk bank or milk kitchen, as these provide better hygienic conditions than fortification on the ward.[79] Milk fortified with supplements should be consumed within 24 hours.[75] The cold chain must always be maintained in all processes.

Milk can be dispensed in collection bottles from which portions are dispensed immediately before the meal under hygienic conditions on the ward, e.g. with the aid of resealable caps. If this cannot be guaranteed, the milk must be portioned into feeding syringes or milk bottles in the central facility.[80] For portions of less than 20 ml, feeding syringes fitted with a sterile cap have proven effective.

Before leaving the central facility, each container must be correctly labeled. Transportation to the wards must take place in accordance with the safety precautions specified in section 8.4. On arrival at the ward, the milk is immediately stored at 4°C, removed from the refrigerator immediately before administration, and gently warmed to drinking temperature. Bottle warmers outfitted with warm air or contact warmers are suitable for this. Warming in the microwave is not permitted (reduced IgA and lysozyme activity, hotspots occurring due to uneven heating, and the risk of scalding).[81,82]

Immediately before giving the milk to the child, the name on the milk portion must match the name of the recipient child. The milk may only be warmed once; any remaining milk must always be discarded.

7. Thermal treatment of human milk

Human milk can serve as a vector for pathogenic bacteria and viruses. Milk-associated neonatal infections are attributed to this transmission pathway.[83] Human milk for premature infants is therefore treated to reduce its bacterial concentration and to inactivate viruses - a standard procedure.[84-86] In practice, heat treatment and freezing are used for this purpose.[28]

Thermal treatment causes a significant loss of quality in human milk, as it leads to an exposure-dependent reduction in vitamins and antioxidant, immunological, enzymatic and hormonally active peptides and proteins.[87-92] This fact highlights the need for precise indications and the correct implementation of thermal treatment. Other physical procedures are not yet available for clinical application.[93]

The data on the clinical relevance of the loss of quality induced by pasteurization is limited.[94] In a retrospective observational study, the use of pasteurized (n=159) compared to unpasteurized MOM (n=164) showed a trend towards a protracted feeding advancement (mean 16.54 versus 13.47 days; p=0.016).[95] A controlled crossover study (n=5) found reduced milk lipase activity to be the cause of lower weight gain in preterm infants fed pasteurized compared to unpasteurized MOM.[96] Additional data is available only on the comparison of unpasteurized MOM to pasteurized DHM.[11,97]

Even if the pasteurization of human milk appears necessary, feeding premature infants with pasteurized human milk is preferable to artificial formula despite such pasteurization-related disadvantages. For example, feeding premature infants with pasteurized human milk halves the probability of necrotizing enterocolitis compared to feeding with artificial formula, despite the milk's pasteurization.[13,14]

This chapter deals with general aspects of the thermal treatment of human milk. Chapter 10 addresses particular aspects of MOM pasteurization, Chapter 16 covers special aspects of the pasteurization of DHM.

7.1. Holder pasteurization

Recommendations 13

- Holder pasteurization should be carried out in a validated and controlled process.
- After heating completely thawed milk to 62.5±0.5°C for 30 minutes (Holder pasteurization), rapid cooling to ≤ 10°C should take place at the end of the plateau phase.
- Post-pasteurization controls should only be carried out if there are special indications.

Strong consensus
7/ 0/ 0 - 1/ 1
(yes/ no/ abstention - not voted on/ exclusion)

By definition, pasteurization leads to a reduction in the concentration of bacteria. As there are no explicit regulatory requirements for the pasteurization of human milk, manufacturers of pasteurizers for human milk are guided by the corresponding EU directives for milk of animal origin. According to Regulation (EC) No. 1662/2006, pasteurization is defined as the measure that leads to the complete inactivation of alkaline phosphatase in the treated product.[98] The heat input into the milk required to inactivate the alkaline phosphatase leads to the inactivation of the indicator organism *Coxiella burnetii*, the most heat-resistant, non-spore-forming bacterium in cow's milk.[99] The time and temperature combination used to achieve this target are not exclusively defined, so the term pasteurization is used in this guideline in a result-oriented manner.

Holder pasteurization is the standard for pasteurizing human milk.[28] In this process, a volume of milk is heated to a plateau temperature of 62.5±0.5 °C in a holding process with the shortest possible time interval and held for 30 minutes, followed by a rapid, ideally automated, cooling process of the milk to less than 10 °C, preferably 4 °C.[34,59] Homogeneity of the milk heating is achieved by complete thawing of the milk before the start of pasteurization and ideally by continuous, automated agitation of the samples.

Pasteurization of human milk should be carried out using specially developed automated time- and temperature-controlled equipment. The use of time-controlled milk bottle warmers or thawing devices for pasteurization is just as inadvisable as boiling the milk. The classic Holder method involves heating the milk samples in a water bath. Hygienic concerns and practical

aspects argue for the use of so-called dry pasteurizers, which use air or solids as a heating medium. However, hot air is not suitable for pasteurizing breast milk due to the inhomogeneous temperature distribution within the devices.[100] Compared to water-based devices, solid-state thermostats have longer heating and cooling times. This leads to lower protein retention when using solid-state thermostats compared to water-based pasteurizers.[101]

The bacterial growth rate in pasteurized milk is significantly higher than in unpasteurized milk.[102] Therefore, non-frozen pasteurized milk must always be cooled at 4 °C until it is administered. In the case of continuous enteral feeding, the limited shelf life of pasteurized milk must be taken into account by regularly changing the feeding system (e.g. every 4 hours, apart from the gastric tube).[103]

Holder pasteurization leads to a reduction in bacterial concentration and complete inactivation of CMV in human milk.[104-107] Clinical data also show a reduction in postnatal human milk-associated CMV infection in premature infants after heat treatment of milk from CMV-seropositive mothers.[95,108] Evidence (bacterial cultures) of inactivation by Holder pasteurization in human milk is also available for SARS-CoV-2[109,110], MERS virus[111]Zika virus[112], human papilloma virus[113], HIV-1[114]HTLV-1 (tested at 56 °C/30 min)[115] and the Ebola and Marburg virus[116]. Incomplete inactivation by Holder pasteurization has been reported for the Coxsackie B4 virus.[104] Spores (e.g. of *Bacillus cereus*) and enterotoxins (staphylococci) are not amenable to classic Holder pasteurization (see Chapter 12).

Microbial controls show institution-dependent variable rates (0.2-7 %) of positive human milk cultures after Holder pasteurization, whereby the influence of downstream contamination, previous bottle sealing and the virulence of surviving pathogens has not been conclusively clarified.[117-120] Therefore, regular post-pasteurization controls cannot be recommended if pasteurizers are used correctly. However, they can be useful on a temporary basis when introducing or changing corresponding processes within a department or as part of spot checks. Frozen retained samples are also suitable for use when necessary. Regular microbiological checks of surfaces and, if necessary, heating and cooling water of pasteurizers should be carried out. It is recommended to draw up written procedural instructions for the implementation and documentation of pasteurization as part of quality management.

7.2. Short-time heating procedures

Recommendations 14

- Validated short-time heating methods can also be used for CMV inactivation.

Strong consensus
7/ 0/ 0 - 1/ 1
(yes/ no/ abstention - not voted on/ exclusion)

By briefly heating a thin film of milk to 62°C with a plateau time of 5 s, complete CMV inactivation can be achieved in naturally and artificially inoculated milk.[121,122] A corresponding device is declared as a CMV inactivation device.[105] Due to the partial alkaline phosphatase reaction obtained with this time-temperature combination, it is not a pasteurization process.[98] Compared to pasteurization, the short-term treatment therefore also shows a significantly lower antibacterial efficiency in the treated milk, and the efficacy cannot be predicted in individual samples.[121,123,124] However, the lower heat exposure during short time treatment results in improved protein preservation in contrast to other inactivation methods.[124,125] Previous data indicate a reduced CMV transmission rate through short-term treated human milk compared to non-treated milk from CMV-seropositive mothers.[108]

7.3. Freezing of human milk

Recommendations 15

- The freezing of human milk for safe CMV inactivation cannot be recommended.
- Freezing to reduce the concentration of bacteria should not be carried out.

Strong consensus
8/ 0/ 0 - 1/ 0
(yes/ no/ abstention - not voted on/ exclusion)

Frozen storage is a technically simple and cost-saving method for reducing a potential cytomegalovirus load in human milk, but does not lead to complete virus inactivation. In human milk naturally colonized or artificially inoculated with CMV, freezing at -20 °C for a period of 3, 4, 7, 10 or 90 days only leads to an extremely variable virus reduction. Replicable CMV could still be detected after one freeze-thaw cycle in each case.[105,107,126,127] Consequently, postnatal, breast milk-associated CMV infections in premature infants after freezing of milk from CMV-seropositive mothers have also been described several times.[128-

[130] A meta-analysis showed a risk reduction of only 13% for CMV infection by freezing the milk compared to giving untreated milk containing CMV.[131] The temperature and duration of the freeze-thaw cycles used in clinical practice vary, with a median of -20 °C and 24 hours.[28,85] For these reasons, freezing cannot be considered a safe measure for CMV prevention.[132]

Short-term freezing of human milk reduces the increase in bacterial concentration, but does not lead to a relevant reduction and is therefore not recommended for this indication.[133-135]

During frozen storage, an increase in free fatty acids leads to a decrease in the pH value in the milk, while the esterase activity, lipase and immunoprotein concentration as well as the energy content are not affected by frozen storage.[136-139]

8. Human milk misadministration

Recommendations 16

- After milk misadministrations, the parents of the recipient child and involuntary donor should be informed.
- No further measures are recommended in the event of a misadministration with pasteurized milk.
- Otherwise, the serologies should be determined according to the risk constellation (see Table 7).

Strong consensus
8/ 0/ 0 - 1/ 0
(yes/ no/ abstention - not voted on/ exclusion)

A milk misadministration is the accidental administration of milk to a child other than the intended one. Exact figures on the incidence of such misadministrations are not available, but we can assume a high number of actual and near-miss cases.[28,140-142] Milk misadministration can lead to considerable uncertainty for parents, to invasive procedures for the involuntarily recipient child and the involuntary donor, represents additional work for the treatment staff, and can have a lasting negative impact on trust in the treating department.[142]

Comprehensive, cross-center analyses of the causes of milk misadministrations are not available. In addition to inherent, individual errors, structural and procedural factors are

relevant.[28] According to detailed root cause analyses at certain centers, the following factors led to a drop in the rate of milk misadministrations: the presence of qualified staff and training of parents in handling milk[141,143], hospital-wide standardized and written procedures for handling milk, spatial and personnel separation of milk preparation from patient care[143,144], structured record-keeping of errors [142,145] and the introduction of a digitalized central and bedside recording system (barcode) for milk products.[140,143,144] The implementation of the aforementioned sets of measures in various combinations led to a reduction in milk misadministrations of more than 80% in individual centers. However, a complete avoidance of misadministration was never achieved in the periods observed. Nevertheless, near and actual misadministrations should be documented via a suitable procedure (e.g. CIRS system) for continuous error analysis, with the aim of continuously improving structural and process quality to lower department-specific misadministration rates.

In the event of a milk misadministration, the parents concerned should be informed promptly, and appropriate written information material and procedural instructions in the event of a milk misadministration are recommended.[146] The medical risk of a milk misadministrations is generally classified as low.[146] If it is a case of the incorrect feeding of pasteurized milk, infectious risks can be practically ruled out. Further measures are therefore not recommended. More frequently, however, it is likely to be a case of misadministering unpasteurized milk. Potentially relevant exposures are shown in Table 7. Recommendations for serological testing of the accidental donor and child recipient are provided in Table 8.

Table 7. Milk misadministration - anti-infective measures

Exposure	Measure	Comment
Human immunodeficiency virus (HIV)	Prophylactic antiretroviral treatment of the recipient child until the potential exclusion of HIV positivity of a donor is not recommended.	HIV transmission through a one-off milk mix-up is highly unlikely due to the low seroprevalence among pregnant women, the low rate of undiagnosed HIV-seropositive pregnant women and the small quantities fed. In the case of accidental administration of milk potentially containing HI viruses, the further procedure (e.g. administration of post-exposure prophylaxis) should be individually coordinated with an infectious disease specialist, taking into account individual risk factors (viral load, excoriatory or inflammatory breast disease).[147]
Hepatitis B (HBV) and C (HCV)	Especially for medicolegal reasons, immunization of the recipient child may be considered in the case of proven HBV infection of the accidental donor.	Contact with maternal blood and secretions sub partu represents the main risk of HBV infection for the newborn. HBV surface antigen and HBV DNA can be detected in the milk of HBV-infected mothers.[148] It is unclear whether this increases the risk of a postnatally transmitted HBV infection in a population not immediately postnatally HBV-vaccinated.[149] There is no evidence for transmission of HCV via breast milk.[150,151]
Human T-cell lymphotropic virus type 1 (HTLV-1)	No measure	Breast milk-associated transmissions of HTLV-1 have been described, particularly with a breastfeeding duration of > 6 months. It cannot be assumed that a single exposure to relatively small amounts of HTLV-positive milk will lead to infection of the newborn.[152] Due to the low seroprevalence of HTLV in pregnant women in Germany (0.01%) and the lack of therapeutic consequences, serological testing of the accidental donor should be considered relying on the individual risk profile.[153]
Cytomegalovirus (CMV)	Prophylactic virostatic treatment is not recommended. The value of prophylactic administration of CMV hyperimmunoglobulin in this context is unclear.[154]	The incidence and clinical relevance of milk-associated, postnatal CMV infection in premature infants has not been conclusively assessed.[155-157] In the case of accidental feeding of potentially CMV-containing milk to premature infants under 32 weeks' gestation, the CMV status of the recipient infant and involuntary donor should be determined immediately after the exposure if the donor's serostatus is unknown and if

		there was any indication of CMV inactivated breast milk for the recipient infant at the time of the misadministration.
Potentially pathogenic bacteria	No preventive antibiotic therapy for the recipient child	The misadministered milk's bacterial concentration and flora may not be known in individual cases.[158]

Residues of drugs, environmental toxins, stimulants and intoxicants can be detected in human milk in varying, exposure-dependent concentrations, but are highly unlikely to be of clinical relevance when fed once.

As there is in some religious legal traditions a milk relationship in the context of an accidental milkadministration, parents should be advised accordingly if they have any questions in this regard (see Chapter 18).

Table 8. Recommended serological tests in the context of a mix-up of unpasteurized milk

	Seronegative donor			**Serostatus of the donor unknown**		
Serologies	Child	Donor	Recipient mother	Child	Donor	Recipient mother
HIV	(-)	+[a]	(-)	+	++	(-)
HBV	(-)	+[a]	(-)	+	++	(-)
CMV	(-)	+[a]	(-)	+[b]	++[b]	(-)
HTLV-1, HCV	(-)	(-)	(-)	(-)	(-)	(-)

(-) = not recommended, + = optional, ++ = recommended
[a]Closing a potential diagnostic gap
[b]If there is an indication of CMV-inactivated milk for the recipient child

Various, differently invasive steps are sometimes taken after a milk misadministration, but they are not recommended due to the low medical risk. The misadministered milk can be removed via a nasogastric tube that is already in place, but this should be reserved for rare high-risk situations, as should the insertion of a new stomach tube to remove incorrectly fed milk, and rinsing the stomach to remove milk.

Part II - Use of mothers own milk

9. Bacteriological screening of mothers own milk

Recommendation 17

- Regular bacteriological testing of mothers own milk cannot be recommended.

Strong consensus
9/ 0/ 0 - 0/ 0

(yes/ no/ abstention - not voted on/ exclusion)

Human milk is not sterile by nature, but contains numerous bacteria of maternal origin (skin, milk ducts). The bacteria ingested with and from the milk contribute significantly to the development of the child's intestinal microbiome and thus have an immunomodulatory and protective effect.[159] In addition to natural bacterial colonization by predominantly non-pathogenic species, the process steps and time course between the collection and administration of human milk can lead to the introduction of facultative pathogenic bacteria and an increase in the bacterial concentration in the milk. This is particularly relevant if the conditions for milk production, transportation (e.g. non-compliance with the cold chain), storage (e.g. temperature instability of refrigerators and freezers) and administration (e.g. continuous tube feeding) are not optimal.[103,160-162]

Bacterial screening of mothers won milk with the aim of preventing milk-associated infectious diseases in premature infants is a standard procedure.[85,86,163] A survey conducted in 2018 revealed that 43% of the participating hospitals from German-speaking countries (n=152) screen mothers own milk for bacteria and, depending on the findings, pasteurize or discard it if necessary.[121] Case reports of MOM-associated *late-onset sepsis* appear to support this approach.[164,165] There is no consensus on the maximum safe bacterial concentration or bacterial species that indicates pasteurization or discarding of MOM. This leads to widely diverging limits of accepted bacterial concentrations before and after pasteurization.[28] The data supporting this approach is inadequate. Due to a low predictive value random testing cannot prevent the use of milk contaminated with facultative pathogens,[158] however, systematic violations of hygiene measures may be detected (process quality). This results in administration of MOM that is colonized with despite regular screening of MOM. In a

monocentric retrospective cohort analysis, this did not lead to an above-average incidence of infectious diseases. None of the septicemias that occurred in this cohort during the observation period could be traced back to a pathogen isolated in the respective MOM (10128 individual doses).[166]

In summary, regular bacteriological testing of MOM is not recommended.[167] Nevertheless, the targeted examination of the bacterial load of MOM still has significance in special circumstances. Mothers own milk has been described several times as a vector in bacterial outbreaks and should be taken into consideration.[167,168] These outbreaks are proof of the importance of correct hygienic handling of MOM in order to avoid contamination of the milk or excessive growth of autochthonous colonization. The Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO) also empirically recommends bacteriological testing of MOM in children with gastrointestinal infections or NEC.[167] Screening tests can also be useful in the event of changes in MOM treatment.

10. Pasteurization of mothers own milk

Recommendations 18

- Pasteurization or the regular discarding of mothers own milk based on routine bacteriological findings is not recommended.

Strong consensus
9/ 0/ 0 - 0/ 0
(yes/ no/ abstention - not voted on/ exclusion)

Pasteurization and regular discarding of MOM as a result of bacterial screening are also widely used measures.[28] A small randomized trial found that feeding pasteurized MOM to VLBW preterm infants tended to result in a higher rate of *late onset* sepsis compared to unpasteurized MOM. However, in this study, milk showing any evidence of potentially pathogenic bacteria was replaced with formula, which may have influenced the results.[169] In a retrospective study in a cohort of 341 preterm infants, Stock et al. also showed no reduction in LOS rates (15.2% vs. 15.3%; p=1.0) and rather a trend towards higher NEC rates (4.8% vs. 1.7%; p=0.129) when feeding pasteurized rather than unpasteurized milk.[95]

In summary, the data available to assess whether and/or when regular microbial testing and pasteurization of breast milk should take place is insufficient for a clear recommendation.

If, as a result of microbial breast milk tests, patient-specific risk factors or general considerations, the decision is made to pasteurize MOM to reduce a potential transmission risk, the following pragmatic procedure is recommended (based on the recommendations of the French Society of Neonatology). This guideline recommends a MOM screening for premature infants with a gestational age <28 weeks or birth weight <1000 g. The MOM should be pasteurized if any gram-negative pathogens, group B streptococci or *Staphylococcus aureus* are detected, and discarded in presence of *Bacillus cereus*.[170]

Table 9. Possible cut-off limits when treating MOM* (adapted from [170])

Evidence of:	**Pasteurization**	**Discard**
Skin flora	≥ 10^4 CFU/ml	-
Staphylococcus aureus	≥ 10^4 CFU/ml	-
Gram-negative bacteria Group B streptococci	any presence	-
Bacillus cereus	-	any presence

*Weekly testing of a representative MOM sample applying validated microbial methods in mothers of premature babies < 28 weeks' gestation. CFU, colony-forming unit.

The regular discarding of MOM based on bacteriological findings cannot be recommended, as pasteurization is an effective and efficient means of lowering bacterial concentrations. The only exception here are spore- and possibly toxin-producing species. Spores (e.g. of *Bacillus cereus*) and enterotoxins (staphylococci) that do not respond to classic Holder pasteurization. If spore-forming bacteria are detected, the milk is usually discarded; this can be considered for enterotoxin-forming species.[28,170] The significance of detecting such bacteria and their clinical relevance has not been conclusively clarified.

11. Medical contraindication to the administration of human milk

11.1. Medical contraindication to the administration of human milk

Recommendation 19

- Before deciding against mothers own milk feeding for medical reasons, the attending health care professionals should reach an interdisciplinary consensus.

Strong consensus
9/ 0/ 0 - 0/ 0
(yes/ no/ abstention - not voted on/ exclusion)

There are few absolute contraindications for the administration of human milk (Table 10). Advice from the Pharmacovigilance and Advisory Center for Embryonal Toxicology of Charité-Universitätsmedizin Berlin[171], the *Drugs and Lactation Database* (LactMed) of the *National Institute of Health*[172] as well as the *Arzneiverordnung in Schwangerschaft und Stillzeit*[173] guidelines are recommended as references. Note that data on premature infants are limited in these references. On the other hand, since premature babies benefit especially from a diet of human milk, a critical risk assessment should be carried out and a neonatologist should be consulted before deciding against human milk/breastfeeding, especially if donated human milk is not available as an alternative.

Table 10. Medical contraindications to the administration of human milk

Facts of the case	Contraindication	Comment
Childhood illness	Classic galactosemia	Breastfeeding should be discontinued until a suspected diagnosis has been ruled out; human milk feeding may be possible for very rare non-classical variants after consultation with a specialist.[174]
Maternal illness	HIV, cytostatics	In the case of HIV-RNA copies <50/ml and other conditions, mature babies may be breastfed.[175]
	HTLV-1, Untreated brucellosis	No breastfeeding, no MOM feeding[3,176]
	Untreated, infectious tuberculosis, HSV lesions on the breast, peripartum varicella infection	(Passager) no breastfeeding, breast milk feeding possible[177]

This table cannot be considered exhaustive.

11.2. Breast milk-associated cytomegalovirus infection

Recommendations 20

- Due to inconclusive data, no general recommendation can be made regarding CMV inactivation of breast milk for premature infants.
- Breastfeeding the child should be possible at all times, regardless of the mother's CMV status.

Strong consensus
6/ 0/ 0 - 3/ 0
(yes/ no/ abstention - not voted on/ exclusion)

Cytomegaloviruses (CMV) are reactivated locally in the mammary gland while CMV-seropositive mothers are lactating in > 95% of cases; and is excreted in milk from the end of the first week of lactation.[178] The incidence of postnatal, MOM-associated CMV infections occurring in this constellation amounts to up to 20% on average depending on the infant's maturity.[179] While postnatal CMV infections are usually asymptomatic in mature newborns, symptomatic disease in premature infants is common. Hepatopathy, blood count anomalies (neutrocytopenia, thrombocytopenia) and, in around 4% of cases, sepsis-like clinical presentations have been described.[157] Overall, however, the published transmission rates (6% to 60%) and the rates of symptomatic diseases (0% to 35%) vary greatly, which can be attributed to the different methodological approaches of studies.[157,180-182]

The influence of a postnatal CMV infection on the long-term development of premature infants has not been conclusively clarified. On the one hand, several investigations have reported no adverse effects on hearing or neurocognitive development.[183-186] or neurocognitive development[183,184,187]. On the other hand, there is other evidence justifying the suspicion of hearing impairment [187,188] and disturbed neurological and neurocognitive development[155,189] of premature infants suffering a postnatal MOM-associated CMV infection; these children also experience a longer hospital stay compared to premature infants without a postnatal CMV infection[188,190]. The development of bronchopulmonary dysplasia has been associated with postnatal CMV infection, although the data here are also contradictory.[190-193] A connection with the occurrence of necrotizing enterocolitis has been postulated, but this has not yet been confirmed in larger retrospective studies.[188,194,195]

Due to these uncertainties, measures to reduce MOM-associated CMV infection are implemented in several neonatology departments.[84] Each department's approach to maternal CMV screening is very specific , i.e., how long to administer untreated colostrum from CMV-seropositive mothers, how to carry out heat treatment or the freezing of milk, or the decision whether to discard milk from CMV-seropositive mothers.[28]

According to a survey of 307 neonatology departments in Germany, Austria and Switzerland, the appropriate measures to reduce the risk of CMV transmission are usually implemented up to a current gestational age of 32 weeks' gestation or body weight of 1500 g, while colostrum is fed untreated for a median of four days.[28] This procedure essentially corresponds to the current recommendations of other countries (Table 11).

Table 11. Published recommendations on cytomegalovirus inactivation of breast milk

	Measure	Start	End	Comment
France [170]	HoP	< 28 GA or BW < 1000 g	> 31 + 6 GA	Always possible to breastfeed from the 3rd - 4th day of life
Austria [131]	HoP	< 28 GA or BW < 1000 g	> 31 + 6 GA	HoP from the 4th day of life
USA[196]	HoP, Short-time heat treatment	BW < 1500 g	n. e.	Procedure should be "considered", maternal CMV screening < 32 weeks' gestation

CMV, cytomegalovirus; BW, birth weight; HoP, Holder pasteurization; n. e., not mentioned; GA, gestational age (weeks)

Because of the currently inconclusive clinical data, no general recommendations on the CMV inactivation of MOM for premature infants can be made at present.[5] In the case of MOM treatment, CMV inactivation is usually recommended up to a postmenstrual age of 32 weeks (Table 11).

After informing the parents, breastfeeding should be allowed any time, regardless of the mother's CMV serostatus.[197]

There are various methods for CMV inactivation; Holder pasteurization is the gold standard. However, the advantage of CMV activation must always be weighed against the loss of

protective MOM components through pasteurization. The occasional practice of discarding milk and feeding premature infants with an appropriate replacement formula is not recommended in light of the measures available for CMV inactivation.[28,84]

In addition to CMV inactivation, there is also the option of feeding potentially CMV-containing milk without further treatment after parental information and consent, as is practiced in the majority of neonatology departments in Belgium and Luxembourg surveyed by Cossey *et al.*[86,197] However, whether the continuation of this approach is justified (considering the uncertainty about the potential adverse effects of postnatal CMV infection in premature infants) is questionable.[5,198]

11.3. Newborn screening for severe combined immunodeficiencies (SCID)

Recommendation 21

- Newborns with conspicuous neonatal SCID screening and CMV-seropositive mothers should not be given unpasteurized milk until confirmation diagnostics have been completed.

Consensus
5/ 0/ 1 - 3/ 0
(yes/ no/ abstention - not voted on/ exclusion)

In the case of an abnormal SCID screening result, MOM feeding of mature infants is not recommended until the result of the confirmatory diagnostics has been received if the mother's CMV status is positive or unknown.[199]

After a risk assessment, premature infants can be given CMV-inactivated milk due to the clear advantages of human milk consumption, the generally higher rate of false positive findings in this patient population and a potentially long time period until SCID can be ruled out.[200] CMV-inactivated milk can also be administered in mature infants if they are being cared for in a unit where pasteurization is possible, and to avoid weaning until confirmation diagnostic evidence is available. Data from California show that rapid, decisive action is required to prevent CMV infection. Even the short time between sample collection and receipt of a conspicuous SCID screening result led to the death of two newborns with a CMV infection most likely

transmitted through breast milk. CMV infection is difficult or impossible to treat in infants without T-cell immunity.[201]

11.4. Maternal desire to wean without a medical indication

Recommendation 22

- Breastfeeding without a medical indication should only occur after an interdisciplinary consultation.

Strong consensus
9/ 0/ 0 - 0/ 0
(yes/ no/ abstention - not voted on/ exclusion)

If a mother wants to stop breastfeeding or refuses to breastfeed her newborn, an attempt should be made to evaluate and document her reasons for her decision. In the case of a desire to wean with no medical indication, the disadvantages of not breastfeeding for mother and child should be explained in a neutral, respectful, and open-ended manner.[202] Neonatal expertise should be consulted particularly in of case of a premature birth. The aim of such consultation is to enable parents to make a free and informed decision.[203]

11.5. Breast milk feeding in conjunction with substance abuse

Recommendation 23

- The use of mothers own milk from addicted mothers is only recommended in case of abstinence or established substitution therapy

Consensus
6/ 1/ 0 - 2/ 0
(yes/ no/ abstention - not voted on/ exclusion)

Maternal opiate addiction is not an absolute contraindication to MOM feeding. However, the mother must be abstinent while under medical supervision or undergoing substitution treatment without the parallel consumption of other narcotics.[177]

Breastfeeding during maternal cannabis use is controversial.[204] In summary, efforts should be made to stop or at least significantly reduce cannabis use during breastfeeding.[205]

12. Prepartum milk collection

Recommendation 24

- Prepartum milk can be collected from 36+0 weeks' gestation if there is an indication, e.g. gestational diabetes.

Strong consensus

6/ 0/ 0 - 3/ 0

(yes/ no/ abstention - not voted on/ exclusion)

Prepartum milk collection refers to manual milk collection during pregnancy, and the milk's collection and safe storage until it is given to the newborn. This subject is included in this guideline because it also concerns the use and provision of human milk in healthcare facilities.

The purpose of this measure is to avoid the use of DHM or formula after birth. The prepartum manual collection of MOM also shortens the time from the initiation to full establishment of lactation, and contributes to early and abundant milk production. Colostrum from the child's own mother is the ideal food if supplementary nutrition is potentially required after birth. For mothers with diabetes mellitus and the risk of hypoglycemia after birth, the prepartum collection of colostrum can therefore be a sensible measure.[206] This method can also to applied in other special situations, i.e., when the mother and child must be separated (in conjunction with congenital malformations such as complex heart defects), drinking problems are to be expected (clefts, muscle-hypotonic newborns, e.g. Down's syndrome) or maternal health problems make milk production more difficult (e.g. obesity).[207]). In addition to administering the prepartum colostrum, if enough human milk is available, this may also be an indication to use DHM as a bridging measure.

12.1. Start and frequency of prepartum milk collection by hand

Colostrum is produced from around the middle of the second trimester and can theoretically be collected from this timepoint onwards. The recommendations for a worthwhile and safe start to prepartum milk collection vary. The majority recommend starting from 36+0 weeks of pregnancy.[206] The recommended method is to express by hand. Expressing with a breast pump is not advisable, as it is often only possible to collect a few drops of colostrum, which would stick to the walls of the pump and thus is not collectible.

Expecting mothers should seek advice from trained professionals about the timing, indications and method for expressing prepartum milk. The literature recommends initiating milk expression from week 36 (twice a day for three to five minutes per breast).[208] Expressing should not take longer than ten minutes.[206] If labor contractions occur, the procedure must be stopped immediately. However, there is no evidence from any source that truly effective labor contractions are likely.[207]

Studies on the safety of this measure are limited. However, it seems quite improbable that prepartum hand expression would trigger premature uterine contractions resulting preterm labor. As the uterus contains fewer oxytocin receptors in the early prepartum period, oxytocin does not cause effective contractions during this period. In addition, high progesterone levels during pregnancy keep the smooth muscles of the uterus quiet until it is time to give birth.[209] However, studies on breastfeeding during pregnancy have concluded that some caution is warranted in pregnant women carrying an increased risk of preterm birth, although there is no evidence to suggest that even frequent breastfeeding can induce uterine contractions.[210] In this respect, consideration should be given to teaching women who, for various reasons, are expected to give birth prematurely or whose due date for an early birth is already known, to empty their breasts by hand even before 36+0 weeks' gestation so that they can provide their baby with some of their own urgently needed milk immediately after birth.

Please refer to the existing instructions for extraction and storage.[211]

Part III Use and handling of donor human milk

13. Allocation of donor human milk

Recommendations 25

- Breastfeeding one's own children should always take priority over donating milk.
- The use of donor human milk should be based on a medical indication (see Table 12).

Strong consensus

7/ 0/ 0 - 0/ 2

(yes/ no/ abstention - not voted on/ exclusion)

As the demand for DHM confronts a short supply in the context of prematurity, the allocation of DHM must be prioritized.[25] In principle, feeding one's own children has priority over donating milk. This is particularly important for mothers donating milk after giving birth to multiples. If a multiparous mother is approved as a donor, it is recommended that the donated milk be reserved for her own children until sufficient long-term lactation is ensured.

Pragmatic prioritization within the department according to gestational age and diagnoses is recommended. After premature babies, mature newborns after abdominal surgery or other conditions (e.g. congenital heart defects) can also receive DHM. Donor human milk should always be used as a bridge until, ideally, enough MOM is available.[212] Table 12 provides a suggestion for allocation DHM, even if this approach is not evidence-based.

Table 12. Possible prioritization of allocation of donor human milk

Prioritization	Target group	Comment
1°	Premature infants < 32 weeks' gestation	NEC rate premature infants < 1500 g BW 2.9% in the GNN network [213]
2°	Premature infants ≥ 32 weeks' gestation, newborns after abdominal surgery or with heart defects	Indications of faster feeding advancement compared to artificial infant formula[214] and lower risk of NEC[215,216]
3°	All other newborns	[217,218]

14. Information and consent for feeding donor human milk

Recommendation 26

- The legal guardians should be informed and give their consent to the feeding of a child with donor human milk.

Strong consensus
9/ 0/ 0 - 0/ 0
(yes/ no/ abstention - not voted on/ exclusion)

As DHM is a substance of human origin, despite its classification as a food product, the legal guardians should be asked for their consent to feed their child with donated milk, if necessary initially only verbally, e.g. during a prenatal consultation. In this context, they should be informed verbally and in writing about the benefits and risks of feeding with breast milk in comparison to formula.[59]

15. Human milk donors

15.1. Selection of donors

Recommendation 27

- Donors should be selected after taking a medical history using a standardized questionnaire for documentation.

Strong consensus
9/ 0/ 0 - 0/ 0
(yes/ no/ abstention - not voted on/ exclusion)

In principle, any healthy mother who donates her surplus breast milk voluntarily and free of charge is suitable as a milk donor. They can be the mothers of hospitalized newborns and infants, as well as mothers of healthy infants not in primary contact with the healthcare system. The current and future milk requirements of the mother's own child must be taken into account. Orphaned mothers should not be excluded from donating.[219]

Donors may be excluded on the basis of a medical history not compatible with milk donation. The results of the interview are documented, countersigned and archived using a standardized medical history form. Examples of questionnaires for milk donors are published in German.[220]

General contents of the history are: health status of the donor, her current medications, live vaccinations in the last 4 weeks, dietary habits, questions about possible exposure to environmental toxins and any indications of an infectious disease. Information about a donation must be passed on to potential donors in simple and easily understandable language.

A donor may be ruled out if there is evidence of colonization with MRSA, VRE, 3MRGN or 4MRGN. Recommendations for excluding a milk donation are based on the recommendations of the "Hemotherapy" guideline.[221]

Excluded from donating milk are mothers who:

- Smoke or use other nicotine-containing products
- Consume alcohol
- Consume illegal drugs or have consumed them in the past
- Take medication unauthorized for breast milk donation (see 17.2.)
- Belong to a risk group for HIV disease or have tested positive for hepatitis B or hepatitis C virus infection
- Have had a blood transfusion abroad, been tattooed, undergone piercing, permanent make-up or suffered a needle injury within the last four months
- Have received a live vaccination within the last four weeks
- Follow a vegan diet
- Reveal an increased risk of sexually transmitted diseases due to promiscuous behavior
- Have undergone an organ transplantion

15.2. Medications incompatible with milk donation

Very few medications are incompatible with breastfeeding when a woman breastfeeds her own child (see chapter 13.1.). As donated breast milk is primarily intended for the nutrition of very immature premature babies, stricter criteria must be applied when selecting medications that are compatible with human milk donation.

Depending on the type of preparation and duration of taking a medication, temporary or permanent exclusion from donating human milk may be indicated. During the donation period, the donor should inform the milk bank of any existing or newly initiated intake or use

of prescription or non-prescription medications. Dietary supplements, herbal medicines, or the use of substances from traditional Chinese medicine should also be named. More detailed recommendations are found on the website of the United Kingdom Association of Milk Banking.[222]

The following medications are compatible with milk donation (incomplete list):

- Asthma sprays (steroids, salbutamol)
- Levothyroxine under medical supervision
- Progestogen-containing contraceptives
- Topical steroid preparations (e.g. as therapy for eczema), but not in the breast area
- Insulin
- Vitamin and iron supplements in the recommended dosage
- Subcutaneous heparin preparations

15.3. Donors screening for infectious diseases

Recommendations 28

- Milk donors should be serologically tested at least for hepatitis B and C, HIV 1/2 and Lues.
- Information and written consent should be obtained before performing serological tests and blood sampling.

Strong consensus
9/ 0/ 0 - 0/ 0
(yes/ no/ abstention - not voted on/ exclusion)

Guidelines for testing milk donors for infectious diseases rely on criteria for testing blood donors.[29,221] The following serological tests are recommended before the start of donation: Hepatitis B, Hepatitis C, HIV 1/2, Lues. HTLV serology can be determined by assessing the donor's individual epidemiological risk.[153] If only pasteurized breast milk is donated, CMV diagnostics are not necessary.

Donors must be informed about the blood collection and serological test and must consent to these in writing. Due to the low specificity and the availability of specific tests, the

determination of transaminases, especially postpartum, does not increase diagnostic certainty.[223,224]

15.4. Information for human milk donors

Potential milk donors receive verbal and written information in advance of their donation, which serves as the basis for consent. This includes, in particular, the requirements for milk donation: necessary examinations, necessary hygiene measures, the requirements for milk collection, storage, cooling, freezing and transportation of the donated milk.

Information and equipment:

- Personal hygiene
- Cleaning instructions for preparing the materials (pump and pump-out set)
- Pumping containers (ideally bottles from the corresponding women's milk bank)
- Labeling of containers with pumped milk (name, date, time)
- The criteria for temporary or permanent exclusion from milk donation

15.5. Pausing milk donation

Recommendation 29

- Breast milk donation should be paused in the event of acute illnesses and the intake of a medication incompatible with donation (see chapter 17.2.).

Strong consensus
7/ 0/ 0 - 2/ 0
(yes/ no/ abstention - not voted on/ exclusion)

During the donation period, the milk bank staff communicates with the milk donor at regular intervals, e.g. to identify changes in her state of health. A sick milk donor should inform the milk bank and will be temporarily excluded. Donation must also be paused if the donor is taking contraindicated medication. Illnesses requiring temporary exclusion from donating breast milk include

- Diseases of the mammary glands (milk stasis with mastitis, infectious skin lesions, e.g. herpes simplex or varicella zoster lesions, thrush)

- Acute infectious diseases (e.g. gastroenteritis, respiratory infections, exanthematic viral infections)
- Taking unauthorized medication (see 17.2.)
- Live vaccinations (pausing the donation for four weeks)

15.6. Duration of milk donation

Recommendation 30

- An evidence-based recommendation on the duration of milk donation is not yet possible.

Strong consensus
7/ 0/ 0 - 2/ 0
(yes/ no/ abstention - not voted on/ exclusion)

The composition of human milk changes during lactation and generally exhibits pronounced inter- and intra-individual variability. However, assessment of the available data is complicated by inhomogeneous study groups and varying methodologies. Since some human milk components show a pronounced circadian pattern, samples of unpooled milk are often inadequate for assessing the mean concentrations of individual components. There is insufficient data available to investigate nutrients over the longer term (> 6 months after the start of lactation). Moreover, few studies have investigated the composition of human milk in the second year of lactation. Perinn et al. found that stable concentrations of several nutritive and immune-protective and -enhancing components including protein, lactose, iron, copper, lactoferrin and sIgA are present in the second year of lactation as long as milk volumes exceed 300 to 400 ml/day. Concentrations of the antimicrobial protein lysozyme appear to increase into the second year of lactation.[225] Another study by the same author found higher concentrations of the antimicrobial proteins lysozyme, lactoferrin and IgA in the second year of lactation. Their study also showed that human milk contains stable or rising concentrations of macronutrients and bioactive factors in the second year after birth, with a small reduction in zinc and calcium concentrations if breastfeeding or pumping continues at least three to four times a day. Since IgA and lactoferrin have their highest concentrations only in the first days of lactation, but then drop very quickly, even donated milk from the second year of lactation with its higher concentrations of those substances could be better suited to the needs of

premature infants than donated milk from the first year, according to one of the authors' hypotheses.[226]

The regulations on the acceptable duration of breast milk donation vary depending on the individual milk bank. On average, milk donations are accepted up to a lactation period of 6 months. However, as there is no clinical evidence on feeding premature babies with milk that is not age-matched, this approach is not evidence-based. Some milk banks therefore do not specify an upper limit for the lactation age. An evidence-based recommendation on the duration of DHM donation is therefore not possible at this time.[227]

15.7. Remuneration for milk donation

Recommendations 31

- Financial compensation for donating milk is not recommended.
- Expenses incurred by milk donors in direct connection with the donation can be reimbursed.

Strong consensus
9/ 0/ 0 -0/ 0
(yes/ no/ abstention - not voted on/ exclusion)

It is not financial motives but altruism, the solidarity principle, and personal conviction of the benefits of breastfeeding that are the driving forces behind the decision to donate human milk. Available information about donating DHM in general and the presence of local milk banks in particular, as well as the social and family environment are further factors in the decision to become a milk donor.[228]

Milk donation is generally not remunerated in Germany. However, some facilities pay donors an expense allowance.[29]

16. Use of pasteurized donor human milk (microbial aspects)

Recommendations 32

- Due to the lack of evidence, regular microbial testing of donor human milk before and after pasteurization are not recommended.
- For quality assurance after pasteurization, random microbial tests can be carried out.

Strong consensus
9/ 0/ 0 - 0/ 0
(yes/ no/ abstention - not voted on/ exclusion)

The *European Society for Paediatric Gastroenterology, Hepatology and Nutrition* (ESPGHAN)[5], the *European Milk Bank Association (*EMBA)[59], the *Human Milk Bank Association of North America* (HMBANA)[50] and the *American Academy of Pediatrics* (AAP)[7] unanimously recommend the use of pasteurized donor human milk.

The various processing steps of human milk in a clinical setting can result in a contamination with facultative pathogenic bacteria and an increase in the concentration of autochthonous flora.[164] Recommendations for implementing microbiological pre- and post-pasteurization controls are inconsistent; as a rule, the discarding of donor human milk is recommended even when low concentrations of bacteria are detected after pasteurization.[59] While several recommendations define the upper limit of acceptable bacterial concentrations in DHM, the detection of bacteria before pasteurization is not a fundamental exclusion criterion for further use (see Table 13).

Table 13. Threshold values for bacterial contamination of donor human milk before and after pasteurization (adapted from [59])

	Concentration before pasteurization **Frequency**	**Concentration according to pasteurization** **Frequency**	**Comment**
Australia [229]	≤ 10^5 CFU/ml each pooled batch	any evidence each pooled batch	not used in case of Enterobacteriacae or potentially toxin-producing pathogens
Germany [52]	≤ 10^5 CFU/ml with every new milk donor, then 1-2-weekly	Controls not required	Bacterial differentiation if concentration ≥ 10^3 CFU/ml
France [230]	≤ 10^6 CFU/ml each pooled batch	any evidence each pooled batch	*Staphylococcus aureus* ≤ 10^4 CFU/ml
Italy [231]	≤ 10^5 CFU/ml for each new milk donor and random samples in interval testing	any evidence at regular intervals	*Enterobacteriaceae* or *Staphylococcus aureus* ≤ 10^4 CFU/ml
Austria [34]	< 10^6 CFU/ml for every new milk donor and in suspected cases	n. e. Retain samples for eventual testing	*Staphylococcus aureus* < 10^4 CFU/ml
Sweden [232]	No upper limit value defined with every new milk donor	any evidence at regular intervals	
Switzerland [35]	< 10^5 CFU/ml At regular intervals	random checks, any evidence at regular intervals	Differentiation from a concentration ≥10^3 CFU/ml, not to use in the presence of pathogenic species
UK [233]	≤ 10^5 CFU/ml each pooled batch	*Enterobacteriaceae or Staphylococcus aureus* ≤ 10^4 CFU/ml at regular intervals	any evidence
North America[50]	n. e. each pooled batch	any evidence n. e.	

CFU, colony forming units; n. e., not mentioned

Due to the lack of evidence, no recommendation can be made for the regular execution of pre- and post-pasteurization controls.[120] The recommendation on the frequency of microbiological testing before pasteurization ranges from testing every single milk bottle to testing every new donor once.[34,234]

If a decision is perform microbial testing of DHM before and/or after pasteurization for fundamental considerations, department-specific or patient-specific reasons, we recommend the corresponding recommendations of the EMBA (Table 16) to standardize the procedure.[59]

Table 14. Potential indication for excluding the administration of donor human milk[59]

Before pasteurization*	**After pasteurization****
• ≥ 10^5 CFU/ml • Detection of *Bacillus cereus*	any (culture) evidence

*Testing of an aliquot from a milk donor's pooled sample
**Testing of an aliquot from an arbitrary sample

If breast milk is subjected to microbiological testing of despite pasteurization, those results must be immediately incorporated within the hygiene advice given to the donor. Tests must always be initiated in suspected cases or in the case of sensory altered samples.

17. Use of non-pasteurized donor human milk

Recommendations 33

- Evidence-based recommendations on the use of non-pasteurized donor human milk cannot be made at present.
- When administering non-pasteurized donor human milk, milk's microbial load should be controlled by relying on stringent quality criteria.

Strong consensus
9/ 0/ 0 - 0/ 0
(yes/ no/ abstention - not voted/ exclusion)

Pasteurized human milk is associated with the degradation and inactivation of many bioactive substances.[92] Because of human milk's biological value, some institutions refrain from pasteurizing donor human milk.[29] Taking this approach, Germany, together with Norway,

occupies a special position internationally.[235] There are no uniformly recognized limits for bacterial contamination of non-pasteurized donor human milk. Department-specific limits sometimes differ greatly from one another. As comparative studies on the safety of the use of non-pasteurized compared to pasteurized DHM are unavailable, no evidence-based recommendations on the administration of non-pasteurized DHM can be made. When deciding on administering non-pasteurized DHM, we recommend following the existing procedures in Germany and Norway, which are summarized in Table 15. This table provides an overview of the historically evolved definitions and recommended use of non-pasteurized DHM. This classification can serve as a basis for determining the maximum permissible bacterial concentration for a donor milk bank.

Prerequisites for the use of non-pasteurized donor human milk:

- Milk donor CMV-IgG and CMV-IgM negative
- Repeated CMV serology at least every 3 months
- Bacteriological examination of the DHM before use
- Discarded if any *Bacillus cereus* is detected
- Donor milk from donor with a MRE colonization (MRSA, 3MRGN, 4MRGN, VRE) should not be used non-pasteurized.

Table 15. Historical classification of donor human milk (adapted from [52,235-237])

Category	Bacterial -concentration	Bacterial -differentiation	Characteristics	Use
I	10^3 CFU/ml	Not applicable	Fresh, not heat-treated, not deep-frozen	Feeding to FG < 1500 g without prior heat treatment
II	> 10^{-3} ≤ 10^4 CFU/ml	Skin germs	Stored at -20 °C	used without prior heat treatment, for feeding FG > 1500 g or older infants
III[a]	> 10^4 - 10^5 CFU/ml	carry out	Stored at -20°C, heat-treated at 62.5 °C for 30 min	Pasteurize if the proportion of potentially pathogenic bacteria[b] ≤ 10^5 CFU/ml Discard if the proportion of potentially pathogenic bacteria[b] > 10^5 CFU/ml

CFU, colony forming units
[a]A type IV formerly recommended for the discarding of DHM if the bacterial concentration exceeds > 10^5 CFU/ml regardless of the species; this procedure is no longer recommended
[b] Potentially pathogenic bacteria: *Staphylococcus aureus*, gram-negative bacteria, A and B streptococci, *Pseudomonas aeroginosa*

18. Special aspects of feeding newborns with donor human milk

18.1. Milk kinship

In some religions (e.g. Islam, Judaism) and religious communities, the donation of milk to another person's child establishes a kinship-like relationship between the recipient and donor child (*milk kinship*). A single, valid assessment of the possibility of milk donation is not possible due to different religious interpretations, but DHM use is often feasible after parental counseling.[238] For parental counseling in the context of milk donation, please refer to the relevant literature.[239-241]

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Note on this translation

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The content corresponds to the original German version. All participating medical societies and professional associations approved the publication of this translation following the formal review process.