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SPECIAL ARTICLE

Recommendations for the creation and operation of maternal milk banks in Spain☆,☆☆

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Abstract It is widely agreed that the best source of nutrition for the newborn is the milk of their own mothers. In those cases where it is not available, especially in very premature and/or very low birth weight infants, as well as other sick newborns, the preferred choice before formula is human milk provided by selected donors. This indication is supported by the highest international bodies dedicated to the health of the child population, including the World Health Organisation as well as the main national and international scientific societies in the field of Paediatrics.

Milk banks are health institutions responsible for the collection, processing and distribution of donated human milk. Currently, there are 14 human milk banks operating in Spain, grouped in the Spanish Association of Human Milk Banks, created in September 2008.

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In order to homogenise the criteria and to unify the working methods of the different milk banks, the Spanish Association of Human Milk Banks has developed standards to harmonise the protocols, and to serve as a guide for the start-up of new milk banks in the Spanish territory. These standards, set out in the present article, range from the donor selection and the evaluation process to the collection, processing, storage, and distribution of donor human milk.

PALABRAS CLAVE
Banco de leche materna;
Leche materna donada;
Pasteurización;
Enterocolitis necrosante;
Prematuro de bajo peso;
Prematuro de extremo bajo peso

Recomendaciones para la creación y el funcionamiento de los bancos de leche materna en España

Resumen La mejor alimentación para un recién nacido es la leche de su propia madre. En aquellos casos en los que esta no está disponible, especialmente en los recién nacidos muy prematuros o de muy bajo peso al nacer, así como en otros recién nacidos enfermos, el alimento de elección es la leche materna de donantes seleccionadas, antes que la fórmula artificial. Esta indicación está respaldada por los máximos organismos internacionales dedicados a la salud de la población infantil, como la Organización Mundial de la Salud, así como las principales sociedades científicas nacionales e internacionales en el ámbito de la Pediatría.

Los bancos de leche surgen como instituciones sanitarias responsables de la gestión de las donaciones, del procesamiento y de la distribución de leche materna donada. Actualmente existen 14 bancos de leche materna en España, agrupados en la Asociación Española de Bancos de Leche Humana, creada en septiembre de 2008.

Con el fin de homogeneizar los criterios y unificar los métodos de trabajo, la Asociación Española de Bancos de Leche Humana ha elaborado unos estándares para armonizar los protocolos de los diferentes bancos y para que sirvan de guía para la puesta en marcha de nuevos bancos de leche en el territorio español. Dichos estándares, presentados en este artículo, abarcan desde el proceso de selección y evaluación de la donante hasta la recogida, el procesamiento, el almacenamiento y la distribución de leche materna de donante.

Introduction

Human milk is a collection of essential nutrients and bioactive components that facilitate the transition from intrauterine to extrauterine life and the subsequent growth of the infant. It not only meets the infant's nutritional needs, but also promotes the maturation of several organs, such as the intestines and the brain.[1,2] When the infant's own mother's milk is unavailable, the best alternative is donated human milk (DHM), collected and processed in human milk banks (HMBs). This is recommended by numerous scientific associations and international institutions.[3–5] In 2005, the Asociación Española de Pediatría (Spanish Association of Paediatrics)[6,7] recommended the creation of at least one HMB in each autonomous community.

Human milk banks are health care institutions whose mission is to collect, process, store and distribute DHM under the highest quality and safety standards. The main beneficiaries are very preterm or very low birth weight newborns, in whom the literature has described improved outcomes with DHM feeding versus formula feeding in terms of a reduced incidence of infection, necrotising enterocolitis and retinopathy of prematurity, better long-term neurodevelopmental outcomes, and a higher tolerance to the introduction of enteral feeding.[8–10]

The first HMB was created in Vienna in 1909, and at present there are nearly 1000 worldwide, including 214 in Europe (http://www.europeanmilkbanking.com). In Spain, the first HMB opened in 2001 in the Balearic Islands, and another 13 banks have been established since in 12 autonomous communities (Balearic Islands, Madrid, Valencia, Catalonia, Andalusia, Aragón, Extremadura, Castilla y León, Galicia, Asturias, Basque Country and Cantabria).

In Spain, the distribution of DHM has increased from 774 L given to 333 recipients in 2009 to 4937 L given to 2281 recipients in 2016 (http://www.aeblh.org). There is also evidence that the creation of new HMBs is associated with increases in breastfeeding rates at hospital discharge. The current evidence demonstrates that HMBs and the availability of DHM promote and support breastfeeding.[11,12]

Several countries have developed national guidelines to standardise the criteria applied to HMBs.[13–17] Based on these guidelines and on customary practice in Spanish HMBs, and through a consensus process involving the banks currently operating in Spain, the Asociación Española de Bancos de Leche Humana (Spanish Association of Human Milk Banks) has developed standards to be used as reference for the establishment and operation of HMBs in our country in order to ensure the safety and quality of the distributed DHM.

Recruitment of donors

- Donor recruitment is carried out through a variety of channels, including: written materials (distributed in prenatal care or paediatric clinics, among others), referral (other donors, health care professionals), mass media, social networks, or associations for breastfeeding support.
- Currently grieving mothers may be donors.

Selection of donors

- The selection process includes an oral interview, the completion of a written health questionnaire and signing of informed consent to donation.
- In the interview, new donors are told about the procedures used for handwashing and local hygiene of the breast, milk extraction and cleaning of breast pumps, storage (refrigeration and freezing), labelling, transportation, and any other question that may arise regarding milk production.
- It is important to reinforce the information regarding all these procedures in donors that donate contaminated milk repeatedly.
- The information obtained from the donor during the selection process should include: general health, lifestyle habits, health of donor's baby, medication, exposure to environmental hazards, exposure to infectious agents and recent vaccinations.[18]
- The donor must undergo serologic tests to rule out infection by HBV, HCV, HIV and syphilis, and previous testing conducted during pregnancy cannot substitute for them. Depending on donor risk factors or whether donors are from endemic regions, serologic tests must also be done for screening of HTLV I/II or Chagas disease.
- It is recommended that donors undergo nucleic acid tests for HIV, HBV and HCV. Donors with positive viral loads for any of the 3 viruses will be turned down.
- Serologic tests do not need to be repeated at the time of milk donation unless specific circumstances have emerged that justify it. If the bank has the technological resources to do so, it is recommended that DHM is subjected to viral nucleic acid testing (HBV, HCV and HIV) after pasteurisation.
- A positive antibody test for CMV is not considered a contraindication for donating milk, and CMV does not need to be ruled out prior to donation.
- Potential donors will be turned down if they consume alcohol. Occasional consumption of alcoholic drinks can be permitted, allowing at least 12 h to pass before collection of milk for donation.
- Potential donors will be excluded for any of the following: smoking habit or consumption of products containing nicotine, consumption of illicit drugs or methadone (in any amount), infection (HIV, hepatitis B or C, HTLV or syphilis), ovo-lacto vegetarian or vegan diet in the absence of adequate vitamin B_{12} supplementation during pregnancy and lactation, or dialysis.
- Potential donors are not eligible if they are at high risk of variant transmissible spongiform encephalopathy increased risk of having familial Creutzfeldt-Jakob disease.
- The following are criteria for temporary exclusion: 6 months for transfusions of blood products, body piercings or tattoos, acupuncture with non-disposable needles, tissue or organ transplant, high-risk sexual partner or imprisonment. In banks using nucleic acid amplification techniques for screening of HIV, HBV and HBC, the duration of exclusion will be of 4 months.
- Other temporary exclusion criteria include: acute disease—in case of mild infectious disease, the need to temporarily exclude donation and the duration of this period will be determined based on the type of infection. Mastitis or local skin infection on the breast, or herpes zoster or varicella zoster virus reactivation—although pasteurisation eliminates nearly all microorganisms, a period of exclusion from donation is established as a precaution until the lesions have formed scabs or the mastitis/fungal infections has resolved.
- Vaccination with live attenuated viruses: studies have shown that the rubella virus can pass to the mother's milk and thus to breastfed infants after vaccination. In agreement with the laws on the transfusion of blood products, we recommend an exclusion period of 4 weeks following the administration of live attenuated vaccines.
- Donors must agree to inform the HMB of any changes in their health, medication, etc., as some of these changes may be reason to exclude them as donors temporarily or permanently.
- Consumption of donated milk differs from breastfeeding a healthy newborn, as recipients are immature patients with a higher risk of complications from exposure to drugs. Before accepting donations from mothers that are consuming medication, we recommend consulting references such as www.e-lactancia.org or LactMed (https://toxnet.nlm.nih.gov/newtoxnet/lactmed.htm), taking into account the pharmacokinetics of the drugs in question. Any drug classified as high- or very-high-risk is a contraindication for donation, and drugs classified as posing a low or very low risk should lead to careful assessment.
- The protein content of human milk is highest at birth and decreases progressively in the first year post birth. Given the importance of protein intake in very preterm or very-low-birth-weight newborns, banks should prioritise collection of milk in the first three months of lactation. Depending on the needs of the recipients of local HMBs (if they only serve very preterm or very-low-birth-weight newborns), banks can set limits on the window for donation of up to 6 months or 1 year following birth.

Handling of milk at home

- We recommend expression by hand or with a pump, although the cleaning and sterilisation of the latter must be guaranteed.
- Donors must be reminded of proper pump hygiene and handwashing technique.
- We recommend against breast pump exchanges.
- Following extraction, milk should immediately be stored at cold temperature (refrigerated or frozen).

- Milk can be stored in the refrigerator for up to 24 h, as there is no significant bacterial growth during this period. The container will remain in the refrigerator at a temperature of 7 °C or less between extractions.
- Pooling the milk obtained from different extractions in a single container is allowed as long as newly extracted milk is refrigerated prior to pooling.
- Freeze the milk at home within 24 h from extraction. Maximum acceptable temperature in the freezer: −15 °C.
- It is recommended that frozen milk not be kept at home for more than 4 weeks before submitting it to the HMB.
- It is preferable to store milk in containers provided by the HMB for storage/freezing.
- Containers for milk storage should be made of glass (sterilisable) or food-grade rigid plastic (single-use). The containers must be sterile and closed with solid lids.
- We recommend against the use of milk storage bags or plastic bags.
- Containers should be filled to a maximum of ¾ capacity to prevent breakage on freezing.
- Containers should be labelled with the name/code of the donor and the date of collection/extraction.
- Exposure of milk to sunlight should be minimised.

Handling of milk in HMBs

- Donated milk must be stored in the freezer immediately on arrival to the HMB.
- If possible, the appliances used for storage of donated milk (refrigerator and freezers) should be devoted exclusively to HMB purposes.
- Freezer temperatures must be monitored continuously.
- If possible, raw and pasteurised milk will be stored in different freezers or in different compartments of a single freezer.
- Donated milk must be handled following sterile procedure in laminar flow cabinets.
- Gloves must be worn when handling milk. The use of masks, caps and lab coats is also recommended.
- Milk should never be thawed in a microwave oven.
- It is best to thaw frozen raw milk at 4 °C prior to pasteurisation, although partial thawing in a water bath is also allowed.
- DHM should be discarded if it does not meet the criteria established in the bank's guidelines.
- The labels on the donated milk bottles must include the name/code of the donor and the date of collection/extraction.
- Milk that has not been frozen should not be kept at room temperature.
- Raw milk can be stored in the freezer before pasteurisation up to 3 months at −20 °C/−30 °C or up to 12 months at −80 °C from the date of extraction.
- Raw milk can be stored in the refrigerator prior to pasteurisation for a maximum of 24 h.
- The maximum temperature of the freezer can vary between −20 °C and −80 °C, but the temperature of storage will affect the expiration date of the milk.
- The maximum temperature allowed in refrigerators where DHM is stored is 7 °C.

Milk mixing and pooling before pasteurisation

- Banks can accept pooled raw milk extracted from a single donor.
- Depending on the criteria established by each HMB, a mixture of acceptable raw DHM from different donors can be accepted as long as it is later pasteurised.
- Milk should never be pooled after pasteurisation.
- A single pool of milk can be used to create different lots of processed milk (a lot is the group of containers that fit in a pasteuriser).

Transportation

- It is key to ensure that DHM remains frozen the entire time it is in transit.
- In case a third party transports the milk, a contract must have been signed beforehand to guarantee the necessary conditions for transportation.
- If milk is transported from one HMB to another, new labelling is required.
- Dry ice can be used to keep DHM frozen during transportation.
- When packaging DHM, cold temperature must be maintained, filling out all empty spaces.
- The container used for transportation must be insulated, rigid and easy to clean.
- The transportation protocol must have been validated. Otherwise, temperature must be measured and recorded throughout transportation.

Milk testing before pasteurisation

- Before processing, each lot of milk will undergo testing according to the protocols validated by each HMB.
- In HMBs that conduct microbiological testing before pasteurisation, each lot should be tested before treatment, performing a count of viable microorganisms in the milk and specifically testing for the presence of *Staphylococcus aureus* and spore-forming *Bacillus* species.
- If raw milk is not subjected to microbiological testing before pasteurisation, the quality of the milk should be assessed by means of the Dornic acid test.
- The organoleptic properties of donated milk should be assessed: colour, unpleasant odour, presence of foreign bodies/impurities.
- The protein content will be measured with the additional measurement, where possible, of the content of other nutrients such as carbohydrates or lipids.

Donor human milk processing

- Milk must be pasteurised, preferably with the Holder method (62.5 °C, 30 min).
- Pasteurising/processing temperatures of 61–63 °C can be allowed as long as the method has been validated by the HMB.
- We recommend that the pasteurisation temperature (monitored by a control bottle probe) does not exceed 64 °C or fluctuate by more than 2 °C.

- The pasteurisation/heat treatment must last 30 min.
- Processed milk should be cooled rapidly (within 20 min) to 4 °C or at least to a temperature of less than 8 °C.
- Temperatures must be monitored and recorded continuously during heat treatment.
- Processing equipment, including pasteurisers and temperature probes, must be calibrated periodically.

Milk testing after pasteurisation

- The microbiological contents of each lot of milk must be assessed after pasteurisation. Milk samples must be collected using aseptic technique.
- Pasteurised milk containing 10 CFU/mL or more after pasteurisation should be discarded.
- We recommend discarding the container of milk from which the sample for testing was collected.
- We recommend that discarded milk be handled in the same manner as other clinical residues.
- Labels on pasteurised milk containers must include, at minimum: date of pasteurisation, bank identifier, lot number and unit number.
- Pasteurised milk can be stored in the freezer for up to 3 months at −20 °C to −30 °C or up to 12 months at −80 °C.

Recipient prioritisation

- All DHM recipients will be given milk that has been previously pasteurised.
- Whenever possible, consumption of own mother's milk should be promoted over consumption of DHM.
- Donated human milk is only supplied by medical prescription and with a purchase order from the hospital.
- The physician in charge of setting up the supply of DHM must obtain the informed consent of the guardian of the recipient.
- If demand for DHM exceeds supply, the HMB can reach out to other banks.
- The bank must have formal pre-established prioritisation criteria, prioritising very preterm newborns (gestational age <28 weeks) or extremely low birth weight newborns (birth weight <1000 g) and other newborns at risk of developing necrotising enterocolitis.
- Further prioritisation criteria should be established by each bank/neonatal unit.

Quality control. Traceability

- We recommend that quality controls include risk analysis and critical checkpoints.
- The HMB must track DHM from the donor all the way to the hospital and the receiving newborn.
- The documentation on each donor must be kept.
- The receiving hospital must record/document how the DHM is used.
- For each lot of pasteurised milk, the bank must keep records on the raw milk included in the lot, the date of defrosting and pasteurisation, the prepasteurization microbiological tests or acid test, the postpasteurization microbiological tests, the nutritional contents and aliquots produced, and the recipients that consumed the milk.
- Records concerning freezer, refrigerator and heat treatment temperatures must also be kept.
- All DHM and every container must be labelled at each stage.
- Records should be kept for a period of time after the expiration, use or discarding of DHM. The length of this period is to be determined by the protocols of each bank.
- When donated milk is transferred from one HMB to another, the donor identification and label information must also be transferred to the new bank, which will be responsible for traceability from the moment it receives the containers of donated milk.
- We recommend the establishment of internal traceability procedures (audits).
- We recommend running identification simulations or performing videotaped tests of bank protocols on a regular basis.

Staff and staff training

- The HMB team must include a manager with a degree in health sciences and sufficient staff to carry out the daily operations of the HMB.
- The staff must receive continuous education to update their knowledge. Their work must be audited periodically.
- Staff must be trained on all the following: hygiene, quality control, safety and traceability, technical procedures (collection, storage, pasteurisation), law and ethics guidelines and, in banks located in neonatal units, infant nutrition.
- We recommend that staff be trained on breastfeeding and its promotion.
- Professionals working in HMBs must undergo periodical health checkups and be up to date in the required immunizations.

Conclusion

These recommendations have been developed by consensus by the different HMBs grouped under the Asociación Española de Bancos de Leche Humana. One of our objectives in their development was to provide a reference to HMBs for the development of standardised protocols in their operations, so that they can set quality standards that ensure the safety of donor milk users. This is a living document, to be continually updated as new evidence emerges on lactation and the processing of human milk.

In recent years, there has been a significant increase in the number of HMBs in Spain. However, we are still far from the desired target of at least 1 bank in each autonomous community. We hope that these guidelines will contribute to facilitating the creation of new milk banks in Spain, which will certainly have the undivided support of the Asociación Española de Bancos de Leche Humana.

Conflicts of interest

The authors have no conflicts of interest to declare.

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