Toolkit for establishing and organising human milk banks

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Preface and introduction

Because of its unique nutritional composition, breast milk is the optimal nutrition for almost all infants, and it should be available immediately after birth - in particular for preterm infants. Breast milk is ideally adapted to an infant's needs, contains an ideal combination of nutrients, and making it without a doubt the best and most natural form of food for infants in the first months of life.[1]

When mother's own milk is not, or not sufficiently, available, the Committee on Nutrition of the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN)[2], the World Health Organization (WHO)[3,4], and the American Academy of Pediatrics[5] recommend that infants - in particular preterm and ill infants - are given quality-controlled donor milk. The National Nursing and Nutrition Commissions and the Swiss Society of Neonatology also recommend feeding preterm infants, infants with low birth weight, or ill infants, whose mothers are not yet able to nurse, with donor milk whenever possible.[6-8]

Human milk banks play an important role in ensuring that preterm and ill infants receive the valuable donor milk they need. Human milk banks make donor milk accessible to all newborn infants. However, it is not possible to guarantee a full supply of donor milk in most European countries, as the demand for donor milk for preterm babies is often larger than the supply.[2] It is yet unknown how large the discrepancy between supply and demand truly is in each country.*

In order to provide hospitals with the best possible support in establishing and organising human milk banks, this toolkit has been developed by a collaborative expert panel consisting of well-known professionals in the fields of obstetrics, neonatology, lactation, and nutrition, as well as patient representatives. Its goal is to provide helpful information and support for the establishment and organisation of human milk banks.

Please notice that the content still needs to be adapted to country-specific conditions as the documents are tailored to the needs and structures of German speaking countries.

In order to improve the supply of breast milk to preterm and ill infants, practical examples, concrete instructions, and templates to support hospitals in the establishment of a human milk bank are provided.

We hope that this toolkit will help you in your work and in establishing your own human milk bank.

Sincerely, Silke Mader

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*For further information, see: EFCNI position paper "Recommendations for promoting human milk banks in Germany, Austria, and Switzerland" www.efcni.org/milkbanks.

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Definition of terms

Breast milk	Breast milk can be differentiated into mother's own milk and donor milk.
Mother's own milk	Milk used to nourish one's own child.
Donor milk	Milk from a nursing / lactating woman who is not the biological mother of the child.
Human milk bank (HMB)	Institution which collects, tests, processes, stores, and supplies breast milk.
Milk donor	Healthy mother who is nursing or pumping milk for her own child and voluntarily donates her excess milk.
Raw donor milk	Untreated (unpasteurised) donor milk
Pasteurised breast milk	Breast milk that has undergone heat treatment.
Pooled donor milk	Donor milk from multiple donors combined within a collection period.
Collected breast milk	The combined breast milk collected from one donor within 24 hours.
HACCP ("hazard analysis critical control point") concept	A management system in which food safety is addressed through the monitoring of biological, chemical, and physical hazards associated with processing and assessing risks, in order to promptly implement appropriate measures.

1. Human milk banks in Germany, Austria, and Switzerland

In Germany, there are currently 20 human milk banks in operation, the majority of which are located in the new federal states (former East Germany). In Austria, there is one public breast milk collection site, located in Vienna Semmelweis Women's hospital, and there are internal human milk banks at the Graz, Innsbruck, Salzburg, and Vienna University Hospitals. In Switzerland, there are currently seven human milk banks in operation in Aarau, Bern, Basel, Chur, Luzern, and St. Gallen (two human milk banks) (as of April 2018).

Figure 1: Locations of human milk banks in Germany

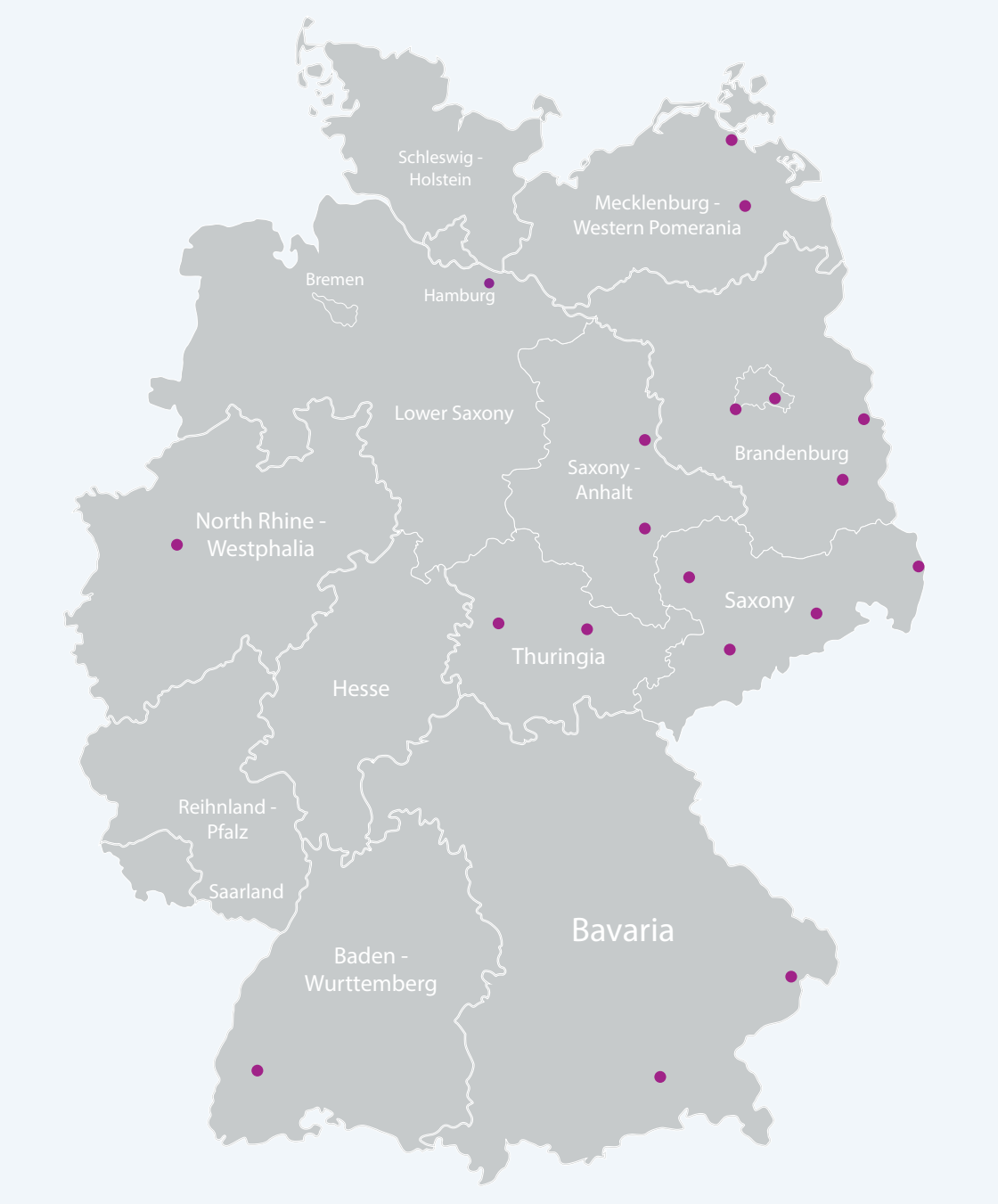

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Figure 2: Locations of human milk banks in Austria and Switzerland

2. Example Germany: Legal regulations

There is currently no uniform legal regulation on breast milk in Germany and Switzerland. Only in the federal states of Baden-Wuerttemberg, Bavaria, and Saxony, breast milk is defined as food.

> *Excerpt from the resolution of the government of Upper Bavaria for the human milk bank at the University Hospital in Munich, Großhadern: "...we can inform you that the Bavarian State Ministry for Health and the Environment shares our interpretation of breast milk being considered as food in the sense of Art. 2 of ordinance (EC) no. 178/2002".*

In Austria, breast milk is defined as food, and the Austrian guideline is legally binding.[9]

The definition of breast milk describes required regulations for hospitals and for the work of human milk banks. Depending on how breast milk is defined by the responsible ministry in a federal state, different licensing regulations, legal interpretations, and subsequent monitoring authorities apply for the specific hospital.

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"Sufficient lead time is required to plan a human milk bank, in particular to ensure that all legal requirements are fulfilled".

Dr Daniel Klotz (Medical Centre, University of Freiburg)

Collaborating and cooperating with licensing agencies, based on an example from Freiburg

- Research on the part of the hospital to determine which ministry is responsible for breast milk
- Enquiry from the hospital to the responsible ministry in Baden-Wuerttemberg to establish a legal definition of breast milk (the responsible ministry in Baden-Wuerttemberg is the Ministry for Rural Affairs and Consumer Protection, department of animal-based food products)
- Breast milk was defined as food by the responsible ministry in Baden-Wuerttemberg
- The hospital contacted and registered with the responsible labour inspectorate which is responsible for food companies and processing facilities
- Ordinance on Food Hygiene: Based on EU ordinance no. 852/2004 – Food Hygiene Regulations for Food Business Operators
- An expert opinion including on-site inspection and controls by the responsible agency / food supervisory authority was required before beginning operations
- After all requirements had been fulfilled and reviewed, the hospital received approval for operating the human milk bank from the responsible agency / food supervisory authority
- Regular inspections of the human milk bank are conducted by the responsible agency / food supervisory authority

3. Structural requirements and resources

3.1. Organisation and project management – from concept to practice

Advanced project management is required for the planning and organisation before a human milk bank can be established.

Indication

It must be defined in advance which infants will receive donor milk from the human milk bank (target group).

Objective

It must be clearly defined, which type of human milk bank the hospital wants to establish: human milk bank to supply infants at the hospital or one that supplies breast milk to other hospitals as well.

Personnel

All key personnel must be involved in the planning and organisation process:

- Hospital management
- Senior physicians / Chief physicians
- Nursing staff
- Nursing management
- Non-scientific staff council
- Scientific staff council
- IT department
- Legal department
- Human Resources department
- Medical Director
- Hygiene specialist
- Microbiologist / medical specialists in infectious disease
- Administration

Clarification of resources for obtaining required space

- Does the hospital already have a room for milk preparation?
- Does the hospital have the required space to establish a human milk bank?

Materials

- Are necessary materials and the equipment for a human milk bank already available?
- Which additional materials and equipment must be purchased, and in what amount?

Personnel and time

- Assembling a project team
- Are sufficient personnel available to work in the human milk bank?
- Do the personnel have sufficient time resources to do the work?
- Is it necessary to create a new position for the human milk bank?

"When we were planning to open a new human milk bank, it was a big help to us to be able to contact our colleagues at the human milk bank at the Freiburg University Hospital to discuss issues that came up".

Dr Stefanie Baranowski (Ulm University Hospital)

3.2. Spatial resources

The space that is required for the human milk bank must be adapted to the conditions of the hospital. For logistical reasons, the milk bank should be located close to the neonatal unit, and only authorised personnel is granted access. An air conditioning system or ventilation system must ensure a constant room temperature. Spatial requirements must be clarified with the hygiene specialist early in the planning process. Detailed information is provided in the British[10], Swiss[11], and Austrian[9] guidelines.

The following areas are required:

- An area for acceptance, administration, preparation, and issuance of the breast milk
- An area for the refrigerators and freezers
- A "dirty" room for cleaning all utensils
- Area for storing breast milk
- Separate area with places to sit and breast pumps for donors

Excerpt from the Austrian "Guideline on establishing and operating a human milk bank and for institutions which process donor milk":[9]

"Minimum spatial requirements:

- *an area for milk acceptance,*
- *a separate area for processing and pasteurising, to which only qualified personnel have access,*
- *a storage room with different zones for quarantining milk samples and for compliant and non-compliant products,*
- *a room for cleaning and disinfecting milk bottles and other utensils with organisational division into a clean and a non-clean area,*
- *a room for storing and supplying cleaning utensils,*
- *if microbiological controls are completed by the milk bank itself, an appropriately equipped room must also be available on site for completing this testing".*

"The knowledge that their child is able to receive the best possible nutrition, relieves women of pressure and stress. This helps them produce their own milk much more quickly".

Janine Grunert University Children's Hospital Basel (UKBB)

3.3. Personnel resources

Administering and processing donor milk places high demands on the personnel working in a human milk bank. The required personnel resources will depend on the conditions of the hospital itself and the quantities of milk processed.

The following section illustrates the personnel resources of human milk banks by showing three practical examples from Berlin, Munich-Großhadern, and Leipzig.

Example: Human milk bank at the Clinic for Neonatology at Charité Berlin, Germany

Contact person: Dr Monika Berns

1) Key figures on the clinic and the human milk bank

Type of human milk bank:

The human milk bank at the Clinic for Neonatology at Charité Berlin supplies pasteurised donor milk to infants.

Number of beds in the unit:

- 68 beds in the neonatal unit
- In addition, breast milk is stored, processed and prepared for patients at the German Heart Centre Berlin.

Target group for the donor milk supply:

- Newborn infants <1,500 g and selected ill newborn infants (mostly with digestive problems) are supplied with donor milk

Number of breast milk donors per year:

- 80-100 breast milk donors per year

Quantity of donor milk collected annually at the human milk bank:

- 800 L of donor milk are collected at the human milk bank each year
- In addition, a large percentage of breast milk is stored and processed for the mothers' own children, e.g. if newborn infants suffer from congenital heart defects or need to undergo paediatric surgery

Number of children receiving donor milk each year:

- 250-300 children are supplied with donor milk each year

2) Personnel resources:

Number of employees working exclusively in the human milk bank:

- 2 employees, both working part-time (75%) in the human milk bank. The employees are also responsible for the individual enrichment of breast milk according to the doctor's prescriptions.

Number of hours worked exclusively in the human milk bank per week:

- 80 hours per week (includes both employees and additional temporary support from colleagues)

Type of professional training and professional requirements for human milk bank personnel:

- Pharmaceutical-technical assistant
- Chemical-technical assistant
- Registered nurse/paediatrician's assistant

Regular training / education for personnel:

- Structured internal training
- Internal training on hygiene
- Training on food hygiene by the health authority

3) Financing

- The human milk bank is fully financed by the Charité

Example 2: Human milk bank at the Neonatal Intensive Care Unit of the University Hospital of Munich-Großhadern, Germany

Contact person: Dr Susanne Herber-Jonat

1) Key figures on the clinic and the human milk bank

Type of human milk bank:

The human milk bank at the Neonatal Intensive Care Unit of the University Hospital of Munich-Großhadern administers raw (unpasteurised) donor milk to infants.

Number of beds in the unit:

- 16 beds in the neonatal intensive care unit
- 8 beds in the neonatal unit ("intermediate care station")

Target group for the donor milk supply:

- The goal is to supply all preterm babies <1,500 g or <32nd week of pregnancy

- Due to limited resources, the supply is only ensured for children <1,250 g at present
- Independent of their birth weight and age, all children with gastrointestinal abnormalities are supplied with donor milk

Number of breast milk donors per year:

- 10-12 breast milk donors per year

Quantity of donor milk collected annually at the human milk bank:

- 20-25 L of donor milk are collected at the human milk bank each year

Number of children receiving donor milk each year:

- 60-70 children are supplied with donor milk each year

2) Personnel resources:

Number of employees working exclusively in the human milk bank:

- A part-time paediatric nurse (50%)

Number of hours worked exclusively in the human milk bank per week:

- 20 hours per week

Type of professional training and professional requirements for human milk bank personnel:

- The personnel in the human milk bank consists of neonatologists and paediatric nurses
- If possible, personnel are trained as nursing and lactation consultants IBCLC

Regular training / education for personnel:

- The human milk bank endorses and supports that 1-2 nurses are trained as nursing and lactation consultants each year
- Regular training sessions on hygiene and nutrition for preterm and newborn infants
- Regular internal team meetings with the human milk bank team, neonatologists, and paediatric nurses (every 3 months)

3) Financing:

- The part-time (50%) position in the human milk bank is financed by donations of the parental support association affiliated with the clinic.
- The other personnel help out in the human milk bank whenever they can fit it into their daily work.
- Microbiological testings of donor milk portions and donor examinations are financed by the hospital's budget.

Example 3: Human milk bank at the University Children's Hospital of Leipzig, Germany

Contact person: Dr Corinna Gebauer

1) Key figures on the clinic and the human milk bank:

Type of human milk bank:

The human milk bank at the Leipzig Children's Hospital uses both raw and pasteurised donor milk. The goal is to use raw breast milk (only from CMV negative donors). Pasteurised frozen donor milk can be supplied to other hospitals if required.

Number of beds in the unit:

- 41 beds in the neonatal unit

Target group for the donor milk supply:

- All infants hospitalised in the neonatal unit or in the paediatric unit who receive no or not enough breast milk are eligible to receive donor milk.

Number of breast milk donors per year:

- 50-60 breast milk donors per year

Quantity of donor milk collected annually at the human milk bank:

- Approx. 100 L of donor milk are collected at the human milk bank each year

Number of children receiving donor milk each year:

- Approx. 400 children are supplied with donor milk each year

2) Personnel resources:

Number of employees working exclusively in the human milk bank:

- 1-2 employees each day (human milk bank and milk preparation room are one department with a total of 7 employees)

Number of hours worked per week exclusively in the human milk bank:

- Approx. 80 hours per week spread over 7 days

Type of professional training and professional requirements for human milk bank personnel:

- Head of the human milk bank from a medical or social background with additional training within a human milk bank
- Medical area: e.g. healthcare and nursing

Regular training / education for personnel:

- Instructions in accordance with Sec. 42 Infection Protection Act
- Regular training on hygiene

3) Financing:

- Both the personnel and the microbiological testing of the human milk bank are financed by the hospital.

3.4. Equipment and materials

Specialised equipment is required to process and manage breast milk.

This equipment is used for the work in the human milk bank only.

- Refrigerators
  - Refrigerator for raw, untreated breast milk until further processing / testing
  - Refrigerator for short-term storage of approved breast milk
  - Compliance with temperature specifications

- Temperature controls on refrigerators
- External labels for the refrigerators indicating their content
- Emergency plan (interventions required in case of technical problems)
- Retained samples of breast milk

- Freezers
  - Freezer for raw, untreated, or pasteurised breast milk
  - Freezer for approved breast milk
  - Compliance with temperature specifications
  - Temperature controls on the freezers
  - External labels for the freezers indicating their contents
  - Connection to external warning centre
  - Emergency plan (interventions required in case of technical problems)
  - Retained samples of breast milk

- Pasteuriser
  - Electronic temperature checks during the pasteurisation process
  - Documentation of the date, time, and duration of the pasteurisation process

- Pumps and adequate accessories
  - Electric breast pumps should be provided to donors
  - The bottles recommended by the human milk bank should be provided to donors

- Cleaning equipment
  - Specialised steriliser or a device for thermal disinfection

- Required equipment / resources for transportation from home to the clinic

- Information materials and working documents for the human milk bank
  - Information materials and working documents are required to recruit and inform potential donors (see section 6: attachments)
  - Pre-printed labels are required for easy labelling of pasteurised breast milk (donation date, ID number, quantity, date of pasteurisation)

The Austrian[9] and British[10] guidelines provide detailed specifications, including regulations on equipment and temperature.

4. Financing and costs

The following cost factors must be taken into consideration when establishing and organising a human milk bank. Please note that these costs will depend on the organisation and previous project management completed by the hospital:

- Screening examinations of donors
- Processing of donor milk (supply of raw or pasteurised donor milk to children)
- Microbiological testing of donor milk
- Space, equipment, and materials (purchasing costs and costs for maintenance / service)
- Additional expenses for personnel / training

5. Organising a human milk bank

5.1. Indications for using donor milk

- It must be defined in advance which infants will receive donor milk from the human milk bank (target group).

"Especially preterm infants greatly benefit from being fed with breast milk after receiving optimal pre- and perinatal care. That's why it is my personal mission to promote not only nursing but also the collection of donor milk".

Professor Michael Abou-Dakn (St. Joseph Hospital Berlin Tempelhof)

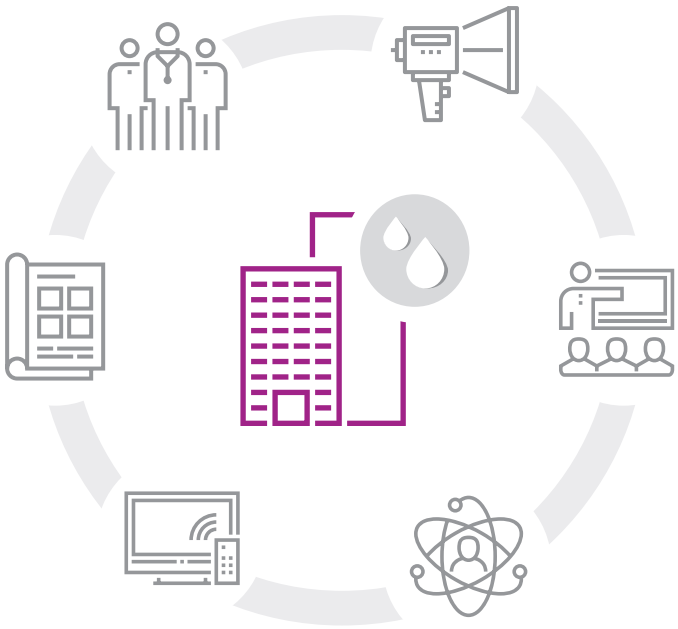
5.2. Acquiring / recruiting suitable donors

Possible materials that can be used for acquisition and recruiting:

- Information materials for interested donors and donor families
  - ✓ See sample document (Attachment 1)
- Information materials on the importance of feeding breast milk
  - ✓ See sample document (Attachment 2)

Donors can be acquired or recruited through or by:

- Doctors
- Paediatric nurses
- Midwives
- Lactation specialists
- Healthcare professionals
- Mothers of preterm or newborn infants
- Adding a flyer to certain booklets
- Hospital website
- Local TV / media
- Local press / radio
- Local parent organisations
- Various social media channels
- Information materials for nursing staff
- Information on human milk banks
- Networking with multipliers
- Mother centres / post-partum courses



In addition, healthcare professionals require sufficient information on the breast milk donation process.

- Information materials for professionals on the breast milk donation process
  - ✓ See sample document (Attachment 3)

5.3. Providing information to donors and donor families

Breast milk can only be donated after thorough consultation with a healthcare professional.

- Consent form and anamnesis questionnaire for breast milk donation
  - ✓ See sample document (Attachment 4)

- Checklist for the explanatory meeting on breast milk donation for the healthcare professionals
  - ✓ See sample document (Attachment 5)

5.4. Providing information to recipient families

The parents of the infant receiving the human milk need to have a consultation with a healthcare professional who thoroughly informs them about breast milk donation.

- Information and consent form on feeding donor milk
  - ✓ See sample document (Attachment 6)

5.5. Selecting donors

Similar to blood donations, strict criteria apply to breast milk donors. Before a woman can become a donor, medical history is assessed, and her breast milk is tested bacteriologically. A physician analyses the findings and ultimately approves the donor.

- Checklist for the explanatory meeting on breast milk donation
  - ✓ See sample document (Attachment 5)

5.6. Hygiene and safety standards

Women receive oral and written instructions on pumping, storage, and transportation of donor milk, along with relevant hygiene instructions.

- Information sheet on pumping, storage, and transportation of donor milk
  - ✓ See sample document (Attachment 7)

In addition, the following measures are required (or should be considered) for human milk bank personnel in order to ensure optimal quality:

- Procedural rules on nursing and handling breast milk must be followed by both healthcare professionals and the breast milk donors themselves.
- Orientation towards the hospital's own hygiene guidelines or the hygiene plan of the milk preparation room (if available) in consultation with the internal hygiene specialist.

- The Hazard Analysis and Critical Control Points (HACCP) concept is recommended. This concept has proven optimal in ensuring quality when handling breast milk at neonatal intensive care units. The hazards associated with each processing step are considered through a risk analysis. Risks are then assessed so that appropriate measures can be implemented promptly.

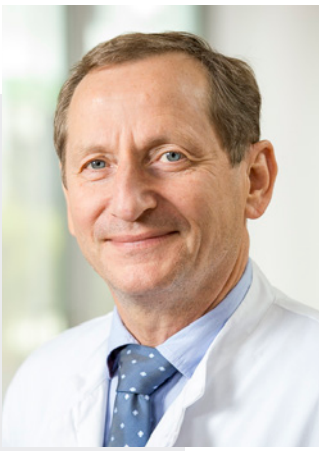
5.7. Microbiological screening / bacteriological testing of breast milk

Breast milk must undergo bacteriological testing as part of a microbiological screening process.

- The reference values (number of bacteria and germ differentiation) for handling donor milk must be determined by the hospital.
- If the donor milk does not fulfil the quality requirements, it cannot be used.
- An overview table of recommended reference values from the European recommendations and guidelines is provided in the EFCNI Position Paper.*

5.8. Handling, storage and transportation

- Depending on test results of the bacteriological screening, donor milk is fed either raw or pasteurised to an infant, or it is disposed.
- Pasteurisation is seen as the global standard, and very few human milk banks use freeze-drying, etc.
- Donor milk (raw or pasteurised) is stored in freezers and refrigerators provided for this purpose until it is used.



"Upon request, donor milk can be picked up from the donor's home and be brought to the milk bank by the hospital's own transport services. This approach facilitates donor acquisition, and helps to ensure that transportation fulfils the required quality standards, e.g. in terms of cooling and hygiene".

Professor Michael Radke (Ernst von Bergmann Hospital, Potsdam)

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*EFCNI position paper "Recommendations for promoting human milk banks in Germany, Austria, and Switzerland", ***www.efcni.org/milkbanks.***

- Donor milk can be donated in person at human milk banks or it can be picked up at the donor's home by a trained and delegated transport service, which usually belongs to the hospital.
- British, Swiss, and Austrian guidelines provide detailed recommendations on transportation.[8-10]
- Information sheet on pumping, storage, and transportation of donor milk
  ✓ See sample document (Attachment 7)

"We are very happy about the great willingness to donate breast milk, and in particular about the fact that women who did not give birth in our children's hospital donate their milk at our human milk bank".

Dr Susanne Herber-Jonat (University Hospital of Munich-Großhadern)

5.9. Administration and documentation

Each work step carried out in a human milk bank - from donation to when the donor milk is fed to an infant - must be recorded and documented based on internally defined standards.

- Donors must be added to a specific documentation system during their first donation.
- Anonymity of donors must be ensured by labelling each bottle with a specific ID number.
- Each bottle is logged to ensure it is traceable, and logs are archived.
- It should be possible to trace the donor from which the child received the breast milk.
- An electronic tracking system may be useful for administration and documentation.

Attachments

The content and sample documents developed for this toolkit should serve as a basis for the work of a human milk bank, and can be adjusted as needed before use. When using these sample documents, please indicate that their content has been adapted from this toolkit.

We take no responsibility for completeness or the compliance with local guidelines and regulations in your country. We recommend that you review each document internally at your hospital before adapting it.

We would like to thank all participating hospitals* for providing their documents so that we could prepare these sample documents.

Attachment 1: Information materials for interested donors and donor families

Attachment 2: Information materials on the importance of feeding breast milk

Attachment 3: Information materials for healthcare professionals on the breast milk donation process

Attachment 4: Consent form and anamnesis questionnaire for breast milk donation

Attachment 5: Checklist for the explanatory meeting on breast milk donation

Attachment 6: Information and consent form on feeding breast milk

Attachment 7: Data sheet on pumping, storage, and transportation of donor milk

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* Universitäts-Kinderspital beider Basel (University Children's Hospital Basel - UKBB), Klinik für Neonatologie der Charité Berlin (Hospital for Neonatology at Charité Berlin), Klinikum der Universität München-Großhadern (University Hospital Munich-Großhadern), Universitätsklinik für Kinder- und Jugendliche Leipzig (University Hospital for Children and Young People Leipzig), Universitätsklinikum Salzburg (University Hospital Salzburg), Kantonsspital St. Gallen (Cantonal Hospital St. Gallen KSSG)

Dear mother,

You have enough breast milk for your own child, you are in good health, and you have an excess amount of milk?

Please consider donating your excess milk to the ..... human milk bank ***(please enter the name of your human milk bank).*** By doing so, you provide another child with the opportunity to benefit from being fed with breast milk / donor milk. Donating will never interrupt the supply of your own child.

Importance of breast milk

Breast milk provides the best nutrition for newborn infants, and in particular for preterm infants. If they do not have access to mother´s own milk permanently or at least temporarily, donor milk is a good alternative for preterm and ill newborn infants according to the World Health Organization.

What should you know before donating?

Donating breast milk is voluntary, unpaid, and subject to strict criteria, which are similar to the ones used for donating blood. Only healthy mothers with an adequate milk supply can become donors. Each donor needs to undergo blood testing to exclude potential infections with HIV, Hepatitis B and C, cytomegalovirus (CMV), syphilis, and other illnesses.

In addition to blood testing, there will be an explanatory meeting in which you will also need to fill out an anamnesis questionnaire on your current health status and lifestyle.

The personal data collected during breast milk donation is subject to a duty of confidentiality, and will always be treated accordingly. Recipients will not receive any information on your identity.

Once all the testing is finished, your milk will undergo a bacteriological screening to ensure that it does not contain any germs that could be hazardous to the receiving child.

Why are some donors excluded?

You will be excluded from donating due to:

- infection with one of the pathogens / illnesses indicated above
- consuming nicotine, alcohol, or drugs
- drinking large quantities of caffeinated beverages
- vegan diet

- having new tattoos, piercings, and permanent make-up in the last 6 months
- having undergone blood transfusions in the last 6 months (if they were delivered in a country where blood products do not undergo controlling measures)
- sexual contact with various partners (professionally)
- *Any further exclusion criteria must be defined by the hospital*

If one or more of the grounds for exclusion indicated above apply during your donation, you must inform the personnel at the human milk bank immediately, since you will no longer be able to donate.

Our safety measures

The procedures used for donor selection, screening of milk samples, storage, and documentation were developed based on those of blood donation, and correspond in every respect to the procedures at established human milk banks in Germany and Europe.

If you are interested in donating, please contact us at:

Human milk bank contact: .....

Contact person: .....

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Attachment 2: Importance of breast milk and nursing

Dear parents,

Because of its unique nutritional composition, breast milk is the optimal nutrition for almost all infants and it should be available immediately after birth - in particular for preterm infants. Various studies have shown that especially ill and preterm infants benefit from receiving breast milk. Breast milk provides vital nutrients and delivers important antibodies, factors of human growth and maturity, and the bacteria children need to develop a healthy intestinal flora and well-functioning defences against infection.

Even the smallest amounts of breast milk are very valuable for your child. That's why we want to support you in building your milk supply as quickly as possible. Drink and eat regularly, pump regularly according to the instructions you received from hospital personnel, and be proud of every drop of milk you can give to your child.

It is not always possible to nurse preterm babies during the first days after birth. In most cases, preterm babies receive pumped breast milk, or donor milk delivered through a feeding tube.

If you are (not yet) able to nurse or if you need to increase your milk supply first, we can provide your child with donor milk from our human milk bank.

If you have questions, you are welcome to contact our staff at any time.

Contact person: .....

Attachment 3: Information materials on the donation process for healthcare professionals

- The employees at the human milk bank, together with healthcare professionals and the responsible physician, decide which women may be potential donors. This decision takes factors such as her typical milk supply, the child's gestational age, the mother's general hygiene standards, linguistic communication, and religious background into consideration.
- Employees at the human milk bank contact the mother to ask if she is interested in donating breast milk.
- It is important to provide the mother with the following information:
  - her own child always comes first. If her milk supply decreases, she and the hospital will reassess the situation and breast milk donation will be stopped if necessary.
  - breast milk donors can stop donating at any time.
- The mother should be informed that:
  - breast milk donation is subject to requirements that are similar to blood donation.
  - the required blood tests and personal questions are mandatory in order to minimise the risk of infection for the receiving child.
- Mothers receive the document "Information materials for interested donors and donor families".
- Employees at the human milk bank inform responsible healthcare professionals that the recruitment of a potential breast milk donor is being considered.
- If the mother decides to donate breast milk, they will discuss and fill out the "Consent form and anamnesis questionnaire for breast milk donation" with her.
- The form "Checklist for the explanatory meeting on breast milk donation" is available to employees at the human milk bank for consultations.
- If the information indicates the woman is eligible for milk donation, blood testing can be completed as a next step.
- Once all results and information are available, including serology, a healthcare professional decides whether the mother is a suitable breast milk donor, and confirms the decision with their signature.
- All completed documents are then transmitted to the human milk bank.
- As a last step, the donor milk is subject to bacteriological testing.
- Employees at the human milk bank are now responsible for further procedures and for processing the donor milk.

Attachment 4: Consent form and anamnesis questionnaire for breast milk donation

Mother's last name, first name: .....

Mother's date of birth: .....

Address: .....

Telephone number: .....

E-mail address: .....

Child's last name, first name: .....

Child's date of birth: .....

Gestational age at birth: .....

Dear mother,

We are very pleased that you have decided to help other children by donating your excess breast milk. Donor milk is very important for preterm and ill infants when their mothers cannot (yet) produce sufficient milk.

In order to ensure the quality of donor milk and the safety of the receiving child, we will complete the following blood tests before you are approved as a donor: Hepatitis B, hepatitis C, syphilis, cytomegalovirus (CMV), HIV, liver values. If there are any abnormalities in your testing, your doctor will inform you.

In addition to the blood tests, we would like to ask you to answer the following list of questions on your health status and lifestyle. We are aware that these are very personal questions. We assure you that all personal data and test results collected during the milk donation process are subject to data privacy protection and confidentiality obligations. Data is saved only for traceability of donor milk and quality assurance.

Please answer the following questions:

Do you feel healthy? ○ yes ○ no

Do you take any medications on a regular basis (such as antibiotics, pain, blood pressure, or allergy medications), hormones, vitamins, or homeopathic agents, or have you ever been treated with growth hormones? ○ yes ○ no

If so, which ones? .....

Do you smoke?* ○ yes ○ no

If so, how many cigarettes per day?: .....

Do you drink alcohol?* ○ yes ○ no

If so, how often and how much: .....

Do you drink caffeinated beverages* (coffee, black tea, etc.)? ○ yes ○ no

If so, how many cups per day? .....

Are you vegan? ○ yes ○ no

Do you suffer from a chronic illness (such as high blood pressure, epilepsy, diabetes, autoimmune disorders, hepatitis, etc.)? ○ yes ○ no

If so, which one: .....

Have you ever had tuberculosis, or have you had direct contact with someone who was ill with tuberculosis? ○ yes ○ no

Is there anyone in your family who suffers from Creutzfeldt-Jakob disease? ○ yes ○ no

Have you ever received a corneal, dura mater, or other transplant? ○ yes ○ no

Have you received a blood transfusion or any treatments using plasma (such as immunoglobulins, coagulation factors) in the last 6 months? ○ yes ○ no

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*The quantity of nicotine, alcohol, and caffeinated beverages which will exclude a woman from donation should be established/defined.

If so, which country? .....

Have you been vaccinated in the last 4 weeks (e.g. against rubella, measles, mumps, chickenpox)? ○ yes ○ no

Have you been to any non-European country in the last 6 months? ○ yes ○ no

If so, which country? .....

Have you got a tattoo or piercing in the last 6 months, or have you had any permanent make-up done? ○ yes ○ no

Do you or your partner take drugs, or have you ever taken drugs in the past? ○ yes ○ no

Have you ever had sexual contact with others on a professional basis? ○ yes ○ no

---

We kindly ask you to confirm your statements by checking the following boxes:

☐ I hereby agree to donate my excess milk to the ..... human milk bank ***(please enter the name of your human milk bank here).*** Breast milk donations are anonymous.

☐ I have read and understood the information sheet for breast milk donors, and I have received specific information on the breast milk donation process. All of my questions on this process have been answered.

☐ I have received information on what blood tests I will be required to undergo before starting breast milk donation, and I give my consent to have these tests done.

☐ I have been informed and accept that my breast milk will be tested bacteriologically.

☐ I will immediately inform the human milk bank if any of the statements given above changes, or if I get any acute illness or infection.

☐ I hereby confirm that I have answered all questions truthfully.

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☐ I agree with the storage of my personal data for the purposes of quality assurance and traceability. I also agree to scientific evaluations of my data.

....

Date, place Donor signature

Thank you very much for allowing us to use your donor milk to help other children.

The explanatory meeting was conducted by:

Physician name: .....

Signature: .....

Place, date: .....

Donor consent for breast milk donation:

Name, first name: .....

Signature: .....

Place, date: .....

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Attachment 5: Checklist for the explanatory meeting on breast milk donation

Mother's last name, first name: .....

Mother's date of birth: .....

Address: .....

Telephone number: .....

E-mail address: .....

Child's last name, first name: .....

Child's date of birth: .....

Gestational age at birth .....

The questionnaire on health status and lifestyle has been completed (anamnesis questionnaire) ○ yes ○ no

---

Information materials have been provided to interested donors: ○ yes ○ no

---

Consent form and anamnesis questionnaire for breast milk donation has been provided: ○ yes ○ no

Clarifications / results .....

HBsAG: ..... Anti HCV: .....

HIV1: ..... HIV2: .....

TPHA: ..... Transaminases: .....

Date: ..... Physician signature: .....

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This donor's milk is suitable for the milk donation: ○ yes ○ no

---

The breast milk donor has been informed of the testing results: ○ yes ○ no

..... .
Date, place

..... .
Donor signature:

Documentation complete. ○ yes ○ no

Human milk bank:

Breast milk which is not needed for the donor's own child is collected by the human milk bank and labelled with a unique ID number.

ID number: .....

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Attachment 6: Explanation and consent form for recipient families on milk supply to their child

Dear parents,

Your child is supposed to receive donor milk. Before administering the donor milk, your doctor will explain the requirements for donors and donor milk to you, and also how the milk will be administered to your child. You should be well informed of the advantages and possible risks of donor milk, so that you can make an informed decision on whether or not you want your child to receive donor milk. This information sheet intends to help you prepare for the discussion with the doctor.

When should children receive donor milk?

- Donor milk is a good choice for children if:
- Your child was born before …….. *(please enter week of pregnancy here)* weeks of pregnancy
- Your child is severely ill
- You do not (yet) have sufficient breast milk for your child

Since donor milk is the best nutrition for your child (except for your own milk), we recommend providing your child with donor milk instead of artificial preterm baby formula. In many cases, children need to receive donor milk only for a short period of time, until the mother is (once again) able to produce sufficient milk herself.

Where do we get our donor milk from?

At our neonatal unit, we receive our donor milk from healthy mothers who donate their excess breast milk.

If a mother is interested in donating her excess milk, her blood is tested for HIV, hepatitis B+C, syphilis, and cytomegalovirus (CMV). The mother is also asked to fill out a questionnaire which is similar to the questionnaire required before donating blood. In addition, she receives information about specific hygiene requirements. If the mother is a suitable donor, her milk is subject to bacteriological testing. Once all tests have been completed and passed, the donor milk can be provided to other children.

The donor's identity is treated confidentially.

What happens to donor milk before it is given to my child?

A sample for bacteriological testing is taken from donor milk that has been dropped off by the donors in our milk preparation room. As a next step, the milk is frozen ***(to be adapted to local situation).*** If a family gives consent for their child to receive donor milk, the required amount will be thawed, pasteurised ***(to be adapted to local situation)*** and given to their child.

Are there any risks or complications?

The likelihood of a complication is very low, since donor milk and donors are carefully examined. A low risk of infection always remains though. However, the advantages of feeding donor milk outweigh this risk.

Notes on the explanatory meeting:

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Refusal:

I decline to have donor milk provided to my child.

.....

Date, place

.....

Signature of the parent/guardian

Consent:

I was thoroughly informed about the risks and benefits of donor milk during an explanatory meeting. I had the opportunity to ask all the questions I had, and they were answered to my satisfaction.

I do not have any further questions, and I agree that donor milk will be given to my child. I have received a copy of the information material and consent form.

.....

Date, place

.....

Signature of the parent/guardian

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Attachment 7: Data sheet on pumping, collecting, storage, and transportation of donor milk

In order to obtain the benefits of donor milk and to ensure hygiene for the recipient child, donor milk must be carefully collected, correctly stored, and cooled continuously during transportation. Our lactation specialist will explain the unique considerations associated with breast milk donation to you. This will also give you the chance to ask any further questions that may arise.

Instructions

The special considerations associated with providing milk for your child and for breast milk donation will be explained to you in a personal meeting with a healthcare professional. The meeting will include the procedures of pumping, collecting, storage, and transportation of breast milk.

To allow you reading about the specific processes at home if necessary, we would like to provide you with a list of all special considerations.

Milk bottles

- Please use the milk bottles provided by the hospital to collect your breast milk.
- Please pay attention to cleanliness when opening, filling, and closing the milk bottles. *(to be adapted to local situation)*

Personal hygiene measures

- Showering or bathing daily is very important. Please use a fresh new towel to dry off.
- Please do not use any body lotions on your breasts.
- Please use fresh nursing pads each time you pump.

Routines before each pumping session

- Please wash your hands thoroughly with soap.
- Please use a clean towel or disposable towel to dry your hands.
- Please disinfect your hands.
- Provide you with your pumping equipment, and also something to drink.

Cleaning the pumping equipment

- Please clean the pump set thoroughly after each use (with detergent and warm water).
- Please boil the pumping equipment 1 x each day or wash it at a minimum of 60 °C in the dishwasher.
- Then place the pumping equipment on a clean pad or towel and cover it with a clean cloth.

Collecting and storing donor milk

- You can combine the milk you have pumped, but only over a 24-hour period.
  (to be adapted to local situation)
- Please store pumped milk in the refrigerator at 3-5 °C until it is delivered to the hospital.
  (to be adapted to local situation)
- Please freeze breast milk if it can't be collected or dropped off within the next 24 h.
  (to be adapted to local situation)

Transportation of donor milk

- Please maintain the cold chain when transporting donor milk (3-5 °C when stored in the refrigerator, temperature <0 °C for frozen donor milk) and stick to hygiene regulations.
  (to be adapted to local situation)
- If possible, please use a washable cool box with cooling elements and clean transportation utensils regularly.

Delivering donor milk to the human milk bank

You can drop off the collected donor milk to the human milk bank during the following hours:

(to be adapted to local situation)

Human milk bank contact: .....

Contact person: .....

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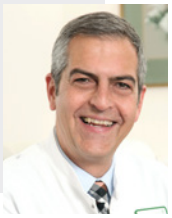
The authors



Professor Michael Abou-Dakn is the Chief Physician at the Clinic for Gynecology and Obstetrics at St. Joseph's Hospital in Berlin Tempelhof, and a professor of midwifery and childbirth at the Protestant University of Applied Sciences Berlin (Evangelischen Hochschule Berlin). He focuses specifically on perinatology and obstetrics. In addition to numerous other qualifications, including as a lactation specialist, he is past president of the WHO/UNICEF "Baby-friendly Hospital Initiative" in Germany and a member of the National Nursing Commission, and other organisations.

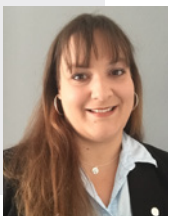
Dr Stefanie Baranowski is a specialist in paediatric and youth medicine focusing on neonatology. She has been Senior Physician in the neonatology and paediatric intensive care unit at the Clinic for Paediatric and Youth Medicine at the Ulm University Hospital since 2016. She is working towards the establishment of a human milk bank in Ulm.

Dr Monika Berns is a specialist in paediatrics and youth medicine and a neonatologist. She has been working at the Neonatology Clinic at Charité Berlin University Hospital since 2003 as Senior Physician. As a nursing and lactation specialist, she manages the human milk bank at Charité, which has been providing donor milk to preterm babies since 1995.

Katarina Eglin is an editor and PR spokeswoman for the Bundesverband „Das frühgeborene Kind" e.V. (Federal Association for Preterm Children in Germany), author of a variety of information brochures for parents on preterm birth, a long-time consultant of the telephone help line, organised by the federal association for parents of preterm babies, and mother of an extremely preterm born child herself.

Dr Corinna Gebauer is a specialist in paediatrics and youth medicine / neonatology. She has been working in the Clinic and Polyclinic for Children and Adolescents at the Leipzig University Hospital since 2000. She has been the Medical Director of the human milk bank in Leipzig since 2007, and is a founding member and board member of the European Milk Bank Association (EMBA).

Dr René Glanzmann is a specialist in paediatrics with a focus on neonatology, and is the Deputy Chair of Neonatology at the Universitätsspital beider Basel (University Children's Hospital Basel - UKBB). As a neonatologist, he has been supervising the "Laktarium" (milk collection station) for many years, and is committed to raising awareness on human milk banks. He works nationally as an examiner / tester for future neonatologists. He is also responsible for the interdisciplinary "Schreisprechstunde" (consultation of parents whose babies won't stop crying or have sleeping difficulties) and presides the drug commission at the UKBB.



Janine Grunert has been a trained registered nurse at the "Lactarium"/human milk bank at the Universitätskinderspital beider Basel (University Children's Hospital Basel - UKBB) since 2012. She previously worked at the paediatric intensive care unit and then started working at the NICU of the UKBB. There, she completed a year of additional training in neonatology. Ms. Grunert worked in the parents' group for preterm babies until she gave birth to a preterm daughter herself. Today, she works both nationally and internationally to promote awareness of human milk banks.

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Professor Nadja Haiden is the Senior Physician in the department of neonatology and paediatric intensive care at the Medical University of Vienna (MUW). Her research focuses on nutrition for preterm and newborn infants, as well as breast milk and neonatal haematology. She leads her own research team at the MUW, and is the Chair of the Austrian Nutrition Commission for the Society for Paediatrics and Youth Medicine.

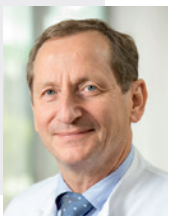
Dr Erna Hattinger-Jürgenssen is a specialist in paediatrics and youth medicine and has done a specialisation in paediatric cardiology at the Vienna University Hospital and in neonatology at the Salzburg University Hospital, where she has been working as Senior Physician and deputy manager of the neonatal unit since 1996. She is a trained psychotherapist, nursing consultant (IBCLC) and NIDCAP professional. She implemented nursing and feeding preterm babies with breast, NIDCAP, and developmental care at the neonatal unit in Salzburg, and serves as a consultant on multiple boards dealing with related issues.

Dr Susanne Herber-Jonat studied medicine in Hamburg and completed her specialist training in paediatrics at the University of Kiel. In 2002, she started working at the Hauner Children's Hospital in Munich, and has served as the Deputy Director of neonatology at the University Hospital Munich-Großhadern since 2015. She has a special interest in nutrition of extremely immature preterm babies, and has helped manage the human milk bank at the University Hospital Munich-Großhadern since 2012.

Dr Daniel Klotz is a specialist in paediatrics and youth medicine with a focus on neonatology and paediatric intensive care. After holding several positions in Germany and abroad, he is now a Senior Physician at the Centre for Paediatrics and Youth Medicine at the Freiburg University Hospital. There, his research focuses on breast milk and he manages the newly established human milk bank.

Dr Andreas Malzacher is a paediatrician and neonatologist, and has been Head of the Neonatal Unit at the Women's Clinic at the St. Gallen Cantonal Hospital for 18 years. He also treats children and preterm babies in the intensive care unit of the east Swiss children's hospital in the perinatal centre. Both locations of the perinatal centre have their own milk banks. Dr Malzacher is a member of the Swiss Society of Neonatology (SGN) and instructor for the Neonatology Skills Course Start4Neo.

Caroline Peter has been working as a trained registered nurse at the "Lactarium" (human milk) bank of the Universitätskinderspital beider Basel (University Children's Hospital Basel - UKBB) since 2008, and is mother of two children. She completed her training at the former Basel Children's Hospital and has worked in the neonatal unit for seven years. Today, she offers trainings on human milk banks both within the hospital and throughout Switzerland.



Professor Michael Radke is a specialist for paediatrics and youth medicine focusing on paediatric gastroenterology and nutrition. After working as the Senior Physician at the Rostock University Hospital for many years, he took over the position of a Chief Physician at the Children's Hospital of the Ernst von Bergmann Hospital in Potsdam in 1997. He has been the Director of the Paediatric and Youth Clinic, University Medicine, Rostock, since early 2015. The Potsdam perinatal centre established a human milk bank under Professor Radke's leadership, which supplies all preterm babies in the unit with human donor milk in addition to providing milk to other hospitals.

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Recommended literature

Position paper "Recommendations for promoting human milk banks in Germany, Austria, and Switzerland"

The interdisciplinary expert panel has compared and summarised current guidelines from other European countries. Based on these guidelines, they have formulated joint recommendations for promoting human milk banks in Germany, Austria, and Switzerland. These are based on current scientific knowledge, and consider factors for practical implementation in everyday hospital work. The recommendations are meant to assist the development of national guidelines, as well as a joint German guideline, by the respective healthcare societies.

From the contents:

- Importance of breast milk
- Current status: Human milk banks in Europe
- Comparison of European recommendations and guidelines
- Requirement analysis at perinatal centres in Germany for supplying preterm babies with breast milk
- Practical examples
- Recommendations for structural and quality requirements for human milk banks

The position paper is available for download in German and English at *www.efcni.org/milkbanks*.

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Be a voice of change and become a supporting member

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Send a message of hope and create special moments with your loved ones to help preterm and newborn infants and their families.

Corporate Partnership Programme

We believe in good collaboration and fruitful partnerships for both parties. If you would like to support our work and thus help us improving maternal and newborn health, we would love to hear from you.

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Despeena, born at 24 weeks weighing 820 grams

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Many thanks.

Such a complex project is only possible with the support of great partners. We'd like to warmly thank our expert panel and our partners for their collaboration and their trust in our work.

The position paper "Recommendations for promoting human milk banks in Germany, Austria, and Switzerland" served as the basis for this toolkit, and was supported by the following professional associations and organisations:

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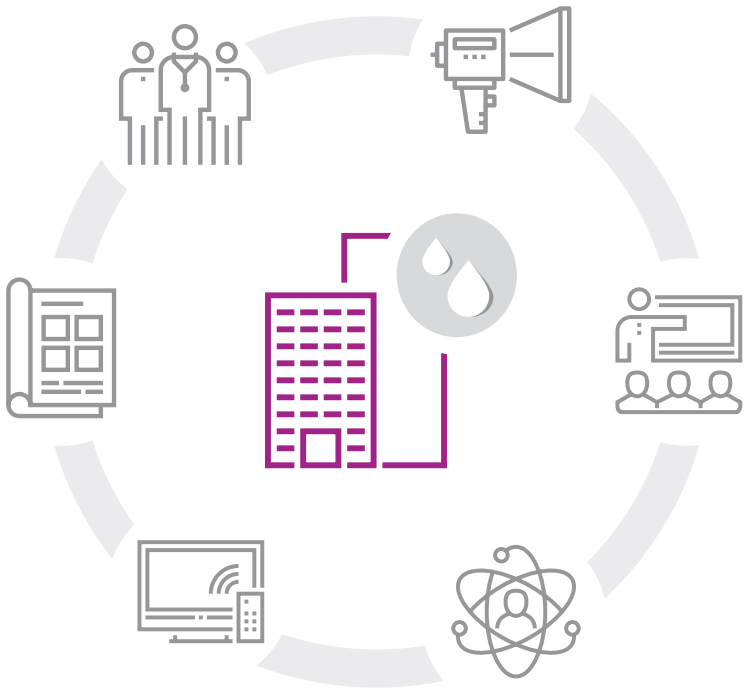

About EFCNI

The European Foundation for the Care of Newborn Infants (EFCNI) is the first pan-European organisation and network to represent the interests of preterm and newborn infants and their families. It brings together parents, healthcare experts from different disciplines, and scientists with the common goal of improving long-term health of preterm and newborn children by ensuring the best possible prevention, treatment, care, and support.

For more information, visit us at: ***www.efcni.org***

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