Position paper

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

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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.
Frozen breast milk	Breast milk that has been stored at temperatures of at least -20°C either raw or after pasteurisation.
Pasteurised breast milk	Breast milk that has undergone heat treatment.
Raw donor milk	Untreated (unpasteurised) donor milk.
Single donor principle	The donor milk a child receives comes from only one donor. This means donor milk from different donors is not mixed.
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.
DRG coding	A reimbursement system based on diagnosis related groups (DRG) according to which patients are allocated to certain groups based on their diagnosis and the method of treatment.

1. Introduction

Breast milk is ideally adapted to an infant's needs, making it without a doubt the best and most natural form of nutrition for children in their first months of life.[1] Numerous studies have proven the importance of breast milk for feeding infants, in particular preterm and ill infants, in comparison to other nutrition options.

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. If this is not available either, artificial infant formula, or preterm infant formula which comply with the current EU guidelines for these products, can be given. 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] This is where human milk banks fulfil a key function, as they ensure that preterm and ill infants can be supplied with the valuable donor milk. As the demand for donor milk for preterm infants is often larger than the supply, it is not possible to guarantee a full supply of donor milk in Europe these days.[2] It is yet unknown how large the discrepancy between supply and demand truly is in each country.

In this position paper, a working panel from Germany, Austria, and Switzerland, some of whom manage human milk banks themselves, have collated their experience and knowledge and compared it to several current guidelines in Europe. Furthermore, this position paper illustrates the demand and supply of donor milk for preterm infants through a requirement analysis for Germany. On this basis, the expert panel has formulated joint recommendations for promoting human milk banks in Germany, Austria, and Switzerland which build on current available scientific knowledge and take the day-to-day clinical practice into account.

Goals of the position paper

This position paper offers both existing human milk banks and hospitals, which are interested in establishing a human milk bank, a sound and uniform basis for their work. In addition, its goal is to inform the public of the importance of nursing and nutrition with donor milk and to increase awareness for this fundamental issue. The recommendations on promoting human milk banks formulated by the expert panel are meant to assist with the development of national guidelines, as well as a joint German guideline, by the respective healthcare societies.

2. Background

2.1. Importance of breast milk

Because of its unique nutritional composition, breast milk is the best and first choice for almost all infants. It should be available immediately after birth - in particular for preterm infants. In addition, breast milk induces the establishment of intestinal microbiota (intestinal flora), helps prevent illness, and strengthens the immune system while promoting growth and development in infants.[9-11] One of the many positive health effects of feeding infants breast milk is the beneficial long-term effect on cognitive development.[12]

Various studies have shown that especially ill and preterm infants benefit from receiving breast milk directly after birth rather than starting off on formula. The digestive system and intestinal microbiota of preterm infants are immature, not yet occupied by a physiological microbiome and therefore more susceptible to infections. Breast milk provides vital nutrients and delivers important antibodies, immunological, growth, and maturation factors, and the bacteria children need to develop a healthy intestinal flora and well-functioning immune system.

Breast milk not only reduces the risk of necrotizing enterocolitis (NEC), a life-threatening inflammatory bowel disorder, sepsis, and other infections, but also stimulates the development of the preterm infant's digestive and immune systems.[4,13-15] Depending on how long they are nursed, infants may also have a lower risk of obesity in adulthood. Infants who were nursed exclusively for four to six months also have a lower risk of developing a metabolic syndrome and associated disorders: Diabetes mellitus type 1 and 2, high blood pressure, and elevated blood lipid levels (LDL concentrations). They also have better leptin and insulin metabolism.[5]

2.2. Current status

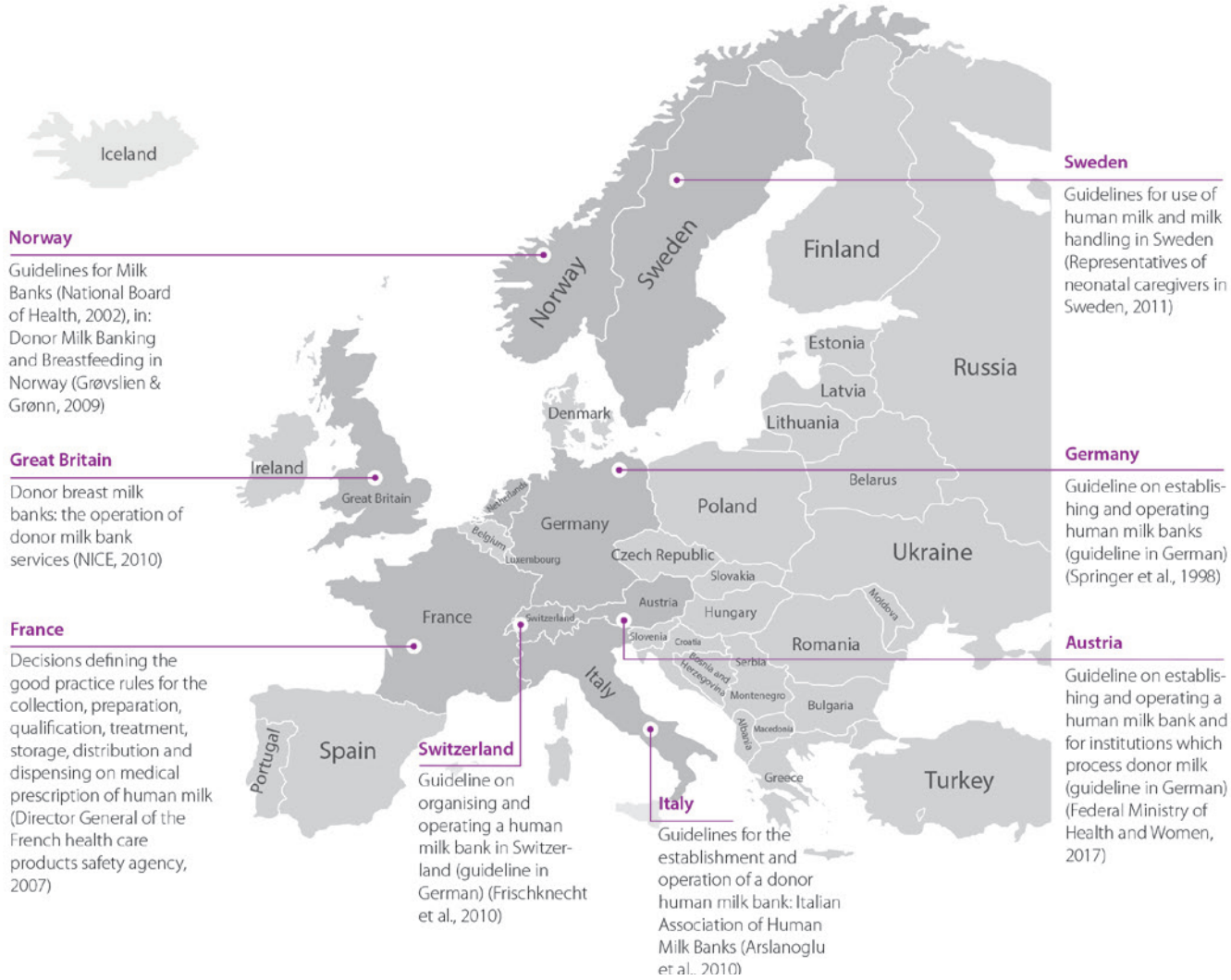
Human milk banks around the world play a key role in nourishing newborn and preterm infants. According to the European Milk Bank Association (EMBA), there are currently 225 human milk banks operating in Europe and another 16 human milk banks in the planning stage (as of April 2018). A total of 28 human milk banks are in operation in Germany, Austria, and Switzerland: 20 in Germany, seven in Switzerland, and one public breast milk collection site in Austria.[16]

All human milk banks are located in perinatal centres, and most of them supply donor milk to newborn and preterm infants in their own units. Some human milk banks also provide donor milk to infants hospitalised in other neonatal units.

2.2.1. Current status in Europe

There are no uniform recommendations or guidelines for establishing and organising human milk banks in Europe at the moment. Figure 1 illustrates the European countries in which national guidelines or recommendations are available.[17-24]

Figure 1: Overview of European recommendations and guidelines



2.2.2. Commonalities and differences between European guidelines and recommendations

The following overview table compares the content of the available recommendations and guidelines from Germany (DE, 1998), Austria (AT, 2017), Switzerland (CH, 2010), France (FR, 2008), Sweden (SE, 2011), Italy (IT, 2010), Norway (NO, 2009), and United Kingdom (UK, 2010).

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Table 1: Comparison of European recommendations and guidelines

Content from the recommendations and guidelines	AT	CH	DE	FR	UK	IT	NO	SE
Exclusion criteria for breast milk donation								
Alcohol, nicotine and/or drug consumption Medication use Chronic illnesses	•	•	•	•	•	•		•
Caffeinated drinks, vegan diet, tattoos, piercings		•				•		•
New tattoos, piercings, and permanent make-up in the last 6 months	•	•						
Blood transfusions (in the last 6 months without testing)	•	•	•	•		•		•
Professional / varying or unprotected sexual contacts / at-risk behaviour for HIV infection	•	•				•		•
After the 6th month of lactation		•						
Organ transplant				•		•		
Artificial insemination/In vitro fertilisation				•				
Increased risk of Creutzfeldt-Jakob disease (CJD))				•	•	•		
Cancer								•
Travel to endemic areas with risk of tropical illnesses (3 months before breast milk donation)						•		
Chronic degenerative organ or systemic diseases, autoimmune disorders	•							
Malignant tumours and other malignant neoplasms	•					•		
Before each donation, the donor must be asked for other reasons that may lead to a temporary exclusion from breast milk donation						•		
Testing required before breast milk donation								
Serological testing								
HIV, Hepatitis B, C (A*)	•	•	•		•	•	•	•
HBs-antigens, HBc-antibodies	•							
Syphilis	•	•	•		•	•		
Human cytomegalovirus (hCMV)			•				•	•
Transaminases			•					
Tuberculosis						•		
Human T-cell lymphotropic virus (HTLV-1 and 2)					•		•	•
Bacteriological testing of donor milk								
Bacteriological testing of each bottle before pasteurisation			•					•
Microbiological testing before processing initial milk samples	•	•						
Bacteriological testing every 5 days, once after pasteurisation		•						
Bacteriological testing of each bottle before and after pasteurisation				•	•	•		
Criteria for using donor milk								
< 10^4 CFU/ml unrestricted use 10^4 CFU/ml – 10^5 CFU/ml differentiation > 10^5 CFU/ml no use			•					
< 10^3 CFU/ml unrestricted use 10^3 CFU/ml – 10^5 CFU/ml differentiation >10^5 CFU/ml no use		•						
< 10^6 CFU/ml aerobic flora < 10^4 CFU/ml staphylococcus coagulase				•				
< 10^6 CFU/ml total bacterial count and < 10^4 CFU/ml staphylococcus aureus	•							

Content from the recommendations and guidelines	AT	CH	DE	FR	UK	IT	NO	SE
Criteria for using donor milk								
< 10^5 CFU/ml pathogenic germs < 10^8 CFU/ml gram-positive bacteria								•
< 10^5 CFU/ml total bacterial count and < 10^4 CFU/ml enterobacteriaceae and < 10^4 CFU/ml staphylococcus aureus					•	•		
> 10^4 CFU/ml no use							•	
< 10^3 CFU/ml use for very small preterm infants (<1500 g)							•	
Transport and storage at home and in the hospital								
Donor milk is frozen at home at -20 °C		•	•					•
Pasteurised donor milk in unopened bottles can be stored for 48 hours at 4 °C			•	•				•
Pasteurised donor milk can be stored for a maximum of 72 hours at 4 °C if the cold chain is maintained. After opening the bottle, the pasteurised donor milk must be used within 24 hours	•							
Pasteurised donor milk may be stored for 24 hours at 4 °C in unopened bottles		•						
Refrigerated or thawed pasteurised donor milk can be stored at 4 °C and should be administered within 24 hours		•				•		
Raw donor milk can be stored in the hospitals' refrigerator for up to 72 hours at 4 °C		•				•		
Raw donor milk can be stored in the hospitals' refrigerator for up to 24 hours at 4 °C	•							
Breast milk is collected within 24 hours, stored at 4 °C, and then frozen		•	•		•			•
Cold chain is not interrupted during transport	•	•	•	•	•	•		•
Donor milk should be pasteurised within 3 months after the pumping date		•						
Frozen donor milk can be stored for up to 6 months at -20 °C		•	•			•		•
Frozen donor milk can be stored for up to 3 months at -18 °C	•							
Frozen donor milk can be stored for a maximum of 3 months for preterm infants						•		
Thaw in the refrigerator at 4 °C or under flowing water			•					•
Either thaw very slowly in the refrigerator over 24 h or thaw under cold running water or with specialised thawing equipment	•	•						
Do not thaw in the microwave	•	•	•			•		•
Thaw slowly in the refrigerator over a maximum time period of 24 hours or thaw in a water bath or under running water that is colder than 37 °C						•		
Thawed breast milk should not be re-frozen		•				•		
Pasteurisation								
Temperature: Minimum 57 °C, maximum 63 °C			•					
Temperature: 62.5 °C ± 0.5 °C	•	•		•	•	•		•
For a total duration of 30 minutes	•	•	•	•	•	•		•
Quickly cool afterwards			•					
Cool using a programme or an ice block (25 °C per 10 minutes)		•						
Cool to 4 °C as soon as possible	•			•	•			
Quickly cool to 10 °C (40 °C per 10 minutes)						•		
Random quality checks of donor milk after pasteurisation	•	•				•		
Samples of each batch are frozen and stored for 6 months for testing	•							
Pasteurised donor milk can be stored for a maximum of 72 hours if the cold chain is maintained (maximum of 4°C) and can be stored frozen for 3 months at -18°C or colder	•							

2.2.3. Current status: Human milk banks in Germany, Austria, and Switzerland

National recommendations and guidelines have been established in Germany, Austria, and Switzerland, however, these recommendations and guidelines are not legally binding except in Austria.

Germany

The number of human milk banks in Germany has increased over the last few years. In 2000, there were only 10 human milk banks, all of them located in the new federal states (former East Germany) and in Berlin. Despite the closure of numerous human milk banks in the 1990s, these milk banks were preserved. Currently, there are 20 human milk banks in operation - the majority of which are still located in the new federal states. The establishment of further human milk banks is primarily planned in the old federal states (former West Germany). A publication by Dr. Skadi Springer from 1998 contains recommendations for establishing and operating human milk banks in Germany.[18]

Austria

There is currently one public breast milk collection site in Austria, located in the Vienna Semmelweis Women´s Clinic. At the university hospitals in Graz, Innsbruck, Salzburg, and Vienna, there are internal human milk banks. The guideline, updated by the Federal Ministry of Health and Women in 2017, is binding for all hospitals.[19]

Switzerland

There are currently seven human milk banks in operation in Switzerland, located in Aarau, Bern, Basel, Chur, Luzern, and St. Gallen (two human milk banks). The national guideline, approved by the Swiss Association of Neonatology, was published in 2010 and is currently under revision.[24]

Legal classification of breast milk

Breast milk is neither classified as food nor as medication in Austria, Switzerland, and Germany (except for the federal states Bavaria, Saxony, and Baden-Wuerttemberg, where it is classified as food). Therefore, the use of breast milk is currently in a legal grey area without regulated controls or supervision by the government. For this reason, it is necessary to define and legally classify breast milk in each respective country. It is recommended that breast milk receives a uniform definition on a national level.

2.2.4. Comparison of recommendations and guidelines in Germany, Austria, and Switzerland

The recommendations and guidelines in Germany, Austria, and Switzerland are mostly based on the content of Springer's publication[18], although they differ in some aspects (such as the duration and temperature used for pasteurisation and the thawing process). The Swiss guideline is particularly detailed, which served as the basis for the Austrian guideline. For infectiological reasons, the three publications recommend exclusively providing pasteurised donor milk. Actual practices, however, are unknown and may differ from these recommendations. In the German human milk bank at the Ludwig Maximilian University hospital in Munich, donor milk is mostly used raw. At the Leipzig and Dresden University hospitals and the Görlitz hospital, donor milk is used raw whenever possible.[25]

Recommendations in Germany and Switzerland suggest that the donor milk for an infant comes from one donor rather than combining the donor milk from multiple donors ("single donor principle"). In contrast, the Austrian guideline recommends that donor milk from various donors may be combined in order to compensate for possible individual nutritional differences. In Germany and Switzerland, the literature recommends completing bacteriological testing of donor milk on three subsequent days at the beginning of the donation before pasteurisation. In Switzerland, bacteriological controls are repeated every 3-5 days during the donation period. In Austria, a sample must be taken before each initial donation and also if there is any suspicion of contamination or non-hygienic handling practices throughout the donation process.

2.3. Results of a requirement analysis at perinatal centres in Germany for supplying preterm infants with breast milk

In Germany, it is unknown how many preterm infants receive breast milk and how many infants would require donor milk. Furthermore, there is no data available on the interests of perinatal centres in establishing their own human milk banks or on the acceptance of donor milk among parents of preterm or ill infants. For these reasons, a questionnaire was developed as part of a Master's thesis and sent out as an online survey to all level 1* and level 2 perinatal centres in Germany. A total of 223 perinatal centres, 15 of which have their own human milk banks, were invited to take part in the survey (survey period: August - October 2016).

*The international classification of "Level III" Perinatal Centers is equivalent to "Level I" Perinatal Centers in Germany. Thereby, a Perinatal Center Level I has the highest level of care.

The total response rate was 17% (37/223), among the perinatal centres with human milk banks it was 60% (9/15); 11% (24/223) actively declined to participate, and the other centres did not submit answers despite receiving several reminders to do so. Figure 2 shows the participating perinatal centres. Eight human milk banks provided information on donor milk quantities. According to this information, they collected between 17 and 1060 L (total 2,721.35 L, on average 340 L) of donor milk from a total of 169 donors in 2015. 44% (4/9) of the human milk banks also sold donor milk to other hospitals. Among the perinatal centres without an own human milk bank, 7% (2/28) purchased donor milk from other hospitals. In both perinatal centres with and without a human milk bank, donor milk was most frequently used for preterm infants, based on their gestational age (usually after 23 weeks). Furthermore, the perinatal centres were asked up to which gestational age donor milk was administered to preterm infants. The answers to this question varied from "administered up to 32 weeks of gestation" to "administered until discharge" between the participating perinatal centres. In other perinatal centres, the administration period was based on the preterm or newborn infant's body weight (until they reached 1000 g – 1800 g).

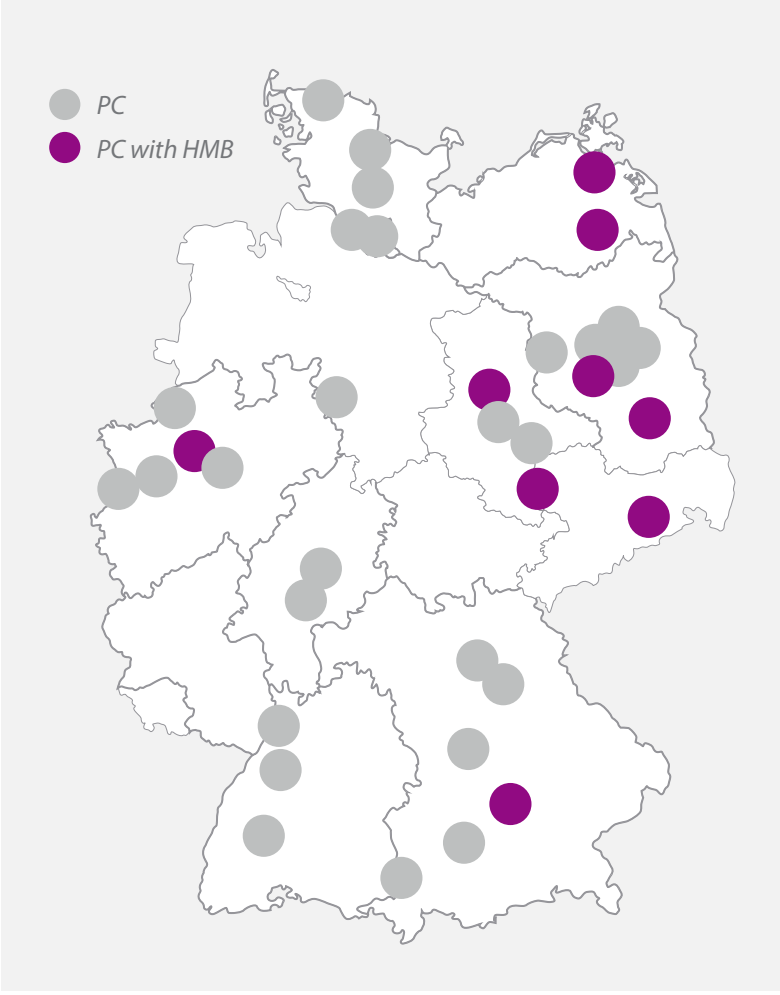


Figure 2: Locations of participating perinatal centres (PC)

In 48% (19/40) of the perinatal centres, 50-80% of preterm infants were partially or exclusively fed with breast milk. In 45% of the perinatal centres >80% of preterm infants were fed with breast milk. 47% of the perinatal centres indicated that 50-80% of preterm infants were fully breastfed by the time of discharge, and 8% indicated that this was the case for >80% of preterm infants. In 11% (3/28) of the perinatal centres without a milk bank, preterm infants received donor milk during their inpatient treatment. The results are summarised in table 2.

Table 2: Results of the survey

		Perinatal centres that provide breast milk to preterm infants		Perinatal centres in which preterm infants are exclusively breastfed by the time of discharge		Perinatal centres in which preterm infants receive donor milk during inpatient treatment	
Percentage of preterm infants (<37 weeks of gestation)	%	n	%	n	%	n	%
	0 %	0	0	0	0	24	67
	<5 %	0	0	2	5	3	8
	5 - 10 %	0	0	1	3	0	0
	10 - 30 %	2	5	5	13	0	0
	30 - 50 %	1	3	9	24	3	8
	50 - 80 %	19	48	18	47	3	8
	> 80 %	18	45	3	8	3	8
	Total	40	100	38	100	36	100

The number of preterm infants who received donor milk varied widely between the different perinatal centres with human milk banks, and likewise between the different perinatal centres without human milk banks. The majority of perinatal centres with human milk banks indicated that <5 % of parents refused the use of donor milk for their child, 11% reported a refusal rate of 5 – 10% and another 11% indicated a 30 – 50% refusal rate. One perinatal centre without a human milk bank also reported that donor milk was not wanted. Two perinatal centres explicitly expressed their wish to establish their own human milk banks; 27% could imagine establishing their own human milk bank; the majority (17/26) said that they did not want to establish their own human milk bank for various reasons; one third indicated a lack of structural requirements as a reason, although there was a need for donor milk.

The requirement analysis shows that there is low availability of donor milk in Germany. Due to the very low response rate, these results should be interpreted with caution. In addition, there is a disparity between East and West in the response rates.

In order to ensure a supply of donor milk across the country, it is necessary to establish further human milk banks and to overcome the associated hurdles. In addition, it is important to promote the relevance of human milk banks and the acceptance among perinatal centres and parents of giving preterm and ill infants donor milk.

2.4. Practical examples

Human milk bank at the University Hospital Leipzig and human milk bank at the Clinical Centre Ernst von Bergmann Potsdam, Germany

The human milk bank at the University Hospital in Leipzig has been in operation since 1951 and is currently the largest and oldest of the 20 existing human milk banks in Germany – measured by factors such as total quantity of donor milk. With approx. 1,000-1,200 L of donor milk per year, in particular small preterm infants (<1,500 g birth weight), ill infants, and larger preterm infants can be provided with donor milk. Excess donor milk can be supplied to other perinatal centres. Mothers of both preterm and ill infants treated in the paediatric clinical centre, as well as external donors, are allowed to donate breast milk. Before being registered, potential donors must undergo an interview on medical history (anamnesis) and a serological testing for hepatitis B and C, HIV, CMV, and syphilis. They receive information material and a consent form that needs to be signed. Donor milk - refrigerated or frozen - can be donated on a daily basis. In addition, there is a transport service which can pick up donor milk twice per week. Each individual bottle is bacteriologically tested before use, and may not contain any pathogenic bacteria. Donor milk which contains less than 10,000 CFU/ml skin bacteria and comes from CMV negative donors can be fed raw. Donor milk from CMV-IgG positive donors is pasteurised and can be given to larger preterm infants. Feeding donor milk has a long tradition in the neonatal unit at the University hospital Leipzig. This is reflected in its very low NEC rate.

The Clinical Centre Ernst von Bergmann in Potsdam also has a human milk bank that was founded in 1951. It was renovated in 2008 as part of the establishment of a new perinatal centre. Its methodology and structure are similar to those in Leipzig. The human milk bank currently covers all the needs of the city of Potsdam and supplies pasteurised donor milk to other perinatal centres.

Human milk bank at the neonatal intensive care unit of the University Hospital of Munich-Großhadern, Germany

When the internal human milk bank at the neonatal intensive care unit in the perinatal centre of the Ludwig Maximilian University, Großhadern campus was established in 2011, it was not clear which licensing and supervisory agencies would be responsible for the human milk bank. At that time, breast milk was neither classified as food nor as a drug in Germany, and therefore not subject to food or pharmaceutical legislation. After obtaining an expert opinion, the Upper Bavarian government, in collaboration with the Bavarian State Ministry of Health and Environment, determined that breast milk is legally

defined as food in the sense of Art. 2 of ordinance (EC) no. 178/2002. Therefore, the approval for the operation of the human milk bank was granted by the Bavarian State Office of Health and Food Safety. The overall concept of the human milk bank was primarily based on the Swiss guideline. The board of the University hospital approved this concept, so that the first breast milk donation could take place in March 2012. At present, the human milk bank's operations are based partially on collaboration with the transfusion medicine department, the Max von Pettenkofer Institute, the Institute for Laboratory Medicine, and the hospital hygiene department. The management of the Children's Clinical centre is primarily responsible for the operation of the human milk bank.

At this stage, the human milk bank is able to provide donor milk only to preterm infants <1,500 g and severely ill newborn infants in the hospital's own neonatal intensive care unit, and does not serve as a collection site for other hospitals. The criteria for approving donors and approving individual portions of breast milk are subject to especially strict requirements, since the donor milk is not pasteurised but rather fed raw in Großhadern. Therefore, only healthy, CMV negative mothers who are able to pump each individual breast milk donation under supervision in the perinatal centre's facilities are allowed to donate. Generally, these are mothers whose own children are patients in the neonatal intensive care unit, and who have a high milk production. First, they provide their own child with sufficient breast milk and then they donate excess milk to the human milk bank. Each individual donation is tested separately and approved for donation after all microbiological findings are returned. The current system is very complex and cost-intensive. The hospital's hygiene processes for pumping, controlling, and storing donor milk have been optimised over the past few years so that 85% of all milk donations can be fed raw after they have been approved by the laboratory.

Public breast milk collection site at the Semmelweis Women's Clinic in Vienna, Austria

A public breast milk collection site, located in the Vienna Semmelweis Women's Clinic, has been in operation in Austria since 1939. Donor milk is either prescribed by a doctor, or is available to mothers who want to purchase donor milk for their children for a fee on a private basis. Donor milk is prescribed, for instance, for infants with allergies, children with weakened immune systems, multiple births, children whose mothers are temporarily on medication or severely ill, and for foster and adopted children. In addition, donor milk can be sold to other hospitals. The Semmelweis Women's Clinic in Vienna receives the excess donor milk for free and primarily supplies hospitals with neonatal or obstetric departments with

the donor milk. Potential donors from Vienna and the surrounding area can donate their excess milk after completing a selection process and receive a small expense allowance in return (2.33 EUR/L). Donor milk can be picked up at the woman's home, and the hospital provides sterile bottles and information - material on hygiene guidelines. After the donor milk has undergone microbiological testing and smell sensory, potentiometric, and visual inspections, donor milk is always pasteurised before it can be fed to the child. The breast milk collection site is financed by the Vienna Hospital Association.

Human milk bank at the University Children's Hospital of Basel, Switzerland

At the University Children´s Hospital of Basel, a so called "Lactarium" (milk bank) was established in approx. 1938. Most donors are mothers of infants who also received donor milk during their stay at the neonatal intensive care unit. In addition, external donors are accepted under identical donation criteria. Donor milk is primarily given to preterm infants <32 weeks of gestation/<1800 g and ill infants with gastrointestinal or renal problems. (Expecting) parents need to sign a consent form and receive information on the process, ideally before their child is born. Donors complete an anamnesis questionnaire and undergo blood testing (similar to the tests for donating blood), and donor milk is fed to infants after regular bacteriological controls and pasteurisation. Donors are provided with sterile bottles and labels. In addition, they are allowed to borrow an electric double pump including pumping accessories free of charge during the time they are donating. Breast milk donations are voluntary and not compensated. Donor milk for ill newborn and preterm infants is included in the diagnosis-related reimbursement groups (DRG) and is not charged separately. The seven human milk banks in Switzerland hold an annual joint meeting. If necessary, donor milk is provided to other human milk banks to cover the lack of donor milk.

3. Recommendations for structural and qualitative requirements for human milk banks

A human milk bank collects, screens, and prepares donor milk for feeding preterm and newborn infants. In the course of milk donation, the following steps are required:

- Recruiting suitable donors
- Collecting and bacteriological testing
- Processing and storing the donor milk
- Feeding the donor milk

Since there are currently no uniform structural and qualitative requirements for human milk banks in Germany, Austria, and Switzerland, the expert panel has agreed on the following recommendations based on current practices in existing human milk banks. It should be noted that not all facilities will be able to implement the requirements immediately, or to the same extent.

3.1. Spatial resources

The spatial requirements for a human milk bank must be adapted to the circumstances of the respective perinatal centre. The following areas are required: an area for acceptance, administration, preparation, and issuance of the donor milk, an area for refrigerators, a "dirty room" for cleaning all utensils, and an area for storing the donor milk. In addition, an area for donors is necessary, along with sufficient breast pumps and adequate equipment.

3.2. Personnel resources

Administering and processing donor milk places high demands on the personnel working in a human milk bank. The human milk bank or the perinatal centre should offer regular continued training for the human milk bank personnel. Employees from a variety of departments - such as neonatology, hygiene, lactation consulting, nursing, and the laboratory - also need to be trained. In addition, donors need support,

instruction, and advice from nursing and lactation consultants. Good support for donors will both strengthen their relationship of trust and help assure the quality of the human milk bank as well.

3.3. Financing

In addition to organisational work, personnel and material / financial expenses must be taken into consideration when establishing and organising a human milk bank. Currently, there is no regulated financial framework for human milk banks in Germany, Austria, and Switzerland which would help to cope with these additional financial expenses. In order to ensure a sufficient supply of donor milk for preterm infants, public and financial support for hospitals from the national health system is necessary. Hospitals can work to help establish regulations such as flat-rate charges, or work towards integration into the DRG system.

3.4. Education and information for donors and recipient families

Providing standardised tools and templates for a variety of working documents (such as information material for interested donor and recipient families, information brochures, anamnesis questionnaires, labels and signs, storage, etc.) is a good way to support hospitals in establishing and organising a human milk bank. Ideally, relevant information material for donor and recipient families is also available in digital format and in multiple languages on the website.

If a woman indicates her interest in donating breast milk, an anamnesis questionnaire is used to ensure the donation will be safe, and the woman's written consent is obtained for voluntary donation and blood testing. In a personal meeting, the donor family is provided with information on the benefits and risks of a donation. If the woman meets the requirements for a donation, she must also be instructed on procedures for pumping, storing, and transporting donor milk. In addition, recipient families must be informed about the benefits and risks of donor milk for their child, and must provide their written consent as well.

Intercultural and ethical aspects

In addition to the informational requirements already described, cultural, religious, and individual aspects should be taken into consideration and addressed appropriately when supplying donor milk. The aspect of milk kinship, in particular, is very important to many families in Muslim and Jewish religious communities. Certain aspects of parenthood or donor milk from mothers of children who have died may also play a role. Such special considerations and requirements for the psychological and psychosocial environment demand a unique approach.

3.5. Hygiene and safety standards

High hygiene standards and standardised work processes are required to manage and process donor milk. Donors receive both oral and written information on hygiene measures to be used during pumping. The hospital's general hygiene guidelines, or specialised hygiene guidelines of the human milk bank, must be adhered to during processing. The blood of the donors is tested to minimise the risk of transmitting infections to the receiving child. According to the National Nursing Commission in Germany, the hygiene regulations used for breast milk donation should be comparable to those for blood donation.[6] At present, there are no generally recognised international guidelines for bacteriological testing or tolerated thresholds. Therefore, there is a need for the development of a guideline which addresses these values regarding the bacteria content if donor milk is used.

In addition, sources of error when handling donor milk have to be analysed regularly, and the hospitals should consider implementing a quality management system. The hazard analysis critical control point (HACCP) has proven to be an effective concept for quality assurance at neonatal intensive care units in handling human milk.[26] This concept focuses on considering hazards associated with the processing procedure based on the principles of a risk analysis and assessing the risks in order to implement appropriate measures promptly.[27]

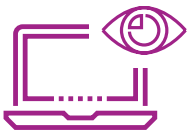
3.6. Pasteurisation

There is no uniform approach with regard to feeding pasteurised or raw donor milk. For reasons related to infectious diseases, many human milk banks only supply pasteurised donor milk. However, pasteurisation does not only kill potentially infectious bacteria and viruses but also reduces some of the immune components and antibodies which help preterm and newborn infants thrive.[28-30] When processing donor milk, it is important to find the right balance between safety against infectious disease for the recipient, and maintaining the nutritional and immunological properties of the donor milk. Apart from the frequently used method of Holder pasteurisation (slowly heating the donor milk to 62.5 °C for 30 minutes) there are also other processes such as short-time pasteurisation (heating the donor milk to 62 °C for 5-15 seconds).[31,32] This position paper underscores the importance of establishing criteria necessary for pasteurisation and related requirements through national guidelines.

3.7. Documentation and data protection

Each work step in a human milk bank must be documented based on defined standard operating procedures. The documentation can be used to ensure complete traceability throughout the different phases of breast milk donation. An electronic tracking system is preferable compared to hand-written documentation. An electronic identification number reduces sources of error and helps ensure that the breast milk donation process runs smoothly and remains anonymous.[33] In addition, information relevant to quality should be documented, easy to identify, and freely accessible to staff.

3.8. Media awareness and marketing



There is currently a trend towards the commercialisation of donor milk, in particular through online retail.[34] However, all information provided in such transactions on how donor milk is collected and stored, as well as on the health status and individual risk profile of the donor, is provided on a voluntary basis. In addition, there are no uniform standards for handling, storage, and shipping, and microbiological testing are solely the responsibility of the provider.[35,36] The existence of such an online market shows the great demand for donor milk. In order to counteract this risky trend, it is important to raise awareness of the benefits of breast milk and to promote the importance of donation in the public. The expert panel uniformly opposes the commercialisation of donor milk, which is also a trend in America, as well as the promotion of profit-oriented human milk banks, and demands for better public sensitisation of the benefits of donor milk.

4. Conclusion and outlook

Breast milk is the ideal nutrition for all newborn infants, and it is especially important for the development of preterm and ill infants. Breast milk donation is a good way to provide these benefits even to infants whose mothers are not or not yet able to provide breast milk to their own child. However, there is not enough donor milk to sufficiently supply all infants in need at the moment. The results of the requirement analysis in Germany emphasise the need to recruit more donors in order to meet future demand to the best possible extent. In addition, financial support will be needed from the public health system. Regarding the importance of breast milk for preterm infants, hospitals should also document their infection rates (such as NEC) and breastfeeding rates (such as type of nutrition at time of discharge) in order to provide a quality management tool.

The recommendations provided in this position paper are intended to raise awareness and to help hospitals through the first steps in establishing and organising a human milk bank. Furthermore, the position paper serves as an impulse for the development of a guideline for national professional societies. In addition to the position paper, the expert panel has developed a practical handbook on the establishment of human milk banks, which is available via www.efcni.org/milkbanks.

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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.

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