Making Human Milk Matter

The need for regulation in the European Union

Policy Recommendations

EFCNI european foundation for the care of newborn infants

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Foreword

The importance of human milk as a means of ensuring growth and disease prevention for newborn infants, particularly those born preterm (before 37 weeks of pregnancy), sick or with low birthweight is scientifically proven.[1] The World Health Organisation (WHO) recommends that mothers worldwide exclusively breastfeed infants for the first six months of life to achieve optimal growth, development and health.[2] It is hence widely recognised that mother's own milk is the preferred option for infant nutrition – yet especially for mothers giving birth to preterm, sick or low birthweight infants, this may be problematic. There are cases where the biological mother is unable to provide enough milk or is not allowed to breastfeed, e.g. due to medical conditions or treatment. Where mother's own milk is not available, international organisations and medical societies alike recommend donor human milk as the best alternative, especially for preterm, sick and low birthweight infants. The next, and last option, is a specifically designed infant formula.[3–5]

Donated human milk is expressed voluntarily by breastfeeding women who are not biologically related to the receiving infant and given to a human milk bank. Human milk banks are established institutions that collect, screen, store, process, and distribute this donor milk.[6] In Europe, roughly 250 human milk banks are currently operating in more than 20 countries.[7] The existence of human milk banks decreases the use of formulas during the first weeks of life. However, it does not lead to a decrease in breastfeeding rates, but act as a bridge to breastfeeding, rather than a substitute.[3,8–11]

Today, human milk banks are not regulated at the level of the EU. A common regulatory framework, however, would ensure that donor human milk's procurement, storage, processing, and distribution meet high quality and safety standards in a harmonised manner. This would ensure a minimum standard and equitable access to safe donor human milk for preterm, sick and low birthweight infants and would contribute towards better health outcomes of this highly vulnerable group of patients.

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Abbreviations

EU	European Union
EFCNI	European Foundation for the Care of Newborn Infants
EMBA	European Milk Bank Association
ESPGHAN	European Society for Paediatric Gastroenterology Hepatology and Nutrition
ESPR	European Society for Paediatric Research
HMB	Human Milk Bank
PATH	Program for Appropriate Technology in Health
UENPS	Union of European Neonatal & Perinatal Societies
UNICEF	United Nations Children's Emergency Fund
WHO	World Health Organisation

Definition of terms

Donated human milk	Human milk expressed by a lactating mother and donated voluntarily to a human milk bank (also referred to as donor milk or banked milk)
Donor human milk bank	A facility established with the purpose of screening donors, collecting, testing, processing, storing, and distributing donated human milk, which is to be used under medical prescription
Fortification	Nutrient supplement to human milk in order to provide additional calories, proteins, minerals, vitamins and trace elements (usually based on bovine milk, and sometimes on donkey milk or human milk)
Fresh human milk	Human milk which has not been frozen or pasteurised. Corresponds to "raw" or "refrigerated" milk. Often called "expressed breast milk" in the literature
Frozen human milk	Human milk stored at a temperature of at least -18°C (±2°C)
Human milk	Milk produced by human mammary glands located in the breast to feed a child
Human milk donor	Healthy woman who is nursing or pumping milk for her own child and voluntarily donates her excess of milk
Infant formula	Human milk substitutes, based on bovine milk, goat milk, or soymilk
Mother's own milk	Milk used from a breastfeeding mother to nourish her own child
Pasteurised human milk	Human milk that has undergone heat treatment at a temperature of 62.5°C for 30 minutes (holder pasteurisation) followed by a rapid cooling at a temperature below 10°C
Preterm born infant	Infant born before 37 completed weeks of gestation
Preterm human milk	Human milk from women who have delivered before the 37th week of gestation, collected within the first 4 weeks after delivery
Raw human milk	For definition see "fresh human milk"
Refrigerated human milk	Human milk stored at +4°C

Executive summary

In Europe and worldwide, preterm birth, low birthweight, asphyxia, congenital abnormalities, infections and birth trauma are the main causes of neonatal death. This paper sheds light on the special care that the extremely vulnerable category of patients – preterm, sick, and low birthweight infants – need, especially from a nutritional perspective. Mother's own milk is the preferred option for infant nutrition to achieve optimal growth, development, and health. When mother's own milk is not available, donor human milk is the next best alternative, especially for preterm, sick and low birthweight infants; the next and last option is a specifically designed infant formula.

Donated human milk is collected, processed, stored, and distributed in human milk services, often referred to as banks. There are an increasing number of these in the European Union delivering high quality work. Human milk banks are well-regulated in some European countries but unregulated in others. Today, human milk and its donation are not regulated at the level of the EU. A common regulatory framework, however, would ensure that human milk's procurement, storage, processing and distribution meet high quality and safety standards in a harmonised and safe manner. This would ensure a minimum standard and equitable access to safe donor human milk for preterm, sick, and low birthweight infants and would contribute towards better health outcomes for this highly vulnerable group of patients. In that regard, and in line with evidence-based and internationally acknowledged recommendations, a human milk diet should be promoted and a uniform regulatory framework on human milk and its donation should be adopted to this end.

In order to guarantee that the highest level of safety for preterm, sick and low birthweight infants and their nutritional needs are met and due to the rise in use of human milk banks, we request European policy makers to ensure that any revision of the Tissues and Cells Directive:

1. Recognises human milk as the best option for preterm, sick and low birthweight infants and has, at its core, the theme of ensuring a safe, secure supply for all mothers in need of milk for their infants. Mother's own milk is the first choice in infant feeding. When mother's own milk is not available, donor milk from a human milk bank is the preferred option.
2. Includes a delegated act on donor human milk to be developed in close cooperation with key stakeholders in infant care and human milk safety.
3. Ensures equitable access to safe donor human milk for preterm, sick and low birthweight infants as a key theme of the legislation and accounts for the practical specifics of human milk donation.
4. Endorses recognition, support and regulation of human milk banks in Europe.
5. Includes the need for EU-wide research and data collection of human milk donation and use.

Making sure that preterm, sick and low birthweight infant conditions and consequent needs are recognised and best care is provided, will not only relieve the pressure from the already challenged healthcare systems but more importantly – save lives and improve quality of life. Morbidity and mortality of sick and preterm infants can only be reduced if their specific medical and nutritional needs are met. Given the scientific evidence and many advantages of human milk for preterm, sick and low birthweight infants, human milk based nutrition must be considered a European public health issue and a human right for all these infants.

1. Introduction

The importance of human milk as a means of ensuring growth and disease prevention for newborn infants, particularly those born preterm (before 37 weeks of pregnancy), sick or with low birthweight is scientifically proven.[1] The World Health Organisation (WHO) recommends that mothers worldwide exclusively breastfeed infants for the first six months of life to achieve optimal growth, development and health.[2] It is hence widely recognised that mother's own milk is the preferred option for infant nutrition – yet especially for mothers giving birth to preterm, sick or low birthweight infants, this may be problematic. There are cases where the biological mother is unable to provide enough milk or is not allowed to breastfeed, e.g. due to medical conditions or treatment. When mother's own milk is not available, international organisations and medical societies alike recommend donor human milk as the best alternative, especially for preterm, sick and low birthweight infants. The next, and last option, is a specifically designed infant formula.[3–5]

Donated human milk is expressed voluntarily by breastfeeding women who are not biologically related to the receiving infant and given to a human milk bank. Human milk banks are established institutions that collect, screen, store, process, and distribute this donor milk.[6] In Europe, roughly 250 human milk banks are currently operating in more than 20 countries.[7] The existence of human milk banks decreases the use of formulas during the first weeks of life. However, it does not lead to a decrease in breastfeeding rates, but act as a bridge to breastfeeding, rather than a substitute.[3,8–11]

Today, human milk banks are not regulated at the level of the EU. A common regulatory framework, however, would ensure that donor human milk's procurement, storage, processing, and distribution meet high quality and safety standards in a harmonised manner. This would ensure a minimum standard and equitable access to safe donor human milk for preterm, sick and low birthweight infants and would contribute towards better health outcomes of this highly vulnerable group of patients.

2. Preterm and sick infants in Europe

In Europe and worldwide, preterm birth complications, low birthweight, asphyxia, congenital abnormalities, infections and birth trauma are the main causes of neonatal death.[12] Preterm birth in particular is the leading cause of death under five years of life, responsible for approximately one million deaths in 2015.[13] In 2018, the number of infants born in the European Union was 4,246 million.[14] Globally more than one in ten infants – an estimated 15 million – are born preterm[15] with an average preterm birth rate of 8.7% in Europe.[16–18] Preterm infants together with sick and low birthweight infants belong to the most vulnerable in our society and deserve the best possible care, including nutrition.

The difference between preterm and term infants

A pregnancy leads to a term infant born after 37 weeks of pregnancy (gestational age). Infants that are born before that period are considered preterm; the WHO defines the following categories:[19]

Infants born preterm have an increased risk for various complications:

Short-term[20–22]	Long-term[15]
• Respiratory problems • Cardiovascular problems • Brain damage • Gastro-intestinal problems; necrotising enterocolitis • Metabolic problems • Infections due to an underdeveloped immune system • Renal disease • Vision disease (retinopathy of prematurity)	• Cerebral palsy • Learning disabilities • Cognitive disabilities • Hearing problems • Vision problems • Growth restriction • Respiratory problems (mainly bronchopulmonary dysplasia) • Hypertension

To reduce the risk for short- and long-term complications, it is crucial that significant efforts are made to help these infants achieve healthy growth and development. These include equitable access to safe donor human milk especially for preterm, sick, and low birthweight infants.

3. Infant feeding and the importance of human milk

Human milk and breastfeeding

Breastfeeding is acknowledged as the unequalled method for feeding infants due to its associated health benefits. Human milk, a substance of human origin with a unique composition of nutrients and biological factors, has numerous benefits not only for term infants, but also for preterm, sick and low birthweight infants. Due to its composition, feeding with human milk reduces the rates of multiple morbidities associated with preterm birth, results in overall better health of the infant, supports neurological and immune system development, consequently reduces the length of hospital stay, and in terms of breastfeeding also has positive mental and physical effects for mother and child.[23–27]

The medical benefits of human milk are hence manifold. It:

- significantly decreases the rate of necrotising enterocolitis, the most serious gastrointestinal disease in the neonatal period,[1,20]
- and is associated with reductions of
  - later hypertension,[28]
  - late-onset sepsis,[29]
  - chronic lung disease/bronchopulmonary dysplasia,[30]
  - vision disease/retinopathy of prematurity,[21,22]
  - and feeding intolerance.[3,31]

Scientific evidence regarding the benefits of human milk is acknowledged by the world's leading health authorities, international bodies and policy makers, also in terms of breastfeeding.[32,33] In general, exclusive breastfeeding can be associated with a significant decrease in infant morbidity and mortality rates[27,34]. The WHO[35] and UNICEF[4], EMBA[6] and ESPGHAN[3,36] therefore strongly recommend exclusive breastfeeding – until six months of age and continuing to two years or beyond – as the optimal way of feeding infants. As a consequence, breastfeeding and human milk are the normative standards for infant feeding and nutrition. Given the documented short- and long-term medical and neurodevelopmental advantages, human milk based nutrition must be considered a public health issue and a well-recognised human right for all newborns.

Donor milk and human milk banks

If mother's own milk is not available, donated human milk is considered the next best choice, especially for preterm, sick, and low birthweight infants.[3,37,38] Scientific evidence supports the health benefits for its use in vulnerable infants, especially in decreasing rates of necrotizing enterocolitis.[37]

Donated human milk is voluntarily provided by women who are nursing or expressing milk for their own children and donate excess milk to established human milk banks.[4,24] They collect, screen, store, process, and distribute donor human milk.[6] Risks associated with improper donor human milk management and disease transmission must be reduced to an absolute minimum thus supporting the requirement for standardised procedures.

National recommendations on the establishment of human milk banks have been developed in many European countries. However, there is currently no regulation in place that promotes harmonised standards across European countries. Evidence-based recommendations are, however, available to guide the establishment and operation of human milk banks. The issues that these cover include:[6,39,40]

- structural requirements and resources,
- financing and cost management,
- organisational requirements, including
  - donor recruitment, screening and follow-up during donation period,
  - expression, handling, and storage,
  - bacteriological testing,
  - milk processing,
  - labelling and packaging,
  - preservation and storage, and
  - transport and delivery.

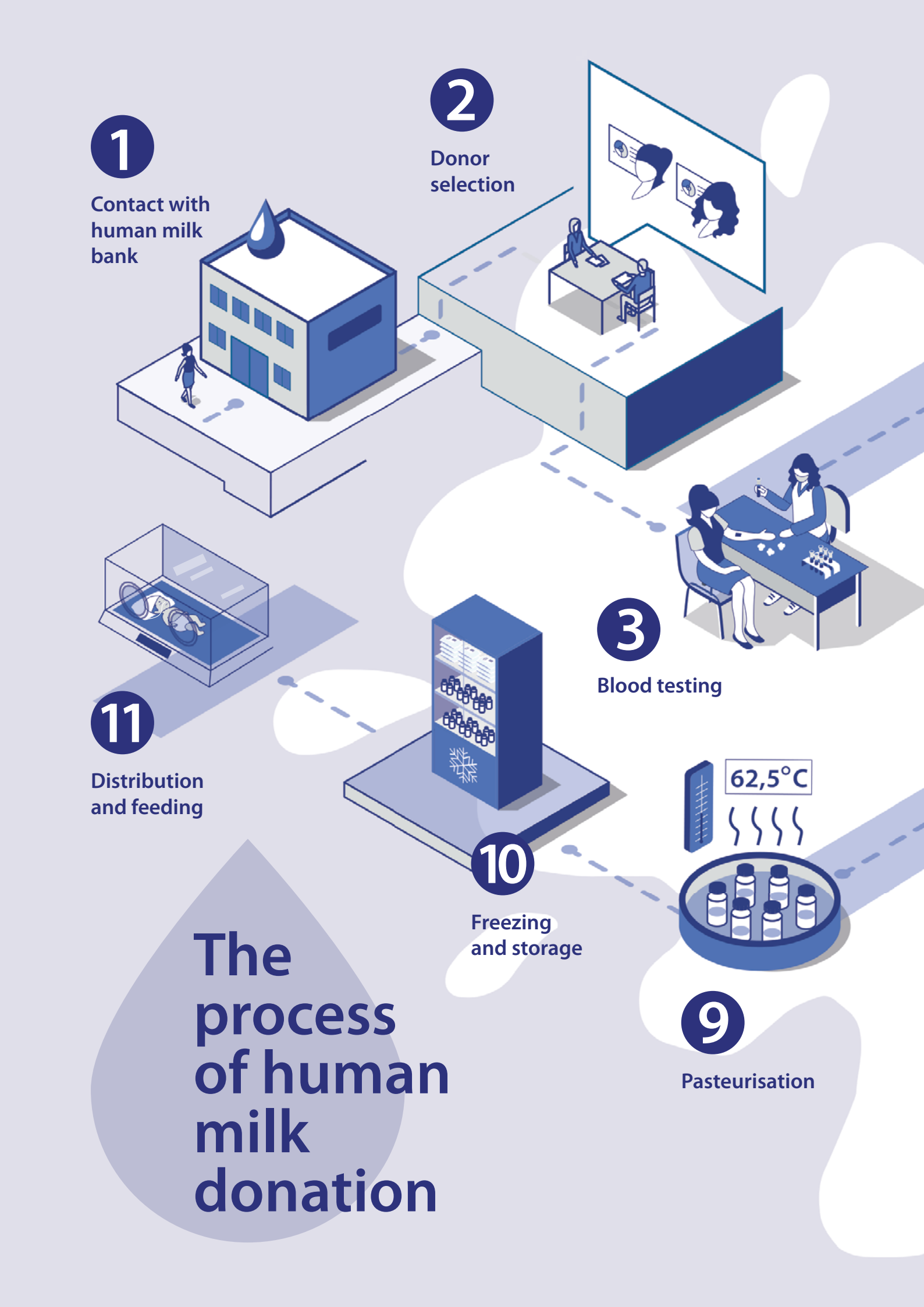
Despite the evidence, a large number of vulnerable infants are fed with cow-milk based formula when mother's own milk is not available.[33] This is partly due to lack of lactation support, but it is also due to lack of access and availability of donor human milk.

Infant formula

Infant formula is a substitute for human milk, mimicking its nutritional composition, and is industrially produced. It is based on other milk sources, such as bovine milk, goat milk or soymilk. For preterm infants, there are specifically designed cow-milk based formulas with higher nutrients content than standard infant formula. In some cases, neither mothers' own milk nor donated milk are available for feeding preterm, sick, or low birthweight infants. In these cases, infant formula is justified.[3] However, scientific evidence shows that human milk (either mother's own milk or donated milk) has many health benefits for preterm, sick and low birthweight infants in comparison to a well-designed cow-milk based infant formula, including lower incidence rates of necrotising enterocolitis (NEC), a severe multifactorial disorder of preterm born infants. This is a crucial reason why human milk should be preferred over formula to nourish this group of patients.[41]

Fortification

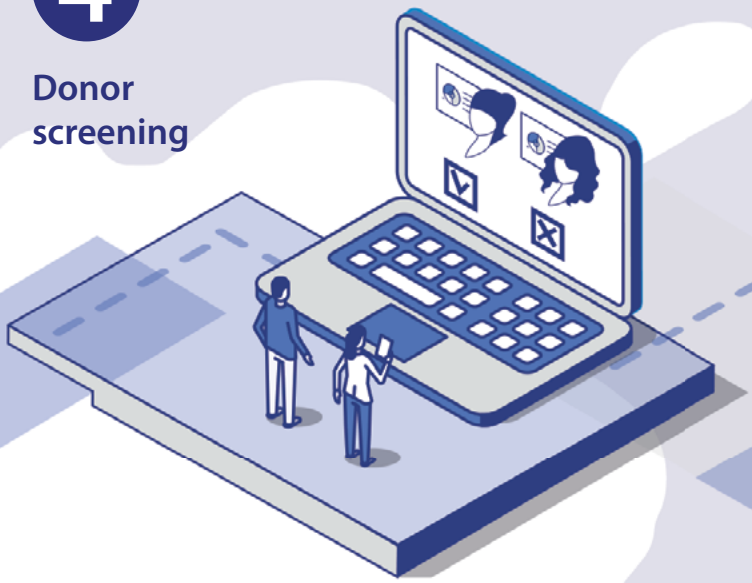
Preterm, sick and low birthweight infants have high requirements for nutrients and need additional protein and calories to support appropriate postnatal growth and development which has been associated with a risk reduction of neurocognitive impairment and other negative health outcomes (e.g. bronchopulmonary dysplasia and retinopathy of prematurity). It is therefore recommended to supplement and hence fortify human milk with nutrients (i.e. calcium, protein, minerals, vitamins and trace elements) to cover high nutritional needs of these infants.[32,33] Fortifiers are traditionally based on bovine milk. More recently, human milk fortifiers are also available in some countries and research is ongoing to define their precise role.[42] Also donkey milk based fortifiers have been recently utilized with positive results.[44]



The process of human milk donation

4

Donor screening



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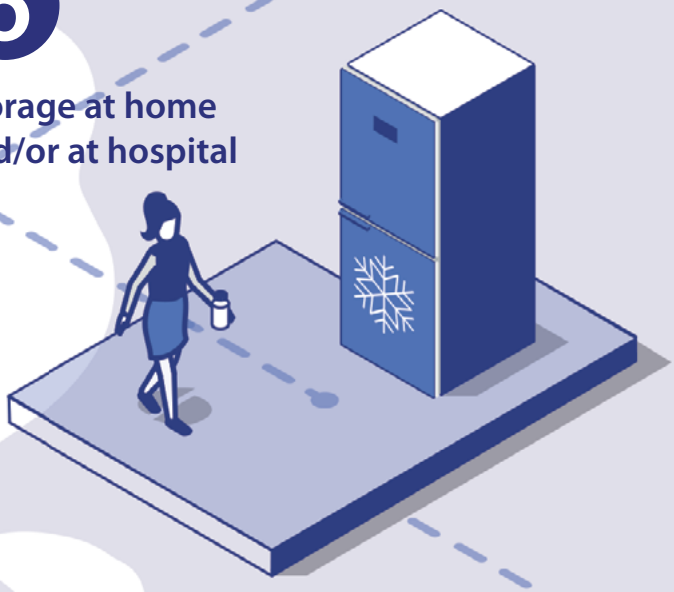
Milk expression at home and/or at hospital

6

Storage at home and/or at hospital



8

Testing quality control

7

Transportation and delivery to the human milk bank

4. Overview of international initiatives

Numerous international initiatives have addressed infant health and nutrition. These include:

1981 | International Code of Marketing of Breast-milk Substitutes[45]

The code was adopted by the World Health Assembly to avoid misinformation and unethical marketing in the field of infant feeding.

2010 | Too little, too late? Why Europe should do more for preterm infants[46]

The EU Benchmarking Report was presented in the European Parliament, provided a compelling picture of the impact on preterm birth across 14 European countries. It revealed a troubling lack of coordinated national and European policy initiatives to improve the quality of treatment and care of preterm infants.

2011 | Caring for Tomorrow – EFCNI White Paper on Maternal and Newborn Health and Aftercare Services[47]

The White Paper calls on policy-makers to support the necessary policies that will help to improve the delivery of quality care and services for mothers and their newborns. It recommends that all EU Member States encourage the use of human milk in Neonatal Intensive Care Units (NICUs).

2012 | Born too soon – The global action report on preterm birth[15]

The WHO and partners placed the issue of preterm birth to the fore of public policy. The report highlights the particular need for human milk for growth and development.

2013 | Donor Human Milk for Preterm Infants: current evidence and research directions[3]

The Committee on Nutrition of ESPGHAN documented the existing evidence of the benefits and common concerns deriving from the use of donor milk in preterm infants in its commentary.

2014 | Every Newborn: an action plan to end preventable deaths[3]

The action plan was adopted in the framework of the UN Secretary-General's global strategy for women's and children's health. It emphasises that expression and storage of human milk should be encouraged in health facilities that care for preterm, sick, and low birthweight infants, complemented by milk banks in selected referral care facilities.

2015 | Global Strategy for Women's, Children's and Adolescent's Health 2016-2030[49]

The strategy published by the Every Woman Every Child movement aims at ending all preventable maternal, newborn and child deaths, including stillbirths, by 2030. It requests extra support for feeding small and preterm babies with human milk.

2018 | European Standards of Care for Newborn Health[50]

EFCNI initiated and developed the European Standards of Care for Newborn Health – a collaboration of more than 220 health-care professionals, parent representatives, care professionals, and parent representatives from more than 34 countries. These 96 standards cover 11 areas for neonatal health and recommend the elaboration of a European comprehensive framework to improve infant health and decrease inequalities throughout Europe.

2019 | Survive and Thrive – Transforming care for every small and sick newborn[51]

The WHO together with UNICEF published the global report and pathway towards 2030. It stresses the need to transform care for every newborn to achieve the global target of health for all.

2019 | Call to action for equitable access to human milk for vulnerable infants[52]

The Oxford-PATH Human Milk Working Group published the call to action and furthermore a "Resource Toolkit for Establishing & Integrating Human Milk Bank Programs".

2020 | Maintaining safety and service provision in human milk banking: a call to action in response to the COVID-19 pandemic[53]

The Virtual Collaborative Network of Human Milk Banks and Associations highlights in its call to action the need for better protection of human milk banks against current and future emergencies.

5. Why action is necessary

Although human milk is clearly recommended as the preferred choice for infant feeding due to its undisputed benefits for infant health outcome, donated human milk is currently underutilised in many neonatal units for a variety of reasons. In the EU, these include but are not limited to legal uncertainty, lacking access, and the administrative and financial aspect in terms of setting up a human milk bank.[54] Adequate nutrition during the neonatal period is, however, vital for optimal growth, development and the overall health status of the child and later in adulthood.

Currently, human milk and its donation, as substances of human origin, are not regulated at EU level. Consequently, donor human milk services including the procurement, testing, processing, preservation, storage, and distribution have not been conducted in a harmonised manner across Member States. This has resulted in significant differences in legislation, funding, and reimbursement, including substantial differences in donation processes across and even within EU countries. Presently, donor human milk services are closely regulated by federal authorities only in France and Italy. As a result, some state-level authorities have independently started to regulate the sourcing and the use of donor human milk, while others have not. Legal uncertainties regarding the status and handling of donor human milk are, however, a hindrance for the application of a human milk based nutrition in preterm, sick and low birthweight infant care and for the adoption of evidence-based practices in Europe. Regulation at European level of donor human milk handling would improve quality of the process, but must not lead to a reduction in availability because of increases in costs and administrative workload. A facilitating role of the regulation is important to ensure access to safe donor human milk for preterm, sick and low birthweight infants.

The need for a regulatory framework

A common regulatory framework at EU level, taking into account cross-cultural variation (i.e. different healthcare systems, and breastfeeding practices), would ensure that human milk banking (procurement, storage, processing, and distribution) meets high safety and quality standards in a harmonised manner for the benefit of preterm, sick and low birthweight infants. It would furthermore allow for better coordination within and across countries to ensure a minimum quality and safety standard and equitable access to safe donor human milk.

However, considering its special nutritional and biological characteristics, human milk and donor human milk should be treated differently, taking these characteristics into account. The first formal evaluation of the EU blood and tissues and cells legislation represents a unique opportunity to fill the legislative vacuum at EU level and to explicitly extend their scope to human milk, and to ensure that the procurement, testing, processing, preservation, storage and distribution of donor human milk meet high safety and quality standards in a harmonised manner across Europe, while ensuring access by minimising costs and administrative workload.

6. Human Milk and the Directive on Tissues and Cells

In 2004, the European Parliament and Council adopted the European Tissues and Cells Directive (Directive 2004/23/EC). It defines the quality and safety standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells and of manufactured products derived from them intended for human application. Currently, the directive does not include human milk.

Upon requests and concerns raised by the competent authorities, discussions have followed around the potential inclusion of human milk in the directive. However, in the absence of an explicit reference to human milk in the text, the European Commission services interpreted it as excluding human milk from the scope of the directive.[55] This interpretation was justified on the basis that the focus on the use of human milk is not the cells contained therein.

In January 2017, the European Commission started the evaluation of the Union's legislation on blood, and tissues and cells to assess the extent to which these directives and their implementing acts have met their original objectives and whether they remain fit for purpose, given the scientific and technological advances in this area. Ever since the adoption of both directives, there has been no evaluation process, despite the considerable degree of scientific and technological progresses in this field.

Following the public consultation launched by the European Commission on 29 May 2017 to gather detailed views and opinions to feed into the evaluation process, many stakeholders (including professional societies, donor and patient organisations, national authorities and industrial associations) urged the European Commission to revise the legislation, as it was considered to be lagging behind the scientific and technological developments in this field. The European Commission is expected to revise the current legal framework to keep up with the latest scientific developments and include substances of human origin which currently are not regulated.

To this end, the directive should include a mandate for the adoption of a specific delegated act which considers the complexity of the substance and the specificities of donation, storage, processing, and distribution of donated human milk. Appropriate standards should be set, as adequate testing of donations for a comprehensive list of certain prescription and illicit drugs and a periodic requalification of human milk donors by serological testing for pathogens, or alternatively testing of each donation for evidence of viral contamination. To ensure that the nutritional and biological properties of human milk are preserved, a testing for alternatives and water dilution should be foreseen for manufactured products derived from human milk.

7. Recommendation for action – a call to European legislators

In order to guarantee that the highest level of safety for preterm, sick and low birthweight infants and their nutritional needs are met and due to the rise in use of human milk banks, we request European policy makers to ensure that any revision of the Tissues and Cells Directive:

1. Recognises human milk as the best option for preterm, sick and low birthweight infants and has, at its core, the theme of ensuring a safe, secure supply for all mothers in need of milk for their infants. Mother's own milk is the first choice in infant feeding. When mother's own milk is not available, donor milk from a human milk bank is the preferred option.
2. Includes a delegated act on donor human milk to be developed in close cooperation with key stakeholders in infant care and human milk safety.
3. Ensures equitable access to safe donor human milk for preterm, sick and low birthweight infants as a key theme of the legislation and accounts for the practical specifics of human milk donation.
4. Endorses recognition, support and regulation of human milk banks in Europe.
5. Includes the need for EU-wide research and data collection of human milk donation and use.

8. Conclusions

In Europe, preterm birth, low birthweight, asphyxia, congenital abnormalities, infections and birth trauma are the main causes of neonatal death. This paper shed light on the special care that the extremely vulnerable category of patients – preterm, sick, and low birthweight infants – need, especially from a nutritional perspective. Mother's own milk is the preferred option for infant nutrition to achieve optimal growth, development and health. When mother's own milk is not available, quality-controlled donor human milk is the next best choice. If this is not available either, specifically designed infant formula can be given.

Today, human milk and its donation are not regulated at EU level. A common and simple regulatory framework, however, would ensure that human milk's procurement, storage, processing, and distribution meet high quality and safety standards in a harmonised manner. This would ensure a minimum standard and equitable access to safe human milk for preterm, sick and low birthweight infants and would contribute towards better health outcomes of this highly vulnerable group of patients. In that regard, and in line with evidence-based and internationally acknowledged recommendations, human milk should be promoted and a simple, uniform regulatory framework on human milk and its donation should be adopted to this end.

Making sure that preterm, sick and low birthweight infant condition and consequent needs are recognised and best care is provided will not only relieve the pressure from the already challenged healthcare systems but more importantly save lives and improve quality of life. Morbidity and mortality of this vulnerable group can only be reduced if their specific medical and nutritional needs are met. Given the scientific evidence and many advantages of human milk for preterm, sick, and low birthweight infants, human milk in infant nutrition must be considered a European public health issue and a human right for all these vulnerable infants.

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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. EFCNI's vision is to ensure the best start in life for every baby.

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