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HEARTS MILK BANK



Human milk banking and the use of donor human milk; ethical considerations

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www.heartsmilkbank.org
www.humanmilkfoundation.org

Conflicts of interest



I have no conflicts of interest to declare
other than that I work in the field of
human milk banking.



Human milk bank (definition)



A human milk bank (HMB) is a service responsible for the recruitment of donor mothers and the collection, screening, processing, quality control, storage and distribution of donor human milk to meet the specific needs of infants and young children in a health establishment or community for whom donor milk is needed while protecting, promoting and supporting breastfeeding. PATH (www.path.org)

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Donor human milk (definition)



Milk expressed by a lactating mother that is then processed by a HMB for use by a recipient that is not the mother's own baby. Payment for the donated milk is not provided.

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What is human milk?



Mother's milk or breastmilk or human milk is a product of human origin.

It is of course a food – it contains complete nutrition for human babies (it may need some additives or fortification for preterm infants or those with some health conditions).



What is human milk?



It can also be considered as a medical product or therapy.

Human milk is used to prevent and to minimise the effects of diseases.

It contains anti-inflammatory components, pre and probiotics, anti infective agents and in its initial raw form, living cells.



What is human milk?



Human milk can also be classified as a tissue.

Are there similarities between milk banks and tissue banks?

Should milk banks be regulated as tissue banks?



European Directorate for the Quality of Medicines and Health



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Guide to the quality and safety of tissues and
cells for human application

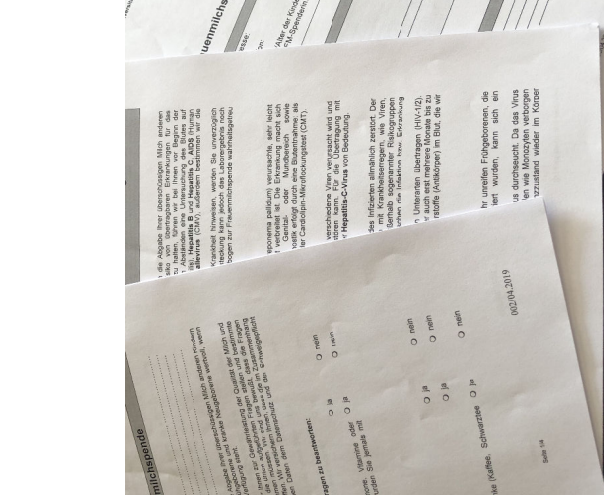
2019 edition – soon to be published

Chapter on Human Milk

[https://www.edqm.eu/en/publications-transfusion-and-
transplantation](https://www.edqm.eu/en/publications-transfusion-and-transplantation)



Human Milk Banking includes:



The recruitment and screening of breastmilk donors



The testing and processing of the human milk



The provision of the milk to recipients (usually in hospital)



Core ethical values



There are three core ethical values that are enshrined in the Code of Ethics for Blood Donation and Transfusion developed by the International Society of Blood Transfusion (ISBT)¹.

- **Respect**
- **Beneficence**
- **Justice**

Should these underpin human milk banking and the use of donor human milk?

1. Code of Ethics for Blood Donation and Transfusion - International Society of Blood Transfusion [http://www.isbtweb.org/fileadmin/user_upload/ About ISBT/ISBT Code of Ethics English.pdf](http://www.isbtweb.org/fileadmin/user_upload/About_ISBT/ISBT_Code_of_Ethics_English.pdf)



Respect:



Individuals should be able to make their own decisions regarding their bodies.

We should consider the privacy, confidentiality and cultural sensitivities of donors and their families and communities when recruiting donors and providing donor milk.

Beneficence



The principle of beneficence means we should always avoid or minimise harm.

Our ethical practices should enable us to develop milk banks that always demonstrate duties of care for donors and their babies and recipients and their families alike.

Justice



Justice is concerned with equality and fairness

This equality should extend to opportunities for donation as well as fairness in the allocation of the milk



Bereaved mothers

“As a bereaved mother I would have liked the opportunity to donate milk whilst I came to terms with my loss. Simply letting my milk dry up was far too traumatic and if I knew I could help other babies it would have helped me grieve.”



“Expressing milk for the babies was the only reason I got out of bed each day”.

Another 10 principles



The Principles on the donation and management of blood, blood components and other medical products of human origin were presented at the 70th World Health Assembly, on April 2017, and result from extensive consultations held within member states, professional associations, collaborating centres, civil society members active in the field.

Ethical considerations



- the advantages and disadvantages of altruistic versus financially compensated provision of human milk – should milk banks pay for the milk?
- balancing the rights and needs of vulnerable infants against the rights of the suppliers of milk and of their infants
- equity of provision of donor milk, its practical allocation and accessibility
- broadening access to donor human milk whilst determining prioritisation and duration of access and optimising protection for donors and their own infants
- balancing safety and quality of donor human milk against barriers to its access, including financial barriers
- the acceptability or otherwise of the current lack of international ethical and legal governance of human milk banking processes

When is a donor not a donor?



The advantages and disadvantages of altruistic versus financially compensated provision of human milk – should milk banks pay for the milk?



Benefits of payment for the milk



- 1) Lack of exploitation of the milk providers whose time and energy and own financial resources have been used to make, to express, store and transport the milk and to undergo the donor recruitment and screening?
- 2) May get more mothers willing to provide milk
- 3) May get more milk

However, this comes at a cost to the milk bank – including the staff time involved in handling the payments. These costs will usually be passed on to the recipient hospitals etc



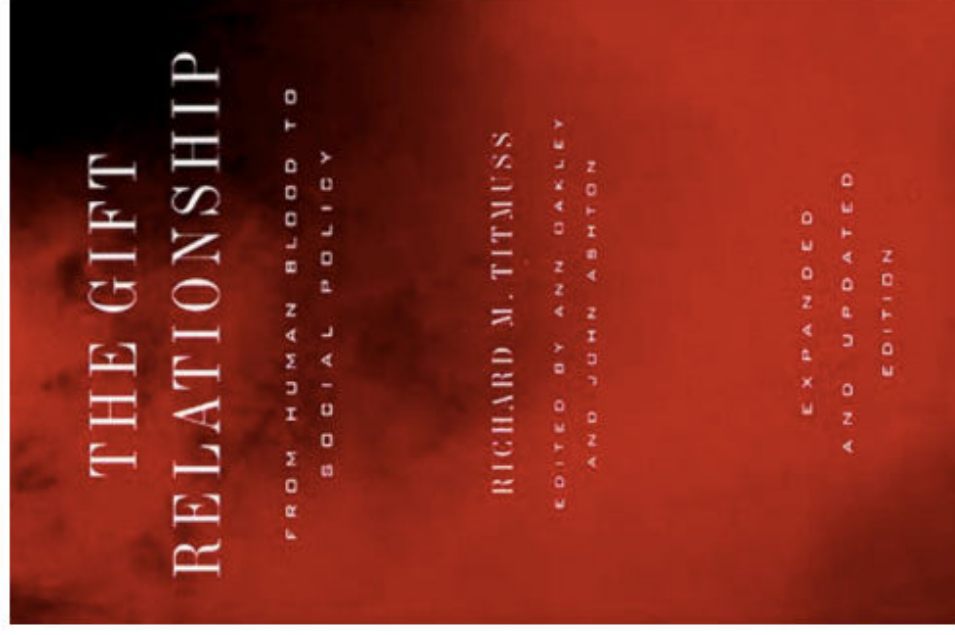
Are there risks associated with paying for milk?



Do payments lead to increased instances of mothers being induced to:

- over produce milk?
- give more milk than is optimal for them?
- give more milk than is optimal for their baby/ies health?
- provide milk that is more likely to be contaminated?
- provide milk that is more likely to be diluted with water/cow's milk etc? (additional testing required?)
- Provide milk that is sub optimal in other ways?

The Gift Relationship



From human blood to social policy:

A comparison of the safety and availability of blood provided altruistically and via payment systems.

Chapter on human milk:
The milk of human kindness

What is a donor?



The term 'milk donor' suggests that there is no payment or other recompense for the milk

Could non-payment or minimal payment be exploitation of the milk provider or be seen as giving unfair advantage to those who can afford to donate?

What about paying expenses?



What about covering expenses?

Mothers should not be disadvantaged as a result of giving their milk – should they be expected to pay:

- To transport the milk to the milk bank?
- To park at the hospital?
- For train and bus fares?
- For containers if providing their own?
- For electricity?
- Pump hire or purchase?

Balancing rights



It is important to balance the rights and needs of vulnerable infants against the rights and needs of the suppliers of milk and of their infants



Viet Nam's first human milk bank opens in Da Nang

DA NANG Today
Published: February 20, 2017

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Viet Nam's first human milk bank was recently opened at the Da Nang Maternity and Paediatrics Hospital.



Mr. Roger Mathisen, the Programme Director for Alive & Thrive in Southeast Asia, (left) with a mother and her newborn baby

Equity of access



Equity of provision of donor milk to preterm, sick and vulnerable infants; does it exist, how best to ensure its practical allocation and accessibility

Few countries provide complete equity of access to donor milk – the larger the country and its population the more complex such provision becomes.

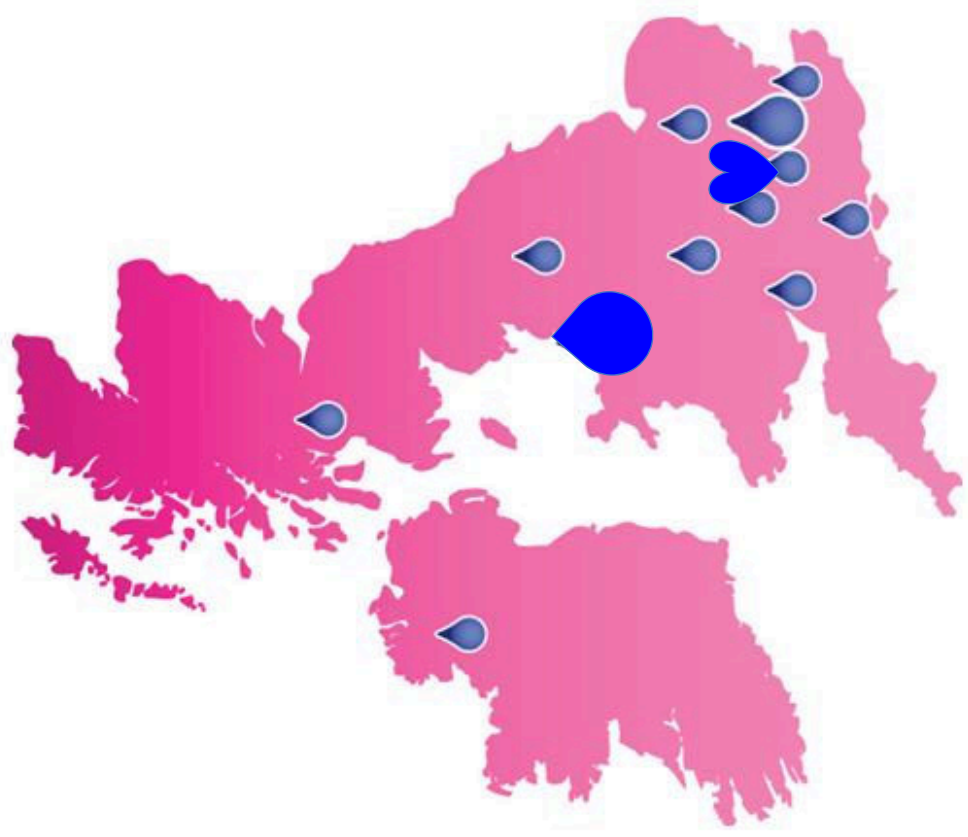
Equity of access should be the universal goal



An example of variation in equity of access



- Scotland – 1 Nationwide Milk Bank
- Northern Ireland – 1 Regional Milk Bank
- England – 14 milk banks (including new independent milk bank), no national or regional services
- Wales – 0 milk banks



Increasing access to donor human milk – the HMF’s work



Broadening access to donor human milk whilst determining
prioritisation criteria and duration of access and optimizing
protection for donors and their own infants



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Our vision

The Human Milk Foundation is working to help more families feed their babies with human milk. We provide screened donor milk to sick, premature babies in NICUs, and to mothers with cancer and other conditions. Please support our work - every pound really does make a difference.



Barriers to accessibility



Balancing safety and quality of donor human milk against barriers to its access, including financial barriers

If we introduce too many safety and quality controls we can increase costs beyond what will be accepted or affordable

If we make human milk banking too costly or introduce unattainable standards we may close down milk banks.

Or prevent them from opening.



International considerations



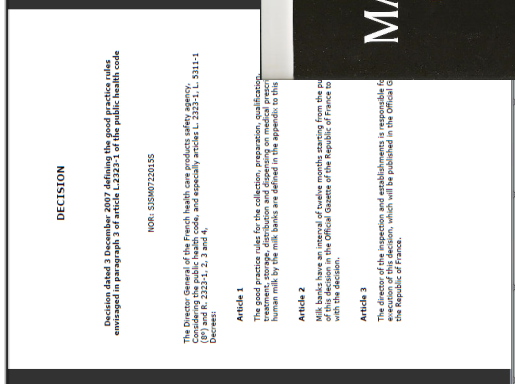
Is the current lack of international ethical and legal governance of human milk banking processes acceptable? How best to change it?

Globally there are approximately 600 human milk banks in 60+ countries



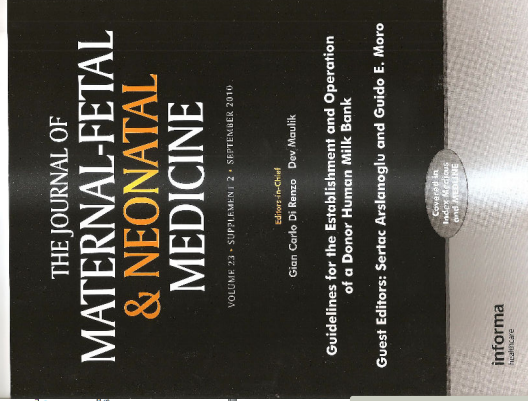
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National guidelines



France

Philippines
South Africa
Brazil



Italy

Early Hum Dev. 2007

Best practice guidelines for the operation of a donor human milk bank in an Australian NICU.
Hartmann BT1, Pang WW, Keil AD, Hartmann PE, Simmer K



UK



North America

Commercialisation of human milk



Inappropriate financial gains should be avoided



Q: When is donor milk not donor milk?



A: When the mother is paid for her milk?

donor milk made simple

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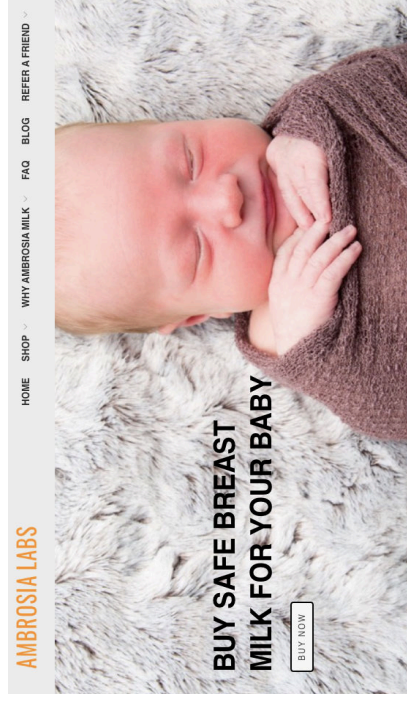
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Growing commercialisation of human milk



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Another 10 principles



The Principles on the donation and management of blood, blood components and other medical products of human origin were presented at the 70th World Health Assembly, on April 2017, and result from extensive consultations held within member states, professional associations, collaborating centers, civil society members active in the field.

The following 10 slides provide a taste of these principles together with questions for discussion about how they apply to or may be practiced by human milk banks.



Principle 1: Regulations



Governments are responsible for ensuring the ethical and effective procurement, distribution and use of medical products of human origin. This responsibility includes the obligation to develop and enforce regulations to ensure the maximum possible level of efficacy, both within and across national borders.

Question: Should all countries have national regulations for human milk banks? Are there milk bank regulations in place in Germany?

Principle 2: Equity (donation)



Equity in donation should be promoted by engaging all segments of society in efforts to meet the need for medical products of human origin.

Question: Are there examples locally or nationally where mothers are not automatically informed about the possibility of donating their surplus breastmilk?

Principle 3: Clinical use



Outside clinical research and for the advancement of science, medical products of human origin should be used only in situations of clinical utility and in the absence of alternative and affordable therapies with a comparable or more favourable balance of risks and benefits.

Question: How would this apply to donor human milk?

Principle 4: Consent



Biological materials from living persons for use as medical products of human origin should be taken only with the donor's prior informed and voluntary consent.

Question: Have you ever been aware of any instances where human milk was taken and used without prior informed and voluntary consent?

Principle 5: Financial neutrality



Policies governing compensation to persons who provide biological materials for use as medical products of human origin should seek to guard against the exploitation of vulnerable individuals and promote equity in donation. The best way to achieve these goals is to adhere to a policy of financial neutrality, in which persons who donate their biological materials for use as medical products of human origin should neither benefit nor lose financially as a result of the donation. Countries should ensure that the burden of donating these materials does not fall primarily on economically disadvantaged groups.

Question? What measures can human milk banks take to ensure or facilitate financial neutrality?

Principle 6: Donor protection



Prospective and actual donors of human biological materials for use in medical products should be protected against physical and psychosocial risks to the fullest extent possible.

Question: Are there any physical or psychosocial risks involved in the donation of human milk?



Principle 7: Origin of product



Depending on the product, and in addition to other information routinely provided when offering medical products of human origin to prospective recipients, the human origin of the product should be disclosed without compromising the confidentiality of the donor's identity.

Question: What measures are undertaken by milk banks to ensure confidentiality?

Principle 8: Equity (access)



Equity in access to the benefits of medical products of human origin should be promoted by sustained efforts to remove barriers to access. Any waiting lists and allocation systems that are developed for medical products of human origin should be based on clinical criteria and ethical norms, not considerations of financial or social status.

Question? What are the main barriers to equity of access to donor human milk? How could these best be removed?

Principle 9: Traceability



In order to minimize the risk of harm to donors and recipients and to protect the stability and sustainability of services for medical products of human origin, all steps in the development and use of medical products of human origin should be fully traceable and subject to effective quality-management systems and vigilance and surveillance programmes.

Question: Is full traceability ever tested in your milk bank / usual donor milk provider by mock recall of donor human milk or by other systems tests?

Principle 10: Transparency



The organization and delivery of activities related to medical products of human origin, as well as their clinical results, must be transparent and open to scrutiny, while ensuring that the confidentiality of donors and recipients is always protected and adheres to national laws.

Question: How can transparency be facilitated by the milk bank management team?