INAC 2017

Milk banking worldwide

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Background



- Breast milk supports the development of the newborn's immature immune and digestive system, and provides components that support anti-infective defenses : ↓ child mortality.
- Not all neonates are able to breastfeed: very pre-term infants
- → Most vulnerable infants are at greatest risk of not receiving breast milk!

Therefore, it is recommended

- (1) Own mother's milk
- (2) Donor human milk from a HMB

(3) Preterm formula

(Term formula and extensively hydrolyzed formula)

Specific health benefits for preterm infants

Donor Human milk (DHM) and practice changes

In the last decade, the use of DHM

has become the standard of care for VLBW (<1500 g) infants when MOM is not available.

DHM banks have been established throughout the world

Haiden et al. 2016

Countries with milk canks	Number of milk banks established	Number of milk banks planned
Europe 25 countries	206	14
India China Kuwait Philippines Malaysia Singapore Vietnam Taiwan Thailand Iran	22 12 1 6 - - 1 1	Many ? - ? 1 1 1 (about to open)
Australia Australia New Zealand	4	1
Africa ^a Others Cape Verde South Africa Cameroon	3 1 approx. 60 6	?
JSA and Canada	26	?
outh America 9 countries	258	?
Central America includ Mexico Others	ling Caribbean islands 17 28	?: ?:

Milk bank

A non-profit structure organized for

- ✓ Recruitment and screening of breast milk donors,
- ✓ Collection of donated human milk,
- ✓ Pasteurization human milk & storage human milk
- ✓ Bacteriological screening
- ✓ Distribution the human milk.
- ✓ Promotion/support breastfeeding in preterm infants

Donors

Mothers, screened for health problems, giving their extra-milk for vulnerable hospitalized babies, under medical prescription.

Altruistic and generous act based on the comprehension of benefits of human milk for preterm

Not mothers who give (or sell) their extra-milk to mothers who delivered a well-being term baby or to companies which sell HM-based products.

Milk banks

are the most institutionalized method

of milk sharing,

and probably the safest,

but different countries run them very differently.

Brazilian model

Since the 1930s

The largest network of breast milk donors in the world

217 milk banks, and 126 milk collection points

Regulated by public health law that stipulates

all the steps required to operate a bank

- ✓ Collection, testing, pasteurization, and distribution of milk.
- ✓ Training programs for community peer counselors who promote and support breastfeeding

No payment for donations

FIOCRUZ statistics 2016

Collected (L) Distributed (L) Donors (n) Receivers (n)

183.025 L 135.397 L 171.967 166.062



Brazilian model

Centrally organized system, well integrated into the country's public health system

✓ At least 1 bank in each of the 26 states

A reference bank per state



- continuous monitoring of the whole system
- ✓ An online portal (RedeBLH)
 - → data collection
 - → information for the public and the government
- **✓** FIOCRUZ Institute
 - → newsletter, research, undergraduate and graduate programs on policy and applied methodologies for milk banking



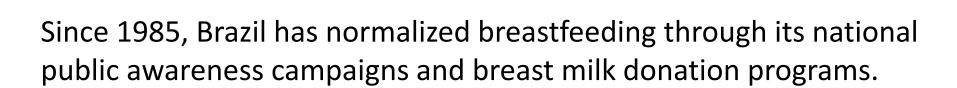
National Day of

Human Milk Donation

Brazilian model

Donated milk is used for infants

- whose mothers are sick or unable to breastfeed
- ✓ in neonatal intensive care units



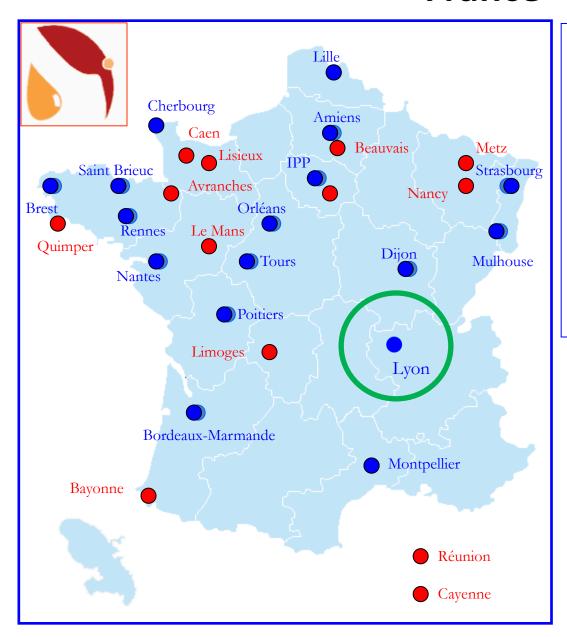
Since 1985, ↓ Brazil's infant mortality rate by more than two-thirds 63 → 20 deaths per 1,000 births.



European model



France



36 HM banks

- 17 HM banks Int & Ext
- 19 HM banks Int

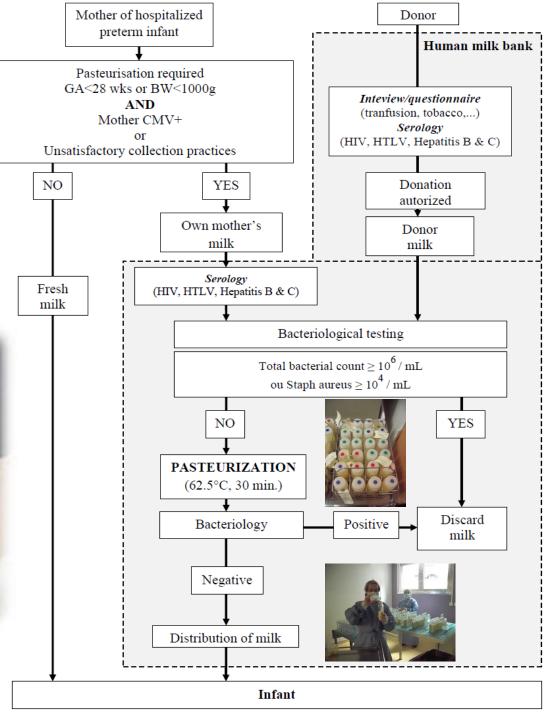
Donor HM OMM

76,818 L collected in 2016

http://www.human-milk-bank-french-association.fr

Human milk banks integrated in the newborn care to support feeding of preterm infant with human milk





Human milk banks in Europe

Same objective: provide safe, high-quality donor milk, high-performing HMB, with **high-level quality assurance and tracking** are required.

Universal common core practices are required, but there are not yet enough evidence for each practice, which leaves the field open to heterogeneity.

More and more work is done in HMB associations to elaborate consensus statements based on evidence, otherwise on

<u>avnarianca</u>

- ✓ France (AFSSAPS 2008)
- ✓ United Kingdom (UKAMB 2010)
- ✓ Italy (Arslanoglu 2010)
- ✓ Switzerland (Frischknecht 2010)
- ✓ Norway (Grøvslien 2009)
- ✓ Sweden (Milknet 2011)





• South Africa (HMBSA 2011)



North-America (HMBNA 2013)



See G Weaver

Norvegian model



No systematic pasteurization of donated milk Possible and reasonable because

- The demand can be met due to very high breastfeeding rates, even with extremely strict donor screening
- Perfect tracing of milk from donor to consumer.
- Small population (4.5 million), high standard of living (frequent retesting), very low HIV and hepatitis rates
- Extremely rigorous and regularly repeated testing of donors.

Every 3 months: HIV, Hep. B&C, HTLV 1 &2

Pasteurization of HM for ELBW in one bank to prevent CMV- transmission (40-50% of lactating women)

Pasteurization of samples (10%) containing pathogens (staph. aureus, klebsiella-, enterobacter- and serratia-species or E. coli) or high bacterial counts (≥10⁵ cfu/mL)

Norvegian model



Unlike in most countries, Norway ensures that mothers don't face economic burdens from donating their milk.

In Oslo, the bank at Rikshospitalet University Hospital pays donors about 20 USD per liter (57 cts/oz) to cover expenses (parking fees, ...) and offers the use of hospital-grade pumps.

All infants who may need donated milk are provided it free of charge.

Development of HM banks

Russia

First donor human milk bank opened in the Scientific Centre of Children's Health in Moscow, in 2014.

Lithuania

First donor human milk bank opened in the Lithuanian University of Health Sciences Kaunas Clinics, in November 2016



Asia

India

5 million babies annually.22 human milk banksIncreasing access to donor human milkbut not adequate to meet the massive needs



Taiwan

First milk bank opened in 2005

Chang et al. Characteristics of the First Human Milk Bank in Taiwan.

Pediatr Neonat 2013

Japan

Raw milk for preter infants

Only one experimental human milk bank in Tokyo

Japanese Human Milk Banking Association in May 2017.





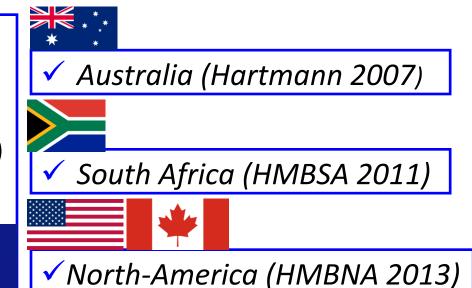
Human milk banks worldwide: practices

To provide safe, high-quality donor milk, high-performing HMB, with high-level quality assurance and tracking are required.

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In many countries, milk banking is still quite limited due to

a lack of political will

 A lack of confidence in the health system in populations with high rates of infectious disease

Cultural and/or religious concerns

Milk Kinship and matrimonial prohibition

Religious and **cultural** importance of breastfeeding in Muslim countries.

 Islam attaches legal importance of breastfeeding as a means of establishing a kinship ("milk kinship"), which prevents marriage between individuals.

The legal theory of milk kinship finds its roots in the Qur'an $(An-Nis\bar{a}'23)$: "Prohibited to you (for marriage) are your milk mothers who nursed you and your sisters through nursing" (Qur'an: An-Nisā' 23)

 In Christianity, breastfeeding also creates milk siblingship in some cultural settings: Coptes egypt (culture>religion)

In Malaysia, religious leaders prefer to call it 'milk sharing', transpiring more the human touch and human values than the term 'bank'.

Few proposals:

- Limit the donor should be limited to a very strict minimum (preferably only one donor per child)
- No mixing of donor's milk
- Adequate labeling of all samples (full identification of the donor)
- Disclosure of the identity of the donor to the recipient's family
- Identity of the donors attached to the child's birth certificate
- Mothers should try to get their own milk production started as soon as possible, to limit the number of donors.
- If some donor mother have only (or mainly) children of one sex, the milk could be preferably reserved for recipients of the same sex.

REVIEW ARTICLE

Acta Paediatrica 2016

Milk kinship is not an obstacle to using donor human milk to feed preterm infants in Muslim countries

Aliaa Khalil^{1,2,3}, Rachel Buffin^{1,2}, Damien Sanlaville^{4,5}, Jean-Charles Picaud (jean-charles.picaud@chu-lyon.fr)^{1,2,5}

Table 1 Practical suggestions for successfully establishing human milk banks in Muslim communities

- All the donor human milk received by the bank should undergo a pasteurisation process.
- The indications for donor human milk should be restricted to high-risk newborn infants who would benefit the most from human milk, for example preterm infants with a birth weight below 2000 g.
- A single-donor policy could be associated with a very well-organised, traceable system to ensure that the donor and the recipient know each other.
- When the policy is to use multiple donors, the milk from at least three donors should be mixed, which requires a sufficient number of donors as well as a well-organised human milk bank.

Other suggestions:

- Milk banks should perform systematic lyophilisation of donor human milk, but this is expensive and complex.
- They should also provide a maximum of five feedings sessions with milk from the same donor, but this may not be practical.

Donor human milk for Muslim infants in the UK Arch Dis Child F & N 2016

T C Williams, ¹ M Z Butt, ² S M Mohinuddin, ^{3,4} A L Ogilvy-Stuart, ⁵ M Clarke, ⁶ G A Weaver, ⁷ M S Shafi²

Roundtable discussion between

- ✓ Representatives of the patients: Muslim Council of Britain
- ✓ Clinicians: British Association of Perinatal Medicine
- ✓ The religious community: Muslim chaplains
- Providers of DHM: UK Association for Milk Banking
- ✓ An expert in Islamic Bioethics (MC)
- → Need for a robust system to ensure the traceability of donated milk.
 - → Milk Bank able to give a binary answer (yes/no) (maintain anonymity of other donors), when a potential bride or groom had received DHM as an infant

Cultural and religious complexities around donor milk

In Turkey, recent survey of Turkish women (Gürol 2014)

- √ 90% never previously heard of the concept of breast milk banking,
- √ 36% had problems of a religious nature with the idea
- ✓ 29% think it would lead to social and moral problems
- → Alternative milk banking model compatible with Islamic beliefs was set up in 2013, but still awaits final legal approval from the Ministry of Health. Details of the donation recorded electronically.

Creating religiously compliant milk banks in the Muslim world: a commentary Alnakshabandi et al Paediatr Intern Child Health 2015 (Saudi Arabia)

Conditional Identified Milk Banking System (CIMBS)

- ✓ Both the donor's and recipient's identities are accessible to all parties through a voluntary registry
- ✓ The milk-pooling is limited to three milk donors.

A survey suggest that there could be receptivity among practicing Muslims and religious leaders to this alternative approach

Breastmilk: a valuable product

In Brazil, prior to 1985, breast milk was bought and sold, incentivizing impoverished mothers to sell excess amounts of breast milk, often to the point at which they were unable to provide for their own infants!

Nowadays, it is still a "highly sought-after material" for some persons

Milk from other mothers from the same country or around

Aim: Milk sharing (term infants from mothers lacking milk)

Risks: Contamination with micro-organisms, or cow milk

Milk collected in underprivileged areas where selling milk represents a significant income for mothers

Aim: To make human milk-based products (fortifiers, ...)

Risks: Inability to provide for their own infants

Increased infant's mortality and morbidity

Microbial contamination of human milk purchased via the internet. Keim SA, et al. *Pediatrics* 2013

74% positive for Gram negative bacteria 21% positive for cytomegalovirus

→ severe sepsis, NEC

Cow's milk contamination of human milk purchased via the internet. Keim SA, et al. *Pediatrics* 2015

10% of Internet samples,

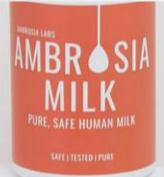
→ milk allergies and intolerances

Retrospective review of serological testing of potential human milk donors. Cohen RS, et al. *Arch Dis Child F&N* 2010

3.3% screened positive for various sexually transmitted diseases (HIV, hepatitis B or C, papillomavirus, ...)

→ A Call for FDA Regulation of Human Milk Sharing. Eisenhauer L. J Hum Lact 2016









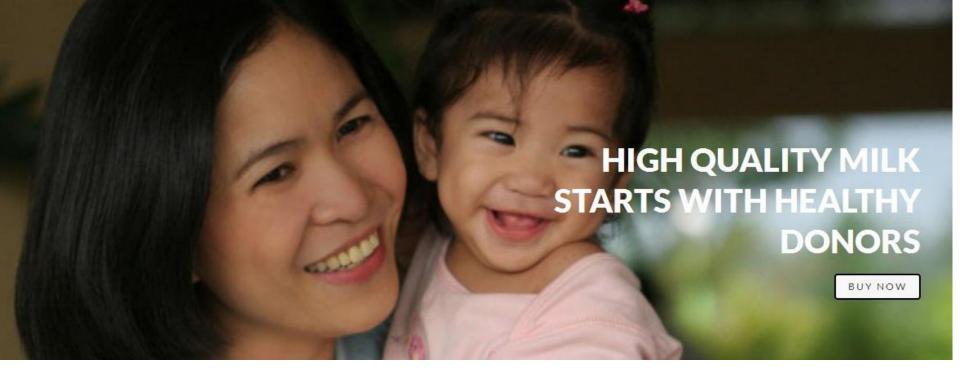


BUYNOW









Our Donors

At Ambrosia Milk we are focused on mothers and babies on both the donating and receiving ends of the equation. Our donors are healthy mothers around the world with excess milk and infants at least six months old. They come to our centers to donate with the help of our carefully trained staff.

To make sure our donors and their children stay healthy, we provide them with medical check-ups and blood tests. In addition to the health benefits we provide our donors, we are committed to empowering them for the long term.

Breastfeeding is hard work and women should have the option to be recognized financially for the valuable milk that they can provide.

Cambodia bans export of human breast milk after US operation raises concern (March 22, 2017)

Cambodia halted breast milk exports by the Utah-based Ambrosia Labs, a company that source the product from overseas and distribute it in USA. Unicef (UN) welcomed the ban, saying the trade was exploitative and that excess breast milk should theguardian



Women often had no other choices and were turning to the controversial trade to boost meagre incomes in one of south-east Asia's poorest countries.

remain in Cambodia, where many babies lack proper nutrition.

The milk was pumped by poor Cambodian women in Phnom Penh, and then shipped to the US, where it was pasteurised and sold for \$20 per 5oz (147ml) pack (= \$136/L, Note: France: legal price \$91/L)

CONCLUSION



There are important differences that need to be taken into account to enable milk banking to work in different countries.

Some of these differences are already known

In many places, reliable information is lacking "as much as donor milk"

Need for surveys to learn from women and doctors how to improve existing systems.

Part of a global supportive breastfeeding policy (political will, cultural acceptance)

CONCLUSION



Human milk banks can contribute to develop

- an integrated system for providing optimal newborn care, together with
 - ✓ kangaroo mother care (skin-to-skin contact),
 - ✓ rooming-in,
 - ✓ respect of the WHO/UNICEF Ten Steps to Successful Breastfeeding expanded in 2011 for use in NICUs (Nyqvist 2013).
- a strategy aiming to provide human milk to most of preterm babies together with
 - √ hospital-based lactation program
 - √ "HM management centers" (Spatz 2014) or "Mother's own milk bank" (Hurst 1998) to provide preterm infants with own mother's milk
 - ✓ mother/baby centers for donor milk donation and lactation support as proposed in Brazil (Rea 1990)

Human milk banks and breastfeeding rates

The presence of a HMB or implementation of donor milk policy improves:

- ✓ Exposure to HM during hospitalization VLBW in 1 NICU (Hartford, USA) (Marinelli 2014)
- ✓ Breastfeeding rates at discharge from NICU
- Arslanoglu 2013: VLBW in 83 Italian NICUs
 Exclusive BF 16% in NICUs without HMB
 Vs 31% in NICUs with HMB
- Parker 2016: BW ≤1500 g in level 3 NICU (Boston)
 MOM at discharge 43% before DM program
 Vs 65% after implementation of DM program

