

# Donor Human Milk Banking in Australia- Issues and Background Paper

---

Online ISBN: 978-1-74186-127-3  
Publications approval number: 10788

Copyright Statements:

## **Internet sites**

© Commonwealth of Australia 2014

This work is copyright. You may download, display, print and reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given the specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the Communication Branch, Department of Health, GPO Box 9848, Canberra ACT 2601, or via e-mail to [copyright@health.gov.au](mailto:copyright@health.gov.au).

# Donor Human Milk Banking in Australia - Issues and Background Paper

## Purpose

This paper describes human milk banking in Australia, and current international and Australian approaches to managing milk banks. It has been prepared in response to an action area of the *Australian National Breastfeeding Strategy 2010-2015*. It examines the evidence on the benefits, risks and costs associated with milk banking; and considerations around the role of governments in this emerging sector.

The Australian Government Department of Health has prepared this paper based on earlier inputs from the Breastfeeding Jurisdictional Senior Officials Group (BJOG), milk bank experts nominated by BJOG, the Therapeutic Goods Administration (TGA) and Food Standards Australia New Zealand (FSANZ).

## What is a human milk bank?

The definition of a ‘donor human milk bank’ for the purposes of this paper is:

*an organisation that collects, stores, processes (to exclude the risk of viral and bacterial transmission) and dispenses donated human milk. This donor milk is excess human milk provided by a mother for use by a recipient that is not the mother’s own baby. This recipient is a hospitalised preterm or ill infant. The human milk is donated on a voluntary, nonremunerated basis and should only be provided based on the clinical need of the recipient. Donor human milk is an alternative to infant formula for special needs infants, not a substitute for the mother’s own milk.*

This definition excludes storing and feeding a mother’s own milk for her own infant (which is already a common practice in Australian hospitals and the community). It recognises the ethical and safety issues associated with paid donations and that milk banks have a responsibility to ensure donor milk does not create a disincentive for mothers to breastfeed or express for their own infants.

This definition does not include informal human milk donation and sharing which is generally a private arrangement between individuals that occurs outside of a clinical setting and supervision.

All existing Australian milk banks pasteurise (heat treat) the donor milk to destroy bacteria and viruses. The product is then described as *pasteurised donor human milk* or PDHM.

In this paper ‘human milk banking’ refers to the practice of providing PDHM to hospitalised preterm infants where there is evidence from the scientific and medical literature that there is clinical benefit in providing PDHM as an alternative to infant formula.

## International context

Internationally, formal milk banking began in 1909 in Vienna (Weaver & Williams 1997). The World Health Organization (WHO) regards human milk banks as one of several alternatives that may be resorted to when a mother’s milk is not available:

*“The vast majority of mothers can and should breastfeed, just as the vast majority of infants can and should be breastfed. Only under exceptional circumstances can a mother’s milk be considered unsuitable for her infant. For those few health situations where infants cannot, or should not, be breastfed, the choice of the best alternative – expressed breast milk from an infant’s own mother, breast milk from a healthy wet-nurse or a human-milk bank, or a breast-milk substitute fed with a cup, which is a safer method than a feeding bottle and teat – depends on individual circumstances.” (WHO & UNICEF 2003, p. 10)*

---

Human milk banking was prevalent in many countries including Australia until the 1980s when the practice was discontinued due to concerns that breast milk could spread blood borne viruses such as HIV (Lording 2006). The development of new protocols for screening and pasteurising human milk has enabled milk banking to rebuild.

The growing numbers of milk banks internationally include:

- 203 active milk banks in Europe including 36 in France, 27 in Sweden, 30 in Italy, 17 in the United Kingdom, 12 in Norway (EMBA 2013);
- 13 milk banks in the Human Milk Banking Association of North America (15 in USA and 2 in Canada) (HMBANA 2013); and
- around 200 milk banks in Brazil.

There are also media reports of new milk banks being recently established in South America, Africa, India, China, and the Philippines.

### **Re-emergence of Milk Banks in Australia**

Informal sharing of human milk in Australian maternity wards has been documented since at least the 1940s (Thorley 2001) 36. An organised human milk bank with formal protocols was operating at the Townsville General Hospital in the 1970s (Beal et al 1978).

Human milk banking was re-established in Australia in 2006 with the opening of the PREM Bank (Perron Rotary Express Milk Bank) in Perth. This has led to renewed clinical and community interest in the use of PDHM and there are now five milk banks operating in Australia:

- PREM bank (based at King Edward Memorial Hospital, WA and also supplying Princess Margaret Hospital);
- Royal Prince Alfred (RPA) Hospital neonatal intensive care unit (NSW);
- Mothers Milk Bank Pty Ltd (a private charity, previously located on the Gold Coast, now at Tweed Heads NSW and supplying the Brisbane Mater Children's Hospital as well as some babies in the community);
- Mercy Health Breastmilk Bank (commenced 2011 at Mercy Hospital for Women, Heidelberg VIC); and
- Royal Brisbane and Women's Hospital (RBWH) Milk bank (commenced November 2012 at the RBWH Grantley Stable Neonatal Unit).

Tasmania, South Australia, Australian Capital Territory and Northern Territory health departments advised that they have no milk banks planned.

The scope of the services varies, however they generally provide for hospitalised preterm (less than 30-34 weeks gestation), and sick and high risk infants, such as those at high risk for or diagnosed with necrotising enterocolitis (NEC) or post-surgery for NEC. Set up and equipment costs are sourced from charitable donations, with ongoing costs absorbed in some cases by hospital budgets.

### **Clinical need**

Breast milk provides both nutrition and immunological support, and numerous studies show better outcomes for breastfed babies compared to formula fed babies - both for healthy, term babies and high risk infants. As well as containing proteins, fats, and carbohydrates in human specific proportions and forms, breast milk contains biologically active factors such as enzymes, immunoglobulins, growth factors, oligosaccharides, nucleotides and live cells.

---

Preterm and low birth weight infants are at higher risk than healthy term babies for a range of life threatening conditions such as NEC and neonatal sepsis. NEC is the leading gastrointestinal emergency of the premature infant. Around 90% of all cases of NEC are in premature babies. The exact causes of NEC are uncertain; it appears linked to infection and the introduction of enteral feeds to the immature digestive system (Updegrave 2004, ANZNN 2010).

In Australia and New Zealand in 2010 the rate of NEC was 2.2% in babies admitted to level III neonatal intensive care units (NICU) but 10.4% for those born before 28 weeks gestation. Of the 179 babies with NEC, 57 died and 103 underwent surgery (ANZNN 2013).

Based on a USA cost analysis study (Ganapathy et al. 2012), NEC treatment could represent on the order of \$26 million per year in hospital costs for Australia. Survivors of NEC are also at higher risk for long term neurodevelopmental impairment including cerebral palsy, cognitive and visual impairment (Schulzke et al. 2007).

Another common complication suffered by premature infants is neonatal sepsis, at a rate of 8.1% in level III NICUs in Australia and New Zealand.

It is now widely recognised as best practice in neonatal intensive care units to encourage and support mothers to breastfeed or express their own milk to feed their own infants.

Unfortunately, the mother's own milk is often unavailable or in insufficient supply, for example due to delayed onset of lactation following premature birth, the baby's inability to suckle, separation of the mother and infant, or illness of the mother. A number of studies indicate that PDHM, while not quite as protective as a mother's own (unpasteurised) milk, is associated with better outcomes and reduced risk of conditions such as NEC compared to infant formula or preterm formula. A 2007 Cochrane systematic review of five research studies found that preterm or low birthweight babies who received infant formula had approximately 2.5 times higher risk of NEC compared to those supplemented with donor human milk (with 95% confidence that the increased risk was between 19% and 508%) (Quigley et al 2007).

The volume of donor milk required to support a preterm infant in the neonatal intensive care unit (NICU) is quite small compared to the breast milk consumption of a healthy older baby which averages around 800mL per day (NHMRC 2012). Donor milk is generally provided for a few weeks with the aim of reducing the risk of infection or NEC during the early critical period, amounting to only a few litres per infant (at PREM bank averaging 2.7L per patient over the entire hospital stay).

### **Recipient population**

Babies born at 37-41 weeks gestation are considered 'born at term'. Babies born before 37 weeks are defined as pre-term. Being pre-term is associated with increased morbidity and mortality.

Prematurity is associated with low birth weight, another risk factor predisposing towards poor health outcomes and mortality (Laws, Grayson & Sullivan 2006). Groups at higher risk for low birth weight include babies of Aboriginal and Torres Strait Islander mothers (twice as likely), those from remote and very remote areas (30% higher than those born in major cities) and those living in the lowest socioeconomic status (SES) areas (30% higher than for the highest SES areas) (AIHW 2011).

Babies below 34 weeks gestation usually do not have the coordination needed to suck, swallow and breathe, so breast or bottle feeding is not feasible for these neonates. Nutrition must be provided by tube to the stomach (enteral) or if this is not tolerated, by parenteral (intravenous) methods (McGuire, Henderson & Fowlie 2004). Enteral feeding begins with tiny milk volumes of only a few millilitres per day.

---

Statistics from the Australian and New Zealand Neonatal Network (ANZNN) indicate that in 2010 there were 6,350 babies admitted to 21 level III neonatal intensive care units (NICU) in Australia, representing 2.1% of live births (ANZNN 2013). This includes babies born prematurely and/or with low to extremely low birth weight. The median length of NICU stay was 30 days, with some babies staying for 100 days or more. 94% of the level III NICU babies survived to go home, however the survival rate varies with gestational age: for those born before 24 weeks only 54.5% of those who were admitted to level III NICU survived to go home.

### **Risk considerations**

Breast milk is unique in being a food that is secreted from the human body. This means that for milk banks there are considerations relating to:

- the human source of the substance (with parallels to blood and tissue banking);
- food safety; and
- ethical considerations around donation and informed consent.

Human milk contains many biologically active substances and living cells, some of which are damaged by pasteurisation and processing such as freezing and thawing, although many beneficial properties still remain in PDHM. A mother's own milk is also specifically adapted to her infant and changes from feed to feed and from start to finish of a feed in terms of its nutrition content. The mother's breast milk provides antibodies and immune cells that, through exposure to the same environment, are precisely tailored to the needs of the individual infant. PDHM is therefore likely to be less beneficial than mother's own unpasteurised milk (Tully, Jones & Tully 2001).

As with donated blood, donor milk is a human body fluid with some accompanying risks. These include viruses (e.g. HIV, hepatitis C), bacteria and other infectious agents such as prions (i.e. vCJD). These risks need to be kept in perspective. While blood borne viruses are found in the breast milk of infected mothers, transmission from mother to child through breast milk is rare, and occurs at much lower rates than with blood (Gribble 2012). Donor screening and pasteurisation reduce the risks even further. Despite a long history of milk banking internationally, reports of adverse events are extremely rare.

The risk management strategies for human milk banks cover three main stages:

- Collection of donor milk - including donor eligibility, recruitment, screening and selection (with similar criteria to blood donation); training and support for donors; and how the donor milk is expressed, stored and transported.
- Processing donor milk- including tests carried out on the milk e.g. for bacteria and nutrient composition, pasteurisation, labelling, tracking and storing (which may include freezing and thawing).
- Providing the donor milk - including recipient eligibility and prescribing of donor milk, informed consent, dispensing and feeding protocols including fortification where required, tracking and record keeping, staff training, supporting mothers to establish their own milk supply, and liability and insurance issues.

### **Guidelines**

In the absence of any specific Australian regulatory requirements for donor human milk banking, WA PREM bank developed its own best practice guidelines which draw on food safety principles (Hazard Analysis Critical Control Point or HACCP), blood and tissue banking Good Manufacturing Practice and donor screening guidelines from other milk banks internationally (Hartmann 2007). The best practice guidelines established by the WA PREM bank involve testing the milk for bacteria both before and after pasteurisation. Other

---

Australian and overseas milk banks have been obtaining guidance from the PREM bank's procedures.

Internationally, there is a range of mostly voluntary milk banking guidelines in different countries. The few jurisdictions understood to have statutory guidelines include Brazil, France, Slovakia, and the US states of Texas, New York and California. The USA Food and Drug Administration does not regulate milk banking. There are a number of milk banking associations internationally, including the European Milk Bank Association, the Human Milk Banking Association of North America, United Kingdom Association for Milk Banking, Brazil's Rede Nacional de Bancos de Leite Humano and Human Milk Banking Association of South Africa.

Of note, the UK National Institute for Clinical Excellence (NICE), a government funded body which develops evidence-based guidelines, produced clinical guidelines for the operation of donor breast milk bank services in 2010. The guidelines cover how milk banks should:

- recruit, screen and support women who donate breast milk; and
- handle and process the breast milk they receive from donors.

### **Donor payment and cost recovery issues**

Australian milk banks do not remunerate their donors. Internationally, some milk banks charge a fee to the hospital or the recipient to cover processing costs and Austria and Norway reimburse donors for expenses. Media reports indicate that US milk banks charge a processing fee to the receiving hospital (which may be passed on to the recipient) of around US\$3-5 per ounce (approximately equivalent to around \$A100-\$170 per litre).

It has been reported that one Australian milk bank (Mothers Milk Bank- operating as a private charity in NSW and QLD) requests a donation of \$80 per litre of donor milk from recipient families, to cover the processing costs (SMH 2013).

A prohibition on payment protects both the donor and the recipient: it can avoid inducing donors to compromise their (or their babies') health by giving too much and it protects recipients from the risk that unhealthy donors may have been attracted by the prospect of payment.

### **Cost benefit of human milk banking**

To date, there are no published Australian studies on the cost effectiveness of human milk banking. A 2007 Cochrane Collaboration systematic review suggests that approximately one case of NEC would be prevented for every 33 NICU patients fed PDHM instead of infant formula (Quigley et al 2007).

Australian and New Zealand Neonatal Network statistics indicate 179 cases of NEC in Australia in 2010, with 103 undergoing surgery. Based on a Californian cost analysis study (Ganapathy et al 2012) this could represent hospital costs on the order of \$26 million per year for Australia. If half of those cases could be prevented by feeding donor human milk, that could represent a potential saving to the Australian hospital system of \$13 million per year. This is without taking into consideration the longer term health consequences and costs associated with NEC, or the costs of other conditions for which breast milk has a protective effect.

A recent interview with the Medical Director of the RBWH milk bank indicates that the costs of setting up a milk bank in Australia are around \$200,000 to \$250,000 with ongoing costs of \$150,000-\$250,000 per year (Cashin-Garbutt 2012).

---

## **Stakeholder needs**

There is a range of stakeholders with varying needs to be considered, including the infant recipients of donor milk; their mothers and families; breast milk donors; managers of milk banks, their host institutions and clinicians.

Some of the needs associated with these groups may include:

- continued availability of appropriate support for breastfeeding/expressing the mother's own milk for her own infant and or appropriate information about formula feeding when necessary;
- assurance about quality, safety, privacy, informed consent and appropriate use of donor milk;
- availability of infrastructure e.g. physical space and equipment and appropriately skilled staff;
- appropriate training for all involved staff and breast milk donors; and
- clarity about the obligations and responsibilities of milk banks, clinicians and host institutions.

## **Other considerations and emerging practices in relation to human milk**

### Breastfeeding support

Milk banks do not replace the need to encourage and support mothers of NICU babies to breastfeed or express breast milk when possible. It is normal practice in Australian NICUs, including those with milk banks, to provide breastfeeding support such as access to lactation consultants. Breastfeeding data were available for half of the babies admitted to level III NICU who survived to go home in 2010, giving a breastfeeding rate at hospital discharge of 78.9% (ANZNN 2013).

Due to the special nutritional needs of premature babies, additional supplementation may still be required even when the mother's breast milk and or donor milk are available. This may involve a special pre-term infant formula, or the addition of fortifiers and other additives to the mother's or donor breast milk.

### Private donation and trading of human milk

Throughout history some families have hired wetnurses to breastfeed their babies or 'cross-nursed' the babies of family and friends.

Increased awareness of the benefits of breast milk, the concept of donor milk, and the use of new social media has led to the establishment of websites promoting informal milk sharing arrangements between individuals. These sites provide a mechanism to connect families seeking donor milk with mothers wishing to give away (or in some cases sell) their excess milk.

Internet sites such as the Facebook groups Eats on Feets or Human Milk 4 Human Babies (HM4HB) provide mothers with information on sharing milk (e.g. considerations around donor selection, milk storage, transport and home pasteurisation methods) and a forum to enable donors and receivers to make contact. The information provided on these sites is presented as assisting families to make informed choices and is not represented as medical advice. The sites take no responsibility for outcomes and do not screen donors or provide absolute guidelines although they strongly discourage buying or selling the milk. They have active Facebook pages in Australia.

The USA's Food and Drug Administration and Canada Health have both issued advice to parents to consider the possible risks of informal milk sharing and recommending against feeding unscreened breast milk acquired through the internet:

---

- [U.S. Food and Drug Administration- Human milk banks](#)
- [Canada Health- Raises Concerns about the use of unprocessed Human milk banks](#)

The [Australian Breastfeeding Association also has a position statement](#) on donor milk (ABA 2011). This statement encourages mothers to be aware of the risks associated with privately sourced donor milk and to make informed decisions based on their own circumstances. It also states that the Australian Breastfeeding Association does not facilitate private milk sharing or allow its resources to be used to link private milk donors and recipient.

In Australia, for any attempt to regulate or advise on such activities, consideration should be given to:

- how the potential buying and selling of breast milk would be viewed in Australia (i.e. would it be captured by existing state and territory prohibitions on selling human tissue?);
- whether Australian governments should consider providing guidance to minimise the potential health risks of informal peer to peer milk sharing;
- whether existing regulations on food businesses, food safety and handling, fair trading, trade practices, health and therapeutic claims, (and potentially human tissues) would be sufficient to discourage unscrupulous trade or profiteering in human milk by an operator with inadequate screening and hygiene processes or making inappropriate therapeutic claims.

#### Future possibilities

Scientific research into human milk may lead to the creation of additional human milk derived products designed to meet the clinical needs of premature infants. Australian researchers have recently identified human stem cells in breast milk. There is a prospect that novel therapies will be derived from human milk, such as concentrates of particular proteins or cells (analogous to the kinds of products made from human blood and plasma).

#### Medical use in adult patients

Australian media have recently reported that the privately run Mother's Milk Bank in northern NSW provided PDHM to a 62 year old woman who has bone marrow cancer (Daily Telegraph 2012).

US milk banks have also reported providing donor human milk to small numbers of adult patients with conditions such as cancer and immune deficiency associated with liver transplant (Tully et al 2004).

#### Genetically engineered cow's milk

There have been several reports in recent years regarding transgenic cows or goats being genetically engineered to produce 'human' milk in China, Argentina and Russia. These claims appear to be based on one or two genes for human milk proteins such as lysozyme and lactoferrin being engineered into animal genomes. Claims that milk from these animals is equivalent to human milk are incorrect, as human milk contains hundreds of unique proteins and maternal antibodies (ABC News in Science 2011, UKMailOnline 2009, Sky News 2011).

### **Australian regulatory frameworks and considerations**

#### The nature of breast milk

Human milk, including PDHM, can be regarded as a food that is secreted by the human body. However, it may also be considered as a human tissue, noting that unprocessed breast milk contains living cells and PDHM still contains biologically active factors. In addition, the use of PDHM in a clinical setting, and its association with reduced risks of complications such as NEC, means it could also be viewed as a medicine, particularly if a therapeutic claim is made.

---

This dual perspective raises uncertainties about the position of PDHM and human milk banking in Australian regulatory frameworks, and creates a challenge for existing and prospective milk banks in identifying their legal obligations.

#### Existing frameworks

Discussions with States and Territories and relevant Commonwealth agencies (FSANZ and TGA) indicate that donor human milk appears to fit the definition of food under the existing food regulatory framework, and may also fit definitions of human tissue under State and Territory Human Tissue Acts. There could also be potential for regulation under the Therapeutic Goods framework.

Considerations on the way forward for milk banking include:

1. encouraging voluntary self-regulation through health professional networks while accepting a level of uncertainty about the legal frameworks surrounding milk banks; or
2. developing a formal Regulation Impact Statement to fully explore a range of regulatory options including whether any of the existing frameworks (food, human tissue, therapeutic goods) is capable of regulating milk banks.

#### Voluntary self-regulation and professional networks

In the absence of explicit government regulation, existing Australian milk banks have developed their own best practice guidelines and standard operating procedures. They are also forming a network of milk banks to further promote best practice.

In April 2011, the WA PREM Bank sought expressions of interest for health professionals to be involved in the establishment of an ‘Australasian Human Milk Banking Network’ (AHMBN). A number of groups and individuals expressed interest in the establishment of a network, including groups hoping to re-establish milk banking in New Zealand.

Dr Ben Hartmann, the manager of PREM Bank, has proposed the following objectives for the AHMBN:

- To foster and promote best practice in donor human milk banking in Australasia.
- To provide a forum for the exchange of information and co-ordination of practice and operational development for human milk banks in the region.
- To provide continuing education for Human Milk Bank staff.
- To provide expert advice and guidance to public authorities who may be responsible for regulating human milk banks.
- To foster a close working relationship with the professional associations involved in human milk banking in the region and internationally.
- To ensure that the practice of human milk banking in Australia is always supportive of mothers breastfeeding their own babies.

These objectives were developed with reference to the similar objectives promoted by the Australasian Tissue and Bio-therapeutics Forum (ATBF). The ATBF is an organisation representing tissue banks throughout Australasia, a ‘Tissue Bank’ being defined as an ‘organisation that retrieves, processes and/or distributes human tissue for transplantation’.

Given that this definition excludes human milk banks from professional affiliation with the ATBF, it is envisaged that the AHMBN could fulfil a similar role for human milk banks while maintaining a close relationship with the ATBF and their expertise in a parallel industry.

#### Considerations regarding food regulatory framework

In relation to food safety, the Australia New Zealand Food Standards Code contains three standards that are relevant to the consideration of human milk banks:

---

- Standard 3.2.2 – Food Safety Practices and General Requirements
- Standard 3.2.3 – Food Premises and Equipment
- Standard 3.3.1 – Food Safety Programs for Food Service to Vulnerable Persons.

These standards were developed as outcome-based standards; this means that they set out a series of outcomes that must be met but generally do not prescribe how the outcomes must be achieved. Standard 3.3.1 requires businesses such as acute care hospitals to have a documented food safety program if they provide potentially hazardous food to persons in their care. The activities involved in collecting, storing and dispensing human milk in a facility covered by Standard 3.3.1 could be considered as food handling operations and covered by food safety program requirements. To assist businesses developing food safety programs, templates and other guidance have been developed by the States and Territories.

A food safety program can be subject to a food safety audit by the States and Territories and a food business prosecuted if found in breach.

If a specific food standard for donor milk were to be considered it could potentially cover such aspects as:

- provision of advice to donors about the expression and subsequent handling of the milk e.g. storage and hygiene requirements of equipment and containers used by the donor;
- acceptance by the milk bank of donated milk transported in a specified manner;
- storage of the donated milk at the milk bank, including temperature requirements;
- testing of milk for microbiological contamination or other compositional requirements;
- application of technological processes e.g. pasteurisation;
- labelling of donated milk;
- restrictions on premises and persons which may supply donated milk;
- tracking and tracing donated milk;
- cleaning of containers and equipment at the milk bank;
- quality control system e.g. maximum storage time;
- batch recall procedures; and
- hygiene requirements for food handlers.

While FSANZ's role is to set standards relating to food, enforcement is conducted by the jurisdictions. Food regulators have the authority to initiate a food recall and could address food safety issues in relation to handling, processing, storage and distribution of donor human milk. However, issues in relation to donor eligibility, recruitment, screening and selection; training and support for donors; and how the donor milk is expressed are likely to be outside the expertise of food regulatory enforcement agencies.

#### Considerations regarding therapeutic goods framework

It appears that human milk is not covered by the general definition of therapeutic goods, because breast milk would need to be represented to be for therapeutic use. Even if represented to be for therapeutic use, the definition excludes goods that have a tradition of use in Australia or New Zealand as foods. However, the *Therapeutic Goods* legislation definition also provides flexibility to declare that a product is a therapeutic good where therapeutic claims are made about the product. A product that has a tradition of use as a food in Australia or New Zealand could still be declared to be a therapeutic good if the product is represented to be for therapeutic use

---

## **Biologicals Regulatory Framework**

The Biologicals Regulatory Framework is part of the Therapeutic Goods Framework. It came into effect on 31 May 2011. The Biologicals Regulatory Framework regulates human cell and tissue-based products as a distinct group of therapeutic goods called 'biologicals' and is administered by the TGA. The framework provides for four different 'classes' of biologicals, with the 'class' and the associated regulatory requirements being assigned on the basis of the degree of associated risk.

When the biologicals framework was agreed by Health Ministers in 2006, human milk banks were only just beginning to be re-established in Australia. Any decision to regulate banked donor human milk as a biological is likely to require Health Ministers' agreement.

Consultation with other stakeholders such as milk banks, health professionals and consumers would also be needed. It would also be necessary to consider whether the use of donor human milk is most appropriately characterised as therapeutic or nutritional, and what the consequences would be for the milk banks sector if donor milk were to be regulated as a therapeutic good.

The Biologicals Framework provides a number of risk categories with different levels of requirements. If banked donor milk were captured as a biological, the TGA would determine which class of biological/risk category applied. This would decide, for example, matters such as whether milk bank facilities would require a manufacturing licence, whether they would be audited and the level of data that would need to be submitted to the TGA to ensure quality, safety and efficacy.

### Regulatory considerations and role of governments

The implementation plan for the Australian National Breastfeeding Strategy undertook to:

Explore the evidence, quality assurance, cost-effectiveness and regulatory issues associated with the establishment of milk banks in Australia.

This action area originated from the Australian Government's response to the 2007 Parliamentary Inquiry into breastfeeding, which had recommended a feasibility study for a network of milk banks in Australia including the development of a national regulatory and quality framework. In its response the Australian Government undertook to work with State and Territory Governments to consider the relevant issues and also confirmed that states and territories have the flexibility to fund milk banks under the National Healthcare Agreement.

In exploring the relationship between Australian regulatory frameworks and milk banks, it is apparent that while existing laws do not explicitly address milk banks, there is guidance available from current food safety standards and other laws. There are also voluntary guidelines and operating procedures developed by Australian milk banks, and overseas guidelines including from the UK's NICE.

All but one Australian milk bank is located within a hospital. Hospitals are well placed to provide a high level of governance, vigilance, and quality control for milk banks and there appears to be scope for enforcement through existing food safety standards. Absence of a specific standard for milk banks places the onus on milk banks to develop appropriate procedures to comply with all relevant laws. This enables a locally tailored risk management approach while enabling flexibility which may provide a more favourable environment for innovation and continuous improvement. The risk of viral transmission through human milk is readily managed through the use of donor screening and pasteurising donor milk.

To this extent, milk banks are already operating under existing regulatory frameworks, so while there is not a perfect fit, there is also not a definite gap. While lack of regulatory certainty can be perceived as a hurdle for establishing milk banks, five have now been successfully established. The existing milk banks demonstrate the level of commitment, problem solving, attention to detail, research and collaboration needed in their establishment

---

and continuation. Additional regulation may not be the best response for the complex and dynamic issues surrounding milk banks.

Depending on its scope and level of prescriptiveness, regulation may reduce the opportunity for Australian research and innovation in the field of milk banking. It could have unintended consequences such as regulatory capture of activities with similarities to milk banking, such as feeding mothers' own milk in hospital or child care settings, wet nursing, and informal milk sharing in the community. Developing specific regulation would involve costs to governments and potentially impose additional costs on milk banks. There are also strong incentives for the sector to act responsibly, given that the occurrence of even a single adverse event could jeopardise the continuation and expansion of Australian milk banking.

Factors favouring regulation of milk banks include formalising risk management for a clinically vulnerable recipient population and promoting a nationally consistent approach to the complex range of issues surrounding milk banks. Regulation could set boundaries around the use of donor milk, ensuring it remains evidence-based. Reduced uncertainty about compliance with Australian law may simplify the process of establishing new milk banks.

Any potential decision making process involving regulatory options for milk banks would require an extensive process of consultation and developing a Regulation Impact Statement (RIS). A RIS needs to clearly identify the regulatory 'problem', establish whether it can be adequately addressed by existing regulations, and the costs and benefits of a range of options. In addition to the cost of developing a RIS, the process of developing standards also incurs costs, either to government or the regulated parties. In the case of the milk banks sector, there may then be further costs in terms of adjusting procedures to meet a new standard and ensuring ongoing compliance.

On balance, this paper finds that the case for developing further, specific regulation of milk banks is not sufficiently strong to be pursued at this time.

### Conclusion

There is a growing body of evidence and expert opinion to support the use of pasteurised donor human milk for hospitalised preterm or sick infants. This includes some evidence that providing pasteurised donor human milk may be a cost-effective intervention in the setting of neonatal intensive care. This is reflected in the establishment of five Australian milk banks in recent years, operating in WA, NSW, VIC, and QLD. These milk banks have been successfully established on a local level, in both public and private hospitals. Supporting mothers to breastfeed their own babies needs to remain a high priority, even when donor milk is available.

In this examination of the issues and background surrounding milk banks, we conclude that, while there are arguments both for and against consideration of further regulatory action on milk banks, the case for regulation is not sufficiently strong to be further pursued at this time. Regulatory considerations can be perceived as a barrier to establishing milk banks, but this is only one of the complex clinical, technical, ethical, legal and resourcing considerations surrounding milk banking. There is a need to provide room for research and innovation while maintaining quality and good governance. Indications are that there is significant good will and collaboration between existing and planned Australian milk banks.

There is strong public and media interest in milk banking, particularly amongst breastfeeding advocates. The existence of five Australian milk banks demonstrates the feasibility of milk banks, and the level of commitment, research and collaboration needed in their establishment and continuation. Decisions about establishing, managing and resourcing milk banks are a matter for consideration by local hospital networks, subject to local priorities.

---

It is recommended that those health organisations considering establishing milk banks be encouraged to work with the existing milk banks, guided by existing Australian legal frameworks and the risk management and operating principles already in use.

---

## References

- Australian and New Zealand Neonatal Network (2013) *2011 Report of the ANZNN* <http://www.npesu.unsw.edu.au/data-collection/australian-new-zealand-neonatal-network-anznn>. Accessed: May 2014.
- Australian and New Zealand Neonatal Network (2010) 2010 Report of the ANZNN. <http://www.npesu.unsw.edu.au/data-collection/australian-new-zealand-neonatal-network-anznn>. Accessed: May 2014).
- Australian Breastfeeding Association (2011) Position Statement on Donor Milk. Available from: <https://www.breastfeeding.asn.au/policy/statement-donor-milk>. Accessed: May 2014.
- Australian Institute of Health and Welfare (2011) *Headline indicators for children's health, development and wellbeing 2011*. Cat. No. PHE 144. Canberra: AIHW
- Beal D, Ashdown LR, Mackay M (1978) The organization of a human milk bank in a North Queensland hospital. *Medical Journal of Australia* 1(1):8-10.
- Bedo S (2012) 'Breast is best for fighting cancer as woman turns to breast milk for treatment' The Daily Telegraph 28 June 2012.
- Cashin-Garbutt A (2012) [Breast milk banks: an interview with Dr Pieter Koorts](#). News Medical. Accessed: May 2012.
- European Milk Bank Association. <http://www.europeanmilkbanking.com>. Accessed: May 2014.
- Ganapathy V, Hay JW, Kim JH (2012) Costs of necrotizing enterocolitis and cost-effectiveness of exclusively human milk-based products in feeding extremely premature infants. *Breastfeeding Medicine – The Official Journal of the Academy of Breastfeeding Medicine* 7(1): 29-37.
- Gribble KD and Hausman BL (2012) [Milk sharing and formula feeding: Infant feeding risks in comparative perspective](#) *Australasian Medical Journal* 5(5):275–283. Published online May 31, 2012. doi: 10.4066/AMJ.2012.1222. Accessed May 2012.
- Hartmann BT et al (2007) Best practice guidelines for the operation of a donor human milk bank in an Australian NICU. *Early Human Development* 83: 667-673.
- Human Milk Banking Association of North America. <https://www.hmbana.org>. Accessed: May 2014.
- Hussey E (2013) 'Is another mother's milk OK for baby?' The Sydney Morning Herald, 3 February 2013.
- Laws PJ, Grayson N, Sullivan EA (2006) Australia's mothers and babies 2004. *Perinatal statistics series no. 18*. AIHW cat.no. PER 34. Sydney: AIHW National Perinatal Statistics Unit.
- Lording RJ (2006) A review of human milk banking and public health policy in Australia. *Breastfeeding Review* 14(3):21-30.
- McGuire W, Henderson G, Fowlie PW (2004) Feeding the Preterm Infant. *British Medical Journal* 329: 1227-1230.
- National Health and Medical Research Council (2012) *Infant Feeding Guidelines*. Canberra: National Health and Medical Research Council.
-

Quigley MA, Henderson G, Anthony MY, McGuire W (2007) Formula milk versus donor breast milk for feeding preterm or low birth weight infants. *Cochrane Database of Systematic Reviews* 17(4):CD002971.

Salleh A (2011) '[Humanised cow's milk has cloudy future](#)', *News in Science*, 5 April 2011, Australian Broadcasting Corporation. Accessed May 2012.

Schulzke SM, Deshpande GC, Patole SK (2007) Neurodevelopmental outcomes of very low-birth-weight infants with necrotizing enterocolitis: a systematic review of observational studies. *Archives of Pediatric and Adolescent Medicine* 161(6): 583-90.

Stewart W (2009) 'We're raising GM goats to make human breast milk, say Russians' UK MailOnline, 11 February 2009.

Thorley V (2001) Initiating breastfeeding in post-war Queensland. *Breastfeeding Review* 9(3): 21-26.

Tully DB, Jones F, Tully MR (2001) Donor milk: what's in it and what's not. *Journal of Human Lactation* 17(2):152-5.

Tully MR, Lockhart-Borman BS, Updegrave K (2004) Stories of success: the use of donor milk is increasing in North America. *Journal of Human Lactation* 20(1):75-77.

Updegrave K (2004) Necrotizing enterocolitis: the evidence for use of human milk in prevention and treatment. *Journal of Human Lactation* 20(3): 335-9.

Weaver G & Williams S (1997) 'A mother's gift: The milk of human kindness'. In *The gift relationship: From human blood to social policy* by Richard M Titmuss. New chapters edited by Oakley A & Ashton J, New York: The New Press (2nd ed, pp.319-332).

Williams H (2011) 'Chinese GM cows make human breast milk', 6 June 2011, Sky News.

World Health Organisation & UNICEF (2003), [Global Strategy for Infant and Young Child Feeding](#). Accessed May 2012.

---