



ACT
Government

ACT Health

Feasibility of establishing a milk bank in the ACT



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Directorate

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Establishing a milk bank in the ACT

Background

The Motion

In October 2018, the ACT Legislative Assembly moved the following motion:

That this Assembly:

6. *calls on the ACT government to investigate the feasibility of establishing an official milk bank in the ACT and/or partnering with neighbouring jurisdictions:*

a) to give ACT region women an opportunity to donate; and

b) to supply breast milk to babies in and out of a hospital setting.

This paper examines the feasibility of several options the ACT Government could enact in relation to this motion, and explores additional considerations that have emerged over the course of this investigation.

Pasteurised donor human milk (PDHM)

The donation of one woman's breast milk for use as food for another baby is an ancient tradition. The practice of 'wet nursing' – direct breastfeeding of a baby that was not birthed by the woman – can be dated back as early as the 4th century (Thorley, 2008), with a 'wet nurse' an accepted profession until the early 20th century in Australia (Thorley, 2008).

The first human milk bank, offering expressed donor milk to infants in need, opened in Europe in the early 20th century. The rise of human milk banks was dampened in the 1980s due to the emergence of HIV, with the subsequent closure of many milk banks (Jones, 2003). These concerns were subsequently alleviated due to the discovery that the Holder pasteurisation processing technique eradicates infection transmission in donor milk (Jones, 2003). This discovery, in addition to the further evidence showing the beneficial effects of pasteurised human milk in pre-term infants (Quigley, Embleton & McGuire, 2019), has allowed milk banks to re-emerge as a vital service for all health systems caring for vulnerable preterm infants. Today, the product distributed by the majority of human milk banks is pasteurised donor human milk (PDHM), and it is provided predominantly to hospitalised infants with insufficient mothers own milk in Neonatal Intensive Care Units (NICUs), who have a clinically indicated increased risk of developing necrotising enterocolitis (Moro et al. 2015).

The World Health Organisation (WHO) acknowledges the importance of milk banks in its *Global Strategy for Infant and Young Child Feeding* (2001), which also highlights the unique and highly beneficial properties of breast milk and recommends exclusive breastfeeding for the first 6 months of life (WHO, 2001). The WHO notes that suitable alternatives to mother's own milk (MOM) are

expressed breast milk from another woman, donor milk from a human milk bank or a breast-milk substitute. The WHO also acknowledges that the choice of the best alternative depends on individual circumstances. The WHO has more recently recommended that based on evidence, “all low birth weight infants [<1500g], including those with very low birth weight, who cannot be fed mother’s own milk should be fed donor human milk [PDHM]” (WHO, 2011). This recommendation is applicable for any setting in which safe and affordable milk-banking facilities are available or can be set up.

Milk banks in Australia

Milk banking began in Australia in Western Australia, with the opening of the PREM Milk Bank at the King Edward Memorial Hospital in Perth in 2006. There are now five milk banks operating in Australia, providing PDHM to NICUs in all states and territories except the Northern Territory. Four milk banks provide to hospital settings, and one milk bank is community based. All milk banks currently, or are in the process of arranging, supply to multiple NICUs.

The Australian Red Cross Milk Bank is a centralised milk bank located in NSW and became operational in 2018. The Red Cross Milk Bank currently provides donor breast milk to a number of hospitals across Sydney and Adelaide and also runs donor milk collection services in both States. In 2019, the Commonwealth Government committed \$2.0 million in the 2019-20 Department of Health budget to nationally expand the Red Cross Milk Bank network and establish a collaborative research program to undertake research into the benefits of donor milk (Australian Government, 2019).

The Australian National Breastfeeding Strategy: 2019 and beyond (the Strategy) includes an action area relating to milk banks. The Strategy acknowledges the evidence of the benefits of providing pasteurised donor human milk to hospitalised preterm or sick infants (COAG Health Council, 2019). The Strategy also recognises that fresh mother’s own milk is the first choice in preterm infant feeding, due to the negative effects of the necessary processing of donor breast milk on important biological components of human milk. For this reason, the Strategy notes that lactation support should be the key focus in hospitals where donor human milk is provided.

The Strategy further commits to a specific action item (Action 2.4) relating to human milk banking. This Action commits the Commonwealth, States, Territories and New Zealand to establish a human milk working group to provide advice to the Australian Health Minister’s Advisory Council (AHMAC) on the regulation and importance of human milk.

PDHM in the ACT

The ACT currently sources PDHM for use in the Canberra Hospital (CH) NICU from Mother’s Milk Bank, located in Tweed Heads NSW. Mother’s Milk Bank is a not-for-profit organisation who can provide PDHM on request to mothers in need, as well as to several health services within Australia. For example, Mother’s Milk Bank was recently supplied PDHM to of a Canberra mother who was unable to breastfeed due to undergoing chemotherapy treatment (Daily Telegraph, 2019). However, PDHM that is received by Canberra Health Services from Mother’s Milk Bank cannot then be provided to community members on request, as it is available only within the hospital setting for premature and underweight babies.

PDHM is provided in the CH NICU to premature and underweight babies based on specific clinical need, to reduce the risk of necrotising enterocolitis (NEC). The incidence of NEC is highest in the

most preterm babies - up to 10 per cent in babies born at less than 28 weeks gestation, 5 per cent in babies born at 28 to 32 weeks gestation and less than 1 per cent in babies born at more than 32 weeks gestation (ANZNN, 2013). Mortality in premature infants with NEC can be as high as 40 per cent (Gephart & et al. 2013). Infants with NEC can have long-term problems such as strictures, with malabsorption occurring in up to 25 per cent of survivors (Chandler & Hebra, 2000).

PDHM is a nutritional alternative to preterm babies of mothers who are unable to supply sufficient quantities of their own breastmilk. Feeding premature babies breastmilk, not formula, has been proven through clinical studies to be protective of NEC. Supplementation with PDHM reduces the incidence of NEC and therefore morbidity and length of hospital stay (Kim, Lee & Chung, 2017; Assad & Elliott, 2015).

The eligibility criteria for the provision of PDHM in the CH NICU is for babies born less than 30 weeks gestation or weighing less than 1250 grams, however the NICU is expanding this criteria to less than 32 weeks gestation or weighing less than 1500 grams, which will be in keeping with the eligibility criteria used in NSW NICUs. This criteria is also consistent within the WHO recommendation that low birthweight infants who cannot be fed mother's own milk should be fed donor human milk (WHO, 2011). Medical staff may recommend PDHM be provided on a discretionary basis in exceptional circumstances.

The contract for receiving PDHM is only between the Mother's Milk Bank and CH. The other public maternity hospital in the ACT, Calvary Public Hospital Bruce (CPHB), does not have access to PDHM. However, infants cared for in the Special Care Nursery (SCN) at CPHB would rarely meet the eligibility requirements for receiving PDHM used by the CH NICU. Some infants who are currently receiving PDHM at Canberra Hospital are eligible for transfer to CPHB, which may reduce patient back transfer to the hospital closest to home or necessitate the early cessation of PDHM.

It is important that any service using PDHM has good quality lactation support to support the availability of expressed mother's own milk and reduce the infant's need for PDHM. The CH currently employs a full-time lactation consultant specific to the NICU to support mothers of infants born very premature or unwell.

Options responding to the Assembly motion

Eligibility

The October 2018 Legislative Assembly motion requested the ACT Government to investigate the feasibility of establishing a milk bank in the ACT for the purpose of supplying breast milk both in and out of a hospital setting. However, a publicly run milk bank that provides PDHM outside of a hospital setting would be unprecedented in Australia, and highly unusual in a global context. Privately run Australian charity organisation Mother's Milk Bank does provide milk in compassionate circumstances to individuals who request PDHM. In most cases the requesting family will pay a cost recovery fee (Department of Health, 2014).

Global guidelines and international best practice generally restrict the use of PDHM to premature and underweight babies. European milk bank guidelines, the *Recommendations for the Establishment and Operation of Human Milk Banks in Europe: A Consensus Statement from the European Milk Bank Association (EMBA)*, do not dictate a specific eligibility criteria for PDHM recipients, however the EMBA does note that across Europe's 226 milk banks donor milk is provided predominantly to preterm and sick infants who are temporarily without access to their mother's milk (Weaver et al. 2019).

Brazil is home to the highest number of milk banks of any country, housing close to 220 milk banks which are fully government funded and integrated into the country's wider breastfeeding policy (DeMarchis et al. 2017). Nevertheless, the majority of these milk banks provide PDHM only to premature or sick infants in a hospital setting (Langland, 2019).

Global public health organization, PATH, has developed a framework for establishing a human milk bank (the PATH Framework). The PATH Framework is framed entirely under the assumption that PDHM should be made available to hospitalised vulnerable preterm infants (PATH, 2019), regardless of whether the milk bank itself is situated in a community or hospital setting. Alternative eligibility options are not further explored in the PATH Framework.

Australian guidelines also echo this practice. The National Health and Medical Research Council *Feeding Guidelines (Information for Health workers)* state that breast milk bank products are only available in Australia for preterm infants or those with serious medical conditions (NHMRC, 2012). The Australian Medical Association in its *Position Statement on Infant feeding and Paternal Health* recognises specifically that hospital-based milk banks provide a valuable source of nutrients for infants with a clinical need for donor human milk, such as those who are premature or underweight, and that the use of donor human milk for premature infants can be significantly beneficial in reducing the risk of gastrointestinal infection (AMA, 2017).

PDHM is a finite resource, supplied by a human donor, and as such decisions regarding distribution of this resource should be made based on evidence and with considerations of the ethical obligations that arise in the use of donated human tissues (Hartmann et al. 2007). The decision of who deserves to receive PDHM should be provided on a needs basis, with the ultimate aim of addressing established clinical need and avoiding wastage as far as practicable.

Despite international and national best practice in which PDHM is provided as short-term supplementation to pre-term or low birth weight infants, there is a push in the ACT from both the community and some relevant stakeholders towards expanding the availability of PDHM to a wider range of eligible recipients. This push should be considered as part of any decisions made on the best option going forward, and further addressed in the context of the reasoning given for the decision.

Demand

While international best practice for provision of PDHM is constrained to temporary supplementation for vulnerable hospitalised infants, there are other circumstances in which both community and local health services stakeholders have expressed a need for increased availability of PDHM. These include:

- healthy mothers with a well baby who intend to breastfeed but are experiencing lactation difficulties;
- parents in the community for whom breastfeeding is physically impossible, for example foster parents, LGBTIQ+ couples, or mothers who have had a double mastectomy; and
- unwell mothers with a well baby who intend to breastfeed but are medically prevented from doing so, for example due to medication such as chemotherapy or treatment that prevents breastfeeding, or women who are critically unwell, such as having experienced significant postpartum haemorrhage.

The volume of PDHM required to support vulnerable preterm infants is can be as small as several millilitres per day. In contrast, well term babies may need as much as 600 - 800 millilitres per day in the first month of life (Costa et al. 2010). The question of eligibility is crucial when determining cost benefit, as supply of PDHM is obtained at a set cost per litre. Currently, CH uses approximately 160 litres of PDHM per year in supply to the NICU, though a planned expansion to include infants up to 32 weeks gestation age will increase this volume. An expansion of eligibility criteria to include term babies would dramatically increase the amount of PDHM required. However, if further expansion of eligibility is desired, this could potentially be achieved through mix feeding with both formula and PDHM rather than complete replacement, to minimise quantities required.

Supply and demand – four scenarios

The cost projections for the options explored in this report are based on a set of eligibility scenarios for the distribution of PDHM. These are outlined below, and referred to in later tables and service descriptions. The below models are based on specific assumptions and therefore volume estimations may differ in practice.

Scenario A – PDHM for premature and underweight infants in the CH NICU (current eligibility)

The supply of PDHM historically needed to supplement preterm and underweight babies in the CH NICU is 163 litres of PDHM annually. This could be covered by an estimated 40 local donors per year, given an approximate average of 6 litres per donor, with a 70 per cent yield after screening and processing. This scenario is modelled on an approximate volume of 160 litres, but it should be noted that due to a small expansion in the CH NICU eligibility criteria the future annual volume required may increase.

However, given community interest in providing PDHM to a wider range of recipients, different scenarios have been additionally modelled for information.

Scenario B – Any infant up to the age of 6 months

For example, if eligibility was extended to provide PDHM to 5 per cent of infants up to the age of 6 months, this would require approximately 40,000 - 50,000 litres of PDHM per annum. This amount would necessitate a donation rate of at least 80 per cent of all lactating ACT mothers, which is highly unfeasible based on breastmilk donation rates in other jurisdictions. There is no evidence to demonstrate benefit for provision of PDHM to this population group.

Scenario C – PDHM for all pre-term infants up to 36 weeks (birth to discharge)

Another example is the provision of PDHM for all pre-term infants aged up to 36 weeks from birth to discharge. This would require roughly 1,000 litres per annum, with an assumption of 9 per cent of all births being pre-term and 2 litres being supplied overall to each infant. Approximately 2 per cent of ACT mothers would need to donate to cover this volume, however, there is limited research to support the benefits of supplying PDHM to this population group. There is some indication that provision of PDHM to pre-term infants can increase breastfeeding rates at discharge (Arslanoglu et al. 2012), although some studies suggest there may be a risk of reducing breastfeeding rates if adequate lactation support is not supplied (Williams et al. 2016).

Scenario D – PDHM for any baby in first few days of life

A final model for consideration is the provision of PDHM to all babies born in the ACT for the first few days of their life, while mothers attempt to establish full feeding. With an assumption that 15 per cent of mothers lack sufficient maternal supply in the first few days of life, and that transitional supply of PDHM is 2.5 litres per infant, this would require 2,300 litres per annum. This would require roughly 5 per cent of ACT mothers to donate to maintain, which may be feasible, however there is no research to support the benefits of supplying PDHM to this population group. Consultations have suggested that potential, unstudied benefits for expanding eligibility to this criteria may be increased breastfeeding rates at discharge, and improved mental wellbeing of the mother.

Option 1 - Sourcing pasteurised donor human milk from Red Cross Milk Bank Australia

Overview

Since 2016, the CH NICU has sourced PDHM from Mother's Milk Bank. The CH is currently in contract negotiations with the Red Cross Milk Bank, for the consideration of transferring responsibility for provision of PDHM from Mother's Milk Bank to the Red Cross Milk Bank.

Benefits

The benefit of this option is that it is the least financial implications, while continuing to align the ACT with international best practice for PDHM distribution.

One of several advantages of transitioning PDHM supply from the current supplier to the Red Cross Milk Bank would be the increased quality and safety assurance through modified processing and transport practices. Currently PDHM sourced from Mother's Milk Bank is transported via plane. Unexpected flight delays may mean the PDHM supply is occasionally delayed while in transit. This risk is mitigated through use of a temperature tracking device attached to the PDHM vessel, to ensure the cold chain has been appropriately maintained. However, variation in delivery times is a risk as staff need to be promptly available to pick up the cargo and store it appropriately within the hospital.

A further benefit of receiving PDHM from the Red Cross Milk Bank would be the capability to place orders daily. As CH already orders and receives blood products from the Red Cross, PDHM could then be easily requested and delivered alongside the daily blood order. This would reduce potential for wastage, as PDHM could be ordered on an ad hoc basis as needed. Given that PDHM is a donated body product and regulated as a tissue in multiple jurisdictions, there are ethical considerations to ensure wastage is as minimal as possible.

As the Red Cross Milk Bank has a steady number of donors and is a large-scale operation in terms of equipment and throughput, a benefit of procuring PDHM through their organisation is guaranteed supply. Electing to utilise the Red Cross Milk Bank as a supplier of PDHM to CH could also allow the ACT opportunities to participate in planned research activities coordinated by the Red Cross Milk Bank.

The Red Cross Milk Bank has already been flagged by mainstream political parties for its potential to expand on a national basis to service many more hospitals around Australia. If this were to occur, the Red Cross could set a national standard in terms of safety and processing practices. The ACT would then be at an advantage in that it could easily guarantee that the PDHM supplied to CH would adhere to national quality standards.

Finally, given that current international best practice is to supply PDHM only to vulnerable or preterm infants, a key benefit of this option is that current protocols within the CH NICU can continue to provide PDHM to infants in need, which positions the ACT so that it does not need to spend money on establishing its own milk bank.

Disadvantages

Obtaining PDHM from the Red Cross Milk Bank is more expensive per litre than from Mother's Milk Bank. However, this is largely due to the benefits already addressed in increased guarantee of supply, assured safety and processing standards and reduced likelihood of wastage.

Currently the negotiations with the Red Cross Milk Bank do not include the possibility of provision of PDHM to CPHB. Although the CPHB SCN would usually not have care of infants meeting eligibility requirements for PDHM, premature infants who have been prescribed PDHM are in some cases transferred to CPHB when they are considered healthy enough to be discharged from NICU. Anecdotally on some occasions a discharge may be delayed by request from a parent to allow the infant to receive PDHM for longer. Therefore, a contract with the Red Cross Milk Bank that included the CPHB SCN as an eligible recipient may have the benefit of allowing timelier discharges of infants from CH NICU.

Cost

The cost for the Red Cross to provide an estimated 160L of PDHM per year (for use in the CH NICU) would be approximately **\$0.050 million**, including transportation to CH from NSW. This is the minimum projected cost, as PDHM volume requirements will likely increase.

The unit price for PDHM from the Red Cross is roughly \$280-290 per litre, depending on the bottle size requested. As Red Cross is a not for profit organisation, price is based on cost recovery.

Option 2 – Establishing an ACT milk bank

Overview

A milk bank in the ACT would need to provide and administrate the following services:

- recruitment of breast milk donors;
- collection of donated milk;
- screening of donors;
- screening of donated milk;
- processing of donated milk (milk then becomes PDHM);
- storage of PDHM; and
- distribution of PDHM.

Best practices for milk bank establishment also recommend the following function (PATH, 2019).

- provision of lactation support.

Of the five operational milk banks in Australia, four are hospital based or provide only to hospitals – the PREM Milk Bank at King Edward Memorial Hospital in Perth, the Mercy Milk Bank in the Mercy Hospital for Women in Melbourne, Queensland Milk Bank at the Royal Brisbane Women’s Hospital in Brisbane (QLD) and the Red Cross Milk Bank in NSW.

If the ACT elects to set up a local milk bank, a choice would need to be made as to whether this service would be better placed in a hospital or a community setting.

The PATH Framework, a best practice guide for setting up a milk bank, outlines the significant space, equipment, staffing and protocols required for such a service.

It is important to note that the PATH Framework emphasises that the key outcome of any milk bank should be the promotion of breastfeeding and lactation support, and that milk banks should exist as part of a larger integrated human milk bank program which supports optimal breastfeeding practices and ultimately increased provision of MOM.

General benefits of an ACT milk bank

The establishment of a milk bank in an ACT hospital would demonstrate a public commitment to ensuring the health of infants in the ACT, and reinforce public health messaging of the value of human breast milk.

An ACT milk bank could allow mothers in the Canberra region the opportunity to donate breast milk, which is a strongly expressed desire of the community. Further, the milk donated would directly benefit local infants. This may enhance the sense of community inclusion and support for both potential donors and the parents of PDHM recipients.

Establishment of an ACT milk bank may provide an opportunity for the ACT to partner with academic institutions and relevant organisations for research purposes. Adequate research on outcome measures of PDHM, particularly to well infants, is currently lacking, although it should be noted that

the Australian Red Cross has been financed by the Australian Government to engage in future research in this area (Australian Government, 2019). A research partnership could allow the ACT to be a national or global leader in much needed research surrounding the eligibility of PDHM recipients, best practice standards for PDHM processing and storage and the differences in long term outcomes between PDHM and MOM.

General disadvantages of an ACT milk bank

The setup requirements for a milk bank are significant, as outlined by the PATH Framework. These include:

- space (for screening, pasteurising and storing PDHM; private rooms for expressing milk; counselling room for donor and recipient families; space for shipping and receiving PDHM; and space for reception and storage of documents and files);
- equipment (for milk expression; containers for PDHM storage; freezers; processing equipment [pasteurisers]; microbial screening [if not done elsewhere]; and computers and administration equipment);
- staff (medical director; milk bank manager; donor outreach and recruitment coordinator; lactation support; processing technician; microbiologist; administrative and regulatory supports); and
- setup processes and protocols (HACCP protocols; standards of practice; specific guidelines; track and trace system; and self-auditing).

A risk of establishing an ACT milk bank would be the guaranteed supply for breast milk donations. While there has been community support for establishing a milk bank, it is not possible at this stage to estimate the numbers of women who would in practice be eligible to donate to a service. Donation involves strict criteria and logistical barriers, which may not be anticipated by the community. For example, a standard screening test includes surveying dietary and lifestyle behaviours, as well as a blood test to screen for a number of transmissible viruses. Eligibility for donation is often preferential for donors currently breastfeeding an infant younger than 6 months, and frozen donations will may not be accepted if they are older than a couple of months (NSW Health, 2018).

Consultation with community stakeholders suggests that some women may prefer not to donate to a milk bank, due to the fact that donations are anonymous. This means there is no chance of a personal relationship between the donor and the parent of the receiving infant. Anecdotally, some women may therefore prefer to donate excess breast milk through an informal sharing process, and in doing so develop the uniquely personal bond that regularly develops from such an experience (Gribble, 2018).

Milk banks and jurisdiction size

Currently, publicly run milk banks in Australia are established in jurisdictions with a larger population catchment than the ACT, and multiple NICUs. The Royal Hobart Hospital (RHH) in Tasmania, which houses the only Tasmanian NICU facility, is more comparable in terms of catchment to the ACT than current Australian hospital-based milk banks. The RHH currently provides PDHM to their NICU, sourced from Queensland Milk Bank. The RHH have previously considered establishing a milk bank

of their own, but determined that the vastly increased costs of commencing operations would not be in proportion to the number of infants they estimate would be eligible to receive PDHM.

Cost

The base cost for the ACT to establish its own milk bank is dependent on the scenario of PDHM provision used.

To process and supply 160 litres per year (**Scenario A**), the base costs for establishing an ACT milk bank are estimated at roughly **\$0.730 million** for the initial setup, in addition to approximately **\$0.168 million** per annum in operational costs.

An indicative breakdown of setup and ongoing costs are provided below.

Table 1: ACT Milk Bank Setup indicative costs – Scenario A (160 litres produced per annum)*
Scenario A is modelled on the provision of PDHM to infants under 32 weeks or 1500 grams

Setup requirement	Cost
Dishwasher	\$2,500
ICT Equipment (Computer, barcode scanners, printer (label, etc.))	\$6,000
Freezer x 4 and Thaw Fridge	\$65,000
Temperature monitoring equipment (freezer modifications, etc.)	\$30,000
Balance, Timers, Sealer, Pump	\$25,000
Pasteuriser (smaller one is closer to \$65K – large \$95K)	\$95,000
Laminar Flow Cabinet	\$7,000
Facility design, fitout, permits, commissioning, validation, audits etc.	\$200,000
ICT Software commissioning, installation, validation	\$100,000
Process and Quality documentation and system development	\$200,000
Total	\$730,500

* Note: these figures are estimates only and do not include full overhead or depreciation; final figures would be subject to final implementation requirements and costing.

Table 2: ACT Milk Bank Annual Operational indicative costs – Scenario A (160 litres produced per annum)*

Scenario A is modelled on the provision of PDHM to infants under 32 weeks or 1500 grams

Operational requirement	Annual Cost
<u>Staffing – 1.0x FTE</u> 0.5 x FTE (Registered nurse) 0.5 x FTE (Administrative and operational support)	\$126,421
Vehicle costs (lease)	\$10,000
Consumables & Blood and Microbiological testing (Outsourced)	\$32,000
Total	\$168,421

However, if eligibility is extended to wider criteria, such as in **Scenarios C and D**, costs would increase due to higher throughput and by extension increased operational capacity requirements.

To process and supply 1,000 – 2,300 litres per year, as in **Scenarios C and D**, the indicative costs for establishing an ACT milk bank are estimated at roughly **\$1.010 million** for the initial setup, in addition to approximately **\$0.650 million per annum** in operational costs, dependent on volume.

Estimated indicative costs for the ACT to establish an ACT milk bank with a higher expected throughput, as outlined in **Scenarios C and D**, are below.

Table 3: ACT Milk Bank Setup indicative costs – Scenarios C and D (1,000 – 2,300 litres produced per annum)*

Scenario C is modelled on the provision of PDHM to all pre-term infants up to 36 weeks

Scenario D is modelled on the provision PDHM to any infant in the first few days of life

Setup requirement	Cost
Dishwasher	\$2,500
ICT Equipment (Computer, barcode scanners, printer (label, etc)	\$6,000
Freezer x 6 and Thaw Fridge x 2	\$100,000
Temperature monitoring equipment (freezer modifications, etc)	\$30,000
Balance, Timers, Sealer, Pump	\$25,000
Pasteuriser x 2	\$190,000
Laminar Flow Cabinet	\$7,000
Facility design, fitout, permits, commissioning, validation, etc	\$350,000
ICT Software commissioning, installation, validation	\$100,000
Process and Quality documentation and system development	\$200,000
Total	\$1,010,500

Table 4: ACT Milk Bank operational indicative costs – Scenarios C and D (1,000 – 2,300 litres produced per annum)*

Scenario C is modelled on the provision of PDHM to all pre-term infants up to 36 weeks

Scenario D is modelled on the provision PDHM to any infant in the first few days of life

Operational requirement	Annual Cost
<u>Staffing – 3.0 x FTE</u> 1.0 x FTE (Milk Bank manager) 1.0 x FTE (Registered nurse) 1.0 x FTE (Laboratory technician)	\$403,236
Vehicle costs (lease)	\$20,000
Consumables, testing (based on 1000L)	\$226,800
Total	\$650,036

* Note: these figures are estimates only and do not include full overhead or depreciation; final figures would be subject to final implementation requirements and costing.

Below is a table representing total and comparative costs for all scenario breakdowns.

Table 5: Indicative setup and operational costs for an ACT milk bank for the first year of operation*

Scenario	Setup cost	Annual operational cost	Total annual cost – first year
A – 160 litres per year (supplied to vulnerable preterm infants in CH NICU)	\$730,500	\$168,421	\$898,921
C & D – 1,000 to 2,300 litres per year (supplied to pre-term infants up to 36 weeks, or all infants in need in the first few days of life)	\$1,010,500	\$650,036	\$1,660,536

Additional location considerations for an ACT milk bank

Hospital setting

Milk banks in a hospital setting may collect milk purely from patients in residence, or additionally accept community donations. Milk banks within hospitals can provide PDHM directly to the NICUs within those hospitals, however in Australia the majority of hospital milk banks have established agreements to provide PDHM to other hospitals both locally and interstate. Should the ACT establish a milk bank in a hospital setting, proximity to the NICU would be imperative, making CH the most likely site for an ACT milk bank.

Benefits

As CH would likely be processing the donated milk, Canberra Health Services (CHS) would have full control and responsibility for quality and safety protocols. Further, as PDHM would not need to be transported from interstate, the complexity of the cold chain would be reduced, lessening the risks of improper storage and potential contamination during the transport process.

The PATH Framework suggests that a benefit of establishing a milk bank can be the creation of an overarching lactation service of which a milk bank is merely a part. Therefore, an in-house milk bank may contribute to an increased focus on lactation support in CH, in addition to the full time lactation consultants currently employed at the CH.

A milk bank housed within CH could utilise existing staff and services for donor screening and PDHM processing.

* Note: these figures are estimates only and do not include full overhead or depreciation; final figures would be subject to final implementation requirements and costing.

Disadvantages

A challenge of establishing a milk bank in an ACT hospital would be locating the necessary space to run such a service.

Community setting

A community-based milk bank could continue ensuring a supply of PDHM to the CH NICU, while also acting as a community lactation support centre (PATH, 2019). A community-based milk bank in the ACT could potentially be housed in an existing CHS community clinic, subject to identifying a suitable site.

Benefits

A milk bank established specifically outside of a hospital setting would have the benefit of potentially reaching more families under the overarching function of a lactation centre, as outlined in the PATH Framework. Further, a community-based milk bank could have the advantage of increased community exposure and as a result, increased donation rates. Better visibility would also send a strong public message regarding the ACT's commitment to supporting infant health, particularly given the historically positive portrayal by local and national media of milk banking and the provision of PDHM to infants in need.

Disadvantages

The core requirements for establishing a community-based milk bank would be the same as a hospital-based milk bank in terms of the extensive setup requirements, outlined above.

A key disadvantage of placing an ACT milk bank in the community rather than a hospital would be the additional need for packaging, transportation and delivery to the NICU. However, the CH NICU does currently receive delivered PDHM and CH staff are familiar with these protocols. Regardless, this process would incur additional costs, in particular staff to package and receive PDHM, a transport vehicle and driver, and a temperature tracking system to ensure the cold chain has been preserved.

Option 3 – Establishing ACT milk collection service

Overview

There are several options for enabling ACT women to donate breast milk in the ACT, outside of establishing a milk bank in the ACT. Costs are dependent on the relevant option.

1. Red Cross monthly collection

The Red Cross could arrange to collect breast milk from ACT women in their homes, as currently occurs in NSW. This would involve Red Cross staff visiting the home, collecting a blood sample, collecting milk, conducting screening and providing lactation support. This would be suitable for a situation such as **Scenario A**, which models a need of roughly 160 litres per year.

2. Red Cross dedicated collection service

The Red Cross could employ, train and keep local collection staff. This would be suitable for a situation such as **Scenario C** or **D**, which model higher volumes of donations and use of PDHM. However, there is limited research to support use of PDHM in these scenarios.

Benefits

A key aspect of the community demand for an ACT milk bank is to benefit women in the ACT and surrounding region an opportunity to donate their excess breast milk to infants in need. An ACT collection setup would meet this demand while the ACT continues to source PDHM through an existing milk bank.

Disadvantages

A potential consideration that may be publicly viewed as a disadvantage is that while women in the ACT region could donate breast milk, there would be no guarantee that their donated milk would be received by an infant within the community. Further, there may be public discontent that while there would be an opportunity to donate, women in the ACT region may not have the opportunity to receive PDHM by request, given current clinical guidelines for PDHM eligibility. However, this opportunity is very rare on a national level regardless, given most milk banks in Australia only provide PDHM predominantly to premature infants in a NICU setting. Therefore a public health messaging campaign may be necessary in order to educate the public regarding the standard uses, benefits and eligibility requirements of PDHM, if the decision is made to continue providing PDHM in accordance with these requirements.

Another disadvantage of the establishment of a collection service in the ACT is that the Red Cross Milk Bank are currently oversupplied with donors. However, the Red Cross Milk Bank will be investigating options for expanding eligibility criteria for receiving PDHM, which may allow the organisation to accept additional donors. As donor milk collection is only needed to meet existing demand, it is important that if such a service was created in the ACT, the community understands that opportunities to donate will be limited by demand.

Cost

Model 1 – Monthly collection by the Red Cross (Scenario A)

A monthly milk collection service in the ACT, run by the Red Cross Milk Bank, is estimated to cost approximately **\$0.010 - \$0.015 million per annum**. This would be appropriate to meet the demands outlined in **Scenario A**. This would be in addition to the cost of PDHM supply, discussed earlier in this paper. Including the cost of supply, the total cost would be approximately **\$0.065 million per annum**.

Model 2 – Red Cross operating a dedicated ACT collection service (Scenarios C and D)

A dedicated local collection service, operated by the Red Cross Milk Bank, is estimated to cost approximately **\$0.300 – 0.350 million per annum** based on **Scenario C** (1,000 litres per year). For meeting the requirements of **Scenario D** (2,300 litres per year), this service would cost approximately **\$0.600 million per annum**. These costs would be inclusive of PDHM processing and supply by the Red Cross Milk Bank.

Table 6: Summary of estimated costs for an ACT milk collection service*

Model	Cost
<p>Model 1 (Monthly collection by the Red Cross) – appropriate for Scenario A</p> <p><i>Scenario A is modelled on the provision of PDHM to infants under 32 weeks or 1500 grams</i></p> <p><i>Total includes collection, processing and supply of 160 litres per year</i></p>	<p>Collection - \$10,000 - \$15,000 per annum</p> <p>Supply (as per Scenario A supply costs): \$50,000</p> <p>Total cost per annum: \$60,000 – \$65,000</p>
<p>Model 2 (Red Cross operating dedicated ACT collection service), covers Scenario C and Scenario D</p> <p><i>Scenario C is modelled on the provision of PDHM to all pre-term infants up to 36 weeks</i></p> <p><i>Scenario D is modelled on the provision PDHM to any infant in the first few days of life</i></p> <p><i>Total includes collection, processing and supply</i></p>	<p>Scenario C (1,000 litres per year)</p> <p>Total cost per annum: \$300,000 – \$350,000</p> <p>Scenario D (2,300 litres per year)</p> <p>Total cost per annum: \$600,000</p>

* Note: these figures are estimates only and do not include full overhead or depreciation; final figures would be subject to final implementation requirements and costing.

Summary of all options

Table 7 summarises the benefits, disadvantages and costs of all options considered, and outlines the different PDHM distribution scenarios used to calculate costs.

Table 7: Summary of options for the ACT

Option	Benefits	Disadvantages	Cost
<p>1. Maintain PDHM supply from external sources (Red Cross Milk Bank transition).</p> <p>- Currently sourced from smaller organisation <i>Mothers Milk Bank</i></p> <p>- Would continue providing solely to CH NICU unless otherwise negotiated</p> <p>Eligibility scenario for cost modelling:</p> <p>A – 160 litres per year (supplied to vulnerable preterm infants in CH NICU)</p>	<ul style="list-style-type: none"> - Lowest cost - Quality assurance - Daily deliveries means less chance of wastage - Secure supply - Potential ease of adhering to future national standards - Adheres to best practice for recipient eligibility/nationally consistent 	<ul style="list-style-type: none"> - More expensive per litre than current supplier - May not allow PDHM supply to CPHB (unless negotiated) 	<p>Setup: \$0</p> <p>Annual: \$50,000</p> <p>Total (first year): \$50,000</p>
<p>2. Establish a milk bank in the ACT (hospital or community based)</p> <p>Eligibility scenarios for cost modelling:</p> <p>A – 160 litres per year (supplied to vulnerable preterm infants in CH NICU)</p> <p>C/D - 1,000 to 2,300 litres per year (supplied to pre-term infants up to 36 weeks, or all infants in need in the first few days of life)</p>	<p><u>General</u></p> <ul style="list-style-type: none"> - Would allow opportunity for donation - Increased sense of community inclusion - Potential research opportunities <p><u>Hospital specific</u></p> <ul style="list-style-type: none"> - Less risks due to no transport required - Increased lactation support at CH - Possibility of utilising some existing staff/equipment 	<p><u>General</u></p> <ul style="list-style-type: none"> - Significant set up requirements (space, equipment, staff, protocols) - Risk of supply - Potential for women to prefer to not donate due to anonymity requirement - Potential community dissatisfaction around eligibility of PDHM recipients <p><u>Hospital specific</u></p> <ul style="list-style-type: none"> - Locating the space required <p><u>Community specific</u></p>	<p><u>Scenario A – 160 litres</u></p> <p>Setup: \$730,500 Annual: \$168,421</p> <p>Total (first year): \$898,921</p> <p><u>Scenario C/D – 1,000 to 2,300 litres</u></p> <p>Setup: \$1,010,500 Annual: \$650,036</p> <p>Total (first year): \$1,660,536</p>

Option	Benefits	Disadvantages	Cost
	<u>Community specific</u> - Potential for bigger reach/visibility if outside of hospital	- Need for packaging and transport to hospital	
3. Establish an ACT PDHM Collection Service <i>-Collection of milk only, in partnership with Red Cross</i> <u>Total cost includes collection, processing and supply</u> Two models of operation <u>Model 1:</u> Red Cross monthly collection <u>Model 2:</u> Red Cross dedicated local collection service Eligibility scenarios for cost modelling: A – 160 litres per year (supplied to vulnerable preterm infants in CH NICU) C - 1,000 litres per year (supplied to pre-term infants up to 36 weeks) D – 2,300 litres per year (all infants in need in the first few days of life)	- Lowest cost option for allowing local women the opportunity to donate milk - Red Cross Milk Bank can be commissioned to run service, with two possible models dependent on anticipated or desired donation supply	- No guarantee that milk donated in the ACT would be provided to ACT infants - Red Cross currently have enough donors (oversupply) - Potential community satisfaction that no opportunity to receive beyond current requirements (if current requirements maintained)	<u>Model 1:</u> (Scenario A – 160 litres) Collection only: 10 - \$15,000 Supply (as outlined in Option 1): \$50,000 Total (first year): \$60,000 – \$65,000 <u>Model 2:</u> (Scenario C – 1,000 litres) Total (first year): \$300,000 – \$350,000 <u>Model 2:</u> (Scenario D – 2,300 litres per year) Total (first year): \$600,000

Note: these figures are estimates only and do not include full overhead or depreciation; final figures would be subject to final implementation requirements and costing.

Other considerations

Community expectations

Consultation with community stakeholders has found that the consistent public health messaging of “breast is best” is taken very seriously by many in the community. In particular, the evidence of the clinical benefits of mother’s own milk in comparison to formula feeding is well regarded and understood. In a highly educated population such as the ACT, parents are often particularly well-informed on the science around breastfeeding.

Community stakeholders have pointed out that perhaps as a result of this public messaging, or perhaps from an inherently biological instinct, some mothers may develop strong feelings of inadequacy if they are unable to breastfeed their child as originally intended. These reports are supported by studies which have found that the public health framing of the “breast is best” message can lead to feelings of shame and failure in mothers struggling to breastfeed (Wolf, 2007; McIntyre, Griffen & BrintzenhofeSzoc, 2018). Some mothers may be especially reluctant to feed their child with formula in situations in which breastfeeding has presented difficulties. In such cases, parents may seek an alternative supply of human breast milk for their child – through informal sharing arrangements, or even through a human milk bank.

This reported phenomenon aligns with research on common reasons for engaging in informal breast milk sharing (Palmquist et al. 2019). To the community, the perceived meaning of “breast is best” can include not just MOM but any human breast milk – whether it be fed directly from a known donor, supplied frozen from an altruistic stranger, or obtained in a pasteurised form from a human milk bank. As an example, a recent petition in the ACT calling for the establishment of a breast milk bank in the ACT, which gained close to 2,000 signatures, suggested the need for such a service lay in the inability of a range of parents to provide human breast milk for their child. Demonstrated community support for this reasoning could suggest two things:

- that the provision of breast milk to an infant can sometimes be seen by community members as an inherent right; and
- that pasteurised donor human milk (PDHM) is equivalent in benefit to MOM.

The first statement is beyond the scope of this investigation, however the second, which has been confirmed by key stakeholders as a common perception within the community, is further explored below.

Mothers own milk vs pasteurised donor human milk

Pasteurised donor human milk (PDHM) is currently only clinically indicated for use in very low birthweight preterm infants. This is acknowledged by both the WHO and the recently released Australian Breastfeeding Strategy (WHO, 2011; Australian Government, 2019).

Preterm and underweight infants are at an increased risk of necrotising enterocolitis, an inflammation of the gut lining which leads to malabsorption and in many cases, death (Lin & Stoll, 2006). A Cochrane review has found that provision of PDHM to very low birth weight preterm infants is protective against both necrotising enterocolitis and sepsis when compared to preterm infants

receiving only formula (Quigley, Embleton & McGuire, 2019). However, use of PDHM in this population results in decreased linear growth, head circumference and weight gain when compared to formula or mother's own milk (MOM) (Quigley, Embleton & McGuire, 2019).

Therefore, the scientific consensus is that while PDHM should be provided to vulnerable premature and underweight infants for its protection against necrotising enterocolitis, it should be fortified with an appropriate fortifier to counteract the effect of decreased growth (Arslanoglu et al. 2013). Due to the severe economic impacts of necrotising enterocolitis, cost benefit analyses have confidently demonstrated that provision of PDHM to vulnerable preterm infants results in considerable savings to the health system – a study estimated a saving as large as \$8167 USD per infant from reduced NEC through the provision of PDHM in NICUs (Ganapathy, Hay & Kim 2012).

As healthy infants born at full term are not at significant risk of necrotising enterocolitis, PDHM continues to be provided in Australia predominantly to vulnerable preterm infants in a NICU setting. As yet, there is no existing evidence or cost benefit analysis that examines the potential clinical benefits or disadvantages of providing PDHM instead of formula to healthy babies in situations where MOM is not available.

Key differences between MOM and PDHM

The most commonly employed method of PDHM processing is Holder pasteurisation, in which milk is heated to 60°C for 30 minutes, in order to eradicate pathogens and eliminate the risk of infection (Peila et al. 2017). The clinical benefits of human milk have been widely studied. The beneficial components of human milk include the balanced range of immune cells, bioactive proteins, oligosaccharides, immunoglobulins, cytokines and a range of nutrients (Walker, 2010).

Several studies have examined the effects of Holder pasteurisation on human milk. Although some elements are preserved throughout the pasteurisation process, many compounds and proteins considered responsible for the beneficial effects of MOM are either heavily reduced or entirely obliterated. This includes lactoferrin, immunoglobulin A, cellular components and probiota (Haiden & Ziegler, 2016). However, the potential deleterious impacts that deactivation of these critical bioactive proteins may have is not yet well studied in the context of providing PDHM to well babies.

In addition to pasteurisation, the storage and freeze thaw cycle processes have been demonstrated to reduce the benefit of PDHM. In particular, milk transfer between containers can reduce the concentration of fat in the milk, due to surface adherence to the original container. The freezing process has also shown to reduce levels of important anti-infective and immunomodulatory component lactoferrin (Meier, Patel & Esquerra-Zwiers, 2017).

Finally, an important difference to note is that the nutritional properties of breastmilk vary greatly depending on the period of time elapsed since birth when the milk is expressed. It is theorised that this is to match the specific nutritional needs of the infant dependent on their age (Meier, Patel & Esquerra-Zwiers, 2017; Perrone et al. 2019). In practice, this means that the breastmilk of a mother nursing a 6 month old infant is nutritionally distinct from a mother a couple of weeks postpartum. As the age of the infants nursed by donor mothers most often do not align with the infants receiving PDHM, this adds further variation between the nutritional needs of the receiving infant and the nutritional profile of the PDHM (Martin, Ling & Blackburn 2016).

While research continues to progress on improved or alternative human milk processing techniques, until these processes are elucidated and adopted it is crucial that PDHM and MOM are not conflated to be considered of equivalent protective benefit to infant health. Public discourse, including that which has surrounded the call to investigate the establishment of a milk bank in the ACT, has not acknowledged the distinction between the clinical properties of PDHM and MOM.

In CH the distribution of PDHM occurs through medical recommendation, in alignment with set criteria reflecting infants most at risk of necrotising enterocolitis, although discretion may be used dependent on individual circumstances.

Informal milk sharing practices

Informal milk sharing (informal sharing), or peer to peer sharing as it is also known, is the practice in which parents seek and supply unpasteurised breast milk to another member of the community through private arrangements. Informal sharing is a growing phenomenon, theorised to be due to the increased access to social media communication channels. While the prevalence of informal sharing has not been estimated, a notable portion of Australian women are known to participate in this practice, given the number of active Australian-based informal sharing networks. Informal sharing has also been acknowledged in position statements by the Australian Breastfeeding Association and Australian College of Midwives. While acknowledging that this practice is increasingly popular, these statements note the inherent risks and recommend parents make efforts to educate themselves to reduce safety risks to their child (ABA 2011; ACM 2014).

International and national community organisations such as Eats on Feets and Human Milk 4 Human Babies (HM4HB) have sprung up over the last several years, aiming to facilitate sharing networks which connect women seeking or supplying breast milk. In the ACT, the main public peer sharing network is a Facebook group established by HM4HB, which currently includes over 1,300 members. Informal sharing also occurs privately through interpersonal relationships, between family, or friends.

Importantly, the evidence vastly demonstrates that informal milk sharing is rarely done anonymously (not including the few occurrences of private breast milk sales in the United States), meaning that a personal relationship, often lasting, arises from participation in informal sharing practices (Palmquist et al. 2019).

Informal sharing activity in the ACT

Based on activity measured on the HM4HB ACT Facebook Group over the last 12 months:

- 52 separate women offered to donate milk;
- 22 separate women advertised that they were seeking milk;
- requests for milk were more likely to receive a response than an offer of milk (60% vs 77% response rate respectively);
- offers of donations included frozen expressed breast milk, frozen colostrum, and on occasion offers to be an ongoing donor;
- the average amount of frozen expressed milk offered per individual woman was 2.75 litres; and

- requests for milk occasionally included specific dietary requirements – for example soy free or vegan.

Reasons for informal sharing practices

Evidence demonstrates that parents engage in informal sharing for a variety of reasons, however a recurring theme is that this type of milk sharing is sought when mothers with a strong drive to breastfeed their child are facing difficulties with continuing or commencing lactation (McCloskey & Karandikar, 2019; Schafer, Ashida & Palmquist, 2018). For these mothers, donor milk is considered the next best option, due to the perceived health protections conferred when compared to feeding supplementation with formula. One study has observed that mothers choosing to seek informally sourced milk from peers often do not seek advice from health professionals, preferring to conduct their own research on the risks and benefits of peer sharing (Cassar-Uhl & Liberatos, 2018). Of significant interest, mothers who engage in informal sharing are more likely to continue breastfeeding for longer than mothers who instead opt for formula supplementation when faced with lactation difficulties, suggesting that the ability to continue providing a human milk based diet to their child is a motivating factor to overcome lactation barriers (Cassar-Uhl & Liberatos, 2018).

While many studies on infant feeding practices focus predominantly on the infant, several studies have documented that the psychosocial wellbeing of the mother is an important factor for health professionals and policy makers to consider when examining the risks and benefits of informal sharing networks. In particular, participation in informal sharing practices may mitigate a risk of post-partum depression in women who have mentally committed to provide their child with human milk, but have been unable to reach their breastfeeding goals (McCloskey & Karandikar, 2019). Stigma, lack of appropriate lactation support and lack of guidance from healthcare professionals can all contribute to feelings of stress in mothers and also contribute a lack of willingness to disclose infant feeding practices – for example participation in peer sharing (Schafer, Ashida & Palmquist, 2018).

Risks of informal sharing

Wet nursing, the practice of direct feeding of an infant by a woman who is not the mother, has long been an accepted practice in many countries. However, the appearance of HIV as well as the progression of scientific understanding in disease transmission has changed the narrative in Western countries, so that peer sharing is now much less accepted or understood (Thorley, 2008). The inherent risks in peer sharing include disease transmission of viruses, bacterial contamination from improper storage and freezing processes, and the unknown lifestyle factors of the donating mother, as undesirable elements of certain dietary, environmental and medication factors can be transmitted in breast milk. However, research has shown that milk exchanged in these practices is predominantly stored appropriately, with low risk of bacterial contamination (Reyes-Foster, Carter & Hinojosa, 2017).

In New Zealand, one jurisdiction has dealt with the tension between the risks of informal sharing and the right to autonomy of the parent by the publication of an information sheet called “Sharing Breastmilk: What you need to know” (Waitemata District Health Board, 2017). This information sheet is directed towards parents and describes the risks of peer sharing, as well as recommending the appropriate steps that a parent seeking to source informally shared milk should take in order to

mitigate this risk, such as screening and blood testing of the donor. This approach emphasises informed consent and empowers parents to make educated choices in relation to infant feeding that are appropriate to their circumstances.

Peer sharing in a hospital setting

Due to the known risk for breastmilk to transmit disease, most Australian hospitals, including CH and CPHB, do not permit women to bring in breast milk other than their own. In practice, anecdotal reports suggest that this still occurs. It appears “common knowledge” that for mothers to provide informally shared milk to an infant in hospital, they must claim it as their own to prevent disposal. In reality, women feeling pressured to be clandestine about their preferred feeding choices is not a desirable outcome for hospitals, particularly if the hospital intends to advocate a supportive breastfeeding policy.

Some hospitals in Australia have recognised the desire for women to provide informally shared breast milk to their infant in certain circumstances while hospitalised, and developed protocols to allow this to occur under supervision of the hospital. For example, one Australian hospital requires mothers wishing to provide informally shared donor milk to their infant to firstly discuss this decision with a lactation specialist. The specialist will request the donor be screened via a blood test, and the parent is required to sign a waiver acknowledging that they are aware of the risks.

The Australian College of Midwives support such a protocol, through their Position Statement on the Use of Donor Human Milk (ACM, 2014). This statement recognises that where a formal procedure of donated human milk is not available, it may be an acceptable and cost effective process to consider the use of donors known to the mother for the provision of a directed donation of breastmilk, which should only occur with proper precautions and testing and the assurance of informed decision-making by the recipient mother and donor.

Regulation

The regulatory status of PDHM varies between different Australian jurisdictions. PDHM tends to be classified as either human tissue, food, or a therapeutic good. In the ACT, there is no clear regulatory status, however PDHM would most likely be regulated under the *Transplantation and Anatomy Act 1978*.

If the ACT Government decides to establish a local milk bank, it would be prudent to first determine which legislation would be the preferred governing regulatory mechanism, noting that different benefits and risks may present depending on the classification. For example, regulation of PDHM as a food, such as in NSW, may technically allow PDHM to be sold as a tradeable product, as currently occurs in some jurisdictions in the United States of America (David, 2011). Classification of PDHM as a tissue, such as in WA, may have additional ethical implications for PDHM donation, distribution and usage. A comprehensive outline of regulatory considerations and implications relating to PDHM are included in the Commonwealth Government’s *Donor Human Milk Banking in Australia – Issues and Background Paper* (Department of Health, 2014).

Breastfeeding support services

Stakeholder consultations and a review of the literature have both demonstrated overwhelmingly that the establishment of a milk bank should only be secondary to the primary overarching goal of adequate lactation services and supports in the community. While PDHM is clinically indicated for a small subset of vulnerable infants, there is not yet evidence to demonstrate that it is an adequate alternative to MOM in well infants. Therefore, provision of enhanced lactation support to the community, rather than making PDHM widely available, could be prioritised.

Both CH and CPHB are accredited as Baby-friendly by the Baby-Friendly Health Initiative (BFHI). While both CH and CPHB possess trained lactation consultants, consultations suggest that additional resourcing and staffing under a dedicated service could be effective in order to reach more women and demonstrate that breastfeeding as an important health priority in the ACT. For example, midwives and nurses wishing to gain further training in lactation support in some circumstances may be responsible for funding their own training fees, which can be considerable. The offer of subsidised lactation support training to appropriate staff in all public maternity wards in the ACT could be considered as a straightforward avenue for increasing capacity and competency in this important area.

Additionally, consultations suggest that a mechanism for ensuring that the lactation support offered in a hospital setting is maintained upon the mother's transition to the community is highly desired. While Maternal and Child Health Clinics in the ACT can offer lactation advice mainly in the form of group sessions, there is no obvious avenue for ACT women to obtain one-on-one lactation counselling and support through the public system, despite this being a common service available in other jurisdictions.

There is strong evidence to suggest that many of the barriers faced in breastfeeding are surmountable, if the right supports are given (Meier et al. 2017; Meier, Patel & Esquerra-Zwiers, 2017; Smith et al. 2018). Given the ACT's acknowledgment of the unique health benefits of breastfeeding, as detailed in the motion passed by the Legislative Assembly in October 2018, enhanced community access to central and consistent lactation support services could be considered.

Research

The Australian Red Cross has been funded by the Commonwealth Government to commence research into the benefits of expanding the current eligibility criteria used by most Australian hospitals receiving PDHM (premature infants born at less than 32 weeks or weighing less than 1500 grams). Potential scenarios to be examined include Scenario C and Scenario D outlined in the Options section of this report. This study may examine two cohort of infants, one receiving PDHM, and one formula, with the aim of measuring the benefits of providing PDHM instead of formula in these groups.

The current public interest in this issue could allow an opportunity for the ACT to partner with the Red Cross and participate in planned research, ultimately assisting in overcoming the current lack of literature examining the use of PDHM in wider population groups.

Final recommendations

1. Based on available evidence, the current eligibility criteria for the distribution of pasteurised donated human milk (PDHM) is appropriate.
2. There is lack of evidence to support expansion of this eligibility criteria.
3. Current arrangements (and also proposed arrangements to access PDHM from a national supplier) for the estimated need of PDHM in the ACT are appropriate, cost effective and ensure (and proposed arrangements will also ensure) access and availability of PDHM when clinically indicated.
4. Development of a local Milk Bank is not a cost-effective option for the ACT at this stage when access and availability of PDHM for agreed eligibility criteria is not at risk or is a concern.
5. A number of Canberrans have a desire to donate human milk to a milk bank. The milk bank provider should be informed about their desire to donate. If there is need for human milk collection by the milk bank, the desire of Canberrans to donate human milk to the milk bank should be facilitated.
6. Should new evidence emerges that demonstrates a clinical benefit for the supply of pasteurised human milk for an expanded eligibility criteria, the ACT should conduct another feasibility investigation into establishing a local milk bank.
7. The ACT invests resources into education for local mothers regarding the indications and appropriate use of PDHM.
8. The ACT supports research into development of evidence in relation to appropriate use of PDHM.
9. That the ACT develops clear policies, protocols and information sets to educate regarding the risks of informal milk sharing with the aim to minimise these practices and therefore the associated risks.

Consultation list

Table 8: List of key stakeholders consulted

Organisation	Role	Consulted
ACT Health	Budget Development Officer	September 2019
ACT Health	Chief Medical Officer	July - October 2019
Australian Breastfeeding Association	Administration Manager ACT/NSW	September 2019
Australian National University	PhD Candidate	August 2019
Calvary Public Hospital Bruce	Senior Midwife Consultant	September 2019
Canberra Health Services	Acute Support Nutrition Manager	August 2019
Canberra Health Services	Clinical Director Neonatology	June - October 2019
Canberra Health Services	Lactation Consultant	September 2019
Canberra Health Services	Nutrition Technician	September 2019
Canberra Health Services	Maternal and Child Health Clinical Nurse Manager	October 2019
PREM Milk Bank	Manager	July 2019
Queensland Milk Bank	Director	July 2019
Red Cross Milk Bank	Integration Manager & Milk Product Owner	September 2019
Royal Hospital Hobart	Senior Lactation Consultant	October 2019
Royal Women's Hospital, Melbourne	Clinical Midwife Consultant	August 2019

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