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Best practice guidelines for the operation of a donor human milk bank in an Australian NICU

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Abstract

Until the establishment of the PREM Bank (Perron Rotary Express Milk Bank) donor human milk banking had not occurred in Australia for the past 20 years. In re-establishing donor human milk banking in Australia, the focus of the PREM Bank has been to develop a formal and consistent approach to safety and quality in processing during the operation of the human milk bank. There is currently no existing legislation in Australia that specifically regulates the operation of donor human milk banks. For this reason the PREM Bank has utilised existing and internationally recognised management practices for managing hazards during food production. These tools (specifically HACCP) have been used to guide the development of Standard Operating Procedures and Good Manufacturing Practice for the screening of donors and processing of donor human milk. Donor screening procedures are consistent with those recommended by other human milk banks operating internationally, and also consistent with the requirements for blood and tissue donation in Australia. Controlled documentation and record keep requirements have also been developed that allow complete traceability from individual donation to individual feed dispensed to recipient and maintain a record of all processing and storage conditions. These operational requirements have been developed to reduce any risk associated with feeding pasteurised donor human milk to hospitalised preterm or ill infants to acceptable levels.

Contents

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1. Introduction

Low initial birth-weight and accelerated weight gain after birth have been recognised as risk factors for later disease [1] and developmental origins of adult disease, such as these, have become important concepts in medical research [2]. Neonatologists continue to make considerable progress in life supporting techniques, particularly in the treatment and prevention of respiratory disorders leading to higher neonatal survival rates and increased survival of very low birth-weight infants. This has necessitated the provision of nutrition that is both adequate and as natural as possible [3]. Both governmental and medical professional organisations have strongly recommended breastfeeding for all infants acknowledging benefits with respect to infant nutrition, gastrointestinal function, host defence and psychological wellbeing [4]. As such, extraordinary efforts are made to encourage and support mother's own milk feeding in neonatal intensive care units (NICU's) internationally. However, mothers of preterm infants, in particular, face many challenges in providing sufficient milk for their child during hospitalisation [3]. This may be due to maternal illness, difficulties in establishing or maintaining lactation or, particularly relevant in the Australian context, geographic isolation. Thus, there are a population of preterm infants who must be fed by an alternative source of nutrition to their own mother's milk.

The use of pasteurised donor human milk (PDHM) as an alternative to artificial formula when mothers own milk (MOM) is unavailable is not a new concept. A number of studies have demonstrated reduced risk of necrotising enterocolitis (NEC) [5] and late-onset sepsis (LOS) [6] in preterm infants fed PDHM compared to formula. However, many neonatologists remain cautious in their support for PDHM due to concerns about the transmission of viruses and/or pathogens and its nutritional adequacy for preterm infants [7,8]. And certainly, when intrauterine growth rate and nutrient accretion are the primary end points of experimental comparisons, both unfortified PDHM and unfortified MOM feeding of preterm neonates often may not achieve desired rates when compared to preterm formula and human milk fortified with non-human derived nutrients [7]. However, artificial formula manufacturers have recently acknowledged, "Formula or cow's milk is low in functional components and can never be fortified to match breast milk" [9]. Given that artificial formula cannot provide many of the benefits beyond basic nutrition (with weight gain as the primary goal) in preterm infants, it is essential that medical researchers provide a better alternative to artificial formula when a mother's own milk is unavailable.

Given the difficulty in replicating the complexity of breastmilk by artificial means, the enormous volumes of human milk discarded by mothers who are producing more milk than their infant requires becomes an incredibly valuable resource. However, it is only valuable if it can be provided safely in terms of both infection control and nutritional adequacy. Indeed, Modi [8] questions the unregulated expansion of donor human milk banking due to the lack of evidence of benefit from randomised controlled trials, and concerns of the imprecise science of fortification of human milk. However, there is risk of greater harm by abandoning donor human milk banking in the short term. Particularly when the proper management and operation of a donor human milk bank can address these concerns, and such milk banks can serve as a focus for research to achieve a better understanding of the nutritional needs of preterm infants.

In this context, the Perron Rotary Express Milk Bank (PREM Bank) has been established at King Edward Memorial Hospital for Women in Western Australia. The NICU comprises 105 cots across 2 campuses (also Princess Margaret Hospital for Children). Based at the only tertiary care maternity hospital in the State, the NICU and PREM Bank service a population of approximately 2.1 million. As the first donor human milk bank to be established in Australia for almost 20 years, best practice guidelines have been developed to address quality, safety and Good Manufacturing Practice during donor human milk banking. It is intended that these guidelines form the basis for the development of National standards for the operation and management of donor human milk banks in Australia. Initially, the scope of these guidelines covers the provision of pasteurised donor human milk to preterm or ill, hospitalised infants, as it is felt that this population represented the greatest need.

The aim of this paper is to define the management strategies and methods of screening donors and processing donor human milk required to re-establish donor human milk banking in Australia. These strategies support the aim of the PREM Bank, which is to provide a safe, nutritionally adequate alternative to artificial formula for feeding preterm or ill infants in Western Australia.

2. Quality management of donor human milk banking

2.1. Good Manufacturing Practice and Hazard Analysis Critical Control Point (HACCP)

To achieve a particular quality objective there must be an appropriately designed and implemented management plan to provide quality assurance. This must be fully documented and its effectiveness monitored. It is not the intent of this paper to provide an exhaustive list of every Standard

Operating Procedure developed for the operation of the PREM Bank, but rather, a definition of the principles adopted from similar operations and industries to ensure quality standards are achieved. Where applicable, specific examples will be given. When assessing the risks associated with a food production process, the likelihood or probability of the risk occurring must be considered in combination with the significance should that risk occur (AS/NZS 4360:1999). Although the risk of the transmission of infectious agents through donor human milk feeding is far less likely than through blood transfusion, the significance should such transmission occur remains the same. Internationally, human milk banks have responded to the risk of the transmission of infectious agents through donor human milk by developing donor screening questionnaires and blood testing based on the requirements for blood and tissue donation and human milk processing methods adapted from the dairy industry [10,11]. Without internationally or nationally recognised guidelines for the operation of human milk banks, individual banks must develop their own quality standards. Currently, the existing legislation in Australia does not specifically recognise human milk as either a food, or to have a therapeutic purpose. Therefore, like many human milk banks, government does not formally regulate Australian human milk banks under specific legislation. Human milk banks operating in Australia must therefore, be committed to the highest standard of self-regulation that is practically and scientifically warranted.

In practice, the PREM Bank has adopted Good Manufacturing Practices from similar industries where appropriate (e.g. Australian Code of Good Manufacturing Practices for Medicinal Products, Therapeutic Goods Administration, August 2002) and utilised internationally recognised hazard management tools (e.g. HACCP) used in the food industry to develop Standard Operating Procedures for the operation of a Human Milk Bank. HACCP is a system to identify, evaluate and control hazards that are significant for food safety. There are twelve steps that must be applied when conducting an HACCP.

1. Assemble multidisciplinary HACCP team
2. Describe product/process
3. Identify the intended use/consumer
4. Construct a flow diagram of process
5. On-site verification of flow diagram
6. List potential hazards, conduct hazard analysis and determine control measures
7. Determine Critical Control Points (CCP's)
8. Establish critical limits for each CCP
9. Establish a monitoring system for each CCP
10. Establish corrective actions for deviations from critical limits
11. Establish verification procedures
12. Establish record keeping and documentation.

The scope of the HACCP prepared for the PREM Bank covers the receipt of raw donor human milk (RDHM) from the donor to dispensing milk to the hospital milk room for fortification (if required). The process steps involved within the scope of the HACCP are described in Fig. 1.

Potential hazards for each process step (see Fig. 1) were identified and defined as physical, chemical or biological. Control measures have been defined to remove or reduce to an acceptable level each of the identified hazards that were considered by the HACCP team to be significant. Critical Control Points were defined during donor human milk processing as steps where control can be applied and a food safety hazard prevented, eliminated or reduced to an acceptable level. For example, as human milk is not a sterile product, a degree of microbiological contamination is expected even when donors follow hygienic milk collection procedures. Human milk banks control this potential hazard by pasteurising donor milk before it is fed to recipients. This process step is therefore considered a Critical Control Point and as such the HACCP plan requires that critical limits be defined (i.e. acceptable temperature and time of heating during pasteurisation) and that these critical limits are monitored during processing. It is also a requirement that adequate documentation is established to verify each batch processed adheres to these critical limits. The specific critical limits and documentation requirements are defined in the appropriate sections of this paper.

2.2. Donor screening

There are no existing standards for the screening of human milk donors in Australia. There are however, evidence based guidelines for donor screening developed by the United Kingdom Association for Milk Banking [11] and Human Milk Banking Association of North America [10] that can be applied in the Australian context. The PREM Bank has committed to meeting these standards. Potential donors to the PREM Bank are also required to consent to a blood test. The specific panel of blood tests required by the PREM Bank are:

- HIV 1 and 2 antibody (anti-HIV 1 and anti-HIV 2)
- Human T cell Lymphotrophic Virus I and II antibody (anti-HTLV-I and anti-HTLV-II)
- Hepatitis C antibody (anti-HCV)
- Hepatitis B surface antigen (HbsAg)
- Hepatitis B core antibody (anti-HBc)
- Syphilis antibody.

These tests meet international recommendations for human milk banking [10,11] and the minimum standards for serological testing recommended by the Australasian Tissue Banking Forum [12]. It is PREM Bank policy that the results of the above tests are given to the donor in person, whether positive or negative. Potential donors are required to attend a follow up appointment to receive the results of the blood test and to receive a hospital grade breast pump and collection kit (thermally disinfected polypropylene bottles, collection instructions and donor ID labels). Donors who continue to donate for more than 3 months from the date of the initial blood test are required to consent to a repeat blood test. Milk collected during this period is quarantined until the results are known. In addition, under certain circumstances the PREM Bank will accept donations of previously expressed milk. Donors are screened in an identical manner, however, questions relating to the use of prescription medication, smoking and alcohol consumption etc. must be answered retrospectively. As many mothers leave the Special Care Nursery at discharge with a large store of previously pumped milk, much of which they cannot store, the PREM Bank is able to screen these mothers and accept large donations of

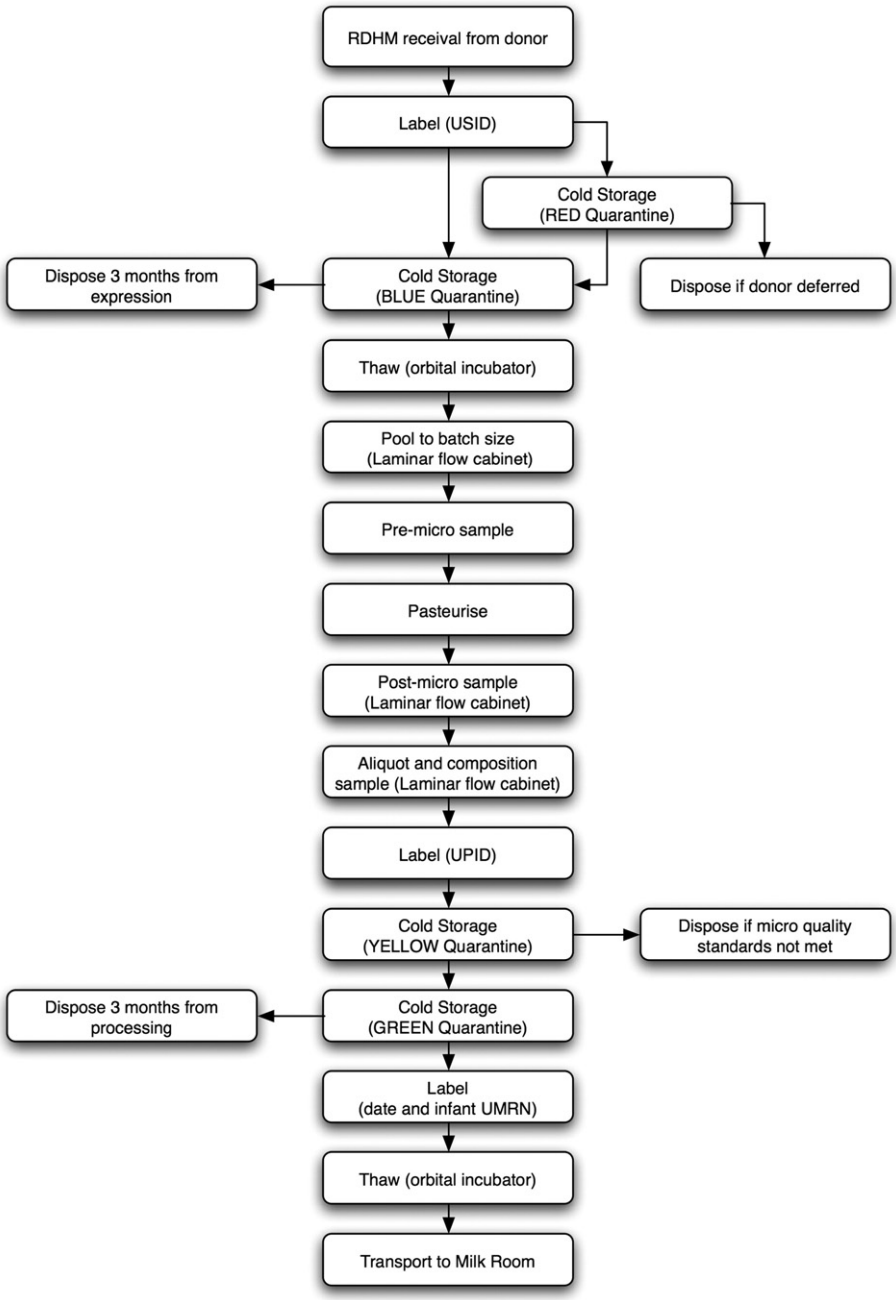

Figure 1 Flow diagram representing donor human milk storage and processing by the PREM Bank.

preterm milk which will be of more appropriate composition for the preterm infants receiving it. In the first six months of operation the PREM Bank has collected over 300 L of donor human milk, most of which has been donated by mothers who have given birth to preterm infants in the unit.

2.3. Milk collection and storage

Donors to the PREM Bank express and collect milk for donation at home, it is therefore important that specific and simple instructions are provided to donors regarding hygienic milk collection and appropriate storage. These instructions are consistent with existing hospital policy and international recommendations for human milk banking [10,11]. Donor mothers are given a written copy of instructions and a verbal explanation during the interview. Donors collecting milk at home are instructed to use collection bottles supplied by the PREM Bank. Raw donor human milk must be labelled with the donors ID sticker and the date of expression recorded on the bottle label. All milk should be immediately placed in the coldest part of the freezer (usually in the lower part to the rear of the freezer) and milk transported frozen to the PREM Bank. Any milk that is inappropriately labelled cannot be accepted by the PREM Bank and any milk that has partially thawed can only be accepted if greater than 50% of the milk volume has remained frozen and the surface temperature of

the bottle (measured with calibrated infra-red thermometer) remains 0 °C or below. The milk bank employee receiving raw product from a donor must record and initial that these product conditions have been met when logging individual bottles into PREM Bank freezer.

Raw donor human milk is stored frozen at −20 °C by the PREM Bank for a maximum of 3 months from the date of expression. This is consistent with international recommendations [10,11]. Once pasteurised, donor human milk may be stored frozen at −20 °C for a maximum of 3 months prior to being dispensed. Storage freezers are equipped with a power loss and high temperature alarm that is connected to the hospitals building management system. A Business Continuity Plan has also been developed to define an appropriate course of action to maintain a safe supply of pasteurised donor human milk in the event of a freezer (or other process equipment) mechanical failure or power loss.

2.4. Pasteurisation of human milk

International best practice requires that donor human milk must be pasteurised (heated to 62.5 °C for 30 min) prior to being fed to recipients [10,11]. The PREM Bank has committed to meeting this standard. All donor milk is pasteurised at 63.5 ± 1.0 °C for 30 min in a custom built flow-through batch pasteuriser (Saurin Pty Ltd). The pasteuriser is temperature calibrated to ±1.0 °C therefore, this temperature range ensures a minimum of 62.5 °C is obtained. An independently calibrated (NATA) temperature probe logs time and temperature of the product during pasteurisation. This data logger file is permanently maintained with the Batch Record. A batch of milk (600–3000 ml of milk from a single donor) is thawed rapidly in an orbital incubator and pooled into a sterile flask under a laminar flow cabinet. A pre-pasteurisation (1 ml) microbiology sample is taken prior to processing. Once pasteurised, PDHM is transferred to the laminar flow cabinet and post-pasteurisation microbiology (1 ml) and composition (8 ml) samples are taken. PDHM is then aliquoted into volumes required for dispensing to the NICU (14, 50 and 100 ml commercially sterile polypropylene containers).

The efficacy of any pasteuriser is dependent on both the pasteurising temperature and hold time and the time taken to heat and subsequently cool product. This will vary between pasteurisers. The custom built flow-through pasteuriser used by the PREM Bank has been subject to experimental validation prior to use. The efficacy of the PREM Bank pasteuriser at removing bacteria from donor milk while preserving the bioactivity of sIgA has been examined [13]. Effective bacterial removal was observed although a significant reduction in protein bioactivity was observed. Although secretory IgA bioactivity was reduced by 24.5% by pasteurisation, these functional components are not present in artificial formula.

As the first human milk bank to be established in Australia for almost 20 years, the PREM Bank is committed to meeting international guidelines for human milk banking. Currently, pasteurisation at 62.5 °C for 30 min is the most common technique employed [7] and thus, is the standard adopted. However, milk banks must be committed to developing novel techniques to process donor milk to ensure bacterial removal and viral inactivation while preserving the bioactive proteins present in human milk.

2.5. Microbiology methods and standards

When donor milk is under the control of the PREM Bank all processing and storage steps are designed to limit the possible proliferation or contamination of the product by microbiological organisms. All pooling and sampling of donor milk is conducted in a laminar flow cabinet using aseptic technique and all containers that come in contact with the product are commercially sterile. Product is stored at −20 °C to limit lipolysis [14] and microbial growth [15]. Prior to processing milk is rapidly thawed in an orbital incubator (37 °C, 150 rpm) until milk is just thawed (unpublished data has shown that the liquid product temperature at the surface of the bottle did not increase above 0 °C under these conditions). It is common practice for human milk banks to thaw product by submerging bottled donor milk in a water bath. Thawing product in an orbital incubator removes the potential hazard of product contamination due to water entering through the screw cap.

Donor human milk is examined bacteriologically both before and after pasteurisation. Critical limits have been defined for the level of contamination acceptable in raw and pasteurised product. These are required as pasteurisation may not be effective if milk is heavily contaminated [16]. In addition, although pasteurisation kills most organisms, the toxins produced by some bacteria may not necessarily destroyed by heat [16]. The PREM Bank's microbiological standards are based on those used by other human milk banks [11]. A 1 ml sample is taken using aseptic technique from pooled donor milk before pasteurisation (Fig. 1). A second 1 ml sample is taken prior to aliquoting the pasteurised product (Fig. 1). A 10 μL (pre-pasteurisation) and 200 μL (post-pasteurisation) sample are cultured on 5% horse blood and CLED (Cystine-lactose-electrolyte deficient) agar and incubated at 35 °C in 5% CO_2 overnight (18–24 h). Any bacterial growth is identified by standard microbiological techniques. Colony growth is also quantified.

Specific microbiology standards are published elsewhere [11], in general, the pre-sample must contain no potential pathogens capable of producing heat-stable enterotoxins, no Enterobacteriaceae nor enterococci, and no confluent growth of organisms indicating a total count exceeding 10^5 colony forming units per ml. Any bacterial growth in the post-pasteurised sample is unacceptable. Any batch not meeting these standards must be immediately removed from the PREM Bank quarantine freezer.

2.6. Record keeping

The PREM Bank has the operational objective of ensuring full traceability from individual donation to recipient and maintaining a record of all storage and processing conditions. Fig. 2 describes an overview of the record keeping system.

The Donor Record (Fig. 2) consists of the Donor's Unique Medical Record Number (UMRN), Consent and Medical History Questionnaire and Pathology results. This record has been established as a hospital medical record and as such will be maintained according to hospital policy. The Specimen Database (Fig. 2) maintains a log of individual donations made by a donor. Each bottle donated to the PREM Bank is given a unique specimen ID (USID) and the milk bank employee receiving the donation must ensure and record that product temperature and labelling is acceptable. The Specimen Database must also

Figure 2 PREM Bank records.

record when raw product is either processed or removed from the quarantine freezer. The Batch Record (Fig. 2) consists of, a record of the USID that are pooled to make up the batch, a record of the time and temperature of pasteurisation, and finally, a record of the microbiological screening results. Once pasteurised, the batch of milk is aliquoted into dispensing volumes, each bottle of pasteurised product is given a unique product ID (UPID) that is recorded on the product label, Batch Record and Product Database. The Recipient Record consists of the parents written consent for Pasteurised Donor Human Milk Feeds and a record of every UPID the recipient receives.

These records allow complete traceability from individual donation to recipient and maintain a record of all treatment conditions product is subjected to during processing. This gives the PREM Bank the ability to adequately respond to appropriate recipients in the event of a batch recall.

2.7. Standard Operating Procedures and document control

Consistent quality assurance requires a consistent approach and methodology. Complete and unambiguous documentation of all procedures is required to ensure consistency in achieving quality standards. The PREM Bank has developed Standard Operating Procedures for all operations undertaken during the collection, storage and processing of donor human milk. In addition to defining the requirements for screening donors and processing donor milk, these documents define the calibration requirements of equipment used during human milk banking, cleaning and sterilisation of equipment, business continuity and critical incident reporting. These procedures are essential for the safe operation of a human milk bank to comparable industry best practice standards. Annual re-evaluation of these procedures should consider efficiency and effectiveness and revision made where required [17]. An appropriate document control system is required to ensure any documentation outlining outdated procedures is removed from circulation.

2.8. Donor milk composition

One of the principal concerns current clinical practitioners' have regarding the use of pasteurised donor human milk is its nutritional adequacy in meeting the needs of preterm infants [7,8,18]. Donor human milk is usually obtained from women who deliver term infants later in lactation so milk composition is similar to the lower nutrient content found in mature milk [7]. The PREM Bank has been established as part of a 105 cot Special Care Nursery and NICU. A total of 47 batches of donor milk were pasteurised in the first 5 months of operation. Only two of these batches were donated by mothers' who gave birth to term infants. A sample from each batch was analysed by standard laboratory methods. Protein content was determined by BioRad Protein Assay, Lactose was measured by ABTS based colorimetric spectrophotometric assay and Fat by Esterified Fatty Acid Assay. The average composition of PDHM is listed in Table 1.

The composition of macronutrients in human milk donated to the PREM Bank during the first five months of operation is different to that reported by other milk banks. Other researchers have reported similar protein and lactose content [16], but lower fat (and consequently energy content) [16,19,20]. However, the composition of milk donated to the PREM Bank, has exhibited considerable variation (coefficients of variation for protein, fat and lactose of 24.52%, 21.54% and 8.93% respectively). As the majority of milk received by the PREM Banks has been donated by mothers who have given birth prematurely this has resulted in the 'richer' composition measured. Although preferentially accepting donations from the mothers of preterm infants may increase average composition of PDHM, the high variation in composition will continue to create difficulty in the clinical application of donor milk feeding. To ensure milk banks provide clinicians with the best possible tools to provide nutritional support to premature infants clinical research should focus on developing methods to provide a standardised composition of PDHM.

3. Conclusion

There is a long history of the safe operation of donor human milk banks internationally. Evidence is continuing to grow demonstrating the benefits of fortified human milk feeding of preterm infants, including the utilisation of pasteurised donor human milk [21]. Milk banks continue to attract criticism due to the variable nature of the macronutrient

Table 1 Macronutrient composition of pasteurised donor human milk

	PREM Bank composition of donor milk (mean ± SD)	Balmer and Wharton (1992) [16] (mean ± SD)	Almeida and Dorea (2006) [19] (mean ± SD)	Vieira et al. (2004) [20] (mean ± SD)
Protein (g/100 ml)	1.35 ± 0.33	1.2 ± 0.1	–	–
Fat (g/100 ml)	4.16 ± 0.90	2.2 ± 0.3	2.27 ± 1.32	3.0 ± 1.2
Lactose (g/100 ml)	6.71 ± 0.60	7.2 ± 0.2	–	–
Energy (Kcal/100 ml)	69.7 ± 8.7	51.8	52.9 ± 8.45	53.6 ± 7.2

composition of the end product and concerns regarding the transmission of infectious agents through donor milk [8]. The proper operation and management of human milk banks can largely address these concerns. There are existing evidence based guidelines describing the requirements for donor screening and human milk processing [10,11]. However, there are management practices and tools used by similar industries that can be adopted by human milk banks to maintain product quality and safety, including Good Manufacturing Practices and HACCP. Ongoing research is required to provide better tools for neonatologists to provide adequate nutritional support to preterm infants. It is clear that artificial formula will never provide the broad range of non-nutritive benefits of human milk. While there is a population of preterm infants whose own mothers are unable to provide sufficient breastmilk for their adequate nutrition there is an ongoing need for a safe, nutritionally appropriate alternative to mothers' own milk.

4. Key guidelines

- A Quality Management Plan incorporation Good Manufacturing Practices and an HACCP plan is an essential part of the operational planning for a human milk bank
- Fortification of pasteurised donor human milk should be consistent with hospital policy, however, donor human milk banks should endeavour to measure composition of major nutrients in PDHM (protein, fat and lactose) and short term clinical outcomes of recipient infants should be monitored as part of a Quality Audit.
- Australian milk banks must develop a network dedicated to standardising practice both nationally and internationally.
- Formal regulation of Australian human milk banks is encouraged.
- It is our opinion that human milk banking in Australia should operate on a not-for-profit basis and donors should not receive financial reimbursement for their donation.

5. Research directions

- Milk banks should actively research alternative methods of donor human milk processing including properly validated low temperature pasteurisation, HTST pasteurisation or novel techniques that are being developed by the food industry (e.g. pulsed electric field and UV sterilisation).
- Simple manipulations of fat and protein content of donor human milk may be technically possible using existing methods used by the dairy industry during food production. Research should be encouraged to develop practical methods to standardise the composition of major nutrients in donor human milk.

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