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Development and evaluation of formal guidelines for donor selection for breast milk banks

[original article]

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The authors do not have any conflict of interests to declare.

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Abstract

Introduction. Donor selection for milk banks is essential to ensure the safety and nutritional quality of the donor milk, and to ensure that the prospective donor and her breastfeeding infant do not come to harm through donating. Australian Red Cross Lifeblood Milk went through a robust process to develop a set of criteria for the selection and screening of potential breast

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milk donors, which included development of a Donor Questionnaire (DQ), supported by a formal set of Guidelines for the Selection of Milk Donors (GSMD). Key screening questions from the DQ were made available to prospective donors to self-screen prior to the formal assessment process.

Methods. We reviewed the outcomes of our donor screening process over the first 12-months (July 2018-June 2019) of operations.

Results. 50/327 donors who responded to the self-screening questions were not able to proceed further. 201 donors were formally screened using the DQ and GSMD, with 9/201 deferred based on their responses. An additional two donors were deferred (failed phlebotomy (n=1) and reactive infectious disease serology (n=1)), with 190/201 (95%) of prospective donors accepted after screening.

Conclusions. Our experience highlighted international differences in practice between milk banks and lack of strong research to inform milk donor selection.. Making a set of key screening questions available to donors for self-screening resulted in a high acceptance rate (95%) for donors who began the formal screening process. Further work is needed to better understand the impact of deferral on prospective milk donors.

Key words: Milk, human; tissue donors; safety; nutrients

Introduction

In 2018, the Australian Red Cross Lifeblood Milk (Lifeblood Milk) launched in New South Wales (NSW) and South Australia (SA), providing pasteurised donor human milk (PDHM) to high risk preterm infants admitted to all neonatal intensive care units (NICUs) across both states. There are many donor human milk banks around the world (including five in Australia and more than 200 milk banks in Europe alone) and one of their primary reasons for operation is that donor human milk reduces the incidence of necrotising enterocolitis in very preterm infants who do not have access to their mother's own milk¹. Donor human milk is recommended by the World Health Organization², the American Academy of Pediatrics³ and the Australian Breastfeeding Association⁴ as a superior alternative to infant formula.

In preparing to launch Lifeblood Milk, a robust process to develop a set of criteria for the selection and screening of potential breast milk donors was undertaken. Although broad guidance on donor selection is offered in local⁵ and several international milk bank guidelines, including those published by the Human Milk Banking Association of North America⁶, the United Kingdom NICE guidelines⁷ and the recent European Human Milk Banking Association guidelines⁸, there is relatively little detailed published guidance on how to approach donor selection for milk banks⁹.

Donor selection for milk banks is essential, both to ensure the safety and nutritional quality of the donor milk, as well as to ensure that the prospective donor and her breastfeeding infant do not come to harm through the donation experience.

Development of guidelines and criteria for the selection of milk donors was based on internationally published recommendations, review of the blood donor selection guidelines, review of other local and international milk bank selection guidelines and literature review of specific risks. A key component to ensuring a robust donor selection process was the development of a Donor Questionnaire (DQ), supported by a formal written document, called the Guidelines for the Selection of Milk Donors (GSMD). This is standard practice in blood donation where the answers to the DQ are evaluated against donor selection guidelines to determine donor eligibility. The Lifeblood Milk DQ and GSMD, whilst having similarities to blood donor selection documents, differed in the assessment of the risks associated with the different products (both for donor and recipient). A set of 'high level' screening questions,

based on immediate exclusions in the GSMD that were related to blood borne virus infection (e.g. for intravenous drug use) or expected to be common deferral reasons (age of mother, baby, alcohol and smoking habits) were made available externally to allow prospective donors to self-screen before offering to donate milk (see Box 1). The selection process also included blood testing for infectious diseases (HIV, hepatitis B, hepatitis C, HTLV and syphilis), and microbiological screening of each batch of donated milk pre- and post-pasteurisation.

The purpose of this review was to discuss the development of formal milk donor selection criteria and to review how these donor selection criteria functioned when applied to prospective Milk Bank donors over the first 12 months of operations (July 2018–June 2019), with a view to optimizing the donor selection process to ensure the safety of both the milk donor and infant recipient.

Methods

Guideline development.

To develop screening and selection guidelines that take into account the local epidemiology and Australian context, the following process was undertaken:

1. Review of evidence based international guidelines such as the 2010 UK National Institute for Health and Clinical Excellence (NICE) clinical guidelines⁷ and the Human Milk Association of North America guidelines⁶ to ensure all questions with adequate evidence were included in our local guideline. These guidelines specified a number of risk mitigation activities that milk banks can implement to ensure the safety of PDHM, including establishing evidence based guidelines for the selection of milk donors, signed donor declarations, donor serological screening, guidelines for milk expression and storage, validated transport methods for frozen PDHM, milk pasteurisation, and pre-and post-pasteurisation bacterial testing with specified acceptance criteria.
2. Review of the Australian Red Cross Blood Service Donor Questionnaire (DQ) and Guidelines for the Selection of Blood Donors (GSBD). These questions were used as the basis for a literature review of the relevance of the questions to donor human milk, taking into account additional processing mitigations such as pasteurisation.

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3. Review of other local milk bank selection criteria, including the Donor Questionnaire of the Royal Brisbane and Women's Hospital Milk Bank and the Western Australian Prem Bank questionnaire. This was done by taking into account the assumed question rationale, the risk it was intended to address, local Australian epidemiology and the available scientific evidence.
 4. Review of published literature for specific subject areas to guide further local risk assessments.

Consultation with external subject matter experts through the Milk Bank Clinical Advisory Board (these included neonatologists, lactation consultants, and consumer representatives) and other experts nationally and internationally. As part of the development process, formal risk assessments including Failure Modes Effects Analysis (FMEA) and Hazards Analysis Critical Control Points (HACCP) were done. For areas of uncertainty, decisions around donor selection were formally presented to, and discussed by the external clinical advisory board, followed by formal endorsement by the Australian Red Cross Lifeblood Donor and Product Safety (DAPS) Committee. As an example, many milk banks and guidelines recommend testing and exclusion of potential donors with blood-borne viruses and exclusion of those at higher risk of acquiring a blood borne virus^{5, 6}. This is a sensible precaution, although the risk profile for donor milk is different to blood, due to additional mitigations such as the pasteurisation process. Some milk banks require more frequent blood-borne virus testing than entry testing as performed in our milk bank¹⁰. Pasteurisation has been shown to inactivate most enveloped viruses, including HIV¹¹, CMV¹² and rubella. The data on hepatitis B (a DNA virus) inactivation is less clear¹³, however, hepatitis B and hepatitis C are not known to be transmitted by breast milk¹⁴. Internal risk assessment for blood-borne viruses (Supplementary Appendix 1) demonstrated that if pessimistic assumptions were used for the theoretical risk of transmission, the risk was miniscule. Therefore, initial testing of donors was considered adequate. This approach was discussed by the CAB and approved by the DAPS Committee.

Using this approach, we developed a formalized donor selection process that included a:

- i) high level screening questionnaire, which aimed to allow donors to self-screen based on key exclusion criteria, such as smoking, alcohol intake or a blood borne virus infection (see Box 1)
- ii) a detailed Milk Bank DQ, to be administered by a registered nurse/ lactation consultant
- iii) 'Guidelines for the Selection of Milk Donors' (GSMD), a formal document for making decisions about acceptance or deferral of donors, which follows a similar format to the document used by the Blood Service for donor selection. See Box 2 for sample entries from the GSMD.
- iv) a recommended set of infectious diseases blood screening tests with pre-specified acceptance criteria and
- v) a recommended donor milk bacteriological screening process, with microbiological testing done in a NATA accredited food safety laboratory, with pre-specified acceptance criteria.

Guideline review

Over the first 12-months of operations, details about all milk donors who began the formal selection process were prospectively entered into the Lifeblood Milk database (Hemasoft systems, Florida, USA). These included responses to the DQ, infectious diseases screening tests, and bacteriological screening results, as well as outcome of the selection process. Where prospective donors were asked the 'high level screening questions' verbally by one of our milk bank staff, their responses (and potential eligibility outcomes) were recorded in an Excel database.

At Lifeblood Milk, data about donor selection based on these documents and criteria is prospectively collected and reported monthly to the Lifeblood Milk Food Safety HACCP committee.

The outcomes of donor screening were formally reviewed for a 12 month period. These including proportion of donors accepted based on responses to the Donor Questionnaire, and

the proportion of donors accepted based on blood-borne pathogen screening. The reasons for deferral based on the DQ were also reviewed.

The study was approved as a low/negligible risk project by the ARCBS ethics committee (approval number: Clifford 25072019).

Results

Over the first 12-month period of operations (1 July 2018 – 30 June 2019), approximately 2200 volunteers contacted Lifeblood Milk to donate their breast milk. Not all prospective donors were screened, as demand for PDHM was not commensurate with potential donor supply. Contacted prospective donors were screened with a set of high level screening questions, usually self-administered or asked by a staff member of a hospital neonatal intensive care unit (NICU) or Milk Bank staff member. 50/327 donors who responded to the high level screening questionnaires administered by Milk Bank staff were not able to proceed further based on their responses.

A total of 201 donors were screened using the Milk Bank DQ; 5 of these donors were bereaved donors. Of these 201 donors, 9 (4%) donors were deferred based on the DQ, following evaluation by the GSMD, and with additional expert advice from subject matter expert where conditions were not covered in the GSMD. Thirty-four donors had conditions that required expert advice on selection. The most common reasons for deferral were pre-existing medical conditions (n=4), medication usage – prescription and herbal/natural preparations (n=3), and receipt of blood products in past 12 months (n=2).

Donors were tested once per lactational period for blood borne viruses (HIV, Hepatitis B, Hepatitis C, HTLV) and syphilis. In one case, the phlebotomist was unable to obtain a blood sample (n=1), so the donor was not accepted. One other donor (n=1) was deferred for an initially reactive result on screening blood tests. This deferral was largely precautionary as further confirmatory testing demonstrated that the donor was uninfected.

Discussion

Prior to the launch of Lifeblood Milk, there was a robust process for development of guidelines and quality systems to support the operations of Lifeblood Milk, including a formal donor questionnaire, written guidelines for donor selection, specification of blood screening

acceptance criteria, as well as milk bacteriological screening acceptance criteria. Many of the donor deferrals specified in the GSMD, including those for infectious pathogens, were precautionary, rather than based on evidence of transmission risk.

Our experience in using the high level screening questions to stratify eligible donors for evaluation using our formal donor selection criteria resulted in a relatively low rate of donor deferral in the first 12 months of Lifeblood Milk operations. Although a substantial proportion of prospective donors were not accepted based on their high level screening responses, 95% of prospective donors who passed this stage were eventually accepted as milk donors.

Deferral rates based on screening processes vary between milk banks. A recent American study reported that a commercial United States Milk Bank, Prolacta™, deferred 29.7% of prospective breastmilk donors through a selection questionnaire¹⁵, which is significantly higher than the rate that we report. Prolacta™ milk bank do accept some remunerated donors, which may affect the risk profile of the source donor population.

International guidance on donor selection

International practices for donor selection vary significantly and there is a lack of specific recommendations for donor screening and selection for milk banks⁹, although there has been work in recent years towards providing consensus guidance on this question^{6, 8}. Many breast milk bank screening questionnaires have been developed using blood donor criteria⁵⁻⁷ and, as such, do not necessarily take into account the specific donor safety and infectious disease risks of pasteurised breast milk.

There are several aspects to donor selection; primary considerations include reduction of risk for the recipient (primarily through transmission of infections or toxins) and ensuring the safety of the donor and her breastfeeding infant⁹. As recipients of PDHM are generally very preterm infants, they represent an exceptionally vulnerable group.

Infectious disease risks

The donor selection process is designed to reduce the microbiological risks of donor human milk. Despite variations in individual operating models for milk banks, there have been no reported cases of blood borne virus transmission via PDHM to an infant¹⁶.

Of milk bank donors tested for blood borne viruses only one donor was excluded based on an initially reactive test result (that was shown on subsequent testing to be consistent with a false positive result). It should be noted that the majority of initially positive tests for blood borne viruses in a very low prevalence population (already screened in pregnancy and again by DQ and GSMD) are likely to represent false positives rather than true infection. A previous study in Australian blood donors demonstrated that the false positive reaction prevalence for all infections was 1 in 205 for new donors¹⁷. Therefore we recommend that further confirmatory testing is used to guide milk donor selection outcomes.

We do not routinely screen for cytomegalovirus (CMV) in donors or donated milk, although we do exclude donors who report a history of recently acquired CMV infection. Appropriate decision making around the acceptance of donors with a history of CMV is not entirely certain. Breast milk is the most common route of transmission from mother to preterm infant and preterm infants are at higher risk of adverse outcomes from CMV infection¹⁸. In the Australian context, at least half of women of childbearing age will have previously had CMV infection. CMV is known to reactivate and be detectable in the breast milk of most CMV-positive mothers in the post-partum period. It is known, however, that CMV is inactivated by Holder pasteurisation¹², which is regarded as a critical control point in ensuring the safety of PDHM. In addition, CMV viral load is significantly reduced by freezing¹². Excluding all donors with a history of CMV would raise significant issues of sufficiency of donors, whilst having minimal impact on the safety of PDHM.

Our guidelines include deferrals for other viral illnesses and contact with such as varicella, measles and mumps. In addition, we chose to defer donors who had recently received a live vaccine within 4 weeks, despite the fact that transmission has never been reported via breast milk. Further work is needed to review whether this level of precautionary deferral is required.

Both the Human Milk Banking Association of North America⁶, the United Kingdom NICE guidelines⁷ include text that those at increased risk of variant Creutzfeldt-Jakob Disease are deferred from donation. This appears to be a recommended based on the precautionary blood donor deferral. There has never been a case of vCJD transmitted by breast milk. Breast milk is classified as a lower infectivity tissue for transmissible spongiform encephalopathies¹⁹. There has never been a case of vCJD diagnosed in Australia and the risk is therefore

negligible. Given international practice, this deferral was incorporated into our guidelines. However, we note that even in blood donors where transfusion-transmission has been documented to have occurred, because of a negligible risk, this deferral has been reversed in Ireland²⁰. We acknowledge that this precautionary deferral is likely unnecessary. Its inclusion demonstrates the difficulties in breaking from standard international practice.

To cover the risk of bacterial contamination we have deferrals for bacterial risks including a temporary deferral for fever, mastitis and other acute bacterial infections and permanent deferrals for conditions where the risk of bacteraemia is significantly higher such as bronchiectasis. In addition to protecting against a recipient safety risk of transmitting a bacterial infection, this also ensures our milk batch bacterial specification failures are kept to a minimum, which maximizes efficiency of milk processing. It should be noted that transmission of bacterial infections from PDHM is extremely uncommon; there is just one published case from a French milk bank where post-pasteurisation contamination of bottles of PDHM led to an outbreak of *Pseudomonas aeruginosa* in the neonatal nursery²¹.

Nutritional risks

PDHM is intended as a supplement to mother's own milk (MOM) for preterm infants, in cases where there is insufficient supply of MOM. Although the benefits of PDHM compared to infant formula for preterm infants are well established^{2, 9, 22, 23}, PDHM remains inferior to MOM for infant feeding. It is likely that selection on donors based on their lactational stage and/or diet could impact the quality of PDHM.

It is known that the composition of PDHM differs in significant ways from the composition of MOM. These are partly due to changes in milk composition due to processing (pasteurisation and storage) but may also be due to the maturity of the donor mammary glands and the lactational stage of the donor mother impacting on milk composition²⁴⁻²⁶.

At Lifeblood Milk, we do not accept donors who have given birth in the previous four weeks. This is to ensure the safety of the donor's infant (to ensure the donor's infant receives all the important benefits of early lactational milk), however it also means that newborn preterm infants may be receiving a product (PDHM) derived from mature lactational milk²⁷ that differs significantly in nutritional content from mother's own early lactational milk^{24, 28}.

A recent prospective cross-sectional study at five milk bank in the United States found that lactational stage had the greatest impact on the composition of PDHM²⁷. The study measured lipid and protein composition in individual PDHM samples, as well as pooled PDHM²⁷. The study also showed that differences in macronutrient composition of donor milk could largely be overcome by milk pooling. At Lifeblood Milk, we pool donations from an individual mother (up to 5 litres) but do not pool donations from multiple donors, so as to ensure traceability of the donation in the event of a donor specific recall e.g. a confirmed infection in the donor such as HIV. However, given the demonstrated low donor related risks of PDHM, future research should focus on whether the benefits of pooling outweighs the requirement for traceability to a donor level.

Donor diet may also affect the nutritional quality of donor milk. Recent EMBA guidelines recommend that donors on an exclusively vegan diet who do not take B12 supplementation should be excluded from donation⁸, which is the practice followed by our milk bank.

Toxin-related risks

A significant proportion of our donor deferrals were due to use of nutritional supplements for which there was inadequate published information to determine whether they were safe in breast milk.

Toxin related risks largely derive from donor use of licit and illicit drugs, but may also be due to exposures to environmental toxins.

Donor selection was also based on the need to reduce the risk of the recipient infant being exposed to other toxins, such as alcohol or drugs. Both the UK NICE guidelines⁷ and the HMBANA guidelines⁶ specify a number of risk mitigation activities that milk banks can implement to ensure the safety of PDHM. These include establishing evidence based guidelines for the selection of milk donors, signed donor declarations, donor guidelines for milk expression and storage, and a policy of voluntary non-remunerated donors. These guidelines do not explicitly recommend testing breast milk for alcohol or drugs.

At Lifeblood Milk, we screen donors for a reported history of drug and alcohol use, using the donor questionnaire and GSMD, but we do not screen the product for potential toxins. This is different to the practice of Prolacta™ milk bank, which routinely tests donor milk for drugs and

nicotine. Interestingly, a recent publication using the Prolacta™ milk bank data reported that drug testing of milk was positive for 42/12 408 (0.3%) of donations; the vast majority of drugs detected by this screening process were cotinine (a nicotine metabolite) and only 2 of 12 408 samples (0.02%) had another drug detected (oxycodone / oxymorphone) ¹⁵.

Donors are deferred for smoking tobacco if this has occurred in the last 6 months. This requirement is different from the NICE and American guidelines where current or occasional smokers are deferred. Nicotine passes readily into breast milk and there evidence that there is a high rate of relapse post-partum²⁹ and up to 25% of pregnant smokers do not disclose their smoking status³⁰. In addition, there is ambiguity about the definition of a current smoker and how donors may interpret this. Therefore the 6 month period was chosen as a compromise to allow donors who had given up immediately on becoming pregnant or who may have a premature baby whilst ensuring we would not be allowing donors who had more recently ceased smoking (due to risk of relapse).

The expected harm to an infant receiving a unit of PDHM contaminated with a toxin is unknown, as it will depend on the substance, the concentration of the substance and the weight and health of the recipient infant. Overall the risk to an infant receiving PDHM is likely to be lower than for an infant receiving maternal breast milk contaminated with the same toxin, as the PDHM the infant receives over time is likely to be from multiple batches (and from different donors), thus reducing overall toxin exposure. Toxin exposure would also be expected to be reduced by pooling.

Impact of milk donor deferral

Milk donor deferral is an important issue, as there is the potential for impact not only on the mother, but also on her relationship with her own breastfeeding infant. At Lifeblood Milk, our trained lactation consultants provide counselling to donors who are deferred, with the help of standardised scripts that are designed to reassure women that their breast milk remains the best possible nutritional choice for their own baby (see box 3). Additional counselling for complex cases is provided by Lifeblood medical doctors and/or medical specialists as required.

Recognising that milk donor deferral is an underexplored area, Lifeblood Milk, in collaboration with researchers from the University of Queensland, has begun a research project to better understand the impact of milk donor deferral.

Conclusions

Our experience of developing donor selection guidelines for Milk banking highlighted international differences in practice between milk banks, as well as a lack of strong research to inform the selection of milk donors, particularly in the area of assessing nutritional risk. Many of the deferrals specified in our GSMD for infectious pathogens are precautionary, rather than based on strong evidence of a transmission risk.

The strength of our process was in the development of a detailed set of written donor selection guidelines, grounded in a risk assessment of the known risks of pathogen transmission in breast milk.

We found that making a set of high level screening questions available to donors for self-screening resulted in a high acceptance rate of donors who began the formal screening process for our milk bank.

Further work is needed to better understand the requirements for donor selection in milk banking. In particular, active surveillance systems to detect adverse events in PDHM recipients would be desirable and could inform further risk assessments for donor selection. In addition, further research is needed to explore the impact of deferral on the prospective donor, and its impact on her breastfeeding relationship with her own infant.

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Box 1: Key high level screening questions for Lifeblood Milk

High Level Screening Questions
Have you smoked or used nicotine replacement therapy in the last 6 months?
Do you regularly consume 2 or more standard drinks of alcohol more than once a week?
Have you used recreational drugs in the past 12 months or ever injected drugs?
Do you have HIV, hepatitis B or C, HTLV or syphilis?
Have you spent more than 6 months cumulatively in the UK from 1980 to 1996?
Is your baby older than 12 months?
Are you under 18 years of age?
Have you received blood products (excluding Anti D) in the last 12 months?

Box 2. Sample deferrals from Lifeblood Milk Guidelines for the Selection of Milk Donors

Condition	Discard expressed milk if:		Deferrals to be applied when event / condition identified
	Event / condition occurs before milk expressed	Event / condition occurs after milk expressed	
Bowel disorders			
• Crohn's disease ²	Yes, all milk collected.	No.	Permanently defer.
• Diverticulitis – acute attack ^{2,3}	Yes, all milk collected in the 3 days before onset of acute attack until deferral expires.	Yes, milk collected in the 3 days before onset of acute attack.	Defer during illness and for 4 weeks following recovery and off antibiotics for 5 days.
• Gastrointestinal ulcers with or without a history of bleeding ²	No.	No.	Defer for this lactating period if on current treatment.
• Inflammatory bowel disease ²	Yes, all milk collected.	No.	Permanently defer.
• Ulcerative colitis ²	Yes, all milk collected.	No.	Permanently defer.
Breast infection ² See also 'Mastitis'	Yes, all milk collected while infection present until deferral expires.	Yes, all milk collected in the 7 days prior to infection developing.	Defer until resolved and off antibiotics for 5 days.
Bronchiectasis ²	Yes, all milk collected.	No.	Permanently defer.
Bronchitis – acute ^{2,3}	Yes, all milk collected during the illness and in the 2 weeks after recovery until deferral expires.	No.	Defer from date of illness and for 2 weeks after recovery and must be off antibiotics for 5 days.
Caffeine consumption – consumption of 4 or more caffeinated beverages a day (equivalent to 400 mg caffeine) ⁴	Yes, all milk collected post consumption until 24 after last consumption.	No.	If regular consumption defer for this lactating period.

Box 3. Sample counselling scripts for donors who are deferred

Deferral reason	Explanation														
Medications	Your own milk is still likely to be safe, and the best possible nutrition, for your own infant. You should speak to your doctor or neonatologist for advice about continuing to breastfeed your own infant. The Milk Bank provides milk for very premature and fragile infants, some of whom may have medical conditions that make them particularly vulnerable to the effect of medicines and toxins. For this reason, we do not accept milk from mums who are taking a wide range of medications.														
Live vaccines (MMR)	Your own milk is still safe, and the best possible nutrition, for your own infant. The Australian immunisation guidelines recommend that all mothers can continue to breastfeed after MMR vaccine. We ask that you do not donate milk for at least 4 weeks after receiving the MMR vaccine. This is just a precaution. The Milk Bank provides milk for very premature and fragile infants, and these infants may be at particular risk of getting vaccine-related infection. Infection related to live vaccines is extremely rare.														
Blood products (excluding Anti-D)	Your own milk is still safe, and the best possible nutrition, for your own infant. We strongly encourage you to continue breastfeeding. We are unable to collect your milk during this lactating period. This is just a precaution as the Milk Bank provides milk for very premature and fragile infants. Australia has one of the safest blood supplies in the world.														
Caffeine consumption	The Milk Bank provides milk for very premature and fragile infants, some of whom may have medical conditions that make them particularly vulnerable to the effect of medicines and toxins. We are unable to collect your milk if you are regularly drinking more than 400mg caffeine per day (see below table for a list of drinks containing caffeine). <table border="1"> <thead> <tr> <th>Food</th><th>Caffeine content</th></tr> </thead> <tbody> <tr> <td>Espresso</td><td>145 mg/50 mL cup</td></tr> <tr> <td>Formulated caffeinated beverages or 'Energy' Drinks</td><td>80 mg/250 mL can</td></tr> <tr> <td>Instant coffee (1 teaspoon/cup)</td><td>80 mg/250 mL cup</td></tr> <tr> <td>Black tea</td><td>50 mg/250 mL cup</td></tr> <tr> <td>Coca Cola</td><td>48.75/375 mL can</td></tr> <tr> <td>Milk chocolate</td><td>10 mg./50 g bar</td></tr> </tbody> </table> As per FSANZ (May 2018) We would be able to accept your milk if your caffeine consumption falls below these limits in the future and you meet the remaining eligibility criteria.	Food	Caffeine content	Espresso	145 mg/50 mL cup	Formulated caffeinated beverages or 'Energy' Drinks	80 mg/250 mL can	Instant coffee (1 teaspoon/cup)	80 mg/250 mL cup	Black tea	50 mg/250 mL cup	Coca Cola	48.75/375 mL can	Milk chocolate	10 mg./50 g bar
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What is already known on this topic

- Donor human milk is the preferred option for feeding preterm infants where mother's own milk is not available
- Milk banks collect and process (usually via Holder pasteurisation) donor human milk to ensure that it is safe for feeding high risk infants
- Robust donor selection processes for milk banks are essential, both to ensure the safety and nutritional quality of the donor milk, as well as to ensure that the prospective donor and her breastfeeding infant do not come to harm through the donation experience

What this paper adds

- We developed a formal multi-tier milk donor selection process for Lifeblood Milk, including self-screening questions, a donor questionnaire supported by formal Guidelines for the Selection of Milk Donors, and infectious diseases testing processes.
- Our experience highlighted international differences in practice between milk banks and lack of strong research to inform milk donor selection.
- Making a set of key screening questions available to donors for self-screening resulted in a high acceptance rate for donors who began the formal screening process.

Development and evaluation of formal guidelines for donor selection for breast milk banks

[original article]

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The authors do not have any conflict of interests to declare.

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