

Issue date: February 2010

Donor breast milk banks: the operation of donor milk bank services

NICE clinical guideline 93

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Introduction

Research has consistently shown that breast milk is the best nourishment for babies and that it is highly beneficial to their health in the short, medium and long term. Women are recommended to breastfeed their baby exclusively for 6 months and continue to breastfeed after 6 months as part of a balanced diet (see www.dh.gov.uk for the latest Department of Health guidance on breastfeeding).

If, after discussion with experienced staff, a mother is unable to express sufficient milk or does not wish to express milk for a baby unable to feed at the breast, donor breast milk can be used.

In this guideline, donor breast milk is defined as breast milk expressed by a mother that is then processed by a donor milk bank for use by a recipient that is not the mother's own baby. Payment for the donated milk is not given.

A Health Technology Assessment (HTA) report entitled 'Breastfeeding promotion for infants in neonatal units: a systematic review and economic analysis' was published in 2009. This report used systematic review methodology and health economic modelling to assess which interventions, including the availability of donor breast milk, effectively promote the initiation and duration of breastfeeding in neonatal, special and intensive care settings. The authors noted that in the UK, donor breast milk is neither widely nor readily available in the majority of units; this was reflected through modelling the use of donor breast milk by availability, not need. They concluded that if mechanisms by which donor milk is provided were improved, donor milk would become cost effective compared with using formula. This was based on a significant improvement in the operation of milk banking, and suggested models include setting up a national donor milk banking system similar to that for blood (Renfrew et al. 2009).

Although this guideline does not make recommendations on the configuration of services, it does make recommendations on the safe and effective operation of donor milk services.

Throughout development, the safety of donor breast milk was considered to be the aim of the guideline and recommendations were made to minimise the risk to recipients of donor milk. Maximising safety comes at a cost and recommendations were made to observe the best possible safety standards without exceeding opportunity costs acceptable to society.

Person-centred care

This guideline offers best practice advice on the operation of donor breast milk bank services.

Good communication between healthcare professionals and service users is essential. It should be supported by evidence-based written information

tailored to the person's needs. All information that service users are given should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

1 Summary

1.1 *Key priorities for implementation*

Quality assurance

- Use Hazard Analysis and Critical Control Point (HACCP) principles in all quality assurance processes.
- Validate, calibrate and maintain all equipment used in donor milk handling and processing and keep records of this. Ensure that the equipment is used according to the manufacturer's instructions.
- All milk bank staff should have ongoing training that is relevant to their job and is recorded. Training should cover good practice and should ensure that each staff member:
 - is competent in performing their job
 - understands the technical processes relevant to their job
 - understands how the milk bank is organised and how its health and safety and quality systems work
 - understands the regulatory, legal and ethical aspects of their work.
- All donor milk administered in the NHS should be from milk banks that can demonstrate adherence to the NICE guidance on the operation of donor milk banks.

Screening and selecting donors

- Follow the stepped screening process detailed in recommendations 1.2.12 to 1.2.21 when recruiting donors.
- Do not routinely repeat serological tests while the donor is donating milk.

Handling donor milk at the milk bank

- Before pasteurisation, test a sample from each batch of pooled donor milk for microbial contamination and discard if samples exceed a count of:

- 10^5 colony-forming units (CFU)/ml for total viable microorganisms **or**
- 10^4 CFU/ml for Enterobacteriaceae **or**
- 10^4 CFU/ml for *Staphylococcus aureus*.
- Regularly test pasteurised donor milk for microbial contamination. Base the testing schedule on the volume and throughput of milk. Test:
 - either at least once a month or every 10 cycles, depending on which comes first,
 - and**
 - on an ad-hoc basis if any new processes, equipment or staff are introduced, or if there are concerns about any part of the process.

Tracking and tracing

- At all stages, donor milk containers should be labelled clearly for identification. Clearly identify milk that is ready to be used.
- Only supply donor milk to hospitals or neonatal units that agree to comply with the tracking procedures for milk outlined by the milk bank.

1.2 List of all recommendations

The recommendations in this guideline are all key to the process of donor milk banking and are dependent on each other. For example, the recommendations on testing milk post-pasteurisation are dependent on the application of the recommendations on quality assurance and equipment maintenance. The safety of donor milk therefore depends on the implementation of all recommendations.

Quality assurance

There is no recognised NHS standard for human milk pasteurisers. In the UK, donor milk banks have been following guidance issued by various bodies, including in 1981, a report on the collection and storage of human milk. (Committee on Medical Aspects of Food Policy 1981) and more recently, guidelines issued in 2006 by the UK Association for Milk Banking. The following recommendations, specifically on maintenance of equipment, need to be viewed in this context.

- 1.2.1 Use Hazard Analysis and Critical Control Point (HACCP) principles in all quality assurance processes.
- 1.2.2 Clean and store all donor milk containers and equipment according to local protocols based on HACCP principles.
- 1.2.3 Validate, calibrate and maintain all equipment used in donor milk handling and processing and keep records of this. Ensure that the equipment is used according to the manufacturer's instructions.
- 1.2.4 Regularly inspect all equipment used in donor milk handling and processing, following the manufacturer's instructions. Ensure that all equipment that may affect temperature or contamination levels has sensors and alarms so that constant conditions can be maintained.
- 1.2.5 All milk bank staff should have ongoing training that is relevant to their job and is recorded. Training should cover good practice and should ensure that each staff member:
- is competent in performing their job
 - understands the technical processes relevant to their job
 - understands how the milk bank is organised and how its health and safety and quality systems work
 - understands the regulatory, legal and ethical aspects of their work.
- 1.2.6 Train milk bank staff in HACCP principles, food hygiene and pasteurisation, and provide ongoing support so that practices reflect these principles.

1.2.7 All donor milk administered in the NHS should be from milk banks that can demonstrate adherence to the NICE guidance on the operation of donor milk banks.

1.2.8 Implement a quality control system that is followed by all staff and is reviewed regularly. It should encompass:

- collecting, testing, processing, storing and transporting milk
- personnel, required documentation, premises and equipment
- batch recall, external and internal auditing, non-conformance to processes and self-inspection
- continuous quality improvement.

Recruiting donors

1.2.9 When promoting the donation of breast milk, aim to reach as many potential donors as possible through a variety of channels, including:

- providing written information to be left in:
 - GP surgeries
 - antenatal clinics and postnatal wards
 - volunteer and other organisations working in maternity and childbirth
 - children's or Sure Start centres
 - maternity shops
- direct referrals or recommendations by:
 - current and previous donors
 - staff at neonatal intensive care units
 - paediatricians assessing babies' progress
 - health visitors (or other healthcare professionals providing postpartum care)
 - childbirth educators
 - organisers and attendees of prenatal and postnatal classes
 - breastfeeding mothers' support groups and related organisations

- features in the media.

1.2.10 Use clear, non-technical language when communicating the use of donor milk and the process of donor milk banking in any written information and activities.

Screening and selecting donors

The following strategy of screening and selection is part of the whole process of donor milk handling and therefore is intrinsically linked with the recommendations on testing and treating the donor breast milk.

1.2.11 Follow the stepped screening process detailed in recommendations 1.2.12 to 1.2.21 when recruiting donors.

1.2.12 Advise a potential donor that she is not eligible to donate milk if she:

- currently smokes or uses nicotine replacement therapy (NRT)
- regularly exceeds recommended alcohol levels for breastfeeding mothers (1 to 2 units, once or twice a week) (see www.dh.gov.uk for information on alcohol and breastfeeding)
- is using, or has recently used, recreational drugs
- has previously tested positive for HIV 1 or 2, hepatitis B or C, human T-lymphotropic virus (HTLV) type I or II, or syphilis
- is at an increased risk of Creutzfeldt–Jakob disease (CJD) (see www.hpa.org.uk for information on the risk of CJD).

Include this information in recruitment material so that potential donors can self-screen for these criteria.

1.2.13 Using a process of informal interview, referring to medical sources (with consent) if necessary, ask the potential donor questions on the topics that follow. Use the information she gives to make a balanced decision about her eligibility to donate based on possible risks to recipients and/or the results of subsequent serological tests (see recommendations 1.2.16 and 1.2.17). Ask questions about:

- her health: to confirm that she is in good general health
- her baby: document the age and health of the baby
- any exposure to passive smoke: is she exposed to high or sustained levels of passive smoke (for example, do other members of her household smoke heavily)?
- any medication that she is taking: is she currently taking any medication or undergoing any other medical therapy?
- any significant environmental or chemical exposure (such as contamination of the local water supply): is she exposed to high or sustained levels of environmental or chemical contaminants that can be expressed in breast milk?
- any recent exposure to infection (including HIV 1 or 2, hepatitis B or C, HTLV I or II, syphilis, herpes, or acute or chronic infections). Depending on the assessment of level of risk, further testing may be needed.
- any recent medical intervention (for example, exposure to diagnostic radioactive isotopes)
 - refer to guidance from the Department of Health on the safety of recent vaccination when breastfeeding (available from www.dh.gov.uk).

Advise the potential donor that depending on her answer to any of these questions she may not be eligible to donate milk.

- 1.2.14 If a potential donor is donating previously expressed breast milk, ask her to answer the screening questions (recommendations 1.2.12 to 1.2.13) for the period when the milk was expressed.
- 1.2.15 Conduct the screening interview, detailed in recommendations 1.2.12 and 1.2.13, with potential donors at a mutually acceptable time and place, either face-to-face or by telephone.

Serological testing

- 1.2.16 When donors first contact the milk bank about donating milk, explain that serological testing is mandatory to reduce the risk of passing on infections. Obtain informed consent before testing.
- 1.2.17 Undertake serological testing of all potential donors for the following and exclude women from donating who test positive for:
- HIV 1 or 2
 - hepatitis B or C
 - HTLV I or II
 - syphilis.
- 1.2.18 Perform all serological screening tests at the time of enrolling for donor milk banking; do not rely on antenatal test results.
- 1.2.19 All tests should be undertaken in laboratories with clinical pathology accreditation (CPA).
- 1.2.20 Ensure that laboratories communicate the results of serological testing clearly and that they provide appropriate interpretive comments.

- 1.2.21 Give serological test results to potential donors either in person or by telephone (unless they prefer to receive them in writing). If needed, offer further help and support based on local protocols, including information about counselling and local support groups.
- 1.2.22 Laboratories should archive samples of blood received from donors.

Consent and continued eligibility

- 1.2.23 Before accepting a donor's milk, obtain her consent for the processing and intended use of the donated milk. Advise her that once donated, milk will not be returned to her.
- 1.2.24 While a donor continues to donate, ask regularly about her general health and the exclusion criteria detailed in recommendations 1.2.12 to 1.2.13. Advise her that if her status or circumstances change in relation to these, she should contact the milk bank immediately.
- 1.2.25 Do not routinely repeat serological tests while the donor is donating milk.

Training and supporting donors

The recommendations in this section are specific to mothers expressing milk for donation, and may differ from advice given to mothers expressing milk for their own babies.

- 1.2.26 Provide all new donors with training, preferably face-to-face with additional information by telephone and in writing. Arrange training at a time and place suitable for both donor and trainer.
- 1.2.27 Training for new donors should cover:
- hand washing and the importance of this
 - good personal hygiene
 - collecting and expressing milk, including cleaning and using breast pumps and containers

- storing donated milk (including cooling and freezing)
- labelling donated milk, and documenting storage conditions
- transportation of donated milk (if needed).

1.2.28 Provide ongoing support to all donors according to their individual needs until no longer required. This may include:

- information and ongoing support on milk bank requirements for their diet and alcohol consumption
- continued support for collecting expressed milk and maintaining lactation
- emotional support.

1.2.29 Offer additional support and information on milk collection to donors whose milk has significant or repeated microbial contamination.

Stopping or suspending milk donations

The recommendations in this section are specific to mothers expressing milk for donation, and may differ from advice given to mothers expressing milk for their own babies.

1.2.30 Consider no longer accepting breast milk from donors who, despite support, consistently supply:

- breast milk that does not meet the microbiological criteria (see recommendation 1.2.58)
- small amounts of breast milk.

- 1.2.31 Advise donors to contact the milk bank to discuss suspending or stopping their breast milk donation if they develop a fever or have contact with a viral exanthematous disease.
- 1.2.32 Advise donors who begin taking any medication that they should contact the milk bank to discuss suspending or stopping their breast milk donation. Use appropriate reference sources¹.
- 1.2.33 Advise donors to contact the milk bank to discuss suspending or stopping their breast milk donation if they develop lesions or infections of the breast (including mastitis or herpes).
- 1.2.34 Provide donors who are stopping their breast milk donations with as much advice and support as needed.
- 1.2.35 Consider the size of the recipient population, the milk bank's stock levels, and the preferences of the donor when discussing how long a woman can donate milk.

Expressing milk at home for donation

- 1.2.36 Advise donors to collect expressed milk rather than 'drip' milk (milk that is passively collected from one breast while the baby feeds at the other) for donation.
- 1.2.37 Actively encourage donors to hand express milk; however, accept pump-expressed milk if donors prefer this method.

Handling donor milk at home

The recommendations in this section are specific to mothers handling and storing milk for donation, and may differ from advice given to mothers expressing milk for their own babies. This is because donated milk needs to undergo various testing and treatment processes at the donor milk bank, all of which affect the nutritional and immunological composition of the milk. The

¹ See the British national formulary for children, the Drugs and Lactation Database LactMed (www.toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT) or the UK Drugs in Lactation Advisory Service (see www.ukmicentral.nhs.uk/drugpreg/guide.htm).

aim therefore is to make sure that milk for donation reaches the donor milk bank as soon as possible to ensure the highest quality before processing.

- 1.2.38 Advise donors that expressed milk collected for donation should be frozen as soon as possible to maintain the nutritional and microbiological quality of the milk. If this is not possible (for example, because of storage capacity), advise donors to refrigerate samples collected over 24 hours, and then freeze the batch.
- 1.2.39 Advise donors that expressed milk for donation should remain frozen during storage at home, and if they have any concerns about storage conditions or freezer temperatures, they should discuss these with the milk bank.
- 1.2.40 Advise donors that frozen expressed milk should be transported to the milk bank as soon as possible. However, if necessary, expressed milk for donation can be stored before transport to the milk bank for up to 3 months in a domestic freezer, at -18°C or lower. If a donor does not have access to a domestic freezer at her home, she may be able to access freezers for milk storage at local donor milk depots or children's centres.
- 1.2.41 Advise donors that expressed milk can only be accepted by the milk bank if it has been collected and stored in milk collection containers provided by, or acceptable to, the milk bank.
- 1.2.42 Advise donors that collection containers for expressed milk should be used according to instructions provided by the milk bank.
- 1.2.43 Ensure that donors can check and document their freezer temperature every day; this may include providing a thermometer.

Handling donor milk during transportation

- 1.2.44 Define critical conditions for transport, including temperature and time limit, to ensure that donor milk remains frozen during transport.

- 1.2.45 Transport donor milk in secure, tamper-evident containers and packaging.
- 1.2.46 If donor milk is transported to the milk bank by a contracted third party, ensure that a documented agreement is in place to maintain the conditions needed.
- 1.2.47 Define in writing the milk bank's procedures for transporting and storing donor milk. Ensure that these procedures maintain the quality of the donor milk and allow accurate identification of samples. Keep records of inventory and distribution (see also recommendations 1.2.68 to 1.2.75 on tracking and tracing).
- 1.2.48 Collect expressed milk from the donors, preferably using an agreed transport provider (ideally a medical courier) or a member of staff from the milk bank. In some instances, donors may be required or may wish to deliver their own milk to the milk bank or depot, in which case they should also follow the milk bank's requirements for transport as outlined. In all cases, use consistent monitoring processes, including recording the journey time.
- 1.2.49 Collect expressed milk from either the donor's home (see recommendations 1.2.38 to 1.2.43) or from donor milk depots that have practices for monitoring freezers and maintaining standards for quality control, storage and security. Ensure that similar processes are in place in any location where the donor milk is stored.

Handling donor milk at the milk bank

The following strategy of handling milk at the milk bank, specifically testing and treating donor milk, is part of the whole process of donor milk handling and therefore is intrinsically linked with the recommendations on recruiting and selecting the donors. It is also predicated on the effective functioning of the human milk pasteuriser.

- 1.2.50 Process all donated milk under hygienic conditions (a sterile environment is not necessary). Practise good hand hygiene at all times, and wear gloves whenever handling donor milk.
- 1.2.51 Check that donated milk arriving at the milk bank:
- is labelled correctly with the donor's name and the date of expression **and**
 - has remained frozen **and**
 - has not been tampered with.
- Transfer all donated milk immediately to the freezer.
- 1.2.52 Store pasteurised and unpasteurised donor milk in separate freezers and refrigerators.
- 1.2.53 Store donor milk awaiting pasteurisation in the freezer at the milk bank (at -20°C) for no longer than 3 months from the date of expression.
- 1.2.54 Discard breast milk from donors who do not meet the selection criteria detailed in recommendations 1.2.12, 1.2.13 and 1.2.17.
- 1.2.55 Before testing and pasteurising, thoroughly thaw the donor milk, and keep in the refrigerator for no longer than 24 hours. Prevent the donor milk from reaching 8°C while thawing.
- 1.2.56 Only pool pre-pasteurised breast milk from the same donor.
- 1.2.57 Do not pool:
- breast milk from different donors,
or
 - batches of pasteurised breast milk from the same donor.

- 1.2.58 Before pasteurisation, test a sample from each batch of pooled donor milk for microbial contamination and discard if samples exceed a count of:
- 10^5 colony-forming units (CFU)/ml for total viable microorganisms **or**
 - 10^4 CFU/ml for Enterobacteriaceae **or**
 - 10^4 CFU/ml for *Staphylococcus aureus*.
- 1.2.59 Ensure that laboratories communicate the results of microbial testing clearly and that they provide appropriate interpretive comments.
- 1.2.60 Seek help from microbiological laboratories to identify and investigate instances of significant or unusual contamination (for example, by undertaking further microbial tests).
- 1.2.61 Pasteurise donated milk at 62.5°C for 30 minutes in a human milk pasteuriser. Rapidly cool the milk to a temperature of 4°C or lower. Remove one bottle for testing if appropriate, then move the remainder of the batch to the freezer.
- 1.2.62 After pasteurising, store frozen donor milk for no longer than 6 months after the date of expression.
- 1.2.63 Do not open the lid of batches of pasteurised donor milk until the milk is to be used, unless it is to test the milk. If the milk is tested, discard the opened bottle.
- 1.2.64 Regularly test pasteurised donor milk for microbial contamination. Base the testing schedule on the volume and throughput of milk. Test:
- either at least once a month or every 10 cycles, depending on which comes first,
and

- on an ad-hoc basis if any new processes, equipment or staff are introduced, or if there are concerns about any part of the process.

- 1.2.65 Discard pasteurised donor milk that has a total viable microbial count of 10 CFU/ml or more.
- 1.2.66 Keep all donor milk in containers made of food grade materials.
- 1.2.67 Staff at the milk bank should not be responsible for adding anything to the donated milk.

Tracking and tracing

- 1.2.68 Track donated milk from the donor through to the recipient hospital.
- 1.2.69 Tracking and monitoring of donor milk processing should include freezer temperatures, pasteurisation processes and stock control.
- 1.2.70 At all stages, donor milk containers should be labelled clearly for identification. Clearly identify milk that is ready to be used.
- 1.2.71 For each donor milk batch, keep the following records.
- About the donor:
 - NHS number/donor ID
 - consent
 - relevant medical history
 - results of serological tests.
 - About each container before pasteurisation:
 - donor ID
 - a testing log, including the tests undertaken and their results.
 - For each pasteurised container:
 - samples making up the batch
 - the batch number
 - a testing log, including the tests undertaken and their results
 - pasteurisation details, including date of the pasteurisation.

- The hospital or neonatal unit that receives the donated milk, or the disposal date of the donated milk, as appropriate.
- 1.2.72 Label each container of pasteurised donor milk with the following information.
- A unique identification number.
 - Confirmation that it contains pasteurised donor breast milk.
 - Instructions to keep frozen, and use within 24 hours if defrosted.
 - An expiry date (no later than 6 months from expression).
- 1.2.73 Only supply donor milk to hospitals or neonatal units that agree to comply with the tracking procedures for milk outlined by the milk bank.
- 1.2.74 The receiving hospital or neonatal unit should keep a record of how the donor milk is used. It should document for each bottle of donor milk:
- the baby's name, NHS number and date of birth, and the date administered
 - the batch number and the date the donor milk was used in the patient record of each baby
 - the condition of the donor milk on arrival following transport
 - the storage conditions.
- 1.2.75 Ensure that all records (including raw data) that are critical to the safety and quality of the donor milk are kept for at least 30 years after expiry date, use or disposal. These records should be confidential.

1.3 Overview

1.3.1 Operating donor milk banks

Seventeen donor breast milk banks are currently in operation in the UK. These provide donor milk to babies, including pre-term babies and babies with growth restriction.

It is widely recognised that there is not enough high-quality evidence on the effectiveness of donor milk in improving health outcomes. There is also concern that research into both the effectiveness of donor milk and access to donor milk is being restricted because of a lack of understanding of the process of donor milk banking, and specifically procedures for ensuring the safety of banked donor milk.

The UK Association for Milk Banking issued 'Guidelines for the establishment and operation of human milk banks in the UK' in 2003. This is still relevant and in use, but is past its review date. There is therefore an urgent need for an updated national guideline to ensure that donor milk banks operate according to the best available evidence and standards of practice.

This short clinical guideline aims to improve the safety of donor milk by making evidence-based recommendations on the operation of donor milk banks.

1.3.2 Who this guideline is for

This document is intended to be relevant to donor milk bank staff, healthcare professionals who care for people who use donor milk, and hospitals or organisations who are considering starting a donor milk bank.

2 How this guideline was developed

2.1 Introduction

'Donor breast milk banks: the operation of donor breast milk services' (NICE clinical guideline 93) is a NICE short clinical guideline. For a full explanation of

how this type of guideline is developed, see 'The guidelines manual' (2009) at www.nice.org.uk/GuidelinesManual

During the initial development work for this guideline, it was clear that there were significant challenges to be addressed. These are reported below, along with strategies agreed with the NICE Short Clinical Guidelines Technical Team and the wider technical team within the Centre for Clinical Practice at NICE.

2.1.1 Evidence appropriate for questions about the operation of services

It is not clear which study designs are most appropriate to answer questions about the operation of services.

Other guidance in related areas ('Infection control' [NICE clinical guideline 2; available from www.nice.org.uk/guidance/CG2] and 'Patient safety and reduction of risk of transmission of Creutzfeldt–Jakob disease [CJD] via interventional procedures' [NICE interventional procedure guidance 196; available from www.nice.org.uk/guidance/IPG196]) placed no restriction on study design, only preferring 'in use' studies to those 'in vitro'.

For this guideline, no restriction was placed on the design of studies included in the evidence review.

In addition, a structured survey was developed by the technical team and two members of the Guideline Development Group (GDG). The aim of the survey was to assess current provision and needs to place the final recommendations in context; it was not intended to be used as primary evidence. The survey asked questions on the topics of:

- rates of donation and use of donor breast milk
- costs of service provision
- descriptions of models of service provision
- perceived problems with current services
- results of completed audits

- further information or research to support the development of services.

The results of the survey are presented in full in appendix 4.

2.1.2 Cost effectiveness of the operation of services

NICE guidelines are required to consider both clinical and cost effectiveness. The cost-effectiveness literature was reviewed for this guideline and we found evidence on the cost effectiveness of indications for donor breast milk, but not for aspects of how milk banks should operate. There was very little quantitative evidence on required data inputs for a de novo model evaluating, for example, milk testing strategies to maximise safety at an acceptable cost. However, we considered cost-effectiveness implications where deemed relevant for this guideline. A costing statement will be developed for the final version of the guideline.

2.1.3 Appraisal and evaluation of laboratory tests

Other guidance in related areas ('Infection control' [NICE clinical guideline 2; available from www.nice.org.uk/guidance/CG2] and 'Patient safety and reduction of risk of transmission of Creutzfeldt-Jakob disease [CJD] via interventional procedures' [NICE interventional procedure guidance 196; available from www.nice.org.uk/guidance/IPG196]) reported no formal quality assessment of studies of laboratory tests using validated checklists – reviewers reported study strengths and weaknesses only.

For this guideline, no formal quality assessment was made of studies of laboratory tests (unless an appropriate checklist was provided in 'The guidelines manual'; available from www.nice.org.uk/GuidelinesManual), but study strengths and weaknesses were documented in the full evidence report and review.

2.1.4 Lack of evidence specific to donor breast milk banking

Where appropriate, the evidence was limited to studies of donor milk banking, but, where there was no evidence, findings were extrapolated from existing evidence-based guidelines or Department of Health guidance on maternal breastfeeding. If no evidence was identified, consensus from within the GDG

was applied. However, the GDG was aware that, for most topics, there was limited or no high-quality evidence. The GDG therefore used formal consensus techniques when drafting and considering the recommendations.

Even in the absence of high-quality evidence, GDGs are generally able to reach agreement through informal consensus. However, because there was also the need for detailed service guidance, and the potential for a large number of recommendations, it was agreed that there was a role for formal consensus development techniques.

The GDG used a modified RAND approach (Brook 1994), similar to that used in 'Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy)' (NICE clinical guideline 53; available from www.nice.org.uk/guidance/CG53) and 'Feverish illness in children' (NICE clinical guideline 47; available from www.nice.org.uk/guidance/CG47) to reach consensus.

A full description of the methods and results are presented in full in appendix 3.

2.2 *Health economic modelling*

It was not considered appropriate or possible to construct a health economic model for this guideline. However, the GDG was mindful of the need to consider both costs and benefits. These considerations are documented, where relevant, in the 'Evidence to recommendations' sections below (for example, see sections 2.6.4 on the screening and selection of donors and 2.16.4 on testing donor milk).

2.3 *Evidence to recommendations*

An overview of the explanations is given in each section. Detailed considerations, as part of the formal consensus process, are presented in full in appendix 3.

2.4 Quality assurance

2.4.1 Review question

Quality assurance was reviewed as part of the evidence review on handling milk in general – see section 2.13.

2.4.2 Evidence review

No references made explicit reference to quality assurance.

2.4.3 Evidence statements

2.4.3.1 No studies were identified that made explicit reference to the use of a specific quality assurance process; however, most studies did make some reference to the need for adequate quality control.

It should be noted that the process of identifying ‘medical’ literature may not be the most effective method of retrieving the relevant evidence. See the ‘Evidence to recommendations’ section below for more details.

2.4.4 Evidence to recommendations

See also appendix 3 for the development of the recommendations using formal consensus techniques.

Although no specific evidence on quality assurance was provided, relevant European directives were identified. Although these do not directly refer to donor milk, milk banks should consider these and use them when drafting their own quality assurance processes.

- Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells
- Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as

regards Community standards and specifications relating to a quality system for blood establishments.

More specifically, milk banks should use the method of HACCP (available from

www.food.gov.uk/foodindustry/regulation/hygleg/hygleginfo/foodhygknow)

to identify critical points in processes and design appropriate measures to prevent errors.

2.4.5 Recommendations

Recommendation 1.2.1

Use Hazard Analysis and Critical Control Point (HACCP) principles in all quality assurance processes.

Recommendation 1.2.2

Clean and store all donor milk containers and equipment according to local protocols based on HACCP principles.

Recommendation 1.2.3

Validate, calibrate and maintain all equipment used in donor milk handling and processing and keep records of this. Ensure that the equipment is used according to the manufacturer's instructions.

Recommendation 1.2.4

Regularly inspect all equipment used in donor milk handling and processing, following the manufacturer's instructions. Ensure that all equipment that may affect temperature or contamination levels has sensors and alarms so that constant conditions can be maintained.

Recommendation 1.2.7

All donor milk administered in the NHS should be from milk banks that can demonstrate adherence to the NICE guidance on the operation of donor milk banks.

Recommendation 1.2.8

Implement a quality control system that is followed by all staff and is reviewed

regularly. It should encompass:

- collecting, testing, processing, storing and transporting milk
- personnel, required documentation, premises and equipment
- batch recall, external and internal auditing, non-conformance to processes and self-inspection
- continuous quality improvement.

2.5 *Recruiting donors*

2.5.1 Review question

How should donor women be recruited, and what information should be provided?

2.5.2 Evidence review

Thirty-five of the 202 studies included in the review provided 73 evidence records (defined as quotes or short summaries of the relevant information from included studies). The studies contained:

- 18 service descriptions
- 8 narrative reviews
- 5 primary studies
- 2 position statements
- 2 opinion pieces.

Their publication dates ranged from 1951 to 2008.

The service descriptions reported practice in the UK, the USA, Denmark, Australia, China, India, Sweden, Poland and Germany.

There was general agreement that active recruitment strategies were needed, but there was less agreement on the most effective methods of recruitment. There was documented variation in the donors, or groups of donors, recruited, and the timing of approach. No specific reference to the costs of different approaches was made.

There was some limited evidence on the attitudes of women who do or do not donate, and the authors drew conclusions based on these for strategies to improve recruitment rates. No primary study compared different recruitment strategies.

2.5.3 Evidence statements

- 2.5.3.1 *Healthy mothers who are breastfeeding their own babies and have more milk than they need are suitable candidates for donating surplus milk².*
- 2.5.3.2 *'Drip' milk (milk that is passively collected from one breast while the baby feeds at the other) from mothers early in lactation may be suitable for donor milk³.*
- 2.5.3.3 *Surplus milk from mothers whose lactation is well established may be suitable for donor milk⁴.*
- 2.5.3.4 *Surplus milk from mothers who have expressed milk for their own babies in the neonatal intensive care unit may be suitable for donor milk⁵.*
- 2.5.3.5 *Mothers of babies who die may find that donating milk to help another baby live is a comforting way to remember their lost child, and may aid in their own grieving process⁶.*
- 2.5.3.6 *Potential donors can be reached through various channels. These can include:*
- *by providing written information to be left in*
 - *GP surgeries*
 - *hospitals (sometimes provided to mothers in the perinatal period)*
 - *volunteer and other organisations working in public health*

² Based on 1 position statement (Anon 1980) and 1 service description (Kimball et al. 1955).

³ Based on 1 position statement (Anon 1985) and 1 service description (Baum 1982).

⁴ Based on 1 position statement (Anon 1985).

⁵ Based on 1 service description (Arnold 1996).

⁶ Based on 2 narrative reviews (Bar-Yam 2003; Bar-Yam 2005).

- *shops for new mothers, babies and children*
- *through direct referrals or recommendation by*
 - *donor women*
 - *staff at the neonatal intensive care units*
 - *paediatricians assessing the progress of the baby*
 - *health visitors (or other healthcare professionals providing postpartum care)*
 - *childbirth educators*
 - *organisers and attendees of pre- or postnatal classes*
 - *breastfeeding mothers' support groups*
 - *organisations such as the La Leche League or the National Childbirth Trust*
- *through mass media contact such as*
 - *newspapers*
 - *newsletters*
 - *magazine articles*
 - *TV*
 - *radio*⁷.

2.5.3.7 *An active recruitment programme is needed because a continuous supply of new donors is required to maintain supplies*⁸.

2.5.3.8 *Recruitment of donors may be increased if the milk bank offers breastfeeding support and services to the donors*⁹.

2.5.3.9 *Many women who donate milk work in health or social services. It might therefore be appropriate for recruitment to target women working in other sectors*¹⁰.

2.5.3.10 *The need for donor milk should be explained in non-technical language*¹¹.

⁷ Based on 1 narrative review (Bar-Yam 2003), 1 position statement (Anon 1985), and 8 service descriptions (Arnold 1999; Beal et al. 1978; Cash and Giacoia 1981; Connor 1982; Kimball et al. 1955; Langerak and Arnold 1991; McEnery and Chattopadhyay 1978; Murray 1953)

⁸ Based on 1 narrative review (Holland 2006).

⁹ Based on 1 primary study (Azema and Callahan 2003).

¹⁰ Based on 1 primary study (Azema and Callahan 2003).

2.5.3.11 *Women may be willing to donate milk for many reasons. These include:*

- *to receive peer support while breastfeeding*
- *to provide milk for babies of family members¹².*

2.5.3.12 *Women are more likely to donate milk when they have:*

- *the presence of a 'significant other'*
- *no work outside the home*
- *less than three children*
- *a positive attitude towards breastfeeding even though they have experienced problems*
- *a desire to help others¹³.*

2.5.3.13 *Women may be unwilling to donate milk for many reasons. These may include:*

- *associating breast milk with female sexuality and body fluids*
- *fear of having an insufficient milk supply*
- *worry over the compatibility of their blood with that of the recipient of the milk*
- *a dislike of the idea¹⁴.*

2.5.3.14 *Ongoing education and motivation of women on postnatal wards may reduce concerns about donating milk and thus increase recruitment¹⁵.*

2.5.3.15 *The cultural beliefs and attitude of the healthcare professional discussing milk donation may influence the decision of the woman to donate¹⁶.*

¹¹ Based on 1 primary study (Azema and Callahan 2003).

¹² Based on 1 narrative review (Holland 2006) and 1 primary study (Ighogboja et al. 1995).

¹³ Based on 1 primary study (Azema and Callahan 2003) and 1 service description (Baum 1982).

¹⁴ Based on 1 narrative review (Holland 2006) and 2 primary studies (Egri-Okwaji et al. 1984; Ighogboja et al. 1995).

¹⁵ Based on 1 service description (Fernandez et al. 1993).

2.5.3.16 *The cultural beliefs and attitude of the woman may influence her decision whether to donate milk. For example, belief in milk kinship restricts the use of donor milk banks under strict Islamic law¹⁷.*

2.5.4 Evidence to recommendations

See also appendix 3 for the development of the recommendations using formal consensus techniques.

The GDG considered that any recruitment strategy should be broad, and not targeted at any specific group of potential donors. In addition, the milk bank should be able to recruit using a flexible approach that balances their workload and costs of recruiting with successful recruitment. Existing milk banks will have their own preferred strategies, but for any newly created milk banks or existing milk banks needing to increase their levels of recruitment, the suggested options will be a useful resource.

2.5.5 Recommendations

Recommendation 1.2.9

When promoting the donation of breast milk, aim to reach as many potential donors as possible through a variety of channels, including:

- providing written information to be left in:
 - GP surgeries
 - antenatal clinics and postnatal wards
 - volunteer and other organisations working in maternity and childbirth
 - children's or Sure Start centres
 - maternity shops
- direct referrals or recommendations by:
 - current and previous donors
 - staff at neonatal intensive care units
 - paediatricians assessing babies' progress
 - health visitors (or other healthcare professionals providing postpartum care)

¹⁶ Based on 1 narrative review (Holland 2006) and 1 opinion piece (Modi 2006).

¹⁷ Based on 1 narrative review (Holland 2006) and 1 opinion piece (Modi 2006).

- childbirth educators
- organisers and attendees of prenatal and postnatal classes
- breastfeeding mothers' support groups and related organisations
- features in the media.

Recommendation 1.2.10

Use clear, non-technical language when communicating the use of donor milk and the process of donor milk banking in any written information and activities.

2.6 *Screening and selecting donors*

2.6.1 Review question

What factors should be assessed to determine the suitability of potential donors?

What initial and repeat serological testing should be undertaken:

- when screening potential donors?
- in donor women while continuing to donate?

2.6.2 Evidence review

Forty-seven of the 202 studies included in the review provided 108 evidence records. The studies contained:

- 24 service descriptions
- 10 narrative reviews
- 5 position statements
- 4 opinion pieces
- 2 primary studies
- 1 case report and 1 meeting report.

Their publication dates ranged from 1951 to 2008.

The service descriptions reported practice in the UK, the USA, Canada, Australia, Sweden, South Africa, China, India, Poland, Germany and Denmark.

There was general agreement that screening and selection of donors was needed, but there was less agreement on the exact nature of these. As with recruitment strategies, there was considerable variation in the delivery, content and timing of screening and selection. There was no direct reference to costs.

There was little evidence on whether adequate screening and selection strategies resulted in less bacterial contamination of donor milk. One primary study (Almeida and Dórea 2006) evaluated all of its quality assurance measures, but did not use a control group for comparison and therefore could not determine that screening and selection alone were effective in reducing bacterial contamination of donor milk.

2.6.3 Evidence statements

- 2.6.3.1 *There is general agreement that any donor milk programme should have an agreed screening and selection process for potential donors. Screening and selection should be based on a balanced consideration of relative risk for the baby and aim to minimise bacterial contamination. However, there is a lack of evidence on what should be screened for based on good studies showing evidence of transmission of infection via donor milk¹⁸.*
- 2.6.3.2 *In the past, not all milk banks have screened potential donors, either by taking a history of past or current infection or by laboratory tests¹⁹.*
- 2.6.3.3 *One milk bank accepts donations of previously expressed breast milk. Although all potential donors are screened in the same way, questions relating to the use of prescription and recreational drugs, smoking, and alcohol must be answered retrospectively when donations have been expressed before the screening²⁰.*

¹⁸ Based on many reports and studies (Anon 1980; Anon 1995; Asquith et al. 1987; Hartmann et al. 2007; Kinsey 1984; Mortimer et al. 1988).

¹⁹ Based on 1 position statement (Anon 1985) and 1 service description (McEnery and Chattopadhyay 1978).

²⁰ Based on 1 service description (Hartmann et al. 2007).

- 2.6.3.4 *Women who are HIV positive or who are at high risk of HIV infection should not donate breast milk²¹.*
- 2.6.3.5 *Women who have received live rubella vaccination postpartum should not donate breast milk soon after vaccination because studies have shown rubella virus in milk 12 days after postpartum vaccination²².*
- 2.6.3.6 *Not all milk banks screen all potential donors for infections such as tuberculosis, syphilis, HIV, hepatitis B or cytomegalovirus (CMV). The decision to screen for an infectious agent may be based on some or all of the following.*
- *The availability of effective treatment processes that eliminate the specific contamination.*
 - *Local testing or screening programmes for pregnant women during the antenatal period.*
 - *Low regional or local prevalence, which means that screening is undertaken only in potential donors from high-risk groups.*
 - *National screening recommendations²³.*
- 2.6.3.7 *Potential donors are asked about:*
- *their general health and medical history (including acute or chronic infections, recent vaccinations, or past blood transfusions)*
 - *the health and nutritional status of their baby*
 - *their diet history and nutritional intake*
 - *any exposure to HIV, toxoplasmosis, tuberculosis, syphilis, hepatitis, rubella, herpes and CMV*

²¹ Based on 1 narrative review (Boyes 1987) and 1 position statement (Anon 1995).

²² Based on 1 position statement (Anon 1985).

²³ Based on 1 narrative review (Bromberger 1982), 2 opinion pieces (Braune 1982; Lucas 1987), 2 position statements (Anon 1985; Gutierrez and de Almeida 1998) and 7 service descriptions (Arnold 1999; Balmer and Wharton 1992; Baum 1982; Bjorksten et al. 1980; Connor 1982; Fernandez et al. 1993; McEnery and Chattopadhyay 1978).

- any exposure to CJD (for example, in the USA, milk donations are not accepted from women who were in the UK for more than 3 months, or in Europe for more than 5 years, between 1980 and 1996)
- use of any drugs and any other medical treatments
- any exposure to pollutants
- any occupational exposure to chemicals
- the presence of diarrhoea
- symptoms of other recurrent infections
- the use of recreational drugs, alcohol and smoking²⁴.

2.6.3.8 *Milk banks use the following tests or investigations when screening or selecting prospective milk donors.*

- General physical examination.
- Chest radiograph, purified protein derivative (PPD) or tine test (for tuberculosis).
- HIV antibody blood test (recommended by the Centers for Disease Control).
- Blood tests for HBsAg and anti-HBc (for hepatitis).
- Venereal disease research laboratory (VDRL) test (for syphilis).

2.6.3.9 *The tests may vary in different milk banks depending on tests routinely undertaken during antenatal and perinatal assessment in local hospitals²⁵.*

2.6.3.10 *The reasons for testing are explained to each woman when she first contacts the milk bank about donating milk. Consent for testing is sought from each woman²⁶.*

²⁴ Based on 1 narrative review (Bromberger 1982), 9 service descriptions (Asquith et al. 1987; Balmer and Wharton 1992; Bjorksten et al. 1980; Cash and Giacoia 1981; Davidson et al. 1979; Fernandez et al. 1993; Kimball et al. 1955; Langerak and Arnold 1991; McEnery and Chattopadhyay 1978), and 3 position statements (Anon 1985; Fernandez et al. 1990; Gutierrez and de Almeida 1998).

²⁵ Based on 8 service descriptions (Asquith et al. 1987; Balmer and Wharton 1992; Baum 1982; Bjorksten et al. 1980; Cash and Giacoia 1981; Connor 1982; Fernandez et al. 1993; Hartmann et al. 2007) and 2 position statements (Anon 1985; Fernandez et al. 1990).

- 2.6.3.11 *One milk bank asked potential donors to attend a follow-up appointment to receive the results of the blood test(s) in person²⁷.*
- 2.6.3.12 *In one milk bank, the potential donor is given a form by the milk bank nurse at her first visit (similar to that given to blood donors) that lists the high-risk groups for HIV infection. The nurse asks the woman not to offer her milk if she falls into a high-risk group. Each woman gives written consent to be tested for HIV antibodies. If a potential donor is HIV positive, arrangements for counselling are made²⁸.*
- 2.6.3.13 *In one milk bank, blood is tested at the potential donor's home to minimise any inconvenience to the woman²⁹.*
- 2.6.3.14 *Tests are repeated if a woman continues to donate 3 months after the date of the initial blood test³⁰.*
- 2.6.3.15 *Various methods are used to collect information for screening potential donors. Examples from different milk banks include information collected from:*
- *scheduled visits to healthcare professionals, such as gynaecologists and paediatricians*
 - *medical records from different healthcare professionals, such as primary care providers and paediatricians*
 - *a simple questionnaire*
 - *an interview at the milk bank*
 - *a visit to the potential donor's home (which may provide information on standards of hygiene).*
- 2.6.3.16 *Information is also collected by different members of staff, including the milk bank coordinator or the milk bank nurse³¹.*

²⁶ Based on 2 service descriptions (Balmer and Wharton 1992; Hartmann et al. 2007).

²⁷ Based on 1 service description (Hartmann et al. 2007).

²⁸ Based on 1 service description (Balmer and Wharton 1992).

²⁹ Based on 1 service description (Balmer and Wharton 1992).

³⁰ Based on 1 service description (Hartmann et al. 2007).

2.6.3.17 *Some studies suggest that because the composition of milk changes over time, any screening and selection of potential donors and/or samples should take this into account when matching adequate nutrition and immunological status for recipient babies³².*

2.6.4 Evidence to recommendations

See also appendix 3 for the development of the recommendations using formal consensus techniques.

The GDG considered the screening and selection of potential donors to be vital to ensure the safety of donated milk; screening and selection also links very closely to the evidence reviews and considerations on testing and treating donor milk.

It was clear that there was no consensus in the evidence on how potential donors should be screened, but there was agreement that it should be done; however, screening tests differed according to the local prevalences of infectious diseases. In the UK, potential donors should be screened for HIV 1 and 2, hepatitis B and C, HTLV I and II, and syphilis; these are all present to some degree in the UK population with local variation (see www.hpa.org.uk for information on the prevalence and incidence). These diseases are known to be transmitted via breast milk or breastfeeding (see www.hpa.org.uk for information on transmission via breastfeeding) or contained in the breast milk of infected mothers (Pronczuk et al. 2002), and have significant consequences if contracted. For other viral contaminants, such as CMV, although there is documented evidence on the risk of transmission, there is also evidence that pasteurisation and other processing techniques, including freezing, destroys the contamination (see section 2.16.4). The point therefore at which the risk is controlled is through adequate pasteurisation and storage, not through screening potential donors for CMV. This risk of transmission for other contaminants needs to be balanced against the effects of pasteurisation

³¹ Based on 1 primary study (Almeida and Dórea 2006), and 9 service descriptions (Arnold 1999; Asquith et al. 1987; Balmer and Wharton 1992; Beal et al. 1978; Connor 1982; Dempster 1982; Langerak and Arnold 1991; McEnery and Chattopadhyay 1978; Murray 1953).

³² Based on 2 narrative reviews (Anon 1987; Bromberger 1982).

and handling of milk (pasteurisation reduces viral and bacterial contamination, but, depending on the levels, may not eliminate all contamination).

The GDG considered that the risk of a recipient of donor milk contracting any of the screened diseases was so serious that any risk of transmission should be minimised through effective screening and pasteurisation of donated milk. Screening incurs an extra cost, but in this context this was considered necessary; the screening is also in line with that recommended for blood and tissue donor programmes in the UK (see www.transfusionguidelines.org.uk/index.aspx).

Screening should be a staged process with women being allowed to self-screen initially. This is followed by a formal testing stage, with a more detailed discussion of screening with potential donors before their acceptance by the milk bank. This is then followed up throughout the donation process, with donors informing the milk bank if their circumstances or situation has changed.

For the draft version of guidance, the GDG recommended a different strategy for ongoing donation compared with a one-off donation. Several concerns were raised about this at consultation, and the GDG discussed the rationale for this. After this discussion, the GDG agreed that there was no evidence on which to base this recommendation, and no rationale to support the recommended difference. One option could be to quarantine all milk until serological test results are available. However, the practicalities and costs of this make it unviable. The risk of both acquiring infection and transmitting it via donor breast milk was considered to be immeasurably small (a minimum estimate of seroconversion in pregnancy is 15%, with an overall prevalence rate in pregnant women of approximately 0.14% in the UK [see the Health Protection Agency website www.hpa.org.uk and the National Study of HIV in Pregnancy and Childhood website www.nshpc.ucl.ac.uk for latest figures from the National Audit on Perinatal Transmission]); particularly when donated milk is then pasteurised. The GDG considered that if the recommended processes are deemed safe for ongoing donation, then in the absence of evidence to the contrary, the same process should be recommended for a one-off donation.

There was no conclusive evidence identified on test accuracies to quantitatively evaluate optimal testing strategies, as well as cost effectiveness of donor screening. However, after the milk has been pasteurised the risk of a baby contracting the diseases screened for above is very low (no cases of transmission of any of the screened conditions via pasteurised donor milk were identified). Therefore, the quality-adjusted life year (QALY) loss associated with every extra avoidable case through relatively economical blood testing is likely to outweigh extra costs. The fact that a 'stepped' screening algorithm is proposed, where self-assessment is recommended before the formal testing stage, ensures that a proportion of donors who would not be eligible for donating breast milk will not have to undergo further, more resource-intensive testing.

As part of the requirements for tracking and tracing, laboratories should archive donor blood samples as recommended in current guidelines from the Royal College of Pathologists (available from www.rcpath.org).

2.6.5 Recommendations

Recommendation 1.2.11

Follow the stepped screening process detailed in recommendations 1.2.12 to 1.2.21 when recruiting donors.

Recommendation 1.2.12

Advise a potential donor that she is not eligible to donate milk if she:

- currently smokes or uses nicotine replacement therapy (NRT)
- regularly exceeds recommended alcohol levels for breastfeeding mothers (1 to 2 units, once or twice a week) (see www.dh.gov.uk for information on alcohol and breastfeeding)
- is using, or has recently used, recreational drugs
- has previously tested positive for HIV 1 or 2, hepatitis B or C, human T-lymphotropic virus (HTLV) type I or II, or syphilis
- is at an increased risk of Creutzfeldt–Jakob disease (CJD) (see www.hpa.org.uk for information on the risk of CJD).

Include this information in recruitment material so that potential donors can self-screen for these criteria.

Recommendation 1.2.13

Using a process of informal interview, referring to medical sources (with consent) if necessary, ask the potential donor questions on the topics that follow. Use the information she gives to make a balanced decision about her eligibility to donate based on possible risks to recipients and/or the results of subsequent serological tests (see recommendations 1.2.16 and 1.2.17). Ask questions about:

- her health: to confirm that she is in good general health
- her baby: document the age and health of the baby
- any exposure to passive smoke: is she exposed to high or sustained levels of passive smoke (for example, do other members of her household smoke heavily)?
- any medication that she is taking: is she currently taking any medication or undergoing any other medical therapy?
- any significant environmental or chemical exposure (such as contamination of the local water supply): is she exposed to high or sustained levels of environmental or chemical contaminants that can be expressed in breast milk?
- any recent exposure to infection (including HIV 1 or 2, hepatitis B or C, HTLV I or II, syphilis, herpes, or acute or chronic infections). Depending on the assessment of level of risk, further testing may be needed.
- any recent medical intervention (for example, exposure to diagnostic radioactive isotopes)
 - refer to guidance from the Department of Health on the safety of recent vaccination when breastfeeding (available from www.dh.gov.uk).

Advise the potential donor that depending on her answer to any of these questions she may not be eligible to donate milk.

Recommendation 1.2.14

If a potential donor is donating previously expressed breast milk, ask her to

answer the screening questions (recommendations 1.2.12 to 1.2.13) for the period when the milk was expressed.

Recommendation 1.2.15

Conduct the screening interview, detailed in recommendations 1.2.12 and 1.2.13, with potential donors at a mutually acceptable time and place, either face-to-face or by telephone.

Recommendation 1.2.16

When donors first contact the milk bank about donating milk, explain that serological testing is mandatory to reduce the risk of passing on infections. Obtain informed consent before testing.

Recommendation 1.2.17

Undertake serological testing of all potential donors for the following and exclude women from donating who test positive for:

- HIV 1 or 2
- hepatitis B or C
- HTLV I or II
- syphilis.

Recommendation 1.2.18

Perform all serological screening tests at the time of enrolling for donor milk banking; do not rely on antenatal test results.

Recommendation 1.2.19

All tests should be undertaken in laboratories with clinical pathology accreditation (CPA).

Recommendation 1.2.20

Ensure that laboratories communicate the results of serological testing clearly and that they provide appropriate interpretive comments.

Recommendation 1.2.21

Give serological test results to potential donors either in person or by telephone (unless they prefer to receive them in writing). If needed, offer

further help and support based on local protocols, including information about counselling and local support groups.

Recommendation 1.2.22

Laboratories should archive samples of blood received from donors.

2.7 Donor consent

2.7.1 Review question

What information should donors and parents or carers of infants using donor breast milk be given to ensure full informed consent, and how should this be recorded?

In discussion with the GDG, it was agreed that consent for use of donated breast milk was not relevant to this guideline; but parents or carers of recipients of donor milk should understand the process of donor milk banking and the 'Understanding NICE guidance' (a summary for patients and carers, available from www.nice.org.uk/guidance/CG93/PublicInfo) explains this.

2.7.2 Evidence review

Only 1 of the 202 studies included in the review contained a service description from a milk bank in Australia (Hartmann et al. 2007) that made reference to the process of recording donor consent; however, no details of the process of obtaining informed consent or the importance of this were reported.

2.7.3 Evidence statements

2.7.3.1 No included study made detailed reference to the process of obtaining consent from donors, although two milk banks did report documenting consent.

2.7.3.2 One milk bank recorded donor consent as part of the donor's medical record (Hartmann et al. 2007)³³.

³³ Based on 2 service descriptions (Hartmann et al. 2007; Penc 1996).

2.7.4 Evidence to recommendations

See also appendix 3 for the development of the recommendations using formal consensus techniques.

As with all donor programmes, donors need to give informed consent for both serological testing and the process of handling their donated milk.

2.7.5 Recommendations

Recommendation 1.2.23

Before accepting a donor's milk, obtain her consent for the processing and intended use of the donated milk. Advise her that once donated, milk will not be returned to her.

2.8 *Training and supporting donors*

2.8.1 Review question

This was extracted from the evidence review on recruitment – see section 2.5.

2.8.2 Evidence review

Twenty-five of the 202 studies included in the review provided 33 evidence records. The studies contained:

- 16 service descriptions
- 3 narrative reviews
- 4 position statements
- 1 case report
- 1 primary study.

The publication dates ranged from 1951 to 2007.

The service descriptions reported practice in the UK, the USA, Australia, Germany, South Africa, Sweden, Denmark, Canada and Brazil.

There was general agreement that training and support for donors was needed, but there was less agreement on the exact content of the training and

the level of support needed. When reported, support and training differed in delivery, content and timing. There was no direct reference to costs.

There was little evidence on whether adequate donor support and training strategies result in less bacterial contamination of donor milk. One primary study (Almeida and Dórea 2006) evaluated all of its quality assurance measures, but did not use a control group for comparison and therefore could not determine that support and training alone were effective in reducing bacterial contamination of donor milk.

2.8.3 Evidence statements

- 2.8.3.1 *Some studies found that donors need constant support, including psychological support, throughout the process of milk donation, because collecting milk is time consuming and the techniques of milk expression are key to successful lactation and its maintenance³⁴.*
- 2.8.3.2 *Frequent contact with, and feedback from, milk bank staff may help to maintain the commitment of donors to collect as much high-quality milk as possible³⁵.*
- 2.8.3.3 *Staff who collect donated milk from the donor's home can inform the milk bank staff about anything new in the donor's home environment that might compromise the quality of the milk. This gives the milk bank the opportunity to intervene as appropriate³⁶.*
- 2.8.3.4 *Donors can be supervised at home (for example, by health visitors) while collecting and storing donations. Such supervision may result in a lower level of contamination of milk, and thus fewer discarded donations³⁷.*

³⁴ Based on 1 narrative review (Bromberger 1982) and 1 position statement (Fernandez et al. 1990).

³⁵ Based on 1 service description (Asquith et al. 1987).

³⁶ Based on 1 service description (Asquith et al. 1987).

³⁷ Based on 2 service descriptions (Connor 1982; Davidson et al. 1979) and 1 position statement (Fernandez et al. 1990).

2.8.3.5 *There was general agreement that donors should be trained in the proper techniques for:*

- *milk expression and collection, including the use of pumps and containers, and their cleaning*
- *milk storage, including the cooling and freezing of milk*
- *personal hygiene, including hand washing and cleaning the breasts.*

Such training can help to minimise bacterial contamination³⁸.

2.8.3.6 *One milk bank trained donors in the proper processes for administration of milk samples, including instructions on the appropriate labelling of milk³⁹.*

2.8.3.7 *Two milk banks gave donors information on diet, and alcohol and caffeine consumption⁴⁰.*

2.8.3.8 *Training provided by the milk banks varied. Some provided written material, others provided face-to-face training by milk bank staff, and some provided both. Training was delivered at different times (for example, on discharge from hospital, at interview for donor selection, or at the donor's home when delivering the equipment provided)⁴¹.*

2.8.3.9 *Two milk banks considered that donors should be provided with the equipment needed for collection and storage of milk. This may include:*

- *a breast pump*

³⁸ Based on 3 narrative reviews (Bjorksten et al. 1980; Bromberger 1982; Kinsey 1984), 4 position statements (Anon 1980; Anon 1985; Fernandez et al. 1990; Gutierrez and de Almeida 1998), 1 primary study (Almeida and Dórea 2006), and 9 service descriptions (Asquith et al. 1987; Cash and Giacoia 1981; Connor 1982; Davidson et al. 1979; Dempster 1982; Hartmann et al. 2007; Kimball et al. 1955; Langerak and Arnold 1991; Morley-Peet 1983).

³⁹ Based on 1 service description (Asquith et al. 1987).

⁴⁰ Based on 2 service descriptions (Asquith et al. 1987; Cash and Giacoia 1981).

⁴¹ Based on 8 service descriptions (Asquith et al. 1987; Beal et al. 1978; Cash and Giacoia 1981; Connor 1982; Dempster 1982; Hartmann et al. 2007; Kimball et al. 1955; Langerak and Arnold 1991).

- *sterile bottles*
- *labels for donations*⁴².

2.8.4 Evidence to recommendations

See also appendix 3 for the development of the recommendations using formal consensus techniques.

It is important to provide donors with initial and ongoing training. The provision of training may be associated with lower levels of contamination in donor milk. The GDG has made recommendations for some important components of training, but any additional training and ongoing support should be individualised and based on the donor's needs.

There was no conclusive evidence linking training interventions, particularly ongoing training programmes, to surrogate outcomes (including levels of contamination in donor milk) or primary outcomes (such as recipient morbidity and mortality). However, the importance of adequate training has been stressed and should meet the donor's needs while ensuring that staff time is used efficiently (for example, arrange a telephone meeting when receiving samples and, instead of face-to-face meetings, when appropriate plan training after routine milk collection or delivery to reduce travel and time requirements for staff).

⁴² Based on 2 service descriptions (Asquith et al. 1987; Hartmann et al. 2007).

2.8.5 Recommendations

Recommendation 1.2.26

Provide all new donors with training, preferably face-to-face with additional information by telephone and in writing. Arrange training at a time and place suitable for both donor and trainer.

Recommendation 1.2.27

Training for new donors should cover:

- hand washing and the importance of this
- good personal hygiene
- collecting and expressing milk, including cleaning and using breast pumps and containers
- storing donated milk (including cooling and freezing)
- labelling donated milk, and documenting storage conditions
- transportation of donated milk (if needed).

Recommendation 1.2.28

Provide ongoing support to all donors according to their individual needs until no longer required. This may include:

- information and ongoing support on milk bank requirements for their diet and alcohol consumption
- continued support for collecting expressed milk and maintaining lactation
- emotional support.

Recommendation 1.2.29

Offer additional support and information on milk collection to donors whose milk has significant or repeated microbial contamination.

2.9 *Stopping or suspending milk donations*

2.9.1 Review question

When should donor women be advised to stop donating milk, either temporarily or permanently?

2.9.2 Evidence review

Twelve of the 202 studies included in the review provided 14 evidence records. The studies contained:

- 9 service descriptions
- 2 narrative reviews
- 1 primary study.

The publication dates ranged from 1951 to 2007.

The service descriptions reported practice in the USA, the UK and Denmark.

There was general agreement that donors should be advised to stop donating in certain circumstances, but there was less agreement on the exact detail of when donors should be advised to stop, either temporarily (for example, if a donor has a raised temperature) or permanently (for example, if a donor stops breastfeeding her own baby).

2.9.3 Evidence statements

2.9.3.1 *One milk bank advised donors who supplied contaminated milk to stop donating milk⁴³.*

2.9.3.2 *One milk bank advised donors who supplied milk with a low protein content to stop donating milk⁴⁴.*

2.9.3.3 *One milk bank advised donors who supplied small amounts of milk (less than 2 ounces daily after a week's trial) to stop donating milk⁴⁵.*

2.9.3.4 *In one study, donors abstaining from donating milk because they were taking medication (50/56 [89.3%] treatments were for infections) were advised to wait for five half-lives of the drug after*

⁴³ Based on 1 service description (Arnold 1999).

⁴⁴ Based on 1 service description (Arnold 1999).

⁴⁵ Based on 1 service description (Kimball et al. 1955).

the last ingested dose before they resumed collecting milk; in most cases, a washout period of 1 day was sufficient⁴⁶.

2.9.3.5 *One milk bank advised donors who had herpetic lesions to stop collecting milk while the lesions were present⁴⁷.*

2.9.3.6 *One milk bank advised donors to stop collecting milk for 3 weeks after rubella vaccination⁴⁸.*

2.9.3.7 *Two milk banks advised donors whose babies became ill to stop donating milk⁴⁹.*

2.9.3.8 *Two milk banks advised donors who became ill to stop donating milk⁵⁰.*

2.9.3.9 *One milk bank advised donors who were taking prescription drugs that they could continue to express and any milk that contained contraindicated drugs should be labelled and would be saved for research projects⁵¹.*

2.9.4 Evidence to recommendations

See also appendix 3 for the development of the recommendations using formal consensus techniques.

Advice to donors about stopping donation relates closely to the staged screening process described above. Donors are required to inform the milk bank of any changes to their situation; this includes any medical treatment, or any prescribed or over-the-counter drugs, or any herbal supplements. The decision to advise donors to suspend or stop donating milk should then be taken by the milk bank.

⁴⁶ Based on 1 primary study (Hoppu et al. 1994).

⁴⁷ Based on 1 service description (Asquith et al. 1987).

⁴⁸ Based on 1 service description (Asquith et al. 1987).

⁴⁹ Based on 2 service descriptions (Balmer and Wharton 1992; Cash and Giacoia 1981).

⁵⁰ Based on 2 service descriptions (Cash and Giacoia 1981; McEnery and Chattopadhyay 1978).

⁵¹ Based on 1 service description (Langerak and Arnold 1991).

There are many reference sources on drugs and breastfeeding; for example, the 'British national formulary for children' (BNF-C). However, any decision on whether a donor should suspend donation needs to be taken based on the anticipated recipient; for example, although one drug may be safe for a full-term healthy baby, a milk bank may decide not to accept milk from a donor taking the same drug if the milk will be used for a pre-term baby with significant health problems. Because of this, the GDG decided that it was not possible to make detailed recommendations on advising donors to suspend or stop donation when they start taking drugs or herbal supplements; the donor informing the milk bank of any new drug or supplement they are taking is therefore paramount.

The same issues apply for any other changes in the donor's circumstances (for example, a significant change in diet), and it is imperative that she contacts the milk bank for a full discussion.

Milk banks sometimes advise donors to stop donating when their own baby reaches a certain age, such as 12 months. This is because changes in the composition of breast milk are known to occur with time from birth. However, it is not possible to know either the recipient of the donor milk or the effect of receiving 'age-inappropriate' milk. The GDG therefore recommended that each milk bank should advise donors when to stop donating based on their local requirements; this could include, for example, the milk banks' anticipated recipient population or the current stock levels.

2.9.5 Recommendations

Recommendation 1.2.24

While a donor continues to donate, ask regularly about her general health and the exclusion criteria detailed in recommendations 1.2.12 to 1.2.13. Advise her that if her status or circumstances change in relation to these, she should contact the milk bank immediately.

Recommendation 1.2.25

Do not routinely repeat serological tests while the donor is donating milk.

Recommendation 1.2.30

Consider no longer accepting breast milk from donors who, despite support, consistently supply:

- breast milk that does not meet the microbiological criteria (see recommendation 1.2.58)
- small amounts of breast milk.

Recommendation 1.2.31

Advise donors to contact the milk bank to discuss suspending or stopping their breast milk donation if they develop a fever or have contact with a viral exanthematous disease.

Recommendation 1.2.32

Advise donors who begin taking any medication that they should contact the milk bank to discuss suspending or stopping their breast milk donation. Use appropriate reference sources⁵².

Recommendation 1.2.33

Advise donors to contact the milk bank to discuss suspending or stopping their breast milk donation if they develop lesions or infections of the breast (including mastitis or herpes).

Recommendation 1.2.34

Provide donors who are stopping their breast milk donations with as much advice and support as needed.

Recommendation 1.2.35

Take into account the size of the recipient population and the milk bank's stock levels when discussing how long a woman can donate milk.

⁵² See the British national formulary for children, the Drugs and Lactation Database LactMed (www.toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT) or the UK Drugs in Lactation Advisory Service (see www.ukmicentral.nhs.uk/drugpreg/guide.htm).

2.10 *Expressing milk at home for donation*

2.10.1 Review question

What are the best (safest) methods for collecting, storing and handling donor breast milk?

- How should donor milk be expressed?

2.10.2 Evidence review

Thirty-nine of the 202 studies included in the review provided 65 evidence records. The studies contained:

- 20 service descriptions
- 8 narrative reviews
- 8 primary studies
- 3 position statements.

The publication dates ranged from 1951 to 2007.

The service descriptions reported practice in the UK, the USA, Denmark, China, Australia, Sweden, South Africa, India, Canada and Venezuela.

Practice differed between milk banks, and there was some limited evidence comparing expression techniques or process with the level of bacterial contamination in donor milk. No direct reference to costs was made.

2.10.3 Evidence statements

2.10.3.1 There is no consensus on whether drip milk should be accepted for use. However, there is general agreement that drip milk is lower in fat (and therefore energy) than expressed milk⁵³.

⁵³ Based on 3 narrative reviews (Arnold 1997; Davies 1982; Williams and Pittard, III 1981), 3 primary studies (Almeida and Dórea 2006; Gibbs et al. 1977; Lucas and Roberts 1978) and 5 service descriptions (Balmer and Wharton 1992; Baum 1982; McEnery and Chattopadhyay 1978; Morley-Peet 1983; Tomalin 1983).

- 2.10.3.2 *When drip milk is collected and combined with expressed milk, a considerable increase in energy and fat content is seen compared with drip milk alone⁵⁴.*
- 2.10.3.3 *Many milk banks recommend that donors discard the first 10 ml of expressed milk because this is likely to have a higher level of bacterial contamination. However, one primary study concluded that donors should not discard the first few millilitres of milk because this would result in smaller quantities of milk and would offer no advantage in terms of bacterial contamination (Carroll et al. 1980)⁵⁵.*
- 2.10.3.4 *Higher rates of bacterial contamination and lower energy and total fat content have been seen in milk expressed using pumps compared with milk expressed manually. Many milk banks therefore recommend that donors express milk manually⁵⁶.*
- 2.10.3.5 *However, some milk banks make no specific recommendation on how donor milk should be expressed. It is therefore assumed that the preference of the donor is taken into account. For example, one milk bank provides donors with a hand breast pump because although they note that manual expression is the 'cleanest method' of expression, most women prefer to use a hand breast pump (Balmer and Wharton 1992)⁵⁷.*
- 2.10.3.6 *One study noted a specific need to support donors when they stop expressing milk if their own baby has died⁵⁸.*

2.10.4 Evidence to recommendations

See also appendix 3 for the development of the recommendations using

⁵⁴ Based on 1 narrative review (Davies 1982) and 1 primary study (Stocks et al. 1983).

⁵⁵ Based on 3 narrative reviews (Kinsey 1984; Roy and Lescop 1979; Williams and Pittard, III 1981), 1 position statement (Anon 1980), 3 primary studies (Asquith and Harrod 1979; Carroll et al. 1980; West et al. 1979) and 5 service descriptions (Asquith et al. 1987; Beal et al. 1978; Dempster 1982; Greenwood Wilson 1951; Pedersen 1982).

⁵⁶ Based on 2 narrative reviews (Kinsey 1984; Williams and Pittard, III 1981), 1 position statement (Anon 1980), 4 primary studies (Almeida and Dórea 2006; Boutte et al. 1985; Liebhaber et al. 1978; Tyson et al. 1982) and 4 service descriptions (Asquith et al. 1987; Beal et al. 1978; Cash and Giacoia 1981; Langerak and Arnold 1991).

formal consensus techniques.

All breastfeeding mothers should be given clear information on how to express milk for their own babies. The GDG therefore made recommendations about expressing milk only where techniques or practice are different for donated milk.

It is accepted that different expression techniques (for example, the use of pumps) affect the composition of the milk. The aim of recommending hand expression, and not 'drip milk', was to ensure the optimal levels of nutritional components, such as fat, with minimal bacterial contamination. However, the GDG recognised that manual expression may not be preferred by all donors.

2.10.5 Recommendations

Recommendation 1.2.36

Advise donors to collect expressed milk rather than 'drip' milk (milk that is passively collected from one breast while the baby feeds at the other) for donation.

Recommendation 1.2.37

Actively encourage donors to hand express milk; however, accept pump-expressed milk if donors prefer this method.

2.11 *Handling milk at home*

2.11.1 Review question

What are the best (safest) methods for collecting, storing and handling donor breast milk?

- How, and for how long, should donor milk be stored at home, including refrigeration and freezing?

⁵⁷ Based on 8 service descriptions (Arnold 1996; Arnold 1999; Asquith et al. 1987; Balmer and Wharton 1992; Bjorksten et al. 1980; Hoey et al. 1980; Kimball et al. 1955; Sauve et al. 1984).

⁵⁸ Based on 1 narrative review (Woo and Spatz 2007).

2.11.2 Evidence review

Twenty-six of the 202 studies included in the review provided 43 evidence records. The studies contained:

- 19 service descriptions
- 3 position statements
- 2 narrative reviews
- 1 case report
- 1 primary study.

The publication dates ranged from 1951 to 2007.

The service descriptions reported practice in the UK, the USA, Denmark, Australia, Brazil, Sweden, South Africa, Canada and Germany.

The milk banks differed in their instructions to donors on how milk should be handled in the home. However, there was general agreement that milk banks should give guidance on the handling of milk in a donor's home. No direct reference to costs was made.

See also the evidence review on milk handling in general below.

2.11.3 Evidence statements

2.11.3.1 Milk banks differ in their instructions to donors on how milk should be handled in the home. However, there is general agreement that milk banks should give guidance on the handling of milk in a donor's home⁵⁹.

2.11.3.2 Good hygiene is important for all aspects of milk handling in a donor's home⁶⁰.

2.11.3.3 Most milk banks provide donors with instructions on how milk should be stored before collection, and most recommend that milk

⁵⁹ Based on many references; a specific example is from 1 service description (Pedersen 1982).

⁶⁰ Based on 1 narrative review (Davies 1982), 1 primary study (Minder et al. 1982) and 1 service description (Cash and Giacoia 1981).

should be stored in a freezer. Some milk banks allow storage in a refrigerator if milk is being collected on a daily basis (or as soon as possible)⁶¹.

2.11.3.4 One milk bank reported a marked reduction in bacterial contamination before pasteurisation when donors were advised to store milk in home freezers rather than in the refrigerator⁶².

2.11.3.5 One milk bank instructed donors that any expressed milk should not be left uncovered or allowed to reach room temperature after collection had been completed. After an outbreak of infection caused by contaminated milk, the milk bank also recommended that milk should be refrigerated immediately after collection had been completed⁶³.

2.11.3.6 Brazilian milk banks advised donors that milk should be stored in the freezer for no longer than 5 days or in the refrigerator (at 5°C) for no longer than 24 hours before being transported to the milk bank⁶⁴.

2.11.3.7 One milk bank advised donors that milk should be stored in the freezer for no longer than 7 days before being transported to the milk bank⁶⁵.

2.11.3.8 One primary study reported that safe, unpasteurised milk could be collected from donors if a 'careful aseptic collection technique under adequate microbiological control' is used. Two milk banks also reported that by following agreed procedures, milk was collected that showed no bacterial growth⁶⁶.

⁶¹ Based on 1 narrative review (Kinsey 1984), 1 position statement (Anon 1985) and 12 service descriptions (Arnold 1999; Balmer and Wharton 1992; Baum 1982; Beal et al. 1978; Bjorksten et al. 1980; Cash and Giacoia 1981; Davidson et al. 1979; Hoey et al. 1980; Kimball et al. 1955; Sauve et al. 1984; Springer 1997; Tomalin 1983).

⁶² Based on 1 service description (Lucas et al. 1979).

⁶³ Based on 1 service description (Beal et al. 1978) and 1 case report (Ryder et al. 1977).

⁶⁴ Based on 1 position statement (Gutierrez and de Almeida 1998).

⁶⁵ Based on 1 service description (Cash and Giacoia 1981).

⁶⁶ Based on 1 primary study (Murphy et al. 1982) and 2 service descriptions (Asquith et al. 1987; Pedersen 1982).

2.11.3.9 *There is no consensus on the type of container that donors should use to collect expressed milk. Examples of containers provided by milk banks include aluminium jugs, milk jars, and glass or rigid plastic containers. Such containers are often supplied by the milk bank. However, there is general agreement that any container used should be sterilised (for example, by washing in a sterilisation solution)⁶⁷.*

2.11.3.10 *Some milk banks do not allow donors to use containers other than those provided⁶⁸.*

2.11.3.11 *Some milk banks instruct donors to pool milk collected over 24 hours⁶⁹.*

2.11.3.12 *One milk bank instructed donors to express only once into autoclaved bottles, which were then stored in the refrigerator until collection⁷⁰.*

2.11.4 Evidence to recommendations

See also appendix 3 for the development of the recommendations using formal consensus techniques.

The recommendations on handling milk at home were also based on the evidence and considerations on handling milk at the milk bank.

Overall, the GDG considered the safety of the milk (that is, the level of bacterial contamination) to be paramount. Although refrigerated milk is safe for maternal use, as recommended in ‘Improving the nutrition of pregnant and breastfeeding mothers and children in low-income households’ (NICE public health guidance 11; available from www.nice.org.uk/guidance/PH11), because of transportation to the milk bank and the use of donor milk for babies who

⁶⁷ Based on 1 position statement (Anon 1985), 2 primary studies (Lloyd-Jones et al. 1979; Minder et al. 1982) and 8 service descriptions (Beal et al. 1978; Bjorksten et al. 1980; Cash and Giacoia 1981; Greenwood Wilson 1951; Hartmann et al. 2007; Kimball et al. 1955; Tully 2000; Tully 2001).

⁶⁸ Based on 3 service descriptions (Cash and Giacoia 1981; Dempster 1982; Hartmann et al. 2007).

⁶⁹ Based on 3 service descriptions (Bjorksten et al. 1980; Radcliffe 1989; Tomalin 1983).

⁷⁰ Based on 1 service description (McEnery and Chattopadhyay 1978).

may be pre-term and may have significant health problems, freezing milk at the donor's home was recommended. Recommendations were made about length of storage. 'Improving the nutrition of pregnant and breastfeeding mothers and children in low-income households' (NICE public health guidance 11; available from www.nice.org.uk/guidance/PH11) recommended that breast milk for use with the mother's own baby can be frozen for up to 2 weeks in the freezer compartment of a fridge or for up to 6 months in a domestic freezer at -18°C or lower. The recommended storage times for donated milk were modified to ensure that milk received at the donor milk bank is of the highest nutritional and immunological quality and to reflect the time needed at the milk bank to process the donated milk. There were also concerns about the efficient performance of domestic freezers; again supporting the need to transport the donor milk to the donor milk bank as soon as possible.

2.11.5 Recommendations

Recommendation 1.2.38

Advise donors that expressed milk collected for donation should be frozen as soon as possible to maintain the nutritional and microbiological quality of the milk. If this is not possible (for example, because of storage capacity), advise donors to refrigerate samples collected over 24 hours, and then freeze the batch.

Recommendation 1.2.39

Advise donors that expressed milk for donation should remain frozen during storage at home, and if they have any concerns about storage conditions or freezer temperatures, they should discuss these with the milk bank.

Recommendation 1.2.40

Advise donors that frozen expressed milk should be transported to the milk bank as soon as possible. However, if necessary, expressed milk for donation can be stored before transport to the milk bank for up to 3 months in a domestic freezer, at -18°C or lower. If a donor does not have access to a domestic freezer at her home, she may be able to access freezers for milk storage at local donor milk depots or children's centres.

Recommendation 1.2.41

Advise donors that expressed milk can only be accepted by the milk bank if it has been collected and stored in milk collection containers provided by, or acceptable to, the milk bank.

Recommendation 1.2.42

Advise donors that collection containers for expressed milk should be used according to instructions provided by the milk bank.

Recommendation 1.2.43

Ensure that donors can check and document their freezer temperature every day; this may include providing a thermometer.

2.12 *Transporting milk to the milk bank***2.12.1 Review question**

What are the best (safest) methods for collecting, storing and handling donor breast milk?

- How, and for how long, should donor milk be stored during transportation?

2.12.2 Evidence review

Twenty-seven of the 202 studies included in the review provided 47 evidence records. The studies contained:

- 23 service descriptions
- 2 position statements
- 2 narrative reviews.

The publication dates ranged from 1951 to 2003.

The service descriptions reported practice in the UK, the USA, Germany, Brazil, Sweden, South Africa, Canada, Australia, India, Denmark and Finland.

Practice differed between milk banks, but few details were reported. No direct reference to costs was made.

2.12.3 Evidence statements

- 2.12.3.1 *Details of how milk should be handled during transport were reported only rarely.*
- 2.12.3.2 *When reported, most milk banks transported frozen milk from the donors' homes to the milk banks. Although some milk banks reported collecting milk that was refrigerated⁷¹.*
- 2.12.3.3 *Milk banks transported milk from the donors' homes to the milk banks by air, bus, taxi, milk bank vehicle, hand delivery, collection by the milk bank nurses, community midwives, 'milk man' or volunteers, the American Red Cross, a system using grocery stores as exchange points, or firemen⁷².*
- 2.12.3.4 *Milk banks transported milk from the donors' homes to the milk banks using a variety of containers, including Styrofoam containers with 'blue ice' lids labelled 'perishable, frozen, human milk', bottles packed into cooler boxes, polystyrene foam cooler with an ice brick, polystyrene cool boxes, bottles in a tin bucket, or boxes insulated with crumpled newspaper or packing beads, with dry ice if needed⁷³.*
- 2.12.3.5 *One milk bank stored collected milk at an intermediary, local depository before transporting it in bulk to the milk bank every 2 weeks⁷⁴.*
- 2.12.3.6 *Periods between collections from donors differed; for example, one milk bank collected milk every 10 days (Balmer and Wharton 1992),*

⁷¹ Based on 1 narrative review (Wight 2001) and 9 service descriptions (Asquith et al. 1987; Balmer and Wharton 1992; Baum 1982; Bjorksten et al. 1980; Hoey et al. 1980; Kimball et al. 1955; Langerak and Arnold 1991; Springer 1997; Tully 2001).

⁷² Based on 11 service descriptions (Arnold 1999; Asquith et al. 1987; Balmer and Wharton 1992; Cash and Giacoia 1981; Davidson et al. 1979; Greenwood Wilson 1951; McEnery and Chattopadhyay 1978; Murray 1953; Siimes and Hallman 1979; Springer 1997; Tully 2002).

⁷³ Based on 11 service descriptions (Asquith et al. 1987; Balmer and Wharton 1992; Beal et al. 1978; Davidson et al. 1979; Dempster 1982; Greenwood Wilson 1951; Gutierrez and de Almeida 1998; Kimball et al. 1955; Langerak and Arnold 1991; McEnery and Chattopadhyay 1978; Tully 2000).

⁷⁴ Based on 1 service description (Baum 1982).

one once a week or at least within one month (Bjorksten et al. 1980), and one twice weekly (Connor 1982)⁷⁵.

2.12.4 Evidence to recommendations

See also appendix 3 for the development of the recommendations using formal consensus techniques.

Milk collected from a donor's home should be frozen and remain frozen during transport to the milk bank. The GDG made recommendations to ensure that the milk remains frozen and that quality assurance processes were followed. When appropriate, guidance was based on European Union directives related to the transportation of blood and tissue (available from www.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:294:0032:0050:EN:P DF and www.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:256:0041:0048:EN:P DF).

2.12.5 Recommendations

Recommendation 1.2.44

Define critical conditions for transport, including temperature and time limit, to ensure that donor milk remains frozen during transport.

Recommendation 1.2.45

Transport donor milk in secure, tamper-evident containers and packaging.

Recommendation 1.2.46

If donor milk is transported to the milk bank by a contracted third party, ensure that a documented agreement is in place to maintain the conditions needed.

Recommendation 1.2.47

Define in writing the milk bank's procedures for transporting and storing donor milk. Ensure that these procedures maintain the quality of the donor milk and allow accurate identification of samples. Keep records of inventory and distribution (see also recommendations 1.2.68 to 1.2.75 on tracking and

⁷⁵ Based on 4 service descriptions (Balmer and Wharton 1992; Bjorksten et al. 1980; Connor 1982; Davidson et al. 1979).

tracing).

Recommendation 1.2.48

Collect expressed milk from the donors, preferably using an agreed transport provider (ideally a medical courier) or a member of staff from the milk bank. In some instances, donors may be required or may wish to deliver their own milk to the milk bank or depot, in which case they should also follow the milk bank's requirements for transport as outlined. In all cases, use consistent monitoring processes, including recording the journey time.

Recommendation 1.2.49

Collect expressed milk from either the donor's home (see recommendations 1.2.38 to 1.2.43) or from donor milk depots that have practices for monitoring freezers and maintaining standards for quality control, storage and security. Ensure that similar processes are in place in any location where the donor milk is stored.

2.13 *Milk handling in general*

2.13.1 Review question

What are the best (safest) methods for collecting, storing and handling donor breast milk?

- How, and for how long, should donor milk be stored at the milk bank, including refrigeration and freezing?

2.13.2 Evidence review

Thirty-three of the 202 included studies provided 48 evidence records. The studies contained:

- 14 primary studies
- 9 narrative reviews
- 7 service descriptions
- 2 opinion pieces
- 1 position statement.

Publication dates ranged from 1953 to 2007.

Service descriptions reported practice in the USA, the UK, Sweden and Germany.

It is known that the composition of milk is affected by storage processes, but it is not clear how important these changes are, or which specific processing method has the least detrimental effect on the nutritional and immunological properties of breast milk.

2.13.3 Evidence statements

2.13.3.1 The composition of milk is affected by storage processes.

Therefore, the balance of benefits from raw, or minimally treated, milk and harms from contaminated, or heavily processed, milk needs to be considered⁷⁶.

2.13.3.2 Because all storage processes affect the nutritional and immunological qualities of milk, any processing should be the minimum required to achieve the required safety⁷⁷.

2.13.3.3 Refrigerating milk:

- *inhibits bacterial growth in non-contaminated milk compared with freezing*
- *does not affect lactose concentrations*
- *has no effect on immunological factors, such as IgA*
- *decreases lipid concentrations*
- *decreases vitamin C concentrations*
- *decreases lysine concentrations*
- *does not denature proteins*
- *retains bactericidal activity (but this decreases after 72 hours)*
- *reduces the antioxidant activity of milk (but less so than freeze-thawing)*

⁷⁶ Based on many references: specific examples include 6 narrative reviews (Baum 1979; Bromberger 1982; Kinsey 1984; Lawrence 1999; Ogundele 2000; Roy and Lescop 1979) and 2 opinion pieces (Lucas 1982; Williams et al. 2007).

⁷⁷ Based on 1 narrative review (Narayanan 1989).

- *increases levels of free fatty acids*
- *retains creatinocrit values*
- *destroys or reduces viable cells, such as macrophages and neutrophils, over time or these cells may adhere to the walls of the container*
- *reduces glutathione peroxidase activity*
- *increases malondialdehyde*
- *has no effect on lymphocyte concentration*⁷⁸.

2.13.3.4 Freezing milk:

- *affects the rate of lipolysis (and therefore levels of free fatty acids)*
- *destroys viable cells, such as leukocytes*
- *does not affect lactose concentrations*
- *decreases lipid concentrations*
- *decreases vitamin C concentrations*
- *decreases lysine concentrations*
- *retains creatinocrit values*
- *reduces the glutathione content (and therefore the antioxidant activity)*
- *has no effect on malondialdehyde*
- *has an effect on the bactericidal and bacteriostatic activity on the milk, but study results are inconsistent*
- *has no effect on immunological factors, such as IgA, IgM and IgG (although one narrative review states that IgG and IgM are destroyed)*
- *does not inhibit bacterial growth in milk compared with refrigeration*
- *increases bile salt-independent esterase activity*
- *increases lipase activity*

⁷⁸ Based on 2 narrative reviews (Bromberger 1982; Ogundele 2000) and 9 primary studies (Buss et al. 2001; Hanna et al. 2004; Martinez-Costa et al. 2007; Miranda et al. 2004; Pardou et al. 1994; Pittard, III and Bill 1981; Silprasert et al. 1987; Silvestre et al. 2006a; Williamson and Murti 1996)

- *destroys, or markedly reduces, CMV*
- *does not destroy HIV*
- *does not destroy Semliki Forest virus*
- *does not destroy herpes simplex virus type 1*
- *does not destroy coxsackie virus*⁷⁹.

*However, the effects of freezing are not accepted universally; for example, one meeting report advised that frozen milk can be stored for extended periods with no appreciable change in composition, and one narrative review concluded that there is no effect on the nutritional or 'anti-infective' quality of the milk*⁸⁰.

2.13.3.5 *Hydrolysis of triglycerides occurs in milk frozen at –20°C, but not at –70°C*⁸¹.

2.13.3.6 *Freeze-thawing milk:*

- *denatures HTLV I*
- *increases cell loss*
- *has no effect on vitamin A levels*
- *decreases levels of vitamin C*
- *increases concentrations of free fatty acids*
- *reduces creatinocrit values*
- *activates lipolysis, and therefore the levels of free fatty acids and glycerides*
- *does not cause unacceptable levels of bacterial growth in milk that had not been pasteurised*
- *has no effect on lipoprotein lipase or bile salt-stimulated lipase*
- *reduces bacteriostatic activity.*

⁷⁹ Based on 16 primary studies (Ankrah et al. 2000; Buss et al. 2001; Clark et al. 1984a; Clark et al. 1984b; Curtis et al. 2005; Friis and Andersen 1982; Hamprecht et al. 2004; Hernandez et al. 1979; Lavine and Clark 1987; Miranda et al. 2004; Pardou et al. 1994; Reynolds et al. 1982; Silprasert et al. 1987; Silvestre et al. 2006a; Silvestre et al. 2006b; Welsh et al. 1979) and 3 narrative reviews (Bromberger 1982; Ogundele 2000; Oxtoby 1988).

⁸⁰ Based on 1 meeting report (Silverman 1971) and 2 narrative reviews (Wight 2001; Williams and Pittard, III 1981).

⁸¹ Based on 2 primary studies (Berkow et al. 1984; Bitman et al. 1983).

However, fast freeze-thawing may preserve more of the antibacterial and nutritional components of the milk, but may also require more effort and equipment⁸².

2.13.3.7 Microwaving milk decreases 'anti-infective' properties⁸³.

2.13.3.8 Lyophilising (freeze-drying) milk preserves bacteriostatic activity⁸⁴.

2.13.3.9 A proposed solution to address concerns about leukocytes, trace minerals and fats adhering to the storage container is to thoroughly agitate and mix any stored milk before feeding⁸⁵.

2.13.3.10 Tocopherols appear to be stable when milk is stored after heating or freezing⁸⁶.

2.13.3.11 One primary study examining the effect of milk banking processes (including refrigeration at home and freezing at the milk bank, but not pasteurisation) on levels of fatty acids in milk concluded that banked milk, even after processing, is a good source of long-chain polyunsaturated fatty acids⁸⁷.

2.13.3.12 One primary study examining the effect of milk banking processes (including Holder pasteurisation and freezing for up to 90 days) on fat and L-lactate content and on lipid composition found that the treatment reduced fats and L-lactate, and induced triglyceride hydrolysis. However, the study also noted that different results had been seen in similar analyses⁸⁸.

⁸² Based on 1 narrative review (Van de et al. 1992) and 8 primary studies (Berkow et al. 1984; Friend et al. 1983; Honour and Dolby 1979; Morera et al. 1998; Rechtman et al. 2006; Reynolds et al. 1982; Silprasert et al. 1987; Wardell et al. 1981).

⁸³ Based on 1 narrative review (Wight 2001).

⁸⁴ Based on 1 primary study (Honour and Dolby 1979).

⁸⁵ Based on 1 narrative review (Williams and Pittard, III 1981).

⁸⁶ Based on 1 primary study (Moffatt et al. 1987).

⁸⁷ Based on 1 primary study (Luukkainen et al. 1995).

⁸⁸ Based on 1 primary study (Lepri et al. 1997).

2.13.3.13 *One primary study examining the effect of different storage processes on esterolytic activity concluded that storage in the freezer was the preferred method⁸⁹.*

2.13.3.14 *One primary study examining the effect of different storage processes on pH and antibacterial activities found that freezing maintained up to two-thirds of the bactericidal activity compared with refrigeration, but the loss of bactericidal activity with refrigeration was compensated for by enhanced bacteria sequestration⁹⁰.*

2.13.4 Evidence to recommendations

See also appendix 3 for the development of the recommendations using formal consensus techniques.

2.13.5 Recommendations

Recommendations related to milk handling are covered both here and in the specific sections for handling in the donor's home and at the milk bank.

Recommendation 1.2.38

Advise donors that expressed milk collected for donation should be frozen as soon as possible to maintain the nutritional and microbiological quality of the milk. If this is not possible (for example, because of storage capacity), advise donors to refrigerate samples collected over 24 hours, and then freeze the batch.

Recommendation 1.2.39

Advise donors that expressed milk for donation should remain frozen during storage at home, and if they have any concerns about storage conditions or freezer temperatures, they should discuss these with the milk bank.

Recommendation 1.2.40

Advise donors that frozen expressed milk should be transported to the milk bank as soon as possible. However, if necessary, expressed milk for donation

⁸⁹ Based on 1 primary study (O'Connor and Walde 1985).

⁹⁰ Based on 1 primary study (Hegde and Vikyath 2007).

can be stored before transport to the milk bank for up to 3 months in a domestic freezer, at -18°C or lower. If a donor does not have access to a domestic freezer at her home, she may be able to access freezers for milk storage at local donor milk depots or children's centres.

Recommendation 1.2.41

Advise donors that expressed milk can only be accepted by the milk bank if it has been collected and stored in milk collection containers provided by, or acceptable to, the milk bank.

Recommendation 1.2.42

Advise donors that collection containers for expressed milk should be used according to instructions provided by the milk bank.

Recommendation 1.2.43

Ensure that donors can check and document their freezer temperature every day; this may include providing a thermometer.

Recommendation 1.2.50

Process all donated milk under hygienic conditions (a sterile environment is not necessary). Practise good hand hygiene at all times, and wear gloves whenever handling donor milk.

Recommendation 1.2.51

Check that donated milk arriving at the milk bank:

- is labelled correctly with the donor's name and the date of expression **and**
- has remained frozen **and**
- has not been tampered with.

Transfer all donated milk immediately to the freezer.

Recommendation 1.2.52

Store pasteurised and unpasteurised donor milk in separate freezers and refrigerators.

Recommendation 1.2.53

Store donor milk awaiting pasteurisation in the freezer at the milk bank (at –20°C) for no longer than 3 months from the date of expression.

Recommendation 1.2.54

Discard breast milk from donors who do not meet the selection criteria detailed in recommendations 1.2.12, 1.2.13 and 1.2.17.

Recommendation 1.2.55

Before testing and pasteurising, thoroughly thaw the donor milk, and keep in the refrigerator for no longer than 24 hours. Prevent the donor milk from reaching 8°C while thawing.

Recommendation 1.2.63

Do not open the lid of batches of pasteurised donor milk until the milk is to be used, unless it is to test the milk. If the milk is tested, discard the opened bottle.

Recommendation 1.2.66

Keep all donor milk in containers made of food grade materials.

Recommendation 1.2.67

Staff at the milk bank should not be responsible for adding anything to the donated milk.

2.14 *Handling donor milk at the milk bank***2.14.1 Review question**

What are the best (safest) methods for collecting, storing and handling donor breast milk at the milk bank?

2.14.2 Evidence review

Forty-eight of the 202 included studies provided 105 evidence records. The studies contained:

- 27 service descriptions

- 10 primary studies
- 6 narrative reviews
- 3 position statements
- 1 meeting report
- 1 case report.

Publication dates ranged from 1951 to 2007.

Service descriptions reported practice in the UK, the USA, Sweden, Australia, China, India, South Africa, Germany, Finland, Venezuela, Poland and Denmark.

Reports of milk banking practice showed that milk banks differ in their handling of donor milk. However, there is general agreement that each milk bank should have agreed documented procedures to ensure the safe handling of donor milk. There is no high-quality evidence on exactly what these procedures should be or their impact on the safety of the donor milk.

2.14.3 Evidence statements

2.14.3.1 Milk banks differ in their procedures for handling donor milk. But there is general agreement that each milk bank should have agreed documented procedures to ensure the safe handling of donor milk⁹¹.

2.14.3.2 Freezing is the most common method of storing pasteurised donor milk, although some milk banks refrigerate milk⁹².

2.14.3.3 One milk bank refrigerates milk rather than freezes it to minimise the effects of pasteurisation and freezing (see the evidence statements on milk handling in general in section 2.12.2)⁹³.

⁹¹ Based on many references: specific examples include 1 narrative review (Baum 1979), 1 position statement (Anon 1985), 1 service description (Tully 2000) and 1 opinion piece (Williams et al. 2007).

⁹² Based on 1 narrative review (Oxtoby 1988) and 23 service descriptions (Asquith et al. 1987; Balmer and Wharton 1992; Baum 1982; Beal et al. 1978; Bjorksten et al. 1980; Cash and Giacoia 1981; Davidson et al. 1979; Dempster 1982; Fernandez et al. 1993; Greenwood Wilson 1951; Hartmann et al. 2007; Hoey et al. 1980; Ikonen et al. 1982; Langerak and Arnold 1991; McEnery and Chattopadhyay 1978; Morley-Peet 1983; Murray 1953; Pedersen 1982; Penc 1996; Reid 1988; Tomalin 1983; Tully 2001; Wight 2001).

- 2.14.3.4 *A meeting report stated that, after thawing, milk should not be refrozen⁹⁴.*
- 2.14.3.5 *In general, because of the need to culture all donated samples to test for bacteriological and viral contamination, two complete cycles of freezing and thawing are required⁹⁵.*
- 2.14.3.6 *There is variation in the length of time milk is stored at the milk bank (with an upper limit of 12 months). For example, in the UK the recommended period for storing frozen milk is 3 months post-pasteurisation⁹⁶.*
- 2.14.3.7 *One narrative review stated that most milk banks limit storage to 3–4 months at below -7°C ⁹⁷.*
- 2.14.3.8 *Brazilian milk banks follow recommendations to store pasteurised milk in the refrigerator for up to 24 hours, in the freezer for up to 6 months, and after lyophilisation (freeze-drying) for up to 12 months⁹⁸.*
- 2.14.3.9 *One milk bank recommends that freezers should not be self-defrosting, and should be monitored with a recording thermometer or a thermometer with an alarm⁹⁹.*
- 2.14.3.10 *Pasteurisation is the most common method of treating donor milk, although some milk banks use 'raw' donor milk (unpasteurised, unfrozen) when possible¹⁰⁰.*

⁹³ Based on 1 case report (Ryder et al. 1977).

⁹⁴ Based on 1 meeting report (Silverman 1971).

⁹⁵ Based on 1 narrative review (Roy and Lescop 1979).

⁹⁶ Based on 1 narrative review (Van de et al. 1992) and 9 service descriptions (Arnold 1999; Balmer and Wharton 1992; Dempster 1982; Greenwood Wilson 1951; Hartmann et al. 2007; Hoey et al. 1980; Murray 1953; Reid 1988; Tomalin 1983).

⁹⁷ Based on 1 narrative review (Williams and Pittard, III 1981).

⁹⁸ Based on 1 position statement (Gutierrez and de Almeida 1998).

⁹⁹ Based on 1 service description (Tully 2000).

¹⁰⁰ Based on 8 service descriptions (Asquith et al. 1987; Bjorksten et al. 1980; Davidson et al. 1979; Dempster 1982; Fernandez et al. 1993; Hartmann et al. 2007; Ikonen et al. 1982; Tomalin 1983).

- 2.14.3.11 *Milk banks differ in their procedures for cooling donor milk after pasteurisation; different cooling temperatures, times, and methods of cooling are used.*¹⁰¹
- 2.14.3.12 *One milk bank specifies that raw donor milk is used within 72 hours of collection*¹⁰².
- 2.14.3.13 *One milk bank stores milk by freeze-drying large volumes of donor milk*¹⁰³.
- 2.14.3.14 *In the USA, milk for pre-term babies is processed separately*¹⁰⁴.
- 2.14.3.15 *Two milk banks examine each container for appearance, taste, colour or odour, which could indicate spoilage or flavouring from the mother's diet and may affect safety or taste*¹⁰⁵.
- 2.14.3.16 *One primary study found that there was a link between the presence of off-flavour milk and higher rates of microorganisms*¹⁰⁶.
- 2.14.3.17 *Similar to handling milk in the home, there was no consensus on the most suitable containers to be used when handling milk at the milk bank. Examples reported include plastic containers made of food grade material, polypropylene pots with a screw lid, 40 ml plastic specimen bottles, and stainless steel containers. However, one narrative review concluded that glass is the least destructive container. This was supported by a primary study that showed more viable cells were retained on storage in glass compared with steel*¹⁰⁷.

¹⁰¹ Based on 1 opinion piece (Baum 1980), 4 primary studies (Bertino et al. 2008; Brown et al. 2000; Gibbs et al. 1977; Minder et al. 1982), and 4 service descriptions (Balmer and Wharton 1992; Baum 1982; Kimball et al. 1955; Morley-Peet 1983).

¹⁰² Based on 1 service description (Springer 1997).

¹⁰³ Based on 1 service description (Springer 1997).

¹⁰⁴ Based on 1 narrative review (Wight 2001).

¹⁰⁵ Based on 2 service descriptions (Asquith et al. 1987; Pedersen 1982).

¹⁰⁶ Based on 1 service description (Novak et al. 2008).

¹⁰⁷ Based on 1 narrative review (Lawrence 1999), 1 meeting report (Silverman 1971), 4 service descriptions (Asquith et al. 1987; Connor 1982; Dempster 1982; Fernandez et al. 1993) and 1 primary study (Williamson and Murti 1996).

- 2.14.3.18 *One milk bank uses milk in rotation, with the oldest milk being used first¹⁰⁸.*
- 2.14.3.19 *Handling of the milk at some milk banks is minimised to prevent contamination and procedures are carried out under sterile conditions or using sterilised equipment¹⁰⁹.*
- 2.14.3.20 *One milk bank handles (pools and samples) all milk in a laminar flow cabinet using aseptic technique and all containers are commercially sterile¹¹⁰.*
- 2.14.3.21 *One milk bank transfers milk from breast pumps to reusable, non-sterile bottles, which are cleaned between uses in a dishwasher. Other milk banks also report using dishwashers to clean equipment¹¹¹.*
- 2.14.3.22 *One milk bank works in an open system because they are not aiming for a sterile product¹¹².*
- 2.14.3.23 *In the USA (in 1995), health and safety regulations did not require milk bank staff to wear gloves for the routine handling of milk, but the American Academy of Pediatrics recommended that when exposure to expressed human milk was frequent or prolonged (as in donor milk banks), staff should wear gloves¹¹³.*

2.14.4 Evidence to recommendations

See also appendix 3 for the development of the recommendations using formal consensus techniques.

Overall, the GDG considered the safety of the milk (that is, the level of bacterial contamination) to be paramount. However, the evidence is not clear about which storage methods are the least damaging to the nutritional and

¹⁰⁸ Based on 1 service description (Beal et al. 1978).

¹⁰⁹ Based on 3 service descriptions (Asquith et al. 1987; Kimball et al. 1955; Penc 1996).

¹¹⁰ Based on 1 service description (Hartmann et al. 2007).

¹¹¹ Based on 3 service descriptions (Arnold 1999; Balmer and Wharton 1992; Tully 2000).

¹¹² Based on 1 service description (Arnold 1999).

¹¹³ Based on 1 position statement (Anon 1995).

immunological components of donor milk. The GDG therefore recommended a pragmatic combination of refrigeration and freezing, noting that freezing can also destroy some viral contamination (such as CMV).

As with milk at the donor's home, recommendations about length of storage were based on 'Improving the nutrition of pregnant and breastfeeding mothers and children in low-income households' (NICE public health guidance 11; available from www.nice.org.uk/guidance/PH11), but were modified to reflect the time needed at the milk bank to process the donated milk.

The GDG considered that donor milk should be processed in a hygienic environment, but that this need not necessarily be sterile. However, processing in a non-sterile environment increases the importance of good handling techniques and processes; the principles are described more fully in the sections on staff training and quality assurance.

There was much discussion about the process of cooling milk after pasteurisation. In 1981, guidance on the collection and storage of human milk (Committee on Medical Aspects of Food Policy 1981) suggested that 'the mixed milk temperature should be reduced to 25°C within 10 minutes'. No references were cited to support this, and although, more recently, milk banks have described that cooling is required after pasteurising, very few details were reported. The GDG therefore recommended rapid cooling of milk to 4°C¹¹⁴ after pasteurisation. In the absence of evidence on specific cooling protocols and their comparative effectiveness, no further details were specified.

2.14.5 Recommendations

Recommendation 1.2.50

Process all donated milk under hygienic conditions (a sterile environment is not necessary). Practise good hand hygiene at all times, and wear gloves whenever handling donor milk.

¹¹⁴ Temperature recommended to be consistent with "Improving the nutrition of pregnant and breastfeeding mothers and children in low-income households." NICE public health guidance 11 (2008). Available from www.nice.org.uk/PH11

Recommendation 1.2.51

Check that donated milk arriving at the milk bank:

- is labelled correctly with the donor's name and the date of expression **and**
- has remained frozen **and**
- has not been tampered with.

Transfer all donated milk immediately to the freezer.

Recommendation 1.2.52

Store pasteurised and unpasteurised donor milk in separate freezers and refrigerators.

Recommendation 1.2.53

Store donor milk awaiting pasteurisation in the freezer at the milk bank (at –20°C) for no longer than 3 months from the date of expression.

Recommendation 1.2.54

Discard breast milk from donors who do not meet the selection criteria detailed in recommendations 1.2.12, 1.2.13 and 1.2.17.

Recommendation 1.2.55

Before testing and pasteurising, thoroughly thaw the donor milk, and keep in the refrigerator for no longer than 24 hours. Prevent the donor milk from reaching 8°C while thawing.

Recommendation 1.2.63

Do not open the lid of batches of pasteurised donor milk until the milk is to be used, unless it is to test the milk. If the milk is tested, discard the opened bottle.

Recommendation 1.2.66

Keep all donor milk in containers made of food grade materials.

Recommendation 1.2.67

Staff at the milk bank should not be responsible for adding anything to the donated milk.

2.15 *Pooling donor milk*

2.15.1 Review question

Should donor milk be pooled?

2.15.2 Evidence review

Thirty-eight of the 202 included studies provided 49 evidence records. Studies included:

- 20 service descriptions
- 6 narrative reviews
- 6 primary studies
- 3 position statements
- 2 opinion pieces
- 1 meeting report.

Publication dates ranged from 1951 to 2007.

Service descriptions reported practice in the UK, the USA, South Africa, Germany, Finland, Australia, Poland, Denmark and Canada.

Although many studies used the term ‘pooling’, it was often not clear whether this meant pooling of donations from different donors or pooling of separate donations from individual donors. There were reported differences in practice, and there was some support and benefits found for pooling between different donors although the evidence on this was not consistent.

2.15.3 Evidence statements

See also evidence statements on how donors are advised to pool milk at home before transport to the milk bank (section 2.10.2).

2.15.3.1 *Advantages of pooling pasteurised, frozen milk from different donors include:*

- *dilution of any undesirable compounds*
- *uniformity of composition*

- *making milk pools to a specific composition (for example, a high protein pool)*
- *simplification of procedures*
- *more efficient handling because of larger volumes.*

Pooling of donations from different donors is used by some milk banks and recommended¹¹⁵.

2.15.3.2 When milk from different donors is pooled, there is variation in the number of different donors contributing to the pool; ranging from 2 to 25 donors¹¹⁶.

2.15.3.3 One meeting report recommended that pooling raw milk from different donors should not be done because the risk of bacterial contamination, even with careful surveillance of donors, was too great¹¹⁷.

2.15.3.4 One milk bank reported pooling all milk, although raw and pasteurised donations were pooled separately¹¹⁸.

2.15.3.5 There was also concern about the pooling of milk from different donors, particularly if the milk is not pasteurised. Pooling of separate donations from individual donors was favoured because it allows for control of the stage of lactation, it may limit contamination, and it allows donors with consistently high levels of contamination to be identified. However, it was also noted that this

¹¹⁵ Based on 1 meeting report (Silverman 1971), 2 position statements (Anon 1980; Anon 1985), 3 narrative reviews (Bromberger 1982; Williams and Pittard, III 1981; Woo and Spatz 2007), 2 primary studies (Michaelsen et al. 1990; Smith et al. 1984) and 6 service descriptions (Arnold 1999; Asquith et al. 1987; Baum 1982; Siimes and Hallman 1979; Tully 2000; Wilson-Clay 2006).

¹¹⁶ Based on 1 meeting report (Silverman 1971), 3 primary studies (Lucas and Roberts 1978; Michaelsen et al. 1990; Smith et al. 1984) and 3 service descriptions (Asquith et al. 1987; Morley-Peet 1983; Tully 2000).

¹¹⁷ Based on 1 meeting report (Silverman 1971).

¹¹⁸ Based on 1 service description (Tomalin 1983).

may increase the risk of concentration of toxic substances excreted in the milk¹¹⁹.

2.15.3.6 In the UK, donor milk from different donors is not pooled. Pooled milk is prepared from separate donations of individual donors and is stored in aliquots before use¹²⁰.

2.15.4 Evidence to recommendations

See also appendix 3 for the development of the recommendations using formal consensus techniques.

Although there was some evidence and logic for pooling milk from different donors, there was clear consensus in the GDG that donor milk should not be pooled in this way. The primary reason for this was the theoretical, unknown risk of CJD transmission via donor milk. If new evidence shows that vertical transmission of CJD can be ruled out or if a reliable test becomes available, this could be re-evaluated in any update of this guideline.

2.15.5 Recommendations

Recommendation 1.2.56

Only pool pre-pasteurised breast milk from the same donor.

Recommendation 1.2.57

Do not pool:

- breast milk from different donors,
- or**
- batches of pasteurised breast milk from the same donor.

¹¹⁹ Based on 2 narrative reviews (Roy and Lescop 1979; Van de et al. 1992), 1 opinion piece (Braune 1982), 2 position statements (Anon 1980; Anon 1985), 1 primary study (Stocks et al. 1983) and 6 service descriptions (Davidson et al. 1979; Dempster 1982; Hartmann et al. 2007; McEnery and Chattopadhyay 1978; Penc 1996; Springer 1997).

¹²⁰ Based on 1 opinion piece (Modi 2006).

2.16 *Testing donor milk*

2.16.1 Review question

How should donor milk be tested?

2.16.2 Evidence review

Fifty-eight of the 202 included studies provided 109 evidence records. Studies included:

- 29 service descriptions
- 11 primary studies
- 10 narrative reviews
- 4 position statements
- 2 case reports
- 1 meeting report
- 1 opinion piece.

Publication dates ranged from 1951 to 2009.

Service descriptions reported practice in the UK, the USA, Sweden, Finland, Australia, Denmark, India, South Africa, Germany, Canada and Poland.

Different milk banks reported the use of different testing processes, including different testing schedules and acceptance criteria. Although reports of neonatal infection from donor breast milk were extremely rare, there was an overall acceptance that milk should be tested and treated, if appropriate, before use.

2.16.3 Evidence statements

2.16.3.1 Different milk banks use different testing processes, including different testing schedules and acceptance criteria. Although reports of neonatal infection from donor breast milk are extremely

rare, there is a general acceptance that milk should be tested and treated, if appropriate, before use¹²¹.

2.16.3.2 Although adequate pasteurisation destroys HIV in milk, most milk banks adopt a dual approach of pasteurisation and screening of donors to prevent any transmission of HIV through donor milk. Some may rely on pasteurisation only¹²².

2.16.3.3 One case report describes the postnatal transmission of HIV via pooled, raw donor milk from different donors. The case occurred in an area of high prevalence of HIV (8–15% of pregnant women were HIV positive)¹²³.

2.16.3.4 Testing schedules may differ because of:

- *local disease prevalence*
- *local levels of specific contaminants*
- *storage procedures used*
- *costs, time and availability of tests¹²⁴.*

2.16.3.5 Milk banks test for a variety of contaminants. These include:

- *dichlorodiphenyltrichloroethane (DDT) concentrations*
- *levels of bacteria*
- *CMV*
- *methicillin-resistant S. aureus (MRSA)*
- *enteric pathogens*
- *indicator organisms*
- *heat-resistant Bacillus species that can form spores*

¹²¹ Based on many references: specific examples include 3 narrative reviews (Baum 1979; Oxtoby 1988; Williams and Pittard, III 1981) 1 opinion piece (Williams et al. 2007), 2 position statements (Anon 1980; Anon 1985) and 2 primary studies (Carrol et al. 1978; Law et al. 1989).

¹²² Based on 1 opinion piece (Morley and Lucas 1993) and 2 narrative reviews (Oxtoby 1988; Van de et al. 1992).

¹²³ Based on 1 case report (Nduati et al. 1994).

¹²⁴ Based on 1 narrative review (Narayanan 1989) and 2 position statements (Anon 1980; Penc 1996).

- *dilution with water or cows' milk (especially when donors receive payment)*¹²⁵.

2.16.3.6 *Some milk banks test for specific contaminants if the donor has a diagnosed infection, such as mastitis*¹²⁶.

2.16.3.7 *When testing, milk banks test using different schedules. These include:*

- *testing of pooled samples*
- *testing of some individual samples*
- *testing of all individual samples*
- *monitoring samples regularly (for example, at weekly intervals or twice a month)*
- *spot checks (that is, randomly)*¹²⁷.

2.16.3.8 *One case report describes an outbreak of Salmonella kottbus traced to contaminated donor milk from a single donor*¹²⁸.

2.16.3.9 *Milk banks test using different criteria of bacterial contamination to accept or reject milk. These include:*

- *rejection of raw milk that*
 - *contains organisms other than normal breast flora or commensal skin flora*
 - *shows growth of Gram-negative bacteria and colony counts of more than 10,000 organisms/ml of Staphylococcus epidermis and/or more than 4000 organisms/ml of S. aureus*
 - *exceeds 10⁴ colony-forming units (CFU)/ml of normal skin flora*

¹²⁵ Based on 1 meeting report (Silverman 1971), 2 primary studies (Lindemann et al. 2004; Novak et al. 2000) and 4 service descriptions (Greenwood Wilson 1951; Sauve et al. 1984; Siimes and Hallman 1979; Wilson-Clay 2006).

¹²⁶ Based on 2 service descriptions (Asquith et al. 1987; Omarsdottir et al. 2008).

¹²⁷ Based on 1 meeting report (Silverman 1971), 3 narrative reviews (Oxtoby 1988; Roy and Lescop 1979; Williams and Pittard, III 1981), 1 position statement (Anon 1980) and 7 service descriptions (Arnold 1999; Balmer and Wharton 1992; Cash and Giacoia 1981; Fernandez et al. 1993; Greenwood Wilson 1951; Kimball et al. 1955; Morley-Peet 1983).

¹²⁸ Based on 1 case report (Ryder et al. 1977).

- contains pathogens or coliform bacteria
- rejection of pasteurised milk that
 - contains any measurable levels of bacteria
 - contains pathogenic bacteria
 - contains more than 10^5 CFU/ml of saprophytic bacteria
 - exceeds 25 CFU.

There is a recognition however, that such standards are empiric and unproven, and are often determined by the microbiologist responsible for the milk bank¹²⁹.

2.16.3.10 It is not clear what effect different organisms and different levels of contamination have on the recipient baby, and whether this differs according to the recipient group¹³⁰.

2.16.3.11 One milk bank defined the microbiological criteria for accepting milk for pasteurisation as:

- *milk with bacterial contamination of less than 10^3 CFU/ml is used regardless of the organisms present*
- *milk with bacterial contamination of more than 10^5 CFU/ml is not used*
- *milk with bacterial contamination between 10^3 and 10^5 CFU/ml is only used if the organisms are skin commensals (for example, *S. epidermis*, *Streptococcus viridans* and diphtheroids)*
- *milk is not used if it has more than 10^3 CFU/ml of *S. aureus*, any Gram-negative rod (lactose-fermenting and *Pseudomonas* species), beta-haemolytic streptococci or *Streptococcus faecalis*¹³¹.*

¹²⁹ Based on 2 narrative reviews (Arnold 1997; Wight 2001), 1 position statement (Anon 1985), and 6 service descriptions (Arnold 1999; Balmer and Wharton 1992; Beal et al. 1978; Cash and Giacoia 1981; Dempster 1982; Langerak and Arnold 1991).

¹³⁰ Based on many references: specific examples include 1 narrative review (Narayanan 1989) and 1 opinion piece (Arnold et al. 1997).

¹³¹ Based on 1 service description (Balmer and Wharton 1992).

2.16.3.12 *One milk bank defined ‘arbitrary’ microbiological criteria for using and treating milk.*

- *Milk with a quantitative count of less than 2500 organisms/ml (consisting of, for example, micrococci, Staphylococcus albus, ‘viridans type’ streptococci or diphtheroids, which were considered to be contaminants probably derived from skin flora but unlikely to be pathogenic) was used unheated.*
- *No donation was used unheated or pasteurised if the pilot sample gave either a total count of more than 5000 organisms/ml or any detectable potential pathogen. On an arbitrary basis the potential pathogens were defined as S. aureus, beta-haemolytic streptococci, Pseudomonas species, Proteus species, S. faecalis, and any other organism from a potential enteric or water-borne source (here defined as ‘coliforms’ for convenience).*
- *No donated milk with a total bacterial count of 2500–5000 organisms/ml was used unheated. If the pilot sample had a bacterial count in this range, but none of the organisms listed above, the donated milk was pasteurised at 63°C for 30 minutes in a water bath and then subjected to the same bacteriological screening, plus the alkaline phosphatase test. (Alkaline phosphatase is destroyed within 30 minutes at 63°C and is used as evidence of adequate pasteurisation of cows’ milk). Provided effective pasteurisation was established by no detectable growth on culture and a satisfactory phosphatase test, the milk was issued for use.*

The milk bank discarded 45% of samples from home collection based on these criteria¹³².

2.16.3.13 *One milk bank used criteria that, in general, the pilot sample must contain no potential pathogens capable of producing heat-stable*

¹³² Based on 1 service description (Davidson et al. 1979).

enterotoxins, no Enterobacteriaceae or enterococci, and no confluent growth of organisms indicating a total count exceeding 10^5 CFU/ml. Any bacterial growth in the sample post-pasteurisation is unacceptable¹³³.

2.16.3.14 One milk bank used criteria as follows.

- If the sample contains less than 2.5×10^6 non-pathogenic organisms/l, then that aliquot of milk will be given to a baby without further processing.*
- If there are between 2.5×10^6 and 1×10^9 non-pathogenic organisms/l, the milk samples are placed individually in a sterile jug within boiling water for 10 minutes (milk temperature 63–65°C) shortly before being fed to babies.*
- All milk that contains more than 1×10^9 organisms/l and grows *S. aureus*, *Pseudomonas*, *Klebsiella* or *Proteus* species, or other enteropathogenic organisms is not fed to babies¹³⁴.*

2.16.3.15 One milk bank used criteria as follows.

- Bacteriological tests are done on all donated milk and milk must meet the following standards to be used.*
 - Total bacteria count must not exceed 10^5 CFU/ml.*
 - The presence of pathogenic bacteria (for example, *S. aureus*, *Escherichia coli*, *Klebsiella* species, *Pseudomonas aeruginosa*, or alpha- and beta-streptococci) is not acceptable.*
 - Batches of non-pathogenic cutaneous microflora of 10^3 to 10^4 CFU/ml are preferable.*
 - No bacteriological growth should be observed in pasteurised milk; conditional growth of 1–2 CFU/ml is acceptable¹³⁵.*

2.16.3.16 One milk bank used criteria as follows.

¹³³ Based on 1 service description (Hartmann et al. 2007).

¹³⁴ Based on 1 service description (McEnery and Chattopadhyay 1978).

¹³⁵ Based on 1 service description (Penc 1996).

- *A bacterial count of less than 10^4 /ml (or less than 10^7 /l) organisms and no demonstrable pathogens is taken as evidence that the milk, at the time of sampling, is safe to use.*

Using this standard, bacterial cultures at one milk bank during the past 5 years showed that when significant bacterial growth occurred in post-pasteurisation samples, pasteuriser malfunction was detected and the samples were repasteurised before use¹³⁶.

2.16.3.17 One primary study assessed the link between bacterial contamination and clinical suspicion of infection in recipient babies. The study found that feeding milk containing more than 10^3 Gram-negative bacilli/ml is associated with increased feeding intolerance and higher levels of 10^6 /ml are associated with suspected sepsis¹³⁷.

2.16.3.18 Milk banks also test:

- *the fat, protein or lactose content*
- *the carbohydrate or caloric content*
- *the acidity*
- *the sodium levels*
- *for evidence that procedures are being followed (for example, by testing after pasteurisation to ensure effective treatment)*
- *to identify donors with consistently high rates of contamination*
- *to determine if samples should be used raw¹³⁸.*

2.16.3.19 Not all milk banks routinely test for bacterial contamination both before and after pasteurisation. For example, one milk bank

¹³⁶ Based on 1 service description (Sauve et al. 1984).

¹³⁷ Based on 1 primary study (Botsford et al. 1986).

¹³⁸ Based on 2 narrative reviews (Davies 1982; Williams and Pittard, III 1981), 3 position statements (Anon 1985; Fernandez et al. 1990; Gutierrez and de Almeida 1998), 5 primary studies (Almeida and Dórea 2006; Lindemann et al. 2004; Spencer and Hull 1981; Wojcik et al. 2009; Wright and Feeney 1998) and 11 service descriptions (Arnold 1999; Bjorksten et al. 1980; Davidson et al. 1979; Dempster 1982; Fernandez et al. 1993; Greenwood Wilson 1951; Ikonen et al. 1982; Omarsdottir et al. 2008; Pedersen 1982; Sauve et al. 1984; Wilson-Clay 2006).

reported testing samples after pasteurisation four times a year, and one tests 1 in 40 bottles after pasteurisation¹³⁹.

2.16.3.20 Not all milk banks routinely test for bacterial contamination and, in one survey, seven milk banks were reported to use no defined standards or to test routinely¹⁴⁰.

2.16.3.21 Not all milk banks routinely test all samples from donors. For example, one milk bank reported testing only the first batch received from a donor and one reported testing only the first three donations¹⁴¹.

2.16.3.22 One milk bank does not routinely test milk donated in the hospital because this milk is collected in autoclaved shells or bottles. However, for 1 day every 3 months, all samples and all equipment are screened for bacterial contamination¹⁴².

2.16.4 Evidence to recommendations

See also appendix 3 for the development of the recommendations using formal consensus techniques.

Questions addressed by the GDG focused on the following areas.

- Why should milk banks test donor milk before pasteurisation and what should it be tested for?
- Why should milk banks test donor milk after pasteurisation and what should it be tested for?

The GDG recognised that, although raw milk may be used in rare circumstances and only under the supervision of the prescribing physician, in general milk banks would not be providing raw milk. Recommendations were therefore made only for milk to be pasteurised.

¹³⁹ Based on 2 service descriptions (Arnold 1999; Tomalin 1983).

¹⁴⁰ Based on 1 survey of services (Sauve et al. 1984).

¹⁴¹ Based on 2 service descriptions (Arnold 1999; Bjorksten et al. 1980).

¹⁴² Based on 1 service description (Bjorksten et al. 1980).

The GDG discussed the importance of avoiding any duplication of tests and debated the usefulness of each test at each stage. If tests do not have an added benefit in identifying contaminated donated breast milk and therefore minimising any impact on infant outcomes, testing at that stage will not be cost effective and will displace scarce health resources for other NHS patients.

The GDG reconsidered the recommendations on donor screening and remained in agreement that the donor screening processes were adequate and in line with other national donor programmes. In the absence of evidence that pasteurisation completely destroys all viral contaminants of concern, a precautionary approach was adopted and a recommendation made that any woman who tests positive, or who has previously tested positive, on any of the recommended tests should be excluded from donating milk.

For other viral contaminants, such as CMV, although there is documented evidence on the risk of transmission, there is also evidence that pasteurisation and other processing techniques, including freezing, destroys the contamination. The point therefore at which the risk is controlled is through adequate pasteurisation and storage, not through the screening of potential donors for CMV. Screening of potential donors for CMV is not recommended, but adequate storing and pasteurisation at 62.5°C for 30 minutes in a human milk pasteuriser is vital.

Regarding bacterial contamination: two groups of bacteria are present in breast milk. These are low virulence skin commensals, such as coagulase-negative staphylococci, and bacteria with greater virulence, such as *S. aureus* and *E. coli*, which may originate from skin or other sources. High levels of either type of bacteria are more likely to be associated with the expression, storage or handling of the milk rather than any significant health problem in the donor.

Adequate pasteurisation (recommended in this guideline as 62.5°C for 30 minutes in a human milk pasteuriser) will reduce normal levels of bacterial contamination to minimal levels that pose no risk to the recipient. But any milk

with very high levels should be discarded because pasteurisation may not reduce the levels to acceptable amounts, and may not destroy any bacterial toxins.

The GDG recommended criteria for the levels of bacterial contamination above which donor milk should be rejected, and these were based on the expert knowledge of the GDG and reference to criteria used in the food industry. However, any such levels are arbitrary (that is, there is no evidence on which to base such criteria). Therefore, as with other recommendations, a precautionary approach was taken. It was agreed that some maternal milk will inevitably be contaminated with bacteria and that this is acceptable, and in some circumstances preferable, but contamination is much more difficult to justify if the milk comes from a milk bank. The recommended *S. aureus* limit is consistent with that for ready-to-eat foods and cows' milk for human consumption. A combination of total bacterial count and a count of those pathogens that are recognised as problematic in food-borne illness was agreed to be appropriate (because this would then reflect significant contamination rather than the effects, alone, of poor processing).

In the GDG's view, this combination of criteria for rejecting donated milk before pasteurisation appropriately balances the necessity to ensure safety for the recipient and the need to use donor breast milk from screened donors effectively and efficiently.

Pasteurisation is effective as long as the procedure is followed correctly; therefore, the most crucial element of the testing process is that the correct quality control and monitoring processes are followed.

There was a lot of discussion about the testing schedule and how any failure in process (for example, if a pasteuriser breaks down) would have an impact on the amount of tracking back required. The importance of regular and ongoing calibration and checking of critical equipment was stressed, as was staff training.

It was understood that testing after every cycle of pasteurisation promotes confidence in the safety of the milk. However, this may be false reassurance

because not all bottles undergoing pasteurisation are tested and there is also a risk of introducing contamination during testing, unless this is done under strict conditions. Testing after pasteurisation only rarely identifies contamination (if the pasteuriser is working correctly – that is, at the correct temperature for the recommended time); testing carries a risk of introducing contamination (if not conducted in appropriate conditions) and is unlikely to positively change recipient outcomes and thus unlikely to be worth the additional cost.

The GDG agreed the following principles.

- Testing post-pasteurisation should be kept to the minimum required to achieve maximum confidence in the treated milk.
- Testing every sample was not appropriate or necessary because the risk of introducing contamination was high (unless under strict conditions).
- Testing every batch would not have a significant cost impact (so the decision to reduce post-pasteurisation testing was not made on a cost-saving assumption).
- Any bottle from which milk is taken for testing should be discarded.
- Any testing should be part of a defined quality control and monitoring process.
- The timing of testing should be based on the volume and throughput of donor milk.

The GDG agreed recommendations to reflect these principles. It was recognised that the recommendations should specify the requirements of testing; however, in some circumstances milk banks could exceed this if this was indicated, for example by the recipient population.

Concern was expressed that low levels of *Bacillus* species may be present in donor milk, and it is known that such spores are not destroyed by pasteurisation. However, this type of contamination can be controlled by proper storage and handling after pasteurisation, which should prevent any *Bacillus* species that are present from growing.

2.16.5 Recommendations

Recommendation 1.2.58

Before pasteurisation, test a sample from each batch of pooled donor milk for microbial contamination and discard if samples exceed a count of:

- 10^5 colony-forming units (CFU)/ml for total viable microorganisms **or**
- 10^4 CFU/ml for Enterobacteriaceae **or**
- 10^4 CFU/ml for *Staphylococcus aureus*.

Recommendation 1.2.59

Ensure that laboratories communicate the results of microbial testing clearly and that they provide appropriate interpretive comments.

Recommendation 1.2.60

Seek help from microbiological laboratories to identify and investigate instances of significant or unusual contamination (for example, by undertaking further microbial tests).

Recommendation 1.2.63

Do not open the lid of batches of pasteurised donor milk until the milk is to be used, unless it is to test the milk. If the milk is tested, discard the opened bottle.

Recommendation 1.2.64

Regularly test pasteurised donor milk for microbial contamination. Base the testing schedule on the volume and throughput of milk. Test:

- either at least once a month or every 10 cycles, depending on which comes first,
and
- on an ad-hoc basis if any new processes, equipment or staff are introduced, or if there are concerns about any part of the process.

Recommendation 1.2.65

Discard pasteurised donor milk that has a total viable microbial count of 10 CFU/ml or more.

2.17 *Treating donor milk*

2.17.1 Review question

How should donor milk be tested?

2.17.2 Evidence review

Ninety-six of the 202 included studies provided 156 evidence records. Studies included:

- 44 primary studies
- 25 service descriptions
- 17 narrative reviews
- 5 opinion pieces
- 3 position statements
- 1 case report
- 1 meeting report.

Publication dates ranged from 1951 to 2008.

Service descriptions reported practice in the UK, the USA, Denmark, Sweden, India, South Africa, Germany, Canada, Australia, Finland and Poland.

Different milk banks reported the use of different treatment processes. Although reports of neonatal infection from donor breast milk were extremely rare, there was an overall acceptance that milk should be tested and treated before use.

It is known that treatment can destroy or inactivate viral and bacterial contaminants, but there is no treatment process that can destroy the agent of CJD. It is not clear which treatment process is the most effective and the least detrimental to the nutritional and immunological components of breast milk. Nor is it clear what levels of pre-pasteurisation contamination are safe for donor milk.

2.17.3 Evidence statements

- 2.17.3.1 *There are many methods of treating milk with heat, usually with the aim of pasteurisation. As with the storage of milk, the balance of benefits from raw or minimally treated milk, with harm from contaminated or heavily processed milk, need to be considered¹⁴³.*
- 2.17.3.2 *The majority of reviews recommend the use of Holder pasteurisation rather than sterilisation, and most milk banks support and follow this recommendation¹⁴⁴.*
- 2.17.3.3 *There are several studies comparing different heat treatments; these are primarily laboratory studies and as such may not reflect effects in practice. However, there is some indication that high-temperature, short-time processing may have some benefits, although most authors conclude that further research is needed. For example, one primary study showed that high-temperature, short-time pasteurisation eliminated key bacteria and viruses, and may also preserve more of the important milk protein than Holder pasteurisation; however, it is extremely expensive¹⁴⁵.*

Although some studies evaluated the effects of some of the processes of milk banking, no studies compared different processing arrangements (the complete processing from expression through to post-storage) directly.

2.17.3.4 *Storing milk at 23°C (room temperature):*

- *has no effect on vitamin A levels*
- *reduces levels of vitamin C¹⁴⁶.*

¹⁴³ Based on many references: specific examples include 4 narrative reviews (Baum 1979; Boyes 1987; Lawrence 1999; Roy and Lescop 1979) and 2 opinion pieces (Lucas 1982; Williams et al. 2007).

¹⁴⁴ Based on many references: specific examples include 7 narrative reviews (Bromberger 1982; Davies 1982; Kinsey 1984; Oxtoby 1988; Roy and Lescop 1979; Tully et al. 2001; Wight 2001), 1 position statement (Anon 1980), and 1 primary study (Lucas and Roberts 1979).

¹⁴⁵ Based on 11 primary studies (Donnelly-Vanderloo et al. 1994; Fidler et al. 1998; Ford et al. 1977; Gaffin et al. 1983; Hamprecht et al. 2004; Silvestre et al. 2006a; Silvestre et al. 2008; Terpstra et al. 2007; Viazis et al. 2007; Viazis et al. 2008; Wills et al. 1982).

¹⁴⁶ Based on 2 primary studies (Honour and Dolby 1979; Rechtman et al. 2006).

2.17.3.5 *Heating milk to 56–57.5°C for 30–33 minutes:*

- *has no effect on IgG, IgA or IgM*
- *destroys HIV*
- *destroys HTLV-I-infected lymphocytes*
- *has no effect on gangliosides or glycoconjugates*
- *destroys complement*
- *reduces lysozyme and lactoperoxidase levels*
- *reduces levels of bacteria such as E. coli, S. aureus and group B beta-haemolytic streptococci*
- *tends to preserve higher levels of IgA, lactoferrin and lysozyme (than Holder pasteurisation)¹⁴⁷.*

2.17.3.6 *Heating milk to 62.5–63°C for 30 minutes:*

- *reduces bacterial growth inhibitory properties*
- *decreases lysine concentrations*
- *reduces levels of vitamin A*
- *destroys HIV*
- *destroys CMV*
- *does not destroy hepatitis B or C*
- *has no effect on lactose content*
- *has no effect on total and specific oligosaccharides*
- *kills Listeria innocua*
- *has little effect on lysozyme activity (although it is affected by an increase in temperature)*
- *has little effect on insulin-like growth factors and insulin-like growth factor binding proteins*
- *causes some loss of IgG, IgA and IgM*
- *has no effect on gangliosides or glycoconjugates*
- *reduces lactoferrin*
- *reduces C3 complement*

¹⁴⁷ Based on 2 narrative reviews (Eglin and Wilkinson 1987; Ogundele 2000) and 2 primary studies (Wills et al. 1982; Yamato et al. 1986).

- *destroys milk cells*
- *destroys bacteria such as E. coli, S. aureus and group B beta-haemolytic streptococci*
- *inactivates human milk lipases*
- *has little effect on long-chain polyunsaturated fatty acids (LC-PUFA) proportions but does reduce levels of total triglycerides*
- *destroys enzymes and the activity of alkaline phosphatase*
- *reduces levels of glutathione peroxidase*
- *does not destroy Semliki Forest virus*
- *does not destroy herpes simplex virus type 1*
- *does not destroy coxsackie virus¹⁴⁸.*

2.17.3.7 *Heating milk to above 65°C causes a progressive loss of bacteriostatic activity¹⁴⁹.*

2.17.3.8 *Heating milk to 72°C for 10 seconds destroys CMV¹⁵⁰.*

2.17.3.9 *Heating milk to 75°C for 15 seconds:*

- *decreases lysine concentrations*
- *kills L. innocua*
- *destroys CMV*
- *decreases levels of glutathione peroxidase*
- *reduces bactericidal activity¹⁵¹.*

2.17.3.10 *Heating milk to 90°C for 10 minutes destroys HTLV I¹⁵².*

2.17.3.11 *Other pasteurisation methods include heat treatment at 56°C, 62°C, 65.6°C or 65°C, and for different times (most commonly*

¹⁴⁸ Based on 4 narrative reviews (Chen and Allen 2001; Ogundele 2000; Simmer 2000; Tully et al. 2001), 18 primary studies (Bertino et al. 2008; Chen and Allen 2001; Donovan et al. 1991; Dworsky et al. 1982; Evans et al. 1978; Ford et al. 1977; Friis and Andersen 1982; Henderson et al. 1998; Orloff et al. 1993; Rees 1987; Ribeiro et al. 2005; Roberts and Severn 1978; Silvestre et al. 2006a; Silvestre et al. 2008; Wardell et al. 1984; Welsh et al. 1979; Wills et al. 1982; Yamato et al. 1986) and 1 opinion piece (Morley and Lucas 1993).

¹⁴⁹ Based on 1 primary study (Honour and Dolby 1979).

¹⁵⁰ Based on 1 narrative review (Stagno 2002).

¹⁵¹ Based on 5 primary studies (Chen and Allen 2001; Hamprecht et al. 2004; Silvestre et al. 2006a; Silvestre et al. 2008; Terpstra et al. 2007).

¹⁵² Based on 1 primary study (Yamato et al. 1986).

30 minutes). For example, one primary study reported over 90% destruction of the inoculated bacteria after heating the milk at 62.5°C for only 5 minutes¹⁵³.

2.17.3.12 Sterilising milk:

- destroys IgA, IgG and IgM
- has no effect on gangliosides or glycoconjugates, or bifidobacterium growth factor
- destroys lactoferrin
- destroys lysozyme and lactoperoxidase
- has no effect on lipid levels
- reduces fat content¹⁵⁴.

2.17.3.13 One milk bank reported autoclaving milk at 100°C for 5 minutes¹⁵⁵.

2.17.3.14 One primary study showed that heating to 105°C, then freezing and thawing, reduces rates of:

- IgA and IgG
- lactoferrin and alpha-1 trypsin¹⁵⁶.

2.17.3.15 One primary study showed that pasteurisation followed by freezing caused redistribution of zinc, but did not affect other nutrients¹⁵⁷.

2.17.3.16 One primary study showed that high-pressure processing retained higher levels of IgA and lysozyme compared with Holder pasteurisation¹⁵⁸.

¹⁵³ Based on 3 service descriptions (Arnold 1996; Asquith et al. 1987; Balmer and Wharton 1992) and 1 primary study (Lloyd-Jones et al. 1979).

¹⁵⁴ Based on 1 narrative review (Ogundele 2000) and 2 primary studies (Fidler et al. 1998; Raptopoulou-Gigi et al. 1977).

¹⁵⁵ Based on 1 service description (Langerak and Arnold 1991).

¹⁵⁶ Based on 1 primary study (Raptopoulou-Gigi et al. 1977).

¹⁵⁷ Based on 1 primary study (Goes et al. 2002).

¹⁵⁸ Based on 1 primary study (Viazis et al. 2007).

2.17.4 Evidence to recommendations

See also appendix 3 for the development of the recommendations using formal consensus techniques.

Any recommended pasteurisation method needs to balance safety with any destruction or reduction in the nutritional and immunological components of donor milk.

The recommended pasteurisation process is one that is currently used by most, if not all, milk banks in the UK. Although there is no direct evidence of the effect on health outcomes of reducing specific nutritional components through a higher temperature (62.5°C) – and no certainty that all microorganisms will be destroyed even at 62.5°C – the GDG considered this to be the most appropriate level for pasteurisation.

NICE clinical guidelines generally do not make specific recommendations about the exact equipment that should be used. Instead, a general recommendation was made that all equipment should be fit for purpose (as outlined in section 2.4) and a recommendation was made on the conditions needed for pasteurisation; it was assumed that milk quality would be controlled if these recommendations are followed.

As before, any equipment used for treating should be part of a quality control system that has both mechanisms for critical incident reporting and defined systems for monitoring and documenting.

2.17.5 Recommendations

Recommendation 1.2.61

Pasteurise donated milk at 62.5°C for 30 minutes in a human milk pasteuriser. Rapidly cool the milk to a temperature of 4°C or lower. Remove one bottle for testing if appropriate, then move the remainder of the batch to the freezer.

2.18 Fortifying donor milk

2.18.1 Review question

Fortifying donor milk was reviewed as part of the evidence review on handling milk in general – see section 2.13.

2.18.2 Evidence review

Ten of the 202 included studies provided 13 evidence records. The studies contained:

- 3 service descriptions
- 2 narrative reviews
- 2 primary studies
- 2 opinion pieces
- 1 position statement.

Publication dates ranged from 1982 to 2008.

Service descriptions reported practice in the USA, Sweden and Denmark.

There was very limited evidence and few descriptions of the process of milk fortification in milk banking; the GDG specifically excluded evidence related to the provision of donor milk to recipients, because this was not considered to be a core task of a donor milk bank.

2.18.3 Evidence statements

Very few included studies referred to the process of milk fortification.

- 2.18.3.1 *The aim of fortification was generally understood to be a match of the nutritional content of the milk to the recipient baby¹⁵⁹.*
- 2.18.3.2 *Some safety concerns about the effects of fortification, specifically on the osmolality of the milk and on host defence properties, were expressed¹⁶⁰.*
- 2.18.3.3 *There was general agreement that, if milk was to be fortified, this should only be undertaken after an analysis of the donor milk composition, because this varies considerably¹⁶¹.*
- 2.18.3.4 *One milk bank reported routine supplementation, but no further details were reported¹⁶².*
- 2.18.3.5 *A survey of milk banks indicated that all neonatal units enriched donor milk, either based on nutritional analysis or blindly¹⁶³.*
- 2.18.3.6 *One author noted that milk banks in the UK do not determine the nutritional content of breast milk¹⁶⁴.*

2.18.4 Evidence to recommendations

See also appendix 3 for the development of the recommendations using formal consensus techniques.

The GDG wanted to clarify that although some milk banks may fortify milk, this was not a key function of a milk bank and the recommendation therefore emphasises this.

¹⁵⁹ Based on 1 narrative review (Anon 1987) and 1 service description (Arnold 1999).

¹⁶⁰ Based on 1 opinion piece (Braune 1982), 1 position statement (Anon 1985) and 1 primary study (Santiago et al. 2005).

¹⁶¹ Based on 1 narrative review (Anon 1987) and 2 opinion pieces (Braune 1982; Modi 2006).

¹⁶² Based on 1 service description (Langerak and Arnold 1991).

¹⁶³ Based on 1 service description (Omarsdottir et al. 2008).

¹⁶⁴ Based on 1 opinion piece (Modi 2006).

2.18.5 Recommendations

Recommendation 1.2.67

Staff at the milk bank should not be responsible for adding anything to the donated milk.

2.19 *Disposing of donor milk*

2.19.1 Review question

How should donor milk samples be disposed of?

2.19.2 Evidence review

Eight service descriptions from the 202 included studies provided 12 evidence records. Publication dates ranged from 1978 to 2007.

Service descriptions reported practice in the UK, Australia, the USA, Finland and South Africa.

2.19.3 Evidence statements

2.19.3.1 *There was general agreement about disposing of contaminated milk (as measured by agreed criteria) and samples arousing any safety concerns. However, no details of any specific method of disposal were described¹⁶⁵.*

2.19.3.2 *One milk bank reported that contaminated milk (as measured by agreed criteria) was retained for use in research¹⁶⁶.*

2.19.3.3 *Three milk banks reported discarding stored milk after a specific period. However, the time period ranged from 3 (two milk banks) to 6 months (one milk bank)¹⁶⁷.*

¹⁶⁵ Based on 6 service descriptions (Asquith et al. 1987; Balmer and Wharton 1992; Beal et al. 1978; Dempster 1982; Hartmann et al. 2007; Ikonen et al. 1982).

¹⁶⁶ Based on 1 service description (Asquith et al. 1987).

¹⁶⁷ Based on 3 service descriptions (Beal et al. 1978; Connor 1982; Hartmann et al. 2007).

2.19.4 Evidence to recommendations

See also appendix 3 for the development of the recommendations using formal consensus techniques.

Donor milk should be disposed of in the same way as any other clinical waste, so local waste disposal policies should be followed (see www.dh.gov.uk for information on disposal of clinical and other waste).

2.19.5 Recommendations

No specific recommendations were made on how donor milk should be disposed of.

2.20 *Tracking and tracing*

2.20.1 Review question

How should donor breast milk samples be tracked and traced?

- How should donor milk samples be archived?

2.20.2 Evidence review

Forty-six of the 202 included studies provided 139 evidence records. The studies contained:

- 28 service descriptions
- 9 narrative reviews
- 3 opinion pieces
- 2 position statements
- 2 primary studies
- 1 meeting report
- 1 case report.

Publication dates ranged from 1951 to 2008.

Service descriptions reported practice in the UK, the USA, Denmark, Australia, Sweden, India, Germany, Finland, Poland and Brazil.

Only some of these studies specifically mentioned tracking and tracing, but all referred to the need to have proper administrative procedures, many of which would facilitate tracking and tracing.

2.20.3 Evidence statements

2.20.3.1 There was general agreement that a system of administration of milk samples, including tracking and tracing, was needed. However, different milk banks used different systems¹⁶⁸.

2.20.3.2 No evidence on the most effective and efficient tracking and tracing system was identified.

2.20.3.3 Even where administration systems were in place, procedures were not always followed¹⁶⁹.

2.20.3.4 When reported, components of administration systems used in milk banks included:

- a registry of 'raw' milk donors*
- labelling or record of each sample*
- donor identity*
- details of any prescription drugs*
- date of expression*
- date of collection*
- date of deposit*
- nutritional content*
- date of clearance (bacteriologic)*
- expiry date*
- labelling of each pool, both between and within donors*
- bacteriological results*
- pasteurisation log*

¹⁶⁸ Based on many references: specific examples include 1 narrative review (Van de et al. 1992), 1 position statement (Gutierrez and de Almeida 1998) and 3 service descriptions (Asquith et al. 1987; Hartmann et al. 2007; Morley-Peet 1983).

¹⁶⁹ Based on 1 case report (Ryder et al. 1977).

- *record of recipient use, either individual baby or other organisation¹⁷⁰.*

2.20.3.5 It is generally accepted that, whichever system is used, adequate resources (for example, money, staff and equipment) are needed to implement an effective and efficient administration system¹⁷¹.

2.20.3.6 A report from a meeting recommended that contingency samples should be frozen before treatment and archived for 'investigational purposes which may arise'¹⁷².

2.20.3.7 Although no explicit link was made in the literature, it could be speculated that, as there are significant barriers to the use of donor milk because of safety concerns, the implementation of an effective tracking and tracing system could address some of these, and thereby increase the use of donor milk¹⁷³.

2.20.3.8 A position statement on the running of milk banks in Brazil states that:

- *all human milk banks are responsible for clinical and quality control*
- *every procedure should be recorded*
- *all records of procedures should be available to the health inspection laboratories*
- *periodic reports of donations, quality control test results, total volume of milk collected, and total number of recipients should be sent to the local health authorities*

¹⁷⁰ Based on 1 meeting report (Silverman 1971) and 8 service descriptions (Arnold 1999; Asquith et al. 1987; Balmer and Wharton 1992; Beal et al. 1978; Cash and Giacoia 1981; Hartmann et al. 2007; McEnery and Chattopadhyay 1978; Tully 2000).

¹⁷¹ Based on 3 narrative reviews (Bromberger 1982; Lording 2006; Weaver 2001) and 1 service description (Tully 2000).

¹⁷² Based on 1 meeting report (Silverman 1971).

¹⁷³ Barriers based on 1 narrative review (Lording 2006).

- *all milk samples should be marked with the name, date and time of collection¹⁷⁴.*

2.20.3.9 *One milk bank stated, as an operational objective, their commitment to ‘ensuring full traceability from individual donation to recipient and maintaining a record of all storage and processing conditions’. To achieve this, the following databases and records were maintained:*

- *donor record*
- *medical record number*
- *consent*
- *medical history questionnaire*
- *pathology results*
- *specimen database*
- *specimen ID*
- *processing information*
- *batch record*
- *specimens pooled*
- *pasteurisation log*
- *microbiological screening results*
- *recipient record*
- *consent*
- *product used¹⁷⁵.*

2.20.4 Evidence to recommendations

See also appendix 3 for the development of the recommendations using formal consensus techniques.

Tracking and tracing of milk samples was considered to be the most important function of any administration system used in a milk bank, and the GDG was keen to make detailed recommendations on the principles to follow and the information to be collected.

¹⁷⁴ Based on 1 position statement (Gutierrez and de Almeida 1998).

¹⁷⁵ Based on 1 service description (Hartmann et al. 2007).

No guidelines on the archiving of donor milk samples or critical information were found. Although the GDG initially wished to make recommendations on the archiving of milk samples; based on stakeholder comments, the GDG accepted that there was no evidence to support this and no existing guidance that could be cited. Therefore, the GDG changed the recommendation to refer to archiving of blood samples only and referred to the Royal College of Pathologists' guidelines (see www.rcpath.org/resources/pdf/g031retentionstorageaugust09.pdf), which give recommendations on the retention and storage of pathological records and specimens, including blood.

2.20.5 Recommendations

Recommendation 1.2.68

Track donated milk from the donor through to the recipient hospital.

Recommendation 1.2.69

Tracking and monitoring of donor milk processing should include freezer temperatures, pasteurisation processes and stock control.

Recommendation 1.2.70

At all stages, donor milk containers should be labelled clearly for identification. Clearly identify milk that is ready to be used.

Recommendation 1.2.71

For each donor milk batch, keep the following records.

- About the donor:
 - NHS number/donor ID
 - consent
 - relevant medical history
 - results of serological tests.
- About each container before pasteurisation:
 - donor ID
 - a testing log, including the tests undertaken and their results.
- For each pasteurised container:

- samples making up the batch
- the batch number
- a testing log, including the tests undertaken and their results
- pasteurisation details, including date of the pasteurisation.
- The hospital or neonatal unit that receives the donated milk, or the disposal date of the donated milk, as appropriate.

Recommendation 1.2.72

Label each container of pasteurised donor milk with the following information.

- A unique identification number.
- Confirmation that it contains pasteurised donor breast milk.
- Instructions to keep frozen, and use within 24 hours if defrosted.
- An expiry date (no later than 6 months from expression).

Recommendation 1.2.73

Only supply donor milk to hospitals or neonatal units that agree to comply with the tracking procedures for milk outlined by the milk bank.

Recommendation 1.2.74

The receiving hospital or neonatal unit should keep a record of how the donor milk is used. It should document for each bottle of donor milk:

- the baby's name, NHS number and date of birth, and the date administered
- the batch number and the date the donor milk was used in the patient record of each baby
- the condition of the donor milk on arrival following transport
- the storage conditions.

Recommendation 1.2.75

Ensure that all records (including raw data) that are critical to the safety and quality of the donor milk are kept for at least 30 years after expiry date, use or disposal. These records should be confidential.

2.21 Staff training

2.21.1 Review question

What training and competencies should the following have?

- Milk bank staff.
- Staff working with mothers and babies who may benefit from, or who are receiving, donor breast milk.
- Staff working with potential donors.

In discussion with the GDG, it was agreed that training for staff working with the recipients was not relevant to this guideline; but they should understand the process of donor milk banking.

2.21.2 Evidence review

Ten of the 202 included studies provided 16 evidence records. The studies contained:

- 4 service descriptions
- 4 narrative reviews
- 2 opinion pieces.

Publication dates ranged from 1981 to 2007.

Service descriptions reported practice in the USA, Brazil and Poland.

2.21.3 Evidence statements

2.21.3.1 There was general support for education of all staff involved in milk donation and use, and specifically on the benefits and processes.

2.21.3.2 Two narrative reviews stated that healthcare professionals did not have a full understanding of the benefits of milk donation or the process of milk banking¹⁷⁶.

¹⁷⁶ Based on 2 narrative reviews (Bar-Yam 2003; Woo and Spatz 2007) and 3 service descriptions (Nommsen-Rivers 1997; Penc 1996; Williams et al. 2007).

2.21.3.3 *Some milk banks reported specific components of training packages they delivered. These included:*

- *hygiene*
- *quality control*
- *collection and storage procedures*
- *an update on research on the role of breast milk for the neonate¹⁷⁷.*

2.21.3.4 *One milk banking system required milk bank staff to be certified following a training course, and federal law required all milk bank directors to be certified¹⁷⁸.*

2.21.4 Evidence to recommendations

See also appendix 3 for the development of the recommendations using formal consensus techniques.

The GDG recognised that staff training is key to the safety of donor milk. It therefore recommended changes in practice in the expectation that all staff involved in milk banking would be adequately and appropriately trained.

2.21.5 Recommendations

Recommendation 1.2.5

All milk bank staff should have ongoing training that is relevant to their job and is recorded. Training should cover good practice and should ensure that each staff member:

- is competent in performing their job
- understands the technical processes relevant to their job
- understands how the milk bank is organised and how its health and safety and quality systems work
- understands the regulatory, legal and ethical aspects of their work.

¹⁷⁷ Based on 2 service descriptions (Asquith et al. 1987; Cash and Giacoia 1981).

¹⁷⁸ Based on 1 service description (Tully 2001).

Recommendation 1.2.6

Train milk bank staff in HACCP principles, food hygiene and pasteurisation, and provide ongoing support so that practices reflect these principles.

3 Research recommendations

We have made the following recommendations for research, based on our review of evidence, to improve NICE guidance in the future.

Although it was not part of the scope of this guideline, it is known that there is limited high-quality evidence on the benefits of donor breast milk. The aim of this guideline is to provide guidance on the operation of donor milk banks; however, our expectation is that, once any risks of donor milk banking are minimised, further research can be undertaken to evaluate the benefits of donor milk, and to identify the recipient babies who would benefit most.

The research recommendations below relate to the process of donor milk banking. Where appropriate, they also recommend evaluating outcomes in the recipient population.

3.1 *The process of handling donor milk*

What is the effect of the process of milk banking on the nutritional and immunological components of donor milk?

Why this is important

The handling of donor milk includes a range of processes – including transport, storage and heat treatment – and is known to affect various biological, nutritional and immunological properties of breast milk. In addition, new methods of processing, such as heat or pressure treatment, are now being used in the food industry. However, there is very little comparative evidence on the different effects of the processes and how changes in the detailed process (for example, a change in temperature of 1°C) may affect the biological, nutritional and immunological properties of the milk. There is also no direct evidence of how these changes affect outcomes for recipients.

Further research is needed on the comparative effects of all milk handling processes on nutritional and immunological components, and, where possible, the impact of these on health outcomes for the recipients and on resource use during milk banking and following supply to recipients.

3.2 *Nutritional assessment of donor milk*

How and when should the nutritional components of donor breast milk be assessed?

Why this is important

It is known that the process of donor milk banking (for example, storage and heat treatment) affects the nutritional composition of milk. It is not clear how such changes affect health outcomes for recipients. Currently, in the UK, nutritional assessment of donor breast milk is not common practice.

Further research is needed to define clinically important changes and to determine the most useful methods and timing of measuring these in UK milk banking practice.

3.3 *Milk donors*

What are the attitudes and behaviours (including lifestyle factors such as diet) of milk donors, and can they affect the quality of donor milk?

Why this is important

There is very limited evidence on the attitudes and behaviours of milk donors, including the reason why they choose to donate. There is no evidence on how these factors (for example, ongoing donation or a one-off donation or dietary behaviours) may be associated with the quality of donated milk.

Further research is needed to understand the link between donor attitudes or behaviours and the quality of milk.

4 Other versions of this guideline

This is the full guideline. It contains details of the methods and evidence used to develop the guideline. It is available from our website (www.nice.org.uk/guidance/CG93/Guidance).

Quick reference guide

A quick reference guide for healthcare professionals is available from www.nice.org.uk/guidance/CG93/QuickRefGuide

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N2094).

‘Understanding NICE guidance’

A summary for patients and carers (‘Understanding NICE guidance’) is available from www.nice.org.uk/guidance/CG93/PublicInfo

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N2095).

We encourage NHS and voluntary sector organisations to use text from this booklet in their own information about milk donation.

5 Related NICE guidance

Published

- Maternal and child nutrition. NICE public health guidance 11 (2008). Available from www.nice.org.uk/guidance/PH11
- Postnatal care. NICE clinical guideline 37 (2006). Available from www.nice.org.uk/guidance/CG37

6 Updating the guideline

NICE clinical guidelines are updated so that recommendations take into account important new information. New evidence is checked 3 years after publication, and healthcare professionals and patients are asked for their views; we use this information to decide whether all or part of a guideline

needs updating. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations.

7 References, glossary and abbreviations

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See also Appendix 2 for a full list of included studies

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7.2 Glossary

Donor breast milk Breast milk expressed by a mother that is then processed by a donor milk bank for use by a recipient that is not the mother's own baby. Payment for the donated milk is not given.

Donor milk depot Any storage facility where donor milk can be stored before transfer. The depot can be run by the milk bank (for example, where donors are from wide geographic areas) or run by volunteers, who are often donors or past donors themselves.

Hazard Analysis and Critical Control Point Further information can be found on the Food Standards Agency Website www.food.gov.uk

7.3 Abbreviations

Abbreviation	Meaning
CMV	Cytomegalovirus
CPA	Clinical pathology accreditation
HACCP	Hazard Analysis and Critical Control Point
MRSA	Methicillin-resistant <i>Staphylococcus aureus</i>
QALY	Quality-adjusted life year
VDRL	Venereal disease research laboratory

7.4 *Appendices*

Appendices 1 to 6 are filed as separate documents:

Appendix 1: Scope

Appendix 2: Key guideline questions

Appendix 3: Methods of guideline development

Appendix 4: Survey of donor milk banks

Appendix 5: Evidence reports part 1

Appendix 6: Evidence reports part 2

8 Contributors

8.1 *The Guideline Development Group*

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8.2 *The short clinical guidelines technical team*

A short clinical guidelines technical team was responsible for this guideline throughout its development. It prepared information for the Guideline Development Group, drafted the guideline and responded to consultation comments. The following NICE employees made up the technical team for this guideline.

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8.3 *The Guideline Review Panel*

The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring adherence to NICE guideline development processes. In particular, the panel ensures that stakeholder comments have been adequately considered and responded to. The panel includes members from the following perspectives: primary care, secondary care, lay, public health and industry.

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8.4 *Declarations of interest*

A full list of all declarations of interest made by this Guideline Development Group is available on the NICE website (www.nice.org.uk).

8.5 *Authorship and citation*

Authorship of this document is attributed to the NICE Short Clinical Guidelines Technical Team and members of the Guideline Development Group under group authorship.

The guideline should be cited as:

National Institute for Health and Clinical Excellence (2010) Donor breast milk banks: the operation of donor breast milk bank services. London: National Institute for Health and Clinical Excellence. Available from: www.nice.org.uk/guidance/CG93

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Donor breast milk banks: the operation of donor breast milk bank services

1.1 Short title

Donor breast milk banks

2 Background

- a) The Department of Health has asked the National Institute for Health and Clinical Excellence (NICE or 'the Institute') to develop a guideline on the use of donor breast milk in preterm babies for use in the NHS in England and Wales. This follows referral of the topic by the Department of Health (see appendix B). The guideline will provide recommendations for good practice on the operation of donor breast milk banks that are based on the best available evidence.
- b) NICE clinical guidelines support the implementation of National Service Frameworks (NSFs) in those aspects of care for which a Framework has been published. The statements in each NSF reflect the evidence that was used at the time the Framework was prepared. The clinical guidelines and technology appraisals published by NICE after an NSF has been issued have the effect of updating the Framework.
- c) NICE clinical guidelines support the role of healthcare professionals in providing care in partnership with patients, taking account of their individual needs and preferences, and ensuring that patients (and their carers and families, where appropriate) can make informed decisions about their care and treatment. NICE also produces

service guidance, which focuses on the broad configuration and provision of clinical services rather than on details of clinical practice. It should be noted that this guideline will be structured as service guidance on the operation of donor breast milk banks.

3 Clinical need for the guideline

- a) Research has consistently shown that breast milk is the best nourishment for babies and that it has important benefits to an infant's health in the short, medium and long term. Women are recommended to breastfeed their baby exclusively for 6 months and continue to breastfeed after 6 months as part of a balanced diet, for as long as mother and baby wish.
- b) If a mother does not wish to express milk despite discussion with experienced staff and information regarding benefits to herself and her baby, or is not able to express sufficient milk, donor breast milk can be used as an alternative to infant formula, because it has been shown to have significant nutrient and non-nutrient benefits.
- c) A Health Technology Assessment (HTA) report entitled 'Breastfeeding promotion in special care and neonatal intensive care units; an evidence synthesis' is due to be published in July 2009. This report uses systematic review methodology to assess which interventions effectively promote the initiation and duration of breastfeeding in neonatal, special, and intensive care settings, including the availability of donor breast milk. This guideline will refer to the HTA report as appropriate where evidence on the role of donor breast milk in breastfeeding initiation and continuation is needed.
- d) Concerns have been raised on the safety of handling and processing donor breast milk (for example, adequate pasteurisation) and on the long-term safety of donor milk, in particular regarding the transmission of prion diseases such as Creutzfeld–Jakob disease.

- e) Currently, 17 donor breast milk banks are in operation in the UK; these provide donor milk to babies, including preterm babies and babies with growth restriction. The key guideline is the 2003 UK Association for Milk Banking 'Guidelines for the establishment and operation of human milk banks in the UK'; however, this is past its review date for updating, but still relevant and in use. There is therefore an urgent need for an updated national guideline to ensure that donor milk banks operate according to best available evidence and standards of practice. Local needs will determine how services are commissioned to implement the guideline recommendations.

4 The guideline

- a) The guideline development process is described in detail in two publications that are available from the NICE website (see section 6, 'Further information').
- b) This scope defines exactly what this guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on a referral from the Department of Health (see appendix A).
- c) The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

- a) Infants who receive donor breast milk.
- b) Mothers and carers of infants who receive donor breast milk.
- c) Women who donate breast milk.
- d) Staff involved in the collection, storage and handling of donor milk.

4.1.2 Groups that will not be covered

- a) Infants who do not receive donor breast milk.
- b) Mothers and carers of infants who do not receive donor breast milk.

4.2 *Healthcare setting and services*

- a) Donor breast milk banks.
- b) Special care baby units, neonatal units, transitional care units and other settings (such as paediatric wards) that require access to donor breast milk.
- c) Community services that support breast milk donors and mothers or carers of infants receiving donor milk.

4.3 *Clinical management*

The following areas of clinical management have direct implications for service delivery.

4.3.1 Areas that will be covered

- a) Recruitment, assessment and selection of donor women. This will include:
 - an assessment of factors that affect suitability, including:
 - relevant lifestyle factors, such as smoking status and alcohol intake
 - relevant medical history, including existing conditions or infections, vaccination history and current medication
 - serological testing of potential donors.

Reasons for stopping donation of breast milk, either temporarily or permanently, will also be covered.

- b) Collection, storage and handling of donor breast milk. This will include:
- collection of donor milk
 - storage of milk at the donor's home, during transportation and at the milk bank, including refrigeration and freezing
 - testing and treatment of donor milk, including pasteurisation
 - pooling of donor milk
 - archiving of donor milk samples
 - disposal of donor milk samples.
- c) Administration of the collection, storage and handling of donor breast milk, specifically the tracking and tracing of milk. This will also include the administration of records of consent to donation and to use of donor milk.
- d) Training and competencies of donor breast milk bank staff.
- e) Training and competencies of other staff working with mothers and babies who may benefit from, or who are receiving, donor milk, and those working with donors and potential donors.
- f) Information for parents or carers, donors and potential donors. The needs of different ethnic, religious and cultural groups will be considered.

4.3.2 Areas that will not be covered

- a) Indications for use of donor breast milk.
- b) Collection, storage and handling of breast milk for a mother's own baby.

4.4 Key outcome measures

- a) Safety of donor milk, defined as the minimisation of transmission risk for specific conditions, such as Creutzfeld–Jakob disease.

- b) Process measures of service delivery. For example, rates of screened donor women who are accepted as donors, and the number of milk donations with complete tracking and tracing data.

4.5 *Economic aspects*

The developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. They will conduct a review of the economic evidence and carry out analyses as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see 'Further information').

It should be noted that because this guideline focuses on identifying the optimal configuration of a milk bank service and not the indications for donor breast milk per se, a cost-effectiveness analysis of the health benefits of donor milk will not be undertaken. Moreover, it is not clear that QALYs can be estimated appropriately for this guideline. Any departures from preferred NICE methods will be clearly documented. It is anticipated that the key outcome of any analysis would relate to the avoidance of any significant safety risks (see section 4.4).

4.6 *Status*

4.6.1 *Scope*

This is the final scope.

4.6.2 *Guideline*

The development of the guideline recommendations will begin in April 2009.

5 *Related NICE guidance*

Published

Improving the nutrition of pregnant and breastfeeding mothers and children in low-income households. NICE public health guidance 11 (2008). Available from www.nice.org.uk/PH11

Routine postnatal care of women and their babies. NICE clinical guideline 37 (2006). Available from www.nice.org.uk/CG37

6 Further information

The guideline development process is described in:

- 'How NICE clinical guidelines are developed: an overview for stakeholders' the public and the NHS'
- 'The guidelines manual'.

These are available from the NICE website (www.nice.org.uk/guidelinesmanual). Information on the progress of the guideline will also be available from the NICE website (www.nice.org.uk).

Appendix A: Referral from the Department of Health

The Department of Health asked NICE:

'To produce a short clinical guideline on the use of human donor breast milk in preterm babies.'

Appendix 2 Description of process of systematic review(s) for DBM, including key guideline questions

Contents

Key references and guidelines	2
Key guideline questions	4
Included studies	6
Excluded studies	17
References cited – selected citation mapping	42

Key references and guidelines

Scoping searches identified the UKAMB and the HMBANA guidelines. Full-text copies of all references in the UKAMB guidelines (117) and those references assessed as relevant from the title and abstract from the HMBANA guidelines (78) were ordered and checked for inclusion or exclusion.

Any relevant references from the HMBANA position paper (10) were also retrieved and checked for inclusion in the review.

A focussed search was conducted by information services and 5236 references retrieved (with 2 additional from Medline Update – 5238 in total). These were scanned (see the review protocol below) and 406 references were selected on the title and abstract. These were imported into the master database, and any duplication with the UKAMB/HMBANA guidelines corrected. This left a set of core references for full-text examination (525 in total).

References were added from reference lists of relevant articles and where published versions of unpublished/grey reports were found.

Any excluded papers (including those excluded from the HMBANA guidelines) were documented in the Excluded Studies table below.

	Details	Additional comments	Status
Review question	What processes and procedures should be undertaken to ensure the safety of donor breast milk?	Indications for donor milk are excluded. Only included paper if explicit reference to donor milk. Excluded therefore for example, studies describing different chemical composition of sample unless directly linked to donor milk services/processes. Included any studies on the handling/ storage/ pasteurization of human milk, and only those studies related to the process of fortification.	
Objectives	To identify all relevant literature on the running of donor breast milk services.		
Language	English only		
Study design	No restriction. Published papers only.	Excluded only articles/publications assessed as 'news' or 'magazine' items.	
Population	Babies receiving donor milk; donor milk services; donor women.	Excluded studies on maternal milk only.	
Outcomes	N/R		
Other criteria for inclusion/exclusion of studies	None applied.		Some studies excluded as 'not relevant to the UK'. Where a service was described more than once, only the most recent description was included.
Search strategies	See saved searches.		Re-ran in Feb 2009. Medline updated in Jan 2009, so

			searches re-ran earlier than planned – only 2 additional references, neither of which were relevant at ti,ab scan.
Review strategies	Narrative summary.	Quality assessment tools may not be available for all study designs, so some adaptation may be needed.	

Key guideline questions

- How should donor women be recruited, and what information should be provided? The needs of different ethnic, religious and cultural groups will be considered.
- What factors should be assessed to determine the suitability of potential donors?
- What initial and repeat serological testing should be undertaken:
 - When screening potential donors?
 - In donor women whilst continuing to donate?
- When should donor women be advised to stop donating milk, either temporarily or permanently?
- What are the best (safest) methods for collecting, storing and handling donor breast milk?
 - How should donor milk be expressed?
 - How, and for how long, should donor milk be stored at home, during transportation and at the milk bank, including refrigeration and freezing?
 - How should donor milk be tested and treated?
 - Should donor milk be pooled?
 - How should donor milk samples be archived?
 - How should donor milk samples be disposed of?
- How should donor breast milk samples be tracked and traced?

- What information should donors and parents or carers of infants using donor breast milk be given to ensure full informed consent, and how should this be recorded?
- What training and competencies should the following have:
 - Milk bank staff?
 - Staff working with mothers and babies who may benefit from, or who are receiving, donor breast milk?
 - Staff working with potential donors?

During the development of the evidence reports, it was clear that some evidence reports would include several questions; the GDG were therefore presented evidence on the following areas:

- Administration, including tracking and tracing
- Donor recruitment
- Donor screening and selection, including testing
- Donor stopping
- Donor training and support
- Donor training
- Milk disposal
- Milk expression
- Milk fortification
- Milk handling
- Milk handling at home
- Milk handling at the milk bank
- Milk handling during transportation
- Milk pooling
- Milk testing
- Milk transportation
- Milk treatment
- Staff training

Included studies

See also Appendix 5 for the evidence reviews by clinical question.

Anon (1980) American Academy of Pediatrics. Committee on Nutrition. Human milk banking. *Pediatrics* 65: 854-7.

Anon (1985) Statement on human milk banking. Nutrition Committee, Canadian Paediatric Society. *Canadian Medical Association Journal* 132: 750-2.

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Arnold LDW (1999) Currents in human milk banking: donor milk banking in Scandinavia. *Journal of Human Lactation* 15: 55-9.

Asquith MT, Harrod JR (1979) Reduction of bacterial contamination in banked human milk. *Journal of Pediatrics* 95: 993-4.

Asquith MT, Pedrotti PW, Stevenson DK et al. (1987) Clinical uses, collection, and banking of human milk. *Clinics in Perinatology* 14: 173-85.

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Balmer SE, Wharton BA (1992) Human milk banking at Sorrento Maternity Hospital, Birmingham. *Archives of Disease in Childhood* 67: 556-9.

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323 references were excluded at the full-text stage.

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Human milk for feeding premature infants: benefits, risks and precautions for a donor program.

EXC - not available.

(1979)

The neonate: a day in the life of a wet nurse.

EXC - historical article on wet nursing.

(1980)

WHO/UNICEF joint statement: meeting on infant and young child feedings.

EXC - reference. See also NICE PH11 on maternal and infant nutrition.

(1980)

WHO/UNICEF meeting on infant and young child feeding.

EXC - statement on need to provide human milk through banks. Not operation of services.

(1981)

The collection and storage of human milk. Report of a Working Party on Human Milk Banks, Panel on Child Nutrition. Committee on Medical Aspects of Food Policy.

EXC - not available.

(1981)

Human milk banks.

EXC - editorial. No detailed reference to operation of milk banks.

(1982)

Acute hemorrhagic conjunctivitis.

EXC - cited in HMBANA for use in adults.

(1988)

Milk banks: in the light of history.

EXC - editorial. No detailed reference to operation of milk banks.

(1988)

HIV infection, breastfeeding, and human milk banking.

EXC - based on 1988 DHSS report, which is assumed to be no longer current.

(1989)

HIV infection, breastfeeding and human milk banking in the United Kingdom.

EXC - report no longer available, and assumed to be out-of-date.

(1991)

Premature babies need breast-milk.

EXC - news article.

(1991)

Nutrition during lactation.

EXC - assumed no longer current. See NICE PH11 on maternal and infant nutrition.

(1994)

American Academy of Pediatrics Committee on Drugs: The transfer of drugs and other chemicals into human milk.

EXC - information on drugs in breast milk. Refer to latest BNF information.

(1995)

Policy no 5: infant feeding policy.

EXC - general statement on breast feeding. No specific reference to donor milk.

(1999)

EASL International Consensus Conference on Hepatitis C. Paris, 26-28, February 1999, Consensus Statement. European Association for the Study of the Liver.

EXC - statement on screening for HepC. No specific reference to donor milk. Also assumed no longer current.

(1999)

Guidelines for the establishment and operation of human milk banks in UK. Second edition.

EXC - assumed to be UKAMB guidelines. Also no longer current.

(2001)

WHO resolution.

EXC - resolution on the benefits of breast feeding.

(2002)

Infant and young child nutrition: global strategy on infant and young child feeding.

EXC - global strategy. See also NICE PH11 on maternal and infant nutrition.

(2002)

Guide for parents. The right way to store breast milk.

EXC - basic information on storage. Noted that applies to milk for healthy infants only. Will refer to more current guidelines.

(2002)

Ensuring the safety of stored breast milk.

EXC - promotional article on a specific type of bottle. No references.

(2005)

Kids' health & safety: borrowing breast milk.

EXC - magazine article

(2006)

Standards for blood banks and transfusion services.

EXC - see UK standards, if relevant.

(2006)

Handling of expressed breast milk (EBM) in acute care facilities: position statement Pediatric Interest Group, CHICA-Canada.

EXC - relates to maternal milk in acute care facilities.

(2008)

Neonatal intensive care feeding management system implemented.

EXC - promotional article on a specific type of bottle. No references.

(2008)

Donor breast milk service.

EXC - news article on establishment of satellite service.

(2008)

Donation of portable pumps to NICUs aims to reduce the number of babies missing out on breastmilk.

EXC - magazine article

Acheson, D. (1988)

HIV infection, breastfeeding, and human milk banking.

EXC - based on 1988 DHSS report, which is assumed to be no longer current.

Afolabi, O. A. and others. (1985)

A preliminary survey of aerobic bacteria in breast milk of mothers from the low-income group in Nigeria.

EXC - study to assess the quality of milk from a specific group of women. Not relevant to UK.

Agarwal, R. and others. (2004)

Effect of Fortification with Human Milk Fortifier (HMF) and other Fortifying Agents on the Osmolality of preterm Breast Milk.

EXC - aims to assess the safety of specific fortifiers. Not donor specific or related to the process.

Ajusi, J. D. and others. (1989)

Bacteriology of unheated expressed breast milk stored at room temperature.

EXC - study to determine appropriate storage time for maternal milk for working mothers.

Al Naqeeb, N. A. and others. (2000)

The introduction of breast milk donation in a Muslim country.

EXC - duplicate. See Al Naqeeb 2000 Currents...

Al Naqeeb, N. A. and others. (2000)

Currents in human milk banking: the introduction of breast milk donation in a Muslim country.

EXC - specifically related to donor milk banking in a Muslim country.

Almroth, S., Greiner, T., and Latham, M. C. (1979)

Economic importance of breastfeeding.

EXC - not donor specific.

American Academy of Pediatrics. (1943)

Recommended standards for the operation of mothers' milk bureaus.

EXC - assumed no longer current.

Anderson, A. and Arnold, L. D. W. (1993)

Use of donor breastmilk in the nutrition management of chronic renal failure: three case histories.

EXC - indications for donor milk.

Anderson, J. W., Johnstone, B. M., and Remley, D. T. (1999)

Breast-feeding and cognitive development: a meta-analysis.

EXC - rationale for breast feeding.

Arnold, L. and Erickson, M. (1988)

The early history of milk banking in the USA.

EXC - not available.

Arnold, L. (1993)

Milk bank screening procedures.

EXC - quoted HMBANA guideline recommendations.

Arnold, L. (1997)

Contamination in expressed breast milk: a non-issue.

EXC - duplicate. See Arnold 1997.

Arnold, L. D. (1990)

Clinical uses of donor milk.

EXC - not available.

Arnold, L. D. (1991)

The statistical state of human milk banking and what the future holds.

EXC - duplicate. See Arnold 1991 Currents...

Arnold, L. D. and Asquith, M. T. (1991)

Currents in human milk banking: the evolution of services in modern human milk banking.

EXC - historical article describing the evolution of services over time

Arnold, L. D. (1992)

North American milk banks.

EXC - detailed description of services provided (not processes used). Assumed to be out-of-date.

Arnold, L. D. (1992)

Human milk storage and preservation in the early 1900s.

EXC - descriptive historical article.

Arnold, L. D. (1993)

HIV and breastmilk: what it means for milk banks.

EXC - quoted HMBANA guideline recommendations.

Arnold, L. D. (1993)

HMBANA guidelines on breast pumps and human milk storage and handling.

EXC - quoted HMBANA guideline recommendations.

Arnold, L. D. and Larson, E. (1993)

Immunologic benefits of breast milk in relation to human milk banking.

EXC - quoted HMBANA guideline recommendations.

Arnold, L. D. and Courden, M. (1994)

The lactariums of France, Part 2: How association milk banks operate.

EXC - duplicate.

Arnold, L. D. (1994)

Informal sharing of human milk: not-so-hypothetical questions, concrete answers.

EXC - quoted HMBANA guideline recommendations.

Arnold, L. D. (1994)

Donor human milk for premature infants: the famous case of the Dionne quintuplets.

EXC - duplicate. See Arnold 1994 Currents...

Arnold, L. D. (1994)

The lactariums of France: Part 1. The lactarium Docteur Raymond Fourcade in Marmande.

EXC - duplicate.

Arnold, L. D. (1995)

Use of donor milk in the treatment of metabolic disorders: glycolytic pathway defects.

EXC - duplicate. See Arnold 1995 Currents...

Arnold, L. D. (1995)

Use of donor human milk in the management of failure to thrive: case histories.

EXC - duplicate. See Arnold 1995 Currents...

Arnold, L. D. (1995)

Storage containers for human milk: an issue revisited.
EXC- duplicate. See Arnold 1995 Currents...

Arnold, L. D. (1996)
Possibilities for donor milk use in adult clinical settings--a largely unexplored area.
EXC - duplicate. See Arnold 1996 Currents...

Arnold, L. D. (1996)
Donor milk banking in China: the ultimate step in becoming baby friendly.
EXC - duplicate. See Arnold 1996 Currents...

Arnold, L. D. and Borman, L. L. (1996)
What are the characteristics of the ideal human milk donor?
EXC - see Arnold 1996 Currents...

Arnold, L. D. (1997)
Currents in human milk banking: how North American donor milk banks operate: results of a survey... part 2.
EXC - survey of US services. Assumed no longer accurate description of services.

Arnold, L. D. (1997)
A brief look at drip milk and its relation to donor human milk banking.
EXC - duplicate. See Arnold 1997 Currents...

Arnold, L. D. (1998)
How to order banked donor milk in the United States: what the health care provider needs to know.
EXC - duplicate. See Arnold 1998 Currents...

Arnold, L. D. (1998)
Cost savings through the use of donor milk: case histories.
EXC - duplicate. See Arnold 1998 Currents...

Arnold, L. D. (1999)
Donor milk banking in Scandinavia.
EXC - duplicate. See Arnold 1999 Currents...

Arnold, L. D. (2001)
Trends in donor milk banking in the United States.
EXC - quoted HMBANA guideline recommendations. Also describes US services - assumed no longer accurate description.

Arnold, L. D. (2002)
The cost-effectiveness of using banked donor milk in the neonatal intensive care unit: prevention of necrotizing enterocolitis.
EXC - cost effectiveness linked to health outcomes for pre-term babies (indications)

Arnold, L. D. (2006)
The ethics of donor human milk banking.
EXC - discussion of the ethics using theoretical case studies and personal experiences

Arnold, L. D. (2006)
Global health policies that support the use of banked donor human milk: a human rights issue.
EXC - discussion of the human rights issues. Not process specific.

Arnold, L. D. (2008)
U.S. Health policy and access to banked donor human milk.
EXC - US health policies. Not UK relevant.

Arnold, L. D. W. (1991)

Currents in human milk banking: the statistical state of human milk banking and what the future holds.

EXC - quoted HMBANA guideline recommendations.

Arnold, L. D. W. (1993)

Human milk for premature infants: an important health issue.

EXC - not available.

Arnold, L. D. W. (1994)

The lactariums of France: the Lactarium Docteur Raymond Fourcade in Marmande... part 1.

EXC - survey of services in France. Assumed no longer accurate description of services.

Arnold, L. D. W. and Courden, M. (1994)

The lactariums of France: how association milk banks operate... part 2.

EXC - survey of services in France. Assumed no longer accurate description of services.

Arnold, L. D. W. (1994)

Currents in human milk banking: donor human milk for premature infants: the famous case of the Dionne quintuplets.

EXC - case report. Also quoted HMBANA guideline recommendations.

Arnold, L. D. W. (1995)

Currents in human milk banking: use of donor milk in the treatment of metabolic disorders: glycolytic pathway defects.

EXC - case report.

Arnold, L. D. W. (1995)

Currents in human milk banking: use of donor human milk in the management of failure to thrive: case histories.

EXC - case report. Also quoted HMBANA guideline recommendations.

Arnold, L. D. W. (1995)

Currents in human milk banking: storage containers for human milk: an issue revisited.

EXC - not available.

Arnold, L. D. W. and Borman, L. L. (1996)

Currents in human milk banking: what are the characteristics of the ideal human milk donor?

EXC -quoted HMBANA guideline recommendations.

Arnold, L. D. W. (1996)

Currents in human milk banking: possibilities for donor milk use in adult clinical settings -- a largely unexplored area.

EXC - indications for donor milk in adults.

Arnold, L. D. W. (1997)

Currents in human milk banking: how North American donor milk banks operate: results of a survey... part 1.

EXC - survey of US services. Assumed no longer accurate description of services.

Arnold, L. D. W. (1997)

How North American donor milk banks operate: results of a survey, Part 1.

EXC - duplicate. See Arnold 1997 Currents...

Arnold, L. D. W. (1998)

Currents in human milk banking: cost savings through the use of donor milk: case histories.

EXC - not available.

Arnold, L. D. W. (1998)

Currents in human milk banking: how to order banked donor milk in the United States: what the health care provider needs to know.

EXC - quoted HMBANA guidelines.

Asp, K. (2007)

Good health. Banking on breast milk.

EXC - magazine article.

Asquith, M. T. and others. (1984)

The bacterial content of breast milk after the early initiation of expression using a standard technique.

EXC - relates to the timing of expression of milk by mothers for their own pre-term babies.

Asquith, M. T. (1989)

Human Milk Banking Association of North America.

EXC - statement of the aims of the HMBANA.

Atkinson, A. (2001)

Decontamination of breast milk collection kits: a change in practice.

EXC - decontamination of breast pumps on the neonatal units for maternal milk. Not donor specific.

Atkinson, H. C., Begg, E. J., and Darlow, B. A. (1988)

Drugs in human milk. Clinical pharmacokinetic considerations.

EXC - information on drugs in breast milk. Refer to latest BNF information.

Ball, T. M. and Wright, A. L. (1999)

Health care costs of formula-feeding in the first year of life.

EXC - rationale for breast feeding.

Balmer, S. E. and Williams, A. F. (1995)

Guidelines for the establishment and operation of human milk banks in the UK.

EXC - report of UK 1994 guidelines. Assumed no longer current.

Balmer, S. E. and Williams, A. F. (1995)

Guidelines for the establishment and operation of human milk banks in the UK.

EXC - report of UK 1994 guidelines. Assumed no longer current.

Balmer, S. E. (1995)

Currents in human milk banking: donor milk banking and guidelines in Britain.

EXC - report of UK 1994 guidelines. Assumed no longer current.

Balmer, S. E. (1995)

Donor milk banking and guidelines in Britain.

EXC - duplicate. See Balmer 1995 Currents...

Bank, M. R. and others. (1985)

Effect of storage time and temperature on folacin and vitamin C levels in term and preterm human milk.

EXC - storage of milk in freezers for home use. No specific reference to donor milk.

Barness, L. A., Dallman, P. R., and Anderson, H. (1980)

Human milk banking.

EXC - not available.

Baron, S. and others. (2000)

Oral transmission of human immunodeficiency virus by infected seminal fluid and milk: a novel mechanism.

EXC - specific action of milk on HIV. Not related to processing of donor milk.

Barrie, H. (1982)

Human milk banks.

EXC - letter explaining why donor milk should not be used. Supports the need for evidence based guidelines for donor milk, not the processes to be followed. Also assumed to refer to practices no longer current.

Bateman, C. (2002)

Another mother's milk saves AIDS babies.

EXC - news article on new service in South Africa.

Bateman, C. (2007)

Breastmilk banking regains vital expression.

EXC - news article on service in South Africa.

Bates, C. J. and others. (1985)

Susceptibility of riboflavin and vitamin A in breast milk to photodegradation and its implications for the use of banked breast milk in infant feeding.

EXC - related to the use of tubing when feeding premature babies to preserve nutrients.

Baum, J. D. (1982)

Human milk banking.

EXC - duplicate. See Baum 1982 Donor...

Baumer, J. H. (2004)

Guidelines for the establishment and operation of human milk banks in the UK.

EXC - report of UKAMB guidelines 3rd edition.

Beckholt, A. P. (1990)

Breast milk for infants who cannot breastfeed.

EXC - historical description of services, with some mention of the effect of HIV.

Berlin, C. M., Jr., Yaffe, S. J., and Ragni, M. (1980)

Disposition of acetaminophen in milk, saliva, and plasma of lactating women.

EXC - drugs in breast milk. Refer to BNF.

Berlin, C. M., Jr. and others. (1984)

Disposition of dietary caffeine in milk, saliva, and plasma of lactating women.

EXC - drugs in breast milk. Refer to BNF.

Bernshaw, N. (1996)

Where can mothers donate excess milk?

EXC - organisation of HMBANA members in the US.

Bevinetto, G. (2002)

Nutrition now. Storing breast milk.

EXC - magazine article

Biancuzzo, M. (1998)

The breastfeeding advisor. Using banked donor milk: a realistic option.

EXC - magazine article

Binkiewicz, A., Robinson, M. J., and Senior, B. (1978)

Pseudo-Cushing syndrome caused by alcohol in breast milk.

EXC - maternal alcohol, not donor. Refer to latest guidance on alcohol and breast feeding.

Bishop, N. J. and others. (1996)

Early diet of preterm infants and bone mineralization at age five years.

EXC - indications for donor milk.

Blenkharn, J. I. (1989)

Infection risks from electrically operated breast pumps.

EXC - related to use of equipment by several mothers, so specific to expression on neonatal unit. Not process of donor milk banking.

Boo, N. and others. (2001)

Contamination of breast milk obtained by manual expression and breast pumps in mothers of very low birthweight infants.

EXC - related to contamination of maternal milk for pre-term/LBW babies. Not donor specific.

Borman, L. L. (1991)

Human milk bank.

EXC - reference to HMBANA.

Briggs, E., Crandall, M., and Kelley, M. (1985)

Development of a breast milk banking program at a University Medical Center "nursing at a distance".

EXC - not available.

Briggs, G. G., Freeman, R. K., and Yaffe, S. J. (1998)

Drugs in pregnancy and lactation.

EXC - reference text. Assumed to be out-of-date.

Brink, S. (1977)

The successful use of human breast milk in a premature infant with the surgical short gut syndrome.

EXC - indications for donor/breast milk.

Brown, S. (1981)

Milk for life... milk banks.

EXC - magazine article.

Calvo, E. B., Galindo, A. C., and Aspnes, N. B. (1992)

Iron status in exclusively breast-fed infants.

EXC - study on need for additional supplementation for breastfed babies.

Candelaria, L. (2007)

Got milk -- but what do I do with it? Teaching patients about the process of donating human milk.

EXC - news article.

Candelaria, L. (2007)

Got milk -- but what do I do with it? Teaching patients about the process of donating human milk.

EXC - news article.

Candelaria, L. (2008)

RN appreciates knowing where to donate breast milk... "Banking on breast milk"...
September/October 2007.

EXC - news article.

Casey, C. E., Neville, M. C., and Hambidge, K. M. (1989)

Studies in human lactation: secretion of zinc, copper, and manganese in human milk.

EXC - trace elements in breast milk.

No effect of storage/treatment reported.

Chan, M. M. and others. (2003)

Lecithin decreases human milk fat loss during enteral pumping.

EXC - fortification to minimise fat loss during enteral pump delivery.

Chaney, N. E., Franke, J., and Wadlington, W. B. (1988)

Cocaine convulsions in a breast-feeding baby.

EXC - maternal drug use. Refer to latest guidance on drug use and breast feeding.

Chardigny, J.-M. and others. (1995)

Trans mono- and polyunsaturated fatty acids in human milk.

EXC - fats in breast milk.

No effect of storage/treatment reported.

Charnock, J. (2007)

RN appreciates breastmilk article... "Banking on breastmilk" (June issue).

EXC - news article.

Cohen, R. S. (2009)

Current issues in human milk banking.

EXC - not available.

Corbett, A. (1992)

Banking on breast milk.

EXC - review/description of other milk services.

Costa, K. M. (1989)

A comparison of colony counts of breast milk using two methods of breast cleansing.

EXC - not donor specific. Assume will refer to latest guidance on breast feeding/expressing.

Coveney, J. (1985)

Is breast milk the best food for all infants?

EXC - review article on breast feeding. Not donor specific. Also refer to latest guidance on breast feeding for contraindications.

Cowan, S. T. (1981)

Cowan and Steel's Manual for the identification of medical bacteria.

EXC - reference text. Assumed out-of-date.

Crossley, P. (2002)

People to people ambassador programs: breastfeeding and human lactation delegation to the People's Republic of China.

EXC - report of visit to China. No detailed report of donor milk processes.

Daley, A. J. (1998)

Breast milk and infection.

EXC - not available.

DARE, E. G. (1948)

The human milk bank.

EXC - service description of Queen Charlotte's milk bank. Old report, and newer descriptions available.

Davis, M. K. (2001)

Breastfeeding and chronic disease in childhood and adolescence.

EXC - rationale for breast feeding.

Davis, W. E. (1913)

Statistical comparison of the mortality of breast-fed and bottle-fed infants.

EXC - rationale for breast feeding.

Davy, S. T. (1975)

Human milk banks.

EXC - service description of Sorrento milk bank. More recent report available.

de Louvois, J. (1982)

Laboratory monitoring of banked human milk.

EXC - service description of Queen Charlotte's milk bank. More recent report available.

de Louvois, J. (1990)

Milk banking at Queen Charlotte's.

EXC - no details of process (overview only).

Department of Health. (2003)

Transmissible spongiform encephalopathy agents: safe working and the prevention of infection. Infection control of CJD and related disorders in the healthcare setting.

EXC - no longer current. Latest guidance is at

<http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/Index.htm> but does not appear to have any reference to breast milk.

Department of Health and Social Security. (1989)

HIV infection, breastfeeding and human milk banking. Committee on Medical Aspects of Food Policy.

EXC - report no longer available, and assumed to be out-of-date.

Dickens, V. (2007)

Every drop counts: report of a study day: understanding and supporting preterm breastfeeding for optimal nutrition, Bristol, 6 July 2007.

EXC - report of a meeting describing the UK milk banking services.

Dickens, V. (2007)

Daisy or Doreen: choices for mothers where human milk is banked for donation: report from the United Kingdom Association for Milk Banking (UKAMB) Roadshow.

EXC - report of a UKAMB workshop.

Dougherty, D. and Giles, V. (2000)

From breast to baby: quality assurance for breast milk management.

EXC - detailed process for management of maternal milk in the NICU, not donor milk.

Drenckpohl, D., Bowers, L., and Cooper, H. (2007)

Use of the six sigma methodology to reduce incidence of breast milk administration errors in the NICU.

EXC - detailed process for management of maternal milk in the NICU, not donor milk.

Dunn, D. T. and others. (1992)

Risk of human immunodeficiency virus type 1 transmission through breastfeeding.

EXC - review of reports of maternal transmission of HIV through breastfeeding. Not donor specific.

Dworsky, M. and others. (1983)

Cytomegalovirus infection of breast milk and transmission in infancy.

EXC - maternal transmission, not donor specific or treatment to prevent this.

Dyas, A. (1986)

Evaluation of the 'NUK-2000 Steam Steriliser', an alternative baby bottle disinfectant.

EXC - baby bottle disinfection.

el Mohandes, A. E. and others. (1993)

Bacterial contaminants of collected and frozen human milk used in an intensive care nursery.

EXC - maternal milk and related processes. Not donor specific.

el Mohandes, A. E. and others. (1997)

Use of human milk in the intensive care nursery decreases the incidence of nosocomial sepsis.

EXC - rationale for human milk.

Fenton, T. R. and Belik, J. (2002)

Routine handling of milk fed to preterm infants can significantly increase osmolality.

EXC - the effect of fortifiers on milk chemistry.

Fernandez, A., Mondkar, J., and Vaz, C. (1990)

Experiences with milk banking in Bombay.

EXC - more current description included.

Ferreira, C. S. and others. (2001)

Pasteurization of human milk to prevent transmission of Chagas disease.

EXC - not relevant to UK.

Fidler, N. and others. (2001)

Fat content and fatty acid composition of fresh, pasteurized, or sterilized human milk.

EXC - duplicate report of Fidler 1998.

Francis, J. and others. (2008)

Comparative analysis of ascorbic acid in human milk and infant formula using varied milk delivery systems.

EXC - methods of feeding.

Gartner, L. M. and others. (2005)

Breastfeeding and the use of human milk.

EXC - rationale and policy on breast feeding. See also NICE PH11 on maternal and infant nutrition.

Garza, C. and Nichols, B. L. (1984)

Studies of human milk relevant to milk banking.

EXC - report of previous study Garza 1984.

Gazzard, J. and Lee, C. (1979)

A "personalised" human milk bank.

EXC - description of process for maternal 'milk-bank'.

Geraghty. (2005)

Erratum: "The development of a research human milk bank".

EXC - research milk bank, not 'clinical' milk bank.

Geraghty, S. R. and others. (2005)

The development of a research human milk bank.

EXC - research milk bank, not 'clinical' milk bank.

Giacchia, G. P. (1980)

Human breast milk banking in Oklahoma.
EXC - more current description included.

Gilks, J., Gould, D., and Price, E. (2007)
Decontaminating breast pump collection kits for use on a neonatal unit: review of current practice and the literature.
EXC - equipment for maternal expression in the NICU setting.

Goldblum, R. M. and others. (1984)
Rapid high-temperature treatment of human milk.
EXC - not available.

Golden, J. (1988)
From wet nurse directory to milk bank: the delivery of human milk in Boston, 1909-1927.
EXC - historical article.

Golding, J. (1997)
Unnatural constituents of breast milk--medication, lifestyle, pollutants, viruses.
EXC - contaminants in breast milk. Refer to latest guidance on breast feeding. No effect of storage/treatment reported.

Goldman, A. S. and others. (1982)
Immunologic factors in human milk during the first year of lactation.
EXC - milk composition. No effect of storage/treatment reported.

Goldman, A. S. and others. (1994)
Immunologic protection of the premature newborn by human milk.
EXC - rationale for breast milk. Only very brief discussion of effect of storage on composition, with no specific mention of donor milk.

Greenough, A. (2007)
Antioxidant properties of human milk.
EXC - brief review on the composition of milk, citing Hanna 2004.

Greer, F. R. (2001)
Feeding the premature infant in the 20th century.
EXC - historical article.

Groh-Wargo, S. and others. (1995)
The utility of bilateral breast pumping system for mothers of premature infants.
EXC - maternal expression, not donor specific.

Gutierrez, D. and de Almeida, J. A. (1998)
Human milk banks in Brazil.
EXC - duplicate. See Gutierrez 1998 Currents...

Gyorgy, P. (1962)
Are human milk banks still necessary?
EXC - not available.

Hale, T. (2002)
Medications in mother's milk.
EXC - reference text. Refer to latest BNF information.

Hamosh, M. and others. (1984)
Handling and storage of human milk specimens for research.
EXC - research milk bank, not 'clinical' milk bank.

Hamosh, M. and others. (1996)

Breastfeeding and the working mother: effect of time and temperature of short-term storage on proteolysis, lipolysis, and bacterial growth in milk.

EXC - storage for breast feeding mothers (upto 24 hours). Not donor specific.

Hamosh, M. and others. (1997)

Digestive enzymes in human milk: stability at suboptimal storage temperatures.

EXC - storage for breast feeding mothers (upto 24 hours). Not donor specific.

Hamosh, M. (2001)

Bioactive factors in human milk.

EXC - rationale for human milk.

Hamprecht, K. and others. (2008)

Cytomegalovirus transmission to preterm infants during lactation.

EXC - review of the process of transmission. Not focus on the treatment of milk to prevent transmission.

Hanson, L. A. (1999)

Human milk and host defence: immediate and long-term effects.

EXC - rationale for human milk.

Henker, J. and Schmidt, B. (1989)

[History of the human milk collection bank of the Pediatric Department of the Dresden Medical Academy].

EXC - not English language.

Hernell, O. and others. (1986)

Killing of *Giardia lamblia* by human milk lipases: an effect mediated by lipolysis of milk lipids.

EXC - specific parasite. Not donor milk banking specific.

Hino, S. and others. (1985)

Mother-to-child transmission of human T-cell leukemia virus type-I.

EXC - not donor transmission. Refer to latest guidance on breast feeding.

Holland, R. (2005)

Donor human milk -- part 1: historical, national and international perspectives.

EXC - historical review. Also compares international systems citing references - all of which are reviewed in this guideline.

Hopkinson, J., Garza, C., and Asquith, M. T. (1990)

Human milk storage in glass containers.

EXC - not available.

Hornby, P. J. and Abrahams, T. P. (1996)

Pulmonary pharmacology.

EXC - drugs in milk. Refer to BNF.

Hughes, V. (1990)

Guidelines for the establishment and operation of a human milk bank.

EXC - quoted HMBANA guidelines.

Hughes, V. (1992)

Testimony presented at public hearing on regulation of tissue and organ transplantation.

EXC - duplicate. See Hughes 1992 Currents...

Hughes, V. (1992)

Currents in human milk banking: testimony presented at public hearing on regulation of tissue and organ transplantation.

EXC - report of testimony to a Working Group on US policy. Assumed to be no longer current.

Hulme, H. (1992)

Midwives' Journal. Working mothers. (Expressing and storing breast milk).

EXC - generic guidance to mothers. Not donor specific.

Human Milk Banking Association of North America. (2000)

Guidelines for the establishment and operation of a human donor milk bank.

EXC - see 2008 edition.

Hurst, N., Myatt, A., and Schanler, R. (1998)

Growth and development of a hospital-based lactation program and mother's own milk bank.

EXC - mother's own milk bank. May be some relevant information, but not donor specific.

Hylander, M. A., Strobino, D. M., and Dhanireddy, R. (1998)

Human milk feedings and infection among very low birth weight infants.

EXC - rationale for human milk.

Igumbor, E. O. and others. (2000)

Storage of breast milk: effect of temperature and storage duration on microbial growth.

EXC - focus on storage of maternal milk. Not donor specific.

Jameson, M. (2005)

Feeding a need.

EXC - news article.

Janjindamai, W. and Chotsampancharoen, T. (2006)

Effect of fortification on the osmolality of human milk.

EXC - assesses the effect of fortification on the osmolality of milk. Not donor specific, or about the process of fortification.

Jelliffe, D. B. and Jelliffe, E. F. (1977)

Breast milk banks: the new model.

EXC - letter from authors offering to provide/collect information on milk banks. No primary information.

Jocson, M. A., Mason, E. O., and Schanler, R. J. (1997)

The effects of nutrient fortification and varying storage conditions on host defense properties of human milk.

EXC - study on the fortification and use of milk on the NICU. Not process of donor milk banking.

Jones, E., Dimmock, P. W., and Spencer, S. A. (2001)

A randomised controlled trial to compare methods of milk expression after preterm delivery.

EXC - not donor specific, or about the process of milk banking.

Jones, F. (2003)

Currents in human milk banking: history of North American donor milk banking: one hundred years of progress.

EXC - historical article. Also report of the 2003 HMBANA guidelines.

Jones, F. and Human Milk Banking Association of North America. (2003)

History of North American donor milk banking: one hundred years of progress.

EXC - duplicate. See Jones 2003 Currents...

Jones, L. (1996)

Breast feeding. Mother's own expressed breast milk: guide-lines for storage.

EXC - duplicate. See Jones 1996.

Jones, L. (1996)

Mother's own expressed breast milk: guide-lines for storage.

EXC - maternal milk. Some reference to donor guidelines, but focus is not on donor milk banking.

Kerrey, B. T. and others. (2006)

Breast milk as a source for acquisition of cytomegalovirus (HCMV) in a premature infant with sepsis syndrome: detection by real-time PCR.

EXC - report of maternal transmission, and exploration of tracking of viral load. Not related to process of donor milk banking.

Klein, E. B., Byrne, T., and Cooper, L. Z. (1980)

Neonatal rubella in a breast-fed infant after postpartum maternal infection.

EXC - maternal transmission. Refer to latest guidance on breast feeding.

Koff, R. S. (1992)

The low efficiency of maternal-neonatal transmission of hepatitis C virus: how certain are we?

EXC - maternal transmission. Not donor specific.

Krugman, S. (1975)

Letter: Vertical transmission of hepatitis B and breast-feeding.

EXC - not donor specific, and no storage/treatment issues reported. Refer to latest guidance on breast feeding.

Labrecque, M. and others. (1989)

Feeding and urine cotinine values in babies whose mothers smoke.

EXC - maternal smoking. Refer to latest guidance on breast feeding.

Lal, R. B. and others. (1993)

Evidence for mother-to-child transmission of human T lymphotropic virus type II.

EXC - maternal transmission. Refer to latest guidance on breast feeding.

Lal, R. B. and others. (1994)

Mother-to-child transmission of human T-lymphotropic virus type II (HTLV-II).

EXC - maternal transmission. Refer to latest guidance on breast feeding.

Lang, S., Orme, R., and Lawrence, C. (1993)

A comparative study of hand and mechanically expressed human milk - nutritional content and effect on babies' weight and growth.

EXC - assumed to be report of Lang 1994.

Lang, S. and others. (1994)

Sodium in hand and pump expressed human breast milk.

EXC - maternal milk. Not donor milk banking specific.

Larson, E. and others. (1984)

Storage of human breast milk.

EXC - related to maternal milk. Not specific to donor milk banking.

Lawrence, R. A. (2001)

Milk banking: the influence of storage procedures and subsequent processing on immunologic components of human milk.

EXC - almost identical review to Lawrence 1999. No additional references.

Lee, N. (2008)

Donating milk... "Got milk -- but what do I do with it?".

EXC - news article

Linnemann, C. C., Jr. and Goldberg, S. (1974)

Letter: HBAg in breast milk.

EXC - maternal transmission. Refer to latest guidance on breast feeding.

Liston, J. (1998)

Breastfeeding and the use of recreational drugs--alcohol, caffeine, nicotine and marijuana.

EXC - maternal use of drugs. Refer to latest guidance on breast feeding.

Little, R. E. and others. (1989)

Maternal alcohol use during breast-feeding and infant mental and motor development at one year.

EXC - maternal alcohol. Refer to latest guidance on breast feeding.

Losonsky, G. A. and others. (1982)

Effect of immunization against rubella on lactation products. II. Maternal-neonatal interactions.

EXC - maternal transmission. Refer to latest guidance on breast feeding.

Lucas, A. and others. (1980)

A human milk formula.

EXC - method of adjusting the composition of human milk for feeding preterm neonates.

Lucas, A. and others. (1984)

Multicentre trial on feeding low birthweight infants: effects of diet on early growth.

EXC - rationale and indications for donor milk.

Lucas, A. and Cole, T. J. (1990)

Breast milk and neonatal necrotising enterocolitis.

EXC - indications for donor milk.

Lucas, A. and others. (1992)

Breast milk and subsequent intelligence quotient in children born preterm.

EXC - rationale for breast milk.

Lucas, A. and others. (1994)

A randomised multicentre study of human milk versus formula and later development in preterm infants.

EXC - indications for donor milk.

Luck, W. and Nau, H. (1985)

Nicotine and cotinine concentrations in serum and urine of infants exposed via passive smoking or milk from smoking mothers.

EXC - maternal smoking. Refer to latest guidance on breast feeding.

Luukkainen, P., Salo, M. K., and Nikkari, T. (1994)

Changes in the fatty acid composition of preterm and term human milk from 1 week to 6 months of lactation.

EXC - indications for donor milk.

Mascola, M. A. and others. (1998)

Exposure of young infants to environmental tobacco smoke: breast-feeding among smoking mothers.

EXC - maternal smoking. Refer to latest guidance on breast feeding.

McGee, D. H. (1959)

Mothers' milk bank at the Delaware Hospital.

EXC - not available.

McGuire, W. and Anthony, M. Y. (2003)

Donor human milk versus formula for preventing necrotising enterocolitis in preterm infants: systematic review.

EXC - indications for donor milk.

Mehta, N. R. and Subramanian, K. N. (1990)

Human milk banking: current concepts.

EXC - review of the HMBANA guidelines.

Merhav, H. J. and others. (1995)

Treatment of IgA deficiency in liver transplant recipients with human breast milk.

EXC - indications for donor/breast milk.

Mitoulas, L. R. and others. (2002)

Efficacy of breast milk expression using an electric breast pump.

EXC - not specific to donor milk banking.

Mitoulas, L. R. and others. (2002)

Effect of vacuum profile on breast milk expression using an electric breast pump.

EXC - not specific to donor milk banking.

Morley-Peet, P. (1983)

Enteropathogenic Escherichia coli.

EXC - duplicate. See Morley-Peet 1983.

Morley, R. and Lucas, A. (2000)

Randomized diet in the neonatal period and growth performance until 7.5-8 y of age in preterm children.

EXC - indications for donor milk.

Narayanan, I. and others. (1980)

Partial supplementation with expressed breast-milk for prevention of infection in low-birth-weight infants.

EXC - indications for donor/breast milk.

Narayanan, I., Prakash, K., and Gujral, V. V. (1981)

The value of human milk in the prevention of infection in the high-risk low-birth-weight infant.

EXC - indications for donor/breast milk.

Narayanan, I. and others. (1982)

A planned prospective evaluation of the anti-infective property of varying quantities of expressed human milk.

EXC - indications for donor milk.

Navas, S. A., Sabino, M., and Rodriguez-Amaya, D. B. (2005)

Aflatoxin M(1) and ochratoxin A in a human milk bank in the city of Sao Paulo, Brazil.

EXC - not relevant to UK [TO check with GDG]**

Nduati, R. W. (1994)

Erratum: Postnatal transmission of HIV-1 through pooled breast milk.

EXC - erratum for Nduati 1994 (see annotated paper).

Nehlig, A. and Debry, G. (1994)

Consequences on the newborn of chronic maternal consumption of coffee during gestation and lactation: a review.

EXC - maternal caffeine intake. Refer to latest guidance on breast feeding.

Neville, M. C. and others. (1991)

Lipoprotein lipase in human milk: compartmentalization and effect of fasting, insulin, and glucose.

EXC - description of effect of freezing and thawing, but had no reported link to infant nutrition or safety. Not related to the process of donor milk banking.

Newell, M. L., Gray, G., and Bryson, Y. J. (1997)

Prevention of mother-to-child transmission of HIV-1 infection.

EXC - maternal transmission. Refer to latest guidance on breast feeding.

Nicoll, A. and Moisleley, C. (1994)

Antenatal screening for syphilis.

EXC - maternal transmission. Refer to latest guidance on breast feeding.

Nightingale, S. and others. (1993)

Antenatal survey for the seroprevalence of HTLV-1 infections in the West Midlands, England.

EXC - maternal prevalence, not donor specific. Refer to latest guidance on breast feeding.

Nwankwo, M. U. and others. (1988)

Bacterial growth in expressed breast-milk.

EXC - not relevant to the UK.

O'Connor, C. J., Longbottom, J. R., and Walde, P. (1986)

Inactivation of bile-salt-stimulated human milk esterase: effect of storage and heat.

EXC - same study as O'Connor 1985.

Olowe, S. A. and others. (1987)

Bacteriological quality of raw human milk: effect of storage in a refrigerator.

EXC - storage of milk for a mother's own baby. Not donor milk specific. Also study conducted in a tropical environment - not relevant to UK practice.

Olukunle, O. F. and Adetuyi, F. C. (2008)

Microbial growth in stored human breast milk.

EXC - storage for only 6 hours maximum. Not relevant to donor milk banking.

Pagliuca, A., Pawson, R., and Mufti, G. J. (1995)

HTLV-I screening in Britain.

EXC - maternal prevalence and transmission. Refer to latest guidance on breast feeding.

Parks, Y. A. and others. (1987)

Methicillin resistant *Staphylococcus aureus* in milk.

EXC - report of infection on a SCBU, but neither infection route nor control measures specific to donor milk banking.

Parry-Hilhorst, G. M. (1968)

The mothers' milkbank.

EXC - not available.

Penc, B. (1996)

Organization and activity of a Human Milk Bank in Poland.

EXC - duplicate. See Penc 1996 Currents...

Philipp, B. L. and Merewood, A. (2002)

A primer on breast pumps.

EXC - not specific to donor milk banking.

Philipp, B. L. and Merewood, A. (2003)

Encouraging patients to use a breast pump.

EXC - duplicate. See Philipp 2002.

Picciano, M. F. (2001)

Nutrient composition of human milk.

EXC - rationale for human milk.

Pierce, K. Y. and Tully, M. R. (1992)

Mother's own milk: guidelines for storage and handling.

EXC - maternal milk only. No reference to donor milk banking.

Pittard, W. B., III and others. (1985)

Bacteriostatic qualities of human milk.

EXC - related to 24h room temperature effect on maternal milk. Not relevant to donor milk banking.

Quan, R. and others. (1992)

Effects of microwave radiation on anti-infective factors in human milk.

EXC - related to the thawing of milk for feeding. Not donor milk banking.

Radcliffe, A. (1989)

Setting up a nursing mother's room.

EXC - duplicate. See Radcliffe 1989.

Radcliffe, A. (1989)

Milk banks and milk banking. Setting up a nursing mother's room.

EXC - not available.

Rangecroft, L., de San, Lazaro C., and Scott, J. E. (1978)

A comparison of the feeding of the postoperative newborn with banked breast-milk or cow's-milk feeds.

EXC - indications for donor/breast milk.

Rees, M. (1999)

Breast pumps: the good, the bad and the noisy.

EXC - review of breast pumps. No specific mention of use for donor milk banking.

Renfrew, M. J. and others. (2008)

Assessing levels of contaminants in breast milk: methodological issues and a framework for future research.

EXC - process and rationale to 'develop guidelines for the most effective way to establish and maintain a national archive of breast-milk samples.' Not donor milk banking.

Reynolds, G. and Lewis-Jones, D. I. (1982)

Simplified milk banking.

EXC - letter citing published paper. See Reynolds 1982.

Reynolds, G. J. and others. (1982)

Simplified banking of human milk.

EXC - report of published paper. See Reynolds 1982.

Ridell, D. G. (1989)

Use of banked milk for feeding infants with abdominal wall defects.
EXC - no published reference found.

Riordan, J. M. (1997)

The cost of not breastfeeding: a commentary.

EXC - rationale for breast feeding.

Rozolen, C. D., Goulart, A. L., and Kopelman, B. I. (2006)

Is breast milk collected at home suitable for raw consumption by neonates in Brazilian public neonatal intensive care units?

EXC - evaluated maternal milk only.

Ryu, J. E. (1985)

Caffeine in human milk and in serum of breast-fed infants.

EXC - maternal intake. Refer to latest guidance on breast feeding.

Sakaguchi, M., Tomomasa, T., and Kuroume, T. (1995)

Cytolytic action of stored human milk on blood cells in vitro.

EXC - 24 hours storage only. No specific reference to donor milk banking.

Schanler, R. J. and Oh, W. (1980)

Composition of breast milk obtained from mothers of premature infants as compared to breast milk obtained from donors.

EXC - indications for donor milk.

Schanler, R. J. and Atkinson, S. A. (1999)

Effects of nutrients in human milk on the recipient premature infant.

EXC - indications for donor/breast milk.

Schanler, R. J., Shulman, R. J., and Lau, C. (1999)

Feeding strategies for premature infants: beneficial outcomes of feeding fortified human milk versus preterm formula.

EXC - indications for donor/breast milk.

Sibbald, B. (2000)

Canada's only human milk bank may close.

EXC - news article.

Simmer, K. (2000)

Neonatology for the generalist: human milk banks and evidence-based medicine.

EXC - duplicate. See Simmer 2000.

Singhal, A., Cole, T. J., and Lucas, A. (2001)

Early nutrition in preterm infants and later blood pressure: two cohorts after randomised trials.

EXC - rationale for human milk.

Singhal, A. and others. (2003)

Low nutrient intake and early growth for later insulin resistance in adolescents born preterm.

EXC - effect of diet. Not donor specific.

Slusher, T. and others. (2007)

Electric breast pump use increases maternal milk volume in African nurseries.

**EXC - evaluating the effect of different breast pumps to increase maternal milk volume.
Not donor specific.**

Springer, S. (1997)

Human milk banking in Germany.

EXC - duplicate. See Springer 1997 Currents...

Springer, S. (2000)

News about human milk banking in Germany.

EXC - brief article. See Springer 1997 for a fuller description of practice.

Springer, S. (2004)

Donor milk for preterm and sick children: human milk banking in Germany.

EXC - brief article. See Springer 1997 for a fuller description of practice.

Stepans, M. B. and Wilkerson, N. (1993)

Physiologic effects of maternal smoking on breast-feeding infants.

EXC - maternal smoking. Refer to latest guidance on breast feeding.

Stiehm, E. R. and Keller, M. A. (2001)

Breast milk transmission of viral disease.

EXC - maternal risk, no specific reference to donor milk. Refer to latest guidance on breast feeding.

Sunshine, P. (1980)

Human breast milk-storage and safety considerations: protective effects.

EXC - although some mention of milk banking, refers mainly to the process of storing maternal milk.

Tagge, M., Lee, N., and Sakamoto, P. (2008)

Breast milk for all in need... "Got milk -- but what do I do with it?" Dec. 17.

EXC - news article

Tagge, M. E. (1995)

Donor human milk: a gift of life and health.

EXC - not available.

Taneja, N. and others. (2003)

Nosocomial outbreak of diarrhoea by enterotoxigenic *Escherichia coli* among preterm neonates in a tertiary care hospital in India: pitfalls in healthcare.

EXC - infection not related to process or provision of donor milk.

Terry, J. (2004)

Teaching mothers to express and store breast milk.

EXC - guidance for maternal expression and storage/use of milk. Not specific to donor milk banking.

Thorley, V. (2008)

Sharing breastmilk: wet nursing, cross feeding, and milk donations.

EXC - historical review.

Tully, M. R. (1990)

Banked human milk in the treatment of IgA deficiency and allergy symptoms.

EXC - indications for donor milk.

Tully, M. R. (1991)

Human milk banking in Sweden and Denmark.

EXC - more recent service descriptions included. See Arnold 1999.

Tully, M. R. (1999)

Is pasteurized mother's own or donor milk an answer to the HIV crisis?

EXC - duplicate. See Tully 1999 Currents...

Tully, M. R. (1999)

Donating human milk as part of the grieving process.

EXC - duplicate. See Tully 1999 Currents...

Tully, M. R. (1999)

Currents in human milk banking: is pasteurized mother's own or donor milk an answer to the HIV crisis?

EXC - focus on the use of donor milk for mothers with HIV or babies with HIV. Some mention of donor milk processes, but very general with no details.

Tully, M. R. (2000)

Currents in human milk banking: recommendations for handling of mother's own milk.

EXC - duplicate. See Tully 2000 Currents...

Tully, M. R. (2000)

Recommendations for handling of mother's own milk.

EXC - general paper on process for maternal milk.

Tully, M. R. (2000)

A year of remarkable growth for donor milk banking in North America.

EXC - duplicate. See Tully 2000 Currents...

Tully, M. R. (2000)

Cost of establishing and operating a donor human milk bank.

EXC - duplicate. See Tully 2000 Currents...

Tully, M. R. (2001)

Excelencia em bancos de leite humano: uma visao do futuro--the First International Congress on Human Milk Banking.

EXC - duplicate. See Tully 2001 Currents...

Tully, M. R. (2002)

Recipient prioritization and use of human milk in the hospital setting.

EXC - duplicate. See Tully 2002 Currents...

Tully, M. R., Lockhart-Borman, L., and Updegrove, K. (2004)

Stories of success: the use of donor milk is increasing in North America.

EXC - duplicate. See Tully 2004 Currents...

Tully, M. R., Lockhart-Borman, L., and Updegrove, K. (2004)

Currents in human milk banking: stories of success: the use of donor milk is increasing in North America.

EXC - article reporting three cases of recipient babies. Not process of donor milk banking.

Tully, M. R. (2008)

Milk bank online resource... "Got milk -- but what do I do with it?" Dec. 17.

EXC - news article

Tully, M. R. (2008)

More on milk donation... "Got milk -- but what do I do with it?" Oct. 18, 2007.

EXC - news article

United Nations. (1989)

Convention on the rights of the child.

EXC - legal rights for highest standards of health care.

Updegrove, K. (2005)

Human milk banking in the United States.

EXC - see more recent service description, Wilson-Clay 2006.

van Zoeren-Grobbe, D. and others. (1993)

Lipid peroxidation in human milk and infant formula: effect of storage, tube feeding and exposure to phototherapy.

EXC - related to the handling of donor milk prior to feeding, not donor milk banking specific.

Voyer, M., Nore, R., and Magny, J. F. (2000)

Human milk banks organization in France: legal proceedings and their consequences on milk bank activities.

EXC - magazine article.

Wallingford, J. (1989)

Effects of pasteurization on anti-infective agents and other proponents of human milk. Presentation at the HMBANA Annual Conference.

EXC - no published reference found. See also Orloff 1993.

Wallis, P. (2005)

Baby milk storage advice is relevant.

EXC - letter with no primary data or recommendations. Not donor specific.

Weaver, G. (1999)

The milky way: the remarkable history of the Queen Charlotte's and Chelsea Hospital Milk Bank.

EXC - duplicate. See Weaver 1999 Good idea!...

Weaver, G. (1999)

Every drop counts: news from the United Kingdom Association for Milk Banking.

EXC - duplicate. See Weaver 1999 Currents...

Weaver, G. (1999)

Currents in human milk banking: every drop counts: news from the United Kingdom Association for milk banking.

EXC - report of UKAMB meeting.

Weaver, G. (1999)

Good idea! The milky way: the remarkable history of the Queen Charlotte's and Chelsea Hospital milk bank.

EXC - history of a milk bank. Not service description.

Weaver, G. (2007)

UKAMB: celebrating ten years of 'making every drop count'.

EXC - magazine article

Wharton, B. A. (1987)

Nutrition and feeding of the preterm infant.

EXC - reference text. Assumed out-of-date.

Wiggins, P. K. and Arnold, L. D. (1998)

Clinical case history: donor milk use for severe gastroesophageal reflux in an adult.

EXC - indications for donor milk in adults.

Wight, N. E. (2005)

Donor milk: down but not out.

EXC - discussion of Schanler 2005 paper on indications/use of donor milk.

Wilks, S. and Meier, P. (1988)

Helping mothers express milk suitable for preterm and high-risk infant feeding.

EXC - refers to maternal milk, and expressing at hospital. May have some relevance if no other data specific to donor milk banking available.

Williams, A. F. and others. (1985)

Human milk banking.

EXC - see Baum 1982. Although a more recent description of the John Radcliffe service, it is less descriptive and adds nothing to the older article.

Williams, A. F. (1993)

Human milk and the preterm baby.

EXC - related to the use of milk, and fortification linked to indications. Not relevant to the process of donor milk banking.

Williams, L. S. (1992)

Even milk banks for preemies have been affected by AIDS.

EXC - not available.

Williamson, S. and others. (1978)

Organisation of bank of raw and pasteurised human milk for neonatal intensive care.

EXC - more recent service description. See Tomalin 1983.

Worden, M. (2007)

Food for thought?

EXC - editorial on the need for donor milk. Not process or details of service operation.

Wright, N. (2001)

Donor human milk for preterm infants.

EXC - duplicate. See Wight 2001.

References cited – selected citation mapping

As part of the final checking, we wished to see which references were cited most commonly in the included studies. We counted how many times and by whom these had been cited. This was to give an indication of how much weight had been placed on any single primary study. Due to the number of studies, we selected studies known to be cited multiple times.

AUTHOR	TOTAL NO OF PAPERS CITING AUTHOR	CITED BY and in how many evidence records	COMMENTS
BJORKSTEN (1980)	25	OGUNDELE (2000)-14; TULLY (2001)-2; ASQUITH (1987)-1; AHLFORS (1985)-1; DEMPSTER (1982)-1; HOEY (1980)-2; KINSEY (1984)-2; OGUNDELE (2000)-1; OXTOBY (1988)-1	
LEIBHABER (ANY)	25	DAVIDSON (1979)-1; ROY (1979)-1; KINSEY (1984)-1; AMERICAN ACADEMY OF PEDIATRICS (1980)-1; CASH (1981)-2; BROMBERGER (1982)-1; DEMPSTER (1982)-1; TULLY (2001)-1; CANADIAN PAEDIATRIC SOCIETY (1985); KINSEY (1984)-2; OGUNDELE (2000)-6; AHLFORS (1985)-1; DEMPSTER (1982)-1; TULLY (2001)-2; BJORSTEN (1980)-2; BROMBERGER (1982)-1	
FORD (ANY)	20	KINSEY (1984)-2; OGUNDELE (2000)-1; RYDER (1977)-1; ASQUITH (1987)-1; MCENERY 1978)-2; BROMBERGER (1982)-2; LAWRENCE (1999)-1; ROY (1979)-1; TULLY (2001)-4; WRIGHT (2001)-1; AMERICAN ACADEMY OF PEDIATRICS (1980)-1; BJORSTEN (1980)-2; CASH (1981)-1	
GIBBS (1977)	7	WILLIAMS (1981)-1; BAUM (1982)-1; ASQUITH (1987)-1; BAUM (1980)-1; BJORSTEN (1980)-2; DEMPSTER (1982)-1	
HERNANDEZ (ANY)	13	BROMBERGER (1982)-3; KINSEY (1984)-1; OGUNDELE (2000)-5; CASH (1981)-2; ASQUITH (1987)-1; BJORSTEN (1980)-1	
LAWRENCE (ANY)	8	CANADIAN PEDIATRIC SOCIETY (1985)-1; LAWRENCE (1999)-2 ; WRIGHT (2001)-2; MICHIE (2001)-1; TULLY (2001)-1; KINSEY (1984)-1	WRIGHT (2001) CITES LAWRENCE (1999) TWICE FOR ONE QUOTE. LAWRENCE (1999) CITES HIMSELF

AUTHOR	TOTAL NO OF PAPERS CITING AUTHOR	CITED BY and in how many evidence records	COMMENTS
LUCAS (ANY)	16	SIMMER (2000)-1; TOMALIN (1983)-1; BROMBERGER (1982)-2; WILLIAMS (1981)-1; ASQUITH (1987)-2; LUCAS (1979)-1; SMITH (1984)-1; DAVIES (1982)-1; CANADIAN PAEDIATRIC SOCIETY (1985)-1; MCENERY (1978)-1; CHOTO (1990)-1; NARAYANAN (1989)-1; BJORSTEN (1980)-1; WILLIAMS (2007)-1	LUCAS (1979) CITES HIMSELF
OGUNDELE (1999)	3	OGUNDELE (2000)-3	
RYDER (ANY)	6	TYSON (1982)-1; ROY (1979)-1; BROMBERGER (1982)-1; AMERICAN ACADEMY OF PEDIATRICS (1980)-1; CANADIAN PAEDIATRIC SOCIETY (1985)-1; MENON (2007)-1	
STAGNO (ANY)	6	BROMBERGER (1982)-2; BRAUNE (1982)-1; STAGNO (2002)-1; CANADIAN PAEDIATRIC SOCIETY (1985)-1; ASQUITH (1987)-1	
TULLY (ANY)	7	WOO (2007)-3; MODI (2006)-1; HOLLAND (2006)-1; FERNANDEZ (1993)-1; LORDING (2006)-1	
WARDELL (ANY)	5	OGUNDELE (2000)-2; O'CONNOR (1985)-1; LAWRENCE (1999)-1; NARYANAN (1989)-1	
WIGHT (2001)	2	WOO (2007)-1; LORDING (2006)-1	
WILLIAMSON (1978)	19	MCENERY (1978)-2; IKONEN (1982)-1; KINSEY (1984)-3; OGUNDELE (2000)-2; WILLIAMS (1981)-1; ASQUITH (1987)-1; CARROL (1978)-1; BALMER (1992)-1; DEMPSTER (1982)-2; BROMBERGER (1982)-1; LAWRENCE (1999)-1; ROY (1979)-1; AMERICAN ACADEMY OF PEDIATRICS (1980)-1; CASH (1981)-1	BALMER (1992) CITES WILLIAMSON (1978) TWICE FOR ONE QUOTE.
YAMATO (1986)	4	VAN DE PERRE (1992)-2; OXTOBY (1988)-1; TULLY (2001)-1	

Appendix 3 Methods of guideline development

See 'The guidelines manual' (2009) at www.nice.org.uk/GuidelinesManual for more information on how NICE clinical guidelines are developed.

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Background

Extrapolation from other evidence

From the initial scoping work, it was clear that there were many areas where there is limited or no high-quality evidence. One solution was to extrapolate from evidence in other areas. In this case, there was a wealth of evidence related to breastfeeding that could inform the development of recommendations on donor milk. For example, on the question of transmission of HIV through milk, we searched for evidence on transmission via donor milk, and as no evidence was identified, we extrapolated from current UK guidance on breastfeeding for HIV-positive mothers.

We also referred to other relevant NICE or DH guidance, and health and safety guidance as appropriate.

Formal consensus development

Most GDGs are able to reach agreement through informal consensus. However, when combined with the need for such detailed service guidance, the lack of high-quality evidence, and the large number of potential recommendations, we considered there was a role for the use of formal consensus development.

An example of the use of formal consensus development in a NICE clinical guideline can be seen in 'Feverish illness in children: assessment and initial management in children younger than 5 years' (NICE clinical guideline 47). A detailed description is given in appendix A of the full guideline (<http://www.nice.org.uk/nicemedia/pdf/CG47Guidance.pdf>).

Methods of formal consensus development

Usually, where good evidence exists, a GDG can reach consensus through informal methods; however, formal consensus methods are increasingly being used to develop clinical guidelines. (Murphy et al. 1998)

Formal consensus methods are those in which the structure, process and output are explicit from the outset. Three main approaches have been used in the health field

- the Delphi method
- the nominal group technique (NGT)
- the consensus development conference (Murphy et al. 1998).

A modified version of the Delphi method – the RAND method – is often used in guideline development. This involves several stages including the mailing of questionnaires, elicitation of private decisions, formal feedback of group choices, face-to-face contact, structured interaction, and an explicit aggregation method. (Murphy et al. 1998)

Cues and clinical scenarios

In the RAND process, cues are defined as ‘factors which influence clinical decision making’, and these are used as dimensions (or indications) that group members are asked to take into account when making their decisions. (Murphy et al. 1998; Raine et al. 2005) Cues are used to develop and refine clinical scenarios which are then rated by the group. This guideline does not lend itself easily to the development of cues (because interventions for a specific condition or indications for using an intervention are not within the remit). Even if it were possible to define cues for one topic area, these would not be relevant for other topics. Therefore, we considered that if the aim of the cues is to systematically describe all the possibilities that may occur, we could explore the ‘extremes’ and range of possible options through the ratings of recommendations which reflect these. The recommendations and their ratings can be seen below.

Choosing and preparing the scientific evidence

A review of identified evidence was provided to the GDG members at least one week before the meeting. The evidence reports were presented in tables, summarising the included studies, with quotes where appropriate. Evidence statements summarising the body of evidence were also provided to the GDG

before the meetings. The evidence reports can be seen in full in Appendices 5 and 6.

At the meetings, the GDG were asked to discuss the evidence and to agree the evidence statements, with any revisions as agreed. Evidence statements can be seen in the NICE guideline.

Rating the recommendations

The GDG were asked to rate the draft recommendations on the scale below. We did not ask the GDG to rate these via a postal questionnaire, but did this at the meeting, keeping individual responses anonymous.

1	2	3	4	5	6	7	8	9	Don't know
Strongly disagree		Somewhat disagree		Uncertain		Somewhat agree		Strongly agree	

The rating was repeated for a second round. It should be noted however, that although two or more rating rounds are likely to result in some convergence of individual judgments, it is unclear whether this increases the accuracy of the group decision. (Murphy et al. 1998)

Structuring the interaction

After the initial rating (round 1) results, both individual and summary results were revealed to the GDG and a discussion held about each recommendation that did not achieve consensus. This discussion was facilitated by the Chair as would other GDG discussions, adopting the ground rules specified in chapter 3 of 'The guidelines manual' (2009) (section 3.1, box 3.2).

Synthesising individual judgements

We adopted an explicit definition of 'agreement' based on the median of the ratings to determine the decision, with a measure of strength of consensus.

The more demanding this measure of strength of agreement, the more anodyne the results will be; either no statements will qualify or those that do will be of little interest (Murphy et al. 1998).

The GDG decision on a recommendation was:

- AGREE where the median >6
- DO NOT AGREE where the median <4
- NOT SURE where the median 4–6.

The measure of consensus stated that there was a group consensus if at least 75% of the responses lay in any one range, and there was group uncertainty if this range lay in the 4–6 response. So if 75% of GDG responses:

- lay in 1–3 then DO NOT AGREE
- lay in 7–9 then AGREE
- otherwise, NOT SURE.

This is the same method as applied in the NICE clinical guideline on feverish illness. However, we also calculated a measure of consensus as described in the RAND manual.(Brook 1994) This measure, 'D9R' considers all ratings and if at least one rating falls in the 1–3 (do not agree) range and at least one falls in the 7–9 range (agree), then there is considered to be a lack of consensus.

We planned to discuss any recommendation that did not achieve consensus based on either criteria. In practice, the GDG tended to discuss all recommendations regardless of consensus. If a recommendation did not achieve consensus (on either measure), members who had rated against the majority were asked if they wanted to explain why they had done so, and a full discussion of the recommendation then ensued, with revisions made to the wording as agreed. If the recommendation did achieve consensus, GDG members often still discussed it, and made minor revisions to the recommendation.

All recommendations, rating results and a summary of the discussions can be seen below.

Summary of process

- Informal consensus methods to agree evidence statements
 - Formal consensus methods to develop recommendations.
- GDG members:
- rated the recommendations privately
 - returned responses for analysis and pooling
 - received the pooled results, individual ratings and their position compared with others (at all points, individual results were kept confidential unless identified by the person themselves)
 - discussed all recommendations, with a focus on those for which group consensus was not achieved
 - re-rated recommendations
 - made minor revisions to recommendations, with a focus on those for which group consensus was not achieved.

References

Brook RH (1994) The RAND/UCLA appropriateness method. In: McCormick KA, Moore SR, Siegel RA, editors. *Clinical practice guidelines development: methodology perspectives*. Rockville, MD: US Department of Health and Human Services, p

Murphy MK, Black NA, Lamping DL et al. (1998) Consensus development methods, and their use in clinical guideline development. *Health Technol.Assess.* 2: i-88.

Raine R, Sanderson C, Black N (2005) Developing clinical guidelines: a challenge to current methods. *BMJ* 331: 631-3.

Recommendations and the ratings

Key to corrections:

A – agree

CON – consensus

These relate to corrected results when GDG responses were checked after the GDG meeting.

Round 1 – donor recruitment

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	GDG considerations	Recommendation for Round 2
R1a	Recruit donor women from any of the following groups: mothers early in lactation (usually 'drip milk')	3	5	3	0	0	Do not agree	No consensus	Consensus	There was some discussion about the timing of recruitment. This may include the early recruitment of women who have lost their babies. The mother's preference should be respected. The discussion included whether this was about selection or recruitment. It was agreed that the issue was about when women should be approached about donating milk, so the word 'donor' was revised to 'potential donor' throughout. The general agreement was to recommend a broad recruitment strategy, but with some specific groups named, such as bereaved mothers (see recommendations below). See R2 which covers all these groups.	...
R1b	mothers whose lactation is well-established	9	0	0	8	0	Agree	Consensus	Consensus	See R2 which covers all these groups.	...
R1c	mothers whose infant has died.	8.5	0	0	8	0	Agree	Consensus	Consensus	See R2 which covers all these groups.	...
R2	Recruit donor women from any mother who has surplus breast milk.	9	0	1	7	0	Agree	Consensus	Consensus	There has been a minor word change to reflect recruitment, rather than selection.	Recruit potential donor women from any mother who has surplus breast milk.
R3	Do not use surplus milk from mothers who have expressed milk for their own babies in the NICU.	1.5	8	0	0	0	Do not agree	Consensus	Consensus	It was agreed that the revised recommendation should be a positive one on the use of surplus milk.	Use surplus milk from mothers who have expressed milk for their own babies in the NICU.

R4	Consider using surplus milk from mothers who have expressed milk for their own babies in the NICU only if milk from other donors is not sufficient to meet demand.	2	7	1	0	0	Do not agree	Consensus	Consensus	See recommendation R3.	...
R5	Do not actively recruit donor women.	1	7	1	0	0	Do not agree	Consensus	Consensus	Revised recommendation to be positive recommendation on active recruitment.	Actively recruit donor women.
R6a	Recruit potential donors through a variety of channels. This can include - providing written information packs to be left in - doctors' offices	8.5	0	0	8	0	Agree	Consensus	Consensus	There was general discussion about the variety of methods that could be used to recruit potential donors. The approach of each milk bank will depend on local circumstances, including level of funding and need to recruit. General recommendations were therefore agreed, with a broad strategy overall. It was decided that minor revisions made to wording should be less specific about the details of how the information should be provided (e.g. the removal of packs in R6a-d).	Recruit potential donors through a variety of channels. This can include - providing written information to be left in - doctors' offices - hospitals (sometimes provided to mothers in the perinatal period) - volunteer or health-related organisations working in public health - infant, children and maternity shops
R6b	- providing written information packs to be left in - hospitals (sometimes provided to mothers in the perinatal period)	9	0	0	8	0	Agree	Consensus	Consensus	Merged with R6a	...
R6c	- providing written information packs to be left in - volunteer or health-related organisations working in public health	8.5	0	1	7	0	Agree	Consensus	Consensus	Merged with R6a	...

R6d	- providing written information packs to be left in - infant, children and maternity shops	8	0	3	4	1	Agree	No consensus	Consensus	Merged with R6a	...
R6e	- or through direct referrals or recommendation from - donor women	9	0	0	8	0	Agree	Consensus	Consensus		- or through direct referrals or recommendation from - donor women - staff at the NICUs - attending paediatricians when assessing the progress of the infant - health visitors (or other healthcare professionals providing post-partum care) - childbirth educators - organizers and attenders of pre- or post-natal classes - nursing mothers' groups - breast feeding support or related organisations
R6f	- or through direct referrals or recommendation from - staff at the NICUs	9	0	0	8	0	Agree	Consensus	Consensus	Merged with R6e.	...
R6g	- or through direct referrals or recommendation from - attending paediatricians when assessing the progress of the infant	9	0	0	7	1	Agree	Consensus	Consensus	Merged with R6e.	...

R6h	• or through direct referrals or recommendation from ○ health visitors (or other healthcare professionals providing post-partum care)	8.5	0	0	8	0	Agree	Consensus	Consensus	Merged with R6e.	...
R6i	• or through direct referrals or recommendation from ○ childbirth educators	8.5	0	0	8	0	Agree	Consensus	Consensus	Merged with R6e.	...
R6j	• or through direct referrals or recommendation from ○ organizers and attenders of pre- or post-natal classes	9	0	0	8	0	Agree	Consensus	Consensus	Merged with R6e.	...
R6k	• or through direct referrals or recommendation from ○ nursing mothers' groups	9	0	0	8	0	Agree	Consensus	Consensus	Merged with R6e.	...
R6l	• or through direct referrals or recommendation from ○ organisations, such as the La Leche League, or the National Childbirth Trust	9	0	0	8	0	Agree	Consensus	Consensus	The recommendation was made more general, with the removal of specific organisations (in line with NICE policy on recommendations). It was noted, however, that the 'Understanding NICE Guidance' would include some named organisations. Merged with R6d.	...

R6m	- or through mass media contact, such as - newspaper	8	1	0	6	1	Agree	Consensus	No consensus	The recommendation was revised to reflect that it refers to publicity for the donor milk bank and its work – it is not a paid advertisement. There was agreement that any mass publicity or advertising would need to be balanced with increased workload, and that it should be focused to try to limit interest. There was also a question about whether donors recruited in this way would be as informed as others. Overall, donor breast milk is a public health issue, and so it does need to be in the public domain. Anecdotal, such publicity may work better at local rather than national level, and there are good reports from experience in local areas. All strategies were deemed to be appropriate, depending on local circumstances. And as with any strategy, the confidentiality and wishes of any potential donor or donor would need to be respected.	- or through mass media contact, such as - newspaper articles - newletters - magazine articles - TV and radio - internet
R6n	- or through mass media contact, such as - newsletters	9	0	1	6	1	Agree	Consensus	Consensus	Merged with R6m.	...
R6o	- or through mass media contact, such as - magazine articles	8	0	1	6	1	Agree	Consensus	Consensus	Merged with R6m.	...

R6p	- or through mass media contact, such as - TV	8	1	1	6	0	Agree	Consensus	No consensus	Merged with R6q Again this refers to publicity for the donor milk bank and its work – it is not a paid advertisement.	...
R6q	- or through mass media contact, such as - radio	8	1	1	6	0	Agree	Consensus	No consensus	Merged with R6m. Although the evidence did not refer to the use of the internet (owing to the age of the publications), this was agreed to be a valuable area for recruitment and general publicity.	...
R7a	Provide other services to encourage donor women such as breastfeeding support	8	1	2	5	0	Agree	No consensus	No consensus	There was agreement that support and other services could be given as needed, but that this was not the key role of the milk bank. Also, donors should not be given access to services that would not otherwise be available to them, because this would breach all principles of donation. Recommendations will be made on the ongoing support needed by donor women, but not the provision of additional services to 'encourage' donors. It was decided to remove this recommendation because of the principle of donation.	...
R7b	other relevant services	6	1	3	3	1	Uncertain	No consensus	No consensus	See above.	...
R8	When recruiting donor women, aim to reach all women through a broad strategy with no targeting.	7	2	2	4	0	Agree	No consensus	No consensus	The wording was revised to make a general statement on the need for a broad strategy See also R1a.	When recruiting potential donor women, aim to reach all women, including mothers whose baby has died, through a broad strategy.

R9a	Target women who do not work in the health or social sectors	5	2	4	2	0	Uncertain	No consensus	No consensus	In the situation where there are limited resources, is there a principle that one needs to focus on those groups where recruitment is likely to more successful? Often, there is a perception about a 'type' of donor, but there are many exceptions. So a broad approach should be used, within resources. The provision of clear, accurate information then allows women to select themselves. There was agreement that all lactating women have a right to be considered as potential donors, and therefore any strategy should be broad and not target specific groups based on attitudes or beliefs. See R8.	...
R9b	Target women who have a positive attitude to breastfeeding	8	1	0	7	0	Agree	Consensus	No consensus	See above.	...
R9c	Target women who express the 'need to help others'	7.5	1	0	7	0	Agree	Consensus	No consensus	See above.	...
R9d	Target women who have support and time to donate milk.	8	1	1	6	0	Agree	Consensus	No consensus	See above.	...
R10a	Communicate the need for donor milk banking, and the process in clear, non-technical language, using either written or verbal communication.	9	0	0	8	0	Agree	Consensus	Consensus	The GDG agreed some revised wording.	Communicate the need for donor milk banking, and the process in clear, non-technical language, using either written and/or verbal communication.
R10b	using written information alone.	3.5	4	1	3	0	Uncertain	No consensus	No consensus	See above.	...

R10c	using verbal communication alone.	3.5	4	2	2	0	Uncertain	No consensus	No consensus	See above.	...
R11	Do not elicit the beliefs and attitudes of the potential donor in any discussion of donor milk banking.	2	4	2	1	1	Do not agree	No consensus	No consensus	Although there may be different cultural beliefs and attitudes to donor-milk banking, there was general agreement that, by using a broad strategy with clear information, any women, regardless of religion, socioeconomic class etc., would have access to information and could decide, with support from milk-bank staff if needed, whether she wished to be considered as a potential donor.	...

Round 1 – donor screening and selection

Due to the complexity, the level of technical detail, and the importance of this area, the GDG requested that each recommendation be discussed in full regardless of the consensus ratings.

	RECOMMENDATION	Median	1- 3	4- 6	7- 9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	Corrections made to ratings post meeting	GDG considerations	Recommendation for Round 2

SS1	Follow an agreed screening process when selecting donors. This should be based on a balanced consideration of relative risk for the infant and aim to minimise bacterial contamination. •	8	1	1	5	1	Agree	No consensus	No consensus	The GDG noted that health economic considerations are very relevant to the screening and selection process. There is also a need to consider the National Blood and Transplant recommendations and practice in this area. It was also noted that the aim of screening and selection is not simply to minimise contamination. Agreed wording of revised recommendation. Overall, the recommendations were revised to reflect • Which ones would make a donor be refused? • Which would result in delay? • Which would not be picked up in a history? • Which ones are screened for by questioning and then followed up by testing? • Which can be self-excluded for? It is also important to recognise that most infections can be ruled out at the initial blood test, but seroconversion may result in a false negative. Any information requested should be used when making the decision to accept a donor, and should not be collected without clear justification and use.	Follow an agreed screening process when selecting donors. This should be based on a balanced consideration of relative risk for the infant.

SS2	Do not screen potential donors.	1	8	0	0	0	Do not agree	Consensus	Consensus		See above.	...
SS3a	Collect information from prospective donors on: their general health and medical history (including acute or chronic infections, recent vaccinations, blood transfusions)	9	0	0	8	0	Agree	Consensus	Consensus		All of the following recommendations need to be clear about the difference between the risk of and the exposure to the various infectious diseases. Where appropriate, this was revised as agreed. There was agreement that there should be balance between asking specific questions with providing information to women on screening and selection (allowing them to self-screen) and then the taking of a comprehensive medical history by a trained person.	Collect information from prospective donors on: their general health and medical history (including acute or chronic infections, recent vaccinations, blood transfusions)
SS3b	the age, health, and nutritional status of their baby	9	0	0	7	1	Agree	Consensus	Consensus			the age, health, and nutritional status of their baby
SS3c	diet history and nutritional intake	7	0	2	6	0	Agree	No consensus	Consensus	**Corrected is A-CON-CON		diet history and nutritional intake
SS3d	any exposure to HIV	9	0	1	7	0	Agree	Consensus	Consensus		Revised to clarify risk of exposure.	the risk of exposure to HIV
SS3e	any exposure to toxoplasmosis	9	1	2	5	0	Agree	No consensus	No consensus		Most people are exposed to toxoplasmosis often without their knowledge, so to use this as a screening question is neither sensitive or specific. Although there is clear evidence that toxoplasmosis is a risk to the fetus during pregnancy, there is no evidence on the risk of toxoplasmosis for babies. Agreed to remove.	

SS3f	any exposure to tuberculosis	9	1	1	6	0	Agree	No consensus	No consensus	**Corrected is A-CON-NoCON	The GDG discussed the role of the milk bank in identifying communicable diseases such as TB. Specifically, most TB is acquired in childhood (in the UK) which then leads then to clinically silent disease. When pulmonary TB presents, the risk of transmission is primarily through coughing. If a donor has clinically silent TB then her milk may be infected, but pasteurisation would destroy this. Symptomatic TB should be identified through the existing public health systems. Agreed to remove.	...
SS3g	any exposure to syphilis	9	0	2	6	0	Agree	No consensus	Consensus	**Corrected is A-CON-CON	Revised to clarify risk of exposure.	the risk of exposure to syphilis
SS3h	any exposure to hepatitis	9	0	1	7	0	Agree	Consensus	Consensus		Revised to clarify risk of exposure.	the risk of exposure to hepatitis

SS3i	any exposure to rubella	6.5	1	3	4	0	Agree	No consensus	No consensus		Rubella is one of many viral infections, and it is not clear why screening and selection would specify rubella alone. If a mother was infected with rubella, this would not be a reason to refuse her as a donor, but would just delay any donations until she was clear of infection. The GDG agreed therefore that this would be covered in a general recommendation to screen for any exposure to infection and a detailed history – see revised recommendation and SS3a above on current infection.	any recent exposure to infectious diseases
SS3j	any exposure to herpes	8	0	3	5	0	Agree	No consensus	Consensus			any exposure to herpes
SS3k	any exposure to CMV	6	3	1	3	1	Uncertain	No consensus	No consensus		Most people will not know they have been exposed to CMV so not a useful screening question. Also proper treatment of any infected milk will destroy CMV. Agreed to remove..	...
SS3l	any exposure to CJD	8	0	3	5	0	Agree	No consensus	Consensus		The GDG agreed to refer to DH guidance on the risk of CJD and the advice that if the woman is identified as being at increased risk of CJD, she should not donate breast milk.	any public health risk of CJD (**TO ADD cross reference to DH guidance)
SS3m	medication use	9	0	0	8	0	Agree	Consensus	Consensus			medication use
SS3n	any medical treatment (other than medication use)	8.5	0	2	6	0	Agree	No consensus	Consensus	**Corrected is A-CON-CON		any medical treatment (other than medication use)

SS3o	any exposure to pollutants	5	2	5	1	0	Uncertain	No consensus	No consensus		The GDG were not clear which pollutants would be screened for. Also, this was not considered to be highly relevant to the UK, as there are clear standards of health and safety that are adhered to. Where there may be specific situations (for example, water contamination, or chemical fires) these will be covered by the environmental health/public health laboratory response and information from these and the Health Protection Agency as appropriate should be sought. However, it was noted that such instances are rare, but that milk banks should know of processes to follow in the event of such exposure.	**TO ADD rec on communication in the event of chemical exposure?
SS3p	any occupational exposure to chemicals	7	0	2	5	1	Agree	No consensus	Consensus		The GDG did not consider this to be highly relevant to the UK, as there are clear standards of health and safety that are adhered to and any woman who works with chemicals harmful during pregnancy should receive a full risk assessment through occupational health services. Agreed to remove.	...
SS3q	the presence of diarrhoea	6.5	1	3	4	0	Agree	No consensus	No consensus		This would be identified through a comprehensive history as recommended in SS3a above.	...

SS3r	symptoms of other recurrent infections	8.5	1	1	6	0	Agree	No consensus	No consensus	**Corrected is A-CON-NoCON	This would be identified through a comprehensive history as recommended in SS3a above.	...
SS3s	alcohol intake	9	0	0	8	0	Agree	Consensus	Consensus		...	alcohol intake
SS3t	smoking	9	0	0	8	0	Agree	Consensus	Consensus		...	smoking
SS3u	'recreational' drug use	9	0	0	8	0	Agree	Consensus	Consensus		...	'recreational' drug use
SS4	If donations of previously expressed breast milk are to be accepted, do not screen donors.	1	7	0	0	1	Do not agree	Consensus	Consensus		...	...
SS5	If donations of previously expressed breast milk are to be accepted, screen donors as usual; questions relating to the use of prescription medication, smoking and alcohol consumption etc. should be answered retrospectively.	9	1	0	7	0	Agree	Consensus	No consensus		...	If donations of previously expressed breast milk are to be accepted, screen donors as usual; questions relating to the use of prescription medication, smoking and alcohol consumption etc. should be answered retrospectively.
SS6a	Use the following tests or investigations for screening or selecting prospective milk donors: general physical examination	3	4	1	2	1	Do not agree	No consensus	No consensus		The GDG were not clear as to the purpose of a physical examination and did not consider it a useful addition to a comprehensive medical history and appropriate testing. Agreed to remove.	...
SS6b	chest radiograph, PPD, or tine test (for tuberculosis)	3	6	1	0	1	Do not agree	Consensus	Consensus		See SS3f on TB screening.	...
SS6c	HTLV-III and HIV antibody test (for HIV)	9	0	1	6	1	Agree	No consensus	Consensus	**Corrected is A-CON-CON	Revised to reflect out-dated use of HTLV. Also current tests.	HIV 1 & 2 antigen/antibody test

SS6d	HBsAg and anti-HBc blood test (for hepatitis)	9	1	2	4	1	Agree	No consensus	No consensus		Revised to reflect current testing processes for hepatitis. If adequate treatment processes are followed, the pasteurisation of milk will destroy any infection, so only need to test for surface antigen. However, the GDG agreed to test as for other human products, such as blood, to minimise any risk from hepatitis. Although rates of hepatitis C are low in the UK, higher rates are seen in other countries and/or ethnic groups. However, even if the donor has hepatitis C, she is unlikely to excrete this in her milk and therefore testing for this may not be cost effective because adequate treatment can destroy the infection. However, recent data suggests that treatment of milk may not be as effective as thought (see recommendations on treatment) and concerns over hepatitis transmission are often cited as reasons for not using donor milk.	HBsAg and anti-HBc blood test , anti hep c antibodies (for hepatitis)
SS6e	VDRL (for sexually transmitted diseases, specifically syphilis))	9	0	1	6	1	Agree	No consensus	Consensus	**Corrected is A-CON-CON	Revised to reflect current testing processes for sexually transmitted diseases.	a test for anti-treponemal antibodies (for sexually transmitted diseases, specifically syphilis)

SS7	Test for those conditions to be screened and results communicated according to local protocols.	6	1	3	3	1	Uncertain	No consensus	No consensus		There was general agreement that this guideline should make specific recommendations on how testing should be undertaken and results communicated, whilst recognising both national best practice for human donated products and local practice. See recommendations below on the process of testing.	...
SS8	All tests should be performed at the time of enrolling for donor milk banking.	7.5	0	3	5	0	Agree	No consensus	Consensus		The timing of testing also depends on the nature of the donation – for example, some donations are one-off donations and as such testing at the time of donation may not reflect the health state at the time of donation. Recommendation therefore on the need to test at 3 months, allowing time for the appropriate testing and treatment of the milk and any seroconversion of the donor.	All tests should be performed at the time of enrolling for donor milk banking, even where results from antenatal tests are available. Delay testing for 3months if a donor provides a one off donation.
SS9	Do not repeat tests routinely undertaken during antenatal and perinatal assessment unless the history indicates possible infection or exposure after the initial tests have been done.	1	5	0	2	1	Do not agree	No consensus	No consensus		See SS10.	...
SS10	Do not repeat any tests routinely undertaken during antenatal and perinatal assessment.	1	6	0	1	1	Do not agree	Consensus	No consensus		There was general agreement that results from antenatal tests should not be used and this was added to SS8 above.	...

SS11	Do not test for any other condition or infections, even if clinically suspicious.	3	5	2	0	1	Do not agree	No consensus	Consensus		The GDG agreed that the role of the milk bank is not to provide general healthcare to women, so should not be requesting any tests other than those recommended above specific to the donation of milk.	...
SS12a	Consider other tests as appropriate, based on some or all of the following: the use of effective treatment processes to eliminate the specific contamination	7	1	2	4	1	Agree	No consensus	No consensus		There was general agreement that this guideline should make specific recommendations on how testing should be undertaken and results communicated, whilst recognising both national best practice for human donated products and local practice. See recommendations above on the process of testing.	...
SS12b	local testing/screening protocols during the antenatal period	4	3	2	2	1	Uncertain	No consensus	No consensus		As above.	...
SS12c	regional or local prevalence; where appropriate, consider screening only in donors from high risk groups	2	6	1	1	0	Do not agree	Consensus	No consensus		As above.	...
SS12d	other national screening recommendations.	9	0	0	7	1	Agree	Consensus	Consensus		As above.	...
SS13	Testing is mandatory, and as such no explanation or consent from the donor is required.	2.5	7	1	0	0	Do not agree	Consensus	Consensus		See SS14.	...

SS14	Explain the reasons for testing to every mother when she first contacts the milk bank about donating milk (to minimise risks to the recipient baby) and seek informed consent before testing.	9	0	0	8	0	Agree	Consensus	Consensus		The mandatory nature of testing is important, and has been added to this recommendation as agreed in the GDG.	Testing is mandatory. Explain the reasons for testing to every mother when she first contacts the milk bank about donating milk (to minimise risks to the recipient baby) and seek informed consent before testing.
SS15	Communicate the results of all tests.	9	0	1	7	0	Agree	Consensus	Consensus		Merged with the mode of communication below – see SS17a.	...
SS16	Communicate the results of any positive tests.	9	1	0	7	0	Agree	Consensus	No consensus		See SS16.	
SS17a	Communicate the results of tests in person at a follow-up appointment. Where appropriate, offer counselling and/or information on local support groups.	6	2	2	4	0	Uncertain	No consensus	No consensus		There was general agreement that the communication of all test results needs to be both woman focused and in accordance with local protocols. Recommendations therefore reflect the need to balance the preference of the woman and adherence to local testing protocols.	Communicate all results of tests verbally, either in person at a follow-up appointment or via a telephone call, or in writing depending on the preference of the woman and in accordance with local protocols. Where appropriate and in accordance with local protocols, offer counselling and/or information on local support groups.
SS17b	Communicate the results of tests verbally, through a telephone call. Where appropriate, offer counselling and/or information on local support groups.	4	4	2	2	0	Uncertain	No consensus	No consensus		See SS17a.	...

SS17c	Communicate the results of tests verbally, either in person at a follow-up appointment or via a telephone call depending on the preference of the woman. Where appropriate, offer counselling and/or information on local support groups.	6	2	2	4	0	Uncertain	No consensus	No consensus		See SS17a.	...
SS17d	Communicate the results of any tests in writing. Where appropriate, offer counselling and/or information on local support groups.	5	2	3	3	0	Uncertain	No consensus	No consensus		See SS17a.	...
SS18	Inform women who are positive for HIV infection that they are able to donate breast milk.	1	7	1	0	0	Do not agree	Consensus	Consensus		Revised for clarification.	Inform women who are positive for HIV infection that they are unable to donate breast milk.
SS19	Inform women who have received live rubella vaccination that they should never donate breast milk.	1	7	1	0	0	Do not agree	Consensus	Consensus		The GDG agreed to cross refer to the DH guidance on vaccination, and have revised the recommendation appropriately. Current guidance is that breastfeeding is not a contraindication to routine immunisation and that where additional precautions are required – “refer to the relevant chapter for further information”:	Refer to guidance from the DH on the safety of recent vaccination in breastfeeding for women who are potential donors (**TO ADD cross reference to Green Book)
SS20	Inform women who have received live rubella vaccination not to donate breast milk near the time of their vaccination.	7	1	1	5	1	Agree	No consensus	No consensus		See also SS20.	Inform women who have received live vaccinations not to donate breast milk in the month prior of their vaccination.

SS21a	All tests should be undertaken, • if possible, at the woman's home.	3	5	2	1	0	Do not agree	No consensus	No consensus		The GDG agreed that it was not appropriate to make recommendations on where testing should be undertaken.	...
SS21b	• where possible, in the setting preferred by the potential donor.	7.5	1	0	7	0	Agree	Consensus	No consensus		See above.	...
SS22	Do not repeat any tests whilst the woman continues to donate milk.	1.5	6	2	0	0	Do not agree	Consensus	Consensus		The GDG acknowledged that repeated testing would increase safety. Some services retest at 3 months and then release the frozen 3 months-old milk. A balance between testing (for example, many donors may need to be tested to identify one case of infection) and treatment (even if the donor and her milk are infected, proper treatment will destroy the infection in the milk) needs to be achieved. Logistically the storage of milk for 3 months would increase costs but also risk of mistaken administering of milk. **TO ADD HE when considered Revised to ensure that no seroconversion has occurred.	Do not repeat any tests whilst the woman continues to donate milk. When donation stops repeat tests 3 months after stopping.
SS23	Repeat tests if women continue to donate for more than 3 months from the date of the initial blood test.	5	1	5	2	0	Uncertain	No consensus	No consensus		See SS22.	...
SS24	Repeat tests if women continue to donate for more than 6 months from the date of the initial blood test.	5	1	5	2	0	Uncertain	No consensus	No consensus		See SS22.	...

SS25a	Collect information for screening using the most up-to-date source. This may include - from healthcare records including - routine health data from different healthcare professionals, such as primary care providers and paediatricians	5	2	5	1	0	Uncertain	No consensus	No consensus		The GDG considered that any recommendation on healthcare records was not appropriate.	...
SS25b	- from healthcare records including - information from visits to healthcare professionals, such as gynaecologists and paediatricians, arranged by the milk bank if appropriate	5	2	5	1	0	Uncertain	No consensus	No consensus		See above.	...
SS25c	- from the donor - by questionnaire	8	1	1	6	0	Agree	No consensus	No consensus	**Corrected is A-CON-No CON	Revised as agreed.	Collect information for screening using the most up-to-date source. This may include - from the donor - by interview
SS25d	- from the donor - by interview	8.5	0	1	7	0	Agree	Consensus	Consensus		See above.	...
SS26a	If possible, the questionnaire and/or interview should be conducted in the potential donor's home.	6	2	3	3	0	Uncertain	No consensus	No consensus		Again, the preference of the woman should be considered if possible.	If possible, the questionnaire and/or interview should be conducted at a place suitable to both parties.
SS26b	at the milk bank.	6	1	4	3	0	Uncertain	No consensus	No consensus		See above.	...

SS27a	All questionnaires and/or interviews should be conducted in the potential donor's home.	3	5	2	1	0	Do not agree	No consensus	No consensus	**Mistyped one response - no effect on result. Corrected in spreadsheet	See SS26a.	...
SS27b	at the milk bank.	3	5	2	1	0	Do not agree	No consensus	No consensus	**Mistyped one response - no effect on result. Corrected in spreadsheet	See SS26a.	...
SS28	No one approach will cover all information necessary and a variety of approaches is recommended. Where possible, information should be confirmed by other sources or additional history taking and/or testing.	6.5	3	1	4	0	Agree	No consensus	No consensus		The GDG did not consider this recommendation to be specific or helpful, so it was removed.	...
SS29	If information is not available, just leave blank.	2.5	6	2	0	0	Do not agree	Consensus	Consensus		The GDG did not consider this recommendation to be specific or helpful, so it was removed.	...

Round 1 – donor training and support

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	GDG considerations	Recommendation for Round 2
TS1a	Train donors in the proper techniques for milk collection and expression, including the use of pumps and containers and their cleaning	9	0	0	9	0	Agree	Consensus	Consensus	Agreed no changes needed.	Train donors in the proper techniques for milk collection and expression, including the use of pumps and containers and their cleaning
TS1b	milk storage, including the cooling and freezing of milk	9	0	0	9	0	Agree	Consensus	Consensus	Agreed no changes needed	milk storage, including the cooling and freezing of milk
TS1c	personal hygiene, including cleaning of the hands and breasts	9	0	0	9	0	Agree	Consensus	Consensus	Agreed no changes needed	personal hygiene, including cleaning of the hands and breasts
TS1d	administration of milk donations, such as the labeling of stored samples.	9	0	0	9	0	Agree	Consensus	Consensus	Agreed no changes needed	administration of milk donations, such as the labeling of stored samples.
TS2a	Provide information to donor women on intake of diet	8	1	1	6	1	Agree	No consensus	No consensus	The wording was revised to clarify that this is about information on continued exclusions – for example, when a woman may be following a strict vegan diet without supplements. This is more about general advice on dietary intake for breastfeeding, not a dietary recommendation.	Provide information to donor women on diet
TS2b	alcohol	9	0	0	9	0	Agree	Consensus	Consensus	Revised wording for clarity.	alcohol consumption
TS2c	caffeine	9	0	0	9	0	Agree	Consensus	Consensus	Revised wording for clarity.	caffeine consumption

TS3a	Provide training through written information alone	3	8	1	0	0	Do not agree	Consensus	Consensus	Any strict recommendation on either verbal or written information may give rise to practical problems, in terms of provision of information. The wording was revised to allow flexibility and to meet the needs of the donor.	Provide training verbally, which may be face-to-face or over the telephone, with appropriate supplementary information to be given to the donor.
TS3b	face-to-face, with supplementary written information	8	0	0	9	0	Agree	Consensus	Consensus	See TS3a.	...
TS3c	face-to-face alone	3	5	4	0	0	Do not agree	No consensus	Consensus	See TS3a.	...
TS4a	Provide training on discharge from hospital	5	3	3	3	0	Uncertain	No consensus	No consensus	By specifying the timing of training, this would result in it being suitable for some donors, but not for all. Also the ideal timing and setting would be at a time/place of mother's preference, but this may not always be possible. The GDG revised the wording to reflect these concerns.	Provide training at a time and place suitable for both parties.
TS4b	at a time and place suitable for the donor	7	0	2	7	0	Agree	Consensus	Consensus	See TS4a.	...
TS4c	after milk samples are accepted	3	8	1	0	0	Do not agree	Consensus	Consensus	See TS4a.	...
TS5	Provide ongoing support to all donor women,	8	0	1	8	0	Agree	Consensus	Consensus	There was general agreement that support should be provided to all women with the option to opt-out when no longer needed.	Provide ongoing support to all donor women until no longer required.
TS6	Only provide ongoing support to donor women who have specifically requested it.	3	5	3	1	0	Do not agree	No consensus	No consensus	See TS5.	...
TS7a	Support should include continued support for the collection and milk and the maintenance of lactation	8	0	1	8	0	Agree	Consensus	Consensus	There was much discussion about the exact definition of support because little, if any, detail was reported in the included studies. In practice, support can range from a simple thank-you through to full support for the woman in whichever way she needs. The wording was revised to reflect this.	Support may include - continued support for the collection of milk and the maintenance of lactation - emotional support.

TS7b	psychological support.	7	2	2	5	0	Agree	No consensus	No consensus	As above, it was not clear exactly what was meant by psychological support. The role of the milk bank is primarily about support for continued donation, not breastfeeding alone, although obviously there may be a significant overlap. Also, there may be very specific support needs – for example, if a woman who has lost her baby wishes to continue to express, support should be available to support her decision. The term 'emotional support' may be better as psychological support may not always be needed. Merged with TS7a above.	...
TS8a	Provide contact and feedback only to those donors who request it	3	6	3	0	0	Do not agree	No consensus	Consensus	As with support, there was much discussion on the definition of contact and feedback. Although the evidence reported one milk bank that did feed back quality and quantity to each donor, the GDG did not consider that this was enough to recommend it in this guideline. There was also the possibility of such feedback having negative impact, both on the donor (e.g. if she feels under pressure) and on the milk bank (in terms of time). The GDG considered that contact and feedback was about thanking the donor, feeding back any problems with the milk, and periodic enquiry about progress – but that any contact and feedback should be tailored to the individual donor's needs.	Provide ongoing, individualised contact and feedback to all donors
TS8b	to all donors	8	0	1	8	0	Agree	Consensus	Consensus	See TS8a.	...
TS8c	after each collection	5	4	4	1	0	Uncertain	No consensus	No consensus	See TS8a.	...

TS9a	Contact and feedback should include amount of milk collected	5	1	5	2	1	Uncertain	No consensus	No consensus	See TS8a. Such feedback may discourage small donations. Current practice differs: - Some milk banks provide a certificate for the period of donation. - Some donors may enquire on an individual basis. - Some donors may not be interested in the amount donated. - Some donors track their own amounts. The GDG agreed that the most important point was that a milk bank knows the amount and quality of the milk donated, not necessarily the mother unless requested.	...
TS9b	quality of milk collected	6	1	4	4	0	Uncertain	No consensus	No consensus	See TS8a. Where there are implications for a mother's own baby, the GDG agreed that the issue of quality would need to be fed back to the mother; however, it would need to be based on clear guidelines and evidence. Other than in such specific cases, it may not be helpful to feed back routinely – it would depend on what is meant by quality.	...

TS10a	When collecting milk samples from the donor's home, make a formal assessment of any changes in the home environment that may require additional support or intervention from the milk bank staff.	4	4	3	2	0	Uncertain	No consensus	No consensus	Although one milk bank reported assessment of this kind as part of their practice, the GDG considered it to be unnecessary if clear, comprehensive screening processes were in place, with good training and support. Change in the home environment would not be easy to assess, not all women would be visited at home, and there is no evidence-based link to the quality of milk. It could also be viewed as inappropriate – an invasion of privacy. Any changes in lifestyle will be covered in the screening and selection/stopping recommendations. The GDG agreed not to make any recommendations in this area.	...
TS10b	enquire, informally, about any changes in the home environment that may require additional support or intervention from the milk bank staff.	7	2	2	5	0	Agree	No consensus	No consensus	See TS10a.	...

TS11a	Supervise all domiciliary milk collection	3	6	2	1	0	Do not agree	No consensus	No consensus	As above, the definition of supervise was not clear and may differ in the included studies (although few details were reported). The GDG considered that, if 'supervise' meant watching women collect the milk, then they would not want to recommend supervision. However, if 'supervision' was about provision of additional advice or training, then there was general support. It was noted that it would not be appropriate to encourage women to continue to donate milk if it were continually being rejected on bacteriological criteria. The GDG therefore recommended additional information and support if bacterial contamination were significant and repeated, noting that this information and support could range from a simple intervention (e.g. reminding them of processes to be followed) through to a more involved intervention (e.g. repeated training).	Offer additional information and support on domiciliary milk collection if bacterial contamination is significant and repeated.
TS11b	domiciliary milk collections where possible	3	6	1	2	0	Do not agree	No consensus	No consensus	See TS11a.	...
TS11c	domiciliary milk collections if bacterial contamination is significant and repeated.	8	0	3	6	0	Agree	No consensus	Consensus	See TS11a.	...

Round 1 – donor stopping

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	GDG considerations	Recommendation for Round 2
S1a	Do not continue to accept milk from donors who supply contaminated milk	4	4	4	0	0	Uncertain	No consensus	Consensus	The GDG interpreted 'contaminated' to mean milk that does not meet the bacteriological standards. This draft recommendation was based on one study where donors were 'dismissed' if they were not able to provide 'clean' milk. The GDG considered those circumstances in which a milk bank would wish to ask a donor not to continue to collect milk; any recommendation would therefore need to cover most, if not all, circumstances. Also, it is not clear whether a donor should be asked to stop donating or to suspend donation for a defined time. In practice, few donors return once they have suspended donation. It was also recognised that some mothers will always supply milk that does not meet the bacteriological standards, while others will need some support or simple intervention to prevent this happening. However, there is also the issue of whether and how to communicate the underlying concern to the mother. Based on limited evidence, it is not clear that bacteriological contamination is a safety issue for babies, but the balance of risks and benefits may differ for donor milk in recipient babies; therefore, the bacteriological standards applied to donated milk may be stricter than those that would be applied to milk for a mother's own baby.	Consider no longer accepting milk from donors who supply milk that does not meet the microbiological criteria despite support
S1b	milk with a low protein content	4.5	2	2	2	2	Uncertain	No consensus	No consensus	Routine measurement of protein content is not done, so the recommendation was removed.	...

S1c	small amounts of milk (less than 2 ounces daily after a week's trial).	3	5	2	1	0	Do not agree	No consensus	No consensus	Although the draft recommendation specifies a small amount, the GDG considered that, in practice, it may not be possible to define this; and if a milk bank needs milk then small amounts may be accepted. Also a week's trial is not generally sufficient. The issue of resources was important, and the GDG considered that, if milk banks are to be financially accountable, then it may not be cost effective to collect very small amounts as a matter of routine. However, this may average across a milk bank if other donors provide larger amounts. In principle, the GDG agreed that it is legitimate and appropriate to consider not processing small amounts, particularly if they are one-off donations or from a long distance away. The definition of 'small' will therefore depend on local circumstances.	small amounts of milk

S2a	Advise women that if they become ill, they can continue to donate milk.	3	6	2	0	0	Do not agree	Consensus	Consensus	The GDG revised the wording to define 'ill'. The GDG also discussed whether it was relevant if a baby became ill, and it was felt to be relevant only where there was clear evidence that the baby's illness came from the mother. The GDG agreed therefore that the mother is the focus of this recommendation. The concern over the illness will also depend on the treatment processes used for the milk, because many infections are destroyed with adequate processing. If a mother has chicken-pox, the virus will be in the milk but after pasteurisation the risk will be minimised for both the recipient and the staff handling the milk. Milk-bank staff may also need to consider the issue of illness retrospectively, because women may donate milk that has been stored. Other considerations may be the physical effects of any illness (for example, not being able to get out of bed) and the implications for milk collection.	Advise women that if they develop a temperature or have contact with other exanthema, to contact the milk bank to discuss temporary suspension of milk donation.
S2b	if their baby becomes ill, they can continue to donate milk.	3	5	2	1	0	Do not agree	No consensus	No consensus	See S2a.	...
S3	Advise donor women who are taking short courses of medication for infection that they should stop collecting milk for donation.	7	1	2	5	0	Agree	No consensus	No consensus	The GDG agreed that it was the responsibility of the donor to inform the milk bank if she were taking any medication, and it was then the responsibility of the milk bank to advise on any action to be taken, including temporary suspension of donation.	Advise donor women who begin taking medication that they should inform the milk bank to discuss temporary suspension of milk donation.
S4	Advise donor women who are taking short courses of antimicrobial medication that they should stop collecting milk for donation.	7	0	3	5	0	Agree	No consensus	Consensus	See S3.	...

S5	Advise donor women who are taking short courses of medication that they should wait for 5 half-lives of the drug after the last ingested dose; in most cases, a wash-out period of 1 day will be sufficient.	5.5	2	5	1	0	Uncertain	No consensus	No consensus	See S3.	...
S6a	Advise donor women that they should temporarily discontinue to collect milk for donation if they have herpetic lesions	8	0	2	4	2	Agree	No consensus	Consensus	The GDG discussed whether herpes infection should be considered a risk. Recurrent cold sores are localised, and the virus may not appear in milk; the risk may come from contamination after expression, not viral material in the milk. As discussed before, the risk of any infection in the milk depends on the treatment processes used. The recommendation was reworded to include breast infections or lesions. In these circumstances, there are many risks including risk to the mother with damage to the skin from the pump, or blood in the milk. The recommendation was also expanded to include any changes in the colour or consistency of the milk. As with the use of medication, the recommendation was reworded to emphasise that women should inform the milk bank, with the milk bank then advising on any action to be taken. Milk banks work in a climate of trust – but more monitoring and checking is appropriate. So any donor who becomes unable to meet the initial recruitment criteria should contact the milk bank for advice.	Advise donor women that they should inform the milk bank if - they have any breast lesions or infection (including mastitis) such as herpes to discuss temporary suspension of milk donation - they have any changes in the colour or consistency of the milk - they have had any vaccination - they no longer meet the initial recruitment criteria
S6b	they have had a recent rubella vaccination (a minimum of 3 weeks before they can start to donate again).	8	1	0	4	3	Agree	No consensus	No consensus	See S6a.	...

S7a	Advise donor women that they should discontinue to collect milk for donation if they have herpetic lesions	5	3	1	3	1	Uncertain	No consensus	No consensus	See S6a.	...
S7b	they have had a rubella vaccination in the past month.	3	4	1	1	2	Do not agree	No consensus	No consensus	See S6a.	...
S8a	Advise donors who are taking medication for a period of time that they should stop collecting milk for donation	5	2	3	3	0	Uncertain	No consensus	No consensus	See S3.	...
S8b	they may continue to express, and any milk that contains contraindicated medication should be labelled and will be used for research projects	4.5	3	4	1	0	Uncertain	No consensus	No consensus	See S3. Milk banks do not need to register as tissue banks but, if milk were being collected for research, then they would need to register. Research governance now would not allow the collection of milk in this way.	...

S9	NEW									The issue of when donors should be advised to stop expressing milk for donation was raised. Although there is general advice on how long breastfeeding should be continued, when to stop is still the decision of the mother. For milk donation, it may be appropriate to ask donors to stop when their own baby reaches a certain age. This age would depend on the target population of the milk bank – generally, the main recipient population is pre-term babies, so it may be appropriate to restrict donation according to the age of the baby. The recipient population will differ by milk bank. The reason for such a criterion is based on evidence that suggests that levels of zinc in breast milk decrease over time; 'more mature' milk may therefore not be suitable in nutritional composition for pre-term babies. Should donors who become pregnant be advised to stop donating? There is no evidence on this, and, based on the experience of the GDG, mothers will stop by choice. As in all milk donation, there is a need to respect the mother's decision if she wishes to continue to donate, but there may be implications for the mother because, by accepting the milk, there is an implicit support of that process..It was agreed, therefore, not to make a recommendation on this.	Local policies should be set up to define when donors should be advised to stop donating milk based on the age of their own baby, and this should be based on the recipient population.

Round 1 – milk expression

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	Corrections made post meeting	GDG considerations	Recommendation for Round 2

MExp1a	Advise donors to collect both expressed milk, and drip milk.	4	4	3	1	0	Uncertain	No consensus	No consensus	Generally, although drip milk (as part of a donation) would be accepted, there was concern expressed about advising a donor to collect drip milk exclusively and accepting drip milk exclusively because of the low energy content. There may be some rare occasions, where exclusive drip milk would be needed. If drip milk is mixed with expressed milk, although this may improve the energy content when compared to drip milk alone, there was concern that the expressed milk would then be 'diluted'. Anecdotally, women who are collecting drip milk are 'good' lactators, and produce large amounts of milk. A key issue was that of advising donors – so that drip and expressed milk could be collected but kept separately. Further advice is then needed on the mixing of drip and expressed milk – and this should be based on the recipient. The GDG considered that there was a balance to be reached between reinforcing the view that donor milk is 'not good' but without ruling out the 'rare' use of drip milk – as there are circumstances when drip milk would be used. Any storage and processing recommendations need also to apply to drip milk as well.	Advise donors to collect expressed milk; however for donors who do produce drip milk they should be advised to collect and keep it separate from expressed milk.

MExp1b	keep the drip milk and expressed milk separate.	6	2	3	3	0	Uncertain	No consensus	No consensus		See MExp1a above	...
MExp2	Advise donors to collect only expressed milk.	7	0	3	5	0	Agree	No consensus	Consensus		See MExp1a above	...
MExp3a	Advise donors to discard the first 5 ml of expressed milk.	4	3	2	2	1	Uncertain	No consensus	No consensus		There is evidence of higher levels of bacteria in first few mls of expressed milk, but it is not clear how much milk should be discarded nor levels of bacterial contamination that would be accepted (see also recommendations on testing). The GDG agreed therefore that, because of the adequate testing and treatment of donor milk, and discarding is not widespread, that no recommendation should be made. However, if donors are consistently provided milk with high levels of contamination that they should be supported as recommended previously.	...
MExp3b	discard the first 10 ml of expressed milk.	3	4	3	0	1	Do not agree	No consensus	Consensus		See MExp3a above	...
MExp3c	discard the first 15 ml of expressed milk.	3	5	2	0	1	Do not agree	No consensus	Consensus		...	...
MExp3d	discard the first 20 ml of expressed milk.	3	5	2	0	1	Do not agree	No consensus	Consensus		...	...
	Advise donors to express milk										...	

MExp4a	using hand expression alone.	2.5	7	0	1	0	Do not agree	Consensus	No consensus		The GDG considered that the evidence showed hand expression was preferable, but that milk expressed by pump was acceptable if the donor was unable to, or did not wish to hand express. Costs of providing pumps were discussed, but most mothers purchase or have access to pumps if required.	Actively encourage donors to hand express milk however pump expressed milk is acceptable.
MExp4b	using hand breast pumps alone.	3	6	0	1	1	Do not agree	No consensus	No consensus	**Corrected is CON-No CON	See MExp4a above	...
MExp4c	using electric breast pumps alone.	3	6	0	1	1	Do not agree	No consensus	No consensus	**Corrected is CON-No CON	See MExp4a above	...
MExp4d	preferably using hand expression, but using pumps if the donor prefers.	4.5	4	1	3	0	Uncertain	No consensus	No consensus		See MExp4a above	...
MExp4e	using any method of expression preferred by the donor	8	1	0	7	0	Agree	Consensus	No consensus		See MExp4a above	...
MExp5a	Provide advice and support on stopping expressing milk to all donors.	7	2	0	6	0	Agree	No consensus	No consensus	**Corrected is CON-No CON	The GDG agreed that this is part of the role of the donor milk bank service; any donor who requires support when stopping expressing milk should have access to advice and support as needed.	Provide advice and support on stopping expressing milk to donors as required.
MExp5b	donors until no longer required.	7	2	1	4	1	Agree	No consensus	No consensus		See MExp5a above	...
MExp5c	donors whose baby has died.	9	0	1	6	1	Agree	No consensus	Consensus	**Corrected is CON- CON	It was agreed that these donors need support, but it was not necessary to specify these in the recommendation.	...

Round 1 – milk handling at home

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	Corrections made post meeting	GDG considerations	Recommendation for Round 2
MHHome1	Advise donors that they should handle expressed milk for donation as they would milk for their own baby.	5	3	2	3	8	Uncertain	No consensus	No consensus		It was generally agreed that the handling of donor milk is not as for maternal milk and recommendations were revised as below.	...
MHHome2a	Advise donors that expressed milk for donation should be allowed to reach room temperature before freezing or refrigerating.	2	8	0	0	8	Do not agree	Consensus	Consensus		Expressed milk for donation should be frozen/refrigerated immediately.	Advise donors that expressed milk for donation should should be refrigerated or frozen immediately after collection
MHHome2b	not be left uncovered.	8.5	0	0	8	8	Agree	Consensus	Consensus		Open containers should no longer be used – see also the recommendations on containers to be used.	not be left uncovered.
MHHome3a	Advise donors that, before transport to the milk bank all milk expressed for donation should be frozen.	7.5	0	2	6	8	Agree	No consensus	Consensus	**Corrected to CON-CON	Some people do bring fresh milk so would not want to rule this out, but the majority of donor milk will be received at the milk bank in a frozen state.	Advise donors that, before transport to the milk bank all milk expressed for donation should be frozen.
MHHome3b	all milk expressed for donation should be refrigerated.	2	5	1	2	8	Do not agree	No consensus	No consensus		See MHHome3a above.	all milk expressed for donation should be refrigerated.

MHHome3c	all milk expressed for donation should be frozen, unless milk is being transported to the milk bank on a daily basis. In this case, milk can be refrigerated.	8	0	2	6	8	Agree	No consensus	Consensus	**Corrected to CON-CON	See MHHome3a above.	all milk expressed for donation should be frozen, unless milk is being transported to the milk bank on a daily basis. In this case, milk can be refrigerated.
MHHome4a	Advise donors to refrigerate each collected sample individually	6	0	5	3	8	Uncertain	No consensus	Consensus		The British Dietetic Association guidelines for mothers expressing milk on neonatal units for their own baby recommend that milk can be refrigerated for upto 48 hours before use, but if the milk is going to be frozen, it should be frozen immediately. However, there are different issues for the storage and handling of milk for donation. For example, milk stored at 4 degrees or less will have increased lipolysis over time (upto 48 hours), but the levels will not be enough to reject the milk. In addition milk for donation is going to be pasteurized, so such strict storage conditions (related to bacterial contamination) may not be necessary. The GDG queried why if the donor has access to a freezer, would she not freeze the milk.	Advise donors to freeze milk as soon as possible.

MHHome4b	freeze each collected sample individually	4.5	2	4	2	8	Uncertain	No consensus	No consensus		The GDG had a preference for freezing individual samples immediately, but based on practical considerations, it was accepted that samples could be pooled over 24 hours then frozen. Donors should store expressions separately at home but this will mean more containers and more administration. There is no cost impact around the use of additional containers as any new expression still needs to be into a new container.	it is preferred that milk is collected as individual samples, however if mother finds it necessary then pool.
MHHome4c	refrigerate collected samples over 24 hours, then freeze the pooled collection	7	1	2	5	8	Agree	No consensus	No consensus		There are significant practical issues of storing lots of containers in a fridge with other items and the refrigerator being opened often. Freezers may be more stable. The risk of pooling at home is related to handling of the containers more (for example, opening the container to add the new sample) and cross contamination. However, the GDG recognized that pragmatically, women may need to pool their milk.	refrigerate collected samples within 24 hours, then freeze the milk
MHHome4d	freeze collected samples over 24 hours, by adding each new sample to the frozen or freezing pool	4	4	1	3	8	Uncertain	No consensus	No consensus		See MHHome4a-c	...
MHHome4e	refrigerate collected samples over 2 days, then freeze the pooled collection	3	5	1	2	8	Do not agree	No consensus	No consensus		See MHHome4a	...

MHHome4f	freeze collected samples over 2 days, by adding each new sample to the frozen or freezing pool	3	4	3	1	8	Do not agree	No consensus	No consensus		See MHHome4a	...
MHHome4g	refrigerate collected samples over 1 week, then freeze the pooled collection	1	8	0	0	8	Do not agree	Consensus	Consensus		See MHHome4a	...
MHHome4h	freeze collected samples over 1 week, by adding each new sample to the frozen or freezing pool	2	5	3	0	8	Do not agree	No consensus	Consensus		See MHHome4a	...
MHHome5a	Advise donors that expressed milk for donation can be stored for up to 1 days in the main part of a fridge, at 4°C or lower before transport to the milk bank.	7	1	0	6	8	Agree	No consensus	No consensus	**Corrected to CON-No CON	As for above, the key issues are around practical considerations of handling and storing, but also degradation of nutrients, for example, and larger fat globules. The GDG referred to the NICE PH11 guidance on storage of maternal milk , but because of the extended period of storage at the milk bank, there was a need to recommend lower temperatures and shorter times than recommended for maternal milk.	Advise donors that expressed milk for donation can be stored for up to 1 day in the main part of a fridge, at 4°C or lower before transport to the milk bank.
MHHome5b	up to 2 days in the main part of a fridge, at 4°C or lower before transport to the milk bank.	3	4	1	2	8	Do not agree	No consensus	No consensus		See MHHome5a	...
MHHome5c	up to 3 days in the main part of a fridge, at 4°C or lower before transport to the milk bank.	3	5	2	0	8	Do not agree	No consensus	Consensus		See MHHome5a	...

MHHome5d	up to 4 days in the main part of a fridge, at 4°C or lower before transport to the milk bank.	3	6	1	0	8	Do not agree	No consensus	Consensus	**Corrected to CON-CON	See MHHome5a	...
MHHome5e	up to 5 days in the main part of a fridge, at 4°C or lower before transport to the milk bank.	2	7	0	0	8	Do not agree	Consensus	Consensus		See MHHome5a	...
MHHome5f	up to 2 days in the freezer compartment of a fridge before transport to the milk bank.	4.5	3	1	2	8	Uncertain	No consensus	No consensus		See MHHome5j	...
MHHome5g	up to 5 days in the freezer compartment of a fridge before transport to the milk bank.	3.5	3	2	1	8	Uncertain	No consensus	No consensus		See MHHome5j	...
MHHome5h	up to 1 week in the freezer compartment of a fridge before transport to the milk bank.	4.5	3	2	1	8	Uncertain	No consensus	No consensus		See MHHome5j	...
MHHome5i	up to 10 days in the freezer compartment of a fridge before transport to the milk bank.	3	4	2	0	8	Do not agree	No consensus	Consensus		See MHHome5j	...
MHHome5j	up to 2 weeks in the freezer compartment of a fridge before transport to the milk bank.	4	3	2	1	8	Uncertain	No consensus	No consensus		There was a recognition that some women may not have access to a separate freezer, and though not ideal, milk for donation can be stored in a freezer compartment of a refrigerator, but the recommended period of storage is much shorter than for a separate freezer. See MHHome5p.	up to 2 weeks in the freezer compartment of a fridge before transport to the milk bank preferable at -18 but in some circumstances can be stored in this

MHHome5k	up to 5 days in a domestic freezer , at minus 18°C or lower before transport to the milk bank.	2.5	6	1	1	8	Do not agree	No consensus	No consensus	**Corrected to CON-CON	See MHHome5p	...
MHHome5l	up to 1 week in a domestic freezer, at minus 18°C or lower before transport to the milk bank.	2.5	5	1	2	8	Do not agree	No consensus	No consensus		See MHHome5p	...
MHHome5m	up to 2 weeks in a domestic freezer, at minus 18°C or lower before transport to the milk bank.	2.5	5	1	2	8	Do not agree	No consensus	No consensus		See MHHome5p	...
MHHome5n	up to 1 month in a domestic freezer, at minus 18°C or lower before transport to the milk bank.	6.5	2	2	4	8	Agree	No consensus	No consensus		See MHHome5p	...
MHHome5o	up to 2 months in a domestic freezer, at minus 18°C or lower before transport to the milk bank.	5.5	1	5	2	8	Uncertain	No consensus	No consensus		See MHHome5p	...

MHHome5p	up to 3 months in a domestic freezer, at minus 18°C or lower before transport to the milk bank.	7	1	3	4	8	Agree	No consensus	No consensus		Again, the GDG were guided by the NICE PH11 recommendations on storage of maternal milk. A shorter storage time was recommended because, practically, donations need to be tested and pasteurised within 3 months of expression – but this is based on the capacity of the milk bank not the evidence on storage. The recommended storage time of 3 months at home plus a maximum of 3 months to process at the milk bank is therefore consistent with the PH11 guidance of 6 months total storage. The GDG considered that the optimal storage location for the milk is at the milk bank, recognizing the better equipment and explicit processes, so donors should be encouraged to transport the donations to the milk bank as soon as possible. See also the recommendations on transportation.	up to 3 months in a domestic freezer, at minus 18°C or lower. Take into account the time needed by the milk bank to process it. Get it to the milk bank asap
MHHome5q	up to 4 months in a domestic freezer, at minus 18°C or lower before transport to the milk bank.	2	5	2	0	8	Do not agree	No consensus	Consensus		See MHHome5p	...
MHHome5r	up to 5 months in a domestic freezer, at minus 18°C or lower before transport to the milk bank.	1	6	1	0	8	Do not agree	No consensus	Consensus	**Corrected to CON-CON	See MHHome5p	...

MHHome5s	up to 6 months in a domestic freezer, at minus 18°C or lower before transport to the milk bank.	1	6	1	0	8	Do not agree	No consensus	Consensus	**Corrected to CON-CON	See MHHome5p	...
MHHome6a	Advise donors to collect expressed milk for donation in any container they can find	1	8	0	0	8	Do not agree	Consensus	Consensus		See MHHome6e	Advise donors to collect expressed milk for donation in
MHHome6b	aluminium jugs	1	7	1	0	8	Do not agree	Consensus	Consensus		See MHHome6e	...
MHHome6c	plastic bottles or jars	3	4	0	3	8	Do not agree	No consensus	No consensus		See MHHome6e	...
MHHome6d	glass bottles or jars	3	4	0	3	8	Do not agree	No consensus	No consensus		See MHHome6e	...
MHHome6e	containers provided by the milk bank	9	0	0	8	8	Agree	Consensus	Consensus		The GDG agreed that donors should be provided with containers from the milk bank.	containers provided by the milk bank
MHHome6f	Only accept donations that are in containers provided by the milk bank.	3	5	2	1	8	Do not agree	No consensus	No consensus		If donations are collected in hospital then the mother will be provided with appropriate containers from there. When mothers express milk for their own baby at home, they often use other container such as bags. The GDG agreed donations should only be accepted in containers designed for the collection of milk.	Only accept donations that are in containers provided by the milk bank however for one-off donations containers specifically designed for the collection of breast milk
MHHome7a	Advise donors that, before used, collection containers should be washed in cold, soapy water	1	6	1	1	8	Do not agree	No consensus	No consensus	**Corrected to CON-No CON	See MHHome7g	Advise donors that, before used, collection containers should be
MHHome7b	washed in hot, soapy water	4	4	1	3	8	Uncertain	No consensus	No consensus		See MHHome7g	...

MHHome7c	sterilized using sterilizing fluid	6	3	1	3	8	Uncertain	No consensus	No consensus		See MHHome7g	...
MHHome7d	sterilized by heating in the oven	3	4	1	2	8	Do not agree	No consensus	No consensus		See MHHome7g	...
MHHome7e	cleaned as they would clean the bottles for feeding their own baby	5	3	3	2	8	Uncertain	No consensus	No consensus		See MHHome7g	...
MHHome7f	washed in the dishwasher, if possible	5	3	2	2	8	Uncertain	No consensus	No consensus		See MHHome7g	...
MHHome7g	used as received from the milk bank	9	0	0	8	8	Agree	Consensus	Consensus	The milk bank should provide sterile containers for one-off use. This ensures, not only, that the container is sterile, and that the material is suitable – for example, plastics may react to different heat processes and leaching of plasticisers may be increased. Practically, the use of a standard bottle also makes handling easier within the milk bank. Milk banks need to demonstrate that the quality of the milk is the highest – so there is a need to discard and refuse some milk – and donors should therefore be advised that they should follow the instructions from the milk bank.	used as received from the milk bank	

Round 1 – milk handling at the milk bank 1

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	Corrections made post meeting	GDG considerations	Recommendation for Round 2
MHMB1a	Process <u>all</u> milk under sterile conditions.	3	6	1	1	1	Do not agree	No consensus	No consensus		See MHMilkBank1b	...
MHMB1b	Process <u>all</u> milk under hygienic conditions, that may not necessarily be sterile.	8	0	2	7	0	Agree	Consensus	Consensus		There was a general agreement that a balance needed to struck between treatment and the effect of such processing on the milk.	Process <u>all</u> milk under hygienic conditions, that may not necessarily be sterile.
MHMB2a	On receipt at the milk bank, • thaw any frozen samples.	3	5	1	2	1	Do not agree	No consensus	No consensus		See MHMilkBank2d	On receipt at the milk bank,
MHMB2b	• allow all samples to reach room temperature.	2.5	8	0	0	1	Do not agree	Consensus	Consensus		See MHMilkBank2d	...
MHMB2c	• refrigerate all samples.	3	7	0	2	0	Do not agree	Consensus	No consensus		See MHMilkBank2d	...
MHMB2d	• freeze all samples.	8	0	0	7	2	Agree	Consensus	Consensus		This is based on the previous recommendations that donors should provide frozen or refrigerated samples.	• freeze all samples.

MHMB2e	refrigerate those samples which are to be used <u>raw</u>, if meet testing criteria.	5	2	1	2	4	Uncertain	No consensus	No consensus		The GDG recognized that, although raw milk may be used in rare circumstances and only under the supervision of the prescribing physician, in general milk banks would not be processing raw milk. Recommendations were therefore made only for milk to be treated.	...
MHMB3	On receipt at the milk bank, process milk for use in pre-term babies (that is, milk from the appropriate stage of lactation) separately.	6	3	1	4	1	Uncertain	No consensus	No consensus		As the guideline is not covering indications for the use of milk, this recommendation was not considered relevant and removed.	...
MHMB4	Store frozen samples direct from the donor in the same freezer as pasteurized samples.	1	9	0	0	0	Do not agree	Consensus	Consensus		...	Do not store frozen samples direct from the donor in the same freezer as pasteurized samples.
MHMB5	Store refrigerated samples direct from the donor in the same fridge as thawed, pasteurized samples.	1	9	0	0	0	Do not agree	Consensus	Consensus		...	Do not store refrigerated samples direct from the donor in the same fridge as thawed, pasteurized samples.
MHMB6	Store milk to be used <u>raw</u> in the same fridge as samples to be pasteurised.	1	8	0	0	1	Do not agree	Consensus	Consensus		...	Do not store milk to be used <u>raw</u> in the same fridge as samples to be pasteurised.

MHMB7a	Examine samples from the donor for appearance (including the presence of blood)	8	1	1	7	0	Agree	Consensus	No consensus		It is important to check the samples visually, but there is no evidence on how any discolouration or other factor (taste, odour) relates to any risks. Colour – appearance, can indicate some specific situations, such as medication being taken. But generally, the GDG agreed that a visual inspection to exclude obvious 'wrong' samples should be made.	Examine samples from the donor for appearance
MHMB7b	taste	1	8	1	0	0	Do not agree	Consensus	Consensus		See MHMilkBank7a	...
MHMB7c	colour	7.5	2	1	5	1	Agree	No consensus	No consensus		See MHMilkBank7a	...
MHMB7d	odour	3	5	3	1	0	Do not agree	No consensus	No consensus		See MHMilkBank7a	...
MHMB8a	Discard samples which appear to contain contaminants	8	2	1	6	0	Agree	No consensus	No consensus		See MHMilkBank8e	Discard samples which
MHMB8b	taste unusual	1	4	2	0	3	Do not agree	No consensus	Consensus		See MHMilkBank8e	...
MHMB8c	are an unusual colour	6	2	5	2	0	Uncertain	No consensus	No consensus		See MHMilkBank8e	...
MHMB8d	smell unusual	5.5	3	3	2	1	Uncertain	No consensus	No consensus		See MHMilkBank8e	...
MHMB8e	on examination, raise any safety concerns	8	1	0	8	0	Agree	Consensus	No consensus		See MHMilkBank7a	on examination, raise any safety concerns
MHMB9	Discard samples from donors who subsequently fail to meet selection criteria	9	1	0	8	0	Agree	Consensus	No consensus		...	Discard samples from donors who subsequently fail to meet selection criteria

MHMB10a	Discard samples stored, <u>post expression and prior to testing</u> • in the refrigerator for 1 day	1.5	7	0	1	1	Do not agree	Consensus	No consensus		The GDG agreed that these should be linked to the storage periods defined in the Milk Handling at Home section.	Accept samples stored, <u>post expression and prior to testing</u> in the refrigerator for upto 1 day
MbHMB10c	• in the refrigerator for 2 days	2	7	0	0	2	Do not agree	Consensus	Consensus		On discussion, the GDG agreed to link these to the storage periods defined in the Milk Handling at Home section.	...
MdHMB10e	• in the refrigerator for 3 days	7	2	0	5	2	Agree	No consensus	No consensus		See MHMilkBank10a	...
MfHMB10g	• in the refrigerator for 4 days	7	1	1	5	2	Agree	No consensus	No consensus		See MHMilkBank10a	...
MHMB10h	• in the refrigerator for 5 days	7	1	1	5	2	Agree	No consensus	No consensus		See MHMilkBank10a	...
MHMB10i	• in the freezer for 1 week	1	7	0	0	2	Do not agree	Consensus	Consensus		See MHMilkBank10a	...
MHMB10j	• in the freezer for 2 weeks	1	7	0	0	2	Do not agree	Consensus	Consensus		See MHMilkBank10a	...
MHMB10k	• in the freezer for 1 month	1	7	0	0	2	Do not agree	Consensus	Consensus		See MHMilkBank10a	...
MHMB10l	• in the freezer for 2 months	1.5	7	1	0	1	Do not agree	Consensus	Consensus		See MHMilkBank10a	...
MHMB10m	• in the freezer for 3 months	2	7	0	0	2	Do not agree	Consensus	Consensus		See MHMilkBank10a	• in the freezer for upto 3 months
MHMB10n	• in the freezer for 4 months	7	1	2	4	2	Agree	No consensus	No consensus		See MHMilkBank10a	...
MHMB10o	• in the freezer for 5 months	7	1	1	5	2	Agree	No consensus	No consensus		See MHMilkBank10a	...
MHMB10p	• in the freezer for 6 months	7	1	1	5	2	Agree	No consensus	No consensus		See MHMilkBank10a	...
MHMB11a	Discard samples stored, <u>post expression and prior to using raw</u> • in the refrigerator for 1 day	1.5	4	0	0	5	Do not agree	No consensus	Consensus		(Not making recommendations on the handling of raw milk)	...

MHMB11b	• in the refrigerator for 2 days	2	5	0	0	4	Do not agree	No consensus	Consensus	1-3 4 D/K 5	(Not making recommendations on the handling of raw milk)	...
MHMB11c	• in the refrigerator for 3 days	7	2	0	3	4	Agree	No consensus	No consensus	1-3 1 D/K 5	(Not making recommendations on the handling of raw milk)	...
MHMB11d	• in the refrigerator for 4 days	7	2	0	3	4	Agree	No consensus	No consensus	Median 7.5 1-3 1 D/K 5	(Not making recommendations on the handling of raw milk)	...
MHMB11e	• in the refrigerator for 5 days	7	2	0	3	4	Agree	No consensus	No consensus	Median 7.5 1-3 1 D/K 5	(Not making recommendations on the handling of raw milk)	...
MHMB12	Before selecting for testing, always choose the 'newest' samples first.	3	6	1	0	2	Do not agree	No consensus	Consensus	Median 2 1-3 7 4-6 0 CON-CON	The milk bank should operate a method of stock control, and the GDG agreed that this would be covered through general quality assurance. No recommendation was therefore made.	...
MHMB13	Thaw samples for testing when a donor has been shown to meet the selection criteria (that is when the results of any serological testing are available).	8	3	1	5	0	Agree	No consensus	No consensus	1-3 4 4-6 0	The process of testing differs depending on whether a one-off donation or ongoing. Please see therefore the recommendations on testing batches later.	...
MHMB14a	Thaw samples by • using a hot water bath (manual)	3	5	1	2	1	Do not agree	No consensus	No consensus	4-6 0 7-9 3	See MHMilkBank14d	Thaw samples by

MHMB14b	heating in a microwave	1.5	7	1	0	1	Do not agree	Consensus	Consensus	Median 1 1-3 8 4-6 0	See MHMilkBank14d	...
MHMB14c	running under a hot tap	2	7	1	0	1	Do not agree	Consensus	Consensus	1-3 8 4-6 0	See MHMilkBank14d	...
MHMB14d	using a hot water bath (electric)	2.5	5	0	3	1	Do not agree	No consensus	No consensus	4-6 1 7-9 2	The various options for defrosting were discussed. There are advantages of defrosting at a monitored temperature, although frozen milk can be thawed in a refrigerator or by leaving it out at room temperature. If milk is stored at very low temperatures (-35°) it will take longer to defrost and also the size of the bottles has an impact.	using a temperature controlled environment such as a water bath (electric) or refrigerator
MHMB14e	leaving in the refrigerator	7.5	1	1	6	1	Agree	No consensus	No consensus	Median 8 4-6 0 7-9 7 CON-No CON	See MHMilkBank14d	leaving in the refrigerator

MHMB14f	leaving out to reach room temperature	3	5	0	3	1	Do not agree	No consensus	No consensus		However, there are guidelines that say that the milk shouldn't be at room temperature for longer than a certain length of time; in general the period at which milk is kept at an uncontrolled temperature should be minimised.	leaving out to reach room temperature

MHMB15a	<u>Before pasteurisation</u>, test all samples	7.5	3	0	5	1	Agree	No consensus	No consensus		Every donation should be tested, but donations from a single donor can be pooled (see previous recs on Milk Handling at Home) and the batch tested. Although this means that larger amounts may have to be discarded, this is balanced with lower costs as testing every donation is very expensive, but testing by batch (1-2l) is less costly. The aim of testing pre-pasteurisation tests is for levels of contamination but testing post pasteurisation is to check the effectiveness of the process. (See also recs on testing post-pasteurisation)	<u>Before pasteurisation</u>, test all samples but this should be done in batches
MHMB15b	a random selection of samples	5	4	0	4	1	Uncertain	No consensus	No consensus		See MHMilkBank15a	...
MHMB15c	samples only once a week	2	6	1	0	2	Do not agree	No consensus	Consensus		See MHMilkBank15a	...
MHMB15d	samples only twice a month	2	6	0	1	2	Do not agree	No consensus	No consensus		See MHMilkBank15a	...
MHMB15e	only the first sample received from a donor	1	7	0	0	2	Do not agree	Consensus	Consensus		See MHMilkBank15a	...

MHMB15f	the first three samples received from a donor	1	7	0	0	2	Do not agree	Consensus	Consensus		See MHMilkBank15a	...
	Before pasteurisation , test samples for the following:											Before pasteurisation , test samples for the following:
MHMB16a	environmental or other contaminants	3.5	3	3	0	3	Uncertain	No consensus	Consensus		In general, the GDG agreed that in the UK, it is not necessary to test for such contaminants.	...
MHMB16ai	DDT concentrations	3.5	3	2	1	3	Uncertain	No consensus	No consensus		This is not a routine test.	...
MHMB16aii	water	2	5	1	0	3	Do not agree	No consensus	Consensus		This test was mainly recommended in those milk banks where donors were paid, to check for dilution.	...
MHMB16aiii	cow's milk	2	4	1	0	4	Do not agree	No consensus	Consensus		This test was mainly recommended in those milk banks where donors were paid, to check for dilution.	...

MHMB16bi	• viral infection	4	4	2	2	1	Uncertain	No consensus	No consensus		The GDG discussed which viruses could be tested for and agreed not to test for viruses in milk based on the likelihood of contamination and the prevalence (minimized through the recommended donor screening process). In addition, pasteurisation destroys or inactivates the viruses so no pre-pasteurisation check was recommended.	...
MHMB16bii	◦ CMV	3	5	1	3	0	Do not agree	No consensus	No consensus		See MHMilkBank16bi	...
MHMB16biii	◦ MRSA	4.5	3	2	3	1	Uncertain	No consensus	No consensus		See MHMilkBank16bi	...
MHMB16biv	◦ HIV	3	5	1	3	0	Do not agree	No consensus	No consensus		See MHMilkBank16bi	...
MHMB16bv	◦ Semliki Forest virus	3	5	1	1	2	Do not agree	No consensus	No consensus		See MHMilkBank16bi	...
MHMB16bvi	◦ herpes simplex virus	3	5	0	3	1	Do not agree	No consensus	No consensus		See MHMilkBank16bi	...
MHMB16bvii	◦ coxsackie virus	3	5	1	2	1	Do not agree	No consensus	No consensus		See MHMilkBank16bi	...
MHMB16bviii	◦ HTLV-1	3	5	0	4	0	Do not agree	No consensus	No consensus		See MHMilkBank16bi	...
MHMB16bix	◦ hepatitis B	4.5	4	1	3	1	Uncertain	No consensus	No consensus		See MHMilkBank16bi	...
MHMB16bx	◦ hepatitis C	4.5	4	1	3	1	Uncertain	No consensus	No consensus		See MHMilkBank16bi	...

MHMB16ci	• bacterial contamination	9	0	0	8	1	Agree	Consensus	Consensus		As with viruses, milk banks need to check for specific indicator bacteria.	• bacterial contamination
MHMB16cii	○ enteric pathogens	9	1	0	7	1	Agree	Consensus	No consensus		See MHMilkBank16ci	○ enteric pathogens
MHMB16ciii	○ pathogens with the potential to be enteric	9	1	1	6	1	Agree	No consensus	No consensus		See MHMilkBank16ci	○ pathogens with the potential to be enteric
MHMB16civ	○ non-pathogenic organisms	7.5	3	0	5	1	Agree	No consensus	No consensus		See MHMilkBank16ci	○ non-pathogenic organisms
MHMB16cv	○ coliform bacteria	8.5	0	0	8	1	Agree	Consensus	Consensus		See MHMilkBank16ci	○ coliform bacteria
MHMB16cvi	○ saprophytic bacteria	8	1	2	4	2	Agree	No consensus	No consensus		See MHMilkBank16ci	○ saprophytic bacteria
MHMB16cvii	○ heat resistant bacillus	8	1	1	7	0	Agree	Consensus	No consensus		See MHMilkBank16ci	○ heat resistant bacillus
MHMB16cviii	○ from mastitis	8	1	2	4	2	Agree	No consensus	No consensus		See MHMilkBank16ci	○ from mastitis
MHMB16cix	○ Salmonella Kottbus	9	1	0	6	2	Agree	No consensus	No consensus		See MHMilkBank16ci	○ Salmonella Kottbus
MHMB16cx	○ normal breast flora	5	4	0	4	1	Uncertain	No consensus	No consensus		See MHMilkBank16ci	○ normal breast flora
MHMB16cxi	○ commensal skin flora	4	4	1	3	1	Uncertain	No consensus	No consensus		See MHMilkBank16ci	○ commensal skin flora
MHMB16cxii	○ Staph epidermis	8	3	0	4	2	Agree	No consensus	No consensus		See MHMilkBank16ci	○ Staph epidermis
MHMB16cxiii	○ Staph aureus	9	0	1	6	2	Agree	No consensus	Consensus		See MHMilkBank16ci	○ Staph aureus
MHMB16cxiv	○ Staph albus	8.5	1	1	4	3	Agree	No consensus	No consensus		See MHMilkBank16ci	○ Staph albus
MHMB16cxv	○ viridans streptococci	9	1	0	5	3	Agree	No consensus	No consensus		See MHMilkBank16ci	○ viridans streptococci
MHMB16cxvi	○ diphtheroids	9	1	0	5	3	Agree	No consensus	No consensus		See MHMilkBank16ci	○ diphtheroids
MHMB16cxvii	○ gram-negative rod	9	0	1	4	4	Agree	No consensus	Consensus		See MHMilkBank16ci	○ gram-negative rod
MHMB16cxviii	○ haemolytic streptococci	9	1	0	6	2	Agree	No consensus	No consensus		See MHMilkBank16ci	○ haemolytic streptococci
MHMB16cxix	○ Strep faecalis	9	1	0	6	2	Agree	No consensus	No consensus		See MHMilkBank16ci	○ Strep faecalis
MHMB16cxx	○ Pseud spp	9	1	1	5	2	Agree	No consensus	No consensus		See MHMilkBank16ci	○ Pseud spp

MHMB16cxi	○ Proteus spp	9	1	0	5	3	Agree	No consensus	No consensus		See MHMilkBank16ci	○ Proteus spp
MHMB16cxii	○ Enterobacteriaceae	9	0	0	7	2	Agree	Consensus	Consensus		See MHMilkBank16ci	○ Enterobacteriaceae
MHMB16cxiii	○ enterococci	9	1	0	5	3	Agree	No consensus	No consensus		See MHMilkBank16ci	○ enterococci
MHMB16cxiv	○ Klebsiella	9	1	0	5	3	Agree	No consensus	No consensus		See MHMilkBank16ci	○ Klebsiella
MHMB16cxv	○ E coli	9	0	0	8	1	Agree	Consensus	Consensus		See MHMilkBank16ci	○ E coli
MHMB16cxvi	○ listeria	9	1	0	7	1	Agree	Consensus	No consensus		See MHMilkBank16ci	○ listeria
MHMB16di	• nutritional factors	5	3	2	3	1	Uncertain	No consensus	No consensus		Testing for nutritional composition, if done, should be post pasteurization.	...
MHMB16dii	○ fat	5	4	3	2	0	Uncertain	No consensus	No consensus		See MHMilkBank16di	...
MHMB16diii	○ caloric value (energy)	5	3	3	3	0	Uncertain	No consensus	No consensus		See MHMilkBank16di	...
MHMB16div	○ carbohydrate	5	4	3	2	0	Uncertain	No consensus	No consensus		See MHMilkBank16di	...
MHMB16dv	○ protein	4	4	4	1	0	Uncertain	No consensus	No consensus	Median 5 1-3 3 7-9 2	See MHMilkBank16di	...
MHMB16dvi	○ lactose	4	4	4	1	0	Uncertain	No consensus	No consensus		See MHMilkBank16di	...
MHMB16dvii	○ vitamins	3	5	3	1	0	Do not agree	No consensus	No consensus		See MHMilkBank16di	...
MHMB16dviii	○ minerals	3	5	3	1	0	Do not agree	No consensus	No consensus		See MHMilkBank16di	...
MHMB16dix	○ sodium	4	4	4	1	0	Uncertain	No consensus	No consensus		See MHMilkBank16di	...
MHMB16dx	○ zinc	4	4	4	1	0	Uncertain	No consensus	No consensus		See MHMilkBank16di	...
MHMB16dxi	○ immunologic factors	4	4	4	1	0	Uncertain	No consensus	No consensus		See MHMilkBank16di	...
MHMB16dxii	○ enzyme activity	3	5	3	1	0	Do not agree	No consensus	No consensus		See MHMilkBank16di	...

MHMB16e	acidity	4	3	3	1	2	Uncertain	No consensus	No consensus	Median 3 1-3 4 D/K 1 DO NOT AGREE	Some countries use acidity as an indirect indicator for bacteria. But acidity could also be a chemical contaminant rather than bacterial contamination. When bacterial testing is being done, acidity gives no added information. Acidity may affect the acceptability of the milk; if this was caused by bacteria then the bacteria would be destroyed during pasteurization but the pH may have shifted and affect acceptability but there is no clear evidence on the effect on the recipient baby – some view that acidified donor milk (yoghurt) would not have any problems for the baby.	acidity
	Discard <u>samples for raw use</u> that contain										(Not making recommendations on the handling of raw milk)	...
MHMB17a	organisms other than normal breast flora or commensal skin flora	7	2	1	4	2	Agree	No consensus	No consensus		(Not making recommendations on the handling of raw milk)	...

MHMB17b	• gram negative bacteria	5	3	0	3	3	Uncertain	No consensus	No consensus		(Not making recommendations on the handling of raw milk)	...
MHMB17c	• $\geq 10,000$ organisms/ml Staph epidermis	3	4	1	0	4	Do not agree	No consensus	Consensus		(Not making recommendations on the handling of raw milk)	...
MHMB17d	• $\geq 4,000$ organisms/ml Staph aureus	6	2	2	2	3	Uncertain	No consensus	No consensus	Median 6.5 4-6 1 7-9 3 AGREE	(Not making recommendations on the handling of raw milk)	...
MHMB17e	• $\geq 10^4$ CFU/ml of normal skin flora	3	4	1	1	3	Do not agree	No consensus	No consensus	4-6 0 7-9 2	(Not making recommendations on the handling of raw milk)	...
MHMB17f	• pathogens	7	2	0	3	4	Agree	No consensus	No consensus		(Not making recommendations on the handling of raw milk)	...
MHMB17g	• coliform bacteria	5	3	0	3	3	Uncertain	No consensus	No consensus	Median 8	(Not making recommendations on the handling of raw milk)	...

MHMB18	Discard <u>samples for pasteurisation</u> that contain										Lower levels of any bacterial contamination are acceptable as pasteurisation would destroy these, but there some that are important organisms—for example, staph aureus – that release toxins that would remain even if the organisms are destroyed. Also, if there were high levels of contamination, then the resultant contamination may remain at an unacceptable level (pasteurization destroys logarithmically, so effectiveness depends on the starting level) . The Dairy industry test for fewercontaminants , but this is not being fed to 23 week old babies. The GDG recognized the need to assume that the main recipients are preterm, sick but that may not be the case. Key to these recommendations is the confidence in the pasteurisation process.	Discard <u>samples for pasteurisation</u> that contain

MHMB18a	• any organisms	1	7	0	0	2	Do not agree	Consensus	Consensus		See MHMilkBank18	• any organisms
MHMB18ai	• $\geq 10^2$ CFU/ml of any organisms	1.5	5	1	0	3	Do not agree	No consensus	Consensus		See MHMilkBank18	• $\geq 10^2$ CFU/ml of any organisms
MHMB18aii	• $\geq 10^3$ CFU/ml of any organisms	1.5	5	1	0	3	Do not agree	No consensus	Consensus		See MHMilkBank18	• $\geq 10^3$ CFU/ml of any organisms
MHMB18aiii	• $\geq 10^4$ CFU/ml of any organisms	3	5	1	1	2	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^4$ CFU/ml of any organisms
MHMB18aiv	• $\geq 10^5$ CFU/ml of any organisms	2.5	4	1	1	3	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^5$ CFU/ml of any organisms
MHMB18av	• $\geq 10^6$ CFU/ml of any organisms	6	2	1	3	3	Uncertain	No consensus	No consensus		See MHMilkBank18	• $\geq 10^6$ CFU/ml of any organisms
MHMB18bi	• any skin commensals	1	6	1	0	2	Do not agree	No consensus	Consensus		See MHMilkBank18	• any skin commensals
MHMB18bii	• $\geq 10^2$ CFU/ml of skin commensals	1	6	0	0	3	Do not agree	No consensus	Consensus		See MHMilkBank18	• $\geq 10^2$ CFU/ml of skin commensals
MHMB18biii	• $\geq 10^4$ CFU/ml of skin commensals	2	5	1	0	3	Do not agree	No consensus	Consensus		See MHMilkBank18	• $\geq 10^4$ CFU/ml of skin commensals
MHMB18biv	• $\geq 10^5$ CFU/ml of skin commensals	2	4	1	1	3	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^5$ CFU/ml of skin commensals
MHMB18bv	• $\geq 10^6$ CFU/ml of skin commensals	3.5	3	1	2	3	Uncertain	No consensus	No consensus		See MHMilkBank18	• $\geq 10^6$ CFU/ml of skin commensals
MHMB18biv	• $\geq 10^6$ CFU/ml of skin commensals	6	2	1	3	3	Uncertain	No consensus	No consensus		See MHMilkBank18	• $\geq 10^6$ CFU/ml of skin commensals
MHMB18ci	• any Staph aureus	4	3	1	2	3	Uncertain	No consensus	No consensus		See MHMilkBank18	• any Staph aureus
MHMB18cii	• $\geq 10^2$ CFU/ml of Staph aureus	4.5	3	0	3	3	Uncertain	No consensus	No consensus		See MHMilkBank18	• $\geq 10^2$ CFU/ml of Staph aureus
MHMB18ciii	• $\geq 10^4$ CFU/ml of Staph aureus	7	2	0	3	4	Agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^4$ CFU/ml of Staph aureus
MHMB18civ	• $\geq 10^5$ CFU/ml of Staph aureus	7	2	0	3	4	Agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^5$ CFU/ml of Staph aureus
MHMB18cv	• $\geq 10^6$ CFU/ml of Staph aureus	7	2	0	3	4	Agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^6$ CFU/ml of Staph aureus
MHMB18civ	• $\geq 10^6$ CFU/ml of Staph aureus	7	2	0	3	4	Agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^6$ CFU/ml of Staph aureus
MHMB18di	• any gram-negative rod bacteria	4.5	3	0	3	3	Uncertain	No consensus	No consensus		See MHMilkBank18	• any gram-negative rod bacteria
MHMB18dii	• $\geq 10^2$ CFU/ml of any gram-negative rod bacteria	1.5	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^2$ CFU/ml of any gram-negative rod bacteria
MHMB18diii	• $\geq 10^4$ CFU/ml of any gram-negative rod bacteria	2	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^4$ CFU/ml of any gram-negative rod bacteria

MHMB18div	• $\geq 10^5$ CFU/ml of any gram-negative rod bacteria	2	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^5$ CFU/ml of any gram-negative rod bacteria
MHMB18dv	• $\geq 10^6$ CFU/ml of any gram-negative rod bacteria	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• $\geq 10^6$ CFU/ml of any gram-negative rod bacteria
MHMB18div	• $\geq 10^6$ CFU/ml of any gram-negative rod bacteria	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• $\geq 10^6$ CFU/ml of any gram-negative rod bacteria
MHMB18ei	• any haemolytic streptococci	5	3	1	3	2	Uncertain	No consensus	No consensus		See MHMilkBank18	• any haemolytic streptococci
MHMB18eii	• $\geq 10^2$ CFU/ml of any haemolytic streptococci	1.5	3	1	0	5	Do not agree	No consensus	Consensus		See MHMilkBank18	• $\geq 10^2$ CFU/ml of any haemolytic streptococci
MHMB18eiii	• $\geq 10^3$ CFU/ml of any haemolytic streptococci	2	3	1	0	5	Do not agree	No consensus	Consensus		See MHMilkBank18	• $\geq 10^3$ CFU/ml of any haemolytic streptococci
MHMB18eiv	• $\geq 10^4$ CFU/ml of any haemolytic streptococci	2	3	1	0	5	Do not agree	No consensus	Consensus		See MHMilkBank18	• $\geq 10^4$ CFU/ml of any haemolytic streptococci
MHMB18ev	• $\geq 10^5$ CFU/ml of any haemolytic streptococci	3	2	1	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^5$ CFU/ml of any haemolytic streptococci
MHMB18eiv	• $\geq 10^6$ CFU/ml of any haemolytic streptococci	3	2	1	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^6$ CFU/ml of any haemolytic streptococci
MHMB18fi	• any Strep faecalis	5	3	1	3	2	Uncertain	No consensus	No consensus		See MHMilkBank18	• any Strep faecalis
MHMB18fii	• $\geq 10^2$ CFU/ml of Strep faecalis	1.5	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^2$ CFU/ml of Strep faecalis
MHMB18fiii	• $\geq 10^3$ CFU/ml of Strep faecalis	1.5	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^3$ CFU/ml of Strep faecalis
MHMB18fiv	• $\geq 10^4$ CFU/ml of Strep faecalis	2	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^4$ CFU/ml of Strep faecalis
MHMB18fv	• $\geq 10^5$ CFU/ml of Strep faecalis	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• $\geq 10^5$ CFU/ml of Strep faecalis
MHMB18fiv	• $\geq 10^6$ CFU/ml of Strep faecalis	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• $\geq 10^6$ CFU/ml of Strep faecalis
MHMB18gi	• any heat-resistant bacteria	5	3	1	3	2	Uncertain	No consensus	No consensus		See MHMilkBank18	• any heat-resistant bacteria
MHMB18gii	• $\geq 10^2$ CFU/ml of any heat-resistant bacteria	3	3	0	2	4	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^2$ CFU/ml of any heat-resistant bacteria
MHMB18giii	• $\geq 10^3$ CFU/ml of any heat-resistant bacteria	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• $\geq 10^3$ CFU/ml of any heat-resistant bacteria
MHMB18giv	• $\geq 10^4$ CFU/ml of any heat-resistant bacteria	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• $\geq 10^4$ CFU/ml of any heat-resistant bacteria
MHMB18gv	• $\geq 10^5$ CFU/ml of any heat-resistant bacteria	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• $\geq 10^5$ CFU/ml of any heat-resistant bacteria
MHMB18gvi	• $\geq 10^6$ CFU/ml of any heat-resistant bacteria	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• $\geq 10^6$ CFU/ml of any heat-resistant bacteria

MHMB18hi	• any Pseudomonas	7	3	0	4	2	Agree	No consensus	No consensus		See MHMilkBank18	• any Pseudomonas
MHMB18hii	• $\geq 10^2$ CFU/ml of Pseudomonas	1.5	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^2$ CFU/ml of Pseudomonas
MHMB18hiii	• $\geq 10^3$ CFU/ml of Pseudomonas	1.5	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^3$ CFU/ml of Pseudomonas
MHMB18hiv	• $\geq 10^4$ CFU/ml of Pseudomonas	2	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^4$ CFU/ml of Pseudomonas
MHMB18hv	• $\geq 10^5$ CFU/ml of Pseudomonas	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• $\geq 10^5$ CFU/ml of Pseudomonas
MHMB18hiv	• $\geq 10^6$ CFU/ml of Pseudomonas	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• $\geq 10^6$ CFU/ml of Pseudomonas
MHMB18ji	• any Klebsiella	4.5	3	0	3	3	Uncertain	No consensus	No consensus		See MHMilkBank18	• any Klebsiella
MHMB18jii	• $\geq 10^2$ CFU/ml of Klebsiella	1.5	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^2$ CFU/ml of Klebsiella
MHMB18jiii	• $\geq 10^3$ CFU/ml of Klebsiella	1.5	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^3$ CFU/ml of Klebsiella
MHMB18jiv	• $\geq 10^4$ CFU/ml of Klebsiella	2	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^4$ CFU/ml of Klebsiella
MHMB18jv	• $\geq 10^5$ CFU/ml of Klebsiella	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• $\geq 10^5$ CFU/ml of Klebsiella
MHMB18jv	• $\geq 10^6$ CFU/ml of Klebsiella	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• $\geq 10^6$ CFU/ml of Klebsiella
MHMB18ki	• any Proteus	4.5	3	0	3	3	Uncertain	No consensus	No consensus		See MHMilkBank18	• any Proteus
MHMB18kii	• $\geq 10^2$ CFU/ml of Proteus	1.5	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^2$ CFU/ml of Proteus
MHMB18kiii	• $\geq 10^3$ CFU/ml of Proteus	1.5	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^3$ CFU/ml of Proteus
MHMB18kiv	• $\geq 10^4$ CFU/ml of Proteus	2	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^4$ CFU/ml of Proteus
MHMB18kv	• $\geq 10^5$ CFU/ml of Proteus	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• $\geq 10^5$ CFU/ml of Proteus
MHMB18kv	• $\geq 10^6$ CFU/ml of Proteus	7	1	0	2	6	Agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^6$ CFU/ml of Proteus
MHMB18li	• any entero-pathogenic bacteria	7.5	2	0	4	3	Agree	No consensus	No consensus		See MHMilkBank18	• any entero-pathogenic bacteria
MHMB18lii	• $\geq 10^2$ CFU/ml of any entero-pathogenic bacteria	2	2	0	1	6	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^2$ CFU/ml of any entero-pathogenic bacteria
MHMB18lii	• $\geq 10^3$ CFU/ml of any entero-pathogenic bacteria	3	2	0	1	6	Do not agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^3$ CFU/ml of any entero-pathogenic bacteria

MHMB18liv	• $\geq 10^4$ CFU/ml of any enteropathogenic bacteria	7	1	0	2	6	Agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^4$ CFU/ml of any enteropathogenic bacteria
MHMB18lv	• $\geq 10^5$ CFU/ml of any enteropathogenic bacteria	7	1	0	2	6	Agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^5$ CFU/ml of any enteropathogenic bacteria
MHMB18liv	• $\geq 10^6$ CFU/ml of any enteropathogenic bacteria	7	1	0	2	6	Agree	No consensus	No consensus		See MHMilkBank18	• $\geq 10^6$ CFU/ml of any enteropathogenic bacteria

Round 1 – milk handling at the milk bank 2

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	Corrections made post meeting	GDG considerations	Recommendation for Round 2
MHMB19	Discard <u>samples for pasteurisation</u> that contain										It was agreed that samples should not tested for environmental contaminants or viruses, so these recommendations all fell.	Discard <u>samples for pasteurisation</u> that contain
MHMB19ai	environmental or other contaminants	6.5	1	2	3	2	Agree	No consensus	No consensus		See MHMB19	...
MHMB19aii	DDT concentrations	6	1	3	3	1	Uncertain	No consensus	No consensus		See MHMB19	...
MHMB19aiii	water	5	3	3	2	0	Uncertain	No consensus	No consensus		See MHMB19	...
MHMB19aiv	cow's milk	5	3	2	3	0	Uncertain	No consensus	No consensus		See MHMB19	...
MHMB19bi	viral infection	6	2	1	2	3	Uncertain	No consensus	No consensus		See MHMB19	...
MHMB19bii	CMV	4.5	4	1	3	0	Uncertain	No consensus	No consensus		See MHMB19	...
MHMB19biii	MRSA	3	5	0	2	1	Do not agree	No consensus	No consensus		See MHMB19	...
MHMB19biv	HIV	7	3	0	4	1	Agree	No consensus	No consensus		See MHMB19	...
MHMB19bv	Semliki Forest virus	3	4	1	1	2	Do not agree	No consensus	No consensus		See MHMB19	...
MHMB19bvi	herpes simplex virus	4	4	1	3	0	Uncertain	No consensus	No consensus		See MHMB19	...
MHMB19bvii	coxsackie virus	5.5	2	2	2	2	Uncertain	No consensus	No consensus		See MHMB19	...
MHMB19bviii	HTLV-1	6	3	1	3	1	Uncertain	No consensus	No consensus		See MHMB19	...
MHMB19bix	hepatitis B	7.5	3	0	5	0	Agree	No consensus	No consensus		See MHMB19	...
MHMB19bx	hepatitis C	7.5	3	0	5	0	Agree	No consensus	No consensus		See MHMB19	...

MHMB20	Pasteurise, or heat treat for	1	2	0	0	6	Do not agree	No consensus	Consensus		Pasteurisation is commonly used, and milk banks have considerable experience with this treatment process. The GDG considered whether they could recommend a variety of methods depending on the aims of treatment – for example, best bacterial safety whilst preserving most qualities.	Pasteurise, or heat treat for – give some variations on this
MHMB20a	56.0 degrees C for 30 minutes	1	4	0	0	4	Do not agree	No consensus	Consensus		See MHMB20	...
MHMB20b	57.5 degrees C for 30 minutes	1	4	0	0	4	Do not agree	No consensus	Consensus		See MHMB20	...
MHMB20c	56.0 degrees C for 33 minutes	1	4	0	0	4	Do not agree	No consensus	Consensus		See MHMB20	...
MHMB20d	57.5 degrees C for 33 minutes	1	4	0	0	4	Do not agree	No consensus	Consensus		See MHMB20	...
MHMB20e	62.0 degrees C for 30 minutes	2	4	0	0	4	Do not agree	No consensus	Consensus		See MHMB20	...
MHMB20f	62.5 degrees C for 5 minutes	3	5	0	0	3	Do not agree	No consensus	Consensus		See MHMB20	...

MHMB20g	62.5 degrees C for 30 minutes	8	1	0	5	2	Agree	No consensus	No consensus		There is a need to balance the temperature and the time. It may be appropriate to recommend a lower temperature to preserve the immunological components, but this may impact on the defined threshold for discarding milk. If the temperature is lower, then the time may need to be extended.	56 or 57 (+ or -) degrees C for 30 minutes
MHMB20h	63.0 degrees C for 30 minutes	7	1	0	4	3	Agree	No consensus	No consensus		See MHMB20	...
MHMB20i	65.0 degrees C for 30 minutes	3	2	0	1	5	Do not agree	No consensus	No consensus		See MHMB20	...
MHMB20j	72.0 degrees C for 10 seconds	5	1	1	1	5	Uncertain	No consensus	No consensus		See MHMB20	...
MHMB20k	72.0 degrees C for 15 seconds	5	1	1	1	5	Uncertain	No consensus	No consensus		See MHMB20	...
MHMB20l	90.0 degrees C for 10 minutes	2	2	1	0	5	Do not agree	No consensus	Consensus		See MHMB20	...
MHMB20m	100.0 degrees C for 5 minutes	1	2	1	0	5	Do not agree	No consensus	Consensus		See MHMB20	...
	Alternatively, treat using											Alternatively, treat using
MHMB21a	heating to 105.0 degrees C, then freeze-thawing	2	3	0	0	5	Do not agree	No consensus	Consensus		The Dairy industry is using this method increasingly, but currently there is little evidence in its use in donor milk banks and it requires a high capital investment.	heating to 105.0 degrees C, then freeze-thawing (RESEARCH REC – to be moved)

MHMB21b	high-pressure	4.5	2	1	1	4	Uncertain	No consensus	No consensus		See MHMB21a	high-pressure (RESEARCH REC – to be moved)
MHMB22a	<u>After treatment</u> , test all samples	4.5	3	0	3	2	Uncertain	No consensus	No consensus	Median 2 7-9 2 D/K 3 **Corrected to Do not agree – NO con – NO con	Routine post pasteurisation also can check that samples have not been contaminated through leakage into the bottles and may identify some specific contamination.	<u>After treatment</u> , test all samples

MHMB22b	a random selection of samples	8	2	0	5	1	Agree	No consensus	No consensus	7-9 6 D/K 0 **Corrected to Agree – Con – NO con	A accurate pasteurisation log with some indicative testing should be enough to be confident that the process has worked. Testing should be done to check that the pasteurisation process has worked so levels of alkaline phosphatase and other indicator tests (bacterial) should be measured both routinely (as part of a defined quality control programme), and after any changes in the process, if there is any suspicion of problem or for a specific reason. The timing of the quality control testing should be based on volume and throughput.	a random selection of samples
MHMB22c	samples only once a week	1	4	1	0	3	Do not agree	No consensus	Consensus		The timing of the quality control testing should be based on volume and throughput.	samples only once a week

MHMB22d	samples only twice a month	1	4	0	1	3	Do not agree	No consensus	No consensus		The timing of the quality control testing should be based on volume and throughput.	samples only twice a month
MHMB22e	samples four times a year	1	5	0	0	3	Do not agree	No consensus	Consensus		The timing of the quality control testing should be based on volume and throughput.	samples four times a year
MHMB22f	1 in 40 bottles	1	3	2	0	3	Do not agree	No consensus	Consensus		The timing of the quality control testing should be based on volume and throughput.	1 in 40 bottles
MHMB23	<u>After treatment</u> , test samples for										Testing should be done to check that the pasteurisation process has worked so levels of alkaline phosphatase and other indicator tests (bacterial) should be measured.	<u>After treatment</u> , test samples for
MHMB23a	environmental or other contaminants	1	4	1	1	2	Do not agree	No consensus	No consensus		See MHMB23	...
MHMB23ai	o DDT concentrations	1	4	1	1	2	Do not agree	No consensus	No consensus		See MHMB23	...
MHMB23aii	o water	1	4	1	1	2	Do not agree	No consensus	No consensus		See MHMB23	...
MHMB23aiii	o cow's milk	1	3	1	1	3	Do not agree	No consensus	No consensus		See MHMB23	...
MHMB23bi	viral infection	1	5	0	0	3	Do not agree	No consensus	Consensus		See MHMB23	...
MHMB23bii	o CMV	1	5	0	0	3	Do not agree	No consensus	Consensus		See MHMB23	...
MHMB23biii	o MRSA	1	5	0	0	3	Do not agree	No consensus	Consensus		See MHMB23	...
MHMB23biv	o HIV	1.5	5	0	1	2	Do not agree	No consensus	No consensus		See MHMB23	...

MHMB23bv	○ Semliki Forest virus	1.5	5	0	1	2	Do not agree	No consensus	No consensus		See MHMB23	...
MHMB23bvi	○ herpes simplex virus	1.5	6	0	0	2	Do not agree	No consensus	Consensus	**Corrected to Do not agree – CON – CON	See MHMB23	...
MHMB23bvii	○ coxsackie virus	1.5	5	0	1	2	Do not agree	No consensus	No consensus		See MHMB23	...
MHMB23bviii	○ HTLV-1	1.5	5	0	1	2	Do not agree	No consensus	No consensus		See MHMB23	...
MHMB23bix	○ hepatitis B	2	5	1	0	2	Do not agree	No consensus	Consensus		See MHMB23	...
MHMB23bx	○ hepatitis C	2	5	1	0	2	Do not agree	No consensus	Consensus		See MHMB23	...
MHMB23ci	• bacterial contamination	8	1	0	6	1	Agree	No consensus	No consensus	**Corrected to Agree – CON – CON	See MHMB23	...
MHMB23cii	○ enteric pathogens	7.5	2	0	4	2	Agree	No consensus	No consensus		See MHMB23	...
MHMB23ciii	○ pathogens with the potential to be enteric	7.5	2	0	4	2	Agree	No consensus	No consensus		See MHMB23	...
MHMB23civ	○ non-pathogenic organisms	8	2	0	3	3	Agree	No consensus	No consensus		See MHMB23	...
MHMB23cv	○ coliform bacteria	7.5	1	0	5	2	Agree	No consensus	No consensus		See MHMB23	...
MHMB23cvi	○ saprophytic bacteria	8	2	0	3	3	Agree	No consensus	No consensus		See MHMB23	...
MHMB23cvii	○ heat resistant bacillus	7.5	2	0	4	2	Agree	No consensus	No consensus		See MHMB23	...
MHMB23cviii	○ from mastitis	2.5	4	0	2	2	Do not agree	No consensus	No consensus		See MHMB23	...
MHMB23cix	○ Salmonella Kottbus	7.5	2	0	4	2	Agree	No consensus	No consensus		See MHMB23	...
MHMB23cx	○ normal breast flora	2	5	0	2	1	Do not agree	No consensus	No consensus		See MHMB23	...
MHMB23cxi	○ commensal skin flora	3	4	0	3	1	Do not agree	No consensus	No consensus		See MHMB23	...
MHMB23cxii	○ Staph epidermis	5.5	3	0	3	2	Uncertain	No consensus	No consensus		See MHMB23	...
MHMB23cxiii	○ Staph aureus	7.5	2	0	4	2	Agree	No consensus	No consensus		See MHMB23	...
MHMB23cxiv	○ Staph albus	8	2	0	3	3	Agree	No consensus	No consensus		See MHMB23	...

MHMB23cxv	○ viridans streptococci	8	2	0	3	3	Agree	No consensus	No consensus		See MHMB23	...
MHMB23cxvi	○ diphtheroids	8	2	0	3	3	Agree	No consensus	No consensus		See MHMB23	...
MHMB23cxvii	○ gram-negative rod	8	2	0	3	3	Agree	No consensus	No consensus		See MHMB23	...
MHMB23cxviii	○ haemolytic streptococci	7.5	2	0	4	2	Agree	No consensus	No consensus		See MHMB23	...
MHMB23cxix	○ Strep faecalis	7.5	2	0	4	2	Agree	No consensus	No consensus		See MHMB23	...
MHMB23cxx	○ Pseud spp	7	2	1	3	2	Agree	No consensus	No consensus		See MHMB23	...
MHMB23cxxi	○ Proteus spp	8	2	0	3	3	Agree	No consensus	No consensus		See MHMB23	...
MHMB23cxxii	○ Enterobacteriaceae	7.5	1	0	5	2	Agree	No consensus	No consensus		See MHMB23	...
MHMB23cxxiii	○ enterococci	8	2	0	3	3	Agree	No consensus	No consensus		See MHMB23	...
MHMB23cxxiv	○ Klebsiella	8	2	0	3	3	Agree	No consensus	No consensus		See MHMB23	...
MHMB23cxv	○ E coli	8	2	0	5	1	Agree	No consensus	No consensus		See MHMB23	...
MHMB23cxvi	○ listeria	8	2	0	5	1	Agree	No consensus	No consensus		See MHMB23	...
MHMB23di	● nutritional factors	5	2	2	2	2	Uncertain	No consensus	No consensus	4-6 3 7-9 0 D/K 3 **Corrected to Uncertain – NO Con – Con	See MHMB23	...
MHMB23dii	○ fat	5	2	3	2	1	Uncertain	No consensus	No consensus		See MHMB23	...
MHMB23diii	○ caloric value (energy)	5	2	3	2	1	Uncertain	No consensus	No consensus		See MHMB23	...
MHMB23div	○ carbohydrate	5	2	3	2	1	Uncertain	No consensus	No consensus		See MHMB23	...
MHMB23dv	○ protein	5	2	3	2	1	Uncertain	No consensus	No consensus		See MHMB23	...
MHMB23dvi	○ lactose	5	2	4	1	1	Uncertain	No consensus	No consensus		See MHMB23	...
MHMB23dvii	○ vitamins	5	2	4	1	1	Uncertain	No consensus	No consensus		See MHMB23	...

MHMB23dviii	○ minerals	5	3	3	1	1	Uncertain	No consensus	No consensus		See MHMB23	...
MHMB23dix	○ sodium	5	3	3	1	1	Uncertain	No consensus	No consensus		See MHMB23	...
MHMB23dx	○ zinc	5	3	3	1	1	Uncertain	No consensus	No consensus		See MHMB23	...
MHMB23dxi	○ immunologic factors	5	2	4	1	1	Uncertain	No consensus	No consensus		See MHMB23	...
MHMB23dxii	○ enzyme activity	5	2	3	1	2	Uncertain	No consensus	No consensus	4-6 4 D/K 1	See MHMB23	...
MHMB23e	• acidity	3.5	2	1	1	4	Uncertain	No consensus	No consensus		See MHMB23	...
MHMB23f	• alkaline phosphatase	5	2	2	2	2	Uncertain	No consensus	No consensus	1-3 1 D/K 3	See MHMB23	...
	Discard <u>samples after treatment</u> that contain											Discard <u>samples after treatment</u> that contain
MHMB24a	• any organisms	9	1	1	3	3	Agree	No consensus	No consensus	Median 7 1-3 2 D/K 2	The GDG deferred this recommendation to the next meeting	...
MHMB24ai	• $\geq 10^2$ CFU/ml of any organisms	8	2	0	3	3	Agree	No consensus	No consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24aii	• $\geq 10^3$ CFU/ml of any organisms	8	1	0	4	3	Agree	No consensus	No consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24aiii	• $\geq 10^4$ CFU/ml of any organisms	8	1	0	5	2	Agree	No consensus	No consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24aiv	• $\geq 10^5$ CFU/ml of any organisms	9	1	0	4	3	Agree	No consensus	No consensus		The GDG deferred this recommendation to the next meeting	...

MHMB24av	• $\geq 10^6$ CFU/ml of any organisms	9	1	0	4	3	Agree	No consensus	No consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24bi	• any skin commensals	8	1	1	4	2	Agree	No consensus	No consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24bii	• $\geq 10^2$ CFU/ml of skin commensals	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24biii	• $\geq 10^4$ CFU/ml of skin commensals	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24biv	• $\geq 10^5$ CFU/ml of skin commensals	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24bv	• $\geq 10^6$ CFU/ml of skin commensals	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24biv	• $\geq 10^6$ CFU/ml of skin commensals	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24ci	• any Staph aureus	8.5	0	1	5	2	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...

MHMB24cii	• $\geq 10^2$ CFU/ml of Staph aureus	8	0	0	4	4	Agree	No consensus	Consensus	Median 9 7-9 4 D/K 5	The GDG deferred this recommendation to the next meeting	...
MHMB24ciii	• $\geq 10^4$ CFU/ml of Staph aureus	9	0	0	3	5	Agree	No consensus	Consensus	7-9 4 D/K 4	The GDG deferred this recommendation to the next meeting	...
MHMB24civ	• $\geq 10^5$ CFU/ml of Staph aureus	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24cv	• $\geq 10^6$ CFU/ml of Staph aureus	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24civ	• $\geq 10^6$ CFU/ml of Staph aureus	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24di	• any gram-negative rod bacteria	8.5	1	0	5	2	Agree	No consensus	No consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24dii	• $\geq 10^2$ CFU/ml of any gram-negative rod bacteria	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24diii	• $\geq 10^4$ CFU/ml of any gram-negative rod bacteria	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...

MHMB24div	• $\geq 10^5$ CFU/ml of any gram-negative rod bacteria	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24dv	• $\geq 10^6$ CFU/ml of any gram-negative rod bacteria	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24div	• $\geq 10^6$ CFU/ml of any gram-negative rod bacteria	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24ei	• any haemolytic streptococci	8.5	0	1	5	2	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24eii	• $\geq 10^2$ CFU/ml of any haemolytic streptococci	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24eiii	• $\geq 10^3$ CFU/ml of any haemolytic streptococci	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24eiv	• $\geq 10^4$ CFU/ml of any haemolytic streptococci	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24ev	• $\geq 10^5$ CFU/ml of any haemolytic streptococci	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...

MHMB24eiv	• $\geq 10^6$ CFU/ml of any haemolytic streptococci	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24fi	• any Strep faecalis	8	0	1	6	1	Agree	No consensus	Consensus	**Corrected to Agree – CON - con	The GDG deferred this recommendation to the next meeting	...
MHMB24fii	• $\geq 10^2$ CFU/ml of Strep faecalis	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24fiii	• $\geq 10^3$ CFU/ml of Strep faecalis	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24fiv	• $\geq 10^4$ CFU/ml of Strep faecalis	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24fv	• $\geq 10^5$ CFU/ml of Strep faecalis	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24fiv	• $\geq 10^6$ CFU/ml of Strep faecalis	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24gi	• any heat-resistant bacteria	9	1	0	4	3	Agree	No consensus	No consensus		The GDG deferred this recommendation to the next meeting	...

MHMB24gii	• $\geq 10^2$ CFU/ml of any heat-resistant bacteria	7.5	0	2	2	4	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24giii	• $\geq 10^3$ CFU/ml of any heat-resistant bacteria	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24giv	• $\geq 10^4$ CFU/ml of any heat-resistant bacteria	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24gv	• $\geq 10^5$ CFU/ml of any heat-resistant bacteria	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24gvi	• $\geq 10^6$ CFU/ml of any heat-resistant bacteria	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24hi	• any Pseudomonas	9	0	1	4	3	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24hii	• $\geq 10^2$ CFU/ml of Pseudomonas	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24hiii	• $\geq 10^3$ CFU/ml of Pseudomonas	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...

MHMB24hiv	• $\geq 10^4$ CFU/ml of Pseudomonas	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24hv	• $\geq 10^5$ CFU/ml of Pseudomonas	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24hiv	• $\geq 10^6$ CFU/ml of Pseudomonas	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24ji	• any Klebsiella	9	0	1	4	3	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24jii	• $\geq 10^2$ CFU/ml of Klebsiella	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24jiii	• $\geq 10^3$ CFU/ml of Klebsiella	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24jiv	• $\geq 10^4$ CFU/ml of Klebsiella	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24jv	• $\geq 10^5$ CFU/ml of Klebsiella	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...

MHMB24jiv	• $\geq 10^6$ CFU/ml of Klebsiella	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24ki	• any Proteus	9	0	1	4	3	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24kii	• $\geq 10^2$ CFU/ml of Proteus	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24kiii	• $\geq 10^3$ CFU/ml of Proteus	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24kiv	• $\geq 10^4$ CFU/ml of Proteus	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24kv	• $\geq 10^5$ CFU/ml of Proteus	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24kiv	• $\geq 10^6$ CFU/ml of Proteus	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24li	• any entero-pathogenic bacteria	8.5	0	0	6	2	Agree	No consensus	Consensus	**Corrected to Agree – CON - con	The GDG deferred this recommendation to the next meeting	...

MHMB24lii	• $\geq 10^2$ CFU/ml of any entero-pathogenic bacteria	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24liii	• $\geq 10^3$ CFU/ml of any entero-pathogenic bacteria	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24liv	• $\geq 10^4$ CFU/ml of any entero-pathogenic bacteria	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24lv	• $\geq 10^5$ CFU/ml of any entero-pathogenic bacteria	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB24liv	• $\geq 10^6$ CFU/ml of any entero-pathogenic bacteria	9	0	0	3	5	Agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
	Discard <u>samples after treatment</u> that contain										The GDG deferred this recommendation to the next meeting	...
MHMB25ai	• environmental or other contaminants	6	1	1	2	4	Uncertain	No consensus	No consensus		The GDG deferred this recommendation to the next meeting	...
MHMB25aii	○ DDT concentrations	6	1	2	2	3	Uncertain	No consensus	No consensus		The GDG deferred this recommendation to the next meeting	...

MHMB25aiii	○ water	3	2	2	0	4	Do not agree	No consensus	Consensus		The GDG deferred this recommendation to the next meeting	...
MHMB25iv	○ cow's milk	4	2	0	2	4	Uncertain	No consensus	No consensus		The GDG deferred this recommendation to the next meeting	...
MHMB25bi	• viral infection	8.5	1	1	6	0	Agree	No consensus	No consensus	**Corrected to Agree – CON – no con	The GDG deferred this recommendation to the next meeting	...
MHMB25bii	○ CMV	8	1	1	5	1	Agree	No consensus	No consensus		The GDG deferred this recommendation to the next meeting	...
MHMB25biii	○ MRSA	8	1	1	5	1	Agree	No consensus	No consensus		The GDG deferred this recommendation to the next meeting	...
MHMB25biv	○ HIV	8	1	0	6	1	Agree	No consensus	No consensus	**Corrected to Agree – CON – no con	The GDG deferred this recommendation to the next meeting	...
MHMB25bv	○ Semliki Forest virus	8	1	0	6	1	Agree	No consensus	No consensus	**Corrected to Agree – CON – no con	The GDG deferred this recommendation to the next meeting	...
MHMB25bvi	○ herpes simplex virus	8	1	0	6	1	Agree	No consensus	No consensus	**Corrected to Agree – CON – no con	The GDG deferred this recommendation to the next meeting	...

MHMB25bvii	○ coxsackie virus	8	1	0	6	1	Agree	No consensus	No consensus	**Corrected to Agree – CON – no con	The GDG deferred this recommendation to the next meeting	...
MHMB25bviii	○ HTLV-1	8	1	0	6	1	Agree	No consensus	No consensus	**Corrected to Agree – CON – no con	The GDG deferred this recommendation to the next meeting	...
MHMB25bvix	○ hepatitis B	8	1	1	5	1	Agree	No consensus	No consensus		The GDG deferred this recommendation to the next meeting	...
MHMB25bx	○ hepatitis C	8	1	1	5	1	Agree	No consensus	No consensus		The GDG deferred this recommendation to the next meeting	...
MHMB26a	Discard samples stored, <u>post expression and post testing and treating</u> in the refrigerator for 1 day	1	4	1	0	3	Do not agree	No consensus	Consensus	7-9 1 D/K 2 **Corrected to Do not agree – no Con –NO con	...	Discard samples stored, <u>post expression and post testing and treating</u> in the refrigerator immediately after pasteurisation and should be put in the freezer as soon as it has cooled to fridge temperature
MHMB26b	• in the refrigerator for 2 days	4	3	0	3	2	Uncertain	No consensus	No consensus		See MHMB26a	...
MHMB26c	• in the refrigerator for 3 days	5	3	0	3	2	Uncertain	No consensus	No consensus		See MHMB26a	...
MHMB26d	• in the refrigerator for 4 days	5	3	0	3	2	Uncertain	No consensus	No consensus		See MHMB26a	...

MHMB26e	in the refrigerator for 5 days	7	3	0	4	1	Agree	No consensus	No consensus		See MHMB26a	...
MHMB26f	in the freezer for 1 week	1.5	4	0	2	2	Do not agree	No consensus	No consensus		See MHMB26a	...
MHMB26g	in the freezer for 2 weeks	1.5	4	0	2	2	Do not agree	No consensus	No consensus		See MHMB26a	...
MHMB26h	in the freezer for 1 month	1	5	0	1	2	Do not agree	No consensus	No consensus		See MHMB26a	...
MHMB26i	in the freezer for 2 months	1	5	0	1	2	Do not agree	No consensus	No consensus		See MHMB26a	...
MHMB26j	in the freezer for 3 months	2	4	0	2	2	Do not agree	No consensus	No consensus	This links with the maximum of 3 months in the donor's home freezer to sum to a total of 6 months.	in the freezer for 3 months	
MHMB26k	in the freezer for 4 months	2	4	0	2	2	Do not agree	No consensus	No consensus		See MHMB26a	...
MHMB26l	in the freezer for 5 months	2	4	0	2	2	Do not agree	No consensus	No consensus		See MHMB26a	...
MHMB26m	in the freezer for 6 months	7	3	0	4	1	Agree	No consensus	No consensus		See MHMB26a	...
MHMB27	Refrigerate samples for use.	2	5	2	1	0	Do not agree	No consensus	No consensus		See MHMB26a	...
MHMB28	Freeze samples for use.	8.5	1	0	7	0	Agree	Consensus	No consensus		See MHMB26a	...
MHMB29	Freeze-dry samples for use.	5	1	3	0	4	Uncertain	No consensus	Consensus		See MHMB26a	...
MHMB30	Before selecting for use, always choose the 'newest' samples first.	2	6	2	0	0	Do not agree	No consensus	Consensus	**Corrected to Do not agree – CON - con	...	Before selecting for use, generally choose the 'oldest' batches first.
MHMB31a	Milk should be processed using containers made of glass	6	3	1	3	1	Uncertain	No consensus	No consensus		Concerns expressed about glass containers included the risk of chipping or cracking.	Milk should be processed using containers made of glass

MHMB31b	plastic	3	4	2	1	1	Do not agree	No consensus	No consensus		Concerns expressed about plastic containers included the risk of chipping or cracking. Also, not all plastic is food grade grade and polycarbonate contains bisphenol A.	plastic
MHMB31c	food-grade plastic	7	1	1	5	1	Agree	No consensus	No consensus		The GDG deferred this recommendation to the next meeting	food-grade plastic
MHMB31d	any material that can withstand the necessary hot and cold temperatures	2	6	0	1	1	Do not agree	No consensus	No consensus	**Corrected to Do not agree – CON – no con	The GDG deferred this recommendation to the next meeting	any material that can withstand the necessary hot and cold temperatures
MHMB31e	stainless steel	4	2	2	1	3	Uncertain	No consensus	No consensus		The GDG deferred this recommendation to the next meeting	stainless steel
	Containers and equipment should be											Containers and equipment should be
MHMB32a	washed in cold, soapy water	1	6	0	1	1	Do not agree	No consensus	No consensus	**Corrected to Do not agree – CON – no con	See MHMB32e	...
MHMB32b	washed in hot, soapy water	1	4	1	2	1	Do not agree	No consensus	No consensus		See MHMB32e	...
MHMB32c	sterilized using sterilizing fluid	1	5	1	1	1	Do not agree	No consensus	No consensus		See MHMB32e	...
MHMB32d	sterilized by heating in an oven	1	5	1	1	1	Do not agree	No consensus	No consensus		See MHMB32e	...
MHMB32e	sterilized by autoclaving	8	0	0	7	1	Agree	Consensus	Consensus		...	sterilized by autoclaving

MHMB32f	disposed of after one use	5	2	1	2	3	Uncertain	No consensus	No consensus		See MHMB32e	...
MHMB32g	washed in the dishwasher, if possible	2.5	3	3	0	2	Do not agree	No consensus	Consensus		See MHMB32e	...
MHMB33	Wear gloves at all times when handling donor milk.	9	1	1	6	0	Agree	No consensus	No consensus	**Corrected to Agree – CON – no con	Gloves are important to minimise contamination of the milk. Usual hospital practice is to change gloves between procedures and local infection control protocols should be followed.	Wear gloves at all times when handling donor milk. (TO Look at how often change the gloves & protective clothing in general. Infection control guideline?)

Round 1 – milk pooling

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	GDG considerations	Recommendation for Round 2
MPool1	Pool raw milk within donors (that is, milk from the same donor).	7.5	3	0	5	1	Agree	No consensus	No consensus	...	Pool raw (pre treated) milk within donors (that is, milk from the same donor).
MPool2	Pool raw milk between donors (that is, milk from different donors).	1	8	0	0	1	Do not agree	Consensus	Consensus	...	Do not pool raw milk between donors (that is, milk from different donors).
MPool3	Pool treated milk within donors (that is, milk from the same donor).	5.5	2	3	3	1	Uncertain	No consensus	No consensus	There are theoretical advantages to pooling (dilution of contaminants, more uniformity of milk etc) but because of tracking back, there is a widespread concern about pooling between donors. In the UK context of CJD and other as yet un-recognised risks, then there are justifiable reasons not to pool. A general principle should be that donor exposure is limited for any recipient baby so that would automatically preclude pooling between donors. Ideally, milk banks should not pool the treated milk as this would involve opening containers and this could introduce contamination. But there may be occasions at feeding, where small amounts would be pooled post treatment.	Do not pool treated milk within donors (that is, milk from the same donor). Would be some occasions where may need to pool treated milk
MPool4	Pool treated milk between donors (that is, milk from different donors).	1	7	1	0	1	Do not agree	Consensus	Consensus	...	Do not pool treated milk between donors (that is, milk from different donors).
MPool5	Pool all milk within donors (that is, milk from the same donor).	1.5	5	2	1	1	Do not agree	No consensus	No consensus	Milk banks should never pool treated and untreated milk as would be completely illogical.	...

MPool6	Pool <u>all</u> milk between donors (that is, milk from different donors).	1	7	1	0	1	Do not agree	Consensus	Consensus	...	Do not pool <u>all</u> milk between donors (that is, milk from different donors).

Round 1 – fortification of donor milk

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	GDG considerations	Recommendation for Round 2
MFort1	Fortify all milk routinely.	The GDG agreed not to rate these recommendations as complete consensus and recommendations not relevant to this guideline.								Milk banks should not fortify milk as part of the processing of donor milk. Fortification of carbohydrates and proteins – when mixed with milk - increases osmolality over time and therefore should be added immediately before feeding. If a milk bank acts as a milk kitchen, then fortification would be done, but this is not within the process of milk banking. If milk is to be fortified this should only be done immediately prior to delivery – also the fortifiers may not be sterile, so again need to be done at the point of delivery, according to the manufacturers. The GDG did not recommend routine compositional testing as part of the process of milk banking, so fortification can only be prescribed by the neonatologists for the individual baby. In principle, milk banks should not be involved in adding anything to the milk, and to limit contamination, pasteurised bottles should not be opened until the point of feeding.	Donor breast milk, if fortified or other additives, should only be done so immediately prior to feeding. Do not open the lid until the point of delivery (feeding) this includes fortification or other additives.
MFort2	Fortify milk to match the content of the milk to the recipient.										(Milk Banks should not be responsible for adding anything to the milk)
MFort3	Fortify milk to match the nutritional content of the milk to the recipient.										...
MFort4	Fortify milk to match the immunological content of the milk to the recipient.										...
MFort5	Fortify milk without an analysis of the content of the milk.										...
MFort6	Fortify milk without a nutritional analysis of the content of the milk.										...
MFort7	Fortify milk without an immunological analysis of the content of the milk.										...

Round 1 – track and trace

See also the chapter on quality assurance principles for donor milk banking.

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	Changes made post meeting	GDG considerations	Recommendation for Round 2
MTrackTrace1	Do not systematically monitor milk samples so they can be tracked and traced.	1	8	0	0	1	Do not agree	Consensus	Consensus		There are two aims of the administration of milk samples • stock control • traceability If there was a barcoding system, this would do both tracking and tracing, and stock control. Currently this monitoring is done manually. And therefore we need to ensure that the track and trace and the QA documentation are linked and that there is a minimum of duplication of effort...	Monitor milk samples so they can be tracked and traced.
MTrackTrace2	Track and trace milk samples.	9	0	0	8	1	Agree	Consensus	Consensus		...	Track and trace milk samples.
MTrackTrace3	Track and monitor milk processing.	9	0	0	8	1	Agree	Consensus	Consensus		...	Track and monitor milk processing.

	Maintain and monitor the following:										...	Monitoring would include: freezer temperatures, pasteurisation, stock control
MTrackTrace4a	a registry of 'raw' milk donors	9	0	0	8	1	Agree	Consensus	Consensus		(Not making recommendation on the use of 'raw' milk)	...
MTrackTrace4bi	donor record	9	0	0	8	1	Agree	Consensus	Consensus		...	donor record
MTrackTrace4bii	- medical record/NHS number	9	0	0	8	1	Agree	Consensus	Consensus		...	- medical record/NHS number
MTrackTrace4biii	- consent	9	0	0	8	1	Agree	Consensus	Consensus		...	- consent
MTrackTrace4biv	- medical history questionnaire	9	0	0	8	1	Agree	Consensus	Consensus		...	- medical history questionnaire
MTrackTrace4bv	- pathology results	9	0	1	7	1	Agree	Consensus	Consensus		...	- pathology results
MTrackTrace4ci	labeling of each sample	9	0	0	6	3	Agree	No consensus	Consensus		...	- labeling of each sample - Labeling pre/post pasteurisation: - Unique ID – each bottle should have one - That it is DBM - Batch number - Expiry date
MTrackTrace4cii	- donor identity	9	1	0	7	1	Agree	Consensus	No consensus		...	- donor identity (name or unique ID)
MTrackTrace4ciii	- details of medication (if taken)	6.5	2	2	4	1	Agree	No consensus	No consensus		...	...
MTrackTrace4civ	- date of expression	9	1	0	7	1	Agree	Consensus	No consensus		...	- date of expression
MTrackTrace4cv	- date of collection	9	1	1	6	1	Agree	No consensus	No consensus		...	...
MTrackTrace4cvi	- date of deposit	9	1	1	6	1	Agree	No consensus	No consensus		...	...
MTrackTrace4cvii	- date of bacteriologic clearance	9	2	0	6	1	Agree	No consensus	No consensus		...	...

MTrackTrace4cviii	○ expiry date	9	0	0	8	1	Agree	Consensus	Consensus		...	
MTrackTrace4di	• testing log	9	1	0	5	3	Agree	No consensus	No consensus		...	• testing log
MTrackTrace4dii	○ nutritional analysis	1	5	1	1	2	Do not agree	No consensus	No consensus		...	...
MTrackTrace4diii	○ tests undertaken	9	0	0	8	1	Agree	Consensus	Consensus		...	○ tests undertaken and results thereof
MTrackTrace4div	○ results of testing before pasteurisation	9	0	1	7	1	Agree	Consensus	Consensus		...	...
MTrackTrace4dv	○ results of testing after pasteurisation	9	0	1	7	1	Agree	Consensus	Consensus		...	...
MTrackTrace4ei	• labeling of each pool	9	0	0	6	3	Agree	No consensus	Consensus	7-9 5 D/K 4	...	...
MTrackTrace4eii	○ between different donors	9	1	0	2	6	Agree	No consensus	No consensus	Median 5 7-9 5 D/K 7 **Corrected to Uncertain – No con – No con	...	...
MTrackTrace4eiii	○ within individual donors	9	0	0	6	3	Agree	No consensus	Consensus	7-9 5 D/K 4	...	...
MTrackTrace4fi	• pasteurization undertaken	9	0	0	7	2	Agree	Consensus	Consensus		...	• pasteurization undertaken
MTrackTrace4fii	○ details of the pasteurisation	9	0	1	7	1	Agree	Consensus	Consensus		...	○ date of the pasteurisation
MTrackTrace4gi	• record of recipient use	9	0	0	6	3	Agree	No consensus	Consensus		...	• record of recipient use
MTrackTrace4gii	○ sample(s) used	9	0	0	8	1	Agree	Consensus	Consensus		...	○ sample(s) used
MTrackTrace4giii	○ consent	9	0	1	7	1	Agree	Consensus	Consensus		...	○ consent

MTrackTRace5	NEW recommendation										Record of recipient use should be documented in the patient's notes. The duty of care should be documented, at dispensing level (as with blood products)/. It is therefore the responsibility of the receiving hospital to document fully the recipient information (full audit trail).	It is the receiving hospital's responsibility to document the recipient
MTrackTRace6	NEW recommendation										...	Archiving samples – in line with blood bank milk banks should archive samples for look back and should consider working with blood banks – get advice from tissue banking – clinical expert: transfusional haematologist
MTrackTRace7	NEW recommendation										...	Each aliquot needs to be identified within an individual process and individual batch: At every key stage of the process Milk banks must be able to track back
MTrackTRace8	NEW recommendation										...	Records keeping: Data needed for full traceability shall be kept for a least 30 years and preferably up to ?

Round 1 – transportation

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	GDG considerations	Recommendation for Round 2

MHTrans1a	Transport milk for donation refrigerated									The GDG recognized that they will accept refrigerated milk in some cases, so it does need to be transported, but frozen milk is preferred. Two issues are relevant here – the state and temperature and whether donations are transported by the designated 'carrier' from the milk bank or by the donor. It was recognized that processes used in tissue transportation would be expensive and may not be appropriate for donor milk– but the principle should be that there is demonstrable adherence to processes and that temperatures are monitored. Again, this links closely with the decisions made on pastuerisation, as if the recommended pasteurisation temperature is lowered, then we would need to be even more confident in the safety and monitoring during other stages – such as transport. Temperature is a surrogate marker and measuring only on receipt is not enough. Options include measurement and monitoring by probe. A good practice principle should be that the temperature should be stable – if arrives thawed should then be processed immediately – if reached ambient temp and only in 2 hours, then would process. As new services will be set up, we need to make sure that knowledge and practice are communicated.	Transport milk for donation Temperature should be kept stable (leave frozen and arrive frozen)
		6	3	3	3	0	Uncertain	No consensus	No consensus	10	

MHTrans1b	frozen	9	0	0	9	0	Agree	Consensus	Consensus	After this discussion, the GDG agreed that only frozen milk should be accepted – this is because of the lack of evidence on transportation and the lack of good practice. So any donations should leave the donor's home frozen, arrive frozen at the milk bank, be labelled, and be frozen at any point. The consequences of moving to frozen milk alone are not substantial in the UK, and would improve the confidence in the safety. Some minimal amounts will be refused, and only those women who do not have access to any freezing facilities will not be able to donate.	Milk which was previously frozen but arrives thawed should be processed
MHTrans1c	at ambient temperature	1	8	1	0	0	Do not agree	Consensus	Consensus	See MHTrans1b	Good practice principles should be adhered to
MHTrans1d	in the state received	5	3	3	3	0	Uncertain	No consensus	No consensus	See MHTrans1b	Label the milk with what state the milk was in when transported (frozen)
MHTrans2a	Transport milk from the donor's home by air	5	2	1	2	4	Uncertain	No consensus	No consensus	Any mode of collection is acceptable as long as the recommended process is followed and monitored– so that the milk bank can be confident that quality is maintained.	Transport milk by an appropriate means ensuring a temperature stable environment

MHTrans2b	by package or parcel couriers	7.5	1	0	3	5	Agree	No consensus	No consensus	See MHTrans2a	...
MHTrans2c	by taxi	6	2	1	2	4	Uncertain	No consensus	No consensus	See MHTrans2a	...
MHTrans2d	using a designated milk bank vehicle	8	0	0	5	4	Agree	No consensus	Consensus	See MHTrans2a	...
MHTrans2e	using a Trust or other car	8	0	1	4	4	Agree	No consensus	Consensus	See MHTrans2a	...
MHTrans2f	any appropriate means.	9	1	1	7	0	Agree	Consensus	No consensus	Could transport using a 'responsible' person or system. May need additional guidance Need to ensure that the process is followed – so that quality is maintained.	When transporting from a milk bank transport the milk in a frozen state
MHTrans3	Accept donations delivered by the donor, or her representative (partner, family member).	8	0	0	9	0	Agree	Consensus	Consensus	Any mode of collection is acceptable as long as the recommended process is followed and monitored– so that the milk bank can be confident that quality is maintained.	Accept donations delivered by the donor, or her representative (partner, family member).
MHTrans4	Employ a member of staff (not a nurse) to collect the milk.	7.5	0	0	8	1	Agree	Consensus	Consensus	Any mode of collection is acceptable as long as the recommended process is followed and monitored– so that the milk bank can be confident that quality is maintained.	Employ a member of staff (not a nurse) to collect the milk. Designated and agreed transport preferably a Medical courier, in cases where this is not possible, should use appropriate actions such as sign out when leaving and sign in when arriving
MHTrans5	Use volunteers to collect the milk.	7	1	0	8	0	Agree	Consensus	No consensus	See MHTrans3-4	...
MHTrans6	Employ a nurse to collect the milk.	6	4	1	4	0	Uncertain	No consensus	No consensus	See MHTrans3-4	...
MHTrans7	Collect the milk from the donor's home.	9	1	0	8	0	Agree	Consensus	No consensus	...	Collect the milk from the donor's home.

MHTrans8	Collect the milk from other designated places, such as a local grocery store.	5	3	2	4	0	Uncertain	No consensus	No consensus	...	Collect the milk from other designated places, such as a depot, which have practices in place to monitor the freezers and maintain the standards for quality control, storage and security.
MHTrans9a	Transport the milk in styrofoam containers	8	0	2	5	2	Agree	No consensus	Consensus	...	Transport the milk in styrofoam containers. British standard for cool boxes – look at this
MHTrans9b	cooler boxes	8	0	2	5	2	Agree	No consensus	Consensus	See MHTrans9b	...
MHTrans9c	tin pails	1	9	0	0	0	Do not agree	Consensus	Consensus	See MHTrans9b	...
MHTrans9d	boxes insulated with crumpled newspaper	2	8	0	0	1	Do not agree	Consensus	Consensus	See MHTrans9b	...
MHTrans9e	boxes packed with dry ice	8	0	2	5	2	Agree	No consensus	Consensus	See MHTrans9b	...
MHTrans9f	any container that will maintain the milk at the appropriate temperature	9	1	2	6	0	Agree	No consensus	No consensus	See MHTrans9b	...
	Collect the milk										Collect the milk
MHTrans10a	at least every day	2	9	0	0	0	Do not agree	Consensus	Consensus	See MHTrans10h	...
MHTrans10b	at least every 2 days	3	8	0	1	0	Do not agree	Consensus	No consensus	See MHTrans10h	...
MHTrans10c	at least every 5 days	3	8	1	0	0	Do not agree	Consensus	Consensus	See MHTrans10h	...
MHTrans10d	at least every week	3	7	1	1	0	Do not agree	Consensus	No consensus	See MHTrans10h	...
MHTrans10e	at least every 10 days	3	7	1	1	0	Do not agree	Consensus	No consensus	See MHTrans10h	...
MHTrans10f	at least every 2 weeks	3	7	1	1	0	Do not agree	Consensus	No consensus	See MHTrans10h	...

MHTrans10g	at least every month	7	3	1	5	0	Agree	No consensus	No consensus	See MHTrans10h	...
MHTrans10h	as agreed with the donor	9	1	0	8	0	Agree	Consensus	No consensus	...	as agreed with the donor (see in first set of recs) but at least within 3 months
MHTrans11	NEW recommendation									...	Processes should be put in place to ensure tamper evidence. Similar processes should be in place where the milk is stored. Fridges should meet the standards.

Round 1 – consent

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	GDG considerations	Recommendation for Round 2
Consent1	Obtain consent from each donor prior to accepting any donation.	9	0	0	9	0	Agree	Consensus	Consensus	It was not clear what consent means in this situation – is it implicit that consent on use is in the act of donation?	...
Consent2	Consent should include									There was general agreement that consent should be sought.	Obtain consent from donors before accepting milk, for:
Consent2a	serological testing of the donor	9	0	0	9	0	Agree	Consensus	Consensus		serological testing of the donor
Consent2b	microbiological testing of donated milk	9	0	0	9	0	Agree	Consensus	Consensus		microbiological testing of donated milk
Consent2c	use of donated milk.	9	1	1	7	0	Agree	Consensus	No consensus	The GDG considered the model of tissue donation where donors generally make consent for 'any reasonable use' but additional consent is needed in 'rare' circumstances. For example, some milk donors may not wish their donations to be used in adults. The key is for milk banks to know the recipient population and therefore donors can give informed consent to that use.	use of donated milk (the milk bank should explain clearly the intended use of the milk)
Consent3	[Milk banks should] Obtain consent from the recipient or their representative prior to use.	9	2	0	7	0	Agree	Consensus	No consensus	This was not considered to be the role of the milk bank – no recommendation was therefore made.	...

Consent4	Destroy records of consent after a donor stops donating.	1	8	1	0	0	Do not agree	Consensus	Consensus	The GDG agreed not to make a recommendation on this.	...

Round 1 – quality assurance

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	GDG considerations	Recommendation for Round 2
QA1	Follow quality assurance processes as agreed locally.	7	1	1	7	0	Agree	Consensus	No consensus	The GDG considered this wording to be too vague and consistency across milk banks is needed. Agreed to remove.	...
QA2	All persons involved in the processes of the donor milk bank should recognize the need for quality assurance with management ensuring a systematic approach towards quality and the implementation and maintenance of a quality system.	9	0	0	8	1	Agree	Consensus	Consensus	...	Milk banks should implement and maintain an agreed quality control system for processing milk which is followed by all staff.
QA3	Encompass quality management, quality assurance, continuous quality improvement, personnel, premises and equipment, documentation, collection, testing and processing, storage, distribution, quality control, batch recall, and external and internal auditing, non-conformance and self-inspection in any quality processes.	9	0	0	9	0	Agree	Consensus	Consensus	...	A quality control system for milk banks should encompass: • collection, testing, processing, storage and distribution • personnel, documentation, premises and equipment • batch recall, external and internal auditing, non-conformance and self-inspection • Continuous quality improvement.

QA4	Ensure that all critical processes are specified in appropriate instructions and are carried out in accordance with the standards and specifications set out in these principles. Management shall review the system at regular intervals to verify its effectiveness and introduce corrective measures if deemed necessary.	9	0	0	9	0	Agree	Consensus	Consensus	...	Milk banks should review their quality control system regularly and amend it if needed. Milk bank staff should be given clear written instructions to help them follow the system.
QA5	Use HACCP principles in any quality assurance process.	9	0	0	8	1	Agree	Consensus	Consensus	The Australian donor milk guidelines use HACCP as do the Italian guidelines... HACCP principles are general principles of safety used in food handling, so the concepts should not be new to staff trained in food handling. There was general support for the application of HACCP in milk banking as another process to ensure the safe handling and processing of donor milk.	Use HACCP principles in any quality assurance process agreed locally

Round 1 – test and treat

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	GDG considerations	Recommendation for Round 2
TT1	Advise women who test positive for HIV, hepatitis, or HPV that they should not donate milk.	9	0	0	9	0	Agree	Consensus	Consensus	...	Advise women who test positive for HIV, hepatitis, or HPV that they should not donate milk.
TT2	Test milk before treatment for any bacterial contamination, and discard if - total viable bacterial count is greater than 10^5/ml, or - count of Enterobacteriaceae is greater than 10^4/ml, or - count of Staph aureus is greater than 10^4/ml.	9	1	0	6	2	Agree	No consensus	No consensus	The general principle adopted was that contaminated milk from the mother is OK and safe, but this is more difficult to justify from a non-maternal source so stricter acceptance levels should be applied. The GDG noted however, that any acceptance criteria are arbitrary. The specified micro-organisms will be destroyed at the recommended treatment temperature. If levels of <i>Staph aureus</i> are very high, (above 10^5/ml) toxigenic problems may arise and therefore a lower level was specified; this is also consistent with food levels. Enterobacteriaceae – <i>salmonella</i>, <i>e coli</i> etc – may sometimes be pathogenic but will be destroyed by pasteurisation. There was general acceptance that a combination of TBC and a count of those which are recognised to be problematic in food borne illness would be appropriate (reflecting important contamination rather than simply poor processing).	Test milk before pasteurisation for bacterial contamination and discard it if: - total viable bacterial count is greater than 10^5/ml, or - count of Enterobacteriaceae is greater than 10^4/ml, or - count of Staph aureus is greater than 10^4/ml.
TT3	Microbiology labs should undertake further bacterial tests, as appropriate, if there is any concern about significant or unusual contamination.	9	0	0	9	0	Agree	Consensus	Consensus	...	Microbiology labs should undertake further bacterial tests if there is concern about significant or unusual contamination.

TT4	Cross refer to recommendation on supporting donors if consistently high levels of contamination.	9	0	0	9	0	Agree	Consensus	Consensus	...	Offer support to donors whose milk has consistently high levels of contamination (see recommendation XX).
TT5	Pasteurise milk for donation at 62.5 degrees C for 30 minutes.	9	0	0	8	1	Agree	Consensus	Consensus	...	Pasteurise milk for donation at 62.5 degrees C for 30 minutes.
TT6	Test milk post pasteurisation regularly. The testing schedule should be determined by the milk bank based on the volume and throughput of milk pasteurised.	9	0	1	8	0	Agree	Consensus	Consensus	The GDG raised concerns that if a failure of equipment was not noticed, then babies may be being fed milk with pathogens – this was not an acceptable risk to the baby and to milk banking in general. It was counter-argued that currently only one bottle per cycle is tested so testing in this way may not pick up a problem if there is a problem with the pasteuriser. However, if a full quality assurance process is in place, with appropriate monitoring post pasteurisation this would be the most effective and efficient way to ensure that the processed milk is safe.	Regularly test pasteurised milk for bacterial contamination. Milk banks should decide their testing schedule based on the volume and throughput of milk. Testing should occur: • either at least once a month or every 10 cycles, depending on which comes first, and • on an ad-hoc basis if any new processes, equipment or staff are introduced, or if there are concerns about any part of the process.
TT7	Test post pasteurisation either at least once a month, or every 10 cycles, depending on which comes first.	9	2	0	6	1	Agree	No consensus	Consensus	Added to TT6	...
TT8	Test on an ad-hoc basis if any new processes, equipment, or staff are introduced, or there are concerns about any part of the process.	9	1	1	7	0	Agree	Consensus	Consensus	Added to TT6	...
TT9	Discard any batch that has a total viable bacterial count of 10/ml or more post pasteurisation.	9	0	0	7	2	Agree	Consensus	Consensus	...	Discard milk that has a total viable bacterial count of 10/ml or more post-pasteurisation.

Round 1 – staff training

Recommendations were not rated for this section – we agreed to develop recommendations to address the training needs based on the final recommendations. These recommendations, although not rated, were circulated to the GDG and revisions made as appropriate.

Round 2 – all recommendations

For the final recommendations, including editorial changes (some of which are included in this version), please see the recommendations in the NICE guideline.

RECOMMENDATION	Median	1 - 3	4 - 6	7 - 9	D / K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	Evidence to recommendations	RECOMMENDATION post round 2 discussion
1.1 Donor recruitment									...	...
1.1.1 Aim to reach all potential breast milk donors including mothers who have surplus breast milk.	9	1	0	8	0	Agree	Consensus	No consensus	Agreed to remove final clause.	Aim to reach all potential breast milk donors.
1.1.2 Actively recruit donors through a variety of channels. This can include: • providing written information to be left in: ◇ GP surgeries ◇ antenatal clinics and postnatal wards ◇ volunteer or health-related organisations working in public health ◇ infant, children and maternity shops • through direct referrals or recommendations from: ◇ donors ◇ staff at Neonatal Units ◇ attending paediatricians when assessing the	9	1	0	8	0	Agree	Consensus	No consensus	There was some concern that mass media could be expensive and may not result in any increase in suitable donors. Refined to make clearer. The GDG viewed that this list may be helpful for new milk banks or those banks for whom recruitment is problematic.	Actively recruit donors through a variety of channels. This can include: • providing written information to be left in: ○ GP surgeries ○ antenatal clinics and postnatal wards ○ volunteer or health-related organisations working in public health

progress of the infant ◇ health visitors (or other healthcare professionals providing postpartum care) ◇ childbirth educators ◇ organisers and attendees of pre- or post-natal classes ◇ nursing mothers' groups ◇ breastfeeding support or related organisations • through mass media contact, such as ◇ Newspaper, magazine articles, newsletters, and other written information ◇ TV and radio ◇ The Internet								○ infant, children and maternity shops • through direct referrals or recommendations from: ○ donors ○ staff at Neonatal Units ○ attending paediatricians when assessing the progress of the infant ○ health visitors (or other healthcare professionals providing postpartum care) ○ childbirth educators ○ organisers and attendees of pre- or post-natal classes ○ nursing mothers' groups ○ breastfeeding support or related organisations • through features or article in the mass media

1.1.3	Use clear, non-technical language in any recruitment material or activities, to communicate the need for donor milk banking, and the process.	9	0	0	9	0	Agree	Consensus	Consensus	Revised to reflect usage of milk and process of operation.	Use clear, non-technical language in any recruitment material or activities, to communicate the purposes for which donor milk is used, and the process.
1.2	Donor screening & selection										
1.2.1	Follow the screening process outlined below when selecting donors. This should be based on a balanced consideration of relative risk for the infant.	9	1	0	6	2	Agree	No consensus	No consensus	Revised to note that the risk is about the recipient population, not the mother's own baby.	Follow the screening process outlined below when selecting donors. This should be based on a balanced consideration of relative risk for the recipient population.
1.2.2	Collect information from prospective donors on: • general health and medical history (including acute or chronic infections, recent vaccinations, blood transfusions) • the age and health of their baby • diet history and nutritional intake • The risk of (1) exposure to HIV (2) exposure to syphilis (3) exposure to hepatitis • any recent exposure to infectious diseases • any exposure to herpes • any public health risk of CJD (**TO ADD cross reference to DH guidance)	9	1	0	7	1	Agree	Consensus	No consensus	Information should be collected in a systematic way. However, there is variation in what information is collected and how this is collected. The purpose of collecting this information is to exclude some potential donors. The GDG agreed to allow the technical to restructure these recommendations to allow self-screen, screen with support, and screen during donation The criterion on the age/health of baby was removed as it	Collect information from prospective donors using a systematic checklist to confirm that she is in good general health and that none of the exclusions listed below apply. Exclude from donation women who: • Currently smoke or use NRT • Recent or current recreational drug use • Tested positive to (screening e.g HIV, hepatitis) • At public health risk for CJD(add link) The following should be discussed and may

	• medication use • any medical treatment (other than medication use) • **TO ADD rec on communication in the event of chemical exposure? • alcohol intake • smoking • ?substance misuse/'recreational' drug use								was not clear how this relates to milk safety and composition (but there may be some components, such as zinc, which change in significant levels) – so this was removed.	be excluded: • Alcohol intake – check DH guidance • Exclusion diets • Passive smoking • medication (as there are some that will exclude you from being a donor) • environmental or chemical exposure • risk factors including needle stick injuries, life style factors, tattoos etc etc Refer to guidance from the DH on the safety of recent vaccination in breastfeeding for women who are potential donors (www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917).	
1.2.3	If donations of previously expressed breast milk are to be accepted, screen donors as usual; screening questions should be answered retrospectively.	9	1	0	8	0	Agree	Consensus	No consensus	...	If donations of previously expressed breast milk are to be accepted, screen donors as usual; screening questions should be answered retrospectively.

1.2.4	Use the following tests for screening prospective milk donors: • HIV 1 & 2 antigen/antibody test • HBsAg and anti-HBc blood test , anti hep c antibodies (for hepatitis) • HPV L • a test for anti-treponemal antibodies (for sexually transmitted diseases, specifically syphilis)	9	0	1	8	0	Agree	Consensus	Consensus	Related to hepatitis C– the initial screening will exclude those at recent high risk, and then a good history would exclude more. The current prevalence is low and therefore it is not clear that additional testing for hepatitis C is needed –other than the antibody test.	Use the following tests for screening prospective milk donors: • HIV 1 & 2 antigen/antibody test • HBsAg and anti-HBc blood test , anti hep c antibodies (for hepatitis) • HTLV 1 & 2 • a test for anti-treponemal antibodies (for sexually transmitted diseases, specifically syphilis)
1.2.5	Perform all tests at the time of enrolling for donor milk banking, even where results from antenatal tests are available. Delay testing for 3 months if a donor provides a one-off donation during which time their milk should be quarantined.	9	0	1	8	0	Agree	Consensus	Consensus	This 3 months is based on the seroconversion over this period.	Perform all tests at the time of enrolling for donor milk banking, even where results from antenatal tests are available. Delay testing for 3 months (or sooner if local protocols allow) if a donor provides a one-off donation during which time their milk should be quarantined.
1.2.6	Explain that testing is mandatory and the reason for testing (to minimise risks to the recipient baby) to every mother when she first contacts the milk bank about donating milk and seek informed consent before testing.	9	0	0	9	0	Agree	Consensus	Consensus	...	Explain that testing is mandatory and the reason for testing (to minimise risks to the recipient population) to every mother when she first contacts the milk bank about donating milk and seek informed consent before testing.
1.2.7	Communicate all test results verbally, either	9	0	0	9	0	Agree	Consensus	Consensus	...	Communicate all test results verbally, either

	in person at a follow-up appointment or via a telephone call, or in writing depending on the preference of the woman and in accordance with local protocols. Where appropriate and in accordance with local protocols, offer counselling and/or information on local support groups.										in person at a follow-up appointment or via a telephone call, or in writing depending on the preference of the woman and in accordance with local protocols. Where appropriate and in accordance with local protocols, offer counselling and/or information on local support groups.
1.2.8	Inform women who are positive for HIV infection that they are unable to donate breast milk.	9	1	1	7	0	Agree	Consensus	No consensus	...	See 1.2.2
1.2.9	Refer to guidance from the DH on the safety of recent vaccination in breastfeeding for women who are potential donors (www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917).	9	0	0	9	0	Agree	Consensus	Consensus	...	See 1.2.2
1.2.10	Inform women who have received live vaccinations that they should not donate breast milk in the month after their vaccination.	9	2	0	7	0	Agree	Consensus	No consensus	The GDG agreed to delete as covered in 1.2.9 above	...
1.2.11	Do not repeat tests while the woman continues to donate milk. When donation stops repeat tests 3 months after stopping.	5.5	2	2	2	3	Uncertain	No consensus	No consensus	The risk is that if screened initially, the donor may seroconvert in the window between testing and conversion. Some milk banks quarantine the milk	Do not routinely repeat tests while the woman continues to donate milk.

									until it can be proven that this is not the case. If the testing system is improved, this period can be reduced to days (and it takes this long to express in milk) – however, there is a cost implication. The time period therefore depends on the tests used. However, it was agreed that additional testing is not required if adequate pasteurization is done.		
1.2.12	Collect information for screening from the donor, as well as from medical sources if necessary, using a combination of informal interview and questionnaire	9	1	0	8	0	Agree	Consensus	No consensus	...	Collect information for screening from the donor, referring to medical sources if necessary (with consent from the prospective donor), using a combination of informal interview and questionnaire
1.2.13	If possible, the questionnaire and/or interview should be conducted at a place suitable to both parties.	9	2	0	7	0	Agree	Consensus	No consensus	...	If possible, the questionnaire and/or interview should be conducted at a mutually acceptable time and place.
1.3	Donor Training and Support										
1.3.1	Train donors in the proper techniques for	9	0	0	9	0	Agree	Consensus	Consensus	...	Train donors in the importance of and

	• milk collection and expression, including the use of pumps and containers and their cleaning • milk storage, including the cooling and freezing of milk • personal hygiene, including cleaning of the hands and breasts • administration of milk donations, such as the labelling of stored samples.										proper techniques for • milk collection and expression, including the cleaning and use of pumps and containers • milk storage, including the cooling and freezing of milk • personal hygiene, including cleaning of the hands and breasts • labelling and documentation of milk donations • transportation of donations
1.3.2	Provide information to donor women on • diet • alcohol consumption • caffeine consumption	9	1	1	7	0	Agree	Consensus	No consensus	...	Provide information to donor women on milk bank requirements for their • diet • alcohol consumption • caffeine consumption
1.3.3	Provide donors with training, either face-to-face or by telephone, and offer supplementary written information. • Arrange training at a time and place	9	0	0	8	1	Agree	Consensus	Consensus	...	Provide donors with training, either face-to-face or by telephone, and offer supplementary written information. Arrange training at a time and place

	suitable for both donor and trainer.										suitable for both donor and trainer.
1.3.4	Provide ongoing support to all donors until no longer required. Support may include - continued support for the collection of milk and the maintenance of lactation - emotional support.	9	0	0	9	0	Agree	Consensus	Consensus	...	Provide ongoing individualised support to all donors until no longer required. Support may include - continued support for the collection of milk and the maintenance of lactation - emotional support.
1.3.5	Provide ongoing, individualised contact and feedback to all donors.	9	1	0	8	0	Agree	Consensus	No consensus	The GDG agreed to delete , as added to 1.3.4	...
1.3.6	Offer additional information and support on domiciliary milk collection if bacterial contamination is significant and repeated.	9	0	0	9	0	Agree	Consensus	Consensus	...	Offer additional information and support on milk collection if bacterial contamination is significant and repeated.
1.4	Donor stopping										
1.4.1	Consider no longer accepting milk from donors who supply - milk that does not meet the microbiological criteria despite support - small amounts of milk	9	0	1	8	0	Agree	Consensus	Consensus	It is not possible to define 'small' as is dependent on the milk bank, and its throughput.	Consider no longer accepting milk from donors who supply - milk that does not meet the microbiological criteria despite support - small amounts of milk
1.4.2	Advise women that if they develop a	9	0	0	9	0	Agree	Consensus	Consensus	...	Advise women that if they develop a

	temperature or have contact with other exanthema, to contact the milk bank to discuss temporary suspension of milk donation.									temperature or have contact with other exanthema, to contact the milk bank to discuss temporary suspension of milk donation.
1.4.3	Advise donors who begin taking medication that they should contact the milk bank to discuss temporary suspension of milk donation.	9	0	0	9	0	Agree	Consensus	Consensus	... Advise donors who begin taking medication that they should contact the milk bank to discuss suspension or cessation of milk donation. (add the list of medication/treatments)
1.4.4	Advise donors to contact the milk bank if they: - have breast lesions or infection (including mastitis) such as herpes, to discuss temporary suspension of milk donation - have seen changes in the colour or consistency of the milk - have had vaccinations - no longer meet the initial recruitment criteria.	9	0	0	9	0	Agree	Consensus	Consensus	... Advise donors to contact the milk bank if they: (merge some of the recs e.g. develop a temp) - have breast lesions or infection (including mastitis, herpes) to discuss temporary suspension of milk donation - no longer meet the initial recruitment criteria.
1.4.5	Local policies should be set up to define when donors should be advised to stop donating milk based on the age of their own baby; this should be based on the age of recipient population.	9	1	2	5	1	Agree	No consensus	No consensus	This is a practical issue- and milk banks should decide this for themselves. Local policies should be set up to define when donors should be advised to start and stop donating milk based on local practical considerations.

1.5	Milk expression at home for donation										
1.5.1	Advise donors to collect expressed rather than drip milk for donation; if donors do produce drip milk, advise them to keep it separate from expressed milk.	9	0	0	9	0	Agree	Consensus	Consensus	...	Advise donors to collect expressed rather than drip milk for donation.
1.5.2	Actively encourage donors to hand-express milk; however pump-expressed milk should be accepted if donors prefer this method.	9	0	0	8	1	Agree	Consensus	Consensus	...	Actively encourage donors to hand-express milk; however pump-expressed milk should be accepted if donors prefer this method.
1.5.3	Provide advice and support on stopping expressing milk to donors as required.	9	0	0	8	1	Agree	Consensus	Consensus	...	Provide advice and support on stopping expressing milk to donors as required.
1.6	Milk handling at home									...	
1.6.1	Advise donors that all expressed milk for donation should:										Advise donors that all expressed milk for donation should:
	be frozen immediately after expression	8	2	1	5	1	Agree	No consensus	No consensus	...	be frozen as soon as possible but within 24 hours after expression
	not be left uncovered.	9	0	0	9	0	Agree	Consensus	Consensus	The GDG agreed to delete as would be covered in hygiene training	...
1.6.2	Advise donors to: - freeze individual samples or - refrigerate samples collected over 24 hours if necessary (for example,	9	0	0	7	2	Agree	Consensus	Consensus	...	Advise donors to: - freeze individual samples or - refrigerate samples collected over 24

	because of storage capacity), then freeze the batch.										hours if necessary (for example, because of storage capacity), then freeze the batch.
1.6.3	Advise donors that expressed milk for donation can be stored for: • up to 2 weeks in the freezer compartment of a fridge before transport to the milk bank or • up to 3 months in a domestic freezer, at minus 18°C or lower.	9	0	0	9	0	Agree	Consensus	Consensus	...	Advise donors that expressed milk for donation can be stored for: • up to 2 weeks in the freezer compartment of a fridge before transport to the milk bank or • up to 3 months in a domestic freezer, at minus 18°C or lower.
1.6.4	Advise donors that expressed milk can only be accepted by the milk bank if it has been collected and stored in containers provided by the milk bank. For one-off donations, the milk should be in containers specifically designed for the collection of breast milk.	9	1	0	8	0	Agree	Consensus	No consensus	...	Advise donors that expressed milk can only be accepted by the milk bank if it has been collected and stored in containers provided by or acceptable to the milk bank. For one-off donations, the milk should be in containers specifically designed for the collection of breast milk.
1.6.5	Advise donors that collection containers should be used as received from the milk bank.	8.5	0	1	7	1	Agree	Consensus	Consensus	...	Advise donors that collection containers should be used according to instructions from the milk bank.
1.7	Milk handling at the milk bank										
1.7.1	Process all milk under hygienic conditions	9	0	0	9	0	Agree	Consensus	Consensus	...	Process all milk under hygienic conditions

	(a full sterile environment is not necessary).										(a sterile environment is not necessary).
1.7.2	On receiving milk at the milk bank, transfer all samples immediately to the freezer.	9	1	0	7	1	Agree	Consensus	No consensus	...	On receiving milk at the milk bank, check to ensure they are labeled correctly and in good condition, then transfer all samples immediately to the freezer.
1.7.3	Do not store: - frozen samples direct from the donor in the same freezer as pasteurised samples. - refrigerated samples direct from the donor in the same fridge as thawed, pasteurised samples.	9	0	0	9	0	Agree	Consensus	Consensus	The GDG agreed to remove refrigerated as only accepting frozen milk, and reworded to show that raw and treated milk would not be mixed.	Do not store: - frozen samples direct from the donor in the same freezer as pasteurised samples. - refrigerated raw samples in the same fridge as thawed, pasteurised samples.
1.7.4	Examine samples from the donor for appearance, and discard any samples which raise safety concerns.	8.5	0	1	7	1	Agree	Consensus	Consensus	There is a perception that appearance does indicated quality – however, this is not evidence based. But gross changes in colour and solid contaminants may raise concerns but it was not possible to define these, so it was agreed to remove the recommendation.	...
1.7.5	Discard samples from donors who subsequently fail to meet selection criteria.	9	0	1	8	0	Agree	Consensus	Consensus	...	Discard samples from donors who subsequently fail to meet selection criteria.

1.7.6	Store samples awaiting testing in the freezer for no longer than 3 months.	9	0	0	6	3	Agree	No consensus	Consensus	Milk needs to be used within 6 months of expression (stored in a freezer) and this should be pasteurized at 3 months at the latest after expression. One-off donations are pasteurized immediately (this then allows 3 months for testing) – stock control is therefore paramount.	Store samples awaiting testing in the freezer for no longer than 3 months from the date of expression.
1.7.7	Thaw samples by: • using a temperature-controlled environment such as a water bath (electric) or refrigerator	8	1	1	6	1	Agree	No consensus	No consensus	...	Milk should be completely thawed before pasteurization but should not be allowed to reach room temperature (above 8 degrees). This is best achieved by placing in the refrigerator.
	• leaving in the refrigerator	8	1	1	6	1	Agree	No consensus	No consensus	...	...
	• leaving out to reach room temperature.	8	2	1	5	1	Agree	No consensus	No consensus	...	...
1.7.8	Before pasteurisation, test all samples in batches.	9	0	1	7	1	Agree	Consensus	Consensus	Some milk banks test all samples then test before batching – others do this the other way round. All milk should be tested before pasteurisation, but it will differ by milk bank whether it is	Before pasteurisation, test the milk

										more cost effective to treat each sample and batch only those which pass or batch up then discard a whole batch if failed.	
SEE section below on testing and treating											
1.7.9	After testing and treating, store milk batches immediately in the refrigerator. Move batches to the freezer as soon as fridge temperature is reached, and store for up to 3 months. - in the refrigerator immediately and move to the freezer as soon as fridge temperature is reached - in the freezer for up to 3 months.	8	0	2	7	0	Agree	Consensus	Consensus	The principle adopted was that milk should be cooled before removal from the pasteurizer (below 10 degrees) but there is no clear evidence for this. However, if milk can be cooled as soon as possible, then the growth of spores should be minimized.	After testing and pasteurising, cool the milk to refrigeration temperature (4 degrees) . Move batches to the freezer as soon as fridge temperature is reached, and store for up to 3 months. - in the refrigerator immediately and move to the freezer as soon as fridge temperature is reached - in the freezer for up to 3 months.
1.7.10	When selecting milk for use, generally choose the oldest batches first.	9	0	0	9	0	Agree	Consensus	Consensus	Agreed to delete	...
1.7.11	Milk should be processed using containers made of - glass - plastic - food-grade plastic - any material that can withstand the	7.5	1	1	2	5	Agree	No consensus	No consensus	...	Milk should be processed using food grade materials.

	necessary hot and cold temperatures										
	stainless steel.										
1.7.12	Containers and equipment should be sterilized by autoclaving.	9	1	2	4	2	Agree	No consensus	No consensus	This should be by following HCAPP principles – see quality assurance section	Containers and equipment should be cleaned and stored according to local HACCP principles. (?remove and have a section on the HCAPP principles)
1.7.13	Wear gloves at all times when handling donor milk.	9	0	0	9	0	Agree	Consensus	Consensus	...	Wear gloves at all times when handling donor milk.
Pooling of milk											
1.7.14	Pool all pre-treated milk derived from the same donor. Do not pool: - milk from different donors - batches of treated milk from the same donor.	9	0	1	6	2	Agree	No consensus	Consensus	...	Only pool all pre-pasteurised milk derived from the same donor. Do not pool: - milk from different donors - batches of treated milk from the same donor.
Milk fortification											
1.7.15	Do not open the lid of batches of treated milk until the point of delivery (feeding); this includes when adding fortifiers or other additives.	9	0	2	7	0	Agree	Consensus	Consensus	...	Do not open the lid of batches of treated milk until the point of delivery (feeding);
1.7.16	Milk banks should not be responsible for	9	0	1	8	0	Agree	Consensus	Consensus	...	Milk banks should not be responsible for

	adding anything to the milk.									adding anything to the milk. Fortifiers and other additives should only be added at the point of delivery.
	Tracking and tracing									
1.7.17	Monitor milk samples so they can be tracked and traced.	9	1	1	7	0	Agree	Consensus	No consensus	...
1.7.18	Track and trace milk samples.	9	1	0	8	0	Agree	Consensus	No consensus	Tacking should stop at delivery but there need to be information processes to facilitate and allow track back if needed. If milk banks are supplying their own unit, the tracking and tracing circle would be complete. But this would not be the case in the supply of milk to external units.
1.7.19	Track and monitor milk processing, including freezer temperatures, pasteurization processes, and stock control.	9	0	0	8	1	Agree	Consensus	Consensus	... Ensure traceability by tracking the milk from the donor through to the recipient hospital. Track and monitor milk processing, including freezer temperatures, pasteurization processes, and stock control.
1.7.20	Document the following information about	9	0	0	9	0	Agree	Consensus	Consensus	... Document the following information about

	each sample: • donor records – medical record/NHS number – consent – medical history questionnaire – pathology results – labelling of each sample • testing log, including tests undertaken and their results • pasteurisation details, including date of the pasteurisation • record of recipient use – sample(s) used – consent									each sample: • donor records • medical record/NHS number • consent • medical history questionnaire • pathology results • labelling of each sample • testing log, including tests undertaken and their results • pasteurisation details, including date of the pasteurisation • record of receiving unit	
1.7.21	Label each container (either a sample or a batch) with the following information: – an identification number that is unique to every bottle – a statement that it contains donor breast milk – batch number	9	1	1	5	2	Agree	No consensus	No consensus	...	Label each pasteurised container with the following information: • an identification number that is unique to every bottle • a statement that it contains pasteurised donor breast milk

	– expiry date – donor identity (name or unique identification number) – date of expression.										• expiry date.
1.7.22	It should be the receiving hospital's responsibility to document the recipient use.	9	0	0	9	0	Agree	Consensus	Consensus	...	It should be the receiving hospital's responsibility to document the recipient use.
1.7.23	Archiving samples – in line with blood bank milk banks should archive samples for look back and should consider working with blood banks – get advice from tissue banking – clinical expert: transfusional haematologist	9	0	1	6	2	Agree	No consensus	Consensus	The GDG asked the technical team to cross refer to relevant guidance for the transfusion service or other relevant sources. This was done and revised for the final guideline.	See NICE recommendations
1.7.24	There should be a process to identify each aliquot within any individual process and individual batch.	9	0	0	9	0	Agree	Consensus	Consensus	...	There should be a process to identify each aliquot within any individual process and individual batch. Change wording to reflect the suggestion
1.7.25	At every stage of the process, milk banks should be able to track back to the donor or donors for each sample or batch.	9	0	0	9	0	Agree	Consensus	Consensus	...	...
1.7.26	Data needed for full traceability should be kept for at least 30 years and preferably up to XX.	8.5	0	1	5	3	Agree	No consensus	Consensus	The GDG asked the technical team to cross refer to relevant guidance for the transfusion service or other relevant sources. This was done and revised for the final	See NICE recommendations

									guideline.	
1.8	Milk handling during transportation									
1.8.1	Transport frozen milk by an appropriate means to ensure a temperature-stable environment.	9	0	0	9	0	Agree	Consensus	Consensus	... Whenever transporting frozen milk by an appropriate means to ensure a temperature-stable environment.
1.8.2	Label the milk with its initial state (which should be frozen) when collected	8.5	1	2	5	1	Agree	No consensus	No consensus	The aim is to ensure that the collected milk is frozen and has been handled according to the agreed process, labeled and documentation is provided from the donor on amount, first and last dates. . Provide donor with means to make daily checks on the freezer temperature and be able to document this. All samples are labelled, dates etc.
1.8.3	Donations that are delivered to the milk bank should be delivered either by the donor herself or a representative, for example a partner or family member.	8.5	0	2	6	1	Agree	No consensus	Consensus	The GDG agreed to remove ...
1.8.4	If needed, use a member of staff (not necessarily a nurse) to collect the milk. Alternatively, use a designated and agreed transport provider, preferably a medical courier. In cases where this is not possible, should use appropriate actions such as sign out when leaving and sign in when arriving.	9	0	0	9	0	Agree	Consensus	Consensus	... If needed, use a member of staff (not necessarily a nurse) to collect the milk. Alternatively, use a designated and agreed transport provider, preferably a medical courier. In cases where this is not possible, should use appropriate actions such as sign out when leaving and sign in when arriving.

1.8.5	Collect the milk from the donor's home.	8	1	0	8	0	Agree	Consensus	No consensus	COMBINED with below, allowing anywhere suitable for the donor	...
1.8.6	Collect the milk from other designated places if necessary, such as a depot that has practices in place to monitor the freezers and maintain standards for quality control, storage and security.	9	0	0	9	0	Agree	Consensus	Consensus	...	Collect the milk from the donor's home or from other designated places if necessary, such as a depot that has practices in place to monitor the freezers and maintain standards for quality control, storage and security. Similar processes should be in place where the milk is stored. Freezers should meet the standards
1.8.7	Transport the milk in styrofoam containers that meet the relevant British standards.	9	0	0	8	1	Agree	Consensus	Consensus	Link to relevant blood standard – and would allow for large enough quantities to be transported.	Transport the milk in containers fit for purpose that meet the relevant British standards. (check what is used for transporting blood – need to maintain temperature and hygiene) Processes should be put in place to ensure tamper evidence
1.8.8	Agree with the donor a suitable time to collect the milk, but this should be within 3 months of its expression.	8.5	0	0	8	1	Agree	Consensus	Consensus	The GDG agreed to remove	...
1.8.9	Processes should be put in place to ensure tamper evidence. Similar processes should be in place where the milk is stored. Fridges should meet the standards.	9	0	0	8	1	Agree	Consensus	Consensus	The GDG agreed to remove	...

1.9	Donor consent										
1.9.1	Obtain consent from donors before accepting milk, for:									...	Before accepting her milk, obtain consent from the donor, for:
•	serological testing of the donor	9	0	0	9	0	Agree	Consensus	Consensus	...	• serological testing
•	microbiological testing of donated milk	9	0	1	8	0	Agree	Consensus	Consensus	...	• the processing and intended use of the donated milk.
•	use of donated milk (the milk bank should explain clearly the intended use of the milk)	9	0	1	8	0	Agree	Consensus	Consensus	...	...
1.10	Testing and treating donor milk										
1.10.1	Advise women who test positive for HIV, hepatitis, or HPV that they should not donate milk.	9	0	0	8	1	Agree	Consensus	Consensus	See rec 1.2.2	...
1.10.2	Test milk before treatment for any bacterial contamination, and discard if • total viable bacterial count is greater than 10 ⁵ /ml, or • count of Enterobacteriaceae is greater than 10 ⁴ /ml, or • count of Staph aureus is greater than 10 ⁴ /ml.	9	0	2	6	1	Agree	No consensus	Consensus	...	Before pasteurisation, test the milk for bacterial contamination and discard if the: • total viable bacterial count is greater than 10 ⁵ /ml, or • count of Enterobacteriaceae is greater than 10 ⁴ /ml, or • count of Staph aureus is greater than 10 ⁴ /ml.
1.10.3	Microbiology labs should undertake further bacterial tests, as appropriate, if there is any concern about significant or unusual contamination.	9	0	1	8	0	Agree	Consensus	Consensus	...	Microbiology labs should undertake further bacterial tests if there is any concern about significant or unusual contamination.

NEW											When milk banks request bacterial tests, laboratories should communicate the results clearly in terms of values, interpretation and recommended action.
1.10.4	Cross refer to recommendation on supporting donors if consistently high levels of contamination.	9	0	0	9	0	Agree	Consensus	Consensus	...	Offer support to donors whose milk has consistently high levels of contamination (see recommendation XX).
1.10.5	Pasteurise milk for donation at 62.5 degrees C for 30 minutes.	9	0	0	9	0	Agree	Consensus	Consensus	...	Pasteurise milk for donation at 62.5 degrees C for 30 minutes.
1.10.6	Test milk post pasteurisation regularly. The testing schedule should be determined by the milk bank based on the volume and throughput of milk pasteurised.	9	2	0	7	0	Agree	Consensus	No consensus	It was recognized that this recommendation would set a minimum testing schedule, and that milk banks could decide to test more frequently. Any testing schedule should be determined on throughput – recognising that if there is a failure, milk will need to be discarded. The key point of control is the functioning of the equipment – so calibration and checking is key. Manufacturers should also be able to state the	Regularly test pasteurised milk for bacterial contamination. Milk banks should decide their testing schedule based on the volume and throughput of milk. Testing should occur: • either at least once a month or every 10 cycles, depending on which comes first, and • on an ad-hoc basis if any new processes, equipment, or staff are introduced, or if there are concerns about any part of the process.

									tolerance – deviations may not be important but they should be known. Also training in the use of any critical equipment is important.	
1.10.7	Test post pasteurisation either at least once a month, or every 10 cycles, depending on which comes first.	9	2	0	6	1	Agree	No consensus	Consensus	See 1.10.6 ...
1.10.8	Test on an ad-hoc basis if any new processes, equipment , or staff are introduced, or there are concerns about any part of the process.	9	1	1	6	1	Agree	No consensus	Consensus	See 1.10.6 ...
1.10.9	Discard any batch that has a total viable bacterial count of 10/ml or more post pasteurisation.	9	0	0	8	1	Agree	Consensus	Consensus	... Discard milk after pasteurisation that has a total viable bacterial count of 10/ml or more.
1.11	Quality assurance and staff training									
NEW										... All equipment shall be validated, calibrated and maintained to suit its intended purpose. Operating instructions shall be available and appropriate records kept.
NEW										... All critical equipment and technical devices must be identified and validated, regularly inspected and preventively maintained in

												accordance with the manufacturers' instructions. Where equipment or materials affect critical processing or storage parameters (e.g. temperature, microbial contamination levels), they must be identified and must be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects and to ensure that the critical parameters are maintained within acceptable limits at all times. All equipment with a critical measuring function must be calibrated against a traceable standard if available.
NEW										...		All donor milk prescribed in the NHS should be from milk banks that are part of the overall structure and governance of the linked hospitals/trust.
NEW										...		Only provide donor milk to recipient hospitals who are willing to follow the procedures for tracking use as defined by the supplying milk bank.
1.11.1	Milk banks should implement and maintain an agreed quality control system for processing milk which is followed by all staff.	9	0	0	9	0	Agree	Consensus	Consensus	...		Milk banks should implement and maintain an agreed quality control system for processing milk which is followed by all staff.

1.11.2	A quality control system for milk banks should encompass: • collection, testing, processing, storage and distribution • personnel, documentation, premises and equipment • batch recall, external and internal auditing, non-conformance and self-inspection • Continuous quality improvement.	9	0	0	9	0	Agree	Consensus	Consensus	...	A quality control system for milk banks should encompass: • collection, testing, processing, storage and distribution • personnel, documentation, premises and equipment • batch recall, external and internal auditing, non-conformance and self-inspection • continuous quality improvement.
1.11.3	Milk banks should review their quality control system regularly and amend it if needed. Milk bank staff should be given clear written instructions to help them follow the system.	9	0	0	9	0	Agree	Consensus	Consensus	...	Milk banks should review their quality control system regularly. Milk bank staff should be given clear written instructions to help them follow the system.
1.11.4	Use HACCP principles in any quality assurance process agreed locally	9	0	0	8	1	Agree	Consensus	Consensus	...	Use HACCP principles in any quality assurance process.
NEW										...	All personnel in donor milk banks shall receive initial and continued training appropriate to their specific tasks. Training records shall be maintained. Training programmes shall be in place and shall include good practice. The training programme must ensure and document that each individual:

			• has demonstrated competence in the performance of their designated tasks; • has an adequate knowledge and understanding of the scientific/technical processes and principles relevant to their designated tasks; • understands the organisational framework, quality system and health and safety rules of the establishment in which they work, and • is adequately informed of the broader ethical, legal and regulatory context of their work. If part of their role, train staff in the principles of HACCP, food hygiene, and pasteurisation. Provide continued training and support to ensure that practice reflects these principles.

Appendix 4 Survey of donor milk banks in the UK

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Rationale for the survey

During the scoping work for this guideline it was clear that the evidence base for the operation of donor milk bank services was very limited. We considered that an assessment of current service provision and issues, through a structured survey, would be a useful addition to the published literature. The survey should cover:

- rates of donation and use of donor breast milk
- costs of service provision
- descriptions of models of service provision
- perceived problems with current services
- results of completed audits, and
- further information or research to support the development of services.

As this guideline was not intended to develop ‘true’ service guidance (that is, where the level of need is assessed and guidance is given on how this need should be met), we wanted to be sure that the information collected would directly inform the recommendations. However, we were clear from the outset that the survey would not be considered during the drafting of the recommendations (that is, the survey was not considered as primary evidence) but would be used to focus our questions at the initial stages and to compare the final draft recommendations to current practice and highlight areas where change was required.

Developing the survey

The survey was developed by the guideline technical team and questions were framed based on existing guidelines and other surveys of donor milk banks, primarily the UKAMB milk bank surveys (personal communication; UKAMB 2008). The drafts were discussed and piloted with 2 GDG members (GW and NM), and members of other teams within NICE, including the Implementation Support and Costings teams. The survey was then revised, as appropriate, and a final version agreed. A copy of the final version with the covering letter can be seen at the end of this Appendix.

Methods

The survey was sent to 17 milk banks in the UK, and non-responders were followed-up both by letter and by telephone, if required. Results were collated and a basic analysis

undertaken. We designed the survey simply to describe current practice, not to allow detailed analysis comparing responses with any factor associated with the milk bank.

Results

The summary results were presented to the GDG at two points in the development of the guideline

- results on priorities for the guidelines (section 6 in the questionnaire), perceived problems (section 9) and areas where more information or research is needed (section 10) were presented at meeting 1, and
- the summary results for all sections were presented at meeting 3, after all recommendations had been agreed for consultation.

Overall, 13/17 milk banks returned completed questionnaires (a 76% response rate). Many responses are very detailed with lots of supporting documentation.

Demographic data

The respondent milk banks were from a wide geographical area, and were hosted in different ways (these included neonatal intensive care units, special care baby units, women's and children's services, health visiting services, paediatrics and neonatal medicine). Some milk banks were linked to specific services or units, whilst others were not. Funding arrangements also differed, but the majority of milk banks were funded wholly through the NHS; two milk banks received only 10-12.5% of their funding from the NHS. In one milk bank, the remaining funding was provided through charitable donations. The length of time that the milk banks had been running ranged from 5 years to 70 years.

Current service provision and delivery

The range of responses can be seen in Table 1 below.

Table 1 Level of service provision in 2008-9

	Minimum	Maximum	Median
How many babies in your attached neonatal unit received donor breast milk?	35	234	73.5
How many women donated milk?	7	139	48
How many new donor women were recruited?	11	161	73
How much milk (in litres) was collected?	15.4	1940	209
How much milk (in litres) was pasteurised?	13.5	1740	205.5
How much milk (in litres) was disposed of?	1.9	599	49.9
How much milk (in litres) was received from other milk banks?	0	2	0
How much milk (in litres) was transported to other milk banks?	0	2	0
How much milk (in litres) was received from other hospitals?	0	365	0
How much milk (in litres) was transported to other hospitals?	0	818	34.5
How many babies in other neonatal units received donor breast milk from your unit?	0	65	14

Other caveats to the figures presented include one milk bank reported some responses for 9 months only, one reported figures for 2007 as more recent data were not available, and one reconfigured services during 2008 so figures were not complete.

Most milk banks did not charge local units for the provision of milk (because the funding often is provided through the local unit), however, one milk bank charges £40 per litre.

Most milk banks charged other units between £100 and £150 per litre, as a contribution to costs, but again one charged £40 per litre. As well as providing other units, most milk banks provided to other services, including community services.

Staffing and organisation

Milk banks operated using a variety of staffing structures. Very few milk banks employed full time members of staff; if they did, the types of role included donor screening, milk bank assistant, and manager. Most roles were part-time, and some milk banks supported employed staff with volunteers.

There was a range of staff/roles involved; some could be considered as ‘expert’ roles, and some ‘general’. Examples of role descriptions included:

- consultant
- pasteuriser
- counsellor
- nursery nurse
- administration.

Donor recruitment

Most milk banks (11/13) reported that they actively recruit donors. Examples of some methods included through antenatal classes and wards, local magazines, or a milk bank website. Some milk banks (2/13) reported using leaflets and other promotional material, and ‘word of mouth’.

Most milk banks (7/11) followed the UKAMB guidelines on recruitment, whilst some (3/11) did not. Although some milk banks reported not following the UKAMB guidelines, one interpretation of this could be that they followed most of the recommended process, but adapted them for local circumstances.

Donor screening

Most milk banks used a mixed approach with different strategies being used at different points in the process – for example, an initial screen via telephone, with a more in-depth interview face-to-face.

Table 2 Screening process for donor women

How do you ask screening and/or selection questions to donor women?		
Verbally, face-to-face	12 did (1 mostly)	1 missing response
Verbally, by telephone	10 did (1 mostly)	3 missing responses
By written questionnaire <u>with no</u> support from a milk bank member of staff	4 did not 1 rarely – followed up with phone call	8 missing responses
By written questionnaire <u>with support</u> from a milk bank member of staff	8 did (1 only if by post)	5 missing responses

Most milk banks (11/13) did not rely on the results of relevant antenatal tests, and tested at the time of screening for donation.

The majority of milk banks (9/12) followed the UKAMB guidelines on screening; some (3/12) did not. Reasons given for not following the guidelines were that repeat screening during donation was not done (however, this UKAMB recommendation was specified as 'ideally').

Donor stopping

Most milk banks (12/13) provided information on stopping (temporarily or permanently) to donors; in many cases, this was both written and verbal information and was mainly on medication use. Some milk banks (2/13) used the relevant UKAMB leaflets. However, it is known that more milk banks adapt the UKAMB information to their local needs.

Some milk banks (2/13) suggested that mothers should stop donating when their baby is a defined age (6 or 12 months).

All milk banks (12/12) followed the UKAMB guidelines.

Expressing milk for donation

All milk banks (11/11) followed the UKAMB guidelines. The provision of information on expression differed; some (4/11) milk banks specified using the UKAMB leaflets for donors, others verbally, including by telephone.

Milk storage at home

Most milk banks (11/13) followed UKAMB guidelines; however some (2/13) did not, and reasons given were that home freezer temperatures or freezers on wards (if providing a one-off donation) temperatures were not monitored. A range of support was provided; this included the provision of thermometers, daily recording sheets, and general information.

Milk transportation

Most milk banks (11/13) followed UKAMB guidelines on the transport of donor milk. A range of methods of temperature monitoring were reported, with some milk banks using simple thermometers, and one milk bank reported using 'warm milk' temperature recorders.

Milk storage at the milk bank

Most milk banks (12/13) followed UKAMB guidelines; one milk bank did not, but followed detailed protocols including audio and visual alarms on freezers, twice-daily monitoring and recording. As expected, a range of processes was described. However, most milk banks monitored freezer temperatures once or twice a day, and milk was stored, when stated, at -20 to -21 degrees C.

Testing donor milk

All milk banks (13/13) followed UKAMB guidelines, with some variation in pre- and post-testing; one milk tested random samples, whilst two milk banks tested all batches. No milk bank reported different pre- and post-testing schedules.

Pasteurising donor milk

All milk banks (13/13) followed UKAMB guidelines on treating donor milk. When specified, all milk banks used Holder pasteurisation. There was some variation in the equipment used, but all models had monitoring and recording facilities. In addition to the in-built monitoring feature, one milk bank reported checking temperatures with a probe.

Pooling milk

No milk bank (0/13) pooled milk between donors.

Fortifying donor milk

Donor milk from most (7/12) milk banks was reported as being fortified; however, we did not ask how much of each donor milk banks' milk was fortified. If done, all donor milk would be fortified after pasteurisation.

Archiving samples of donor milk

Few milk banks (3/13) archived samples of milk, and two followed UKAMB guidelines. Reasons given for not archiving included a lack of storage space or equipment, a lack of rationale from the microbiological perspective (for example, if a serum sample is retained), and a lack of evidence.

Disposing of donor milk

A range of methods of disposal was reported, but most milk banks used the same processes as for general clinical waste.

Table 3 Disposing of donor milk

Do you have a process for disposing of donor breast milk?		
Raw milk?	8 did	1 missing response 1 not known
Pasteurised milk?	8 did	1 missing response 1 not known
Milk that does not meet acceptance criteria?	9 did	1 missing response 1 not known

Information recording¹

Milk banks reported various approaches to obtaining consent from the donors from structured, informed consent to verbal, implicit consent (however this was reported as being changed). Consent was stored mainly in hard copy.

All milk banks had processes for tracking and tracing within the milk bank, and between the milk bank and the receiving hospital; however, these differed. Most reported information recording being manual and storage being in hard copy.

Staff training

All milk banks provided staff training; this included food handling, clinical skills, phlebotomy, breastfeeding support training, pasteurisation, UKAMB support training, general orientation to the milk bank process, and ongoing development.

Information provision²

Most milk banks used UKAMB leaflets, or local leaflets, to provide information to donors or potential donors. See also other sections for specific information provision.

Priorities for the NICE guideline

It should be emphasised that the rankings were not used to exclude areas to be covered in the guideline, but to ensure that we focussed on those areas considered most important by the milk banks themselves.

¹ Although we asked for information on consent for use of donor milk by the recipient's parent or carer, we have not reported the information here as this is not considered the responsibility of the donor milk bank.

² Although we asked about the information provided to a potential recipient's parent or carer, we have not reported the information here as this is not considered the responsibility of the donor milk bank.

Table 4 Ranking of priorities

	Median ranking*	Highest ranking	Lowest ranking	Order of priority
Donor recruitment and selection	3	1	5	Important
Collection, storage, and handling of donor breast milk	2	1	5	Important
Administration of the service, including tracking and tracing of donor breast milk	2	1	5	MOST important
Training of staff	3	2	5	LESS important
Information for donors and parents/carers of babies receiving donor breast milk	4	1	5	LEAST important

*1 being the most important and 5 being the least important

Perceived problems with current services

Reported themes were:

- Personal opinion amongst HCP and wider perception as to its benefits
- Lack of funding
- Milk bank needs to be a dedicated job, not part of another job
- Lack of facilities (storage, preparation areas)
- Lack of standard training, which impact on staff recruitment
- Practical challenges of milk collection and transport
- Lack of statutory guidelines
- Lack of coordinated effort to meet wider needs
- Concerns over the robustness of record keeping, including track back from recipient units
- Lack of time and/or staff (both nursing and administrative)

- Dependence on 'good-will' of staff and volunteers
- Recruitment of donors
- Link with microbiological expertise and support

Suggestions to address perceived problems

Reported themes were:

- Development of a NICE Guideline
- Support with funding, including a proper ring-fenced budget
- More staff, both nursing and administrative
- Recognition of the vital service provided
- Research work to demonstrate the cost effectiveness of using DBM in intensive care of the newborn situations, for example in the reduction of NEC
- Dedicated hours for milk bank staff, with job descriptions
- Education of all staff involved in milk banking
- Standardised 'paper trail' to be used by all milk banks, either with computerised/electronic dedicated tracking systems and records or simple computerised forms/data
- Standard training package, with further qualification(s) on management/administration issues.
- More milk collection depots in the community with coordinated local/regional transport systems
- Set up a national service with government funding with regional centres covering the whole country not necessarily within a hospital setting, but with the correct staff & facilities & funding to run a national service

Other information or research needed

Reported themes were:

- Analysis of safety and benefit for recipient babies in different circumstances
- Analysis of milk and how this relates to fortification
- Clear guidelines by NICE, that are cost effective and consider costs (with funding provided if needed)

- DoH support to ensure milk banks are following best practice, with local and national monitoring
- Equitable access for all babies, not dependent on opinions of HCP caring for them
- Coordination between milk banks

Conclusions

Milk banks operate services in different ways but the majority are following the existing UKAMB guidelines.

Acknowledgements

We would like to thank all those who responded to the survey, and we appreciate how much time this would have taken. The results have been extremely useful in the development of the NICE guidelines and helped to ensure that the final recommendations are relevant to current milk banking practice in the UK.

Letter to milk bank managers

Dear

The National Institute for Health and Clinical Excellence (NICE) has been asked to develop a short clinical guideline on the operation of donor breast milk bank services. As part of the work for this guideline, we would like to understand the how existing milk bank services work and the level of service that they provide. This will then enable the Guideline Developers to write practice recommendations that are relevant to current practice in donor breast milk banking.

Please find enclosed a questionnaire asking about how your milk bank services are being operated, and what information you feel you would need to develop the service in future. This questionnaire has been sent to all UK milk banks, and any response is entirely voluntary.

We anticipate that this will take approximately 1 hour to complete.

All results will be confidential, and will be anonymised and summarised in the final report. We will inform you when the draft guideline (which will include the results of the survey) is on the NICE website and we encourage you to register as a stakeholder, through your host organisation. Please see the NICE website for how to register as a stakeholder (www.nice.org.uk).

When completed, please return the survey in the pre-paid envelope **by Monday 6th April 2009** to

Kathryn Chamberlain
National Institute for Health and Clinical Excellence
Level 1A, City Tower
Piccadilly Plaza
Manchester M1 4BD
Tel: 0161 870 3110 | Fax: 0845 003 7785

If you have queries on any aspect of the questionnaire or the guideline, please do not hesitate to contact Kathryn (Kathryn.chamberlain@nice.org.uk).

Yours sincerely

Tim Stokes

Associate Director

Kathryn Chamberlain

Project Manager



NICE questionnaire on donor breast milk services

When completed, please return **Monday 6th April 2009** in the pre-paid envelope to

Kathryn Chamberlain

National Institute for Health and Clinical Excellence
Level 1A, City Tower
Piccadilly Plaza
Manchester M1 4BD
Tel: 0161 870 3110 | Fax: 0845 003 7785

NICE questionnaire on donor breast milk services

The National Institute for Health and Clinical Excellence (NICE) is developing a short clinical guideline on the operation of donor breast milk bank services. As part of this work, we are conducting a survey of existing milk bank services to

- a) determine current practices in donor breast milk banking, and
- b) gain information needed for future practice.

We would very much appreciate if you could complete the questionnaire about your donor breast milk bank service. The information it provides will be an essential part of developing NICE guideline recommendations that are relevant to current practice in donor breast milk banking. All responses will be anonymised in the final report.

Details of your milk bank

Name of donor breast milk bank	
Host organisation – for example, district general hospital	
Department of host organisation with responsibility for the milk bank	
Are your services attached to any specific neonatal/specialist services? If so, which one(s)?	
Approximately how much of your funding in percentage terms is from your NHS Trust?	%
Approximately how much of your funding in percentage terms is charity-based?	%
How long has the milk bank been established?	

Current service provision and design

1 In your milk bank in 2008

If you do not know, please answer 'Not known'

1.1	How many babies in your attached neonatal unit received donor breast milk?	
1.2	How many women donated milk?	
1.3	How many new donor women were recruited?	
1.4	How much milk (in litres) was collected?	
1.5	How much milk (in litres) was pasteurised?	
1.6	How much milk (in litres) was disposed of?	
1.5	How much milk (in litres) was received <u>from</u> other milk banks?	
1.6	How much milk (in litres) was transported <u>to</u> other milk banks?	
1.7	How much milk (in litres) was received <u>from</u> other hospitals?	
1.8	How much milk (in litres) was transported <u>to</u> other hospitals?	
1.9	How many babies <u>in other neonatal units</u> received donor breast milk from your unit?	

Please add any comments or clarifications on the responses above.

2 In your milk bank, how many full-time equivalent members of staff are you currently funded to employ?

If possible, please provide a detailed breakdown – for example, the numbers of staff by grade, job title, and hours worked.

3 In your milk bank

3.1 Do you actively recruit donor women?

Yes/No

This relates specifically to the process of making women aware that the donation of milk is possible.

If yes, please attach any documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

Do you actively recruit donor women as recommended in the UKAMB 2003 guidelines?

Yes/No

Please add any additional detail, if needed, in the box below.

3.2 We wish to determine what processes you have for screening and selection of donor women.

Could you please attach any documentation (either as hard copy or in an electronic version as appropriate) on screening and selection of donors. If no written documentation is available, please can you summarise in the box below.

Do you consider that your processes for screening and selection are as recommended in the UKAMB 2003 guidelines?

Yes/No

Please add any additional detail, if needed, in the box below.

3.3 How do you ask screening and/or selection questions to donor women?

Please check all those which apply.

Verbally, face-to-face

Verbally, by telephone

By written questionnaire **with no** support from a milk bank member of staff

By written questionnaire **with** support from a milk bank member of staff

Other (please give details)

3.4 What processes do you have to validate information provided by donor women?

For example, do you repeat tests that were undertaken antenatally?

Could you please attach any documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

3.5 Do you provide information to donor women on when to stop donation, either temporarily or permanently? Yes/No

If yes, please attach any written documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

Do you advise donor women on when to stop donation (temporarily or permanently) as recommended in the UKAMB 2003 guidelines?
Please add any additional detail, if needed, in the box below.

Yes/No

3.6 What information do you give to donor women on expressing milk?

Could you please attach any relevant documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

Is the information you give to donor women on expressing milk consistent with that recommended in the UKAMB 2003 guidelines?
Please add any additional detail, if needed, in the box below.

Yes/No

3.7 How do you recommend that donor breast milk should be stored?

Could you please attach any documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

Do you advise donors to follow the UKAMB 2003 recommendations on how to store milk **at home**?

Yes/No

Please add any additional detail, if needed, in the box below.

For example, what are the minimum standards for the freezer at the donor's home, and how do you monitor these?

Do you follow the UKAMB 2003 recommendations on how to store milk **during transportation**?

Yes/No

Please add any additional detail, if needed, in the box below.

For example, how are samples stored during transportation, and how do you monitor these?

Do you follow the UKAMB 2003 recommendations on how to store milk **at the milk bank**?

Yes/No

Please add any additional detail, if needed, in the box below.

For example, what are the minimum standards for the freezer at the milk bank, and how do you monitor these?

3.8 How you test donor breast milk?

Where appropriate, please attach any documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

Do you test milk as recommended in the UKAMB 2003 guidelines?

Yes/No

Please add any additional detail, if needed, in the box below.

For example, what bacteriological/microbiological tests do you do? How do you record the results? What criteria, related to the testing, do you use to reject milk?

3.9 How you treat donor breast milk?

This relates to the heat treatment, not the fortification of milk.

Where appropriate, please attach any documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

Do you treat donor breast milk as recommended in the UKAMB 2003 guidelines?

Yes/No

Please add any additional detail, if needed, in the box below.

For example, what pasteurisation process do you use – method of pasteurisation, equipment used? How do you cool the milk? How do you audit the process of treatment?

3.10 Do you pool donor breast milk from different donor women? Yes/No

If yes, please attach any documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

3.11 Do you fortify donor breast milk? Yes/No

If yes, do you do this before or after heat treatment or pasteurisation?

Before/after

Please summarise any additional information in the box below.

3.12 Do you archive samples of donor breast milk? Yes/No

If yes, please attach any documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

Do you archive samples of donor breast milk as recommended in the UKAMB 2003 guidelines?

Yes/No

Please add any additional detail, if needed, in the box below.

For example, how long do you store samples for? What are these kept for?

3.13 Do you have a process for disposing of donor breast milk?

Where available, please attach any documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

Raw milk?

Yes/No

Pasteurised milk?

Yes/No

Infected milk?

Yes/No

Please add any comments or clarifications on the responses above.

3.14 How do you record and store information on

The consent to donate donor breast milk?

The consent to use donor breast milk?

Tracking and tracing donor breast milk <u>within</u> the milk bank?

Tracking and tracing donor breast milk <u>between</u> the milk bank?

4 What training do the following receive?

Donor breast milk bank staff
Other staff working with mothers and babies who may benefit from, or who are receiving, donor breast milk
Other staff working with potential donors

5 What information is provided to the following?

Please attach any relevant documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

Parents or carers of babies receiving donor breast milk
Donors and potential donors

6 What areas of service provision should we focus on in the NICE short guideline on the operation of donor breast milk bank services?

Please rank the following five areas in order, with 1 being the most important and 5 being the least important.

Rank in
order
(1 to 5)

Donor recruitment and selection	
Collection, storage, and handling of donor breast milk	
Administration of the service, including tracking and tracing of donor breast milk	
Training of staff	
Information for donors and parents/carers of babies receiving donor breast milk	

7 Do you have any recent, completed audit information?

If so, and you are willing to share the information, please attach any audit information to the questionnaire (if the information is in an electronic format, please email to Kathryn.Chamberlain@nice.org.uk).

Further information or research

8 In your milk bank

- 8.1 Are you able to estimate how much a litre of donor breast milk costs to produce? Yes/No

If yes, would you be willing for us to contact you at a later date to get more details?

Yes/No

- 8.2 How much do you charge **your local** neonatal unit for donor milk?

- 8.3 How much do you charge **other** neonatal units for donor milk?

- 8.4 Do you supply anyone other than neonatal units with donor milk? Yes/No

If so, what sort of service do you supply to (for example, paediatric intensive care, surgical, oncology)?

9a What are your perceived problems with current services?

9b How could these problems be addressed?

10 What information or research would you need to develop your service in the future?

Thank you for taking the time and effort to complete this questionnaire.



KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Case report	Ryder	1977	"Samples delivered to the hospital were not always properly labelled with the donor's name and date of collection [...]."		
Administration	Meeting report	Silverman	1971	"Contingency samples (a few milliliters of milk from each donor) should be frozen before sterilization and filed in the milk bank 'library' for investigational purposes which may arise."		
Administration	Meeting report	Silverman	1971	"A current registry of raw milk donors should be kept by the milk bank."		
Administration	Narrative review	Bromberger	1982	"Most donors provide milk as a voluntary effort, although some milk banks in Europe pay donors a small amount."		
Administration	Narrative review	Bromberger	1982	"The liability of the donor and milk bank to the recipient is unclear; the majority of milk banks do not use release forms for either donor or recipient."		Not sure if still current practice
Administration	Narrative review	Bromberger	1982	"Most milk banks charge a fee for the milk to help defray the cost of operation."		
Administration	Narrative review	Bromberger	1982	"Money is needed for screening of donors, for maintaining quality of milk, for equipment such as freezers and pasteurizers, and for personnel to keep records and communicate with donors."		
Administration	Narrative review	Davies	1992	"Further thought should be given to maintaining a national network of perhaps half a dozen large milk banks."		
Administration	Narrative review	Lording	2006	Reviewed barriers to the implementation of human milk banks: cultural and religious beliefs.	Al-Naqeeb 2000	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Narrative review	Lording	2006	Review noting various strategies to support human milk banking: support of health professionals, specifically neonatologists - that is, a top-down approach; positive media coverage'; novel fundraising and media awareness	Hartmann 2006 personal communication; Arnold 2006; Mothers Milk Bank 2004	
Administration	Narrative review	Lording	2006	Reviewed barriers to the implementation of human milk banks: concerns about safety of the donor milk. Stressed the need to address concerns upfront through good communication.	UKAMB; Weaver 2001; Wight 2001; Smith 2006 personal communication	
Administration	Narrative review	Lording	2006	Reviewed barriers to the implementation of human milk banks: lack of research and statistics on efficacy.	Arnold 2006; Weaver 2001	
Administration	Narrative review	Lording	2006	Reviewed barriers to the implementation of human milk banks: costs and logistics. Estimated costs were approx £20,000 (2001 costs) to establish a milk bank in the UK; also need "sufficient space available to store, heat process, test milk and maintain records."	Weaver 2001; Tully 2000; Smith 2006 personal communication	
Administration	Narrative review	Lording	2006	Reviewed barriers to the implementation of human milk banks: lack of support by neonatologists.	Arnold 1999; Harris 2005; Schanler 1999; Hartmann 2006 personal communication; Minchin 1998	
Administration	Narrative review	Lording	2006	Reviewed barriers to the implementation of human milk banks: resistance from staff. "Strategies employed to enlist the support of all staff members included the provision of information and education, and the establishment of clinical protocols and feedback regarding the efficacy of the bank's pasteurisation process."	Hartmann 2006 personal communication	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Narrative review	Simmer	2000	"The screening of donors and pasteurisation of milk require resources. These costs need to be balanced against the potential health gains."	Lucas 1990	
Administration	Narrative review	Van de Perre	1992	"Passive surveillance followed by thorough investigations of any possible case of transmission is warranted."		
Administration	Narrative review	Wight	2001	"Donor milk is dispensed only on prescription. Lot numbers are recorded and the milk is shipped frozen, overnight."		US milk banks US
Administration	Narrative review	Wight	2001	"In California, medically necessary donor human milk is covered by MediCal (Medicaid) for outpatients and noncontracting hospital inpatients. MediCal-managed care plans are mandated to provide medically necessary donor human milk for infants as well as prenatal and postnatal breastfeeding education, breast pump rental and supplies, and lactation consultation services. However, many hospitals contract with MediCal for an NICU per diem rate that was negotiated long ago, without considering the need for donor milk. At present, the cost of donor milk and the cost of supporting mothers who provide their own milk (pumps, containers, miscellaneous supplies, lactation consultant services) must come out of low NICU per diem rates."	California Department of Health Services 1999	US milk banks US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Narrative review	Wight	2001	"Although human milk is donated and not purchased, the costs of screening, processing, and shipping the milk are considerable. To remain financially solvent, breastmilk banks have had to rely on charitable donations, as well as billing approximately \$2.50 to \$3.00 per ounce (plus shipping) for the milk provided. It is, however, the policy of all of the milk banks that no infant shall go without milk for financial reasons. New York State enacted a law to promote and support donor milk availability and quality. The World Health Organization/UNICEF has also supported the establishment and use of donor milk banks as part of international efforts to promote breastfeeding."	Public Health Law 2505 NY; WHO/UNICEF 1980	US milk banks US
Administration	Narrative review	Williams	1981	"Practical considerations are transportation and parking for donors, reimbursement for milk donated, personnel to solicit donors, and the storage and distribution of milk. Donor programs are as varied as the number of milk banks."		
Administration	Narrative review	Woo	2007	"Not all healthcare insurance companies cover the cost of human milk, but milk banks do not deny milk to people who are unable to pay."	Angle 2001	
Administration	Narrative review	Woo	2007	"Milk banks are nonprofit organizations, and although the milk is donated, there are still expenses incurred because of the necessary screening, pasteurizing, and distribution of the milk. In the United States, the recipient or institution is charged approximately \$3.00 per ounce of milk, plus shipping charges. According to Tully (2002), this may seem expensive, but it could actually save the life of an infant and greatly reduce the cost of other healthcare services."	Tully 2002	
Administration	Narrative review	Woo	2007	"A representative from the milk bank is notified, and he or he picks up the blood sample and milk donation."	Spatz 2005	Children's Hospital of Philadelphia milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Opinion piece	Modi	2006	"In contrast to blood banks, which are tightly regulated, human milk banks in the UK vary in size and operating procedures and are unregulated, except for the voluntary adoption of standards of practice laid down by the UK Association of Milk Banks (www.ukamb.org). In Canada, Mexico, and the United States the Human Milk Banking Association of North America (www.hmbana.org) has different standards."		
Administration	Opinion piece	Modi	2006	"Research is needed in four key areas: [...] to conduct an economic assessment of the cost of human milk banking to the NHS; [...] and to explore cultural and social attitudes to donor breast milk." "The UK has 17 human milk banks and some 255 neonatal units. If donor breast milk is beneficial, clinical guidelines should reflect objective evidence, access should be equitable, and milk banking procedures should be consistent. If it is not beneficial NHS resources might be better directed towards supporting mothers' own lactation."		
Administration	Opinion piece	Modi	2006	"Human milk banks around the world have arisen through the voluntary efforts of committed individuals. Their altruism is undeniable, but unregulated expansion of human milk banking requires evidence of benefit. Donor breast milk is expensive, and although donors are unpaid the cost of UK human milk banking (£30-150 per litre) is probably an underestimate of the full cost to the National Health Service."	Tully 2000	
Administration	Opinion piece	Weaver	2001	Argues for donor milk banking to be operated on a regional basis, coordinating the recruitment of donors over a large geographical area and providing a service to all neonatal units in that area. If preferred, the current system of local banks could operate within this system. A national scheme for regulation should also be set up.		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Opinion piece	Weaver	2001	"Donor milk banking is simple to carry out from both an operational and a logistical stand point! The set up costs are of the order of £20,000 including a pasteuriser, fridge and several freezers, a computer and some basic office equipment. Ongoing costs are largely the staff salary and most UK milk banks operate with one full time equivalent or less. Serology and bacteriology costs add to a range of minor charges for bottles, stationery etc but overall the benefits are not outweighed by weighty financial costs."		
Administration	Opinion piece	Williams	1992	"Unfortunately, the haphazard organisation of milk banks in the United Kingdom continues to prove an obstacle both to the national study of [the use of donor milk] and to the sophistication of processing techniques capable of controlling or changing the nutritional composition of human milk."	Williams 1987	
Administration	Opinion piece	Williams	2007	"Where transmission of infection through donor milk is concerned, it is essential from a policy perspective to balance risk carefully against the potential benefit associated with a reduction in the risk of death from necrotising enterocolitis. Provided that milk banks are run in accordance with national and regularly updated guidance risk can be minimised. We are not aware of any reported instances of nosocomial or vertically transmitted infection associated with the use of donated milk collected, processed and stored using systems which follow such protocols but agree there is room for closer regulation because historically milk banks have been built from minimal resources within a few neonatal units."	UKAMB 2003; Baumer 2004	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Opinion piece	Williams	2007	"There are currently 17 milk banks in the UK. Audit data collected in 2005 by the United Kingdom Association for Milk Banking show that 850 women in the UK provided a total of 5000 litres of milk for pasteurisation and use on neonatal units. There has been a steady rise in use since 2000 and the use of donor milk is becoming a more established part of neonatal practice. Cost-effectiveness, safety, quality control and equity of access might be served best by the establishment of a national network without delay. Additional benefits of such a step would be sustainability of supply sufficient to resource further clinical research into the questions with which Boyd et al conclude."	Boyd 2007	
Administration	Position statement	Fernandez	1990	"The goal of a Human Milk Bank should not be just the collection, storage, and distribution of milk but the support, encouragement and promotion of successful lactation."		Discussed and agreed not be relevant to UK banking as specific to developing countries.
Administration	Position statement	Gutierrez	1998	"1. The HMBs cannot buy or sell milk. 2. All HMBs are responsible for: donor selection, collection of milk, milk processing, clinical control, quality control, and distribution of milk. 4. Every procedure done in the HMB should be recorded. 5. All records of procedures should be available to the health inspection authorities. 6. Every HMB should send periodic reports of donations, quality control test results, total volume of milk collected, and total number of recipients to the local health authorities. 10. All milk samples should be marked with the name, date and time of collection."		Brazilian milk banks Brazil

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Primary study	Donowitz	1981	"Five patients in a newborn intensive care unit (NICU) developed primary bacteremia due to Klebsiella during a 12-day period, May 2 through June 2, 1979, after feeding for 24-96 hr with contaminated breast milk. All patients had been fed via nasoduodenal tube with milk obtained from a single donor. The donor milk collected via electric suction pump was positive by gram stain for gram-negative rods and by culture for Klebsiella pneumoniae. A culture of hand-expressed milk was negative for gram-negative rods. The breast-pump tubing and safety trap were grossly contaminated with K. pneumoniae. Institution of proper sterilization to the pump equipment controlled the outbreak. This outbreak is the first documentation of nosocomial bacteremia as a major infectious complication of feedings of premature infants with contaminated breast milk." Authors suggested that "[t]he mode of transmission may have been contamination of milk at the time of aspiration." and concluded that "[b]anking of breast milk [...] should be practised in accord with established guidelines for the sterilization of breast-pump equipment between uses by different mothers and for the proper methods of infection control."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Primary study	Osbaldeston	2007	Involvement with the bank - 31% of participants responded other to how they heard about the bank. The most common responses were from lactation consultants, at child birth classes, and at the neonatal intensive care unit. "There is no one dominant mechanism by which donors report learning of the milk bank. Thus, when considering how to recruit new donors, milk banks should focus on a multipronged approach. Most surely, one of these prongs should be word of mouth. The most commonly reported method of hearing about the milk bank was hearing about it from a friend. The fact that 97% of donors say that they would donate again is a very strong statement of the meaningfulness of the experience. Involving former donors in the recruitment process is likely to be an effective method for recruiting new donors."		Austin milk bank US
Administration	Service description	Arnold	1999	"Mothers are paid 145 Danish Crowns (DKr) (about US\$24.00 at current exchange rates) per liter for their milk. This money is tax free. Mothers are paid monthly. In order to receive the stipend, however, milk must meet bacteriological criteria. The first batch of milk received from a mother is tested for bacteria."		Hvidovre milk bank Denmark
Administration	Service description	Arnold	1999	"Each of these women is paid 125 Swedish Crowns (SKr) per liter for her milk (about US\$21.00/liter), again only after the milk has passed bacterial inspection."		Goteborg milk bank Sweden
Administration	Service description	Arnold	1999	"After pasteurization and prior to freezing, a sample bottle from the batch is analyzed in a MilcoScan infrared analyzer, and each bottle is labeled with the fat, lactose, protein, and energy content."		Goteborg milk bank Sweden
Administration	Service description	Asquith	1987	"Individual pools and pools from multiple donors are separately marked for record keeping."		San Jose milk bank US
Administration	Service description	Asquith	1987	"[...] a health history and illness and laboratory test results log are kept for all paid and volunteer staff of the milk bank."		San Jose milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Asquith	1987	"All milk bank equipment is maintained in accordance with standard procedures published by the College of American Pathologists, and maintenance records are kept."		San Jose milk bank US
Administration	Service description	Asquith	1987	"Information concerning the recipients is obtained from their physicians and recorded."		San Jose milk bank US
Administration	Service description	Asquith	1987	"Several different miscellaneous records and summaries are maintained to manage the milk bank and to provide documentation for billing, fund-raising, and research purposes."		San Jose milk bank US
Administration	Service description	Asquith	1987	"The quality of milk donations is recorded in a bacteriologic result log, pool record, and pasteurization log."		San Jose milk bank US
Administration	Service description	Asquith	1987	"All storage freezers and refrigerators at the MMB are equipped with high- and low-temperature alarms that are monitored at all hours."		San Jose milk bank US
Administration	Service description	Asquith	1987	"Each donor receives an instruction packet and provides the MMB with research releases."		San Jose milk bank US
Administration	Service description	Asquith	1987	"Safe and effective operation of the MMB requires extensive record keeping to ensure that any problems that arise may be traced to their source."		San Jose milk bank US
Administration	Service description	Balmer	1992	"Each batch is numbered and it is recorded which batch is fed to each baby or sent to other hospitals in accordance with DHSS recommendations."	DHSS 1988	Sorrento milk bank UK
Administration	Service description	Beal	1978	"The milk is not used until a satisfactory report has been received from the microbiology department, at which time the date of the report is entered into the appropriate column in the book, and the milk is then available for use."		Townsville milk bank Australia

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Beal	1978	"Information concerning the milk is registered in a book and includes the date of collection, the date of deposit in the bank, the milk identity number, the date of clearance by the microbiology department, and the expiry date."		Townsville milk bank Australia
Administration	Service description	Beal	1978	"For use, the milk is signed out from the milk bank by the nursing staff [...]."		Townsville milk bank Australia
Administration	Service description	Cash	1981	"Every donor milk must be assigned a permanent number by the coordinator of the breast milk bank." "Every bottle must be marked with [the donor's] assigned number and the date the milk is collected [...]."		EOPC milk bank US
Administration	Service description	Cash	1981	"The perinatal nursing staff are actively involved with mothers donating milk for their own babies. Their role is to identify mothers desiring to breastfeed, initiate collection and storage of milk, and make referrals to the coordinator of the milk bank."		EOPC milk bank US
Administration	Service description	Cash	1981	"A nurse with neonatal intensive care experience was selected for the milk bank coordinator position. The coordinator's role includes screening all donors; advising on drug intake; providing nutrition education; teaching collection, storage, and transport of milk; obtaining random cultures of milk; and discarding milk with unacceptable bacteria counts and contacting these donors to review techniques."		EOPC milk bank US
Administration	Service description	Connor	1982	"The only expenditure incurred to get the [milk bank] scheme started was in acquiring a chest deep freeze and a pasteuriser. These were placed in the milk kitchen of the special care baby unit (SCBU), where the staff were instructed in the agreed procedure for treating, storing and using the milk [instructions provided in the text]."		Enfield milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Fernandez	1993	"Other team members include two lactation management nurses and an attendant. The nurses are responsible for motivating mothers to donate milk, milk collection, and pooling of milk. Their duties include helping mothers with problems in breastfeeding, providing emotional support for mothers in the special care units, and teaching them milk expression. The attendant carries milk to and from the bank in insulated containers. She washes the milk pumps and containers and packs them for autoclaving."		Bombay milk bank India. May not be directly relevant to the UK, but agreed to leave in with caveats in interpretation.
Administration	Service description	Fernandez	1993	"The bank is headed by the Professor of Neonatology, who is assisted in the functions of supervision and research by members of the neonatal unit and those of the Departments of Obstetrics, Microbiology, and Social Work. An experienced post-graduate technical fulfills the role of milk bank director. Her duties include bacteriological surveillance, heat treatment of the milk, maintenance of records, and assisting on research projects."		Bombay milk bank India. May not be directly relevant to the UK, but agreed to leave in with caveats in interpretation.
Administration	Service description	Greenwood Wilson	1951	"The maximum turnover of the Cardiff Milk Bank in any one week has been 278 pints. The milk is sent all over Great Britain to children's hospitals without depriving any local babies of their needs for human milk of this kind. The maximum earnings of a milk donor in any one week have been £2 8s. 10d. (293 oz. at 2d. per oz.). This figure works out at a little more than 2 pints a day so that with the amount required for her infant this mother must have been producing a good 4 pints of milk a day. (Hutchison and Mottram (1936) say that a healthy woman produces 1, to 4 pints a day, but averages 11 pints.)"	Hutchinson 1936	Cardiff milk bank Wales

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Greenwood Wilson	1951	"(All milk sent out from the milk bank is marked to indicate that at least 2 oz. of orange juice must be given daily to the baby because of the destruction of vitamin C by pasteurization.)"		Cardiff milk bank Wales
Administration	Service description	Hartmann	2007	"Raw donor human milk must be labelled with the donors ID sticker and the date of expression recorded on the bottle label."		PREM milk bank Australia
Administration	Service description	Hartmann	2007	"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 [the] PREM Bank freezer."		PREM milk bank Australia
Administration	Service description	Hartmann	2007	"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."		PREM milk bank Australia
Administration	Service description	Hartmann	2007	"The Batch Record 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 prodcut label, Batch Record and Product Database."		PREM milk bank Australia
Administration	Service description	Hartmann	2007	"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."		PREM milk bank Australia. Also good diagram of process.
Administration	Service description	Hartmann	2007	"The Donor Record 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."		PREM milk bank Australia

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Hartmann	2007	"Key guidelines. A Quality Management Plan incorporat[ing] 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 [...]. 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 out 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."		PREM milk bank Australia
Administration	Service description	Hartmann	2007	"The Specimen Database 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 record when raw product is either processed or removed from the quarantine freezer."		PREM milk bank Australia

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Hartmann	2007	"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. An appropriate document control system is required to ensure any documentation outlining outdated procedures is removed from circulation."	Teske 2001	PREM milk bank Australia
Administration	Service description	Hartmann	2007	"These records allow complete traceability from individual donation to recipient and maintain a record of all treatment conditions [the] 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."		PREM milk bank Australia
Administration	Service description	Hartmann	2007	"The Recipient Record consists of the parents written consent for Pasteurised Donor Human Milk Feeds and a record of every UPID the recipient receives."		PREM milk bank Australia

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Hartmann	2007	"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."		PREM milk bank Australia
Administration	Service description	Hoey	1980	"Gamma-sterilised collection vessels and accessories are supplied by the milk bank."		Salvation Army milk bank UK
Administration	Service description	Kimball	1955	"[The chairman] hears complaints, and obtains the services of one of the League husbands (an engineer) to repair pumps when they fail mechanically. She also moves a pump from one home to another."		Evanston milk bank US
Administration	Service description	Kimball	1955	"The Junior League volunteers have a chairman who collects names, addresses and telephone numbers of donors."		Evanston milk bank US
Administration	Service description	Kimball	1955	"Junior League volunteers travel in pairs, going first to the hospital nursery where they obtain the latest news about the smallest premature or the latest postoperative problem. They also read the Bulletin Board which contains the latest information about the donors."		Evanston milk bank US
Administration	Service description	Kimball	1955	"Donors receive no remuneration for their efforts, nor is any charge made for breast milk supplied by the bank in or out of any of the hospitals. To the best of our knowledge, this makes our bank unique."	Bettinotti 1985; Chambers 1942; Wright 1947; Wilson 1951; Murray 1953; Chicago Board of Health unpublished; Cornish personal communication	Evanston milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Langerak	1991	"The coordinator of the Mothers' Milk Bank uses office space in her home, but the laboratory facilities, processing equipment and freezers are located in the Wilmington Hospital."		Wilmington milk bank US
Administration	Service description	Langerak	1991	"Each batch of milk is labeled, quickly refrozen and stored at -10 [degrees] F in alarm monitored freezers."		Wilmington milk bank US
Administration	Service description	Langerak	1991	"The Mothers' Milk Bank is sponsored by the Medical Center's Junior Board, the Medical Center's auxiliary. The Junior Board is responsible for paying the coordinator's salary. The Medical Center supports the facility, the laboratory work, the supplies, and the labor for the technicians who do the actual processing. The coordinator is responsible primarily for public relations, donor intake, bookkeeping for the Junior Board, and acquiring the prescriptions needed for dispensing the milk. Unlike the situation at other milk banks in the United States, fundraising is not part of the Coordinator's job!"		Wilmington milk bank US
Administration	Service description	Langerak	1991	"Nursing staff, pediatricians epidemiologists, and infectious disease experts are available to answer any questions concerning the safety and quality of the banked milk."		Wilmington milk bank US
Administration	Service description	Langerak	1991	"The Junior Board offers 20 cents (US) an ounce for the milk. Most contributors do not accept this payment, however, being donors in the strictest sense."		Wilmington milk bank US
Administration	Service description	Langerak	1991	"A processing fee of \$1./ounce (US) for infants receiving the banked milk is added to the baby's hospital bill."		Wilmington milk bank US
Administration	Service description	McEnery	1978	"Most breast-milk banks are described as needing extensive resources in terms of extra personnel and space, and laboratory and transport facilities. The organisation of this bank was in the hands of the staff of the special care baby unit."	Davy 1975; Williamson 1978; Du Pan 1955	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	McEnery	1978	"A deep-freezer was installed in the ward. Autoclaving of bottles was carried out by the existing service in the hospital and previously used milk-feed and infusion bottles were used."		Whipps Cross milk bank UK
Administration	Service description	McEnery	1978	"The bank is located in the special care baby unit in the maternity department (3000 deliveries a year) of a general hospital in outer London. It is organised partly by the staff of the special care baby unit and partly by members of a voluntary organisation who contact donors and help to arrange collection."		Whipps Cross milk bank UK
Administration	Service description	McEnery	1978	"The ad-hoc transportation arrangements bear some resemblance to the use of newspaper sellers in Paris, but incurred no expenses apart from the cost of two insulated carrier bags and reimbursement for petrol expenses of volunteers and nurses."	Du Pan 1955	Whipps Cross milk bank UK
Administration	Service description	McEnery	1978	"The donor is asked to label each sample with her name, date of expression, and the name of any drug she is taking."		Whipps Cross milk bank UK
Administration	Service description	McEnery	1978	"Apart from the economics, another advantage of this spontaneous arrangement has been the close contact between hospitals, donors, and voluntary organisation. Further supplies may be obtained at any time by telephone if needed. This is an example of the large store of practical good will existing between some members of the local community and the health service which seems hardly to have been capitalised yet."		Whipps Cross milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Morley-Peet	1983	Report of enteropathogenic Escherichia coli. Current practice was: "Before the new baby unit opened, the appointed sister arranged meetings with members of the infection control team to seek further help and advice on expanding the pooled milk service. On each occasion it was recommended that a separate area, away from the baby unit and the wards, should be considered for a milk bank, to be controlled by a small number of full-time staff because of the increasing workload." After the outbreak, instructions were issued: "The number of nurses handling the milk collections should be limited and the delivery to the milk kitchen should be made more promptly. These nurses should not attend any babies." Further improvements were also recommended: "1. The milk bank/kitchen should be moved from the SCBU and set up as a small, separate department, away from mothers and babies. 2. The staff should be full-time, small in numbers and trained to process all milk collections. 3. Communications between medical, nursing and laboratory staff should be improved. 4. The records and filing system should be re-organised so that early identification of contaminated milk sample was possible, and batches of stored milk could be rotated systematically. 5. The milk bank staff should control all donors and the equipment used for milk collections and sample processing, within and outside the hospital. 6. Records and charts for the pasteuriser should be kept, and a check made that each cycle takes no less than 30 minutes at 62.5 [degrees] C. 7. As much disposable equipment as possible should be used since chemical disinfection has been demonstrated as being unreliable."		North East Essex milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Murray	1953	"The Contemporary Women's Club of Essex County diverted monies from their milk fund to pay for breast milk for the indigent. St. Michael's Hospital in Newark generously donated the deep freezing unit for freezing and storing this precious product. The county medical society assumed complete responsibility for the undertaking. It began and still continues as a special program of the Child Welfare Committee. With funds supplied by the society, the necessary essentials to start the bank, such as bottles for collection and storage, equipment for freezing the milk, etc. were purchased. The bank is operated as a non-profit venture with the sale price of the milk varying from thirty-five cents an ounce down to no charge for deserving cases. Every donor receives ten cents for each ounce of breast milk supplied. The hospital receives ten per cent of the monies collected."		Essex County milk bank US
Administration	Service description	Murray	1953	"The medical board [of the Babies Hospital-Coit Memorial] accepted the idea [of a milk bank] and assumed responsibility for housing the bank, examining the milk for dilution and contamination, determining the bacterial and fat content, pasteurization, freezing, storage and disposal of the milk."		Essex County milk bank US
Administration	Service description	Murray	1953	"The milk is now available to any physician for use anywhere for any deserving case."		Essex County milk bank US
Administration	Service description	Murray	1953	Donors "were willing to donate their milk for free." However, they were paid.		Essex County milk bank US
Administration	Service description	Omarsdottir	2008	"An assistant nurse was in charge in most of the milk banks." Other staff included nurse, pharmacist, or dietician.		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Omarsdottir	2008	This study was designed to document current routines pertaining to breastmilk use for preterm infants in Sweden. METHODS: A questionnaire regarding breastmilk handling and routines was sent to all 36 neonatal units in Sweden in November 2006 and February 2007. [...] CONCLUSIONS: Routines for breastmilk handling differ among the 36 neonatal units in Sweden. New guidelines can standardize the handling of human milk, thereby improving nutrition and minimizing the risk of breastmilk-induced infection in the preterm infant."		
Administration	Service description	Omarsdottir	2008	"Breastmilk donors received a payment of 100-200 Swedish Crowns (\$17-33 US) per liter of donated milk. In times of scarcity, some neonatal units sold donor milk to other units after its processing. The price for donor milk after pasteurization and nutritional analysis ranged from 500 to 1,000 Swedish Crowns (\$84-167 US) per liter."		
Administration	Service description	Pedersen	1982	"Right from the beginning sale has primarily been to hospitals, Fuglebakken Children's Hospital being the largest single recipient. WM has also been sold to individuals, and for non-primary nutritional use [see indication - not reported here as not relevant to this guideline]. This distribution of a quantity of WM invariably smaller than the demand is in agreement with the aims originally set forth by the medical leadership, although not with the wider initial aims of the administrative leadership." Noted also the use of WM for research purposes.	Christensen 1943; Zangenberg 1943; Kobenhavns 1945	Fuglebakken milk bank Denmark

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Pedersen	1982	"In the period under study [1943 to 1977], purchase was generally undertaken individually from lactating women rather than from institutions, and the demand has exceeded the supply so that sale has been limited only by the number of donor. Lack of knowledge of WMBs existence was the vital factor."		Fuglebakken milk bank Denmark. Not clear if this refers to mothers buying donor milk from other mothers?
Administration	Service description	Pedersen	1982	"Long delivery period: daily milking for a period of five years and six months [...]; daily milking for a period of five years and seven months [...]. Large quantum delivered per day: average maximal daily delivery for a period of six months [...] 3,100 ml and for a period of one month 3,170 ml [...]; average maximal daily delivery for a period of six months [...] 2,850 ml and for a period of one month 3,000 ml [...]. Extensive changes in delivery from one birth to the following birth period: over a period of seven months after her second delivery [...] provided 93 litres in all [...], while over 14 months after her third delivery she provided 813 litres in all [...]."		Fuglebakken milk bank Denmark
Administration	Service description	Pedersen	1982	"Approximately 98 percent of the WM collected was sold. Waste constituted about two percent, half of which was needed for routine analyses."		
Administration	Service description	Pedersen	1982	"A reasonable basis of operation of a woman milk bank must thus include routine bacteriological examinations and possibly supplemental examinations guided by visual inspection of the WM collected upon a background of basic instruction in milking procedures and storage conditions and frequently checked work in order to achieve minimal contamination in general."		Fuglebakken milk bank Denmark

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Pedersen	1982	"A few years after the opening of the WMB hospital wet nurses were for a time employed in the Children's Hospital at Fuglebakken."		
Administration	Service description	Penc	1996	"Special permission had to be obtained from the Ministry of Health and Social Welfare, the Mother and Child Institute, the State Institute of Hygiene, and the Administration of the PMMH. Difficulty in obtaining such permissions lay in the lack of relevant national norms. There were no guidelines or standards relating to the quality of human milk. In the rare cases where some hospitals fed premature newborns with donor milk (within small hospital wards), approval was obtained from local Administratio Units for Control of Epidemics and Hygiene Promotion."		Polish Mother's Memorial Hospital milk bank Poland
Administration	Service description	Penc	1996	"Chemical composition and the immunological content of individual batches are not analyzed because of the high costs of such tests and inadequate staffing to perform the tests. The same issues prevent the lyophilization of milk."		Polish Mother's Memorial Hospital milk bank Poland
Administration	Service description	Penc	1996	"When the donor criteria are met and the mother's consent has been obtained (donors receive no payment for their milk), her milk is assigned to a specific infant in the Neonatal Intensive Care ward."		Polish Mother's Memorial Hospital milk bank Poland
Administration	Service description	Penc	1996	"The poor financial state of the health service also did not permit payment to obtain milk."		Polish Mother's Memorial Hospital milk bank Poland

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Siimes	1979	"About 5,00 liters per million of the general population are collected annually. In 1977, about 464 new mothers started to donate human milk for an average of two months; they gave 11,300 liters or an average of 24.4 liters per mother. These totals represent a large number of individual samples because the daily aliquots averaged only 0.4 liter per mother."		Helsinki milk bank Finland
Administration	Service description	Siimes	1979	"All donors are volunteers and are paid a nominal fee of \$4 per liter of milk, to serve as partial compensation. The total cost of running the service in 1977 was \$145,000, about \$13 per liter of milk."		Helsinki milk bank Finland
Administration	Service description	Springer	1997	"Six of the 18 milkbanks are not only collecting milk for use at their own institutions, but also are supplying other hospitals or milk banks with pasteurized or frozen donor milk."		German milk banks Germany
Administration	Service description	Springer	1997	"The physician in charge of the milk bank is responsible for instructing the milk bank staff and setting the guidelines for day to day operations. There are as yet no written guidelines for German milk banks such as those which exist for the United States and the United Kingdom. There are however, recommended methods of operation, and these recommendations encompass the basics of collecting milk and storing it, pasteurization of donor milk, and criteria for selection of donors."		German milk banks Germany
Administration	Service description	Springer	1997	"In 1995, 74 donors supplied 4,200 liters of milk in Leipzig (an average of 56.8 liters per donor or 1,891.7 ounces per donor). These well-trained donors often donate over a period of weeks, months, or even longer. Collecting large volumes of milk from a few well-trained donors is advantageous as it helps the milk bank staff be more efficient."		Leipzig milk bank Germany

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Springer	1997	"Milk banks thrive when the pediatric chief of staff is convinced of the benefits of donor milk and is therefore willing to devote staff and financial resources to the support of donor milk banking operations."		German milk banks Germany
Administration	Service description	Springer	1997	"Conferences of the medical directors are responsible for milk bank operations are held to share information, optimize the work load and increase cooperation between the individual milk banks. Three such conferences have been held in the last nine years."		German milk banks Germany
Administration	Service description	Springer	1997	"Today, most donor milk banks are part of hospitals with neonatal intensive care units. They no longer receive government support."		German milk banks Germany
Administration	Service description	Tomalin	1983	Cited two references, both letters, on the need for milk banks to follow proper processes and to be adequately funded and supported. Barrie 1982 - see EXC list. See also Lucas 1982 in the relevant evidence reports(s).	Barrie 1982; Lucas 1982	Kings College milk bank UK
Administration	Service description	Tomalin	1983	"'We never refuse any amount, however small', says [...]. 'Sometimes the mothers just collect drips from the nipple shields.'"		Kings College milk bank UK
Administration	Service description	Tomalin	1983	"Testing is done by microbiologist [...] from the public health laboratory at neighbouring Dulwich Hospital. [...] spends about eight hours a week testing for organisms such as Staphylococcus aureus, Escherichia coli, Klebsiella and Pseudomonas."		Kings College milk bank UK
Administration	Service description	Tomalin	1983	"[...] believes there should be a small number of large banks which have the equipment and staff to run them. " Also stressed the need for support from bacteriological laboratories.		Kings College milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Tully	2000	"A label printer or a label-making program on the computer for self-adhesive labels is a tremendous time saver, because each individual jat must be labeled with processing batch number and date (Seiko makes a small label printer to interface with a computer, about \$165). A personal computer with a database program facilitates good record keeping."		HMBANA milk banks US & Canada
Administration	Service description	Tully	2000	The Wakemed milk bank was "established in 1992 with a \$72,000 grant from a North Carolina foundation. This was matched by the hospital in the form of salary for the milk bank coordinator, space, and laboratory testing of donors and milk samples. The start-up funding included salary for two half-term lactation consultants for the first year of operation. Since that time, with donations and reimbursement from most recipients, the milk bank has remained economically viable within WakeMed. Patients at WakeMed are not charged for donor milk."		WakeMed milk bank US
Administration	Service description	Tully	2000	"Shipping in from out-of-town donors, and out to recipients and hospitals, requires overnight delivery and is a significant expense."		HMBANA milk banks US & Canada
Administration	Service description	Tully	2000	"Other ongoing expenses besides labor for screening donors (at least 30 minutes per donor), record keeping, and processing milk include serum testing of all donors (cost varies, but around \$100 per donor going through a blood bank or hospital lab) and bacterial testing of each batch of milk (typically about \$30 per sample), sterile water for the water bath, glass containers for processing, containers for donors to use, linens and cleaning supplies, printing of donor screening packets, postage, and shipping for out-of-town donors."		HMBANA milk banks US & Canada

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Tully	2000	"After recruitment, each step requires thorough record keeping and careful decision making. In the United States, most milk banks only survive with the volunteer efforts of many individuals who assist with every step from recruiting through distribution and fund-raising. Funding is a constant concern, since processing of donor milk is often confused with milk as a food, and not considered a reimbursable medical expense."		HMBANA milk banks US & Canada
Administration	Service description	Tully	2000	"Finding the space and equipment required to store, heat process, test, and ship milk and maintain records is relatively simple. The milk processing and storage requires about 650 square feet of space (a little less may be required for a small milk bank). The space must have at least one clean sink and counters or laboratory benches for the processing equipment."		HMBANA milk banks US & Canada
Administration	Service description	Tully	2001	"One of the primary goals of the National Reference Milk Bank is to continue to develop low-tech, inexpensive methods and equipment for donor milk banking that preserve the unique components of the milk and produce a safe product."		Brazilian milk banks Brazil
Administration	Service description	Tully	2001	"The milk banking system is organized from the national to the local level, with a training course for milk bank personnel, a registry of all those who have been certified, and both national and state reference centres. Federal regulation now requires that all milk bank directors be certified and that banks follow federal guidelines [...]"	Gutierrez 1998	Brazilian milk banks Brazil
Administration	Service description	Tully	2002	"Donor milk banks operate as nonprofits. Although the milk itself is donated, there is a significant cost associated with donor screening and milk processing. These expenses are met by charging a processing fee to the ordering institution or the recipient. In each country, the expense is determined by the way the health care system operates."		HMBANA milk banks US & Canada

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Tully	2002	"Milk can be ordered [for recipient babies] from the nearest milk bank, which may coordinate delivery from another milk bank in times of shortage."		HMBANA milk banks US & Canada
Administration	Service description	Weaver	2005	"In the main, the banks that do function are funded by an individual NHS trust, although a couple receive funds from a regional source and one is funded almost exclusively through charitable donations. Some banks make surplus milk available to other hospitals and charge a fee that represents a contribution towards the costs incurred."		UK milk banks

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Wilson-Clay	2007	"After touring existing milk banks and engaging in helpful dialog with the Human Milk Bank Association of North America (HMBANA), the group decided to organize the Austin milk bank as a community-based, free-standing facility. This crucial decision resulted from concerns that over-identification with any single institution would prevent acceptance from competing hospitals and limit widespread community support. Because historical review suggested that milk banks within existing institutions are vulnerable to funding cuts during budget crises, an autonomous milk bank with a supervising board of directors was deemed the most stable model for success. Additionally, the founders committed to the principle of non-profit milk banking in order to protect their ability to provide donor milk by prescription without regard for recipients' ability to pay. Once these organizational and philosophical decisions were made, the group constituted itself as a Board of Directors (BOD). In 1998, with pro bono assistance from a generous attorney, the BOD applied for and was granted status by the US Internal Revenue Service (IRS) as a 501(c)(3) nonprofit organization. The Mothers Milk Bank at Austin (MMBA) owes much of its success to the camaraderie and diverse composition of the BOD, its exceptional staff, and to careful fiscal management. The project is funded by grants, donations, and, increasingly, by milk processing fees paid by hospitals that order supplies of milk for their preterm nurseries. The healthy financial status of the MMBA allows for expansion of services and continual up grading of equipment and methodologies."		Austin milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Wilson-Clay	2007	"In January 2006, the MMBA consisted of a staff of eight, and a well-organized cadre of volunteers. In addition to the BOD, an advisory panel of medical doctors and researchers has been formed, providing an additional expert consulting body. Year-end figures for 2005 report that the MMBA dispensed 186,777 ounces (5524 litres) of milk, routinely supplying milk to 26 hospitals nationally. The MMBA is outgrowing its current facility, which houses the staff, three pasteurizers, nine freezers (equipped with sensors and emergency back-up power sources), a commercial dishwasher, an ice-maker, and a small research laboratory. The BOD plans to launch a campaign to acquire funds for a new space. Ideally this will include a loading dock to better handle deliveries and shipments, expanded research facilities, and space for new, advanced pasteurization technologies."		Austin milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Wilson-Clay	2007	"An early task of the MMBA was the creation of an informational website. In 1999, a community open house helped familiarize local doctors, health care professionals, and the Austin community with the milk bank. A series of publicity events followed involving members of the local arts and music scene. Several outdoor concerts held annually on Mothers Day, and fund-raising events held in nightclubs and coffee houses raised awareness of the value of human milk and endeared the project to the community. While such events generally raised only small amounts of money (averaging US\$5,000.) the publicity and raised community awareness led to increased private and corporate donations. Creative public relations strategies continue to attract donations of milk, money, and assist in recruiting volunteer workers. In the spring of 1999, the BOD and the project's first Executive Director, Andrea Morgan, produced a Policies and Procedures manual, and adopted the milk banking standards and guidelines of HMBANA."	www.mmbaustin.org; HMBANA no date	Austin milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Wilson-Clay	2007	"The founding neonatologists currently serve as President and Vice President of the BOD. A vital liaison with the Austin Blood and Tissue Center was established when their president consented to serve as the MMBA's treasurer. The 21 member BOD meets eight times yearly to review operations, set policy, and continually reevaluate program goals. Initially, BOD members performed operational tasks. Staff now assumes total responsible for the day-to-day running of the milk bank. Consequently, such frequent board meetings are not essential. However, the creative input of the diverse fellowship comprised by the BOD is felt to be one of the cohesive elements guaranteeing the continuing success of the project. Permanent board seats are designated for a representative from La Leche League, an IBCLC, and a public member (either a donor or a mother whose child had been a milk recipient). Another seat is designated for an ethics advisor. An Episcopal priest, a rabbi, and a Catholic nun have served in this capacity. The remaining board seats include representatives from the insurance, business, high tech, advertising, legal, arts and entertainment communities. The diversity of the BOD connects the milk bank project with funding and publicity resources that might otherwise not have been available, and provides a flexible mechanism for accessing valuable consulting expertise at no cost."		Austin milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Wilson-Clay	2007	"The BOD conducts annual strategic planning sessions to chart the course for each up-coming year. This encourages continual evaluation of the goals of the project. The BOD made an early decision to expand collection centers outside of the Austin area in order to keep pace with increasing demands for milk. A milk collection depot was opened in Houston in 2000, the first of nine collection sites around the state. Some hospitals in various US cities that were using MMBA donor milk began exploring the idea of starting their own milk banks. Since the founding of the MMBA, one milk bank has re-opened in Delaware, and four additional US human donor milk banks have been established in Ohio, Indiana, Iowa, and Ft. Worth, Texas, each with mentoring assistance from the MMBA."		Austin milk bank US
Administration	Service description	Wilson-Clay	2007	"Staff members of the MMBA have written a manual entitled Starting a Donor Human Milk Bank: A Practical Guide. The guide includes a historical and research review of milk banking. It provides specific suggestions on creating budgets and by-laws, and addresses a variety of legal and organizational issues. The manual describes staffing and equipment requirements, funding resources, and provides a template for other communities wishing to access the operational model employed by the Austin project."	Bradley 2006	Austin milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Wilson-Clay	2007	"Human donor milk obtained from non-profit milk banks is not sold. A processing fee is charged to partially recover the expense of producing the milk. Production costs include donor screening and blood testing, microbiological testing of milk, pasteurization costs, storage costs, equipment and shipping expenses, staff salaries, and the expenses of operating the physical plant. Because actual production costs exceed the processing fees charged, human donor milk from the MMBA is partially subsidized by charitable donations and grants. The current processing fee charged for one ounce (28 ml) is US\$3.25."		Austin milk bank US
Administration	Service description	Wilson-Clay	2007	"By the end of 1999, the MMBA processed 10,000 ounces (296 litres) of milk and was dispensing milk to three hospitals and one infant in the community. By 2000, the staff grew to include a program director and a program assistant, who supervised all aspects of the donor milk program, including pasteurization. The addition of staff enabled increased enrollment of donors and increased pasteurization capacity. By the end of 2000, the MMBA had 148 donor mothers, and was serving six hospitals and nine outpatients clients from all over Texas. Over 51,000 ounces (1508 litres) of milk were pasteurized."		Austin milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Administration	Service description	Wilson-Clay	2007	"Medicaid is a US government-sponsored program that releases money to the states to help meet the medical needs of specialized groups of citizens, including low income families and children in foster care. A special provision of Medicaid allows preterm infants to be temporarily enrolled as recipients, providing help to families who would otherwise be overwhelmed by their medical costs. Rep. Glen Maxey, state representative from the MMBA's congressional district, successfully sponsored legislation in 2001 to obtain Medicaid funding to pay for human donor milk. The inclusion of Medicaid coverage for donor human milk made it possible to routinely secure donor milk for a wider variety of clients including hospitalized preterm infants without private insurance, outpatient babies with special nutritional needs, and infants in the Texas foster care system."		Austin milk bank US
Donor recruitment	Narrative review	Bar-yam	2003	"For mothers of infants who die, donating expressed milk can be a fitting, comforting way to remember their lost child, by helping another infant to live. Women in this tragic situation may not be aware of this option, or may not think of it at the moment of their loss. Suggestions by providers are appropriate and often much appreciated."		
Donor recruitment	Narrative review	Bar-yam	2003	"When a mother has suffered a stillbirth or neonatal loss, raise with her the possibility of becoming a milk donor."		
Donor recruitment	Narrative review	Bar-yam	2003	"Communities with milk banks use different methods to educate and solicit donors, including brochures in doctors' offices and hospital information packets. Referrals also come from childbirth educators, nursing mothers groups, and La Leche League. Like blood banks, milk banks sometime use newspaper, TV and radio ads to solicit donors, especially when supplies are low."	Arnold 1997	US processes.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor recruitment	Narrative review	Bar-yam	2003	"NICUs with successful breast feeding promotions and support often have mothers with excess milk. When these mothers ask what to do with their excess 'liquid gold' it is appropriate to help them contact a milk bank."	Arnold 1998	
Donor recruitment	Narrative review	Bar-yam	2005	"In all of these circumstances [perinatal loss due to adoption, NICU, death] milk donation to others is a physical as well as a psychological and spiritual comfort to mothers as their bodies, minds, and souls grasp the reality that their baby is no longer with them. Like organ donation, it is important that mothers be offered the possibility to donate milk as a way to help mothers and to aid in their own healing."		
Donor recruitment	Narrative review	Bromberger	1982	"To assure an ongoing supply of milk, the milk bank needs a continual supply of new donors, which necessitates an active public relations program."		
Donor recruitment	Narrative review	Holland	2006	"Use of donor milk challenges perceptions of infant milk as a commodity." "Use of donor human milk values women's natural resources and is environmentally safe."	Van Esterik 1995; Heinig 1998; Radford 1991; Meershoek 1993; Tully 2000; Waring 1988; Campbell 1984; Palmer 1993; Bottorff 1990; Dykes 1999; Mulford 1995; Klein 2000	
Donor recruitment	Narrative review	Holland	2006	"The use of donor human milk banks are not acceptable under strict Islamic law because of the belief of milk kinship."	Maher 1992; Khatib-Chahide 1992; Hathout 1988; Zaki Yamani 1990	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor recruitment	Narrative review	Holland	2006	"A health professional's own cultural beliefs will have a degree of influence on whether or not she/he recommends donor human milk or encourages mother to become human milk donors, just as the cultural beliefs of mothers will influence whether or not women wish to use of donate human milk."		
Donor recruitment	Narrative review	Holland	2006	"There is no research available concerning what prompts mothers to donate human milk or the positive or negative effects of the experience of human milk donation for a breastfeeding mother. However, research into the beliefs and attitudes of blood donors would suggest that the reasons for human tissue donation are social duty, community responsibility and personal benefit. Donating and utilising excess human milk while breastfeeding is a positive way in which mothers could support each other and contribute to the community during a postnatal period when many mothers feel isolated or restricted by their new roles as mothers." Based on blood donor research, authors postulated that the use of donor milk to manage breastfeeding problems would indirectly increase the numbers of donors and therefore milk, creating a cycle of increasing donors and milk.	Moore 1991; Fernandez-Montoya 1998	
Donor recruitment	Narrative review	Holland	2006	"Donor milk may regarded unfavourably because of associations with women's sexuality and body fluids."	Carter 1995; Morse 1988; Henderson 2000; Kitzinger 1989; McConville 1994; Schmied 1999; Hoddinott 1999; Gregg 1989	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor recruitment	Narrative review	Tully	1999	"Although each donor must be screened individually, knowing the general criteria for becoming a milk donor can make it easier to determine which mothers to approach. Any healthy, lactating woman is a potential donor." Screening criteria are from the HMBANA 1999 guidelines.		
Donor recruitment	Narrative review	Tully	1999	"Each milk bank has a distinct protocol for blood testing and shipping of the milk, so it is important to check with the milk bank before making plans with the family. It is also important to allow the mother to decide when she wants the milk to go to the milk bank. Some mothers need to keep it for a few days or weeks, until they are ready to give up the last physical evidence of their struggle for their baby."		
Donor recruitment	Narrative review	Tully	1999	"However, milk banks often receive calls and letters from women whose milk donations are their way of healing. These mothers donate their milk just as others agree to organ and tissue donation - as an important part of healing when a loved one dies." Reported two cases where women donated milk after the death of their infant and how this helped them. "Often, when a baby has been hospitalized in an intensive care unit and the mother is pumping and storing, if the baby dies a member of the hospital staff will call to confirm that a milk bank can accept a donation of her milk before approaching the family. It is helpful to the grieving parents not to suggest something that might later prove to be another disappointment, or 'failure'."		
Donor recruitment	Narrative review	Wight	2001	"Although most donors to milk banks deliver at term, some do not."		US milk banks US
Donor recruitment	Narrative review	Williams	1981	"We ask a mother to donate only when she has excess or when her infant is not feeding orally."		Rainbow milk bank, US
Donor recruitment	Narrative review	Williams	1981	"In our setting, most milk donated is from mothers of premature infants whose infants are in the same unit."		Rainbow milk bank, US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor recruitment	Narrative review	Woo	2007	"At Children's Hospital of Philadelphia, families are provided with written patient family education materials regarding information on weaning and milk donation in the bereavement packets."		Children's Hospital of Philadelphia milk bank US
Donor recruitment	Narrative review	Woo	2007	"Mothers who have lost a newborn should be encouraged to consider donating human milk, because women and families may find it an instrumental part of the grieving process, similar to when a family chooses to donate an organ or tissue of a loved one. Many are comforted by knowing that they can help another sick baby. Although no research evidence exists, anecdotal evidence about milk donation abounds, with parents telling providers about the rewarding emotions when donating milk. For instance, some women choose to pump for the remainder of their maternity leave."	Tully 1999	
Donor recruitment	Narrative review	Woo	2007	"Milk that is expressed from a mother who delivered before 36 weeks' gestation has been shown to be different in composition from milk expressed at term. 'Preterm' milk can be pooled, pasteurized, and distributed separately from 'term' milk at donor milk banks and used for preterm infants who are in need of breast milk in the event that the mother is unable to provide her own milk."	Wight 2001	
Donor recruitment	Narrative review	Woo	2007	"The nurse should find out if a surplus of frozen milk is available to be donated."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor recruitment	Narrative review	Woo	2007	"[Milk donation] can be introduced to the appropriate mothers with sensitivity when the prognosis is grave, or when withdrawing life support is being discussed." Issues highlighted are: only approach mothers who meet the criteria; understand cultural and religious beliefs; a staff member known to the family (or with a relationship) should broach the subject; inform mothers that the banking system is a well-regulated, safe method that can help sick babies or infants with sick mothers; approach the subject before the infant dies; establish a relationship with a local milk bank.	Al-Naqeeb 200	
Donor recruitment	Opinion piece	Modi	2006	"These uncertainties are reflected in the divergent attitudes of clinicians towards the use of donor milk and compounded by variations in acceptability by different communities."	Ighogboja 1995	
Donor recruitment	Opinion piece	Williams	2007	"[...] some concerns about the nutritional quality of pasteurised donor milk could be dealt with by the collection of expressed milk, particularly from preterm donors. Anecdotally milk banks in the UK have reported increasing success with collecting preterm donor milk."		
Donor recruitment	Position statement	American Academy of Pediatrics	1980	"Healthy donors are generally recruited from mothers who nurse their infants but have extra milk."		
Donor recruitment	Position statement	Canadian Paediatric Society	1985	"Donor milk from mothers early in lactation: This milk often includes 'drip' milk donated by mothers of newborns in hospital. In some centres such milk is the major source of milk donations, and special considerations regarding possible contamination and energy content are necessary."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor recruitment	Position statement	Canadian Paediatric Society	1985	"Donor milk from a milk bank: This milk is usually donated by nursing mothers with well established lactation [...]. Donors may be recruited from various volunteer or health-related organizations that operate through public health units, physicians' offices, prenatal and postnatal classroom settings, and postpartum wards in hospitals."		
Donor recruitment	Primary study	Azeema	2003	"Also, the need for donor milk in various situations could be communicated in nontechnical (laypersons') language to reach the nonmedical population."		Survey conducted in France. Relevant to UK?
Donor recruitment	Primary study	Azeema	2003	"It is clear that these results could have implications for targeting donor recruitment. Although certain pre-determined variables seem to correlate with donation (the presence of a significant other, no external work activity, and having fewer than 3 children), there are a number of outreach and education efforts that could be made to attract potential human milk donors. Because many donors are in the medical or social services fields, women outside those professions could be targeted for donor recruitment."		Survey conducted in France. Relevant to UK?
Donor recruitment	Primary study	Azeema	2003	"Finally, health care professionals (lactation consultants, doctors, midwives) could be encouraged to suggest to women who fit the optimistic [defined as still having positive attitudes about breastfeeding despite having problems] and altruistic [reported reason for donation being having a desire to help others] profile that they become human milk donors; thus, a group of women who may not necessarily be having particular difficulties with breastfeeding could be targeted."		Survey conducted in France. Relevant to UK? Authors noted the need for more research on the personality traits of donors.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor recruitment	Primary study	Azeema	2003	"Breastfeeding care and services could be offered by milk banks as part of their recruitment efforts."		Survey conducted in France. Relevant to UK?
Donor recruitment	Primary study	Egri-Okwaji	1984	Interview study to assess attitudes to donation and use of donor milk in users of neonatal and obstetric services at one hospital. 95% of fathers (19/20) and 72% of mothers (43/60) would be willing to agree to the donation of milk. Of the 17 women who were unwilling to donate milk, 47% (8/17) feared an insufficient milk supply, 23% (4/17) were worried about the incompatibility of the blood of the donor and the recipient, and 30% (5/17) merely disliked the idea.		Relevant to UK - study conducted in Nigeria? Reported only data on donation, not use of milk.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor recruitment	Primary study	Ighogboja	1995	Aimed to assess the willingness of mothers to accept donor milk, to donate milk, to accept banked donor milk, and/or to breast feed when HIV positive. Note, only the findings related to donating milk are reported here. 60% (410/680) of the women were willing to donate breastmilk, "but they preferred to do so for a relation's baby; 25 percent feared producing insufficient breastmilk to sustain their own infants if they had to donate milk."		Study conducted in Nigeria - attitudes relevant to the UK? Also reasonably old. Not sure if relevant to UK practice, and also may be a hypothetical response r.t. a response in the presence of milk banks. Also no mention of heat treatment. But recognition that there is a multicultural society in the UK so agreed may be relevant in some areas.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor recruitment	Primary study	Osbaldiston	2007	Positive and negative affect and values - "Donors were asked if they would donate again if given the opportunity, and 97% said they would donate again." No significant differences were seen between donors and non-donors for the PANAS score or values. "They experience positive emotions while donating milk, and they would donate again if the opportunity arises. Donors report more positive emotions about donating to the milk bank than nondonors report about volunteering in general." "These results were not directly comparable because the instructions were different; however, the data indicated that donating milk was a more positive and a less negative emotional experience than simply breastfeeding."		Austin milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor recruitment	Primary study	Osbaldiston	2007	"The primary objective of this study was to help provide a more quantitative and complete picture of donors. Specifically, we sought to measure demographic and lifestyle characteristics, procedure for involvement with the milk bank, reasons or motives for donating, problems while breastfeeding and pumping milk, barriers to donating, affective experiences, and personal values. This study also had 2 secondary objectives. First, we wanted to understand why donation amounts vary considerably. Some donors provided only a relatively small amount of milk and others provided a large amount. By understanding how problems and barriers influence the amount of milk donated, the donation experience may be enhanced to increase the amount of milk donated. Specifically, we hypothesized that donors who reported more problems with breastfeeding and pumping would donate less milk. Furthermore, we hypothesized that donors who reported greater barriers to donating would donate less milk. Second, we wanted to compare the characteristics of donors to a control group of mothers who had pumped milk and breastfed their children but not donated. Again, we hypothesized that nondonors would report greater barriers to donating and more problems while pumping milk than donors."		Austin milk bank US
Donor recruitment	Primary study	Osbaldiston	2007	Demographic information - see Tables 1 and 2 in the published paper. "Most of the donors are married, young, financially secure, well-educated, and healthy."		Austin milk bank US
Donor recruitment	Primary study	Osbaldiston	2007	Barriers to donating milk - Where appropriate, donors and non-donors reported similar barriers, but donors reported significantly lower rates of physical stress from pumping, psychological stress, and depression ($p < 0.01$). "They report relatively few barriers to donating and few problems while pumping."		Austin milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor recruitment	Primary study	Osbaldiston	2007	Amount of milk donated - "One of the secondary objectives of the study was to determine the relationship between the donation experience and the amount of milk donated. The milk bank staff provided the amount donated for each participant. Therefore, this information was an objective measurement that was not reported by the donors or included in the interview. For the amount of milk donated, 2 donors gave very large amounts (211 and 363 liters; these values were double-checked with milk bank records to be sure that there was not a data recording error). Not including these 2 data points, the mean $\pm$ standard deviation amount of milk donated was 29.65 liters $\pm$ 31.13. These 2 extreme values were statistical outliers in that they were 6 and 10 standard deviations greater than the mean. Problems when breastfeeding were assessed using yes-no questions. Donors' responses served as the grouping or independent variable in a t test, and the amount donated served as the dependent variable. With the exception of thrush, there were no statistical differences in amount donated between those who reported having the problem versus those who did not report having the problem. For thrush, the 13 women who reported that their babies had thrush donated an average of 54.02 liters, whereas the 72 women who reported no such problem donated an average of 28.65 liters. Note that this relationship is in the opposite direction than hypothesized. (Recall that this item merely asked if the babies had had thrush. No attempt was made to determine how the occurrence of thrush affected the donation process; the Human Milk Bank Association of North America [HMBANA] guidelines prohibit donation during times of such infections.) Along these lines, we hypothesized that the greater the barriers or problems, the less a person is likely to donate. This hypothesis was not supported. Of the 12 barriers and 11 problems that we asked about, none of		Austin milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
			2007	them had statistically significant negative correlations with donation amount. [...] Regarding the reasons for donating milk, only 2 items were significantly correlated with amount of milk donated, namely, "Had too much milk and wanted to donate it" ($r = .31$, $P < .01$) and "Needed to pump milk to stimulate lactation" ($r = .34$, $P < .01$). There was a clear dichotomy of donors on this latter item. This dichotomy was explored by comparing the 17 donors who responded 7 or above on this item with the 50 donors who responded 0. The mean donation amount $\pm$ standard deviations for these 2 groups were 48.67 liters $\pm$ 46.96 and 23.01 liters $\pm$ 24.54, respectively ($t[66] = 2.91$, $P < .01$). In terms of lifestyle and demographic information, only 1 item was related to donation amount. There was a significant negative relationship between age and donation amount such that younger donors donated more milk ($r = -.24$, $P < .03$). "It is interesting to note that there are few relationships between problems and donation amounts. Problems during breastfeeding do not account for why some women only make moderate donations and others make large donations. Furthermore, in this sample, there are no meaningful correlations between donation amount and barriers, pumping problems, reasons for donations, or lifestyles. As such, this study does not successfully identify factors that could be addressed to increase donation amounts. A small group of donors report that they had to pump milk to stimulate lactation. This group donates significantly more milk than donors who do not need to stimulate lactation. Targeting these women in recruiting efforts might prove fruitful. We did not anticipate the existence of such a distinct subsample and did not ask questions to explore the differences between women who needed to stimulate lactation versus those who did not."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor recruitment	Primary study	Osbaldiston	2007	Reasons for Donating - "The means $\pm$ standard deviations for the 4 highest scoring reasons for donating (to help others, had too much milk and wanted to donate it, know the milk bank needs donations, and would hope someone would do the same if I were in need) were 9.34 ± 1.34 , 8.44 ± 2.56 , 7.79 ± 2.74 , and 7.61 ± 3.18 , respectively. For the item, "Needed to pump milk to stimulate lactation," 19% of respondents reported a value of 7 or higher, including 11 donors who reported a value of 10, and 59% reported a value of 0. The differences between high and low responders on this item are explored below in the section on amount of milk donated." VFI results were similar for both donors and non-donors for values, enhancement, understanding, and protection but were significantly lower in donors for social and career motives ($p < 0.05$). Reasons "or donating have strong altruistic and benevolent themes." "When designing recruiting materials, the fact that most donors are motivated by altruistic and benevolent reasons should be kept in mind. Donating milk is seen most frequently as an outlet for expressing one's personal values, and the values that donors endorse are security, tolerance, self-direction, and social concern."		Austin milk bank US
Donor recruitment	Primary study	Osbaldiston	2007	Study used scripted telephone interviews (30-45 minutes). 114 of 324 invited donors responded (35%) and 87 donors completed the interview. Also 19 control women who had pumped milk whilst breastfeeding their infants were interviewed, using a modified script. Data on demographics, reasons for donation, from the Volunteer Functions Inventory (VFI - measures motives for volunteering), problems with breastfeeding, barriers to donating, from the Positive and Negative Affect Schedule (PANAS), and personal values were collected.		Austin milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor recruitment	Primary study	Pimenteira Thomaz	2008	"The aim of this investigation was to identify factors that influenced or motivated women (N = 737) to donate human milk to human milk banks in Alagoas, Brazil. The most common characteristics of a regular donor were having 4 to 7 pregnancies (relative risk [RR] = 1.9285; 95% confidence interval [CI] = 1.0388-3.5800) and having obtained a higher education level (RR = 2.0625; 95% CI = 1.0097-4.2130). The most commonly reported reasons for donating were "encouragement of a health professional" (61.3%), followed by "the needs of the babies the banks serve" (25.3%). Most of the donors (49.9%) were introduced during their stay in the hospital to the human milk bank to which they donated, and 25.8% chose the bank recommended by a health professional. Health professionals play an indispensable role in motivating mothers to become human milk donors."		CI not significant is rounded to 1 decimal place.
Donor recruitment	Service description	Arnold	1996	"Milk is collected only from mothers in the postpartum hospital unit."		Beijing milk bank China
Donor recruitment	Service description	Arnold	1999	"Milk is obtained from mothers who are referred to the milk bank by health visitors who visit all new mothers and do all well-baby pediatric visits in the home during the first year of life. If more milk is needed, health visitors can be notified of the increased demand."		Hvidovre milk bank Denmark
Donor recruitment	Service description	Arnold	1999	"Contributors learn about the milk bank from brochures, which are given out in the perinatal period. Health visitors also refer prospective contributors."		Goteborg milk bank Sweden
Donor recruitment	Service description	Baum	1982	"Most of this milk [drip milk] is from mothers who were noted to be producing drip breast milk in the early puerperium and continued to do so once they were discharged home. Recently our community midwives have noted that a proportion of mothers who did not initially drip milk began to do so several weeks after delivery and a number of these mothers have now been enrolled as donors to the milk bank."		John Radcliffe milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor recruitment	Service description	Baum	1982	"We believe that involvement with giving spare milk to the bank is gratifying for the mothers and in practice leads them, together with the community midwives, to publicise the charitable idea of providing spare human milk for babies who have special need of it."		John Radcliffe milk bank UK
Donor recruitment	Service description	Beal	1978	"Essentially the donors are nursing mothers who provide more milk than their babies can consume, whilst the infants are generally three to four months old."		Townsville milk bank Australia
Donor recruitment	Service description	Beal	1978	"Milk donors are recruited entirely by the efforts of the NMAA [Nursing Mothers' Association of Australia]. Donors have come forward after visits by representatives of the NMAA to the maternity wards of both private and public hospitals, after local news coverage of the NMAA in the community, and in response to NMAA Newsletters; however, most donors are found by word of mouth. This canvassing requires diligence and time."		Townsville milk bank Australia
Donor recruitment	Service description	Cash	1981	"Several recruitment avenues are utilized to secure new donors. A brochure briefly explaining the program is distributed at physicians' offices, LaLeche League and prepared childbirth organizations' meetings, prenatal classes, and infant, children and maternity shops. The brochure is also given to postpartum patients during their hospitalization. Articles explaining the milk bank have appeared in newspapers, magazines, and newsletters."		EOPC milk bank US
Donor recruitment	Service description	Cash	1981	"Voluntary donors are recruited from breastfeeding and prepared childbirth organizations and any other interested nursing mother."		EOPC milk bank US
Donor recruitment	Service description	Connor	1982	"Donors are recruited from the breastfeeding mothers in the maternity wards. Only mothers with a high standard of hygiene are approached with a view to donating surplus breast milk [...]."		Enfield milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor recruitment	Service description	Fernandez	1993	"Ongoing education and motivation of expectant mothers and mothers in the PNC wards help familiarize them with the concept of milk donation and thus to overcome any inhibitions associated with milk donation [...]."		Bombay milk bank India. May not be directly relevant to the UK, but agreed to leave in with caveats in interpretation.
Donor recruitment	Service description	Fernandez	1993	Donors are "mothers whose breastmilk is in excess of their babies' demands and are willing to donate. [This group] accounts for the major portion of the milk collected. Donors are provided with a glass of milk following donations; no payment is made."		Bombay milk bank India. May not be directly relevant to the UK, but agreed to leave in with caveats in interpretation.
Donor recruitment	Service description	Greenwood Wilson	1951	"Mothers in St. David's Hospital, where most of the hospital confinements in Cardiff take place, are selected before leaving hospital when it is thought that they will be able to provide breast milk in excess of that needed by their own babies."		Cardiff milk bank Wales
Donor recruitment	Service description	Greenwood Wilson	1951	"The Cardiff milk donors are selected from maternity wards which deal with more than half the total confinements in the city every year. They represent a fair cross section of the income group involved and therefore of the variations in nutritional intake that may be found in any typical urban community."		Cardiff milk bank Wales
Donor recruitment	Service description	Hoey	1980	"Expressed breast milk is collected either from mothers on the wards or from mothers who have been discharged."		Salvation Army milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor recruitment	Service description	Kimball	1955	"Donors may be chosen from the mothes who are good producers during the lying-in period."		Evanston milk bank US
Donor recruitment	Service description	Kimball	1955	"More frequently, we find better donors by waiting until the mother becomes established in her home routine."		
Donor recruitment	Service description	Kimball	1955	"With the approval of the attending pediatrician, the Breast Milk Bank program is explained to the mother, and she is asked if she would like to contribute."		Evanston milk bank US
Donor recruitment	Service description	Kimball	1955	"Practically all of our donors are the mothers of private patients, born at the Evanston Hospital, who are cared for by practicing staff pediatricians. There have been only a few donors among the clinic patients."		Evanston milk bank US
Donor recruitment	Service description	Langerak	1991	"Adult education plays an important role in the acquisition of donors to the milk bank. Many donors prepare themselves for childbirth through classes presented by the Department of Parent Education of the Medical Center. In these classes, information about the Mothers' Milk Bank is presented, and letters about the Milk Bank are included in all the information packets given to new mothers. Working through the nursing mothers' groups and classes at the Medical Center is seen as a more efficient method of donor recruitment than the use of newspaper articles and public service announcements."		Wilmington milk bank US
Donor recruitment	Service description	McEney	1978	"Donors - These are found by the local branch of the National Childbirth Trust (NCT) and by staff of the maternity unit, as well as by other means." "Occasionally, a donor was notified by a friend or by a community midwife or health visitor."		Whipps Cross milk bank UK
Donor recruitment	Service description	Murray	1953	"Physicians, particularly obstetricians, procured the donors with aid of the Woman's Auxiliary of the county society. Many community agents cooperated."		Essex County milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor recruitment	Service description	Pedersen	1982	"The number of newly enrolled donors (lactating women) per year for most years was between 150 and 250. Analyses of individual years has shown that a minority of donors delivered the major part of the supply."	Pedersen 1980; Christensen 1946	Fuglebakken milk bank Denmark
Donor recruitment	Service description	Pedersen	1982	"A comparison has been made between the civil and social status, place of residence and parity of donors in 1946 and 1976. In 1946, 90 percent of the newly enrolled donors were registered as married and nine percent as unmarried, while in 1976, 50 percent of the 146 newly enrolled donors were registered as married, and 38 percent as unmarried. Distribution of the donors by social class (social status) was unchanged and corresponded to the general distribution in the population 1953/54 [details reported in th paper, but not reproduced here]. The distribution for 1946 was in agreement with contemporary Swedish figures. In 1946 practically all donors resided in the city of Copenhagen, while the geographical disribution in 1976 was 35 percent for the city of Copenhagen, 35 percent for the county of Copenhagen, and 30 percent for the rest of Zealand. The youngest donors were 17 years old (one in 1946 and one in 1976), theol ders 40 years old (one in 1976) and 42 years old (one in 1946); most of the women enrolled after the birth of the first child, fewer with rising parity. In 1946 one woman donated after seven births, and in 1976 one donated after four births. Several donated after the birth of twins and after sectio caesarea. Women who donated after two and three births continued for a longer period than those who donated after one birth."	Socialforskninginst ituttet 1939; Nordwall 1945	Fuglebakken milk bank Denmark
Donor recruitment	Service description	Penc	1996	"Patients of the HMB who collect far more milk that is needed by their own infants are considered as potential donors."		Polish Mother's Memorial Hospital milk bank Poland

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor recruitment	Service description	Penc	1996	"When it was discovered that these mothers collected more milk than their infants needed, representatives of HMB proposed that this excess milk be collected (free of charge and with the mother's consent) and used to feed other ill newborns whose mothers could not provide breastmilk."		Polish Mother's Memorial Hospital milk bank Poland
Donor recruitment	Service description	Springer	1997	"These well-trained donors often donate over a period of weeks, months, or even longer. Collecting large volumes of milk from a few well-trained donors is advantageous as it helps the milk bank staff be more efficient."		Leipzig milk bank Germany
Donor recruitment	Service description	Springer	1997	"There is a positive relationship between the milk bank in Leipzig and the general public. People are aware that the Children's Hospital is in need of donor milk and that the hospital has collected milk for the past 55 years. In some families, there are now third generation milk donors supplying their excess milk. It is this community acceptance and support that accounts from the generally sufficient supply of donor milk."		Leipzig milk bank Germany
Donor recruitment	Service description	Tomalin	1983	"Another major problem for milk banks is that with nationwide publicity it is hard to find donors. Mothers only find out about milk banks when they are on postnatal wards - recovering from labour and trying to cope with a new infant."		Kings College milk bank UK
Donor recruitment	Service description	Tomalin	1983	"Nursery nurse, [...], goes down on to the wards to talk to the likely mothers [...]"		Kings College milk bank UK
Donor recruitment	Service description	Tomalin	1983	"'It is usually mothers who are having their second child who volunteer' says [...], nursing officer at King's special care baby unit. 'First-time mothers aren't always sure they have enough milk to feed their own babies.'"		Kings College milk bank UK
Donor recruitment	Service description	Wilson-Clay	2007	"The first milk donors were screened and approved following the HMBANA guidelines, (available on the HMBANA website)."	HMBANA no date	Austin milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor screening	Case report	Ryder	1977	"Human milk contaminated with Salmonella kottbus caused an outbreak of illness in seven of 22 infants in a neonatal intensive care unit. A case-control investigation failed to identify any risk factor except consumption of milk from a single donor, whose milk was subsequently found to be contaminated with S kottbus. Collection of human milk from properly instructed donors screened for microbiological pathogens [bacteria and hepatitis B surface antigen], refrigeration of this milk at 1 to 5 degrees C after collection, and controlled distribution by a milk bank should minimize the few hazards associated with its consumption."		
Donor screening	Meeting report	Silverman	1971	"[A]dulteration by ingested drugs is preventable by thorough screening of the donor' s history and the advisement that all drugs (including unusual amounts of alcohol, aspirin, and coffee) be avoided by the donor."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor screening	Narrative review	Anon	1987	"The recent study of Lewis-Jones et al and other similar studies show that the quality and quantity of milk protein changes with time, which is intricately matched to the changing nutritional and immunological needs of the infant. So proper attention should be given to this aspect while contemplating using banked milk for exclusive feeding or supplementation. It may be appropriate to screen banked milk for the concentration of some of its major immunologically protective proteins to ensure adequate and matching immunological potential for the recipient infant. Another approach could be the use of a selected sample of stored human milk from a phase of lactation that approximates the postnatal age of the child. There is also the possibility of modifying artificial formulas to supplement them with the antimicrobial factors present in colostrum and milk. More knowledge, however, about the specific role of the individual protective proteins, isolation procedures, and stability both in vitro and in vivo, is needed before this last approach may be considered."	Lewis-Jones 1985	
Donor screening	Narrative review	Boyes	1987	"It has been recommended that members of groups at high risk [...] for AIDS not donate blood or breast milk. The Centers for Disease Control in Atlanta, Georgia, recommend that all human milk donors be screened with the HTLV-III antibody test."	Resnick 1986	
Donor screening	Narrative review	Bromberger	1982	"At most breast milk banks providing milk from mothers who are unrelated to recipient infants, it is agreed that a health and diet history should be obtained for each donor and that donors should be screened for drug intake and pollutant exposure as well as for exposure to infections such as tuberculosis, syphilis, hepatitis, rubella, herpes, and cytomegalovirus."	See other cited references; Anderson 1979; Gracora 1979	

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Donor screening	Narrative review	Bromberger	1982	"[...] women who have rubella or who are immunized post partum should not donate milk to milk banks for several weeks. [...] Rubella and herpes exposure probably can be ascertained from the donor's history."	Klein 1980; Dunkle 1979	
Donor screening	Narrative review	Bromberger	1982	"Routine screening for hepatitis B for several years in the San Jose, Calif, and San Diego milk banks did not detect any hepatitis B in the general US population. Screening now is done only on high risk donors."	Anon 1982; Stagno 1980; Beasley 1975	
Donor screening	Narrative review	Bromberger	1982	"General nutritional screening and counseling should be provided for all lactating women, and an assessment of the nutritional status of both the mother and her infant should be made for any potential breast milk donor."	Lonnerdal 1976; Wighton 1979	
Donor screening	Narrative review	Bromberger	1982	"Cytomegalovirus represents a risk for milk banks because of its prevalence in the general population, and screening methods need to be developed."	Stagno 1980; Baum 1979	
Donor screening	Narrative review	Kinsey	1984	"Suggestions for breast milk collection thus include: 1. Careful screening of donors [...]."	Bromberger 1982; Cash 1981; Davidson 1979; de Louvois 1982; Lawrence 1980	

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Donor screening	Narrative review	Oxtoby	1988	"The 1980 American Academy of Pediatrics guidelines for milk banks, although written before recognition of HIV or HTLV-I, nevertheless discuss concerns about viral transmission. The Human Milk Banking Association of North America is formulating standard guidelines for donor screening and for milk collection, treatment and storage. To ensure safety of donor milk, minimum standards must be implemented universally. Screening of donors should encompass not only specific blood tests but also systematic evaluation of each donor's medical history and deferral of donors who may be at increased risk for particular infections. Evidence suggests that a combination of donor screening and milk pasteurization may provide the best insurance against transmission of infection in this setting."		
Donor screening	Narrative review	Oxtoby	1988	"Donor screening criteria also vary. The practice has been to include only healthy mothers, without known communicable diseases, who are able to follow the instructions for hygienic expression and storage of milk. Exclusion criteria vary. Most banks have recently made their screening criteria more stringent by including questions about behaviours associated with a risk of acquiring HIV. Some milk banks also review the medical records and perform blood tests for HBV, CMV and/or HIV antibody before accepting a new mother as a donor."		
Donor screening	Narrative review	Roy	1979	"The screening of potential donors [...] are essential components of a human milk bank."		
Donor screening	Narrative review	Tully	1999	"The basic screening criteria are the same for all donors [as for mothers of babies who die], and much of the screening can be done from the infant's chart."	HMBANA 1999	

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Donor screening	Narrative review	Van de Perre	1992	"Compulsory screening is not, at the moment, a common practice in many countries. Self-exclusion of women at risk of HIV-1 infection or who have a steady or occasional sexual partner who is at risk is generally viewed as a discriminatory measure of poor preventive efficacy."		
Donor screening	Narrative review	Van de Perre	1992	"Recently, although no case of contamination by [pooled donor milk] has ever been reported, anxiety about the potential risk of transmission of HIV-1 from an infected donor to a newborn has been raised. Several strategies have been proposed to avoid contamination of human milk banks. These include compulsory screening of all breast milk donors [...]"	Anon 1988	
Donor screening	Narrative review	Wight	2001	"Currently, five US donor milk banks, one Canadian, and one Mexican milk bank belong to the Human Milk Banking Association of North America (HMBANA). All voluntarily follow guidelines drafted in consultation with the Food and Drug Administration (FDA) and the Center for Disease Control and Prevention (CDC). These guidelines include screening of all donors for antibodies to HIV-1, HIV-2, HTLV-1, HTLV-2, HBsAg, hepatitis C, and syphilis. "	AAP 2000; HMBANA 1999	US milk banks US
Donor screening	Opinion piece	Braune	1982	Critical letter in response to general article on milk banks in a nursing journal. Suggests that the reported rate of 80% of donors being CMV positive, with no CMV in the milk samples is not consistent with other studies; where the prevalence may be the same, but that 15-30% of milk is shown to be culture positive. The author of this therefore recommends that the "data suggest that seropositive women should never be donors."	Hays 1972; Stagno 1980;	

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Donor screening	Opinion piece	Lucas	1987	"The decision on whether or not to close milk banks must be based on a balanced consideration of relative risk to the infant. From the foregoing arguments [on the benefits of donor milk], an increase in risk to some newborn babies could be predicted in a major referral centre which disbanded its milk bank. On the other hand the evidence that AIDS can be contracted from breast milk is weak, circumstantial, and scanty. Donors to milk banks are likely to be a low-risk group, and the risk could be reduced further by sensible selection of donors."	Thiry 1985; Ziegler 1985	
Donor screening	Opinion piece	Modi	2006	"For example, in the US milk donations are not accepted from women who were in the UK for more than three months, or in Europe for more than five years, between 1980 and 1996, presumably because of the dangers of Creutzfeldt-Jakob disease."		
Donor screening	Opinion piece	Mortimer	1988	Letter referring to the DHSS guidelines on the collection and storage of human milk. Author suggested that donor milk only be used when "essential", is only from "screened low-risk women", and is "pasteurised under carefully controlled conditions with an adequate safety margin." Also suggested limited pooling of donations. Additional letter from Tedder recommended a stringent screening policy, with pasteurisation only used as a precaution, not a failsafe process.	DHSS 1981	
Donor screening	Position statement	American Academy of Pediatrics	1980	"The screening of potential donors, [...] are essential components of a human milk bank."		
Donor screening	Position statement	American Academy of Pediatrics	1995	"Neonatal intensive care units should develop policies that are consistent with the above recommendations [general recommendations on breastfeeding and HIV] for the use of expressed human milk for the nutrition of neonates."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor screening	Position statement	American Academy of Pediatrics	1995	"Women who are known to be HIV-infected must be counseled to not to breastfeed or provide their milk for the nutrition of their own or other infants."		
Donor screening	Position statement	American Academy of Pediatrics	1995	"Human milk banks should follow the guidelines developed by the United States Public Health Service, which includes screening all donors for HIV infection, and assessing risk factors that pre-dispose to infection, as well as pasteurization of all milk specimens."		
Donor screening	Position statement	Canadian Paediatric Society	1985	"Screening of donors of breast milk must include history-taking for acute or chronic infections and drug use."		
Donor screening	Position statement	Canadian Paediatric Society	1985	"It has been demonstrated that weight-reduction diets, some vegetarian diets and inadequate vitamin intake may adversely affect the quantity and quality of milk produced."	Higginbottom 1978	
Donor screening	Position statement	Canadian Paediatric Society	1985	"Studies have demonstrated isolation of rubella virus in milk 12 days after postpartum vaccination, so mothers who have received live vaccines should not donate milk near the time of their vaccination."	Buimovici-Klein 1977	
Donor screening	Position statement	Canadian Paediatric Society	1985	"Screening for tuberculosis and syphilis might be required in some situations, depending on the prevalence of these diseases and the routine laboratory test done in association with childbirth."		
Donor screening	Position statement	Canadian Paediatric Society	1985	"Laboratory screening for hepatitis B surface antigen (HBsAg) is required in some centres: although the transmission of HBsAg in donor milk has not been described, the antigen is present in most human secretions, so it would seem prudent to refuse donations of breast milk from mothers known or suspected to have hepatitis."	Boxhall 1974; Chin 1983; Smith 1975; Beasley 1975	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor screening	Position statement	Canadian Paediatric Society	1985	"Donors of breast milk should be asked about their use of prescription and nonprescription drugs. Recommendations on the use of milk from mothers who are taking drugs should be made according to the information available in standard reference texts."	Berlin 1981; Wilson 1980; Committee on Drugs, AAP 1983	
Donor screening	Position statement	Canadian Paediatric Society	1985	"Cytomegalovirus excretion is frequent during the perinatal period; the consumption of infected breast milk may cause infection, and in premature infants these infections may lead to serious complications."	Dworsky 1983	
Donor screening	Position statement	Canadian Paediatric Society	1985	"Meticulous screening of donor for infection, to ensure microbiological safety of the milk, is essential. However, a recent survey of Canadian milk banks indicated that 11 (58%) of 19 milk banks did not perform such screening, either by history-taking or by laboratory tests."	Sauve 1984	
Donor screening	Position statement	Fernandez	1990	"8. Milk for banking will come from screened voluntary donors in good health who have a supply in excess of their own infants needs. [...]" Criteria are: "Health lactating women who are: 1. Not on any medications (except Vitamin and mineral supplements and occasional analgesics). 2. Have no history of hepatitis and where facilities available, have been screened and found Australia antigen negative. Are VDRL -ve. 4. With no evidence of tuberculosis (mothers with past history of fully treated and healed tuberculosis may be allowed to donate). 5. Are not malnourished. 6. Have no acute illness. 7. Have no contact with any major communicable illness. 8. Not habitually using tobacco or alcohol. 9. Are normal on physical examination. 10. Not belonging to the high risk population of AIDS e.g. recurrent blood transfusion recipients, prostitutes, drugs addicts, wives of haemophillics, etc."		Discussed and agreed not be relevant to UK banking as specific to developing countries.
Donor screening	Position statement	Gutierrez	1998	"HMBs in Brazil [...] do not require HIV testing for donors."		Brazilian milk banks Brazil

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor screening	Primary study	Almeida	2006	"At the time of a milk donor's enrollment, clinical visits to both a gynecologist and pediatrician were scheduled for routine checkups. A simple questionnaire was conducted to collect maternal data related to social status, maternal experience, occupation, and other pertinent information. "		Not clear if this was as part of the usual testing process, or specific to the research study being undertaken.
Donor screening	Primary study	Stagno	1980	Primary study evaluating the rate of transmission of CMV via (maternal) breast milk. 38 of 278 (13%) excreted CMV at least once into either colostrum or milk. Rates of isolation were 68% (11/16) in women who had just delivered congenitally infected infants; 16% (8/49) in those excreting CMV from other sites late in gestation; 9% (19/200) among seropositive women who did not excrete CMV. CMV was found more in milk (35% - 25/70 milk; 8% - 20/244 colostrum; $p < 0.001$). None of nine bottle-fed infants of mothers shedding CMV only in breast milk became infected, compared to 11/19 (58%) infants fed infected breast milk. Authors concluded that "[w]e must be cautious, however, with expressed banked milk and wet-nurses, since CMV-infected milk might inadvertently be given to infants born to seronegative women or to premature infants, who generally do not receive sufficient quantities of specific transplacental antibodies. It is hoped that means to render the milk noninfectious without destroying its valuable properties will become available in the near future."		
Donor screening	Service description	Arnold	1996	"Donor mothers are screened for TORCH syndrome (toxoplasmosis, rubella, cytomegalovirus, and herpes) [...]"		Beijing milk bank China
Donor screening	Service description	Arnold	1999	"The milk bank coordinator screens each mother for her health history as well as for HIV, Hepatitis B, and Hepatitis C."		Goteborg milk bank Sweden

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor screening	Service description	Arnold	1999	"The mother comes to the milk bank for an initial interview, and a blood test that screens for HIV, Hepatitis B, and Hepatitis C. Currently no screening is done for TB because the Health Ministry feels that is it not necessary for screen Danes for this disease; however, immigrants who supply milk frequently are screened for TB. It is recognized that this might be a test that would need to be standard in the future. The milk bank does accept milk from women who smoke."		Hvidovre milk bank Denmark
Donor screening	Service description	Asquith	1987	"Using a questionnaire and interview, including a home visit, prospective donors are screened and must not smoke or be taking medications (including birth control pills) other than replacement drugs, and must not have had blood transfusions or have used intravenous 'recreational' drugs for 5 years. Prospective donors in the latter two categories may be approved on receipt of documentation ensuring recent negative testing for HTLV-III virus exposure. Their primary health care providers must certify in writing that the donors are Venereal Disease Research Laboratory (VDRL) negative, and have a normal chest radiograph or a negative tine test result. They must have no evidence of hepatitis or other systematic disorders."	Amanth 1978; D'Arcy 1979; Knowles 1965; Lonnerdal 1982; O'Brien 1974; O'Brien 1975; Overbach 1974; Sharma 1974	San Jose milk bank US
Donor screening	Service description	Asquith	1987	"The health of the donor is monitored by MMB personnel and her own physicians. It is also recorded in an initial health history and donor medication and illness logs. Each donor provides a statement of her general good health and freedom from specific conditions from her primary health care provider and approval from her infant's pediatrician."		San Jose milk bank US
Donor screening	Service description	Balmer	1992	"The necessity for a blood test is explained to every mother when she first contacts the milk bank about donating milk."		Sorrento milk bank UK
Donor screening	Service description	Balmer	1992	"Donor mothers are asked about their medical history with particular reference to infectious diseases."		Sorrento milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor screening	Service description	Balmer	1992	"Donors are also questioned about any medications they are receiving. [...]We do not accept milk from mothers (a) who are regularly receiving any drugs other than the contraceptive pill or the occasional analgesic such as aspirin or paracetamol; (b) who have received antibiotics in the previous 48 hours; and (c) who admit to smoking more than 10 cigarettes a day."		Sorrento milk bank UK
Donor screening	Service description	Balmer	1992	"In accordance with the directive from the DHSS all donors at Sorrento Maternity Hospital are now screened for HIV antibodies."	DHSS 1988	Sorrento milk bank UK
Donor screening	Service description	Balmer	1992	"When the milk bank nurse visits the mother for the first time they are given a form (similar to that given to blood donors) which lists the high risk groups for AIDS and asks them not to offer their milk if they could fall into any category. Each mother gives written consent to be tested for HIV antibodies. Should a donor be HIV positive, arrangements for counselling are made."		Sorrento milk bank UK
Donor screening	Service description	Balmer	1992	"All mothers are bled in their own homes to save them any inconvenience."		Sorrento milk bank UK
Donor screening	Service description	Balmer	1992	"The Association of British Insurers have provided us with a leaflet explaining that mothers applying for life insurance will not be affected by having an HIV antibody test as part of our donor screening programme."		Sorrento milk bank UK
Donor screening	Service description	Balmer	1992	"Mothers who are expressing milk for their own babies on the neonatal unit are not tested for HIV antibodies. However if they have a surplus in excess of the requirements of their own baby which could be used for another baby, that mother is also tested."		Sorrento milk bank UK
Donor screening	Service description	Baum	1982	"In the case of cytomegalovirus which, unlike Australian antigen, is heat labile we take comfort that routine pasteurisation effectively eliminates this as a hazard to our new-born infants."	Welsh 1979	John Radcliffe milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor screening	Service description	Baum	1982	"In Oxford all mothers are routinely screened in the antenatal period for hepatitis B surface antigens and those who are found to be positive are not invited to donate milk to the milk bank (although we recognise that in doing so we run the risk of ostracising these unfortunate mothers)."		John Radcliffe milk bank UK
Donor screening	Service description	Bjorsten	1980	"Prospective milk donors are questioned about their general health, exposure to tuberculosis, medication, occupational exposure to chemicals, presence of diarrhoea or symptoms of other recurrent infections, and alcohol and smoking habits and a chest radiograph is taken. Since hepatitis B is uncommon in our region laboratory screening for this virus has not been thought necessary."		Umea milk bank. Sweden.
Donor screening	Service description	Cash	1981	"Prospective donors are interviewed by the milk bank coordinator to obtain information on diet, drug intake, smoking, drinking, and previous history of tuberculosis, hepatitis, or syphilis. A serologic test for hepatitis B and PPD, when there is a history of tuberculosis, are included in the screening process. Recently, a serology test for CMV has also been included. If the test is positive (80% of the donors at EOPC [Eastern Oklahoma Perinatal Center] have a positive reading), a fresh milk sample is taken and a viral culture is performed. Thus far, CMV has not been found in viral cultures at EOPC."	Krugman 1979	EOPC milk bank US
Donor screening	Service description	Connor	1982	"Only mothers with a high standard of hygiene are approached with a view to donating surplus breast milk [...]."		Enfield milk bank UK
Donor screening	Service description	Dempster	1982	"A blood sample is taken for testing by the Natal Blood Transfusion Service for the hepatitis B surface antigen."		Addington milk bank South Africa

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor screening	Service description	Fernandez	1993	"Routine testing for HIV and HBsAg is not done."		Bombay milk bank India. May not be directly relevant to the UK, but agreed to leave in with caveats in interpretation.
Donor screening	Service description	Fernandez	1993	Donor mothers must: a) be healthy and well-nourished; b) have no evidence of tuberculosis; c) have no history of hepatitis, blood transfusions, or repeated infections; d) be on no medications that are contraindicated during breastfeeding; e) be normal on physical exam; f) be non-reactive for syphilis (VDRL negative)."		Bombay milk bank India. May not be directly relevant to the UK, but agreed to leave in with caveats in interpretation.
Donor screening	Service description	Hartmann	2007	"In addition, under certain circumstances the PREM Bank will accept donations of previously expressed breast 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."		PREM milk bank Australia
Donor screening	Service description	Hartmann	2007	"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 and Human Milk Banking Association of North America that can be applied in the Australian context. The PREM Bank has committed to meeting these standards."	UKAMB 2003; HMBANA 2005	PREM milk bank Australia

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor screening	Service description	Hartmann	2007	"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 preterm milk which will be of more appropriate composition for the preterm infants receiving it."		PREM milk bank Australia
Donor screening	Service description	Hartmann	2007	"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 Lymphotropic 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."	UKAMB 2003; HMBANA 2005; ATBF 2003	PREM milk bank Australia
Donor screening	Service description	Hartmann	2007	"Potential donors are required to attend a follow up appointment to receive the results of the blood test [...]"		PREM milk bank Australia
Donor screening	Service description	Hartmann	2007	"It is PREM Bank policy that the results of the [above] tests are given to the donor in person, whether positive or negative."		PREM milk bank Australia
Donor screening	Service description	Hartmann	2007	"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."		PREM milk bank Australia
Donor screening	Service description	Kimball	1955	"All donors are women who have had careful prenatal care and have been screened for tuberculosis and syphilis."		Evanston milk bank US
Donor screening	Service description	Langerak	1991	"Donors are verbally screened for alcohol and tobacco use, use of medications, and for Hepatitis B and tuberculosis. The coordinator also visits 95 percent of the donors at home, and rules out a prospective donor if her home is not clean."		Wilmington milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor screening	Service description	McEnery	1978	"The donors do not undergo examinations or investigations [...]" "In our own antenatal population, white women were found to have a 0.02% incidence of hepatitis B antigenaemia, which made it unlikely that any donor was a carrier."	Chattopadhyay in press	Whipps Cross milk bank UK
Donor screening	Service description	Murray	1953	"The donor and her infant are examined at frequent intervals by the referring physician to check the physical condition of the mother and the weight gain of the nursing baby."		Essex County milk bank US
Donor screening	Service description	Murray	1953	The donors "were carefully screened by their own physicians or in the clinics to rule out infection or disease and to check whether or not they were successfully nursing their babies."		Essex County milk bank US
Donor screening	Service description	Omarsdottir	2008	"In all milk banks, donors were screened by blood test for HIV [100%]. Other screening procedures in the milk banks were blood test of donors for HTLV [52%], HB and HCV [81%], a chest X-ray to exclude active TB [15%], and a bacterial culture of donor's milk [89%]."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor screening	Service description	Omarsdottir	2008	"BACKGROUND: In Sweden preterm infants born <32 gestational weeks are fed maternal breastmilk or, if not available, donor breastmilk. Nutritional and immunological composition of human milk is affected by processing and storage procedures. Additionally, freezing of breastmilk may reduce cytomegalovirus transmission. The present recommendations for human milk use in Sweden are outdated. However, new guidelines to standardize routines are underway. This study was designed to document current routines pertaining to breastmilk use for preterm infants in Sweden. METHODS: A questionnaire regarding breastmilk handling and routines was sent to all 36 neonatal units in Sweden in November 2006 and February 2007. RESULTS: Of the 36 participating neonatal units 27 had their own milk bank. Milk donors were screened for human immunodeficiency virus, human T-lymphotropic virus, and hepatitis B and C viruses by 27, 14, and 22 of the milk banks, respectively."		
Donor screening	Service description	Omarsdottir	2008	"In 25 of the 27 (93%) milk banks, donors submitted a health declaration to be approved before breastmilk donation could be started."		
Donor screening	Service description	Penc	1996	"The main requirement is a woman's general good state of health and current negative tests for HBsAg and VDRL. Women who are positive for tuberculosis, use medications on a regular basis, have had a blood transfusion or received blood products within the last 12 months, use alcohol or tobacco, or have had recent vaccinations are excluded from becoming donors."	HMBANA 1991	Polish Mother's Memorial Hospital milk bank Poland

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor screening	Service description	Reid	1988	Report of how one milk bank responded to the concern over HIV in donor milk. Although the milk bank screened for HIV and hepatitis B, when the results of a national survey were analysed, they considered their procedure (not reported) to be inadequate and closed the donor milk bank, retaining the use of only mothers' own milk.		Ninewells milk bank Scotland
Donor screening	Service description	Reid	1988	Survey of UK milk banks. Breast milk donors screened for HIV 6; Hep B 8; both 6; under review 2; banks closed 2; no response 2.		Ninewells milk bank Scotland. Report of out-dated practice.
Donor screening	Service description	Sauve	1984	"Initial donor screening for infection, by medical history, was performed in 8 of 19 respondent banks, and no history was obtained in the remainder. The details of infectious disease history obtained from donors varied."		Various milk banks Canada
Donor screening	Service description	Springer	1997	"For example, milk donors undergo the same screening process as blood donors."		German milk banks Germany
Donor screening	Service description	Springer	1997	"With modern screening methods, contamination of donor milk has been largely eliminated [...]"		Leipzig milk bank Germany
Donor screening	Service description	Tomalin	1983	"Nursery nurse, [...], goes down on to the wards to talk to the likely mothers and to take the medical history of possible donors to see if they are taking any drugs or there are any other contraindications. Blood tests are also carried out."		Kings College milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor screening	Service description	Tully	2000	"In reviewing screening statistics from the member milk banks, the donor screening process appears to be sufficiently thorough to protect both recipients and donors. In 1999, the pool of donors was again a remarkably healthy, disease-free group. Among the member milk banks, 770 potential donors were serum screened. One donor was excluded for a positive Hepatitis C test, and three were excluded for positive HTLV results. Although further confirmatory tests were negative for these four potential donors, they were excluded in compliance with blood banking guidelines. Thus, out of the entire population, less than 1% (0.52%) of potential donors received positive serum results, all of which proved to be false positives."		HMBANA milk banks US & Canada
Donor screening	Service description	Tully	2000	"Furthermore, the combination of verbal and written screening, coupled with a health statement from the donor's physician and one from her infant's physician stating that her own infant is thriving, provides a safety net for both recipients and donors."		HMBANA milk banks US & Canada
Donor screening	Service description	Weaver	2005	"Up to now, the self-exclusion of donors has shown to be successful in ensuring that those who go on to have blood tests are at low risk of infection - UKAMB has not been informed of any positive HIV test results."		
Donor selection	Narrative review	Bromberger	1982	"Most breast milk banks restrict the donor's drug intake, but no guidelines have been established."	Anderson 1977; Anderson 1979	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor selection	Narrative review	Bromberger	1982	"Other problems are involved in the use of banked breast milk from unrelated donors. Most breast milk bank donors are women who are lactating successfully, whose infants are at least 1 month of age, and whose milk has the protein and mineral content of term milk. As lactation proceeds, protein and mineral content may fall to lower levels. The fat content of human milk changes not only during individual feedings but also over the day, and from day to day. Individual expressions donated to a milk bank may vary in caloric content. The content of linoleic acid in human milk is closely related to the amount of polyunsaturated fats in the mother's diet."	Lonnerdal 1976; Vaughan 1979; Hall 1979; Ref 15 re linoleic acid not cited	
Donor selection	Narrative review	Van de Perre	1992	"Recently, although no case of contamination by [pooled donor milk] has ever been reported, anxiety about the potential risk of transmission of HIV-1 from an infected donor to a newborn has been raised. Several strategies have been proposed to avoid contamination of human milk banks. These include [...] exclusion of high risk donors [...]"	Anon 1988	
Donor selection	Narrative review	Wight	2001	"Breastmilk donors also receive a full health and risk history and a tuberculosis skin test (PPD) if appropriate. "		US milk banks US
Donor selection	Position statement	American Academy of Pediatrics	1980	"Recent information suggests that bacterial contamination is minimized if the donor is properly selected[...]"		
Donor selection	Position statement	Gutierrez	1998	"7. Criteria for excluding a potential donor: mother has a contagious disease; mother takes drugs or medications that are excreted through human milk; mothers being treated with chemotherapy; malnourished mothers."		Brazilian milk banks Brazil

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor selection	Service description	Asquith	1987	"To help ensure that milk banked for clinical purposes is of the highest attainable quality, the protocol of the MMB [Mothers' Milk Bank] includes an extensive enquiry into the suitability of prospective donors and a standardized training program for the donors."		San Jose milk bank US
Donor selection	Service description	Balmer	1992	"Milk is not accepted from mothers who are hepatitis B carriers or have antibodies to syphilis."		Sorrento milk bank UK
Donor selection	Service description	Beal	1978	"A questionnaire [provided in Appendix] is given to each potential donor, and on completion, the results are assessed by the assistant group leader [...]. If problems arise from the questionnaire, the decision to accept or reject the donor is made on the advice received from the paediatric registrar [...] and the senior microbiologist [...]."		Townsville milk bank Australia. Appendix asks about general health, infectious diseases including hepatitis and respiratory tract infection, smoking, oral contraception, and other medication.
Donor selection	Service description	Cash	1981	"Prospective donors are excluded if they are heavy smokers (>20 cigarettes/day), drink alcoholic or caffeine beverages regularly, or receive any medications (except an occasional aspirin)."		EOPC milk bank US
Donor selection	Service description	Davidson	1979	"Only mothers who were free of communicable disease (for example, tuberculosis, respiratory infection, enteric, skin, or breast infection) and those not on drugs transmissible via breast milk were accepted as donors."		Fazackerly milk bank UK
Donor selection	Service description	Dempster	1982	"Donors are registered by a nursing sister who completes a registration form regarding general health, family particulars and home conditions."		Addington milk bank South Africa

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor selection	Service description	Greenwood Wilson	1951	"Human milk donors are chosen from clean, sanitary homes, and have a complete physical examination before being accepted. Tuberculosis, syphilis, gonorrhoea and anaemia must be excluded particularly. The mother must be nursing her baby, and have a surplus after her baby has been fed."		Cardiff milk bank Wales
Donor selection	Service description	Greenwood Wilson	1951	"Enquiries were made at the Cardiff Human Milk Bank as to whether any 'breeds' or types of nursing mothers could be differentiated in the same way as has been done for cows, correlating their anthropological characteristics with their capabilities as quality milk producers. The answer was that although nothing definite had been observed with certainty along these lines, e.g. as to blonde or brunette, or even as to multipara or primipara, there was no doubt that the plentiful or copious milk yield came not, as might have been expected, from the big woman, but rather from the small dainty type."		Cardiff milk bank Wales
Donor selection	Service description	Hoey	1980	"Any mother with overt infection is not accepted as a donor."		Salvation Army milk bank UK
Donor selection	Service description	McEnery	1978	Donors "are asked to withhold their milk when ill, and to notify us if they are receiving drugs."		Whipps Cross milk bank UK
Donor selection	Service description	Penc	1996	"When the donor criteria are met and the mother's consent has been obtained (donors receive no payment for their milk), her milk is assigned to a specific infant in the Neonatal Intensive Care ward."		Polish Mother's Memorial Hospital milk bank Poland
Donor selection	Service description	Springer	1997	"Because of careful selection and close supervision of donors, the milk banks in Leipzig and two additional institutions are able to supply fresh (unfrozen, unpasteurized) donor milk to recipients whose physicians order it."		German milk banks Germany

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor stopping perm	Narrative review	Bromberger	1982	"[...] women who have rubella or who are immunized post partum should not donate milk to milk banks for several weeks. [...]"	Klein 1980; Dunkle 1979	
Donor stopping perm	Narrative review	Woo	2007	"[...] nurses should know that milk banks only accpet milk expressed for 12 months after a due date. Therefore, if a mother whose infant passed away wishes to donate breast milk, she may only do so for 1 year."	Tully 2004	
Donor stopping perm	Service description	Arnold	1999	"If mothers cannot supply clean milk they are dismissed."		Hvidovre milk bank Denmark
Donor stopping perm	Service description	Arnold	1999	"When an individual mother's protein content drops below 0.8gm/100ml, she is dismissed as a contributor to the milk bank. Mothers are often turned away because of lowered protein content."		Hvidovre milk bank Denmark
Donor stopping perm	Service description	Greenwood Wilson	1951	"Milk can be taken up to nine months provided that the baby has not been completely weaned."		Cardiff milk bank Wales
Donor stopping perm	Service description	Kimball	1955	"Usually, if a mother does not produce more than 2 ounces daily after a week's trial, the pump is passed on to another donor."		Evanston milk bank US
Donor stopping perm	Service description	Pedersen	1982	"The WMB has set no such limits [on the length of the donation period or gestational age of the infant]. Only a few earlier investigations were found regarding changes in WM after a lactation period of over 12 months. Pietersen et al of the Children's Hospital at Fuglebakken have shown that the total immunoglobulin content seems constant (possibly increasing) from two to three weeks after birth, with individual variation. The investigation covered 0 to 27 months after birth."	Pietersen 1975	Fuglebakken milk bank Denmark

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor stopping temp	Primary study	Hoppu	1994	Prospective study of temporary drug use by mothers donating breast milk. "Sixty-four of the 284 mothers (22.5%) had to abstain from donating due to medication. The indication was infection in 50/56 treatments (89.3%). Antimicrobial agents were prescribed 44/52 times (84.6%). The channelling of milk from mothers in early phases of lactation to premature and newborn infants was identified as a special risk situation, if mothers on medication are not excluded. The limited number of such donors leads to use of milk unpooled or pooled to small volumes with increased risk for adverse effects to babies as a consequence." Authors recommended "a wash-out period of 5 half-lives of the drug after the last ingested dose. For the majority of drugs in this study, with some important exceptions, a wash-out period of 1 day was sufficient."		Not sure if relevant to current UK medication patterns, or to current guidelines on drugs and breastfeeding.
Donor stopping temp	Service description	Asquith	1987	"Donations are refused during periods when overt herpetic lesions are present and for 3 weeks following rubella vaccination."		San Jose milk bank US
Donor stopping temp	Service description	Balmer	1992	"Donors are asked not to give milk to the milk bank if their baby becomes ill at any time."		Sorrento milk bank UK
Donor stopping temp	Service description	Cash	1981	"Milk is also not accepted if the donor or her infant is ill."		EOPC milk bank US
Donor stopping temp	Service description	Greenwood Wilson	1951	"If the mother or baby is taken ill, collecting ceases for the time being, and the mother is advised to draw off and throw away the surplus until the illness is cleared up."		Cardiff milk bank Wales
Donor stopping temp	Service description	Langerak	1991	"If a donor must take a medication for a period of time, she may continue to express, and any milk that contains a contraindicated medication is labeled and saved for research projects."		Wilmington milk bank US
Donor stopping temp	Service description	McEnery	1978	Donors "are asked to withhold their milk when ill, and to notify us if they are receiving drugs."		Whipps Cross milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor support	Narrative review	Bromberger	1982	"Instructions to mothers about expressing milk should emphasize good hand washing, careful cleaning and sterilization of breast milk pumps, and storage of the milk in sterile containers."	Davidson 1979; Liebhaber 1978; Asquith 1979; Lucas 1979	
Donor support	Narrative review	Bromberger	1982	"Donors need constant encouragement and support because milk collection is a time-consuming process."		
Donor support	Narrative review	Williams	1981	"In our setting, most milk donated is from mothers of premature infants whose infants are in the same unit. This helps develop some camaraderie among the mothers, but first priority must always go to the mother's own infant." "Some hospitals have elected to involve community donors."	Fleischaker 1977	Rainbow milk bank, US
Donor support	Narrative review	Woo	2007	"A woman who has been producing considerable quantities of milk will need support in weaning after her infant dies."		
Donor support	Position statement	Fernandez	1990	"17. Psychological support, knowledge about measures to promote the milk ejection reflex, proper milk expression techniques and a balanced diet are prerequisites to successful lactation, the key to infant survival in our country."		Discussed and agreed not be relevant to UK banking as specific to developing countries.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor support	Primary study	Osbaldiston	2007	Problems While Breastfeeding and Pumping - "Donors were asked about how breastfeeding was going and what problems they were experiencing. In terms of how it was going, 69% responded that it was "excellent" and an additional 20% replied "good." In terms of breastfeeding problems, 58% of donors reported having engorgement, 33% reported cracked or chapped nipples, and 20% reported breast infection or mastitis. Donors were also asked about problems their babies experienced; 13% reported having thrush, 6% reported having slow weight gain, and 25% reported having reflux." Donors and non-donors experienced similar problems pumping milk, but donors reported significantly lower rates of issues with time taken to pump, difficulty with pumping ('harder than anticipated'), dislike of the pump, cleaning the pump, discomfort, tiredness, and 'gladness' to stop pumping ($p<0.01$). "Using a chi-square test to compare donors to nondonors, no statistically significant differences were found for either kind of pump or method of obtainment." "Furthermore, there were no statistically significant differences between donors and nondonors for the occurrences of these problems. Thus, donors do not experience these problems at greater or lesser rates than the nondonors reported. However, these rates of problems are much higher than those reported by Azema and Callahan in their study from France (19%, 10%, and 2%, respectively). Although we cannot account for these differences, other research has provided more support for the findings of the current project. In addition to replicating the methodology of Azema and Callahan,⁶ we also asked 11 items about problems with the pumping process. For 9 of these items, the means were less than a moderate value of 4.00 on an 11-point scale. Similarly, with regard to barriers to donating milk, on an 11-point scale, no	Azema 2003; Humenick 1994; Ziemer 1993; Foxman 2002; Vogel 1999	Austin milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
			2007	items had means that exceeded 4.00. These data suggest that the process of pumping is not particularly troublesome or problematic for donors."		
Donor support	Service description	Asquith	1987	"The interest of the donors in maintaining the amount and particularly the bacteriologic quality of their donations is fostered by frequent contact and feedback by MMB staff."		San Jose milk bank US
Donor support	Service description	Asquith	1987	"The MMB employs a group of volunteer drivers who [...] also notify the MMB of any important developments in the donors' home environments that might compromise the quality of the milk and require MMB intervention."		San Jose milk bank US
Donor support	Service description	Connor	1982	"[Donors] are supervised at home by the health visiting service [...]."		Enfield milk bank UK
Donor support	Service description	Davidson	1979	"Overall only 29% (150 of 513) of hospital donations were discarded compared with 45 % (78 of 175) of domiciliary collections because their bacteriological quality was either quantitatively or qualitatively unacceptable. We feel that probably the collection procedure of the domiciliary EBM was the main cause for 45 % of samples being unacceptable. If the donation was unsatisfactory the donor was again visited and given further advice about hygiene by the domiciliary midwife. To some extent this was done in the case of unsatisfactory hospital donations but an additional factor was the inadequate cleaning of the breast pump and related equipment. This defect was also noted by Liebhaber et al. (1978) who recommended manual expression of milk, thereby reducing the need for pasteurisation. Our figures also reflect the difference caused by lack of supervision of domiciliary collections, and if a neonatal unit relies heavily on domiciliary donations, closer supervision is necessary or it may be advisable to pasteurise all domiciliary donations."	Liebhaber 1978	Fazackerly milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor support	Service description	Greenwood Wilson	1951	"Selected mothers are supplied with apparatus which they are trained to use at home."		Cardiff milk bank Wales
Donor support	Service description	Greenwood Wilson	1951	"Homes of donors are also under observation by the health visitors, if only to protect the interest of those sucklings whose mothers might be tempted partially to wean them prematurely in order to have more milk to sell to the milk bank."		Cardiff milk bank Wales
Donor support	Service description	Greenwood Wilson	1951	"The baby's record is kept by the sister who collects the milk, and it is weighed at least once a month at a clinic."		Cardiff milk bank Wales
Donor support	Service description	Sauve	1984	"[...] and in all cases at least some supplies (containers, labels, or pumps when used) were provided to the donors by the milk bank."		Various milk banks Canada
Donor support	Service description	Springer	1997	"Once a month, the physician in charge of the milk bank meets with each donor mother to discuss any health concerns and counsel the donors on all aspects of milk collection."		Leipzig milk bank Germany
Donor support	Service description	Springer	1997	"There is close contact between donor mothers and milk bank personnel."		Leipzig milk bank Germany
Donor support	Service description	Springer	1997	"Because of careful selection and close supervision of donors, the milk banks in Leipzig and two additional institutions are able to supply fresh (unfrozen, unpasteurized) donor milk to recipients whose physicians order it."		German milk banks Germany
Donor support	Service description	Tomalin	1983	"Interested donors are given a pack of equipment - pump bottles, sterilising tablets, clinical wipes and nipple shields."		Kings College milk bank UK
Donor testing initial	Narrative review	Simmer	2000	"Mothers currently donating milk must have negative serology for CMV, hepatitis B and C, HIV1 and 2, human T-lymphotropic virus 1 and 2, syphilis and tuberculosis."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor testing initial	Narrative review	Van de Perre	1992	"In the United Kingdom, the official recommendation is to cryopreserve milk samples for 3 months. After this period, the stored milk is used only if a serum sample from the donor is unreactive for HIV-1 antibody."	Anon 1988	
Donor testing initial	Service description	Sauve	1984	"Five of 19 required HBsAg laboratory screening of potential donors, but no laboratory screening tests were required of donors in 14."		Various milk banks Canada
Donor testing ongoing	Meeting report	Silverman	1971	"A history of severe or prolonged jaundice in the donor's nursing infant may be taken as a biological screening test [...]"		
Donor testing ongoing	Service description	Sauve	1984	"Information regarding ongoing donor screening for infection during that donating period was not collected."		Various milk banks Canada
Donor testing ongoing	Service description	Springer	1997	"Every 2 months blood work is repeated on donors, including testing for HIV."		Leipzig milk bank Germany
Donor training	Case report	Ryder	1977	"Human milk contaminated with Salmonella kottbus caused an outbreak of illness in seven of 22 infants in a neonatal intensive care unit. A case-control investigation failed to identify any risk factor except consumption of milk from a single donor, whose milk was subsequently found to be contaminated with S kottbus. Collection of human milk from properly instructed donors screened for microbiological pathogens, refrigeration of this milk at 1 to 5 degrees C after collection, and controlled distribution by a milk bank should minimize the few hazards associated with its consumption." "Review of the procedures used in milk collection showed that donors, including the woman whose milk was incriminated, were not aware of the importance of collecting and storing their milk before it was brought to the hospital."		
Donor training	Narrative review	Bromberger	1982	"The donor mothers need instruction in proper expression techniques, use of pumps and containers, and storage of milk."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor training	Narrative review	Kinsey	1984	"Suggestions for breast milk collection thus include: [...] 2. Careful instruction in preparation (cleaning hands, breast, equipment) [...]."		
Donor training	Narrative review	Roy	1979	"[...] [the donors'] training are essential components of a human milk bank."		
Donor training	Narrative review	Roy	1979	"Recent information suggests that bacterial contamination is minimized if the donor is properly trained in expressing her milk manually rather than by the suction breast pump [...]"	Liebhaber 1978	
Donor training	Position statement	American Academy of Pediatrics	1980	"Recent information suggests that bacterial contamination is minimized if the donor is properly selected and trained [...]"		
Donor training	Position statement	American Academy of Pediatrics	1980	"[...] their training [donor women], are essential components of a human milk bank."		
Donor training	Position statement	Canadian Paediatric Society	1985	"Mothers who express milk for their own infants or for other infants should receive instruction on hygienic procedures related to breast-milk expression and collection."	Minder 1982; West 1979	
Donor training	Position statement	Fernandez	1990	"11. Milk collection should be supervised and contamination prevented as far as possible by detailed instructions regarding hand and breast washing prior to every collection with particular attention to hygiene."		Discussed and agreed not be relevant to UK banking as specific to developing countries.
Donor training	Position statement	Gutierrez	1998	"9. HMBs must instruct every mother in the hygienic procedures for the collection of milk."		Brazilian milk banks Brazil

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor training	Primary study	Almeida	2006	"[...] instructions include hygienic procedures to clean the breast, collect the milk, and store it until it is picked up by the Fire Department or social workers specially trained to handle and collect the milk."		
Donor training	Primary study	Almeida	2006	"[...] the donor calls the hospital donor milk bank to provide basic information and receives information on expressing milk. These instructions include hygienic procedures to clean the breast, collect the milk, and store it until it is picked up by the Fire Department or social workers specially trained to handle and collect the milk."		
Donor training	Service description	Asquith	1987	"Training for donors includes instruction in general cleanliness, clean expression of milk into sterile containers provided by the MMB, labeling of containers, and cooling and freezing of milk. Advice on diet, alcohol and caffeine consumption, and on maintenance of lactation is also given."		San Jose milk bank US
Donor training	Service description	Asquith	1987	"Each donor receives an instruction packet and provides the MMB with research releases."		San Jose milk bank US
Donor training	Service description	Beal	1978	"Each donor is given explicit instructions on the collection of milk by a member of the NMAA, who ensures that the mother understands the need to follow faithfully the recommended procedures."		Townsville milk bank Australia
Donor training	Service description	Bjorsten	1980	"The donors are carefully instructed about personal hygiene and milk collection and storage techniques."		Umea milk bank. Sweden.
Donor training	Service description	Cash	1981	"Printed information explaining nutritional needs during lactation is discussed with and given to all donors."		EOPC milk bank US
Donor training	Service description	Cash	1981	"Regardless of the method of expression, collection techniques are demonstrated to all donors and printed instructions are provided [...copy provided as Appendix])."		EOPC milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor training	Service description	Connor	1982	"[...] on discharge from the hospital they are taught the procedure for collecting and storing the milk in their own home [instructions provided in the text]."		Enfield milk bank UK
Donor training	Service description	Davidson	1979	"All mothers received instruction on breast and hand hygiene and on the technique of manual expression of the breast, although most hospital specimens were obtained by the breast pump."		Fazackerly milk bank UK
Donor training	Service description	Dempster	1982	"The sister gives the donor written and verbal instructions on collection technique. Donors are instructed to wash their hands with soap and to dry them on disposable paper towels. Nipples are cleaned by wiping with cotton wool soaked in boiled water."		Addington milk bank South Africa
Donor training	Service description	Greenwood Wilson	1951	"Selected mothers are supplied with apparatus which they are trained to use at home."		Cardiff milk bank Wales
Donor training	Service description	Greenwood Wilson	1951	"[...] it is important to emphasize that human milk donors are selected while they are still in the maternity wards of the St. David's Hospital, and that they are thoroughly trained before they leave hospital in the technique of full manual expression of their breast milk. It is contended that with this groundwork training, and with the constant practise that follows, they are bound to secure a more efficient expression of their breast milk than the mothers who assisted in ad hoc investigations like those reported by Kon and Mawson (1950). The Cardiff mothers so trained on their return home express all the breast milk that remains, after infant feeding, into an aluminium jug whence they pour it into medicine bottles."	Kon 1950	Cardiff milk bank Wales

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor training	Service description	Hartmann	2007	"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 milk hygienic milk collection and appropriate storage. These instructions are consistent with existing hospital policy and international recommendations for human milk banking. Donor mothers are given a written copy of instructions and a verbal explanation during the interview."	UKAMB 2003; HMBANA 2005	PREM milk bank Australia
Donor training	Service description	Hartmann	2007	"Potential donors [...] receive a hospital grade breast pump and collection kit (thermally disinfected polypropylene bottles, collection instructions and donor ID labels)."		PREM milk bank Australia
Donor training	Service description	Hoey	1980	"The mothers are carefully instructed about personal hygiene, milk collection, and storage technique."		Salvation Army milk bank UK
Donor training	Service description	Kimball	1955	"The chairman delivers each pump personally in order to give prospective donors their instructions."		Evanston milk bank US
Donor training	Service description	Langerak	1991	"Written instructions for the sanitary collection of breast milk are distributed to donors."		Wilmington milk bank US
Donor training	Service description	Morley-Peet	1983	Report of enteropathogenic Escherichia coli. Current practice was: "All donors are instructed on the need for high hygiene standards and are taught how to handle their equipment before and after use."		North East Essex milk bank UK
Donor training	Service description	Pedersen	1982	"A reasonable basis of operation of a woman milk bank must thus include routine bacteriological examinations and possibly supplemental examinations guided by visual inspection of the WM collected upon a background of basic instruction in milking procedures and storage conditions and frequently checked work in order to achieve minimal contamination in general."		Fuglebakken milk bank Denmark

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Donor training	Service description	Sauve	1984	"Breast milk expression and collection techniques were taught by a nurse or hospital volunteer in all of the respondeing centres [...]"		Various milk banks Canada
Donor training	Service description	Springer	1997	"These well-trained donors often donate over a period of weeks, months, or even longer. Collecting large volumes of milk from a few well-trained donors is advantageous as it helps the milk bank staff be more efficient."		Leipzig milk bank Germany
Donor training	Service description	Springer	1997	"To assure that safety and quality of the donor milk, all donors receive written instructions about collecting and storing their milk."		German milk banks Germany
Milk disposal	Service description	Asquith	1987	"Questionable donations are discarded or set aside for research."		San Jose milk bank US
Milk disposal	Service description	Balmer	1992	"About 10% of bottles of milk supplied by mothers are discarded as being too contaminated for use."		Sorrento milk bank UK
Milk disposal	Service description	Beal	1978	"If the report indicates that the milk has been contaminated during collection, then all the containers of milk with the same milk bank identity number as the sample are discarded."		Townsville milk bank Australia
Milk disposal	Service description	Beal	1978	"A growth of enteric organisms is suggestive of contamination, and the milk which corresponds to that sample is discarded."		Townsville milk bank Australia
Milk disposal	Service description	Beal	1978	"The expiry date is determined as six months from the date of collection; however, the longest any milk has been held in the bank is three months."		Townsville milk bank Australia
Milk disposal	Service description	Beal	1978	"Any milk that is not used after being thawed is discarded."		Townsville milk bank Australia
Milk disposal	Service description	Connor	1982	"The maximum storage time in the freezer was decided to be three months, after which time the milk would be discarded."		Enfield milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk disposal	Service description	Davidson	1979	"Any thawed specimen not used after 12 hours (although rare) was discarded to reduce risk of bacterial contamination and denaturation."		Fazackerly milk bank UK
Milk disposal	Service description	Dempster	1982	"Donors are asked to inform the Milk Bank of any illnesses that may have occurred in the family during the week, and of any drugs that may have been taken. The milk is discarded if there is any doubt about its safety."	Anderson 1979	Addington milk bank South Africa
Milk disposal	Service description	Hartmann	2007	"Any batch not meeting these [microbiological] standards must be immediately removed from the PREM Bank quarantine freezer." The milk is then disposed of.		PREM milk bank Australia
Milk disposal	Service description	Hartmann	2007	Milk is disposed after 3 months of storage.		
Milk disposal	Service description	Ikonen	1982	"Milk containing more than 1000 cfu/ml potential pathogens is discarded."	McEnery 1978; Williamson 1978; Davidson 1979; Siimes 1979; Working Group of the Finnish Medical Board 1980	Tampere milk bank Finland
Milk expression	Narrative review	Arnold	1997	"While there is nothing specific in the Human Milk Banking Association of North America's (HMBANA) guidelines on procedures for collecting donor milk, US, Canadian, and Mexican milk banks (members of HMBANA) do not accept drip milk from donors, preferring to accept only expressed milk because of its higher fat content and lower bacterial counts. On the rare occasion that a recipient is intolerant of pasteurized milk, milk may be dispensed as raw frozen milk."	HMBANA 1997	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk expression	Narrative review	Davies	1982	"Changing the method of milk collection. This approach, and one which is applicable especially to milk banks which depend primarily on drip milk, is to change the method of milk collection in order to obtain a milk of higher fat content. One approach being explored in Leicester is to encourage mothers to collect both drip and expressed milk (collecting expressed milk alone would be unlikely to provide sufficient amounts of milk). When both expressed and drip milk are collected over the day the average energy content of the combined milk is a great improvement on drip milk alone (unpublished observations)."		
Milk expression	Narrative review	Davies	1982	"With the amount of fat in milk being the major determinant of the energy content, milk banks depending mainly on drip milk will therefore be providing a food much lower in energy than that provided by banks which rely more on expressed milk."		
Milk expression	Narrative review	Doxtator	2006	"Health care facilities should review their reprocessing decisions with key stakeholders within their institutions taking into account the needs of the patient and staff, resources available and the risks and consequences of infections transmitted by breast milk or contaminated equipment. All hospital procedures that involve the cleaning and reprocessing of equipment should be evidence based and reviewed by the Infection Control Services and Central Processing Services."	Jones 2000; Grandsen 1986; Ng 1995; Donowitz 1981; D'Amico 2003; Bolding 2004; Rutala 2004; Health Canada 1996	Not specific to donor milk - but relevant? Use of pumps in the hospital setting, not at home.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk expression	Narrative review	Hands	2003	"Current guidelines available to mothers for storing their expressed breast milk (EBM) were collated. Both research-based and simplified guidelines were inconsistent and confusing, varying from 'use almost immediately to 24 hours at room temperature, 24 hours to eight days in the fridge and three months to 12 months in the deep freeze Primary research showed EBM stored in the fridge and at room temperatures could delay bacterial growth, keeping it safe for longer periods than processed milk. Freezing affects these antibacterial properties, allowing any contaminating bacteria in previously frozen milk to grow uninhibited when warmed. Fat enzymes, although slowed at very low temperatures, break down milk fat and eventually make the milk rancid. The effect of storage on other nutritional and immunological factors in EBM is discussed Careful handling during collection and accurate storage temperature is stressed to prevent bacterial contamination and minimise bacterial growth. Separate and clear guidance is needed for refrigerated storage below and above 4 degrees C. Studies showed EBM to be safe for up to eight days below 4 degrees C and up to three days at 4 to 10 degrees C. It has not been shown if milk is safe (or unsafe) for longer at either refrigeration temperature. There is evidence to suggest that contaminated milk is safer stored at 4 degrees C for eight days than frozen; and that previously frozen breast milk should be kept for as short a time as possible before use. Mothers need to be given choices for storing EBM in the home. In a fridge or insulated container with ice packs at 4 degrees C or below, EBM may be safely stored for up to eight days; otherwise it can be safely refrigerated for up to three days An acceptable limit for bacterial contamination and growth in EBM needs to be established. The effect of initial bacterial load in fresh EBM on subsequent degree of bacterial growth during storage needs to be confirmed. Further research is	Cited primary studies and recommendations from relevant guidelines	Not sure if relevant as is about maternal use?

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
			2003	suggested to confirm maximum storage times at a range of domestic refrigeration temperatures."		
Milk expression	Narrative review	Kinsey	1984	"Suggestions for breast milk collection thus include: [...] 3. Encouraging manual expression of milk [...]"	Liebhaber 1978	
Milk expression	Narrative review	Kinsey	1984	"Suggestions for breast milk collection thus include: [...] 4. Instructions to discard the first 10 cc of expressed milk [...]"	West 1979; Asquith 1979; Williamson 1978	
Milk expression	Narrative review	Roy	1979	"Recent information suggests that bacterial contamination is minimized if the donor is properly trained in expressing her milk [...] and if the first 10mL is rejected. Viable cells are preserved by collecting the expressed milk in plastic bags."	Paxson to be published	
Milk expression	Narrative review	Williams	1981	Cited references demonstrating the bacterial contamination in milk. "The importance of clean collection techniques and bacteriological checks cannot be overemphasized. All collection equipment that touches the milk should be sterilized. This is easily accomplished with boiling, following an initial washing with regular detergents. In addition, a clean collection is greatly facilitated by washing the hands with hot soapy water and cleansing the nipple area with boiled water (no soap) before milk expression." Noted a higher rate of bacterial contamination with the use of a pump than by manual expression. Also cited reference recommending the discarding of the first 5-10ml of milk.	West 1979; Hack 1975; Lucas 1979; Luck 1972; Wright 1947	
Milk expression	Narrative review	Williams	1981	"In some locations, drip milk [...] has been collected to keep milk banks supplied. [...] caloric value of such milk is low and less advantageous for any neonate. This problem could exist with any donor milk because one usually does not know when or how the woman expressed the milk."	Gibbs 1977; Macy 1931	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk expression	Narrative review	Woo	2007	"Physiologically, any woman who has been pumping regularly will need to gradually increase the periods between milk expression, because after the death of an infant, a mother will experience discomfort and possibly engorgement if she does not slowly wean production."		
Milk expression	Position statement	American Academy of Pediatrics	1980	[...] "bacterial contamination is minimized if [...] the first 10ml of milk are rejected."		
Milk expression	Position statement	American Academy of Pediatrics	1980	"Some authors feel that manual expression is preferable to the suction breast pump."	Liebhaber 1978	
Milk expression	Position statement	Canadian Paediatric Society	1985	"Milk may be expressed manually of with the aid of a suction bulb or other types of breast pumps, which are described in breast-feeding manuals."	Lawrence 1980; Helsing 1982	Not sure if donor specific?
Milk expression	Position statement	Canadian Paediatric Society	1985	"If a breast pump is being used the manufacturer's directions should be followed to avoid infection. The cleansing of hands and breast and the use of an uncontaminated pump are essential."		Not clear if donor specific?
Milk expression	Position statement	Gutierrez	1998	"8. Milk collection may be done at the HMB, the hospital, or at home."		Brazilian milk banks Brazil
Milk expression	Primary study	Almeida	2006	"When donor milk comes from drip milk, these values [energy and total fat content] are lower. Hand expression of breast milk can be a contributing factor to low fat content."	McGuire 2004; Garza 1982	
Milk expression	Primary study	Almeida	2006	"All of the donor milk was hand-expressed milk."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk expression	Primary study	Boutte	1985	Measured volume, fat and energy contents in human milk samples collected over 2 24-h periods with either an electric or hand-operated breast pump. "The energy content was significantly higher [634kcal/d vs 662kcal/d*] and the variance for this measurement was significantly lower [49kcal/d vs 109kcal/d] in samples obtained by the electric pump [compared to the hand pump]." There was no statistical difference between the fat content in the electric and the hand pumps (3.35g/d vs 3.42g/d, p>0.05). Authors concluded that "[T]he choice of pump will depend on the milk component of interest, the required precision, and the practical constraints of expense and logistics [...and] is an important consideration when energy content or the content of other nutrients is to be evaluated."		*Appears to be higher in the hand pump? Not sure also how relevant to donor milk specifically?
Milk expression	Primary study	Gibbs	1977	"Biochemically and immunologically, pooled drip milk resembled pooled mature expressed breast milk, although it has a lower fat concentration. About 15% of lactating women are capable of producing drip milk; volumes produced are up to 188 ml/donor/day. A milk bank is described which processes 1400 liters of drip milk/yr. Heat treatment of this milk with a semi-automated holder pasteurizer caused a 21% reduction in IgA concentration and a 36% reduction in lysozyme activity, as well as a decrease in the ability of the milk to inhibit the growth of E. coli. In comparison with boiling, pasteurization was as effective in reducing total bacterial content provided the milk initially contained fewer than 10(6) bacteria/ml."		Reported abstract only - highly cited paper. More detail needed?

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk expression	Primary study	Liebhaber	1978	Retrospective study to quantify the differences in the levels of bacterial contamination in milk collected by different methods: hand expression, or by suction breast pump. Mean colony count for manually expressed milk (n=152 samples) was lower than that collected using a breast pump (n=43 samples; mean colonies/ml 2,500, sem 290 manual; mean colonies/ml 135,000, sem 43,000 breast pump; p<0.001). 94% of the hand-expressed samples could have been used without pasteurization compared to 53% of the samples expressed using the breast pump. Using paired samples, mean colony count for manually expressed milk was lower than that collected using a breast pump (mean colonies/ml 1400, sem 600 manual; mean colonies/ml 300,000, sem 116,000 breast pump; p<0.05). High colonies/ml (>1,000,000) were also cultured from the sterile washes of the 'clean' rubber suction bulbs. Authors concluded that "milk for feeding premature infants be collected by manual expression directly into sterile containers whenever possible, to eliminate the need for pasteurization."		
Milk expression	Primary study	Lucas	1978	"The fat concentration and energy value of D[rip] BM are low, compared with levels reported for EBM: protein, fat, sodium and energy value in DBM fall with the duration of lactation, whereas magnesium and calcium rise, and lactose, potassium osmolality and lysozyme remain constant. The milk fat content of DBM produced by individual donors is linearly related to the daily volume of DBM produced. Studies on 477 women admitted to the Oxford General Practice Obstetric Unit over 1 yr showed that, of the 75% who were lactating successfully 2 wk after delivery, 19% were producing DBM by 2--4 wk. Women who produced DBM did not differ in age or parity from those lactating women who did not, and their babies did not differ in birthweight, gestation, centile or sex."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk expression	Primary study	Maloney	1987	"In an investigation of the source of an outbreak of <i>Serratia marcescens</i> infection in a special care baby unit, several breast pumps used in the hospital and community were examined. The epidemic strain was isolated from two pumps and other Gram-negative organisms, <i>Staphylococcus aureus</i> and <i>Streptococcus faecalis</i> were isolated from seven. The findings indicate that breast pumps may be a potential source of contamination of the user, her breast milk, infant and environment." Authors recommended that "the use of electric breast pumps should be restricted and where possible, replaced by the hand operated Kaneson type. Where their use is unavoidable, we recommend: (1) the type of electric pumps should be standardized in a maternity hospital, SCBU and corresponding community care service, the choice being guided by efficiency, ease of cleaning, handling and cost; (2) pumps should be issued by a designated department in the hospital where a record of users should be kept; (3) on issue of a pump, the mother should be supplied with sterile collection and safety bottles and plastic tubing, and should be instructed in the method of disinfection of these and in correct use of the pump; (4) to prevent milk entering the safety bottle and thence the interior of the pump, we urge manufacturers to place a clear line on the collection inlet tubing to indicate the maximum acceptable volume. Extension of the the inlet tubing in the collection bottle by approximately half an inch would reduce aerosols entering the safety bottle during use; (5) electric breast pumps should be examined bacteriologically at regular intervals. We reiterate the recommendations of Thom et al (1970) that manufacturers design breast pumps which can be disinfected by heat. In the meantime, manufacturers should provide advice on the safest method of disinfection of existing pumps."	Thom 1970	Not donor specific, but does cover use of breast pumps in the community.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk expression	Primary study	Stocks	1983	Pilot study evaluating the energy value of milk consisting of drip milk combined with expressed milk. Donor mothers were asked to collect both drip and expressed milk and combine them as 24 hour collections. These were then pooled at the milk bank. The pooled samples provided 'a considerable improvement over the previous energy value of our donor milk when [...] using the drip method of collection.'	Carroll 1980	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk expression	Primary study	Thompson	1997	"The purpose of this study was to determine if preexpression breast cleansing reduced the bacterial count in expressed breast milk. The study involved the collection of 178 breast milk samples (89 matched samples); 38 matched samples were from mothers of term infants and 51 matched samples were from mothers of preterm infants. One half of the samples were collected following breast cleansing with Phisoderm and tap water. The other half were collected following breast cleansing with tap water only. Hand and equipment washing with Phisoderm and tap water preceded all sample collections. Storage containers were sterile. Samples were cultured for pathogenic and nonpathogenic bacteria and examined at 24 and 48 hours. Data were analyzed by Wilcoxon Matched-Pairs sign test and Chi square. Breast cleansing with Phisoderm and water was not more effective than water alone at reducing nonpathogenic bacteria [mean CFU 6.1×10^4 Phis+water; 8.6×10^4 water; paired test not significant] or eliminating pathogenic bacteria [mean CFU 1.3×10^4 Phis+water; 1.5×10^4 water; paired test $p=0.03$, but decrease was not considered to be clinically significant]. Mothers of preterm infants had higher levels of both nonpathogenic and pathogenic bacteria than mothers of full-term infants. The most common form of bacterial contamination was coagulase-negative Staphylococcus epidermidis. This particular bacteria is found in higher levels in the stools of breast fed infants than formula fed infants and it also the most common contaminant found in the blood of preterm infants who develop sepsis. The findings of this study reveal that chemical interventions may not be effective at rendering breast milk free from pathogenic bacteria. More research is needed to determine the optimal cleansing protocol to achieve bacterial decontamination of breast milk or to determine the		Maternal milk?

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
			1997	clinically acceptable level of contamination based on the effects on infants."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk expression	Primary study	Tyson	1982	"Bank milk collected by manual expression was less likely to be contaminated than milk collected by other methods. Contamination with coliforms and gentamicin-resistant Gram-negative rods was related to the pumps used by donors in their homes. Stringent precautions reduced but did not eliminate contamination." "[...] Netsy cups were associated with the highest percentage of contaminated pools [range 20 to 80%] ($P < 0.01$). The overall rate of contamination associated with Egnell pumps was reduced during period 2 ($P < 0.05$) [median CFU/10³/ml; 5.5 to 0.8]. An intermediate percentage of pools collected by Loyd B pumps was contaminated [range 0 to 23%]. Different species of gentamicin resistant non-fermentative GNR were found in pump-collected pools. Manually expressed pools were less often contaminated [range 0 to 13%] than pools collected by the Egnell pump [range 0 to 50%] during period 1 ($P < 0.05$). Gentamicin-resistant GNR were not identified in manually expressed milk, unlike milk collected by Loyd B pump [10% of pools] or by Egnell pump [29% of pools] during period 1 ($P < 0.01$). This difference occurred even though the number of donors and volume per pool of manually expressed milk (6-1 donors; 105 oz) exceeded that for the Loyd B pump (5-1 donors; 89 oz) and the Egnell pump (2-2 donors; 69 oz). All 7 electric pumps contained GNR. Gentamicin resistant GNR were identified in 4 pumps and coliforms in 1. The nipples of 5 donors were cultured. Two donors had gentamicin-sensitive GNR. None identified in oropharyngeal cultures of the 5 donors' infants. The pumps were used to collect fresh milk from the 5 donors. Gentamicin-resistant GNR ($> 10^7$ colonies/ml) were identified in the milk collected by 1 mother. Gentamicin-sensitive GNR were identified in the milk (> 10, colonies/ml) but not on the nipples of another donor.	Husstedt 1974; Eidelman 1979; Donowitz 1981; Ryder 1977; Stiver 1977; Kenny 1977	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
			1982	The median colony count in 2 previous studies of milk collected by Egnell pump exceeded our values, even during period 1. Klebsiella sepsis has been linked to contaminated breast milk feeds collected by Egnell pump. Human milk feeds have also been incriminated in other neonatal infections."		
Milk expression	Primary study	West	1979	"Staphylococcus epidermidis and other organisms from the skin were found to be the commonest contaminants in 21 samples of human milk donated to a milk bank. Only 2 samples contained enterobacteria; no β -haemolytic streptococci were isolated. Data presented show the difference between bacterial numbers in the first 10 ml and subsequent secretions of milk when drawn sequentially [under supervision CFU/ml Donor A initial 2.3×10^3 ; midstream 2.5×10^2 . Donor B initial 1.5×10^5 ; midstream 1.4×10^3 . Donor C initial 7.3×10^3 ; midstream 3.0×10^2 . Donor D initial 9.4×10^4 ; midstream 3.7×10^3 . No p value reported]. Refrigerated storage led to the growth of some organisms in the milk; no growth occurred in milk stored at -18°C . A miniaturized resazurin dye test was devised but preliminary observations showed that it had a limited value in detecting rapidly milk of poor bacteriological quality." Also noted that "[i]f the first secretions of milk are rejected before each collection, there is a striking trend towards production of almost consistently low-count milk which is less likely to be contaminated with undesirable organisms."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk expression	Primary study - in vitro	Asquith	1979	Aimed to examine the differences in bacterial count in the initial portion of expressed milk compared to the remainder. "Donor expressed the first 5 ml into one container; the remainder was then expressed into a second container. [...] In this study there was a consistent difference in colony counts between the paired samples [first 5 ml mean 3500 CFU/ml, range 200-17000; remainder mean 700 CFU/ml, range <100-4800]. Very little variation in bacteria concentration was found in the stripped milk from the 20 participants. The 'stripping' method of hand expression of human breast milk is recommended for use by human milk banks."		
Milk expression	Primary study - in vitro	Carroll	1980	Aimed to determine whether discarding the first 2-3 ml of expressed milk would yield bacteriologically clearer milk. The authors compared the bacteriology of 20 paired samples of breast milk. "The first sample was the initial 2-3 ml collected from the opposite breast to that first suckled by the baby, and the second was a midstream sample from the same breast. There was no significant difference in the colony counts between the paired samples [Student's paired t-test used, but no details reported], and in no instance did the bacterial flora of the second sample differ from that of the first." Cited reference that 10ml of milk needs to be discarded to improve quality, but that this would result in a much lower amount of donor milk. Concluded that "milk banks whose milk derives mainly from early lactating mothers should not discard the first part of the milk collected, as this will appreciably reduce the quantity of the milk without bacteriological advantage."	West 1979	
Milk expression	Service description	Arnold	1996	"Mothers who have excess milk are asked to express it, either manually or with a piston driven electric pump."		Beijing milk bank China

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk expression	Service description	Arnold	1999	"Mothers are supplied with bottles for collecting their milk. However, if they wish to use a pump to express their milk, they must use part of the 145 DKr/liter to rent or purchase the equipment."		Hvidovre milk bank Denmark
Milk expression	Service description	Asquith	1987	"A convenient manual expression technique has also been developed and advocated during most of the MMB's existence."	Lloyd-Jones 1979	San Jose milk bank US
Milk expression	Service description	Asquith	1987	"Research at the MMB has established that the bacterial contamination of donated milk is minimized by discarding the first 5 to 10 ml of milk expressed at any given session."	Asquith 1979; West 1979	San Jose milk bank US
Milk expression	Service description	Asquith	1987	"Until recently, the design of most commercially available breast pumps formerly did not provide for convenient disassembly for proper cleaning. With the introduction of better-constructed instruments, we have endorsed mechanical expression as a viable alternative. We still discourage the use of most breast pumps of older design and recommend only modern systems that employ either simple collection attachments that lend themselves to easy, thorough cleaning, or disposable attachments intended for one-time use. "	Husseldt 1974; Asquith 1985	San Jose milk bank US
Milk expression	Service description	Balmer	1992	"Donor mothers are provided with a hand breast pump not a breast reliever (a bicycle horn pump). Careful instructions on how to clean and sterilise the pump are provided in a small booklet. Breast relievers are not suitable for collecting banked breast milk because they are difficult to clean and sterilise."		Sorrento milk bank UK
Milk expression	Service description	Balmer	1992	"We [...] encourage the collection of expressed milk, but do not exclude any drip milk."		Sorrento milk bank UK
Milk expression	Service description	Balmer	1992	"Hand expression is the cleanest method of expressing milk but most mothers prefer to use a hand pump".		Sorrento milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk expression	Service description	Baum	1982	"The milk collected for our bank is mostly drip breast milk - that milk which drips spontaneously from the non-feeding breast in about 20% of lactating mothers."	Gibbs 1977	
Milk expression	Service description	Baum	1982	"There are however two reasons why despite [the lower fat concentration in drip milk], we prefer to collect drip milk for the Oxford Human Milk Bank. Firstly drip breast milk is a 'waste' product which many mothers find a nuisance. The collection of this 'waste' milk has a powerful ecological appeal. Secondly collecting milk in this way avoids the necessity of mothers 'pumping' their breasts. Many mothers find the idea of 'breast-pumping' unattractive. Furthermore it requires a substantial capital investment in breast-pumps, and it means that the mother is producing milk over and above the needs of her own baby which worries us a little in terms of possible nutritional consequences for both the mother and her baby."		John Radcliffe milk bank UK
Milk expression	Service description	Baum	1982	"In our system it is relatively rare for mother to contribute expressed breast milk."		John Radcliffe milk bank UK
Milk expression	Service description	Beal	1978	"For convenience and a congenial atmosphere, the mother collects the milk in her own time in the privacy of her home."		Townsville milk bank Australia
Milk expression	Service description	Beal	1978	"The mother is encouraged to collect the milk manually, but if a breast pump is used, recommendations are given for cleaning and sterilization of the apparatus. The breasts and hands of the donor are washed thoroughly with soap and water before collection. Particular attention is given to the papilla and areola. Antiseptics may be used, but if the breasts are washed well and rinsed, it is not essential to use these agents, since sensitization of the skin may occur."	Thom 1970	Townsville milk bank Australia

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk expression	Service description	Beal	1978	"Because enteric organisms may reside in the papilla and lactiferous ducts, the first portion (about 5 ml) is discarded."		Townsville milk bank Australia
Milk expression	Service description	Bjorsten	1980	"Most of our home donors prefer to use the Egnell electric breast pump."		Umea milk bank. Sweden.
Milk expression	Service description	Cash	1981	"Methods of milk collection include manual expression, rubber bulb pum, Lloyd-B pump, and electric pump. Manual expression of breast milk if the method of choice for the voluntary donor. The rubber bulb pump is frequently used by hospitals. However, Liebhaber found that when the rubber bulb pump was used 47% of the milk collected had high colony counts (above 10,000/ml) including pathogenic organisms such as Staphylococcus aureus and Pseudomonas aeruginosa. An alternative method to manual expression for mothers in a hospital setting is the Lloyd-B pump or an electric pump. The components of these pumps which come in direct contact with the milk are sterilizable."	Liebhaber 1978; Eidelman 1979	EOPC milk bank US
Milk expression	Service description	Dempster	1982	"Donors are asked to discard the first 10 drops and to collect milk before they feed their own baby."		Addington milk bank South Africa
Milk expression	Service description	Dempster	1982	"There is considerable variation in individual discard rates, these ranging from 4% to 37%. The reason for this is not yet known. Initial results of a survey investigating the correlation between collection technique and the discard rate indicate that collection of milk according to the instructions has little to do with the discard rate. This investigation is still in progress. The discard rates for 2 enthusiastic donors were found to be very high. A check on their collection technique revealed that they were following that instructions given to them. We then supplied them with a surgical hand cleaner which they were required to rub on their hands after washing. An immediate improvement in discard rate resulted in both cases."		Addington milk bank South Africa

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk expression	Service description	Fernandez	1993	"In striking contrast to milk banks in the West, milk donations are made in hospital."	Beal 1978; Tully 1991	Bombay milk bank India. May not be directly relevant to the UK, but agreed to leave in with caveats in interpretation.
Milk expression	Service description	Greenwood Wilson	1951	"[...] it is important to emphasize that human milk donors are selected while they are still in the maternity wards of the St. David's Hospital, and that they are thoroughly trained before they leave hospital in the technique of full manual expression of their breast milk. It is contended that with this groundwork training, and with the constant practise that follows, they are bound to secure a more efficient expression of their breast milk than the mothers who assisted in ad hoc investigations like those reported by Kon and Mawson (1950). The Cardiff mothers so trained on their return home express all the breast milk that remains, after infant feeding, into an aluminium jug whence they pour it into medicine bottles."	Kon 1950	Cardiff milk bank Wales

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk expression	Service description	Greenwood Wilson	1951	"In relation to these warnings and to Waller's findings [on differences in fore and hind milk], it should be emphasized that the Cardiff human milk donors are all well trained and experienced in expressing the milk fully from their breasts, and that most of them feed their babies first before expressing the milk that is left over. A few of them, whose milk flows exceptionally freely, on medical advice express an ounce before feeding their babies, and then express the rest after that; but since the milk they express in 24 hours is all pooled, and the sample for that mother taken from her pooled 24 hours' supply. The argument is hardly affected."	Waller 1943	Cardiff milk bank Wales
Milk expression	Service description	Greenwood Wilson	1951	"It is often an advantage to mother and child to draw off the excess milk remaining after each feed, because it avoids discomfort to the mother and overfeeding the baby."		Cardiff milk bank Wales
Milk expression	Service description	Hoey	1980	"The milk is expressed either by an electric breastpump or by hand."		Salvation Army milk bank UK
Milk expression	Service description	Kimball	1955	"When the mother pumps herself, she cleans her breasts and proceeds as directed by the instruction sheet given to each donor." Instructions reported in the article.		Evanston milk bank US
Milk expression	Service description	Kimball	1955	"By asking a mother to pump 3 or 4 times daily after nursing, production will frequently be stimulated, and the nursing of her own baby will become better organized. We have observed this many times."		Evanston milk bank US
Milk expression	Service description	Kimball	1955	"The Breast Milk Bank at the Evanston Hospital differs from most in that the mothers are pumped at home without supervision."		Evanston milk bank US
Milk expression	Service description	Kimball	1955	"When the Breast Milk Bank was initiated, 12 electrical breast pumps were purchased [...]; now 22 pumps are in operation [...]"		Evanston milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk expression	Service description	Langerak	1991	"The majority of donors use hand expression."		Wilmington milk bank US
Milk expression	Service description	McEnery	1978	"Although a little of the milk was 'early milk' expressed during the lying-in period, most of it was collected when breast-feeding had been fully established, and was continued as long as the donor was able or willing."		Whipps Cross milk bank UK
Milk expression	Service description	McEnery	1978	"Collection - Although some of the milk is collected during the first few days after delivery, mostly it is hind milk collected when breast-feeding is established. Occasional samples were collected as drips from nipple shields, but more were obtained by expression either manually or by vacuum pump. Before expressing the milk, the donor is asked to wash her nipples with soap and water."		Whipps Cross milk bank UK
Milk expression	Service description	Morley-Peet	1983	Report of enteropathogenic Escherichia coli. Current practice was: "each newly delivered mother is given a sterile shell to collect drip milk during feeding." After the outbreak, instructions were issued: "The use of pooled shell milk for supplementary feeding should stop immediately. The milk was still to be collected but then discarded - so those involved with the system should not be too dramatically discouraged."		North East Essex milk bank UK
Milk expression	Service description	Murray	1953	"In the beginning, most of the donors came to the bank to give their milk."		Essex County milk bank US
Milk expression	Service description	Pedersen	1982	"The most recent WMB instructions state: immediately before each milking, empty (approximately) 1 tablespoonful of milk by hand and dispose of it! This procedure was based on the experience that the presence of possible initial bacteria could thus be reduced."		Fuglebakken milk bank Denmark

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk expression	Service description	Sauve	1984	"Previous reports have compared bacterial contamination rates between methods of milk collection. In 14 banks, manual expression was most commonly used, and in five, manual plastic suction pumps or electric pumps were most commonly used. In eight of the 14 centres using mainly manual expression, breast milk pumps were also sometimes used."		Various milk banks Canada Liebhaber 1978
Milk expression	Service description	Tomalin	1983	"'We never refuse any amount, however small', says [...]. 'Sometimes the mothers just collect drips from the nipple shields.'"		Kings College milk bank UK
Milk expression	Service description	Tully	2001	"[A]ll mothers come to the hospital each time to pump or to hand express for the milk bank."		Caracas milk bank Venezuela
Milk fortification	Narrative review	Anon	1987	"The recent study of Lewis-Jones et al and other similar studies show that the quality and quantity of milk protein changes with time, which is intricately matched to the changing nutritional and immunological needs of the infant. So proper attention should be given to this aspect while contemplating using banked milk for exclusive feeding or supplementation. It may be appropriate to screen banked milk for the concentration of some of its major immunologically protective proteins to ensure adequate and matching immunological potential for the recipient infant. Another approach could be the use of a selected sample of stored human milk from a phase of lactation that approximates the postnatal age of the child. There is also the possibility of modifying artificial formulas to supplement them with the antimicrobial factors present in colostrum and milk. More knowledge, however, about the specific role of the individual protective proteins, isolation procedures, and stability both in vitro and in vivo, is needed before this last approach may be considered."	Lewis-Jones 1985	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk fortification	Narrative review	Narayanan	1989	Narrative review, including fortification of human milk.		Cited references on the reason for fortification, but no details on the process of fortification.
Milk fortification	Opinion piece	Braune	1982	Critical letter in response to general article on milk banks in a nursing journal. Concerns on the addition of chemicals to the milk and their effect on osmolality are expressed.		
Milk fortification	Opinion piece	Modi	2006	"Milk banks in the United Kingdom do not determine the nutritional content of donor breast milk."		
Milk fortification	Opinion piece	Modi	2006	"The protein and mineral content of donor milk can be increased by breast milk fortifier or formula, but this is an imprecise science as the composition of human milk is very variable. Composition alters with maternal diet; the energy content of milk is lower at the beginning of a feed than at the end and in drip breast milk than in expressed breast milk. Donors have also usually delivered at term or have been lactating for some time, both of which result in lower nutritional content. "		
Milk fortification	Position statement	Canadian Paediatric Society	1985	"If any substance is being added to the milk, safety precautions are necessary."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk fortification	Primary study	Santiago	2005	"BACKGROUND: As a component in human milk fortifiers (HMF), iron may equilibrate with human milk for as long as 24 hours, bind important bacteriostatic proteins, and potentially affect the host defense properties of human milk. OBJECTIVE: We compared bacterial growth in human milk prepared with each of two HMF differing in their content of iron. STUDY DESIGN: Samples of human milk obtained from mothers of premature infants were divided and mixed with one of two HMF and maintained at refrigerator temperature. Refrigerated milk samples were removed at 0, 24, and 72 hours for determination of total bacterial colony counts (TBCC). RESULTS: TBCC did not differ between groups but declined from 0 to 72 hours, $p < 0.001$. CONCLUSION: These data suggest that differences in iron content, or other nutrients in HMF, do not affect bacterial growth in human milk. Storage of fortified human milk at refrigerator temperature for 72 hours results in decreased bacterial growth. As a component in human milk fortifiers (HMF), iron may equilibrate with human milk for as long as 24 hours, bind important bacteriostatic proteins, and potentially affect the host defense properties of human milk. We compared bacterial growth in human milk prepared with each of two HMF differing in their content of iron. Samples of human milk obtained from mothers of premature infants were divided and mixed with one of two HMF and maintained at refrigerator temperature. Refrigerated milk samples were removed at 0, 24, and 72 hours for determination of total bacterial colony counts (TBCC)."		Results shown graphically.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk fortification	Primary study - in vitro	Lavine	1989	Aimed to assess the effect of storage and the addition of fortifier on the delivery of lipids through a feeding tube. "Both storage of breast milk for 3 days at 4 degrees C and the addition of breast milk fortifier containing lipid improved the delivery of lipids during continuous pump infusion. The percentage of the original lipid delivered after 8 h of pumping was 9, 25, 58, and 66% from the freshly collected milk, stored milk, freshly collected milk mixed with fortifier, and stored milk mixed with fortifier, respectively. Phospholipid and cholesterol levels also were measured. Their loss during delivery through the tube was similar to the loss of total lipid. While storage improved the delivery of lipids from breast milk, the additional lipid delivered from milk mixed with fortifier was primarily due to lipids from the fortifier."		Not sure if relevant?
Milk fortification	Service description	Arnold	1999	"Fortifiers are used starting after the first week, and are slowly increased. These fortifiers are mixed with the human milk on the unit. The fortifier is Swedish-made and contains hydrolyzed cow milk protein, calcium, and phosphorus. The goal is to individualize the milk for each baby according to that infant's needs. Fortification is thus adjusted in relation to what is already known, through infrared analysis, to be in the milk."		Goteborg milk bank Sweden
Milk fortification	Service description	Arnold	1999	"Donor milk may also be fortified, but cow milk-based fortifiers are avoided. Hydrolyzed egg and wheat protein in powdered form is added to donor milk as a fortifier if necessary."		Hvidovre milk bank Denmark
Milk fortification	Service description	Arnold	1999	"Phosphorus is added to this milk at Hvidovre; other hospitals also add calcium."		Hvidovre milk bank Denmark. Not sure if this refers to high protein milk only.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk fortification	Service description	Langerak	1991	"Banked milk fed to premature infants is routinely supplemented with human milk fortifiers."		Wilmington milk bank US
Milk fortification	Service description	Omarsdottir	2008	"This study was designed to document current routines pertaining to breastmilk use for preterm infants in Sweden. METHODS: A questionnaire regarding breastmilk handling and routines was sent to all 36 neonatal units in Sweden in November 2006 and February 2007. RESULTS: Of the 36 participating neonatal units 27 had their own milk bank. All neonatal units enriched donor milk and maternal milk." "All donor milk was enriched according to nutritional analysis or blindly."		
Milk handling	Narrative review	Baum	1979	General review, quoting similar references to other reviews. Raised specific questions on the handling of milk. "What are the effects of bacterial contamination on the nutritive properties of human milk? Need one worry about the presence of heat stable enterotoxins due to staphylococcus enterotoxin for example? Does the process of freezing, storing and thawing human milk further damage the nutritive and antimicrobial properties of human milk? Do human milk cells survive any system of human milk banking? How desirable is it to preserve the cells in human milk? How much care should be taken in monitoring pharmacological and environmental contaminants in human milk? Need we be concerned about the possible contamination of human milk pools by drugs, or beverages such as caffeine and alcohol? [...] Although neonatal infection from breast milk has not been documented, is it satisfactory to regard the chance of such infection as remote and not screen mothers or milk for it? Alternatively would such a screening system make the practice of human milk banking too complicated and expensive for the average hospital?" Concluded that any milk banks need to take "adequate care" of the milk and to "establish standards of practice".		Not sure if questions are still relevant as reasonably old review.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Narrative review	Bromberger	1982	Freezing "Preserving milk for longer periods involves freezing. Freezing kills all the live cells and destroys IgG and IgM, but preserves the majority of IgA and other macro-molecules. Bacterial growth-inhibiting activity of milk which has been frozen is similar to that of fresh milk. Nutrients are unaffected by freezing. Freezing reduces the numbers of bacteria in the milk by 10% to 60% but does not kill viruses. The generally accepted standard for freezing is -20 [degrees] C for three months, although the levels of IgA or other properties of milk frozen for as long as six months to a year under controlled conditions do not change demonstrably. Many home freezing units do not hold a temperature of -20 [degrees] C reliably."	Liebhaber 1977; Hernandez 1979; Williams 1981; Fomon 1977	
Milk handling	Narrative review	Bromberger	1982	Refrigeration " Because the preterm infant cannot obtain milk directly from the mother, some storage is necessary to preserve the milk. Every step in the process has some effect on both the nutrient and protective qualities. Refrigeration is the gentlest procedure; it mainly affects the viability and function of the live cells in milk. After milk has been refrigerated for 24 hours, phagocytic function decreases by 50% and cell viability by 20%. These effects are intensified after 48 hours of refrigeration. The type of container affects the number of available cells. Storage in glass decreases considerably the numbers of macrophages because macrophages stick to glass. This is less of a problem when milk is stored in plastic. The container material, whether glass, polypropylene, or polyethylenemc hanges the cell's phagocytic activity and decreases cell viability, Refrigeration of fresh milk greatly retards that growth of bacteria. The optimal temperature for minimization of bacterial growth is 4 [degrees] C. Whether milk can be stored safely at 4 [degrees] C beyond 28 hours needs to be investigated."	Pittard 1981; Paxon 1979; Pittard 1980; Hernandez 1981; Williams 1981	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Narrative review	Kinsey	1984	"Increasing numbers of milk banks make it imperative that standards be set for use in practice. Suggestions include: [...] 3. Storing breast milk deep-frozen in plastic containers."	Evans 1978; West 1979; Friend 1983; Murphy 1983; Pittard 1981; Bromberger 1982; Reynolds 1982; de Louvois 1982; Bjorksten 1980; Cash 1981; Liebhaber 1977; Hernandez 1979; Connors 1982; Davidson 1979; Cunningham no date; Paxson 1979; Ford 1977	
Milk handling	Narrative review	Lawrence	1999	"The storage of human milk for use later by the mother's own infant or an unrelated recipient has an impact on its constituents. These effects involve the storage container, heating, cooling and freezing the milk. [...] Milk can be safely refrigerated for 72 h with little change. [...]"	Hamosh 1996; Lavine 1987; Hamosh 1997; Ellis 1992; Pardou 1994; Sosa 1987; Pittard 1981; Clark 1984; Mckay 1995; Silprasert 1986; Lawrence 1999	
Milk handling	Narrative review	Lawrence	1999	"The storage of human milk for use later by the mother's own infant or an unrelated recipient has an impact on its constituents. These effects involve the storage container, heating, cooling and freezing the milk. [...] Freezing destroys cellular activity and reduces vitamins B6 and C. [...]"	Neville 1995; Friend 1983; Jensen 1992; Jensen 1995; HMBANA 1996; Jensen 1995	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Narrative review	Lawrence	1999	"The storage of human milk for use later by the mother's own infant or an unrelated recipient has an impact on its constituents. These effects involve the storage container, heating, cooling and freezing the milk. Overall, glass is the least destructive container. [...]"	Lawrence 1999; Goldblum 1981; Goldblum 1982	
Milk handling	Narrative review	Narayanan	1989	Narrative review, including nutritional aspects of storing human milk. Cited references on the effect of repeated freezing, thawing and heating, noting that this should be minimised.	Wardell 1981; Williams 1978	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Narrative review	Narayanan	1989	Narrative review, with guidelines for the use of human milk in developing countries. "1. Clear instructions should be given to the mother and collection should, where possible, be supervised. Hence, in hospitals, milk is better collected in the nursery rather than the lying-in wards. Expressed milk can also be used in the domiciliary care of low birthweight babies where necessary and where feasible. 2. Mothers should wash their hands and breasts each time with soap and water. Application of cream, oil, or lanolin after expression may be required if the skin gets too dry. 3. Manual expression into sterilised wide mouthed feeding bottles or cups is best in the Third World. Acceptable alternatives include sterilised Kaneson's pumps and others with wide mouths and necks. Electrically operated pumps are not only expensive but also difficult to sterilise properly. The old fashioned pumps with a funnel and rubber bulb should not be used for collecting milk for feeding. 4. Milk should be utilised as soon as possible and should not be kept at room temperature for more than 45 mins. It can be stored in the refrigerator, preferably in the first shelf under the freezer compartment, upto 24 hrs. Bottles should not be kept in the shelves of the door. Samples should be kept separately and not pooled together in a single container. 5. In hospitals, periodic microbiological monitoring of milk samples is important. 6. When the infant's condition permits, he should be allowed the 'empty' breasts after expression of milk. This will stimulate sucking and will also promote milk formation. As the infant gets stronger direct breast feeding should be initiated."		Mainly related to use of maternal milk for preterm babies. Also specific to developing countries - relevant to the UK?

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Narrative review	Ogundele	2000	"The storage of human milk at +4 [degrees] C for 48 h[ours] after expression could also result in a significant loss of cellular viability but does not denature milk proteins. The loss of milk macrophages and neutrophils occur presumably via cell adhesion to the milk container or cytolysis. The milk lymphocyte concentration, however, is not significantly affected by storage. The antibacterial activity of the remaining milk cells is, however, largely retained after storage at +4 [degrees] C for 24-48 h.	Bjoksten 1980; Pittard 1981; Murphy 1983	
Milk handling	Narrative review	Ogundele	2000	"Bacteriostatic activity of human milk against artificially inoculated bacteria of different strains has been shown to be highest in fresh refrigerated or fresh frozen (at - 70 [degrees] C) and thawed milk. Bacteriostatic activity of frozen milk (at - 20 [degrees] C) tends to progressively deteriorate after 1 month of storage. This activity is however lost after pasteurisation. The possibility of accumulation of undesirable bacterial products such as enterotoxins, bacterial enzymes and reactive amines is very unlikely even at refrigerator temperatures because most bacteria are metabolically inactivated at this temperature and the other antibacterial systems in the milk act to prevent any significant bacterial growth and activity."	Hernandez 1979; Reynolds 1982; Bjoksten 1980; Liebhaber 1977	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Narrative review	Ogundele	2000	"Recent studies have shown that the ability of colostrum samples stored by refrigeration (at + 4 [degrees] C in the absence of anticoagulants) to bind to pathogenic bacteria in-vitro was greatly enhanced within the first 3 days of storage, in comparison to freshly collected milk or that frozen at -20 [degrees] C or -70 [degrees] C. The initial increase in the the levels of sequestered bacteria was followed by a progressive fall, gradually approaching the level cultured from the noraml saline control after 3 weeks (personal observations). Similar observations were also made for other transitional and mature whole-milk samples. This sequestration activity was lost by de-fattening of the milk samples by centrifugation. This enhancement of bacteria sequestration has been proposed to be attributed to the effects of accumulated fragments of complement activation in the stored milk."		
Milk handling	Narrative review	Ogundele	2000	"Refrigeration and deep freezing of milk have also been associated with enhanced bacteriostatic activities and reduced contaminant bacterial load. Furthermore, freezing of milk for at least 1 day is known to destroy cytomegalovirus shed into the milk from infected mothers."	Hernandez 1979; Reynolds 1982; Cheesman 1983	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Narrative review	Ogundele	2000	"Free fatty acids produced during prolonged storage of breast milk by the effect of milk lipases have been shown to have very potent cytolytic effects on normal human blood cells, and on pathogenic organisms, including killing of intestinal parasites, Giardia lamblia and Entamoeba histolytica, predominantly gram-positive bacteria and yeast, and causing a membrane disruption of enveloped viruses in cultured cells. The levels of free fatty acids progressively increase in the stored milk in a temperature-dependent manner, but it is highest if it is initially cooled by refrigeration at +4 [degrees] C. The possible activation and involvement of complement components in contributing to this enhanced in-vitro anti-microbial activity have been suggested. The increased titratable acidity of such stored milk samples has been shown to be mainly attributable to levels of free fatty acids rather than lactic acid, which is feared to have been produced by bacterial fermentation of milk sugars."	Sakaguchi 1995; Lavine 1987; Ogundele 1999; Luzeau 1983	
Milk handling	Narrative review	Ogundele	2000	"Most milk samples show a significant drop in the level of bacterial colony counts during refrigeration. This is in sharp contrast to cow's milk formula which shows significant increase in the bacterial counts during 6 h of storage at both room temperature and used refrigeration and no evidence of bacteriostatic activity at any period. A similar decrease in bacterial colony count has also been demonstrated in human milk after 15-21 days freezing at -20 [degrees] C followed by thawing."	Ajusi 1989; Hernandez 1979; Knoop 1985; Olowe 1987; Deodhar 1991	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Narrative review	Ogundele	2000	Major changes in milk stored at - 20 degrees C for upto one month "include progressive loss of upto 89% cell viability and loss of bacteriostatic activity, whereas the other immunoproteins IgA, IgG, IgM, lactoferrin, lysozyme, C3 and C4 complement components, amino acids and fatty acids could be largely preserved or less significantly affected. The proportion of viable cells in those surviving is often reduced, with the appearance of a large number of inactive 'ghost' cells."	Bjosten 1980; Deodhar 1991; Reynolds 1982; Hernandez 1979; Liebhaber 1977	
Milk handling	Narrative review	Ogundele	2000	"Transport to and from milk banks and processing of milk also often necessitate temporary or prolonged storage of milk. Freezing or refrigeration of milk with and without heating has been recommended. The potential ability of rapid freeze-thawing to disrupt milk fat globule membranes and the progressive deterioration in the bacteriostatic capacity of frozen milk, would suggest that refrigeration would be preferable for short-term storage. For storage over periods longer than 3 days up to 1 month, freezing at - 20 [degrees] C could be recommended and fresh freezing at - 70 [degrees] C for longer-term storage. Fears arising from increased acidity of stored milk and about the possible accumulation of undesirable bacterial products such as enterotoxins, bacterial enzymes, and reactive amines have been allayed. On the contrary, certain defensive functions of stored milk are potentially enhanced."	Bjoksten 1980	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Narrative review	Ogundele	2000	"After standard heat sterilisation, IgA and lactoferrin were undetectable in milk samples. Others have found this to significantly alter the levels of major anti-microbial components of milk causing upto 47% loss of IgA, more than 88% loss of IgG, 41%-47% loss of lactoferrin and alpha-1-antitrypsin, and some proteins are also denatured. Holder pasteurisation (62.5 [degrees] C, 30 min) could cause a less significant loss of IgA but destroyed the small content of IgM. Lysozyme and lactoferrin seem to be stable to this treatment. Lysozyme was however progressively destroyed with increasing temperature, to near 100% at 100 [degrees] C. Pasteurisation also leads to near total loss of milk cells. Inactivation of milk bile-stimulated lipase by pasteurisation is also capable of a significant decreases (sic) in the absorption of milk lipids by about 33% corresponding to about 16% of the consumed energy.	Bjoksten 1980; Liebhaber 1977; Sann 1983; Ford 1977; Wardell 1984; Williamson 1978	
Milk handling	Narrative review	Ogundele	2000	"Similar studies under temperate climatic conditions have shown that breast milk stored for up to 48-72 h in the refrigerator is bacteriologically acceptable."	Bjoksten 1980; Deodhar 1991; Knoop 1985	
Milk handling	Narrative review	Ogundele	2000	"From studies conducted under tropical conditions, unheated breast milk could be stored for at least 8 h at room temperature and up to 24 h at +4 [degrees] C in the refrigerator before bacterial multiplication occurs beyond acceptable levels."	Ogundele 1999	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Narrative review	Oxtoby	1988	"Freezing milk as -20 [degrees] C has sometimes been suggested over pasteurization because this treatment may better preserve some immunologic contents and requires no special equipment. Freezing destroys most cells but is not completely effective in eliminating viruses or bacteria. In one study 1 of 10 naturally infected specimens retained CMV infectivity; in another study CMV could be detected even in specimens frozen at -20 [degrees] C for 1 week, although at less than 1% of the original level of activity."	Welsh 1979; Dworsky 1982; Friis 1982	
Milk handling	Narrative review	Roy	1979	"Years ago, the most important property of human milk was its relative freedom from bacterial contamination when compared with bottle feedings. The reverse is true today, and the precautions that need to be taken to make breast milk microbiologically safe constitute a serious drawback, especially in the case of a nonmaternal breast milk donor. A recent outbreak of salmonellosis has been reported in a milk bank. A variety of other bacteria, bacterial toxins, and viruses such as rubella, cytomegalovirus, and hepatitis-[beta] particles, have been identified in breast milk."	Ryder 1977	
Milk handling	Narrative review	Wight	2001	""Preterm" milk is usually processed separately and reserved for the smallest, most immature infants. Donor milk is shipped frozen, thawed to a slurry, cultured, then pooled for pasteurization."		US milk banks US
Milk handling	Opinion piece	Lucas	1982	Criticism of the 1981 DHSS guidelines on collection and storage of milk. Highlights the issues around the effect of processing (storage, testing, freezing, pasteurisation) on milk composition, and the composition of drip milk. Author calls for further data on the recommended approach "before the setting up of more such banks is encouraged."	DHSS 1981; Tyson 1981	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Opinion piece	Morley	1993	Letter on the impact of AIDS on milk banking. No references cited for transmission of HIV through donor milk. Recommended routine pasteurisation (63 degrees C for 30 minutes), and screening of donors by questionnaire (to screen in low-risk donors) with confirmatory blood tests.	Eglin 1987;	
Milk handling	Opinion piece	Williams	2007	"Where transmission of infection through donor milk is concerned, it is essential from a policy perspective to balance risk carefully against the potential benefit associated with a reduction in the risk of death from necrotising enterocolitis. Provided that milk banks are run in accordance with national and regularly updated guidance risk can be minimised. We are not aware of any reported instances of nosocomial or vertically transmitted infection associated with the use of donated milk collected, processed and stored using systems which follow such protocols but agree there is room for closer regulation because historically milk banks have been built from minimal resources within a few neonatal units."	UKAMB 2003; Baumer 2004	
Milk handling	Position statement	American Academy of Pediatrics	1995	"Current OSHA [Occupational Health and Safety Administration] standards do not require gloves for the routine handling of expressed human milk. However, gloves should be worn by health care workers in situations where exposure to breast milk might be frequent or prolonged, for example, in milk banking."	OSHA 1991; WHO 1992	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Primary study	Lloyd-Jones	1979	"In a study of breast milk collected into sterile bottles rinsed in 1% hypochlorite solution the hypochlorite solution adherent to the sides of the bottles apparently caused a large reduction in bacterial contamination of the milk after storage at 4 degrees C for up to four hours. Heating expressed breast milk at 62.5 degrees C for five minutes destroyed over 90% of the Escherichia coli, Staphylococcus aureus, and group B beta-haemolytic streptococci inoculated into the milk samples. Rinsing collecting bottles with hypochlorite solution may be valuable in collecting milk with a low bacterial content for human-milk banks. Furthermore, the currently accepted pasteurisation time of 30 minutes may be excessive."		
Milk handling	Primary study	Luukkainen	1995	"The fatty acid composition of 48 samples of banked human milk for preterm infants and four standard infants formulas available in Finland were analysed by capillary gas liquid chromatography. The banked milk was collected from mothers who had given birth 0-8 weeks previously. Saturated fatty acids accounted for approximately 50% of the fatty acids in both human milk and the formulas, while the relative content of monoenoic fatty acids tended to be higher in human milk than in the formulas. The relative content of 18:2n-6 was higher in the formulas (range 14.7%-23.2%) than in human milk (median 9.1%, range 6.3%-13.4%). Fat of banked human milk contained 0.9% and 0.7% polyunsaturated fatty acids with 20 and 22 carbon atoms (LCP), respectively, which is comparable to that of fresh mature human milk. In contrast, LCP could not be detected in any of the formulas. Conclusion. Banked human milk is a good source of LCP and offers a good alternative to LCP containing formulas."		Related to the effect of storage on donor milk composition.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Primary study - in vitro	Adeola	1998	Assessed physiological and bacterial factors in maternal and formula milk. Tested at 4, 28, and 34 degrees C, and observed every 2h for 12h. "The three storage temperature[s] could be used but the milk should be consumed with 6h of storage. The most preferable temperature for storage is 4 [degrees] C and mothers can bring up the temperature to one suitable for feeding, using a warm water bath prior to feeing their infants."		Not clear if donor specific?
Milk handling	Primary study - in vitro	Ankrah	2000	Evaluated the effect of storage on the glutathione content of human milk. "[...] when human milk was stored at existing room temperatures, 4 [degrees] C or - 20 [degrees] C for 2 h there was a substantial (between 73.0 and 80.6 per cent) loss of its GSH content. [...] The decrease in the GSH level was highly significant (p<0.001) irrespective of the storage temperature of the milk and is in contrast to the reported preservation of GSH in frozen foods. Unlike the anti-infective properties of human milk which may not be affected by the storage conditions as used in the present study, human milk antioxidative action is likely to be largely destroyed by the loss of GSH. [...] In conclusion, the results emphasize the need to avoid feeding infants with stored human milk since this could result in deficits in GSH and adversely affect the need to optimize the antioxidant capacity and detoxification mechanisms of chemical toxins and carcinogens (endo- and exo-genous in origin) of infants, especially in early childhood."	Jones 1995; Meister 1995; Cerutti 1985	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Primary study - in vitro	Buss	2001	Investigated how storage affects level of bioavailable vitamin C. "Total vitamin C levels decreased on average by one-third in the refrigerator or after 1 mo[nth] of freezing, with wide variations between individuals (6 to 76% and 3 to 100%, respectively). After 2 mo[nths] of freezing, the average decrease was two-thirds (7-100%)." Authors recommended "a change in human milk storage practices, to under 24 h in a refrigerator or under 1 mo in a freezer. Alternatively, vitamin C supplementation may be considered."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Primary study - in vitro	Hanna	2004	Measured "the antioxidant activity of fresh, refrigerated (4 degrees C), and frozen human milk (-20 degrees C), stored for two to seven days; to compare the antioxidant activity of milk from mothers delivering prematurely and at term; to compare the antioxidant activity of infant formulas and human milk. METHODS: Sixteen breast milk samples (term and preterm) were collected from mothers within 24 hours of delivery and divided into aliquots. Fresh samples were immediately tested for antioxidant activity, and the rest of the aliquots were stored at -20 degrees C or 4 degrees C to be analysed at 48 hours and seven days respectively. The assay used measures the ability of milk samples to inhibit the oxidation of 2,2'-azino-di-3-(ethylbenzthiazolinesulphonate) to its radical cation compared with Trolox. RESULTS: Antioxidant activity at both refrigeration and freezing temperatures was significantly decreased. Freezing resulted in a greater decrease than refrigeration, and storage for seven days resulted in lower antioxidant activity than storage for 48 hours. There was no difference in milk from mothers who delivered prematurely or at term. Significantly lower antioxidant activity was noted in formula milk than in fresh human milk. CONCLUSIONS: To preserve the antioxidant activity of human milk, storage time should be limited to 48 hours. Refrigeration is better than freezing and thawing."		No specific reference to donor milk

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Primary study - in vitro	Hegde	2007	Aimed to assess cariogenic potential of human milk stored at different temperatures. "The pH, buffer capacity and growth of Streptococcus mutans were assessed in each of these samples. There was a fall in pH of human milk stored at various temperatures. The buffer capacity of human milk increased with duration of storage. There was an increase in Streptococcus colony count in stored human milk proportional to the duration of storage and it increased more rapidly in case of milk stored at higher temperatures (0 degrees C - 4 degrees C) compared to the milk stored in the freezer (-19 degrees C). Milk samples stored at room temperature for 6 hours and in the freezer at -19 degrees C for 2 weeks were found to be relatively safe."		Focus on storage for working mothers, no direct reference to donor milk banking.
Milk handling	Primary study - in vitro	Lavine	1987	Aimed to assess the effect of temperature, storage, and total milk lipid on the level of free fatty acids. "The samples were divided into aliquots and stored at 25, 4, or -11 degrees C for 6, 12, 24, or 48 h. Additional samples were stored at -11 or -70 degrees C for 1, 2, 4, 6, or 8 weeks. [...] There was no measurable lipolysis in milk stored at -70 degrees C. In the other samples both storage temperature and length of storage significantly affected lipolysis of milk lipids. The accumulation of free fatty acids in the milk increased with the length of storage and with increased storage temperature. Total lipid was not a significant factor in the release of fatty acids during the initial 48 h of storage. In samples stored for greater than 48 h at -11 degrees C, total lipid was positively correlated with the release of fatty acids. The pattern of free fatty acids in milk changed as storage progressed with an increase in the proportion of free 18:2, 20:4, and the other long-chain polyenoic acids. This may have implications for infant nutrition as these fatty acids are required for normal growth and development of the neonate."		No specific mention of donor milk but long term storage.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Primary study - in vitro	Lepri	1997	Aimed to determine the effect of pasteurization and storage on the composition of milk. "Pooled human milk was subjected to Holder pasteurization and storage at -20 degrees C up to 90 days and examined for its content of fat and L-lactate and for lipid composition. This treatment reduced fats by 6% and L-lactate by at least 7%. In addition, pasteurization and storage induced triglyceride hydrolysis. The absolute amount of free fatty acids (FFAs) which was 0.5% after collection, doubled after pasteurization and rose even more after storage. Different FFA compositions were found by several authors using the same analytical method even for milk samples subjected to the same treatment. More detailed information on procedures must be given to explain the different results."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Primary study - in vitro	Minder	1982	Technical report on the method of determining the total bacterial colony counts of milk samples. The authors recommended the following process for the optimal collection of breast milk. "1. Immediately before use, boil the pump glass, wrapped in gauze, for 10 min. 2. [Disinfect] the hands with e.g. Remanex for 1 min. 3. Press off the first few drops of milk and discard them. 4. [Disinfect] the breast by placing a 10x10cm gauze soaked with 70% isopropyl alcohol on the breast for 1 min. 5. Immediately after collection, place the milk into an iced water-bath and let it cool for 10 min. 6. Always store the milk in the refrigerator. 7. Transport the milk either directly or at least once a day by special delivery, using only transport boxes supplied by the hospital. 8. Clean pump glass, milk bottle and pump tubing as follows: a) Rinse the pump glass and the milk bottle immediately after use with cold water; b) Then wash and brush these with hot water and soap; c) Rinse thoroughly; d) Milk bottle: sterilization at the hospital (exchange procedure); e) Pump glass: to be stored clean in a safe place (before use proceed as described above under point 1); f) Pump tubing: place in Milton (Richardson-Merrell) when not in use; in addition, have it cleaned at the hospital twice a week."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Primary study - in vitro	O'Connor	1985	Evaluated the effect of storage on the esterolytic activity of human milk. Activity of milk (from one mother) was assessed at 0, 1, 2, 5, 13, 19, and 28 days of storage at various conditions: A storage at room temperature in the dark; B storage in the refrigerator at 4 degrees C; C storage in the freezer at -19 degrees C; D freeze dried and then stored in the refrigerator at 4 degrees C; E freeze dried and then stored in the freezer at -19 degrees C. "In all cases, there was some loss of activity, independent of measurement in the presence or absence of sodium taurocholate, and the loss was highest in milk stored at room temperature, approximating a 50% loss in 1-2 days. Activation and inactivation of solutions of the purified enzyme have been identified by measuring its esterase activity against a variety of 4-nitrophenylalkanoate esters at pH 7.3 within the temperature range 5-46.5 degrees C. The optimum temperature was 42 degrees C. The presence of bile salt partially serves to maintain the conformation of the bile-salt-binding site as the esterolytic binding site becomes inactivated at 50 degrees C. Bile salts thus exert a positive template effect on the enzyme". Author concluded that "the most effective method which is readily available, whether the milk be collected at home or in a hospital, is storage in the freezer. No advantage is to be gained by freeze drying the milk before storage. In agreement with the measurements of Wardell et al the results indicate that milk frozen in the raw state retains its bile-stimulated esterase activity. Donated milk can also be satisfactorily stored for short periods in a refrigerator without serious deleterious effects, but storage at room temperature is not recommended [...]."	Wardell 1984; Dill 1983	Only milk from one woman; no stats reported. Abstract also from O'Connor 1986 - same study.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Primary study - in vitro	Ogundele	1999	"Human milk stored over some period in vitro possesses certain cytotoxic properties, which require further studies. Cytolysis induced by stored human milk has now been further characterized, using rabbit red blood cells as targets, to determine the contribution of other components, particularly the complement system. Cytolysis was found to be temperature dependent, greatly enhanced by low concentrations of magnesium and calcium ions, but inhibited by moderate to excessive amounts of calcium ions, and by heating at 56 degrees C." Author concluded that "expressed fears arising from increased titrability of [...] stored milk samples can now be allayed, since it is mainly attributable to levels of fatty acids, not lactic acid thought to be produced by bacterial fermentation of milk sugars."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Primary study - in vitro	Ogundele	2002	This determined "the effects of different storage methods on the pH and some antibacterial activities of human milk. Portions of milk and colostrum samples from healthy lactating mothers were stored at 4 degrees C and -20 degrees C for periods ranging from one day to 12 weeks. The stored milk samples were analysed for pH, bactericidal and bacteria sequestration activities against a serum-sensitive Escherichia coli, and compared with freshly collected samples, with and without EDTA. Milk became progressively more acidic during storage. [Colostrum: mean (sem) 7.60 (0.20) 0 weeks; 7.30 (0.11) 4 weeks; 7.01 (0.18) 8 weeks; 6.53 (0.16) 12 weeks; mean correlation coefficient -0.987 (0.007). Transitional milk: mean (sem) 7.44 (0.25) 0 weeks; 7.42 (0.16) 4 weeks; 6.82 (0.15) 8 weeks; 6.60 (0.08) 12 weeks; mean correlation coefficient -0.955 (0.014). Mature milk: mean (sem) 7.29 (0.20) 0 weeks; 7.12 (0.23) 4 weeks; 7.00 (0.22) 8 weeks; 6.57 (0.10) 12 weeks; mean correlation coefficient -0.947 (0.011.) While the bactericidal activities of refrigerated samples diminished rapidly, up to two-thirds of the original activity level was maintained by freezing for up to three months. The ability of milk fat globule membrane to adhere to suspended bacteria was gradually lost in frozen milk samples, while it was greatly enhanced during the first few days in refrigerated samples, before declining sharply. This study shows that loss of bactericidal activity in refrigerated milk is well compensated for by enhanced bacteria sequestration activity, and allays any fears that might arise concerning the suitability of stored human milk for infant consumption."		Difficult to extract figures from the graphs as poor reproduction. Also not clear which results are being cited.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Primary study - in vitro	Williamson	1996	"Effects of steel and glass storage containers, duration of storage up to seven hours, and storage temperature on the concentration of humoral and cellular factors in 357 samples of human breastmilk were examined. Leukocytic functions were estimated by E-rosetting of sheep RBCs by T-lymphocytes and phagocytosis of <i>S. cerevisiae</i> by phagocytes. Immunoglobulin (Ig) levels were studied by single radial immunodiffusion technique (SRID). Viability [Mean % (sd) glass and steel resp; 0 hours 91.07 (9.37) 91.89 (13.7) $p>0.05$; 7 hours 70.45 (22.39) 54.63 (31.73) $p<0.05$; 24 hours 60.00 (13.69) 25.00 (11.35) $p<0.01$; 48 hours 54.17 (28.83) 0 $p<0.001$; 72 hours 14.05 (14.97) 0 $p<0.001$] and cell counts [Mean count cells/mm ³ (sd) glass and steel resp; 0 hours 2292.9 (1387.6) 2292.90 (1172.75) $p>0.05$; 7 hours 1730.22 (612.85) 1512.38 (552.61) $p<0.05$; 24 hours 1425.00 (404.66) 791.67 (121.75) $p<0.01$; 48 hours 758.33 (570.93) 0 $p<0.001$; 72 hours 349.17 (324.30) 0 $p<0.001$] reduced during the storage period, but were greater than 60 percent of baseline values. IgG, IgA, and IgM levels in milk did not show significant decline after storage ($p>0.01$). Milk stored in glass yielded a greater number of functional cells after storage at 4 degrees C." "Mean IgA concentration in colostrum was 135-365 mg/dl; in mature milk, it was 30-113 mg/dl. IgM concentration in colostrum was 100-200 mg/dl and in mature milk, 40-50 mg/dl. IgG was 4 to 39 mg/dl in colostrum and in very low concentrations in mature milk."		Time period not relevant for donor milk banking?
Milk handling	Service description	Asquith	1987	"The MMB protocol specifies sterilized glass containers for collection, storage, and transport of milk because it has been shown that SIgA is reduced by nonspecific adsorption to many plastic bottles and bags."	Goldblum 1981; Goldblum 1982	San Jose milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Service description	Balmer	1992	"Milk is transferred from the breast pump to Axicare breast milk bottles (Colgate Axicare, Windsor; 120or 240 ml size). The bottles are reused and are not sterile. In between use all bottles are thoroughly cleaned in a washing machine and dried, which we have found adequately disinfects them."		Sorrento milk bank UK
Milk handling	Service description	Baum	1982	"Every effort is made to avoid leaving large volumes of human milk at ambient temperature (25 [degrees] C) in the special care baby unit because of the risk of bacterial growth."		John Radcliffe milk bank UK. Not in the Scope of this guideline?
Milk handling	Service description	Bjorsten	1980	"[...[we have given raw milk collected in the hospital to newborn infants. [...] we have also routinely used frozen milk delivered by lactating women outside the hospital."		Umea milk bank. Sweden.
Milk handling	Service description	Cash	1981	"The major problem encountered during the initial operation of the bank was an inordinate number of samples with high bacterial counts. The first month over 20% of the milk had to be discarded. The collection technique procedure was changed. Soap was added as a cleansing agent and donors were instructed to wash the breast in a circular motion beginning at the nipple. They were also asked to discard the first teaspoon of milk from each breast. A practical demonstration of manual expression was made mandatory for all donors. Initially, if donors were already familiar with the technique, no demonstration was provided. After the above changes, only 6% of the milk has had to be discarded."		EOPC milk bank US
Milk handling	Service description	Murray	1953	"When milk is needed for an infant, a member of the family procures it in the frozen state at the bank, transports it to the hospital where it is heated and boiled before it is administered. Greatest diligence and precaution are maintained in the procurement, pasteurization and distribution of this product."		Essex County milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling	Service description	Springer	1997	"[Unfrozen, unpasteurised] Donor milk is used fresh within 72 hours of collection"		German milk bank Germany
Milk handling at home	Case report	Ryder	1977	"Human milk contaminated with Salmonella kottbus caused an outbreak of illness in seven of 22 infants in a neonatal intensive care unit. A case-control investigation failed to identify any risk factor except consumption of milk from a single donor, whose milk was subsequently found to be contaminated with S kottbus. Collection of human milk from properly instructed donors screened for microbiological pathogens, refrigeration of this milk at 1 to 5 degrees C after collection, and controlled distribution by a milk bank should minimize the few hazards associated with its consumption."		
Milk handling at home	Narrative review	Davies	1982	"If careful attention to personal hygiene has been given by the mother, the collecting utensils sterilised, and the milk stored in a refrigerator before being taken to the bank, there is less contamination."		
Milk handling at home	Narrative review	Kinsey	1984	"Suggestions for breast milk collection thus include: [...] 5. Instruction on home storage of milk."	West 1979; Williamson 1978; Theberge-Rousselet 1976	
Milk handling at home	Position statement	Canadian Paediatric Society	1985	"Breast milk should not be stored for long periods in a frost-free freezer that is part of a refrigerator; because such freezers had a defrost cycle the milk could be subject to bacterial growth. Frozen breast milk should be discarded after 3 to 6 months of storage."	Baum 1980	Not clear if donor specific?
Milk handling at home	Position statement	Canadian Paediatric Society	1985	"If the breast milk is in fluid form it should be transported to the milk bank at a temperature of 3 [degrees] to 4 [degrees] C. Frozen milk should be kept frozen for transport."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at home	Position statement	Canadian Paediatric Society	1985	"The milk should be collected and stored in glass or rigid plastic containers that are able to withstand freezing and possibly heat. The containers should be sterilized before use and be clearly labelled with the mother's name, the date, the time of collection and any drugs recently taken by the mother."		Not clear if donor specific?
Milk handling at home	Position statement	Canadian Paediatric Society	1985	"Optimal temperatures for and duration of storage of human breast milk are not defined. Vitamin C levels are likely to diminish during refrigeration or freezing."	Legge 1978	
Milk handling at home	Position statement	Fernandez	1990	"12. Milk should be expressed directly into wide mouthed containers with cap in which it may be stored, frozen and pasteurised. The containers should not have the appearance of a feeding bottle."		Discussed and agreed not be relevant to UK banking as specific to developing countries.
Milk handling at home	Position statement	Gutierrez	1998	"11. Prior to processing, milk samples should be stored in a freezer for no more than 5 days or in a refrigerator at 5 [degrees] C for not longer than 24 hours."		Brazilian milk banks Brazil

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at home	Primary study	Murphy	1982	"Breast milk samples were collected from sixty-two donating mothers. The mothers, all at home, were carefully selected, their stools screened for the presence of enteroviruses and then given clear cut instructions on the collection technique. The milk was examined for bacteria, HB(s)Ag and other viruses. Twenty-one per cent of the samples were sterile, 64.5 per cent contained commensals and 14.5 per cent grew potential pathogens. All samples containing pathogens had counts greater than $10^{6.6}$ organisms/litre. There was no evidence of viruses in the donors' stools or in the milk samples examined. It is concluded that safe unpasteurised breast milk can be obtained by using a careful aseptic collection technique under adequate microbiological control." "Potential donors were carefully selected by one of us [...] and her staff. Criteria for selection included a high standard of personal hygiene and household cleanliness, possession of a refrigerator and an appreciation and understanding of the importance of extreme care when collecting milk samples. Donors were supplied with autoclaved glass nipple shields and 500cm³ collection bottles. Instructions regarding the collection of samples were as follows: (1) Wash hands before collection. (2) Wash nipples with cotton wool and water. (3) Do not use the breast that the infant has just suckled. (4) Allow the first few drops of milk to drip onto a piece of tissue paper and discard. (5) Apply the sterile glass shield over nipple and areola. (6) Empty collected milk immediately into the sterile bottle provided. (7) Put in the refrigerator. Milk was collected on alternate days by the milk bank nursing staff."		
Milk handling at home	Service description	Arnold	1999	"Once expressed, the milk is frozen until pick-up."		Hvidovre milk bank Denmark

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at home	Service description	Asquith	1987	"We particularly discourage any collection method, such as 'breast shields' that does not call for immediate refrigeration of collected milk because all such methods promote intolerably high bacterial contamination as well as reduced fat content."	Gibbs 1977; Lucas 1978	San Jose milk bank US
Milk handling at home	Service description	Balmer	1992	"All milk is stored in the donor's freezer at -20 [degrees] C or in the freezer part of her refrigerator at -5 [degrees] C until it is collected by the milk bank staff."		Sorrento milk bank UK
Milk handling at home	Service description	Balmer	1992	"Each mother must have a refrigerator or freezer so that her milk can be stored frozen as the mothers are visited only once every 10 days."		Sorrento milk bank UK
Milk handling at home	Service description	Baum	1982	"There are however two reasons why despite [the lower fat concentration in drip milk], we prefer to collect drip milk for the Oxford Human Milk Bank. Firstly drip breast milk is a 'waste' product which many mothers find a nuisance. The collection of this 'waste' milk has a powerful ecological appeal. Secondly collecting milk in this way avoids the necessity of mothers 'pumping' their breasts. Many mothers find the idea of 'breast-pumping' unattractive. Furthermore it requires a substantial capital investment in breast-pumps, and it means that the mother is producing milk over and above the needs of her own baby which worries us a little in terms of possible nutritional consequences for both the mother and her baby."		John Radcliffe milk bank UK
Milk handling at home	Service description	Baum	1982	"Drip breast milk is collected by the mothers into sterile shells at home and poured into sterile bottles for storage in a deep freeze or in the freezer compartment of the domestic fridge. Our observations on the unreliability of ordinary domestic refrigerators (particularly in the summer months) together with the difficulties of collecting milk daily from each donor's home, have persuaded us of the advantages of routinely freezing milk."		John Radcliffe milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at home	Service description	Beal	1978	"Some donors have difficulty expressing into the standard collection containers, so use instead a jug or larger container which has been sterilized in a freshly prepared 1% solution of sodium hypochlorite (Milton), ensuring that the container has been washed well, is free of detritus and is wholly submerged for at least one hour."	Ayliffe 1970	Townsville milk bank Australia
Milk handling at home	Service description	Beal	1978	"The standard containers are labelled with the donor's name, date of collection and a milk bank number. The sample bottle is labelled only with the milk bank number. Both the milk and sample are then placed immediately in a deep freezer and snap-frozen. If a deep freezer is not available then the milk and sample are placed in the coldest part of the refrigerator and are collected by a member of the NMAA as soon as possible."		Townsville milk bank Australia
Milk handling at home	Service description	Beal	1978	"The milk is collected into these sterilized containers [bottles, or larger container], then aseptically delivered into the standard containers and sample bottle. Only one sample for microbiological examination is required, but the sample is taken at the end of the procedure."		Townsville milk bank Australia
Milk handling at home	Service description	Beal	1978	"It is emphasized to the donor that the milk and sample must not be left uncovered or let stand at room temperature after collection."		Townsville milk bank Australia
Milk handling at home	Service description	Beal	1978	"The remainder [after the first 5 ml] of the milk is then expressed into sterile disposable containers (Kayline Plastics, South Australia), until approximately 50 ml are collected in each container. A small aliquot (1 to 2 ml) is aseptically transferred into a sterile sample bottle (1 oz bijou) for laboratory testing."		Townsville milk bank Australia
Milk handling at home	Service description	Bjorsten	1980	"The portions are then pooled and frozen once daily."	Pooling of one woman's milk pooled at home	Umea milk bank. Sweden.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at home	Service description	Bjorsten	1980	"Collection vessels and other accessories are supplied by the milk bank and are disinfected in dish washers or by boiling before use. The milk collected at each meal over 24 hours is stored in a refrigerator in separate vessels."		Umea milk bank. Sweden.
Milk handling at home	Service description	Cash	1981	"Storage and mode of preparation can affect the in vitro biologic activities of human milk. Because white cells adhere to glass, milk stored in plastic containers yields a higher retrievable leukocyte count. EOPC provides sterile plastic 45 ml containers to all donors for collection and storage."	Paxon 1979	EOPC milk bank US
Milk handling at home	Service description	Cash	1981	"Freezing breast milk immediately after milk collection is the preferred method of storage because bacterial growth is inhibited while the antimicrobial properties are maintained. At EOPC, donors are advised to store the milk in their freezer for no longer than 7 days before transporting the milk to the bank."	Paxon 1979; Hernandez 1979; Evans 1978	EOPC milk bank US
Milk handling at home	Service description	Davidson	1979	"Specimens from home were stored in the ordinary compartment of the domestic refrigerator (not deep frozen) [...]"		Fazackerly milk bank UK
Milk handling at home	Service description	Dempster	1982	"We do not permit donors to use containers other than those supplied [...]"	Liebhaber 1979	Addington milk bank South Africa
Milk handling at home	Service description	Greenwood Wilson	1951	"A few of them, whose milk flows exceptionally freely, on medical advice express an ounce before feeding their babies, and then express the rest after that; but since the milk they express in 24 hours is all pooled, and the sample for that mother taken from her pooled 24 hours' supply. the argument is hardly affected."		Cardiff milk bank Wales

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at home	Service description	Greenwood Wilson	1951	"The Cardiff mothers so trained on their return home express all the breast milk that remains, after infant feeding, into an aluminium jug whence they pour it into medicine bottles. These they place in ice-box containers with which they have been provided in advance, and which are then ready for collection by the sister in charge of the milk bank."		Cardiff milk bank Wales
Milk handling at home	Service description	Hartmann	2007	"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."		PREM milk bank Australia
Milk handling at home	Service description	Hartmann	2007	"Donors collecting milk at home are instructed to use collection bottles supplied by the PREM Bank."		PREM milk bank Australia
Milk handling at home	Service description	Hoey	1980	"The milk collected from mothers at home is refrigerated at 4 [degrees] C and collected twice a week by the Hackney branch of the National Childbirth Trust."		Salvation Army milk bank UK
Milk handling at home	Service description	Kimball	1955	"The donor keeps the filled collecting bottles in her refrigerator."		Evanston milk bank US
Milk handling at home	Service description	Kimball	1955	"Each donor is supplied daily with 4 sterilized bottles. These are clean 4-ounce rubber capped bottles which along with a paper napkin have been wrapped in heavy brown paper (18x24 in.) and autoclaved."		Evanston milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at home	Service description	Lucas	1979	As a result of previous research (see reference ID 2035 Lucas 1979) conducted in winter, along with repeated work in summer (where bacterial counts became progressively higher - attributed to less effective domestic refrigeration at higher summer temperatures) the authors "elected to change our milk banking procedure, and donors were instructed to store their milk after collection in the freezer compartment of their refrigerator, each 24-hour collection being stored in a separate sterile container. After the introduction of home freezing (rather than refrigeration), there was an immediate marked reduction in the prepasteurisation bacterial flora of the milk, and following the next 20 consecutive pasteurisation runs during late August and September we were unable to isolate any potential pathogens. [...] The difference between frozen stored and refrigerator stored milk, with respect to the efficacy of pasteurisation in eliminating potential pathogens, was highly significant ($P < 0.001$ by Fisher's exact probability test)."	Lucas 1979	
Milk handling at home	Service description	McEnery	1978	"Milk is expressed directly into autoclaved glass bottles which are opened and used for only one expression. It is then kept in the domestic fridge until it is sent to the hospital, preferably within 24 hours."		Whipps Cross milk bank UK
Milk handling at home	Service description	Pedersen	1982	"A reasonable basis of operation of a woman milk bank must thus include routine bacteriological examinations and possibly supplemental examinations guided by visual inspection of the WM collected upon a background of basic instruction in milking procedures and storage conditions and frequently checked work in order to achieve minimal contamination in general."		Fuglebakken milk bank Denmark
Milk handling at home	Service description	Pedersen	1982	"By following the WMB's routine milking procedures, it has been possible to obtain WM which shows no evidence of bacterial growth."		Fuglebakken milk bank Denmark

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at home	Service description	Sauve	1984	"Milk was stored in plastic or glass containers in equal numbers of cases and 18 of 19 it was stored in a home deep-freeze or refrigerator freezer, while in one it was refrigerated for immediate pick-up."		Various milk banks Canada
Milk handling at home	Service description	Springer	1997	"Milk which cannot be collected daily is frozen."		Leipzig milk bank Germany
Milk handling at home	Service description	Tomalin	1983	"The mothers collect a 24-hour supply in one bottle which is kept in a fridge and then the freezer to await collection."		Kings College milk bank UK
Milk handling at home	Service description	Tully	2000	"The milk can be stored in any clean containers after the donor pumps it. Disposable plastic bags that can be sealed are quite inexpensive but may tear easily, which can cause contamination or considerable loss during defrosting. There is also some concern about some loss of IgA when the milk is stored in plastic bags. They also tend to be messier to handle. Glass or plastic jars or bottles work well and can be reused as long as they are thoroughly cleaned. Some milk banks use bottles from sterile water provided by formula companies to hospitals, and some use sterile specimen containers with liquid tight lids that are used for many different specimens within a hospital."		HMBANA milk banks US & Canada
Milk handling at home	Service description	Tully	2001	"All donors hand express their milk into jars supplied by the milk bank."		Brazilian milk banks Brazil
Milk handling at the milk bank	Case report	Ryder	1977	"Refrigeration at 1 to 5 [degrees] C after collection will prevent bacterial growth, will not destroy many of the immunologic agents currently compromised by pasteurization and freezing and will probably maximise the benefits associated with consumption of this important biologic product."	Angelatti 1961; Larson 1955; Ford 1977; Pitt 1975	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at the milk bank	Meeting report	Silverman	1971	"The storage of human milk was discussed and no major problems were identified. Plastic containers, if used, should be carefully chosen (preferably of food grade materials) to avoid the problem of leaching of plasticizers."		
Milk handling at the milk bank	Meeting report	Silverman	1971	"Frozen milk can be stored for extended periods with no appreciable change in composition."		
Milk handling at the milk bank	Meeting report	Silverman	1971	"After thawing, milk should not be refrozen for future use."		
Milk handling at the milk bank	Narrative review	Oxtoby	1988	"HIV remains infective in frozen serum and freezing would not be expected to eliminate this virus if present in milk."		
Milk handling at the milk bank	Narrative review	Oxtoby	1988	"Some pasteurize milk; others freeze or use fresh (refrigerated) milk."	Asquith 1987	
Milk handling at the milk bank	Narrative review	Roy	1979	"In the case of samples where the interval between collection and feeding is longer than 24 hours, freezing is necessary. This procedure will destroy viable cells, but a recent recommendation following a symposium on human milk suggests that, until more evidence is available on milk leukocytes as protective agents, attempts to preserve the cells should not influence the processing and storage conditions used for human milk."	Pitt 1976; Widdowson 1978	
Milk handling at the milk bank	Narrative review	Roy	1979	"Since it is exceptional that a donor can deliver fresh milk daily, since it is theoretically undesirable that foreign viable cells be ingested, and since it is a sound practice to culture routinely all samples from a nonmaternal donor, milk banking usually requires that the samples undergo two complete cycles of freezing and thawing."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at the milk bank	Narrative review	Roy	1979	"In view of the decreased nutritional value and immunologic benefits of pasteurized human milk, efforts should be made to collect clean milk with minimal bacterial contamination and to store it immediately in a freezer until it is gently thawed and fed."		
Milk handling at the milk bank	Narrative review	Van de Perre	1992	"In the United Kingdom, the official recommendation is to cryopreserve milk samples for 3 months. After this period, the stored milk is used only if a serum sample from the donor is unreactive for HIV-1 antibody."	Anon 1988	
Milk handling at the milk bank	Narrative review	Van de Perre	1992	"However, pasteurization has been proposed as an effective method of destroying HIV-1 in pooled, banked milk. Indeed pasteurization is effective against cytomegalovirus and other human viruses. HTLV-1 is also rapidly denatured by heat treatment, as it is by a freeze-thawing procedure."	Eglin 1987; Welsh 1979; Yamato 1986; Ando 1986	
Milk handling at the milk bank	Narrative review	Wight	2001	"Freezing inactivates milk cells and most viruses, but does not appear to effect the nutritional or anti-infective quality of the milk. Microwaving clearly decreases the anti-infective properties of human milk; the higher the temperature, the greater the effect."	Lawrence 1999; Quan 1992	
Milk handling at the milk bank	Narrative review	Williams	1981	Reviews the evidence on the effect of freezing on milk. Cites many references on the freezing of cow's milk and the effect of freezing on the cell structure(s). Concludes that freezing is an excellent way to preserve unpasteurised milk for longer periods of time and that most milk banks use storage limits of three to four months at below -7 degrees C .	Harris 1975; Siimes 1979; Ayres 1980; Joklik 1980; Peterson 1974; Winter 1952; Swartling 1968; Fleischaker 1977	
Milk handling at the milk bank	Narrative review	Williams	1981	Reviewed evidence on the effect of storage on nutrients. "Until more investigation is conducted to determine the significance of such effects, these problems can be minimized by thorough agitation and mixing of human milk prior to feeding."	Williamson 1978; Paxson 1979; Brooke 1978	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at the milk bank	Narrative review	Woo	2007	"'Preterm' milk can be pooled, pasteurized, and distributed separately from 'term' milk at donor milk banks and used for preterm infants who are in need of breast milk in the event that the mother is unable to provide her own milk."		
Milk handling at the milk bank	Position statement	Canadian Paediatric Society	1985	"Centres providing breast milk should have clearly described, hygienic thawing procedures (e.g., thawing in warm-water baths) and administration routines (e.g., administration within a fixed time after thawing and, when continuous infusions of milk are being given, disposal of milk that has been kept at room temperature beyond a specified time)."		
Milk handling at the milk bank	Position statement	Fernandez	1990	"15. Milk may be stored in the ordinary compartment of a refrigerator after expression or thawing for a maximum period of 24 hrs. It may be stored in the freezer for upto 3 months."		Discussed and agreed not be relevant to UK banking as specific to developing countries.
Milk handling at the milk bank	Position statement	Fernandez	1990	"9. Milk for banking is to be collected separately as preterm and mature milk."		Discussed and agreed not be relevant to UK banking as specific to developing countries.
Milk handling at the milk bank	Position statement	Gutierrez	1998	"17. Processed samples must be stored under the following conditions: Pasteurized in the refrigerator: 24 hours; Pasteurized in the freezer: 6 months; Pasteurized and lyophilized: 1 year."		Brazilian milk banks Brazil

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at the milk bank	Primary study	Gras-le Guen	2003	"An environmental investigation and a cohort study were carried out to analyse an outbreak of infection caused by a serotype O10 <i>Pseudomonas aeruginosa</i> in a neonatal intensive care unit. Thirty one cases of infection were recorded, including four lethal ones. The outbreak was stopped by eradicating the environmental sources: a contaminated milk bank pasteuriser and bottle warmer [contaminating the outside of the bottles during thawing]." "Milk was only being routinely checked by bacteriological tests before being bottled and then frozen. These tests were not repeated after thawing. Subsequently we found the same organism in the bottle warmer located in the unit and used to warm all the bottles used to feed the infants in the unit. Use of this milk bank pasteuriser and bottle warmer was discontinued immediately. Aseptic techniques during bottle handling were intensified. [...] No further cases of <i>P aeruginosa</i> were recorded."		Post donor milk bank?

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at the milk bank	Primary study	Reynolds	1982	"A simplified system of human milk banking, from milk supplied from home or hospital, has been evaluated for use in a neonatal intensive care unit. Twenty milk samples were obtained at a single expression using a standard hand pump and divided into three parts. Analyses were performed on the raw milk and on samples stored at -20 degrees C for 1 week and 1 month. No pathogens were isolated from any samples and the counts of Staphylococcus albus in the raw milk remained unchanged after storage. 19% of the cells in the original milk survived freezing and remained viable. There was a loss of bacteriostatic activity after storage for one month but significantly less than that caused by pasteurization. No change in levels of IgA, IgM, IgF, lactoferrin, lysozyme, C3 and C4 was apparent and concentrations of amino acids and fatty acids also remained unchanged after storage. We conclude that milk can be safely and conveniently stored by this method without loss or damage to the components of raw breast milk important for preterm and sick infants." Twenty women donated 100 ml of breast milk at a single expression using a hand breast pump (Kaneson) sterilised in 1°, sodium hypochlorite solution. The nipple and areola were cleaned using sterile water. Milk obtained from each donor was divided into three aliquots: the first was sent for immediate analysis while the second and third were poured into sterilised bags, sealed, and frozen at -20'C in a domestic freezer. The bags were constructed of laminated nylon and polyethylene, and a Teflon tape seal was used. Elution of organic and inorganic compounds into the milk was prevented by the nylon layer, and the combination with polyethylene ensured a robust container that would withstand freezing and thawing without damage. The second and third aliquots were thawed at one week and one month respectively. Milk was removed from each bag by wiping one corner with an alcohol	Yamanouchi in Freier 518; Bullen 1972; Carroll 1979	Process for maternal milk - EXC?

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
			1982	swab and cutting with a pair of clean scissors. The three aliquots from each donor were compared for bacterial contamination, bacteriostatic activity, cellular and immunological components, fat, and amino-acids. Colony counts were performed on 100 μl samples added to 10 ml of plate-count agar incubated for 48 hours. Blood agar 02 and McConkey agar were used. Bacteriostatic activity was tested on milk supernatant after centrifugation at 56 000 g and 4°C for 40 minutes. <i>Escherichia coli</i> 0111 was inoculated into each sample after sterilisation through a 0.45 μm oxoid filter (n47/45), and a viable count was performed immediately and at hourly intervals for seven hours. Cell counts were performed on 200 μl samples stained with 0.2% gentian violet and diluted with saline using a standard blood cell count technique. Cell viability was tested with trypan blue dye (C Rolles, personal communication) on a pellet of cells resuspended in 0.3 ml of Hanks's balanced salt solution after centrifugation at 700 g for 15 minutes. The table [not included here] shows that there was no appreciable change in bacterial counts in the fresh and stored samples. Counts were higher when expression had been prolonged or difficult. No pathogens were isolated from any of the samples. Most samples (80.0%) contained less than 2.5×10^6 colony forming units of <i>Staphylococcus albus</i>. Bacteriostatic activity was preserved for at least one week by freezing. Some deterioration occurred during storage for one month, but this was less than that caused by pasteurisation: in an unpublished study we showed that bacteriostatic activity was destroyed by pasteurisation at 63.5°C for 30 minutes. A surprisingly large number of cells in our samples survived storage. Many of the surviving cells remained viable. Cell loss appeared to be related to freezing and		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
			1982	thawing rather than the period of storage. Cell survival and preservation of antibacterial proteins may be enhanced by fast freezing and thawing. In our bags 10 ml milk freezes after 35 minutes, but a similar volume in a standard glass bottle freezes after 57 minutes. Our system of milk banking is safe and reliable and preserves more of the antibacterial and nutritional components of breast milk than has hitherto been reported. Each storage bag costs less than 5p, including sealing tape and labels. This system allows a mother to provide enough milk for her own infant. Milk from a single expression at home or hospital is divided into single-feed volumes, sealed in the bags, and frozen immediately. A 1 ml aliquot may be retained for bacterial quality control. The milk is stored until the sample has passed the criteria of Carroll et al. Single feeds are thawed immediately before use to prevent contamination and waste. Milk may be stored at home until transferred frozen to the hospital freezer. There is minimal handling of milk by donors and staff."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at the milk bank	Primary study - in vitro	Honour	1979	Assayed the bacteriostatic activity for milk-sensitive and milk-resistant indicator strains of Escherichia coli. "Activity is greatest in colostrum which is active directly against all strains of E. coli. One week after delivery of the baby, milk is active against the milk-sensitive strain and becomes active against the milk-resistant strain in the presence of physiological amounts of bicarbonate and iron-binding protein. This activity decreases within 2--4 days on keeping milk unheated at 4 degrees C but is preserved for at least 4 months and often up to 2 years in milk heated to 56 degrees C then stored at 4 degrees C or in milk frozen, unheated, at -28 degrees C provided it is not repeatedly thawed and frozen. Later lactation milks are usually indistinguishable in activity from 1-week post-partum milk but may be less stable on storage particularly if frozen. Lyophilization in vacuo preserves activity of early-lactation milk for at least 6 months. Heating milk to above 65 degrees C causes a progressive loss of activity which can be partially restored by adding bicarbonate and iron-binding protein. Iron abolishes the activity of milk and reduces that of colostrum."		
Milk handling at the milk bank	Primary study - in vitro	Moffatt	1987	"The alpha- and gamma-tocopherols in pooled stored human milk were determined. Storage times and temperatures were t = 0 (up to 2 h after start of pool collection); t = 8 h (25 degrees, 4 degrees C); t = 24 h (25 degrees, 4 degrees, -11 degrees C); and t = 72 h, 1, 4, 8, and 16 weeks (-11 degrees, -20 degrees, -70 degrees C). Lipids were extracted with a modified Folch procedure and tocopherols were analyzed with high-performance liquid chromatography. There were no significant differences in alpha- or gamma-tocopherol at any time or temperature. Therefore, mothers, milk bank operators, and researchers can be assured of the stability of tocopherol in human milk stored under the conditions of this study." Milk was pooled from a minimum of 5 donors, all collected within 2 hours.		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at the milk bank	Primary study - in vitro	Pardou	1994	"Our results suggest that the type and length of storage have an effect on some milk constituents, that this effect is modulated by the bacterial contamination of the milk and that refrigeration has a significant inhibitory effect on bacterial growth which is not observed after freezing. This stresses the importance of collecting noncontaminated milk and justifies the choice of refrigeration at 0-4 degrees C for storage up to 8 days." "Lactose concentrations did not change over time either in refrigerated or in frozen milk. In contrast, lipids concentrations of both refrigerated [Class I, median: 3.92 Day 1; 3.52 Day 4; 3.37 Day 8; not significant. Class II, median: 3.84 Day 1; 3.77 Day 4; 3.58 Day 8; p=0.004. Class III, median: 4.75 Day 1; 4.78 Day 4; 4.46 Day 8; p=0.000]and frozen milk [Class I, median: 3.92 Day 1; 3.61 Day 4; 3.54 Day 8; not significant. Class II, median: 3.84 Day 1; 3.80 Day 4; 3.61 Day 8; p=0.003. Class III, median: 4.75 Day 1; 4.76 Day 4; 4.65 Day 8; p=0.002]decreased over time in the three groups. This decrease was significant only in classes II and III of Carroll (p<0.004) and was observed in refrigerated and frozen milk. IgA concentrations did not change over time either in refrigerated or frozen milk in class I but decreased in class II after freezing [median: 76.80 Day 1; 72.70 Day 4; 65.00 Day 8; p=0.007] and in class III after refrigeration and freezing [median: 92.65 Day 1; 77.60 Day 4; 81.55 Day 8; p=0.007. Median; 92.65 Day 1; 76.35 Day 4; 77.30 Day 8; p=0.006, respectively]."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at the milk bank	Primary study - in vitro	Pardou	1994	"Our results suggest that the type and length of storage have an effect on some milk constituents, that this effect is modulated by the bacterial contamination of the milk and that refrigeration has a significant inhibitory effect on bacterial growth which is not observed after freezing. This stresses the importance of collecting noncontaminated milk and justifies the choice of refrigeration at 0-4 degrees C for storage up to 8 days." "In class I, the milk samples remained sterile after 8 days of refrigeration and were still sterile at 6h at 25 [degrees] C. On the contrary a small amount of bacteria was found after 8 days of freezing and the bacteria increased after 2-6h at 26 [degrees] C. In class II a low count (2.40×10^3 CFU/ml) of bacteria was found on the day of collection and decreased after 8 days of refrigeration to 0.55×10^3 CFU/ml ($p < 0.05$): the bacterial load varied over time from 0.11×10^3 CFU/ml after 2h ($p < 0.05$) to 0.15×10^3 CFU/ml and 4 and 6 h ($p < 0.05$). On the contrary, there was no decrease in bacteria after 8 days of freezing and the content varied from 0.75×10^3 CFU/ml at extraction time to 0.95×10^3 CFU/ml after 8 days of freezing (NS). The bacterial load changed over time from 1.35×10^3 CFU/ml after 2 h (NS) to 2.55×10^3 CFU/ml after 4 h (NS) and to 2.20×10^3 CFU/ml after 6 h (NS) at 25 [degrees] C but this was not significant. In class III the concentration decreased after 8 days of refrigeration and the count decreased from 2.85×10^3 CFU/ml at extraction time to 1.45×10^3 CFU/ml ($p < 0.05$) after 8 days of refrigeration: the bacterial count was stable over time at 26 [degrees] C after refrigeration as it varied from 0.65×10^3 CFU/ml after 2 h (NS) to 1.70×10^3 CFU/ml after 4h (NS) and to 0.75×10^3 CFU/ml after 6h (NS). After 8 days of freezing the count varied from 4.90×10^3		

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			1994	CFU/ml at extraction time to 3.52×10^3 CFU/ml and the bacterial count increased over time at 26 [degrees] C from 3.90×10^3 CFU/ml after 2 h (NS) to 6.20×10^3 CFU/ml after 4h (NS) and to 10.40×10^3 CFU/ml after 6h ($p=0.05$)."		
Milk handling at the milk bank	Primary study - in vitro	Pittard	1981	"The storage of human milk at 4 C for 48 hours after expression resulted in a significant ($p < 0.02$) loss of cellular viability [mean (sd): 89% (4) 0 hours; 78% (10) 24 hours; 73% (12) 48 hours]. Further, the concentration of milk macrophages and neutrophils decreased significantly ($p < 0.02$) [Lymphocyte mean (cell count $\times 10^6$ /ml) (sd): 0.1 (0.09) 0 hours; 0.06 (0.05) 24 hours; 0.05 (0.05) 48 hours; Macrophage mean (cell count $\times 10^6$ /ml) (sd): 0.53 (0.47) 0 hours; 0.49 (0.48) 24 hours; 0.39 (0.48) 48 hours; Neutrophil mean (cell count $\times 10^6$ /ml) (sd): 0.04 (0.04) 0 hours; 0.03 (0.06) 24 hours; 0.01 (0.01) 48 hours] presumably via cell adhesion to the milk container or cytolysis. The milk lymphocyte concentration, however, was not significantly affected by storage. Milk passage through a nasogastric feeding catheter had no additional effect on cell viability or concentration. Thus, while current banking methodologies allow greater availability of breast milk's resistance factors to newborn infants, they do so with significant, but not serious, alterations in both the quantity and quality of these components."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at the milk bank	Primary study - in vitro	Rechtman	2006	"Vitamin analysis showed that there was no appreciable change in the concentration of vitamin A regardless of the test conditions under which the samples were stored. Vitamin C did show a decrease in concentration, losing about one-half of the initial concentration when kept at room temperature for 8 hours. When kept refrigerated for 24 hours, about one-fourth of the initial concentration was lost. [Vit A (IE/100ml) 8 degrees C for 4 hours 100; 8 degrees C for 24 hours 100; 23 degrees C for 4 hours 105; 23 degrees C for 8 hours 100; repeated freeze-thaw 100; control 100. Vit C (mg/100ml) 8 degrees C for 4 hours 2.2; 8 degrees C for 24 hours 1.7; 23 degrees C for 4 hours 1.6; 23 degrees C for 8 hours 1.0; repeated freeze-thaw 1.5; control 2.2]"		No p values or statistical tests appear to have been applied.
Milk handling at the milk bank	Primary study - in vitro	Rechtman	2006	"Analysis of fat failed to detect the presence of aldehydes in any sample at >0.1ppm and were absent altogether in many of the samples. FFAs were measured by comparison of the heights of their chromatographic peaks. Then the samples were ranked for each FFA tested." "The FFA analysis showed that unpasteurized milk held at 23 [degrees] C for 4 hours as well as the control sample had the highest levels of FFA, whereas milk stored at 8 [degrees] C for 4 hours and milk that was repeatedly frozen and thawed had the lowest levels. Moreover, although differences were seen among storage conditions, they appeared to be small and, presumably, clinically insignificant."		No p values or statistical tests appear to have been applied.

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Milk handling at the milk bank	Primary study - in vitro	Rechtman	2006	"We undertook an experiment to measure the effects of ambient temperature conditions and refreezing on the bioburden and nutritional content of human milk. We conclude that unpasteurized human milk is robust and can be used after storage under certain conditions." RESULTS "The results of the microbial analysis show that breast milk that had been frozen at -20 [degrees] C and then thawed did not develop a microbial load approaching 10^4 CFU/ml, which has been the accepted limit for bacterial growth for raw (unpasteurized) milk in most milk banks in North America. [8 degrees C for 4 hours 8.6×10^1 CFU/ml; 8 degrees C for 24 hours 3.5×10^1 CFU/ml; 23 degrees C for 4 hours 1.0×10^2 CFU/ml; 23 degrees C for 8 hours 3.7×10^2 CFU/ml; repeated freeze-thaw 1.1×10^2 CFU/ml; control 1.1×10^2 CFU/ml] These results were the same for milk stored at 23 [degrees] C for 8 hours or that had undergone repeated freeze-thaw cycles [8 degrees C for 4 hours, 8 degrees C for 24 or 4 hours, refrozen to -20 degrees C for 20 hours, rethawed and stored at 8 degrees C for 4 hours, refrozen at -20 degrees C for 20 hours, rethawed and stored at 8 degrees C for 24 hours]."		No p values or statistical tests appear to have been applied.

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Milk handling at the milk bank	Primary study - in vitro	Silprasert	1987	"Human milk samples were collected from mothers on the third post-partum day with a manual breast-pump and pooled. They were divided into aliquots and stored at room temperature (24-25 degrees C), and at 4 degrees, 37 degrees and -20 degrees C. The creatocrit (CR) values decreased significantly after storage at room temperature (P less than 0.03 [mean (se) CR% initial 3.27 (0.39)]), or at 37 degrees C (P less than 0.001 [mean (se) CR% initial 3.76 (0.30)]) for 45 min and 30 min, respectively. Creatocrit remained stable for 14 d at 4 degrees C [mean (se) CR% initial 3.12 (0.30)], and for up to 28 d at -20 degrees C [mean (se) CR% initial 3.32 (0.43)]. However, freezing and thawing samples twice significantly decreased creatocrit values (P less than 0.001 [mean (se) CR% initial 3.27 (0.39)]). The total energy concentration of the samples stored at -20 degrees C was stable for 28 d. These results indicate that strict precautions must be taken when handling and storing human milk samples for analysis of lipid content."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at the milk bank	Primary study - in vitro	Silvestre	2006	"This study aims to analyse global bactericidal activity in fresh human milk and evaluate its stability in relation to milk manipulation and its possible alteration following refrigeration. Nineteen milk samples (mature milk) from 19 healthy women are analysed. Viability testing involving a strain of Escherichia coli NCTC 9111, serovar O111:K58(B4):H- was used to determine the bactericidal effect of human milk. Degree of bacteriolysis is calculated as the difference between E. coli counts in controls and in milk samples, expressed as a percentage of the control sample counts. An evaluation of the effect of refrigeration at 4-6 degrees C after 24, 48 and 72 hours, and at -20 degrees C for seven days on bactericidal capacity is made. Bactericidal activity was detected in all milk samples analysed ([mean] 77.33 +/- 15.14%). This activity persisted after refrigeration for 48 hours [mean 82.1% at 24 hours; 78.9% at 48 hours, p>0.05] and after freezing for 10 [paper reports 7] days [mean 82.18%, p>0.05], but showed a significant decrease after refrigeration for 72 hours [mean 26.61%, p<0.01]. In conclusion, maternal milk has bactericidal capacity, providing defence and protection against infection for newborn infants. This property can be altered during the storage of milk. Consequently, if storage in excess of 48 hours is required, freezing is preferable to refrigeration."		SD assumed?

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at the milk bank	Primary study - in vitro	Silvestre	2006	"Available lysine content is an indicator of protein quality and nutritional value of milk. Many studies have examined the effects of extraction, treatment and storage of human milk upon its components, though no references are found regarding the possible changes in milk quality as defined by its content in essential amino acids such as lysine. The present study investigates the available lysine content in human milk and the variations in lysine resulting from milk manipulation as follows: (a) Cold storage (refrigeration at 4 degrees C for 48 hours, and frozen for 15 days at - 20 degrees C); (b) Thermal treatment under conditions of low (Holder)(63 degrees C/30 minutes) and high pasteurization (75 degrees C/15 seconds). The results obtained show a decrease in milk lysine concentration after storage in both refrigerated and frozen samples [mean (sd) mg Lys/100ml fresh 161.34 (70.768); refrigerated 98.55 (39.191); frozen 94.75 (36.365); p=0.0037 and p=0.0310 vs fresh milk resp]. Pasteurization causes a highly significant loss of available lysine. The lysine losses were greater on applying low pasteurization versus the more gentle conditions of high pasteurization [mean (sd) mg Lys/100ml fresh 181.41 (86.318); low 127.53 (64.991); high 153.55 (74.502); p=0.0000015 and p=0.0000078 vs fresh milk resp; p=0.000015 low vs high]. CONCLUSIONS: While manipulation through cold storage or thermal treatment does not affect the protein content of human milk, its protein quality is modified [mean (sd) g protein/l fresh 12.70 (4.787); refrigerated 11.19 (4.975); frozen 11.74 (3.386); p=n.s. vs fresh milk resp]. When human milk must be subjected to hygienization, it is preferable to apply high temperature treatment (75 degrees C, 15 seconds) than habitual pasteurization (63 degrees C, 30 minutes) [mean (sd) g protein/l fresh 13.78 (6.836); low 12.49 (4.639); high 13.39 (5.4195); p=n.s. vs fresh milk resp]."		SD assumed?

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Milk handling at the milk bank	Primary study - in vitro	Terai	1979	"In the fatty acid composition of triglyceride in colostrum, the proportion of C16:0 was the highest and C10:0, C12:0, and C18:2 was the lowest. The large proportion of fatty acid at the B-position in triglyceride of human milk was C16:0, and C18:1 in commercially available formulas. In the lipid fraction, it was observed that triglyceride was decreased and free fatty acid was increased in the transitional (TG 85.8% fresh; 76.4% -15 degrees; 86.9% -80 degrees). FFA 3.9% fresh; 8.8% -15 degrees; 3.1% -80 degrees) and mature human milk (TG 88.0% fresh; 75.1% -15 degrees; 91.0% -80 degrees. FFA 2.3% fresh; 10.3% -15 degrees; 1.9% -80 degrees) stored at -15 degrees C, but not in the milk stored at -80 degrees C."		Full paper only in Japanese? Also very limited reporting, for example, no details of the length of storage time. No statistics or statistical significance reported.
Milk handling at the milk bank	Service description	Arnold	1996	[...] "milk is pasteurized in a water bath at 62 [degrees] C or 65 [degrees] C, depending on the hospital."		Beijing milk bank China
Milk handling at the milk bank	Service description	Arnold	1999	"Processed milk may be kept for up to 6 months."		Goteborg milk bank Sweden
Milk handling at the milk bank	Service description	Asquith	1987	"Each container of milk is observed for appearance, color, and odor that could indicate spoilage or flavoring from the maternal diet that might render it unsafe or unpalatable for the recipient."	Evans 1981	San Jose milk bank US
Milk handling at the milk bank	Service description	Asquith	1987	"Raw milk containing fewer than 10,000 colony-forming units (CFU) per ml, is kept frozen for a total of 7 days, whereafter it is made available. Pools containing more than that limit are thawed and pasteurized at 65.6 [degrees] C for 30 minutes and refrozen. On retesting in the SPC, pasteurized milk containing fewer than 500 CFU per ml is made immediately available."	Lucas 1979; Hernandez 1979; Sussman 1961; Carroll 1979; Davidson 1979; Williamson 1978; Baum 1979; Bjorksten 1980; Ford 1977; Goldblum 1984; Ikonen 1977; Kon 1961	San Jose milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at the milk bank	Service description	Asquith	1987	"A sample from each pool is removed for subsequent testing, and the milk is returned to the original containers and refrozen at -20 [degrees] C pending test results."		San Jose milk bank US
Milk handling at the milk bank	Service description	Asquith	1987	"On arrival at the MMB, donated milk is thawed at 4 [degrees] C [...]."		San Jose milk bank US
Milk handling at the milk bank	Service description	Balmer	1992	"Often milk is donated before we know the results of the HIV antibody test and this milk is stored in a separate freezer until the result is known."		Sorrento milk bank UK
Milk handling at the milk bank	Service description	Balmer	1992	"Pooled milk is transferred to 250 ml glass Winchester bottles for pasteurising."		Sorrento milk bank UK
Milk handling at the milk bank	Service description	Balmer	1992	"After pasteurisation all milk is stored frozen until use when it is defrosted either in a refrigerator or at room temperature. Pasteurised milk can be stored frozen for up to six months."		Sorrento milk bank UK
Milk handling at the milk bank	Service description	Baum	1982	"In the human milk bank the individual bottles of frozen milk are placed in a reception deep freeze. At a convenient time supplies of this milk are removed and allowed to thaw at room temperature."		John Radcliffe milk bank UK
Milk handling at the milk bank	Service description	Baum	1982	"Orders for human milk are placed one day in advance whenever possible. In this way the nursing auxiliary in charge of the milk bank can thaw the necessary volumes of milk early the following morning."		John Radcliffe milk bank UK
Milk handling at the milk bank	Service description	Beal	1978	"For use, the milk [...] is partially immersed in warm water (37 [degrees] to 40 [degrees] C) until is has thawed. It is then transferred into sterile feeding bottles and used immediately. It is not sterilized by steam or boiling, or pasteurized, but is used direct from the collection containers."		Townsville milk bank Australia
Milk handling at the milk bank	Service description	Beal	1978	"The standard containers with milk are placed in a deep freezer, which is situated in the paediatric ward of the hospital and is used solely for this purpose."		Townsville milk bank Australia

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at the milk bank	Service description	Beal	1978	"Milk is used in rotation, the oldest milk being used first."		Townsville milk bank Australia
Milk handling at the milk bank	Service description	Bjorsten	1980	"Thawed milk may be stored for up to 72 hours at 4 [degrees] C before use, although it is rarely stored for more than 24 hours."		Umea milk bank. Sweden.
Milk handling at the milk bank	Service description	Bjorsten	1980	"Human milk donated in the hospital is collected in autoclaved shells or bottles and is not routinely checked for bacterial contamination. Our intrahospital milk collection system is, however, bacteriologically monitored for one day every three months, when all milk samples delivered that day as well as pumps and other equipment are subject to bacteriological control."		Umea milk bank. Sweden.
Milk handling at the milk bank	Service description	Cash	1981	"Breast milk is stored at the milk bank at a temperature of -18 [degrees to] -20 [degrees] C for 3 months. This temperature and length of storage does not significantly alter breast milk's protectiveness."	Evans 1978	EOPC milk bank US
Milk handling at the milk bank	Service description	Cash	1981	"Banked human breast milk may be altered during preparation for feeding. As heat may decrease the protective properties, milk should not be thawed in hot water. Frozen breast milk is thawed in the refrigerator or under cold running water. Once breast milk is thawed, care must be taken to prevent bacterial growth. Thawed breast milk is kept up to eight hours under refrigeration."		EOPC milk bank US
Milk handling at the milk bank	Service description	Connor	1982	"When the milk is ready to be used, a sterile teat with screw top (supplied by the CSSD) is fitted, and the feeding bottle discarded after use."		Enfield milk bank UK
Milk handling at the milk bank	Service description	Connor	1982	"The containers used for freezing the milk - a polypropylene pot with a screw lid - is supplied unsterile. As it does not tolerate being autoclaved, it was decided to sterilise these pots in hypochlorite solution."		Enfield milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at the milk bank	Service description	Connor	1982	"On arrival at the hospital 50ml of each mother's milk is poured into these [sterile 100ml] feeding bottles [...] and capped [...]. These are then labelled and recorded."		Enfield milk bank UK
Milk handling at the milk bank	Service description	Davidson	1979	"On receipt at the hospital milk bank these domiciliary donations were then also stored at -20 [degrees] C."		Fazackerly milk bank UK
Milk handling at the milk bank	Service description	Davidson	1979	"After the EBM had been collected into autoclaved 100 ml glass bottles, approximately 2 ml milk was decanted into a sterile pilot bottle for bacteriological screening. [...] Those specimens collected in hospital were deep frozen to -20 [degrees] C in the breast milk bank freezer as quickly as possible, often within a few minutes of collection."		Fazackerly milk bank UK
Milk handling at the milk bank	Service description	Dempster	1982	"Milk [...] remains in the original container from the time of collection until used to feed a baby. Milk which satisfies the bacteriological criteria is deep-frozen until needed (or for a maximum period of 3 months) and is available on prescription for any hospitalized baby."		Addington milk bank South Africa
Milk handling at the milk bank	Service description	Dempster	1982	"We supply 40 ml sterile, plastic specimen bottles for the milk, which is frozen immediately after collection."		Addington milk bank South Africa
Milk handling at the milk bank	Service description	Fernandez	1993	"The milk is stored in the freezer in three separate lots: 1) colostrum - collected within 72 hours of delivery; 2) mature milk - collected after 72 hours postpartum; 3) preterm milk - expressed by mothers who have delivered preterm infants."		Bombay milk bank India. May not be directly relevant to the UK, but agreed to leave in with caveats in interpretation.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at the milk bank	Service description	Fernandez	1993	"[... the milk bank uses] labelled autoclaved, stainless steel containers with close-fitting lids instead of glass, polyethylene or polypropylene containers used in the West. These containers are easily available, durable, and easy to clean and autoclave."	Goldblum 1981	Bombay milk bank India. May not be directly relevant to the UK, but agreed to leave in with caveats in interpretation.
Milk handling at the milk bank	Service description	Fernandez	1993	"The bank is equipped with two freezers for storing the milk at -20 [degrees] C, two refrigerators, a shaker waterbath and a geyser [gas-fired water heater that delivers hot water on demand] for heat treatment of milk, and a generator for running the freezers in case of power failure. Other equipment includes a number of manual breast pumps, two electric breast pumps, stainless steel containers for expressing into and storing milk, insulated boxes for transporting milk and thermometers for monitoring temperatures of freezers and the water bath."		Bombay milk bank India. May not be directly relevant to the UK, but agreed to leave in with caveats in interpretation.
Milk handling at the milk bank	Service description	Fernandez	1993	"Our own unpublished studies show that the protein, lactose, and fat content do not alter on storage, and there is no significant reduction in the immunoglobulin levels or the cell count."		Bombay milk bank India. May not be directly relevant to the UK, but agreed to leave in with caveats in interpretation.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at the milk bank	Service description	Greenwood Wilson	1951	"All surplus from current use is frozen. The milk is not frozen in the bottles because it would take too long to melt back when needed. Instead, it is poured into the 10 shallow depressions on each freezing plate, each of which holds about one-third of an inch. The milk is pasteurized before freezing and every care is taken to avoid contaminating the milk. The frozen milk discs are sometimes jocularly described as peppermint creams. All apparatus is sterilized before use, and the nurse wears a mask while at work. The frozen milk discs can be kept for as long as six to 11 months in a special deep freeze apparatus, but there is also an ordinary domestic type refrigerator for short-time storage."		Cardiff milk bank Wales
Milk handling at the milk bank	Service description	Hartmann	2007	"A batch of milk (600-3000 ml of milk from a single donor) is thawed rapidly in an orbital incubator [...]"		PREM milk bank Australia
Milk handling at the milk bank	Service description	Hartmann	2007	"Any milk that is inappropriately labelled cannot be accepted 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 [degrees] C or below."		PREM milk bank Australia
Milk handling at the milk bank	Service description	Hartmann	2007	"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."		PREM milk bank Australia. Also good diagram of process.
Milk handling at the milk bank	Service description	Hartmann	2007	"Product is stored at -20 [degrees] C to limit lipolysis and microbial growth. Prior to processing milk is rapidly thawed in an orbital incubator (37 [degrees] C, 150 rpm) until milk is thawed (unpublished data has shown that the liquid product temperature at the surface of the bottle did not increase above 0 [degrees] C under these conditions)."	Berkow 1984; Pardou 1994	PREM milk bank Australia

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at the milk bank	Service description	Hartmann	2007	"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."		PREM milk bank Australia
Milk handling at the milk bank	Service description	Hartmann	2007	"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)."		PREM milk bank Australia
Milk handling at the milk bank	Service description	Hartmann	2007	"Once pasteurised, donor human milk may be stored frozen at -20 [degrees] C for a maximum of 3 months prior to being dispensed."		PREM milk bank Australia
Milk handling at the milk bank	Service description	Hartmann	2007	"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."		PREM milk bank Australia
Milk handling at the milk bank	Service description	Hartmann	2007	"Raw donor human milk if stored frozen at -20 [degrees] C by the PREM Bank for a maximum of 3 months from the date of expression."	UKAMB 2003; HMBANA 2005	PREM milk bank Australia
Milk handling at the milk bank	Service description	Hartmann	2007	"A pre-pasteurisation (1 ml) microbiology sample is taken prior to processing."		PREM milk bank Australia
Milk handling at the milk bank	Service description	Hoey	1980	"All samples are cultured. Only those yielding Pseudomonas aeruginosa are pasteurised and the rest are pooled and deep frozen."		Salvation Army milk bank UK
Milk handling at the milk bank	Service description	Hoey	1980	"Over the past four years approximately 2500 low-birthweight babies have received frozen unpasteurised breast milk that has been thawed. No ill effects have been noted."		Salvation Army milk bank UK

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Milk handling at the milk bank	Service description	Hoey	1980	"We agree with Dr David Baum (18 October, p 1066) that great caution must be exercised in the administration of a breast milk bank. However, he states that pasteurisation "can preserve the majority of the antimicrobial factors" (our italics). Dr Bjorksten and his colleagues suggest that all the factors are preserved by freezing. Our experience suggests that pasteurisation is unnecessary, timeconsuming, and expensive."	Baum 1980; Bjorksten 1980	Salvation Army milk bank UK
Milk handling at the milk bank	Service description	Hoey	1980	"The milk may be kept frozen for up to two months but usually the demand is so great that this does not occur."		Salvation Army milk bank UK
Milk handling at the milk bank	Service description	Ikonen	1982	"According to our practice all donated milk is frozen before use. Freezing obviously destroys macrophages which has supposed to have some protective influence against necrotising enterocolitis. On the other hand immunologically foreign macrophages can have some harmful effect and even storage of milk in refrigerator at home during collection lowers the number of macrophages. Thus it does not seem necessary to try to avoid freezing in human milk banks, where certain amount of milk must always be stored frozen."	Lawton 1977; AAP 1980; Paxton 1979	Tampere milk bank Finland
Milk handling at the milk bank	Service description	Kimball	1955	"The packed sterile bottles used for daily orders are stored in the refrigerator, and the milk is immediately poured into the cold bottles; it is thus cooled faster than it would be by cooling the total amount."		Evanston milk bank US
Milk handling at the milk bank	Service description	Kimball	1955	"Our usual supply of 1 to 3 quarts of breast milk daily can be poured quickly. When the supply is larger, it is divided and sterilized separately."		Evanston milk bank US
Milk handling at the milk bank	Service description	Kimball	1955	"The method of collection of the milk without handling has prevented any gross contamination and the straining serves only to remove any large particles of coagulate milk which might clog a nipple. Extra milk is poured into 4-ounce bottles and capped for freezing in the bank as recommended by Leighty."	Leighty 1939	Evanston milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at the milk bank	Service description	Kimball	1955	"Sterile tables are set up while the milk is heating and the orders for the day are poured immediately using aseptic technique. (Terminal heating is not used to avoid caramelizing the milk sugar.) During the process of pouring the daily orders, the milk is strained through 4 thicknesses of sterile gauze in a fine mesh strainer."		Evanston milk bank US
Milk handling at the milk bank	Service description	Kimball	1955	"Both the used and unused collecting bottles are sterilized daily in the hospital."		Evanston milk bank US
Milk handling at the milk bank	Service description	Langerak	1991	"It is then thawed, pooled, and autoclaved at 212 [degrees] F for five minutes."		Wilmington milk bank US
Milk handling at the milk bank	Service description	Langerak	1991	"Each batch of milk is labeled, quickly refrozen and stored at -10 [degrees] F in alarm monitored freezers."		Wilmington milk bank US
Milk handling at the milk bank	Service description	McEnergy	1978	"Reception and processing - Milk from each expression is kept separate and deep frozen (-20 [degrees] C) for up to six weeks, while a few millilitres of milk are sent for bacteriological culture and colony count."		Whipps Cross milk bank UK
Milk handling at the milk bank	Service description	Morley-Peet	1983	Report of enteropathogenic Escherichia coli. Current practice was: "Milk collections from donors who produce large supplies, whether in hospital or at home, are put into single containers, sealed, labelled and frozen." After the outbreak, instructions were issued: "All milk collected from long-term donors would be processed as before and screened in the laboratory before use."		North East Essex milk bank UK
Milk handling at the milk bank	Service description	Morley-Peet	1983	Report of enteropathogenic Escherichia coli. Current practice was: "The rest is sealed, labelled, pasteurised and cooled rapidly before freezing, to await the laboratory results. If the results are satisfactory, the milk is stored and used as required. The whole collection is discarded if the results are unsatisfactory."		North East Essex milk bank UK
Milk handling at the milk bank	Service description	Morley-Peet	1983	Report of enteropathogenic Escherichia coli. Current practice was: milk is "taken to the milk kitchen in the SCBU by the nurse supervising these mothers."		North East Essex milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling at the milk bank	Service description	Morley-Peet	1983	Report of enteropathogenic Escherichia coli. Current practice was: "Collections are not always delivered promptly to the SCBU during busy periods and are sometimes left on the entrance hall table."		North East Essex milk bank UK
Milk handling at the milk bank	Service description	Murray	1953	"When the milk is received, it is examined, pasteurized and immediately frozen on bottles. [...] It is now frozen and stored in eight-ounce bottles and can be kept safely in this state for about a year. However, the demand is such that the milk does not remain in the bank longer than six months."		Essex County milk bank US
Milk handling at the milk bank	Service description	Pedersen	1982	"Only over the past couple of years has a large, permanent, deep-frozen stock been built up."		
Milk handling at the milk bank	Service description	Pedersen	1982	"Concerning inspection of raw WM, experiences at the WMB have shown that pus and/or blood could be seen in WM (as sediment after standing in the collection container) before clinical symptoms of breast problems appeared in the donor. The daily evaluation at the WMB included inspection by sight, taste/smell, and bacteriological control, as well as pH measurement, density determination, and serologic reaction."		Fuglebakken milk bank Denmark
Milk handling at the milk bank	Service description	Penc	1996	"Frozen milk expressed by one donor over several days is thawed, mixed, bottled and refrozen. These procedures are carried out under sterile conditions when the milk temperature is only slightly higher than 0 [degrees] C."		Polish Mother's Memorial Hospital milk bank Poland
Milk handling at the milk bank	Service description	Penc	1996	"If the purity of a batch is sufficient, an amount equal is defrosted, pasteurized, and taken to the ward for use."		Polish Mother's Memorial Hospital milk bank Poland

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Milk handling at the milk bank	Service description	Penc	1996	"Requests for donor milk are submitted to the HMB by the neonatologists."		Polish Mother's Memorial Hospital milk bank Poland
Milk handling at the milk bank	Service description	Reid	1988	Survey of UK milk banks. Breast milk stored in freezer at -20 degrees C for 3 months 7; 6 months 7; other 2; banks closed 2; no response 2.		Ninewells milk bank Scotland. Report of out-dated practice.
Milk handling at the milk bank	Service description	Springer	1997	"The Berlin milk bank has the technical ability to freeze dry donor milk if large enough volumes of milk are available. These powdered milk products are then available for use in fortifying either a mother's own milk or donor milk."		Berlin milk bank Germany
Milk handling at the milk bank	Service description	Tomalin	1983	"Milk can be frozen for six months but most of it is used up within a month [...]."		Kings College milk bank UK
Milk handling at the milk bank	Service description	Tomalin	1983	"Batches are frozen to await laboratory results."		Kings College milk bank UK
Milk handling at the milk bank	Service description	Tully	2000	"Large trays (Rubbermaid storage boxes work well, about \$10 each) to hold an ice slurry for quickly chilling the processed milk are needed, as well as clean linens to cover the work area and absorb spills."		HMBANA milk banks US & Canada
Milk handling at the milk bank	Service description	Tully	2000	"Milk can be thawed in a refrigerator over a 2- to 3-day period (an extra expense for the refrigerator), set out to thaw at room temperature for several hours, or quick-thawed standing in warm water."		HMBANA milk banks US & Canada

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Milk handling at the milk bank	Service description	Tully	2000	"Freezers (about \$600-\$800 each) that do not have a self-defrosting cycle and can maintain at least -20 [degrees] C are required for storing milk both before and after processing. Upright freezers are the most convenient. The freezer should not be self-defrosting because the self-defrost cycle warms the freezer every 12 hours. If the milk is processed within 2 days of expressing and then used within 2 days of processing, it only requires a refrigerator that can maintain -4 [degrees] C. Each freezer or refrigerator should be monitored with either an alarming thermometer that is monitored 24 hours a day or a recording thermometer. Hampshire Controls markets a temperature alarm that can be used in a freezer (model #125-50LRB, about \$225 each) and connected to an automatic dialing machine that will alarm to a remote telephone if the freezer alarm is not turned off within 5 mintes (Sensaphone 1104, Price Scientific, about \$400). The drawback of a recording thermometer without the remote alarm capability is that milk can be lost before the problem is discovered."		HMBANA milk banks US & Canada
Milk handling at the milk bank	Service description	Tully	2000	"Typically, a shaking water bath with temperature controls is used for heat processing the milk and upright freezers are used for storage."		HMBANA milk banks US & Canada
Milk handling at the milk bank	Service description	Tully	2001	"The milk is processed and stored frozen at the hospital, but the bacteriologic studies are all done by the Department of Health rather than the individual milk bank in Venezuela."		Caracas milk bank Venezuela
Milk handling during transportation	Narrative review	Wight	2001	""Preterm" milk is usually processed separately and reserved for the smallest, most immature infants. Donor milk is shipped frozen, thawed to a slurry, cultured, then pooled for pasteurization."		US milk banks US
Milk handling during transportation	Narrative review	Wight	2001	"Donor milk is dispensed only on prescription. Lot numbers are recorded and the milk is shipped frozen, overnight."		US milk banks US

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Milk handling during transportation	Service description	Asquith	1987	"Milk is packaged frozen in glass bottles and transported in styrofoam containers with 'blue ice' lids and prominently labeled 'Perishable, Frozen Human Milk'."		San Jose milk bank US
Milk handling during transportation	Service description	Asquith	1987	"The parents of outpatients pick up frozen milk in person at the MMB, enabling the staff to instruct them on storage and use of milk."		San Jose milk bank US
Milk handling during transportation	Service description	Asquith	1987	"The packages [of milk] are delivered by air or bus package express, or locally by taxi or hand delivery by MMB volunteers."		San Jose milk bank US
Milk handling during transportation	Service description	Balmer	1992	"If hospitals further afield require milk, each bottle is wrapped in bubble polythene, packed in cardboard boxes and despatched via the Red Star parcel service or British Rail."		Sorrento milk bank UK
Milk handling during transportation	Service description	Balmer	1992	"While on the 'milk round' the nurses put all bottles of frozen milk into a cooler box to ensure that the milk remains frozen on its journey back to the milk bank."		Sorrento milk bank UK
Milk handling during transportation	Service description	Balmer	1992	"Mothers are visited at home by the milk bank nurses every 10 days to collect the frozen milk and deliver a fresh supply of bottles."		Sorrento milk bank UK
Milk handling during transportation	Service description	Baum	1982	"The frozen milk is then collected at intervals by community midwives and other voluntary workers. In some parts of the Oxford Health Authority the milk is taken to an intermediary local depository (e.g. a freezer in a small town community hospital) whence it is brought in bulk to the John Radcliffe Hospital, approximately every two weeks."		John Radcliffe milk bank UK
Milk handling during transportation	Service description	Beal	1978	"The milk and sample are transported to the milk bank and laboratory respectively in a small polystyrene foam cooler (jablo) with an ice brick."		Townsville milk bank Australia
Milk handling during transportation	Service description	Bjorsten	1980	"The frozen milk is collected once a week or at least within one month."		Umea milk bank. Sweden.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk handling during transportation	Service description	Dempster	1982	"Milk [...] is stored in polystyrene coolboxes during transportation."		Addington milk bank South Africa
Milk handling during transportation	Service description	Dempster	1982	"We have found the polystyrene coolboxes to be very efficient; the milk is often still frozen 6 hours after removal from the donor's freezer."		Addington milk bank South Africa
Milk handling during transportation	Service description	Fernandez	1993	"The pooled milk containers are transferred from the refrigerator in the wards to the milk bank in insulated containers."		Bombay milk bank India. May not be directly relevant to the UK, but agreed to leave in with caveats in interpretation.
Milk handling during transportation	Service description	Kimball	1955	"When the tin pail is in use, if the donor has to leave home before collection is made she may fill the pail with ice and leave it at her door for the volunteer."		Evanston milk bank US
Milk handling during transportation	Service description	Kimball	1955	"It is anticipated that the bottles will soon be placed in a 1-gallon tin pail with a handle similar to that used in the Mother's Milk Bank of San Francisco, California. The use of a pail should facilitate delivery and pick-up."	Miller personal communication	Evanston milk bank US
Milk handling during transportation	Service description	Langerak	1991	"The breast milk which as been collected and frozen by the donor is transported to the hospital in coolers."		Wilmington milk bank US
Milk handling during transportation	Service description	Tully	2000	"Milk can be shipped overnight express in insulated plastic picnic coolers (typically a 48 quart cooler, about \$16) or Styrofoam coolers in fitted cardboard cartons that are designed for shipping frozen goods (often hospital labs receive reactive agents in these cartons). It can be packed tightly with crumpled newspaper or Styrofoam packing beads for insulation and may or may not require dry ice, depending on the weather."		HMBANA milk banks US & Canada

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk pooling	Meeting report	Silverman	1971	"The advantages of pooling donor milks were considered to be real (especially as noted, dilution of undesirable compounds, and insuring uniformity of composition); as a result, relatively large pool sizes (milk from 10 to 20 donors, if possible) were advised. However, this recommendation precludes the use of raw bank milk since the risk of bacterial contamination, even with careful surveillance of the donors, was thought to be too great."		
Milk pooling	Meeting report	Silverman	1971	"[...] dilution by pooling of milks in the bank is a practical way to reduce the likelihood that an infant will receive enough of the inhibitor [related to jaundice] to produce icterus."		
Milk pooling	Narrative review	Bromberger	1982	"Pooling milk to even out [...] variations [in milk composition] is desirable but necessitates heat processing because of the extra handling of the milk."		
Milk pooling	Narrative review	Roy	1979	"As a further precaution to minimize the risks of infection and transmission of viruses and microbial toxins, milk is pooled by individual donor only and the recipient baby is offered the milk from the same donor. This practice is currently favoured even though it increases the risk of undiluted toxic substances such as drugs, nicotine, insecticides, and industrial chemical products that are excreted in milk."		
Milk pooling	Narrative review	Van de Perre	1992	"However, pasteurization has been questioned. Inhibition of reverse transcriptase activity is not regarded as a marker sensitive enough to rule out infectivity. Mortimer and Cooke have proposed that more than one measure should be relied on; donor milk from screened low-risk donors should be used, only when necessary, after it has been pasteurized at 62.7 [degrees] C, and the pooling of donors should be limited. Clearly, if pasteurization is used as a sole preventive measure, it should be performed under severely controlled conditions."	Tedder 1988; Mortimer 1988	

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Milk pooling	Narrative review	Wight	2001	""Preterm" milk is usually processed separately and reserved for the smallest, most immature infants. Donor milk is shipped frozen, thawed to a slurry, cultured, then pooled for pasteurization."		US milk banks US
Milk pooling	Narrative review	Williams	1981	"[...] many banks pool milk from different mothers to achieve a more uniform composition and to dilute any contaminants." Noted that this process may not be ideal for the use of milk in pre-term infants.	Pittard 1979; Ansell 1977; Vaughan 1979; Picciano 1976; Macy 1949; Widdowson 1974; Atkinson 1978	
Milk pooling	Narrative review	Woo	2007	""Preterm' milk can be pooled, pasteurized, and distributed separately from 'term' milk at donor milk banks and used for preterm infants who are in need of breast milk in the event that the mother is unable to provide her own milk."		
Milk pooling	Opinion piece	Braune	1982	Critical letter in response to general article on milk banks in a nursing journal. Suggests that "the 'risk-benefit' ratio suggests potential disadvantages for the use of pooled human milk" where pooled milk is from different women.	Braune 1980	
Milk pooling	Opinion piece	Modi	2006	"In the UK, unlike the rest of the world, donor breast milk is not pooled, but is prepared in aliquots from individual donors."		
Milk pooling	Position statement	American Academy of Pediatrics	1980	"Pooled milk from several donors simplifies routine procedures for ensuring microbiologic safety. The mixing of milk from a group of donors also results in a more uniform nutrient content and dilutes drugs or toxins present in the milk of an individual donor. A possible disadvantage of pooled milk is the increased potential for the transmission of viral infections, particularly if the milk is frozen only."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk pooling	Position statement	Canadian Paediatric Society	1985	"Pooled milk from many donors would serve to dilute possible contaminants and would provide milk of fairly uniform composition and in large enough volumes for efficient handling by the milk banks."		
Milk pooling	Position statement	Canadian Paediatric Society	1985	"Milk from one donor allows for control of the stage of lactation and may limit bacteriologic and environmental contamination."		
Milk pooling	Position statement	Canadian Paediatric Society	1985	"Pooled donor milk may be lacking nitrogen, energy and mineral content; therefore it will not support the needs of premature infants."	Schanler 1980	
Milk pooling	Position statement	Fernandez	1990	"16. All pooled donor samples that are culture positive must be pasteurised." Criteria for pasteurisation: "1. Total count of organisms excess of 2.5×10^6 CFU/L. 2. Presence of any enterobacteriae. 3. More than 10×10^5 CFU/L of Staphylococcus aureus." Process of pasteurization: "1. Thaw milk in domestic refrigerator at 4-8 [degrees] C. 2. Take thawed containers and place under running water to bring temperature of milk to 52 [degrees] C in less than 5 minutes. 3. Transfer containers to shaker water bath previously set at 59 [degrees] C. Hold until temperature of test sample reaches 56 [degrees] C in less than 5 minutes. Keep at 56 [degrees] C for 30 minutes. Place control container with temperature monitor in middle of batch. Sample for microbiological screening selected randomly to check if heat treatment is adequate. 4. After 30 minutes have elapsed transfer to refrigerator or immerse containers in iced water to cool to 25 [degrees] C less than 5 minutes. Transfer immediately to freezer. 5. Enter records of heat treatment, check labels and send samples for microbiological testing. 6. Wash water bath with detergent and allow to air dry. Send stainless steel containers for autoclaving after thorough cleaning."		Discussed and agreed not be relevant to UK banking as specific to developing countries.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk pooling	Primary study	Lucas	1978	Letter reporting presence of group B streptococci in pooled milk (each pool consisted of 75-100 24 hour samples from 25 donors over a 3-4 day period). Pasteurisation at 62 degrees C for 30 mins eliminated all organisms.		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk pooling	Primary study	Michaelsen	1990	"Protein (P), fat (F), and carbohydrate (C) concentration in expressed human bank milk was determined by infrared analysis of 2,554 samples from 224 mothers. The mean contents of P, F, C, and energy (E, calculated from P, F, and C) were 9.0 g/L, 39.0 g/L, 71.9 g/L, and 696 kcal/L, respectively. There was a large variation in the concentration of energy-yielding macronutrients. The contents of P, F, C, and E in the samples with the highest values (97.5 percentile) were 2.3-, 4.8-, 1.2-, and 2.3-fold, respectively, above the contents in the samples with the lowest values (2.5 percentile). The P content decreased exponentially during the 1st 8 months, followed by an increase during the following months. The F content decreased during the 1st 4 months, followed by an almost linear increase. The possible influence of different maternal characteristics on the macronutrient content of the milk was examined. The main results were as follows: the P and F contents increased slightly with increasing body mass index of the mother, the P content decreased with increasing amounts of milk delivered to the milk bank, and the F content was higher in mothers delivering large amounts of milk. By selecting incoming milk with a high P content, we have developed a "high-protein" milk with a P content of about 12 g/L (true protein) and an E content of about 725 kcal/L. Thus, by continuous monitoring of macronutrient content in human bank milk it is possible to develop a "high-protein" milk with sufficient P and E content to cover the needs of preterm infants with very low birth weights (less than 1,500 g)." Authors suggested that continuous monitoring of pooled milk (from five different mothers) could allow the development of 'high protein' milk for use for preterm babies.		Hvidovre milk bank Denmark

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk pooling	Primary study	Smith	1984	"The human milk had been collected by three or four mothers at home over one to five days and stored in the freezing compartment of a domestic refrigerator; after thawing this milk was pooled in 200 ml containers. It consisted of expressed breast milk and milk that had dripped from the opposite breast when the baby was being fed. We measured the fat content of the milk by the creatocrit method. Milk triglycerides were separated by thin layer chromatography, and the fatty acid composition was determined by gas-liquid chromatography. Mean creatocrit values were compared by Student's t test. In pooled banked human milk the maximum creatocrit, 7-26%, was nearly four times greater than the minimum creatocrit, 1-72%, and a third of the creatocrit values were below 4% (figure). By contrast, the creatocrit values in formula milk were distributed over a fairly narrow range (4-75-5-26%). The mean creatocrit in formula milk (5.16 (SD0-19)%) was significantly greater than that in pooled human milk (4-21 (1-24)) ($p<0.001$) (figure). Comparison of the fatty acid composition of our pooled banked human milk with that of mature human milk analysed by the Department of Health and Social Security² showed that our milk contained more linoleic acid and linolenic acid (polyunsaturated fatty acids C18:2 and C18:3) but less lauric acid (saturated fatty acid C12:0). In our 22 specimens of pooled banked milk the mean proportions of linoleic, linolenic, and lauric acids were 1 12%, 1-2%, and 2-7%; the proportions reported by the Department of Health and Social Security were 7-2%, 0-8%, and 5-4% respectively."	Lucas 1978; Danon 1975; Working Party on the Composition of Foods for Infants and Young Children 1977	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk pooling	Primary study	Smith	1985	"[T]he creatinocrit, the percentage of carbon, and the calorie value of milk were determined in 11 samples of pooled pasteurised human milk. The calculated milk energy was compared with direct measurements of milk energy by static bomb calorimetry. The errors in calculation ranged from -5.6 kcal/100 ml to + 19.5 kcal/100 ml in milk samples whose measured energy was 34.5 to 63.1 kcal/100 ml. In 9 milk samples energy values were over-estimated by calculation and in the remaining 2 milk samples energy values were underestimated. The correlation between creatinocrit and measured energy value in pooled pasteurised milk [r=0.59] was weaker than in previous studies using fresh milk. The percentage carbon was determined in our milk samples as a measure of their total organic constituents, and this appeared to be a more accurate predictor of milk energy [r=0.98, p<0.0001] than the predictive value of the creatinocrit which is only a measure of milk fat. In pooled pasteurised milk the relatively weak predictive value of the creatinocrit may be due to variations in the other constituents of milk apart from fat which provide energy, namely protein and lactose."		
Milk pooling	Primary study	Stocks	1983	Pilot study evaluating the energy value of milk consisting of drip milk combined with expressed milk. Donor mothers were asked to collect both drip and expressed milk and combine them as 24 hour collections. These were then pooled at the milk bank. The pooled samples provided 'a considerable improvement over the previous energy value of our donor milk when [...] using the drip method of collection."		Carroll 1980

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk pooling	Primary study - in vitro	Michaelsen	1988	Technical report aiming to "evaluate the precision and accuracy of an IR analyzer (Milko-scan 104) for measuring protein, fat, carbohydrate, and, indirectly, the energy content of human milk. The results of the IR analysis were compared with those of the following reference methods: protein--Kjeldahl (nitrogen minus nonprotein nitrogen); fat--Roese Gottlieb; carbohydrate--lactose enzymatic assay; energy--bomb calorimetry. The precision (repeatability coefficient of variation) of the IR results was high for all four components: protein 0.4%, fat 1.0%, carbohydrate 0.2%, and energy 0.1%. There was a close linear covariation between IR results and reference results. [Protein content was determined with an error (SD) of 0.01 g/100 ml and fat with an error of 0.03 g/100 ml.] The covariation between IR carbohydrate results and the results of the lactose assay was poor, probably because the oligosaccharides in the milk were included in the results from the IR analysis and not in the results from the lactose assay. IR analysis is a valuable method in research, especially in epidemiological surveys, in which large numbers of samples are analyzed, and for continuous monitoring of the nutritional value of human milk in milk banking programs." The authors concluded that "[c]ontinuous monitoring of the nutritional value of human milk used in a human milk bank makes it possible to deliver milk of a more uniform quality. This can be done by considering the level of macronutrients in the individual milk samples when pooling the milk. This will also make it possible to 'produce' human milk with special qualities [...]"		
Milk pooling	Service description	Arnold	1999	"The milk from a smoker is always pooled with milks from nonsmoking mothers so that contamination of milk from smoking by-products is diluted in the pooling process."		Hvidovre milk bank Denmark

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk pooling	Service description	Arnold	1999	"Different individual pools are then combined [after analysis] in proper ratios to create high protein milk (1.2 gm protein/100ml) or ordinary milk (0.9 gm protein/100ml)."		Hvidovre milk bank Denmark
Milk pooling	Service description	Asquith	1987	"On arrival at the MMB, donated milk is [...] aseptically pooled, generally by single donor lots. Donations of less than 300ml from individual donors are pooled to a maximum of 20 donors."		San Jose milk bank US
Milk pooling	Service description	Balmer	1992	"The donor milk is then pooled."		Sorrento milk bank UK. Not clear if refers to pooling milk from different women?
Milk pooling	Service description	Baum	1982	"An additional margin of safety is probably provided by pooling our milk samples, thereby diluting occasional undesirable constituents."		John Radcliffe milk bank UK
Milk pooling	Service description	Baum	1982	"The milk is then pooled and decanted into specially designed screw-top bottles in preparation for pasteurisation [...]."		John Radcliffe milk bank UK. Not clear whether pooling milk from different women.
Milk pooling	Service description	Baum	1982	"[variability of fat concentration] can be overcome by pooling milk [...]."		John Radcliffe milk bank UK
Milk pooling	Service description	Davidson	1979	"We feel that if the donations had been pooled, even after being bacteriologically cleared, it would have added another factor to the procedure, with its attendant risks."		Fazackerly milk bank UK
Milk pooling	Service description	Davidson	1979	"Each bottle was stored separately and not pooled before freezing."		Fazackerly milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk pooling	Service description	Dempster	1982	"Since we do not pool the milk there is a considerable range in the composition of milk the bank."		Addington milk bank South Africa
Milk pooling	Service description	Dempster	1982	"Milk is not pooled [...]"		Addington milk bank South Africa
Milk pooling	Service description	Greenwood Wilson	1951	"The pooled pasteurized milk from the milk bank is sampled daily for bacteriological contamination. The result is invariably less than 20 organisms per ml."		Cardiff milk bank Wales
Milk pooling	Service description	Hartmann	2007	"A batch of milk (600-3000 ml of milk from a single donor) is [...] pooled into a sterile flask under a laminar flow cabinet."		PREM milk bank Australia
Milk pooling	Service description	Hoey	1980	"All samples are cultured. Only those yielding <i>Pseudomonas aeruginosa</i> are pasteurised and the rest are pooled and deep frozen."		Salvation Army milk bank UK
Milk pooling	Service description	Kimball	1955	"Each morning the breast milk collected the previous day is removed from the refrigerator and poured together into a kettle."		Evanston milk bank US
Milk pooling	Service description	Langerak	1991	"It is then thawed, pooled, and autoclaved [...]"		Wilmington milk bank US
Milk pooling	Service description	McEnery	1978	"Boiling and even holder pasteurisation (62.5 [degrees] C for 30 minutes) destroys some of the immune properties of human milk. This is why we decided to keep each milk sample separate [...] Moreover, it allows donors with consistently highly colonised milk to be detected."	Ford 1976	Whipps Cross milk bank UK
Milk pooling	Service description	Morley-Peet	1983	Report of enteropathogenic <i>Escherichia coli</i> . Current practice was: "The total drip milk collection from two to five mothers is pooled into a sterile collection bottle [...]"		North East Essex milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk pooling	Service description	Penc	1996	"Pooled milk was pasteurized."		Polish Mother's Memorial Hospital milk bank Poland
Milk pooling	Service description	Penc	1996	"Milk of two or more donors is never pooled."		Polish Mother's Memorial Hospital milk bank Poland
Milk pooling	Service description	Sauve	1984	"[...] and in seven centres it was pooled and pasteurized before use."		Various milk banks Canada
Milk pooling	Service description	Siimes	1979	"Because we combine each day's collection into two large pools, fluctuations in concentrations of various constituents are relatively minor."		Helsinki milk bank Finland
Milk pooling	Service description	Siimes	1979	"Once donors are accepted, these same [testing] criteria are not applied to individual samples but only to the two pools of milk that are prepared from the samples collected each day."		Helsinki milk bank Finland Assumed from different donors?
Milk pooling	Service description	Springer	1997	"None of the donor milk is pooled to further reduce the risk of contamination."		Leipzig milk bank Germany
Milk pooling	Service description	Tomalin	1983	"All the milk is pooled, although raw and pasteurised milk are kept separately."		Kings College milk bank UK
Milk pooling	Service description	Tully	2000	"The thawed milk from two or more donors is mixed in the large pitchers and aliquoted to the jars for processing."		HMBANA milk banks US & Canada

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk pooling	Service description	Tully	2000	"Other equipment required includes several 1- to 2-quart containers in which to pool milk before aliquoting it to individual bottles for processing, storing, and distribution. These can be standard glass measure pitchers used in a home kitchen or glass beakers designed for laboratory use (prices will vary, but they are generally less than \$20 each), and a stirring rod for mixing the pooled milk."		HMBANA milk banks US & Canada. Not clear whether pooling between donors?
Milk pooling	Service description	Wilson-Clay	2007	"While not an issue for their own, thriving babies, batches of low calorie milk were deemed inadequate for the growth needs of preterm infants. By 2003, the MMBA made the decision to move from random to target pooling to enable the milk bank to dispense labeled bottles of 20, 22, or 24-calorie milk."		Austin milk bank US
Milk testing	Case report	Nduati	1994	Case report of postnatal transmission of HIV-1 through pooled breast milk. Infant was fed "freshly expressed unpasteurised pooled milk from other mothers whose infants were admitted to the same unit." The women were not screened for HIV-1. Authors noted that because of the high prevalence of HIV in pregnant women (8-15%) "an infant who is fed pooled breast milk from multiple donors would have a high likelihood of postnatal exposure to HIV-1." Authors recognised that there are guidelines that recommend both pasteurisation of milk and screening of potential donors, but that these are unlikely to "have found widespread acceptance in developing countries."		Study based in Nairobi.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Case report	Ryder	1977	"Human milk contaminated with Salmonella kottbus caused an outbreak of illness in seven of 22 infants in a neonatal intensive care unit. A case-control investigation failed to identify any risk factor except consumption of milk from a single donor, whose milk was subsequently found to be contaminated with S kottbus. Collection of human milk from properly instructed donors screened for microbiological pathogens, refrigeration of this milk at 1 to 5 degrees C after collection, and controlled distribution by a milk bank should minimize the few hazards associated with its consumption."		
Milk testing	Meeting report	Silverman	1971	"It was concluded that it is not necessary to monitor DDT concentrations in the milk of individual donors (especially since day to day variations are quite small); however it was recommended that measurements be made of pooled samples at regular intervals to detect long-term trends."	Laug 1951; West 1965; Egan 1965	
Milk testing	Narrative review	Arnold	1997	"Bacteria counts in milk to be dispensed raw cannot exceed 10 ⁴ CFU/ml of normal skin flora. The presence of pathogens or coliform bacteria is unacceptable in milk that is to be dispensed raw. Additionally, pasteurized milk [is] not considered 'clean' unless it has bacteria counts of nil."		
Milk testing	Narrative review	Bromberger	1982	"No universally accepted guidelines exist for acceptable bacterial counts in milk. That the milk should be free of pathogenic gram-negative and gram-positive organisms generally is agreed. There is no consensus as to the acceptable number of saprophytic organisms: Some milk banks recommend that all donated milk be heat processed to render bacterial counts negligible."	Ryder 1977; Kenny 1977; Hathaway 1974; Lucas 1979; Jones 1950; Carroll 1979; Davidson 1979; Baum 1979	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Narrative review	Davies	1982	"It has been recommended that a method of quality control - such as the simple, cheap, but reliable 'creamato-crit' - should be instituted to ensure that babies are given milk which is adequate in energy. However, if this was implemented what cut-off point would prohibit the administration of milk? A creamato-crit of 4%, equivalent to an energy content of about 560 kcal/l has been suggested. But is it really acceptable to discard breast milk, especially if it is collected through the goodwill of the mothers and often at considerable inconvenience."	Lucas 1978; Spencer 1981	
Milk testing	Narrative review	Narayanan	1989	Narrative review, including immunological aspects of human milk. Author concluded that the evidence "does not mean that organisms in milk are totally innocuous. It is also not clear how much load can be tolerated by infants. It would also depend on the nature and virulence of the organisms. Ethical considerations would contraindicated studies to determine this information. Clearly, therefore, care must always be taken in collection, handling and administering human milk. It is the practice in our unit to monitor human milk for bacterial growth on a weekly basis. We recommend this for all institutions with appropriate facilities, although the frequency of monitoring may be modified to suit local requirements and resources. This practice is very useful to evaluate whether or not the staff are instructing the mothers correctly and that the latter are following the rules and taking adequate care."	Narayanan 1984; Wills 1982; Narayanan 1983	
Milk testing	Narrative review	Oxtoby	1988	"Procedures for collection and processing differ widely. Most banks perform some bacteriologic culturing, either spot checks or periodic samples from each donor."	Asquith 1987	

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Milk testing	Narrative review	Roy	1979	"Since it is exceptional that a donor can deliver fresh milk daily, since it is theoretically undesirable that foreign viable cells be ingested, and since it is a sound practice to culture routinely all samples from a nonmaternal donor [...]"		
Milk testing	Narrative review	Roy	1979	"Those samples identified by bacteriological screening as unacceptable have to be rejected or undergo some form of heat treatment before being fed."		
Milk testing	Narrative review	Roy	1979	"[...] the set up to carry out routine or spot-check bacteriological cultures are essential components of a human milk bank."		
Milk testing	Narrative review	Simmer	2000	"Milk with pathogenic bacteria and milk with >10 ⁵ colony forming units of saprophytic bacteria is excluded."		
Milk testing	Narrative review	Van de Perre	1992	"Recently, although no case of contamination by [pooled donor milk] has ever been reported, anxiety about the potential risk of transmission of HIV-1 from an infected donor to a newborn has been raised. Several strategies have been proposed to avoid contamination of human milk banks. These include [...] pasteurization [...]"	Anon 1988	
Milk testing	Narrative review	Wight	2001	"Donor milk is released after it is heat-treated and bacterial cultures reveal no growth at 2 days."		US milk banks US
Milk testing	Narrative review	Williams	1981	Discussed the specific method of assessing bacterial contamination, stating that "[u]ntil less time-consuming bacteriological tests for human milk are evaluated, weekly plate counts should be encouraged to detect sanitation problems during collection, storage at home, or transportation of the milk."	Luck 1972	

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Milk testing	Narrative review	Williams	1981	"[...] caloric value of such milk is low and less advantageous for any neonate. This problem could exist with any donor milk because one usually does not know when or how the woman expressed the milk. Periodic checks of banked milks' nutritional content, especially fat, might be advantageous, to standardize and monitor the infant's caloric intake."	Macy 1931	
Milk testing	Narrative review	Williams	1981	"The importance of clean collection techniques and bacteriological checks cannot be overemphasized."		
Milk testing	Opinion piece	Arnold	1997	Letter criticising published article on contamination in expressed breast milk following breast cleansing. "In fact, achieving a sterile fluid or establishing clinically acceptable bacterial limits in expressed milk means that the wrong research questions are being asked. One of the reasons there are no previously established bacteriological limits for expressed human milk is that this is an exercise in futility. Each infant has his/her own individual response to a bacterial level; what may be tolerated by one infant may cause sepsis in another. Whether sepsis occurs is therefore determined by the infant's physiological, developmental, and immunological state, not by the level of contamination. Research money and time would be better spent on education and support of mothers who are expressing their milk over a long period of time for their hospitalized infants."		
Milk testing	Position statement	American Academy of Pediatrics	1980	"The storage of milk by freezing is an alternative to heating for the preservation of optimal nutritional value and immunological benefits. The use of frozen storage requires more attention to bacteriologic screening."		
Milk testing	Position statement	American Academy of Pediatrics	1980	"[...]breast milk can be made microbiologically safe if certain precautions are taken."		

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Milk testing	Position statement	American Academy of Pediatrics	1980	"An important property of breast feeding is the relative freedom from bacterial contamination of breast milk. However, bacterial contamination can be a major problem with banked human milk. The precautions which need to be taken to make breast milk microbiologically safe require careful attention, especially when breast milk is collected and stored prior to feeding. A recent outbreak of salmonellosis has been reported in a milk bank, and recurrent group B streptococcal disease has been associated with the ingestion of infected breast milk. A variety of other bacteria, bacterial toxins, and viruses such as rubella, cytomegalovirus, and hepatitis B particles have been identified. Breast milk may also be a vehicle for transmission of herpes simplex type 1.	Ryder 1977; Kenny 1977; Dunkle 1979	
Milk testing	Position statement	American Academy of Pediatrics	1980	"Milk samples identified by bacteriologic screening as unacceptable must be rejected."		
Milk testing	Position statement	American Academy of Pediatrics	1980	"[...] the set-up to carry out routine or spot check bacteriologic cultures are essential components of a human milk bank."		
Milk testing	Position statement	Canadian Paediatric Society	1985	"Although the standards are, to date, empiric and unproven, milk that is free of pathogens and has a total bacterial colony count of less than 10 [superscript] 7/L at the time of sampling has been considered safe to use."	Sauve 1984	
Milk testing	Position statement	Canadian Paediatric Society	1985	"Apart from occasional isolated reports of infection in neonates caused by the transmission of specific bacteria via breast milk, there are few studies of bacterial contamination of raw breast milk and of clinically documented infections in infants receiving expressed breast milk. Nevertheless, the ensurance of expressed breast milk requires the adoption of microbiologic standards by milk banks."	Stiver 1977; Ryder 1977; Kenny 1977; Narayanan 1984	

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Milk testing	Position statement	Canadian Paediatric Society	1985	"The total fat content can be quantified by the 'crematocrit' method if it has been properly standardized within the centre."	Lucas 1978	
Milk testing	Position statement	Fernandez	1990	"10. To ensure microbiological safety of donor milk, a human milk bank must lay down clear guidelines for collection, processing and distribution of milk. These must be re-evaluated and modified to suit local conditions at regular intervals, in the light of interim evaluation."		Discussed and agreed not be relevant to UK banking as specific to developing countries.
Milk testing	Position statement	Fernandez	1990	"14. Samples should be sent routinely for microbiological screening prior to freezing and a test sample from each lot which is pasteurised as well."		Discussed and agreed not be relevant to UK banking as specific to developing countries.
Milk testing	Position statement	Gutierrez	1998	"14. All samples should be tested for quality control in accordance with the Ministry of Health regulations. 18. Bacteriological and quality control: all milk is tested for coliform bacteria and acidity prior to pasteurization."		Brazilian milk banks Brazil

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Primary study	Ahlfors	1985	Aimed to assess the occurrence of cytomegalovirus (CMV) in donor milk. 89% (30/35) of the women were seropositive to CMV. CMV was only found in samples from seropositive women between 8 and 3 months post partum. 70% (18/23) excreted CMV in milk. "CMV is evidently a very common finding in the milk of seropositive women. Blood-transmitted CMV infections have been shown to cause severe disease in preterm infants born to seronegative mothers. Whether also milk-transmitted CNV infections might be hazardous is not known. Subjecting milk to heat or low temperature changes the infectivity. However, both types of treatment may decrease the potential benefit of the milk."	Yeager 1981; Dworsky 1982; Barnless 1980; Bjorksten 1980; Liebhaber 1977	
Milk testing	Primary study	Almeida	2006	"Immediately upon arrival at the BHM [banked human milk] facility, routine milk bank procedures are followed to test the raw human milk for level of bacterial contamination. Milk that passes this screening is pasteurized and then stored until use."		
Milk testing	Primary study	Almeida	2006	"The microbiologic activity of the studied BHM showed a wide variation in titrable activity (2 [degrees] D - 13 [degrees] D). The titrable activity was below the maximum values set by the Brazilian Ministry of Health (=8 [degrees] D) in 99.2% of the samples. [...] In France, the accepted upper limit is set at 13 [degrees] D."	Luzeau 1983	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Primary study	Botsford	1986	Reviewed infant records to assess clinical suspicion of infection, then correlated this with cultures. "Milk from donors more often had ≥ 10 [superscript] 6 CFU/ml than did mothers milk ($p=0.07$). [...] In-use donor milk was contaminated more frequently and heavily than in-use mothers' milk." Authors concluded that their data "suggest that feeding premature infants human milk with ≥ 10 [superscript] 3 gram-negative bacilli per milliliter is associated with an increased incidence of feeding intolerance, and at higher levels (≥ 10 [superscript] 6/ml) with suspect sepsis." As a result of this study, the use of donor milk was discontinued and the authors stressed that "the use of unpasteurized human milk in premature nurseries without a screening program appears inadvisable."		
Milk testing	Primary study	Carrol	1978	Audited samples to determine level of milk that would be accepted according to alternative testing criteria. 44% of samples showed mixed bacterial growth; using the King's College Hospital criteria for raw milk, 40% of the samples would be accepted for use. Authors noted that "the amount could be increased by giving more attention to the hygiene of milk collection we also believe that there is room for further study into the bacteriological criteria which need to be applied to donor human milk to be given raw."	Williamson 1978	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Primary study	Law	1989	"At the Health Sciences Centre (Winnipeg, Manitoba, Canada), milk is screened once weekly. When a woman's milk is found to have excess bacteria, it is discarded only if she is an unrelated donor (as opposed to an infant's mother). To assess the effectiveness of this screening program, we determined the frequency at which infants fed raw human milk were exposed to milk-associated bacteria and compared the bacterial contents of donor and maternal milk. From February 1986 to April 1987, all human milk fed to 98 premature infants during the first 2 weeks of feeding (n = 10,128 feeds) was cultured quantitatively. Among study infants, 100% were exposed at least once to coagulase-negative staphylococci, 41% were exposed to <i>Staphylococcus aureus</i>, and 64% were exposed to gram-negative bacilli. The proportions of feeds containing bacteria and the quantities (log₁₀ CFU [mean +/- standard deviation]) ingested per positive feed were: 39% and 5.9 +/- 0.5 for coagulase-negative staphylococci; 2.4% and 5.1 +/- 1.0 for <i>S. aureus</i>; and 5.2% and 4.8 +/- 1.1 for gram-negative bacilli. There were no adverse events attributable to ingestion of milk-associated bacteria. Milk coagulase-negative staphylococcal isolates were multiply antibiotic susceptible, whereas infant isolates were antibiotic resistant. Donor milk was significantly less likely than maternal milk to contain coagulase-negative staphylococcal species in any quantity (40 versus 93% of samples, respectively [P < 0.001]) or in concentrations exceeding 10(8) CFU/liter (3 versus 27% of samples, respectively [P < 0.0001]). There was no difference between milk from either source in terms of <i>S. aureus</i> or gram-negative bacterial content (4 to 6%). These results suggest that the Health Sciences Centre screening program is effective in limiting the number of harmless coagulase-negative staphylococcal species but has no impact on the quantity of potentially pathogenic bacteria ingested by premature infants."		Prospective.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Primary study	Lindemann	2004	"METHODS: Between January 1st and December 31st 2001, 69 women delivered 1.973 litres (mean 28.6 litres/woman/year). 73% had college education, were primipara, and with a mean age of 30.7 years. Those who smoked, used alcohol or any medications were refused as donors. They started to deliver approximately 7 weeks after having given birth and continued for a mean of 4 months. Each milk sample was tested for bacterial growth. Every donor was screened for HIV, CMV-IgG and hepatitis B/C before donating milk and thereafter every third month. RESULTS: 62.3% was CMV-IgG positive. Samples containing staphylococcus aureus, klebsiella-, enterobacter- and serratia-species or E. coli, and all samples containing > 10(4) cfu/ml were pasteurised. Overall, only 10.5% of the samples were pasteurised. CONCLUSION: It is possible and important to provide VLBW babies with fresh frozen unpasteurised CMV-IgG negative breast milk until their own mothers' milk production is sufficient."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Primary study	Novak	2000	"The occurrence and characteristics of MRSA in samples of banked human milk were investigated by selective culture, antibiogram and pulsed-field gel electrophoresis. MRSA contamination was found in 11% of 500 samples of expressed, fresh-frozen milk from 500 different donors at five Brazilian milk banks. The great majority of the contaminated samples passed breast milk quality control criteria for dispensing as raw milk under Brazilian and American guidelines. Most of the MRSA isolates belonged to the Brazilian epidemic clone, which is reported to be widespread in several Brazilian states, in Argentina and in Portugal. It is concluded that expressed breast milk can be a reservoir of multiresistant <i>S. aureus</i> epidemic clones. Studies are necessary to assess the source of contamination and potential role of MRSA-contaminated milk in the transmission of MRSA to neonates."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Primary study	Novak	2008	"OBJECTIVE: To verify the existence of a relationship between presence of off-flavor and microorganism load in quality control rejected samples of expressed human milk from a donor milk bank. METHODS: A total of 30 samples of expressed human milk with off-flavor were tested for the occurrence of the following microorganisms: aerobic mesophilic, psychrotrophic, proteolytic, psychrotrophic proteolytic, thermotolerant, psychrotrophic thermotolerant, lactate and lipolytic bacteria, molds and yeasts and Staphylococcus aureus, total coliforms and thermophilic coliforms, in accordance with official methods. RESULTS: Percentage occurrence of microorganisms was as follows: aerobic mesophilic = 80%; psychrotrophic = 36.7%; proteolytic = 46.7%; psychrotrophic proteolytic = 16.7%; thermotolerant = 6.7%; psychrotrophic thermotolerant = 0%; lactate bacteria = 50%; lipolytic = 10%; molds and yeasts = 6.7%; S. aureus = 30%; total coliforms = 53.3%; and thermophilic coliforms = 16.7%. CONCLUSION: A consistent relationship between presence of off-flavor and elevated microorganism counting was observed in the analyzed samples. This correlation highlights the importance of off-flavor research during selection and quality control processes in human milk banks."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Primary study	Spencer	1981	"Expressed breast milk used to feed preterm infants is precious and so, despite heterogeneity of composition, all available milk is used. A study of 274 samples of expressed breast milk supplied by preterm mothers and National Childbirth Trust donors showed pronounced variation in fat content as measured by the "creamatocrit" method. This was not due to differences between term and preterm mothers or between transitional and mature milk. The composition was affected by diurnal variation and method of collection. Substantial amounts of fat were also wasted as a result of continuous nasogastric feeding. Several milk samples did not contain enough fat to supply even a fraction of the recommended energy requirements of these infants. Some type of quality control over samples of expressed breast milk is clearly essential. The creamatocrit method is simple and feasible." "A total of 274 samples were analysed from 21 mothers (those feeding their own preterm infants) and 10 donors (those feeding their own full-term infants at home). The mean creamatocrit was 52.2% (31.5 g/l) for the whole group (table I) and for both donors and mothers when analysed separately. The range was 0.5-13%. The large variation was present both between donors and in samples from just one woman. Transitional milk produced three to 10 days after parturition did not differ from mature milk produced from the 11th day: mean creamatocrit was 5.3±SD23.3% for 69 samples of transitional milk and 5.2±2.40/ for 200 samples of mature milk. On 29 occasions in 13 mothers we compared two samples obtained during the same morning, between midnight and midday. There was a highly significant difference in fat concentration between the first and second samples, the first sample containing much less fat than the second (t=5.23; p < 0.01) (figure). Similarly the foremilk invariably contained less fat than the hindmilk. The		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
			1981	mean difference was 38%. A mean of 34%/ of the fat in expressed breast milk was lost when using the IVAC infusion pump and a mean of 19% lost when using the syringe pump."		
Milk testing	Primary study	Wojcik	2009	"Banked donor milk may be a reasonable substitute for mother's milk for human infants. No data on the macronutrient composition of banked donor milk have been reported. This study determined the composition of donated milk from a large number of banked donor milk samples and compared it to the reported values for macronutrients in mature breast milk. During a 9-month sampling period (May 2006 through February 2007) from a nationwide milk bank network, 415 sequential samples from 273 unique donors were analyzed for fat, protein, and lactose content, as well as energy density. Descriptive statistics were computed, including mean, standard deviation, coefficient of variation, median, and range. Percentiles were determined from the empirical distribution of the data. A ninety-five percent confidence interval was computed using standard, large sample (Gaussian) methods. Banked donor milk mean values (in weight/volume) were found to be 1.16%+/-0.25% for protein, 3.22%+/-1.00% for fat, 7.80%+/-0.88% for lactose, and mean total energy was 65+/-11 kcal/dL. Banked donor milk macronutrient content was found to differ from the values reported in the literature for mature human milk. Unformulated banked donor milk alone, similar to mother's milk alone, does not have sufficient macronutrient content or energy density to sustain a very-low-birth-weight preterm infant. Fortification could make up for these shortcomings, perhaps making formulated banked donor milk a better choice for preterm infants than bovine-based formulas when mother's milk is unavailable."		Related to indications for donor milk?

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Primary study	Wright	1998	"This study was undertaken to assess the application of the British Paediatric Association's (BPA) published guidelines to the bacteriological screening of breast milk donated to a District General Hospital milk bank. Samples of donated milk were subjected to bacterial counts and provisional identification after both 24 and 48 h incubation on cysteine lactose electrolyte-deficient (CLED) and Columbia blood agar. 21.8% (76 out of 348) donations of milk failed to reach the BPA acceptable criteria. The organisms responsible for the rejection of these samples were all evident within 24 h incubation, and were not significantly confined to one medium. A large percentage of rejected samples originated from a small number of donor mothers; 63.2% came from one donor. In applying BPA guidelines, both CLED and Columbia blood agar were found to be equally effective in screening for unacceptable organisms in prepasteurization donated breast milk. The 24 h period allowed for bacteriological screening, prior to pasteurization of milk samples, was sufficient to allow the growth of all potentially pathogenic bacteria in this study. To prevent the donation of consistently contaminated milk, more active communication between the milk bank staff and the donor is recommended."		Huddersfield milk bank UK
Milk testing	Primary study - in vitro	Hudson	1983	Assessed the applicability of a rapid method for the determination of the N content of bovine milk based on the close correlation of absorbance at 280 nm with values for total N as determined by the Kjeldahl procedure to human milk samples. "The procedure is limited by: (1) the dependence of the relation between absorbance value and N content on both the mode of collection and the postnatal age of the donor, and (2) variable interference by non-protein components of the milk. In spite of these shortcomings, the method may be of value as a screening test for certain human milk banks."		Technical issue? Not safety?

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Service description	Arnold	1999	"Mothers are paid 145 Danish Crowns (DKr) (about US\$24.00 at current exchange rates) per liter for their milk. This money is tax free. Mothers are paid monthly. In order to receive the stipend, however, milk must meet bacteriological criteria. The first batch of milk received from a mother is tested for bacteria."		Hvidovre milk bank Denmark
Milk testing	Service description	Arnold	1999	"Milk with bacterial levels greater than 10 [superscript] 4 CFU/ml is sent for further culturing. Postpasteurization cultures are done only about four times a year, just to maintain quality control over the coordinator's technique."		Goteborg milk bank Sweden
Milk testing	Service description	Arnold	1999	"The Hvidovre Milk Bank analyzes the protein, fat, carbohydrate, and caloric content of each batch of milk. Every bottle is then labeled with this information."		Hvidovre milk bank Denmark
Milk testing	Service description	Arnold	1999	"Subsequent batches [of donor milk] are spot tested twice a month."		Hvidovre milk bank Denmark
Milk testing	Service description	Arnold	1999	"Milk is discarded and not paid for if the bacterial counts are greater than 100,000 colony-forming units per ml (10 ⁵ superscript CFU/ml)."		Goteborg milk bank Sweden
Milk testing	Service description	Asquith	1987	"In cases in which the donor has a history of mastitis, a sample of her fresh, unfrozen milk also is requested and tested by the California Mastitis Test. If unusual colony types are observed in the SPC, the plate is sent to a clinical laboratory for bacteriologic identification."	Marth 1978	San Jose milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Service description	Balmer	1992	"The microbiological criteria used at the Sorrento Maternity Hospital for accepting milk for pasteurisation are: (1) Milk with counts of less than 10 ³ colony forming units (cfu)/ml is used regardless of the organisms present. (2) Milk with counts of more than 10 ⁵ cfu/ml is not used. (3) If milk has counts between 10 ³ -5 cfu/ml is only used if the organisms are skin commensals - for example, Staphylococcus epidermis, viridans streptococci, and diphtheroids. Milk is not used if it has counts of more than 10 ³ cfu/ml of Staphylococcus aureus, any Gram negative rod (lactose fermenting and Pseudomonas sp), [beta] haemolytic streptococci or Streptococcus faecalis. These criteria are similar to those recommended by the milk bank at King's College Hospital, London."	Williamson 1978; Williamson 1978	Sorrento milk bank UK
Milk testing	Service description	Balmer	1992	"Milk with very high counts of bacteria is usually contaminated with coliforms and often there is more than one type of bacterium present in each bottle of milk."		Sorrento milk bank UK
Milk testing	Service description	Balmer	1992	"A further check of the bacterial content of the raw pooled milk is than made [...]. This check ascertains that milk has not become contaminated with unacceptable organisms (see above) during straining and pooling. If milk had become contaminated the whole batch would be discarded."		Sorrento milk bank UK
Milk testing	Service description	Balmer	1992	"Most skin bacteria are killed and viruses including HIV are inactivated at 56 [degrees] C for 30 minutes."	Eglin 1987	Sorrento milk bank UK
Milk testing	Service description	Balmer	1992	"Each batch of pasteurised milk is analysed for its chemical composition [...]. The contents of protein, fat, lactose, and sodium are shown on the label of each bottle of milk that leaves the milk bank."		Sorrento milk bank UK
Milk testing	Service description	Balmer	1992	"Each bottle of milk supplied by the mothers is examined bacteriologically."		Sorrento milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Service description	Balmer	1992	"There are no accepted microbiological criteria for the control of donor milk. The DHSS report 'The Collection and Storage of Human Milk' described methods but left criteria 'to the microbiologist concerned with the setting up of each individual milk bank'."	DHSS 1981	Sorrento milk bank UK
Milk testing	Service description	Beal	1978	"The milk is recommended for use only when either no organisms are grown, or there is a growth of normal breast milk flora or commensal skin flora. [...] Results are sent to the paediatric registrar at the milk bank."		Townsville milk bank Australia
Milk testing	Service description	Beal	1978	"The frozen samples of milk are left at room temperature to thaw, then immediately inoculated [...]".		Townsville milk bank Australia
Milk testing	Service description	Bjorsten	1980	"The first three deliveries from each mother are subject to bacteriological control and if the viable counts are 10 ⁸ /l or less the milk is used without heat treatment. No further systematic bacteriological control of that mother's milk is performed."		Umea milk bank. Sweden.
Milk testing	Service description	Cash	1981	"Random cultures of milk are taken for each batch brought to the bank. A batch is defined as all bottles from a donor brought at one time. The sample bottle is discarded and the remaining bottles in the batch are kept on hold until culture results are available. If the bacterial growth exceeds the adopted criteria, the batch is discarded, and the donor is contacted by the milk bank coordinator. The type and sources of the bacteria present in the breast milk are shared with the donor. Collection techniques, storage, and transport of milk are reviewed to identify the break in technique. Donors are then asked to furnish another sample for testing."		EOPC milk bank US
Milk testing	Service description	Cash	1981	"Criteria established require no growth of gram negative bacteria and colony counts of less than 10,000 organisms/ml of Staphylococcus epidermis and/or less than 4,000 organisms/ml of Staphylococcus aureus."	Liebhaber 1978; Eidelman 1979; Siimes 1979	EOPC milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Service description	Davidson	1979	"Provided the milk did not contain greater than 2500 organisms/ml or potential pathogens it was used unheated. Milk containing between 2500 and 5000 organisms/ml and no potential pathogens was used after pasteurisation. Using these criteria, 67% of 460 donations were acceptable. However, because the bacteriological quality varied, 45% of domiciliary donations were discarded compared with only 29% of those from hospital."		Fazackerly milk bank UK
Milk testing	Service description	Davidson	1979	"Before milk was issued, the pilot bottle was removed, allowed to thaw at room temperature, and then bacteriologically screened. This usually took less than 24 hours and no raw specimen of breast milk was used until bacteriologically acceptable. When clearance was given the donation was allowed to thaw at room temperature and issued for feeding. Thawed specimens were stored in the domestic compartment of the refrigerator in the intensive care unit until needed."		Fazackerly milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Service description	Davidson	1979	"Arbitrary criteria applied to the EBM samples were: (1) Milk with a quantitative count of <2500 organisms/ml (consisting of, for example, micrococci, Staphylococcus albus, 'viridans type' streptococci, or diphtheroids which were considered to be contaminants probably derived from skin flora but unlikely to be pathogenic) was used unheated. (2) No donation was used unheated or pasteurised if the pilot bottle gave either a total count >5000 organisms/ml or any detectable potential pathogen. On an arbitrary basis the potential pathogens were defined as Staphylococcus aureus, [beta]-haemolytic streptococci, Pseudomonas spp., Proteus spp., Streptococcus faecalis, and any other organism from a potential enteric or water-borne source (here defined as 'coliforms' for convenience). (3) No donated milk with a total bacterial count of 2500-5000 organisms/ml was used unheated. If the pilot sample had a bacterial count in this range, but none of the organisms listed in (2), the donated milk was pasteurised at 63 [degrees] C for 30 minutes in a water bath and subjected to the same bacteriological screen, plus the alkaline phosphatase test. (Alkaline phosphatase is destroyed by a temperature of 63°C within 30 minutes and is used as evidence of adequate pasteurisation of cows' milk). Provided effective pasteurisation was established by no detectable growth on culture and a satisfactory phosphatase test, the milk was issued for use."	Wright 1947	Fazackerly milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Service description	Dempster	1982	"At arrival at the Milk Bank a sample of milk is taken from each partially thawed bottle for bacteriological examination. The milk is frozen and stored separately until the results of the tests are known. We decided to test each bottle of milk received and to use it raw if it satisfied our bacteriological criteria. We used the same criteria as those adhered to at the King's College Hospital Milk Bank, London i.e.: (i) total bacterial count (colony-forming units (CFUs/ml)) < 2500 ml; (ii) Staphylococcus aureus < 100 CFUs/ml; and (iii) no enterobacteria present."	Williamson 1978	Addington milk bank South Africa
Milk testing	Service description	Dempster	1982	"Choosing criteria for the determination of the acceptability of milk is difficult since no definitive standards have been established. Some milk banks opt for maximum safety and pasteurize all milk received. Other banks pasteurize milk only if the bacterial count is above a certain level and use the remainder of it raw."	Baum ??; Siimes 1979; Williamson 1978; Liebhaber 1979; Hoey 1980; Davidson 1979; Bjorksten 1980; Beal 1978	Addington milk bank South Africa
Milk testing	Service description	Fernandez	1993	"Cultures are repeated post heat treatment and any samples showing growth are discarded."		Bombay milk bank India. May not be directly relevant to the UK, but agreed to leave in with caveats in interpretation.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Service description	Fernandez	1993	"As soon as the milk reaches the bank, a sample from each container is sent for culture."		Bombay milk bank India. May not be directly relevant to the UK, but agreed to leave in with caveats in interpretation.
Milk testing	Service description	Greenwood Wilson	1951	"Each mother's milk is tested by the city analyst for the addition or substitution of cow's milk, and is also analysed for its nutrient content."		Cardiff milk bank Wales
Milk testing	Service description	Greenwood Wilson	1951	"The Cardiff milk donors are selected from maternity wards which deal with more than half the total confinements in the city every year. They represent a fair cross section of the income group involved and therefore of the variations in nutritional intake that may be found in any typical urban community. Against this background and against the clinical report quoted above, should be set the series of Cardiff human milk analyses which seem to discount many of the earlier findings according to which diet affects fat content of human milk, but which agree with the conclusion of Kon and Mawson (1950) that 'no consistent variation in the fat content of (human) milk was observed between the third and 24th weeks of lactation.'"	Kon 1950	Cardiff milk bank Wales
Milk testing	Service description	Greenwood Wilson	1951	"The pooled pasteurized milk from the milk bank is sampled daily for bacteriological contamination. The result is invariably less than 20 organisms per ml."		Cardiff milk bank Wales

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Service description	Greenwood Wilson	1951	"Analyses of human milk supplied to the Cardiff Human Milk Bank have shown enormous variations in the fat content, not only as between the milk of one mother and another, but in that of the same mother almost from hour to hour in the same period of 24 hours' observation. Yet, the clinicians could not detect the slightest effect on the digestion or nutrition of the babies who consumed the milk."		Cardiff milk bank Wales
Milk testing	Service description	Hartmann	2007	"Specific microbiology standards are published elsewhere, 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."	UKAMB 2003	PREM milk bank Australia
Milk testing	Service description	Hartmann	2007	"The PREM Bank's microbiological standards are based on those used by other human milk banks. A 1 ml sample is taken using aseptic technique from pooled donor milk before pasteurisation. A second 1 ml sample is taken prior to aliquoting the pasteurised product. [...] Any bacterial growth is identified by standard microbiological techniques. Colony growth is also quantified."	UKAMB 2003	PREM milk bank Australia
Milk testing	Service description	Hoey	1980	"Organisms probably derived from the skin and microflora of the nipple were present in the milk of 37% of mothers. Although these organisms are potential pathogens we agree that they appear to be harmless even to sick lowbirthweight babies of other mothers."		Salvation Army milk bank UK
Milk testing	Service description	Hoey	1980	"All samples are cultured. Only those yielding Pseudomonas aeruginosa are pasteurised and the rest are pooled and deep frozen."		Salvation Army milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Service description	Ikonen	1982	"During six months' follow-up 1400 donated milk samples have been investigated. Over 60 per cent of all donated milk belonged to class I (fed raw to preterm and sick term infants [<2500 CFU/ml normal skin flora; 0 CFU/ml potential pathogens]). Over 20 per cent could be used without pasteurisation (class II [no upper limit normal skin flora; 0 CFU/ml potential pathogens]). Eight per cent of milk was pasteurised and only six per cent was discarded. Regular donors had much 'cleaner' milk than new or temporary donors. Of the milk of regular donors nearly 70 per cent belonged to the class I milk, whereas less than 40 per cent of the milk of new or temporary donors belonged to class I. The potential pathogens found in these 1400 samples of donated milk [were: Staph. aureus; Str. faecalis; Str. agalaciae; Bacillus cereus; Citrobacter freundii; Esch. coli; Klebsiella sp.; Enterobacteria sp.; Serratia sp.; Pseudomonas sp.; Aeromonas hydrophila; Acinetobact. cal. var. Iwoffii; Flavobacter sp.; Nontypable gram-negative rods; Candida non-albicans.]"		Tampere milk bank Finland
Milk testing	Service description	Ikonen	1982	"A sample for bacteriological culture is taken of every donated milk portion. Milk is then frozen, and not used until the results of the bacteriological culture are available."		Tampere milk bank Finland
Milk testing	Service description	Kimball	1955	"Once a week samples are sent for bacterial study. Thus far, the milk has has a negative report except for 3 times when 1 to 3 colonies/cc. were reported."		Evanston milk bank US
Milk testing	Service description	Langerak	1991	"After autoclaving, the milk is tested for bacteria including skin flora, Salmonella, and coliforms. This testing ensures that the heat treatment has been effective. Only milk with counts of less than 25 CFU is acceptable for dispensing."		Wilmington milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Service description	McEnery	1978	"Unlike others, we have found separate bacteriological culture of samples quite practical. The more heavily colonised milk may also be harmless, but we have no evidence of this."	Lucas 1978	Whipps Cross milk bank UK
Milk testing	Service description	McEnery	1978	"Milk was not checked for contamination with cows' milk or water."		Whipps Cross milk bank UK
Milk testing	Service description	McEnery	1978	"No enteropathogenic organisms were isolated from milk samples. Donors tended to be moderately consistent through several samples in both size of growth and species, the difference between donors being much greater than that attributable to chance alone."		Whipps Cross milk bank UK
Milk testing	Service description	McEnery	1978	"If the sample contains a non-pathogenic count of less than 2.5×10^6 organisms/l, that aliquot of milk will be given to a baby without further processing. If the organism count is more than 2.5×10^6 organisms/l but less than 1×10^9 organisms/l the milk samples are individually placed in a sterile jug within boiling water for 10 minutes (milk temperature 63-65 [degrees] C) shortly before being fed to infants. All milk that contained more than 1×10^9 organisms/l and grew Staphylococcus aureus or Pseudomonas, Klebsiella, or Proteus spp, or other enteropathogenic organisms was not fed to babies."		Whipps Cross milk bank UK
Milk testing	Service description	Morley-Peet	1983	Report of enteropathogenic Escherichia coli. Current practice was: "Samples are tested weekly. If the laboratory report indicates that the bacterial contamination level is unacceptable, these collections [of large donations] are either pasteurised before storing or discarded."		North East Essex milk bank UK
Milk testing	Service description	Morley-Peet	1983	Report of enteropathogenic Escherichia coli. Current practice was: "A sample of this pooled milk is later sent to the laboratory for culture."		North East Essex milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Service description	Murray	1953	"The milk is checked carefully for adulteration and dilution."		Essex County milk bank US
Milk testing	Service description	Omarsdottir	2008	"This study was designed to document current routines pertaining to breastmilk use for preterm infants in Sweden. METHODS: A questionnaire regarding breastmilk handling and routines was sent to all 36 neonatal units in Sweden in November 2006 and February 2007. RESULTS: Of the 36 participating neonatal units 27 had their own milk bank. [...] Bacterial culture was performed on donor milk in 24 milk banks."		Details of bacterial count limits can be seen in Table 2 of the paper.
Milk testing	Service description	Omarsdottir	2008	"This study was designed to document current routines pertaining to breastmilk use for preterm infants in Sweden. METHODS: A questionnaire regarding breastmilk handling and routines was sent to all 36 neonatal units in Sweden in November 2006 and February 2007. RESULTS: Of the 36 participating neonatal units 27 had their own milk bank.[...] Nutritional analysis of donor [...] milk was performed in [17 of the 27 (63%) milk banks]." "The amount of protein, lactose, and fat in the breast milk was determined, and the total energy content in the milk was calculated." Timing of analysis: before pasteurization in 14 milk banks; after pasteurization in 2; when needed in 1; no analysis in 10.		
Milk testing	Service description	Pedersen	1982	"Fat percent: an investigation was made of the fact that experience at the WMB had indicated that the fat percent of WM rose during the later part of extended lactating periods, [...]. "		Fuglebakken milk bank Denmark

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Service description	Pedersen	1982	"A reasonable basis of operation of a woman milk bank must thus include routine bacteriological examinations and possibly supplemental examinations guided by visual inspection of the WM collected upon a background of basic instruction in milking procedures and storage conditions and frequently checked work in order to achieve minimal contamination in general."		Fuglebakken milk bank Denmark
Milk testing	Service description	Pedersen	1982	"Running production control (satisfactory pasteurization) has been built upon bacteriological control."		Fuglebakken milk bank Denmark
Milk testing	Service description	Penc	1996	"Samples of each batch are taken for bacteriological testing."	Burbianka 1983	Polish Mother's Memorial Hospital milk bank Poland
Milk testing	Service description	Penc	1996	"The collected milk must also meet appropriate bacteriological standards. Bacteriological tests are done on all donated milk and milk must meet the following standards to be used: 1) total bacteria count must not exceed 10 ⁵ CFU/ml; 2) the presence of pathogenic bacteria is not acceptable (e.g. Staphylococcus aureus, Escherichia coli, Klebsiella sp., Pseudomonas aeruginosa, alpha- and beta-streptococci); 3) batches of non-pathogenic cutaneous microflora of 10 ³ to 10 ⁴ CFU/ml are preferable; and, 4) no bacteriological growth should be observed in pasteurized milk; conditional growth of 1/2 CFU/ml is acceptable."	Polish Standard for Milk and Dairy Products 1985; Jawetz 1991	Polish Mother's Memorial Hospital milk bank Poland
Milk testing	Service description	Penc	1996	"Each pasteurized batch contains a control bottle for monitoring bacterial content after pasteurization. Chemical composition and the immunological content of individual batches are not analyzed because of the high costs of such tests and inadequate staffing to perform the tests. The same issues prevent the lyophilization of milk."		Polish Mother's Memorial Hospital milk bank Poland

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Service description	Reid	1988	Survey of UK milk banks. Donor milk tested by bacteriology 15; virology 1; banks closed 2; no response 2.		Ninewells milk bank Scotland. Report of out-dated practice.
Milk testing	Service description	Sauve	1984	"At the Calgary Mother's Milk Bank, a bacterial count of $<10^4$ /ml (or $<10^7$ /l SI units) organisms and no demonstrable pathogens is taken as evidence that the milk, at the time of sampling, is safe to use. Using this standard, bacterial cultures done at the Calgary Mother's Milk Bank during the past five years have yielded the results given [below]. In those instances where significant growth occurred in postpasteurization samples, pasteurizer malfunction was detected and the samples were repasteurized before use." Results 1987-1983: prepasteurization tests (pooled samples) 553; no significant growth* 87 (15.7%); significant growth 466 (84.3%); postpasteurization tests (inc prepasteurized samples) 574; no significant growth 544 (94.7%); significant growth (requiring pasteurization) 30 (5.2%). $>10^4$ /ml		Calgary milk bank Canada
Milk testing	Service description	Sauve	1984	"In 12 centres, cultures were routinely taken before the milk was used, but the standards used to consider the milk unsafe vary." Colony count considered unsafe: $\geq 10^8$ colonies/l 5l units 2 centres; $\geq 10^7$ colonies/l 5l units 1 centre; $\geq 10^3$ colonies/l 5l units 2 centres; any growth 2 centres; no standards specified 5 centres; do not routinely culture and do not have established standards 7 centres.		Various milk banks Canada
Milk testing	Service description	Sauve	1984	"Routine viral cultures or other diagnostic tests related to viruses or protozoa were not done in the banks included in the survey."		Various milk banks Canada

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Service description	Sauve	1984	"[M]icrobiological techniques were aimed at the identification of those organisms known to be enteric pathogens (e.g. Salmonella, Shigella, Campylobacter, Yersinia), those which have the potential to be enteric pathogens (e.g. Escherechia coli, Klebsiella sp., Proteus sp., Pseudomonas sp., Clostridia sp., Staphylococcus aureus and Streptococcus pyogens), and nonpathogenic organisms (e.g. Bacillus sp., Corynebacterium, Lactobacillus)."	Jawetz 1976	Calgary milk bank Canada. Results can be seen of the identified organisms in the published paper.
Milk testing	Service description	Siimes	1979	"There have been rare cases where dilution of the donated milk with water or cow milk was suspected. The former possibility is ruled out by a normal osmolality, since the range in individual samples of human milk is narrow, and the latter is easily detectable by routine immunologic techniques."		Helsinki milk bank Finland
Milk testing	Service description	Siimes	1979	"Monitoring the composition of individual milk samples has been done primarily for the purpose of gathering data rather than for quality control. Our routine measurements have included concentrations of total lipid, protein, sodium, potassium, and occasionally of other constituents of interest. The results have not been used to exclude samples at the extremes of the range nor have they been useful in detecting adulteration of the milk."		Helsinki milk bank Finland

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Service description	Siimes	1979	"Monitoring for bacterial contamination is one of the most important aspects of screening milk from human donors once it reaches the milk bank. We have found that about 5% of mothers who volunteer as donors never meet our initial criteria: bacterial growth of less than 10,000 <i>Staphylococcus albus</i> /ml, less than 4,000 <i>Staphylococcus aureus</i> /ml, and no growth of gram-negative bacteria. Once donors are accepted, these same criteria are not applied to individual samples but only to the two pools of milk that are prepared from the samples collected each day. This procedure decreases the load of routine cultures and only rarely results in rejection of the entire day's collection. About 5 to 10% of all the milk collected is discarded on the basis of bacterial cultures, with some seasonal variation; high bacterial counts are obtained more frequently in the summer. There have been only a few mothers without bacterial growth in their milk after repeated cultures for periods of several months. Milk from these mothers only has been used fresh for the smallest high-risk infants."		Helsinki milk bank Finland
Milk testing	Service description	Springer	1997	"Samples from each bottle of milk are collected and screened for bacteria."		Leipzig milk bank Germany
Milk testing	Service description	Springer	1997	"Bacteriological results are available on the following day and decisions on further use of the milk are made at this point. If bacteria in excess of 10 ⁵ colony forming units per milliliter (CFU/ml) are found, the milk is not used." Daily microbiological analysis. Spot checks for acidity, specific weight, fat content.		Leipzig milk bank Germany
Milk testing	Service description	Tomalin	1983	"After pasteurisation one in 40 bottles is tested."		Kings College milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk testing	Service description	Tomalin	1983	"Testing is done by microbiologist [...] from the public health laboratory at neighbouring Dulwich Hospital. [...] spends about eight hours a week testing for organisms such as Staphylococcus aureus, Escherichia coli, Klebsiella and Pseudomonas."		Kings College milk bank UK
Milk testing	Service description	Tully	2000	"Some milk banks also collect a prepasteurization sample from the last jar filled to monitor for any trends in bacterial contamination."		HMBANA milk banks US & Canada
Milk testing	Service description	Wilson-Clay	2007	"Milk samples are drawn and re-tested following pasteurization. No bacterial growth is tolerated in post-pasteurization milk. Pasteurized milk is held in freezers until results of post-pasteurization bacteriological testing are received. The milk is approved once pasteurized milk samples show no growth on 48-hour cultures plated and read by an independent microbiology laboratory."		Austin milk bank US
Milk testing	Service description	Wilson-Clay	2007	"The MMBA adopted protocols for bacteriological screening, milk pasteurization, and nutritional labeling that met or exceeded HMBANA guidelines. Pre-pasteurization milk samples are drawn and plated for identification and counting of bacterial colonies. Milk testing positive for Staphylococcus aureus, methicillin-resistant S. aureus, and any of the bacillus species are discarded owing to the fact that endotoxins of these organisms are heat-resistant. Pasteurization may not render them harmless."	Upedgrove 2005	Austin milk bank US
Milk testing	Service description	Wilson-Clay	2007	"Pasteurization may not render them harmless. Aseptic technique is employed throughout the pasteurization process. Batches of three- and four-ounce (88–118 ml) bottles of milk are pasteurized using the long-term low temperature Holder technique, which holds milk at 62.5 °C for 30 minutes in a shaking water bath."	Upedgrove 2005	Austin milk bank US
Milk transportation	Narrative review	Bar-yam	2003	"Help set up collection stations from which donated milk can be sent to milk banks."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk transportation	Position statement	Fernandez	1990	"13. After collection, the milk containers should be transported to the bank for freezing, in ice, or an insulated box."		Discussed and agreed not be relevant to UK banking as specific to developing countries.
Milk transportation	Position statement	Gutierrez	1998	"12. The samples should be transported in insulated containers. 13. All the samples should be transported at the same temperature as they were stored to keep the 'cold chain'."		Brazilian milk banks Brazil
Milk transportation	Service description	Arnold	1999	"The Hvidovre Milk Bank collects milk weekly from mothers from all over the island of Sjaelland and employs a full-time 'milk man' who drives and collects milk on a regular schedule of routes."		Hvidovre milk bank Denmark
Milk transportation	Service description	Asquith	1987	"The MMB employs a group of volunteer drivers who regularly deliver containers, pick up frozen milk, and remain available to the donors to answer any questions or concerns."		San Jose milk bank US
Milk transportation	Service description	Balmer	1992	"The milk bank has its own vehicle to enable the staff to visit the mothers in their homes."		Sorrento milk bank UK
Milk transportation	Service description	Beal	1978	"A pathology request form together with samples are brought to the laboratory by a representative of the NMAA."		Townsville milk bank Australia
Milk transportation	Service description	Cash	1981	"With the transport system, donors may bring the milk to the bank, take it to a drop-off point, or have the milk picked up at their home."		EOPC milk bank US
Milk transportation	Service description	Cash	1981	"The tranport network, established to transport milk to the bank, has 33 individual transporters and members of local community organizations who accept this as a service project."		EOPC milk bank US
Milk transportation	Service description	Cash	1981	"Providing a system of transporting breast milk to the milk bank is an essential aspect of the program."		EOPC milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk transportation	Service description	Cash	1981	"At EOPC, [a] voluntary transport network has been established and drop-off points identified. Volunteers are recruited from nurses throughout the hospital and interested community members."		EOPC milk bank US
Milk transportation	Service description	Cash	1981	"We have found that most donors prefer having the milk picked up at their home."		EOPC milk bank US
Milk transportation	Service description	Connor	1982	Staff from the health visiting service "collect the milk twice weekly and provide the mothers with a new supply of sterile feeding bottles from the CSSD [central sterile supply department] service."		Enfield milk bank UK
Milk transportation	Service description	Davidson	1979	"Specimens from home were [...] taken to the breast milk bank in an insulated cool box every 48 hours by the donors themselves or by domiciliary midwives."		Fazackerly milk bank UK
Milk transportation	Service description	Dempster	1982	"Milk is collected once a week by a [...] voluntary worker [...]"		Addington milk bank South Africa
Milk transportation	Service description	Greenwood Wilson	1951	"The Cardiff mothers so trained on their return home express all the breast milk that remains, after infant feeding, into an aluminium jug whence they pour it into medicine bottles. These they place in ice-box containers with which they have been provided in advance, and which are then ready for collection by the sister in charge of the milk bank."		Cardiff milk bank Wales
Milk transportation	Service description	Hoey	1980	"The milk collected from mothers at home is refrigerated at 4 [degrees] C and collected twice a week by the Hackney branch of the National Childbirth Trust."		Salvation Army milk bank UK
Milk transportation	Service description	Kimball	1955	"With the day's supply of freshly sterilized collecting bottles, the volunteers start their rounds. At each home they leave 4 bottles and pick up 4 full or empty bottles as the case may be. The full collecting bottles are returned to the hospital nursery where the nurse in charge puts them in the refrigerator."		Evanston milk bank US

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Milk transportation	Service description	Kimball	1955	"These [refrigerated bottles], along with the unused bottles, are collected daily by the Junior League volunteers."		Evanston milk bank US
Milk transportation	Service description	Langerak	1991	"Frozen processed milk is transported as needed by shuttle van to Christiana Hospital fifteen minutes away on the Interstate highway."		Wilmington milk bank US
Milk transportation	Service description	McEnery	1978	"Transport - Milk is brought to the hospital by NCT volunteers, donors or their husbands, nurses and doctors working in the maternity unit, and community midwives. None of these methods is costly, since the carriers usually do not have to deviate greatly from their daily routine. Many collections are done twice a week, but donors often give a sample when it is convenient to bring it to the hospital."		Whipps Cross milk bank UK
Milk transportation	Service description	Murray	1953	"All the milk at the present time is collected at home and transported to the bank by members of the donor' family."		Essex County milk bank US
Milk transportation	Service description	Murray	1953	"The American Red Cross transported donors to the center or brought to the bank breast milk collected at their homes."		Essex County milk bank US
Milk transportation	Service description	Sauve	1984	"Milk was usually transported to the banks in a frozen state [...]"		Various milk banks Canada
Milk transportation	Service description	Siimes	1979	"Our current system for collecting milk samples was established in the 1930s and is based on a contract with a chain of grocery stores with about 100 branches in the metropolitan area of Helsinki. The mothers leave the milk at the stores for identification and delivery to the milk bank, and there receive clean bottles for the next collections. In our experience, even those donors who live relatively close to the hospital have rarely been willing to deliver this milk directly to the bank on a daily basis. Under these conditions, very little milk can be supplied to infants within 24 hours of collection."		Helsinki milk bank Finland

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Milk transportation	Service description	Springer	1997	"On weekdays, a nurse drives to the homes of donors in a car from the hospital driving pool to collect the expressed milk and deliver new sterile containers. On weekends, donor families arrange the transport of the milk to the milk bank."		Leipzig milk bank Germany
Milk transportation	Service description	Springer	1997	"Half of the human milk banks carry out the collection of fresh or frozen donor milk on a daily basis. This makes it possible to provide fresh milk with its clear advantages, especially the immunological ones."		German milk banks Germany
Milk transportation	Service description	Tomalin	1983	"Their names [interested donors] are passed on to the volunteer driver who collects the milk once a week from each mother - although she spends three days collecting."		Kings College milk bank UK
Milk transportation	Service description	Tully	2001	"Some women come to the milk bank daily to express their milk. In the state of Brasilia, where Rio de Janeiro is located, the firemen collect the frozen milk from the homes of donors in their fire station districts and deliver it to the local milk bank."		Brazilian milk banks Brazil
Milk treatment	Case report	Maschman n	2006	"Freezing human milk is recommended to inactivate cytomegalovirus (CMV). A case of a preterm infant exclusively receiving frozen breast milk from his CMV seropositive mother showed that storage of breast milk for two months at -20 degrees C did not prevent symptomatic postnatal CMV infection."		No specific reference to practice of donor milk banking.
Milk treatment	Meeting report	Silverman	1971	"Heat sterilization and boiling will not destroy or inactivate the inhibitory steroid [related to jaundice]."		
Milk treatment	Meeting report	Silverman	1971	"At present, thermal treatment (e.g. classic pasteurization, flash sterilization, or terminal sterilization) is the only safe method which can be recommended for pooled human milk. Unfortunately even moderate heat denatures some immune substances in human milk (especially immunoglobulin A) [...]"	AAP 1965	

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Milk treatment	Narrative review	Boyes	1987	"An alternative to culturing and blood testing is pasteurizing, which minimizes bacteria in human milk by means of heat without destroying its immunological factors. According to the Centers for Disease Control, the AIDS virus in blood is inactivated after ten minutes at 56 [degrees] C. A study in Australia found that boiling milk for five minutes is most effective in eliminating viruses and that pasteurization (at 62.5 [degrees] C for 30 minutes) is less efficient but does decrease the titers. This study found that different viruses have different stabilities: Some are inactivated just by freezing; other are still active after being frozen for five days. It concluded that the lipid antiviral activity of human milk should not be relied on alone and recommended heat treatment of breast milk. A study done in the United Kingdom showed that human milk pasteurized at 62.5 [degrees] C for 30 minutes retains most of its immunological properties. Should a milk bank pasteurization process be instituted, it is essential that quality controls be in place to assure that the right temperature is consistently maintained."	Resnicl 1986; Welsh 1979; Willis 1982	
Milk treatment	Narrative review	Bromberger	1982	Extreme heat "Because of the problems with bacterial contamination of milk, breast milk banks traditionally have used some kind of heat treatment to destroy potential pathogenic bacteria. Autoclaving or boiling of milk denatures all the proteins, including immunoglobulins and anti-infective macromolecules. Boiling of the milk also destroys its bacterial growth-inhibiting activity."	Ford 1977; Hernandez 1979	

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Milk treatment	Narrative review	Bromberger	1982	Pasteurization "Holder pasteurization, maintaining the milk at 62.5 [degrees] C for 30 minutes, is a compromise which allows retention of some of the anti-infective and nutrient properties of the milk while substantially reducing the numbers of potentially pathogenic and nonpathogenic organisms. Sterility of the milk after pasteurization is a function of prepasteurization bacterial counts and individual susceptibility of the microorganisms to heat. Suggested guidelines exist for accepting milk for pasteurization. Following these assures the effectiveness of pasteurization. Milk which has been collected under unhygienic conditions, for example, is excluded."	Baum 1979; Baum 1980; Ford 1977; Williamson 1978; Kabara 1980; Welsh 1979	
Milk treatment	Narrative review	Choto	1990	"Heating breast milk to a temperature of 56-57.5 [degrees] C for 30-33 minutes of sufficient to deactivate the Reverse Transcriptase necessary for its successful replication. [...] The problem to overcome is, therefore, the emotional resistance to pooled or banked breast milk. This will probably prove insurmountable in the short term future, despite the lack of convincing evidence of breast milk transmission."	Lucas 1987; Eglin 1987	
Milk treatment	Narrative review	Davies	1982	"Until the consequences of giving raw milk are better understood, Holder pasteurization (62.5 [degrees] C for 30 minutes) is the best method to achieve a satisfactory reduction in the number of micro-organisms, thereby rendering the milk safe for feeding, and at the same time preserving many of the immunological properties."	Baum 1979	

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Milk treatment	Narrative review	Kinsey	1984	"Increasing numbers of milk banks make it imperative that standards be set for use in practice. Suggestions include: [...] 2. Using raw milk when possible and Holder pasteurization as a viable alternative [...]"	Bromberger 1982; Ford 1977; Williamson 1978; Bjorksten 1980; Davidson 1979; Carroll 1979; Silmes 1978; Schanler 1979; Lemons 1981; de Louvois 1982; Baum 1979; Braune 1983; Evans 1978; Liebhaber 1978; Raptopoulou-Gigi 1977	
Milk treatment	Narrative review	Lawrence	1999	"The storage of human milk for use later by the mother's own infant or an unrelated recipient has an impact on its constituents. These effects involve the storage container, heating, cooling and freezing the milk. [...] Boiling, in addition, destroys lipase and reduces the effect of immunoglobulin A and secretory immunoglobulin A. The nutrient value of human milk is essentially unchanged, but the immunological properties are reduced by various storage techniques."	HMBANA 1996; Williamson 1978; Van Zoeren- Grobben 1987; Ford 1977; Goldblum 1984; Bates 1985; Stocks 1985; Rayol 1993; Martinez 1987; Desai 1987; Hamosh 1988; Carbonare 1996; Quan 1992; Kerner 1897; Wardell 1984	

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Milk treatment	Narrative review	Michie	2001	Review on the risk of viral transmission through breast milk. Cited references on the pasteurisation of milk, and concluded that "[m]ilk banks with pasteurised milk and wet nursing practices may offer local solutions, but will require vigilant supervision. Perhaps the monitoring of milk cell counts or sodium concentrations in addition to bacteriological screening should be studied as a potential method of quality control for such sources."	Lawrence 1999; Wright 1998	
Milk treatment	Narrative review	Narayanan	1989	Narrative review, including immunological aspects of treating human milk. Cited references on the effectiveness of Holder pasteurisation and pasteurisation at 56 degrees C for 15 and 30 minutes.	McDougal 1985; Resnik 1986; Lucas 1984	
Milk treatment	Narrative review	Ogundele	2000	Effect of heating on antimicrobial factors. Lysozyme, lactoperoxidase - some loss at 56 degrees C for 30 mins, destroyed by sterilisation for 15 min.	Bjorksten 1980; May 1984	
Milk treatment	Narrative review	Ogundele	2000	Effect of heating on antimicrobial factors. Gangliosides, glycoconjugates - stable on sterilisation.	Bjorksten 1980; Reynolds 1982; Sann 1983	
Milk treatment	Narrative review	Ogundele	2000	Effect of heating on antimicrobial factors. Secretory IgA - after 30 min stable at 56 degrees C, some loss at 62.5 degrees C; destroyed by sterilisation	Bjorksten 1980; Liebhaber 1977; Mazanec 1993; Raptopoulou 1977; Reynolds 1982; Sann 1983	
Milk treatment	Narrative review	Ogundele	2000	Effect of heating on antimicrobial factors. IgG - after 30 min stable at 56 degrees C, some loss at 62.5 degrees C; destroyed by sterilisation	Bjorksten 1980; Liebhaber 1977; Raptopoulou 1977; Reynolds 1982; Sann 1983	

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Milk treatment	Narrative review	Ogundele	2000	Effect of heating on antimicrobial factors. Milk cells - destroyed after 30 mins at 62.5 degrees C.	Bjoksten 1980; Deodhar 1991; Hernandez 1979; Liebhaber 1977; Murphy 1983; Reynolds 1982; Sann 1983	
Milk treatment	Narrative review	Ogundele	2000	Effect of heating on antimicrobial factors. Complement - destroyed after 30 mins at 56 degrees C.	Nakajima 1977; Ogundele 1999	
Milk treatment	Narrative review	Ogundele	2000	Effect of heating on antimicrobial factors. Cytokines - unknown.	Goldman 1996	
Milk treatment	Narrative review	Ogundele	2000	Effect of heating on antimicrobial factors. Bifidobacterium growth factor - stable on sterilisation.	Bjoksten 1980; May 1984	
Milk treatment	Narrative review	Ogundele	2000	Effect of heating on antimicrobial factors. IgM - after 30 min stable at 56 degrees C, destroyed at 62.5 degrees C.	Bjoksten 1980; Reynolds 1982; Sann 1983	
Milk treatment	Narrative review	Ogundele	2000	Effect of heating on antimicrobial factors. Lipid products - stable on sterilisation.	Cheesman 1983; Luzeau 1983; Wardell 1984; Williamson 1978	
Milk treatment	Narrative review	Ogundele	2000	Effect of heating on antimicrobial factors. Lactose - stable at 85 degrees C for 30 mins.	Bjoksten 1980; May 1984; Sann 1983	
Milk treatment	Narrative review	Ogundele	2000	Effect of heating on antimicrobial factors. Lactoferrin - 66% destroyed after 30 mins at 62.5 degrees C.	Bjoksten 1980; May 1984; Sann 1983	
Milk treatment	Narrative review	Oxtoby	1988	"In summary a variety of studies show pasteurization, with careful monitoring of time and temperature, to be the most effective means of eliminating bacterial and viral pathogens in human milk. Like other processing and storage methods, pasteurization also affects some of the desirable components of human milk."		

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Milk treatment	Narrative review	Oxtoby	1988	"Pasteurization is highly effective against CMV; samples artificially spiked with other viruses (Semliki Forest virus, herpes simplex virus and coxsackievirus) showed lowering of virus titres by 2.8 to 4.7 log [subscript] 10 values, although boiling was required to eliminate them entirely. In one small study 2 samples of milk spiked with free and cell-associated HIV were pasteurized at 56 [degrees] C for 30 minutes, with no reverse transcriptase activity detectable after treatment; this concurs with results from earlier laboratory studies on HIV suggesting its effective destruction in clotting factor concentrates by heat treatment. (However, several lots of lyophilized factor concentrates, heat-treated according to recommended methods, have apparently transmitted HIV.)"	Welsh 1979; Eglin 1987; McDougal 1985; MMWR 1988	
Milk treatment	Narrative review	Oxtoby	1988	"Evidence suggests that a combination of donor screening and milk pasteurization may provide the best insurance against transmission of infection in this setting. The World Health Organization statement supports this general approach, suggesting that in situations where pooled human milk is used pasteurization should be considered, with donor screening as an additional precaution especially in areas of high HIV prevalence."	WHO 1987	
Milk treatment	Narrative review	Oxtoby	1988	"Holder pasteurization (62.5 [degrees] C for 30 minutes) destroys cells, complement and bile salt-stimulated lipase but preserves immunoglobulins, nutritional content including vitamins and most enzyme activity. Other pasteurization methods, 56 [degrees] C for 30 minutes or 72 [degrees] C for 15 seconds, have also been used occasionally but are less well-studied."	Widdowson 1978; Bjoksten 1980	
Milk treatment	Narrative review	Oxtoby	1988	"Heat appears to inactivate the lymphocyte-transforming activity of HTLV-I; [...]"	Yamato 1986	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Narrative review	Roy	1979	"Those samples identified by bacteriological screening as unacceptable have to be rejected or undergo some form of heat treatment before being fed. The extent of heating should be no more severe or prolonged than is required for the destruction of pathogens. Holder pasteurization (62.5 [degrees] C for 30 minutes) seems to be adequate although 6% of samples still may not be acceptable. There is a price to pay even for this modest heat treatment. It has substantial adverse effects on the protective innumochemical constituents of human milk. At 80 [degrees] C, the ability of human milk to inhibit the growth of added bacteria largely disappears. There is little information and conflicting results on the effect of heat treatment on the nutritional properties of human milk. However, a recent study suggests that holder pasteurization adversely affects fat absorption probably through inactivation of milk lipases. Nitrogen retention is only affected if boiling is carried out."	Asquith 1978; Ford 1977; Williamson 1978	
Milk treatment	Narrative review	Simmer	2000	"There are risks associated with feeding donor HM as some viruses (human T-lymphotropic, HIV) and bacteria can be transmitted in HM and cause illness. Pasteurisation at 56-62 [degrees] C for 30 min will destroy most known pathogens except for cytomegalovirus (CMV), hepatitis B and hepatitis C."		

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Milk treatment	Narrative review	Stagno	2002	"Breastfeeding is the most important source of cytomegalovirus (CMV) infections during the first year of life. Forty percent of seropositive mothers who breastfeed their infants for at least one month transmit the infection. The rate of transmission can reach 76% for those with proven viro lactia by means of PCR or culture. This transmission occurs in the presence of transplacentally derived antibodies and the presence of antiviral factors in breast milk. The vast majority of infected infants born at term have no clinical problems and no short- or long-term sequelae. Premature infants, however, are at a significant risk of pneumonitis and worsening respiratory distress and increase in apneic episodes, sepsis-like symptoms, hepatosplenomegaly, hepatitis, thrombocytopenia, neutropenia, and elevated transaminases. Mothers should be encouraged to breastfeed their own, healthy infants born at term. Caution is required with the use of wet nurses and banked milk since CMV infected milk might inadvertently be given to infants born to seronegative mothers. This is particularly important for premature infants in whom even their own mother's milk may be contraindicated. Heat treatment of milk at 72 degreesC for ten seconds eliminates all infectious viruses without affecting the nutritional and immunologic properties. Screening for CMV in milk is costly and impractical."	Stagno 1989; Dworsky 1983; Vochem 1998; Dworsky 1982; Friis 1981; Welsh 1979	Reviewed primarily Stagno 1980 and Dworsky 1983 (exc as maternal transmission only).
Milk treatment	Narrative review	Tully	2001	"[...] as a safeguard against the transmission of certain viral pathogens that may occur in some mothers' milk, Holder pasteurization (62.5 [degrees] C for 30 minutes) is now required by the Human Milk Banking Association of North America, the United Kingdom Association for Milk Bankingm and many other national milk banking guidelindes for donor milk."	HMBANA 2000; UKAMB 1999	

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Milk treatment	Narrative review	Tully	2001	"While Holder pasteurization virtually eliminates the threat of viral contaminants, such as HIV, HTLV-1, and CMV, as well as common bacterial contaminants, it also destroys the B- and T-cell components of milk."	Orloff 1993; Yamato 1986; Welsh 1979; Friis 1982; Wills 1982; Liebhaber 1977; Lawrence 1999	
Milk treatment	Narrative review	Tully	2001	Selected components of human milk after freezing and pasteurization. Component, percentage activity. IgA and sIgA 67-100%. IgM 0%. IgG 66-70%. Lactoferrin (iron-binding capacity) 27-43. Lysozyme 75%. Lipoprotein lipase 0%. Bile salt activated lipase 0%. Monoglycerides (produced by lipolysis of milk triglycerides) 100%. Free fatty acids (produced by lipolysis of milk triglycerides) 100%. Linoleic acid 100%. Alpha-linoleic acid 100%.	Wills 1982; Newman 1995; Liebhaber 1977; Ford 1977; Evans 1978; Stein 1986; Henderson 1998; Lepri 1997; Fidler 1998	
Milk treatment	Narrative review	Tully	2001	"IgA and sIgA, which constitute the majority of the antibodies in human milk, are unaffected by freezing for 4 weeks, but Holder pasteurization reduces immunoglobulin concentration by 20% to 30% and significantly reduces specific antibody titer against Escherichia coli. Still, Carbonare and colleagues found that the decreased titers of IgA and sIgA did not diminish pasteurized milks' reactivity against enteropathogenic E. coli."	Liebhaber 1977; Ford 1977; Evans 1978; Carbonare 1996	
Milk treatment	Narrative review	Tully	2001	"Holder pasteurization has only a minimal effect on lysozyme activity but decreases lactoferrin iron-binding capacity by as much as 60% depending partly on the pH of the particular milk sample."	Bjorksten 1980; Ford 1977; May 1994	
Milk treatment	Narrative review	Tully	2001	"Holder pasteurization has little effect on the relative proportions of LC-PUFA in human milk, although there is a slight (6%) decrease in total triglycerides and corresponding increased in free fatty acids due to lipolysis."	Lepri 1997; Henderson 1998; Fidler 1998	

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Milk treatment	Narrative review	Tully	2001	"However, human milk lipases, including lipoprotein lipase and bile salt-activated lipase, are completely inactivated by pasteurization."		
Milk treatment	Narrative review	Tully	2001	"It is also important to note that micro-organisms that could contaminate the milk after pasteurization will grow faster than they can in raw milk owing to damage to the bacteriostatic systems in the milk."	Bjorksten 1980; Ford 1977	
Milk treatment	Narrative review	Van de Perre	1992	"However, pasteurization has been questioned. Inhibition of reverse transcriptase activity is not regarded as a marker sensitive enough to rule out infectivity. Mortimer and Cooke have proposed that more than one measure should be relied on; donor milk from screened low-risk donors should be used, only when necessary, after it has been pasteurized at 62.7 [degrees] C, and the pooling of donors should be limited. Clearly, if pasteurization is used as a sole preventive measure, it should be performed under severely controlled conditions."	Tedder 1988; Mortimer 1988	
Milk treatment	Narrative review	Van de Perre	1992	"However, pasteurization has been proposed as an effective method of destroying HIV-1 in pooled, banked milk. Indeed pasteurization is effective against cytomegalovirus and other human viruses. HTLV-1 is also rapidly denatured by heat treatment, as it is by a freeze-thawing procedure." Eglin and Wilkinson have shown that pasteurization at either 55 [degrees] C for 30 minutes or 57 [degrees] C for 33 minutes abolished reverse transcriptase activity of milk samples experimentally infected by HIV-1. They considered this procedure as a safe technique for destroying HIV-1 in pooled milk samples, thus rendering all other prevention measures unnecessary."	Eglin 1987; Welsh 1979; Yamato 1986; Ando 1986	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Narrative review	Wight	2001	"Pasteurization (56 or 62.5°C for 30 minutes) does affect some of the nutritional, immunologic and other components of human milk. Heat treatment at 56°C (133°F) or greater for 30 minutes reliably eliminates all functional white blood cells and bacteria, inactivates human immunodeficiency virus (HIV) and human T-lymphotrophic virus, and decreases the titers of other viruses, but in one study did not eliminate cytomegalovirus (CMV). Holder pasteurization [62.5°C (144.5°F) for 30 minutes reliably inactivates HIV and CMV, and will eliminate or significantly decrease titers of most other viruses. Immunologic factors are variously affected by heat treatment. With Holder pasteurization most of the secretory IgA, bifid growth factor, and lysozyme remain (0% to 30% destroyed), lipids are unaffected, but 57% of the lactoferrin, and 34% of the IgG are destroyed. The reader is referred to a more detailed recent review."	Orloff 1993; Yamoto 1986; AAP 2000; Lawrence 1999; Welsh 1979; Evans 1978; Ford 1977; Lawrence 1999	
Milk treatment	Narrative review	Wight	2001	"Most enzymes, growth factors, vitamins, and minerals are unchanged or minimally decreased."	Garza 1982; Van Zoeren-Grobbe 1987	
Milk treatment	Narrative review	Wight	2001	"Donor milk is released after it is heat-treated and bacterial cultures reveal no growth at 2 days. The San Jose Mothers' Milk Bank and all members of the HMBANA currently use Holder pasteurization. "		US milk banks US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Opinion piece	Baum	1980	"To my knowledge there are at least two commercially available machines specifically designed for the precise heat treatment of human milk. We have shown that such a machine can preserve the majority of the antimicrobial factors while reliably eliminating potential pathogens from pooled banked milk. The milk is exposed in 100 ml bottles to a temperature of 62.5 [degrees] C (+/- 0.5 [degrees]) for 30 mins with a rapid and reproducible heating and cooling cycle. Furthermore, the machine is automated and adaptable to other time and temperature settings. Our recent studies (unpublished) have shown that at shorter time and lower temperature settings the bacteriocidal effect is retained with a preservation of antimicrobial factors (other than milk cells) approaching 100%."	Gibbs 1977	
Milk treatment	Opinion piece	Lucas	1987	"There is no clear evidence that HIV persists in milk after standard pasteurisation, though there is a growing view that donor milk should be pasteurised, with accurate and purpose-built equipment. There have been no report of AIDS in preterm infants fed pasteurised donor milk. Further work is needed, both to evaluate the merits of donor milk and to explore strategies for reducing the possibility of HIV transmission by breast milk by, for example, defining the best possible time temperature ratios for pasteurisation and screening of donors."		
Milk treatment	Opinion piece	Menon	2007	Letter citing cases of pathogens transmitted via donor milk. "None of the breast milk [...] was heat-treated." Recommended the use of Holder pasteurization to eliminate and/or inactivate the pathogens.	Ryder 1977; Drhova 1990; Hamprecht 2004; Willis 1982	
Milk treatment	Opinion piece	Modi	2006	"Pasteurisation (62.5°C for 30 minutes) is necessary but this destroys or reduces many of the unique biological properties for which human milk is valued."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Opinion piece	Various	1980	Letters responding to the Bjorksten and Baum debates on the need for pasteurisation. Criticism of the argument for not pasteurizing milk, citing an unscientific approach and the specific context in which it was recommended. Also the need for (further research into milk composition and its use in small babies) and the effect of preserving.		
Milk treatment	Position statement	American Academy of Pediatrics	1980	"The storage of milk by freezing is an alternative to heating for the preservation of optimal nutritional value and immunological benefits. The use of frozen storage requires more attention to bacteriologic screening. Efforts should be made to collect clean milk with minimal bacterial contamination and to store it immediately in a freezer until it is gently thawed and fed."		
Milk treatment	Position statement	American Academy of Pediatrics	1980	"Heat treatment is a widely used method for reduction of bacterial contamination. However, it is important to restrict the extend and duration of heating to that required for the destruction of pathogens. Holder pasteurization (62.5 C for 30 minutes) appears to be adequate, although 6% of the samples may not be acceptable."	Asquith 1978	
Milk treatment	Position statement	American Academy of Pediatrics	1980	"Even this modest heat treatment [62.5 C for 30 minutes] has had significant adverse effects on the protective immunochemical constituents of human milk. At 80 C, the ability of human milk to inhibit the growth of added bacteria largely disappears. There is little information on the effect of heat treatment on the nutritional properties of human milk, and the results are conflicting. A recent study suggests that Holder pasteurization decreases the high coefficient of fat absorption of fresh human milk. The likely explanation is that heat treatment inactivates milk lipase. Nitrogen retention is affected only if milk is boiled."	Welsh 1979; Ford 1977; Williamson 1978	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Position statement	Canadian Paediatric Society	1985	"Pasteurization or freezing at -20 [degrees] C for more than 7 days will destroy cytomegalovirus in human milk."	Dworsky 1983; Stagno 1980; DHHS NIH 1981	
Milk treatment	Position statement	Canadian Paediatric Society	1985	"Pasteurization decreases the levels of IgA, IgM, lactoferrin, lysozyme and the C3 component of complement in breast milk. However, the microbiologic safety of paramount importance."	Liebhaber 1977	
Milk treatment	Position statement	Canadian Paediatric Society	1985	"The milk should be pasteurized and stored in the container that will be used in feeding."		Related to processes for feeding?
Milk treatment	Position statement	Canadian Paediatric Society	1985	"Standard routines for bacterial culture and pasteurization (maintaining a temperature of 62.7 [degrees] C for 30 minutes) should be established to ensure microbiologic safety."		
Milk treatment	Position statement	Gutierrez	1998	"15. All samples should be pasteurized and then stored in a freezer." "HMBs in Brazil pasteurize all milk samples [...]."		Brazilian milk banks Brazil
Milk treatment	Primary study	Brown	2000	Report of contamination of milk samples during pasteurization. All prepasteurization samples were sterile, but postpasteurization <i>Pseudomonas aeruginosa</i> was isolated in 8 of the 28 samples. Pasteurization process was "completely immersed milk bottles in tap water at 60 [degrees] C for 30 mins, and then cooled [...] by immersion in fresh cold tap water before they were stored at -20 [degrees] C". <i>P. aeruginosa</i> was isolated from the water intake pipes, and the process of cooling allowed water into the bottles (even when the lids were tightened), contaminating the sample. Remedial action included thorough maintenance of the machine and plumbing, and resetting the water level so that bottles were no longer completely submersed.		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study	Da Costa	2003	Evaluated the effect of pasteurization on iron, copper, and zinc in the colostrum of mothers of pre-term (P) and term (T) infants. "The following results of Fe, Cu and Zn (means +/- SD) were obtained for the PT and T colostrum samples, non-pasteurized and pasteurized, respectively: PT: 1.96 +/- 0.73 mg/l Fe/Zn/5.39 +/- 2.73 mg/l Zn; T: 1.71 +/- 1.01 mg/l Fe/1.46 +/- 0.99 mg/l Fe, 0.54 +/- 0.29 mg/l Cu/0.49 +/- 0.19 mg/l Cu, 6.97 +/- 2.82 mg/l Zn/6.75 +/- 2.62 mg/l Zn. There was a significant reduction in the levels of Fe, Cu and Zn in the samples of pasteurized colostrum. These results suggest that, despite the observance of a diminution in the levels of Fe, Cu and Zn in the samples of pasteurized colostrum, the values fell within the acceptable range for the specific nutritional needs of new-born infants during this period of lactation." Authors concluded that Holder pasteurization affects the mean composition of colostrum, but that more information on the importance of these findings is needed.		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study	Donelly-Vanderloo	1994	Assessed "the effect of pasteurization, microwaving and warming of milk in a tap water bath (conventional heating) on milk folate content and form. Human milk (n = 10) collected by complete breast expression was pasteurized (62.5 degrees C for 30 minutes), microwaved (720 watts, high power for 30 seconds) or conventionally heated (40 degrees C for 10 minutes). Cow (n = 10) and goat (n = 10) milk was pasteurized as above. The folate content of milk samples was determined using a differential microbiological technique with and without added folate conjugase. A 16% reduction in human milk folate content was noted following pasteurization. Microwaving and conventional heating did not cause a reduction in total milk folate content. [...] The mean folate content of human, cow, and goat milk was 113.7+/-3.7 (mean+/-SEM), 142.8+/-6.8 and 21.3+/-9.0 nmol/L, respectively. [...] Pasteurization (62.5 degrees C for 30 minutes) without the addition of ascorbate may result in intakes of folate below recommended levels for some infants."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study	Evans	1978	"Human milk, after storage and pasteurisation at 73 degrees C for 30 minutes at a milk bank, was found to have little surviving IgA, IgG, lactoferrin, lysozyme, and C3 complement. Accurate pasteurisation at 62.5 degrees C produced a loss of 23.7% of the lysozyme, 56.8% of the lactoferrin 34% of the IgG, but no loss of IgA. Storage by deep freezing at -20 degrees C for 3 months produced no appreciable loss of lactoferrin, lysozyme, IgG, IgA, or C3." Authors concluded that "human milk should be collected in as sterile a manner as possible and deep frozen shortly after collection. If of low bacterial count then its use reheated should be considered. Pasteurisation, if used, should be at the minimum temperature capable of adequate bacterial killing (about 62°C for 30 minutes). Unfortunately, there does not seem to be a commercial apparatus available in the United Kingdom capable of dealing with small volumes and achieving uniform and accurate heating.	Szollósy 1974	Appears to be treatment of 'real' donations, not experimental samples.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study	Friis	1982	Assessed the amount of cytomegalovirus in human milk and the rate of inactivation of CMV during storage at -20 degrees C and during pasteurisation. "Samples of milk from 23 mothers attending the department of obstetrics and gynaecology and 36 who donated milk to the department's milk bank were cultured for cytomegalovirus. Virus was isolated from samples from 12 of the milk donors but none of the mothers attending the department; follow-up studies during lactation in seven of these 12 women showed that five continued to excrete the virus. Samples were taken on three occasions from one woman who regularly excreted high titres of the virus. Storage at -20 degrees C for over three days reduced the titre by over 99%; after pasteurisation at 63 degrees C for eight minutes the milk did not contain any viable virus. It is recommended that raw banked milk used for feeding preterm babies should be kept frozen for at least 72 hours before feeding." For complete inactivation of CMV, pasteurisation at 63 [degrees] C for 8 minutes is needed.		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study	Lucas	1979	"The bacteriological quality of pooled human milk donated to the Oxford milk bank was analysed and the effects on bacteriology of sterilisation of the milk-collecting vessels in the home with hypochlorite solution and of Holder pasteurisation in a purpose-built human-milk pasteuriser were studied. Collecting milk in hypochlorite-sterilised vessels resulted in a significantly lower bacterial count of both pathogens and species of unlikely pathogenicity before pasteurisation and significantly increased the chance of pasteurisation giving a sterile product. Potentially pathogenic organisms grown in untreated milk were <i>Escherichia coli</i>, <i>Staphylococcus aureus</i>, and group B beta-haemolytic streptococci. Seven species of organisms of unlikely pathogenicity were also identified. Pasteurisation eliminated all potential pathogens from milk but did not reliably remove any of the species of unlikely pathogens. Banked human milk may be contaminated with bacteria which are known to be capable of producing lipases, proteases, and decarboxylases. Accurate pasteurisation, together with attention to the sterility of the collecting vessels, results in a bacteriologically safe product that retains many of the protective properties of raw milk."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study	Narayanan	1984	"Supplementary formula feeds inhibited the protective effect of expressed raw and pasteurised human milk in 226 high-risk neonates in a randomised controlled trial. The infection rate in the group given pasteurised human milk and formula (33%) was significantly higher than the rates in the groups given raw human milk (10.5%), pasteurised human milk (14.3%), and raw human milk and formula (16%). This accords with the impressions that some of the association of infection with artificial feeding is partly attributable to the lack of the protective effect of human milk. Heating expressed human milk to 62.5 degrees C for 30 min significantly reduces its protective effect." Authors recommended that "ideally in a developing country collection of milk should be closely supervised to minimise contamination. It should be handled carefully and it should be administered raw as soon as possible. Storage beyond 24 hr in the refrigerator should be avoided unless there are safeguards against voltage fluctuations and electrical failures."	Narayanan 1982; Narayanan 1981	Maternal milk, not donor milk. Old RCT, so very limited detail reported. Not 'true' control group.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study	Ribiero	2005	"Objectives: To analyze the effect of processing on the vitamin A levels of milk that is donated to the Human Milk Bank at the University Maternity Hospital, and to evaluate whether this milk supplies the infants' vitamin A requirement. Methods: Sixty milk samples from the Human Milk Bank were divided into two equal portions. One milk portion was extracted prior to processing, while another fraction was subjected to pasteurization and later extracted. The samples were analyzed using high performance liquid chromatography. Analysis with Student's t test indicated that the difference between mean retinol levels was statistically significant at the $p < 0.05$ level. Results: The retinol content found in the milk prior to processing was 55.4 ± 34.0 $\mu\text{g}/100$ ml, whereas for the processed milk this level was 36.6 ± 26.1 $\mu\text{g}/100$ ml ($p < 0.001$) [before pasteurization assessed to be 69.3% of adequacy for a full term baby or 66% for a preterm baby and after pasteurization to be 45.8% of adequacy for a full term baby or 43.6% for a preterm baby]. Conclusion: It was found that retinol loss occurs during milk processing and that the milk from the Human Milk Bank does not meet infants' vitamin A requirement."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Berkow	1984	Examined the effect of rapid freeze-thawing and storage conditions on free fatty acid (FFA) levels, activities of lipoprotein lipase (LPL) and bile salt-stimulated lipase (BSSL) in human milk. Also investigated the effect of the presence of serum on human milk LPL. "Lipase activity levels were unaffected by rapid freeze-thawing (x3) followed by storage for 1 month at -20 or -70 [degrees] C. [...] Addition of serum had no effect on milk LPL at either temperature." Authors concluded that "LPL and BSSL remain fully active during frozen storage of human milk and that milk fat is hydrolyzed at -20 [degrees] C but not at -70 [degrees] C. We suggest that banked human milk be stored routinely at -70 [degrees] C." Also "[T]hese findings suggest that expressed breast milk may be stored at temperatures below -20 [degrees] C for up to 3 months within minimum change in lipase activity. Ideally, freezing and thawing of banked milk prior to storage should be avoided."		
Milk treatment	Primary study - in vitro	Bertino	2008	Aimed to evaluated the effects of Holder pasteurisation (62.5 degrees C for 30 minutes, then rapidly cooling to 10 degrees C within approx 20 mins by immersion into cold water) on lactose concentration and oligosaccharides. Mean concentrations of lactose, total and specific oligosaccharides showed no statistically significantly change after pasteurization ($p>0.05$). Authors concluded that this study showed "the persistence of the biological value of human milk even after pasteurization."		
Milk treatment	Primary study - in vitro	Bitman	1983	Aimed to compare lipid composition of samples stored at -20 or -70 degrees C. "Storage at -20 [degrees] C was not satisfactory for maintaining milk lipid composition, for it resulted in hydrolysis of triglycerides and the appearance of free fatty acids."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Chen	2001	Investigated the response of antibacterial properties to high-temperature, short-time (HTST, 72 degreesC - 75 degreesC, 15 sec) and low-temperature long-time (LTLT, 65 degrees C, 30min) pasteurization. "Nonpathogenic <i>Listeria innocua</i> ($10^{6.0}$ cfu/mL) was inoculated into raw and processed bovine and human milk; bacterial plate counts twice weekly determined antibacterial activities. Up to 99% of <i>L. innocua</i> were killed and further growth was inhibited in raw and pasteurized human milk for at least 60 days at 4 degrees C. Reactive IgA antibodies against <i>Listeria</i> antigens were demonstrated by enzyme immunoassay in some human milk samples; sIgA activity against <i>Escherichia coli</i> O antigens was significantly decreased by heat treatments (raw, 1.8; HTST, 1.1; LTLT, 1.3 activity units). Adding human lactoferrin (0.5-20 mg/mL) to the <i>Listeria</i> inoculum ($10^{7.0}$ cfu/mL) in 1% peptone water did not inhibit bacterial growth." Authors concluded that both LTLT and HTST pasteurization methods are effective, and that "immunological quality can be maintained using a simple and low-cost system for HTST processing."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Clark	1984	Investigated the effect of storage temperature on lipoprotein lipase activity. "The milk samples were aliquoted and stored at 25, 4, -20, and -70 degrees C. After storage for 3, 6, 12, and 24 h, serum-stimulated and -independent activities were again determined and compared with the initial activities. Storage at 25 degrees C resulted in a significant (p less than 0.05) decrease in lipolytic activity. Serum-stimulated activity decreased 83.4% and serum-independent activity decreased 66.9% over the 24-h period. Storage at 4 degrees C resulted in a significant (p less than 0.05) decrease of 22.6% in serum-stimulated activity and a 7.2% decrease in serum-independent activity. No significant changes were observed in milk stored for 24 h at -20 and -70 degrees C. Milk was stored at -20 and -70 degrees C for an additional 1, 2, and 4 weeks. Serum-stimulated lipolysis did not change significantly over the 4-week period. Serum-independent lipolysis increased significantly (p less than 0.05) with storage time. Storage at -20 degrees C resulted in an increase of 20% and storage at -70 degrees C resulted in an increase of 36% over the 4 weeks." Authors concluded that "frozen storage of milk results in increased activity of a lipase system that requires no further activation to cause hydrolytic rancidity. If the milk is thawed and used immediately, hydrolytic rancidity may not be a problem. But, if milk is thawed and then kept at room or refrigerator temperature, hydrolytic rancidity will develop."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Clark	1984	Investigated the effect of storage temperature and length of storage on bile salt-stimulated lipase (BSSL) and bile-salt stimulated esterase (BSSE) activities immediately after collection. The samples were stored at 25, 4, -20 and -70 [degrees] C. "After 6, 12 and 24 hours of storage BSSL and BSSE activities were determined. Activities were also determined in milk after 2 and 4 weeks of storage at -20 and -70 C. There was no significant change in BSSL activity due to storage. The average activity of BSSL was 1.54 mumole free fatty acid/released/min/ml milk +/- 0.46 (SD). Activity from BSSE was significantly (P < 0.05) increased by storage at 4, -20 and -70 C compared to 25 C. After the initial cooling or freezing of milk, measured at 6 hr, there was no additional change in BSSE activity with storage time. Bile salt-independent esterase activity increased significantly (P < 0.05) due to storage. Upon collection, bile salt-independent esterase activity averaged 0.16 mumoles p-nitrophenol released min/ml milk +/- 0.23 (SD) compared to 1.27 +/- 1.69 (SD) in stored milk." Authors concluded that "the observed increase in bile salt-independent esterase with storage may have important implications for milk banking as the active esterase may alter milk composition".		
Milk treatment	Primary study - in vitro	Curtis	2005	Aimed to determine the effect of freezing on CMV in breast milk. CMV culture positive breast milk was stored at 0-5 degrees C in a domestic refrigerator for 48 hours or frozen for different durations at -20 degrees C. "Cytomegalovirus survived in [43%, 3 of the 7 samples] breast milk despite being frozen for 10 days at -20 degrees C." Authors concluded that "routine freezing may not eliminate CMV from breast milk from mothers of very premature babies."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Deodhar	1991	"Sixty five breast milk samples were subjected to bacteriological studies; each sample thrice (in fresh state, after heating at 100°C and freezing for 5 days at - 20 degrees C). In fresh State, Staphylococci and diphtheroids were predominant organisms. After heating, none of the samples showed any micro-organisms while after freezing for 5 days, all the samples showing presence of micro-organisms earlier, showed decrease in colony counts. None of the milk samples showed inclusions of cytomegalovirus. Serum samples of mothers tested for Hepatitis B surface antigen and human immunodeficiency virus antibodies gave negative results. Such studies i.e. screening of breast milk samples are important if human milk is to be stored in banks and supplied to premature (high risk group) children."		
Milk treatment	Primary study - in vitro	Donovan	1991	Assessed the stability of insulin-like growth factors (IGFs) and insulin-like growth factor binding proteins (IGFBPs) to heat treatment. "The concentration (mean +/- SD) of IGF-I in human milk was 1.5 +/- 0.5 micrograms/L, compared to 2.7 +/- 0.7 micrograms/L for IGF-II. Heat treatment did not significantly affect either IGF-I or -II content. [...] Stability of the IGFBP to heat treatment was assessed and was not significantly affected by heat treatment. Therefore, both IGF-I and -II, and the IGFBP in human milk appear to be stable under heat treatment conditions routinely used for processing banked human milk."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Dworsky	1982	Assessed the effect of various processing and storage procedures on CMV infection in breast milk. Authors concluded that the only process which "completely destroyed CMV infectivity on human milk was the high temperature (62 [degrees] C) treatment." Storage at 4 degrees C or -20 degrees C failed to eliminate CMV. They recommended that "seronegative infants receive milk from seronegative donors only, especially if the donated milk is treated and stored in a fashion designed to fully preserve its immunological and nutritional properties."		
Milk treatment	Primary study - in vitro	Eglin	1987	Tested whether pasteurisation (Oxford pasteuriser - 54.5 to 55 degrees C for 30min; Axicare pasteuriser - 56 to 57.5 degrees C for 33min) of pooled milk inactivates HIV. "Both commercial breast milk pasteurizers inactivated 10 ⁴ HIV infectious units/ml and 10 ⁴ HIV infected cells/ml in 100 ml of 90% breast milk. This level of HIV infectivity greatly exceeds any potential natural HIV infectivity found in one donation of breast milk, and would be further diluted in milk banking. Pasteurisation of pooled breast milk eliminates any risk of transmission of HIV and HIV antibody screening of donors is unnecessary."		Assumed to be pooled milk from different women.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Fidler	1998	Examined the effects of pasteurization (62.5 degrees C for 30 minutes) and sterilization (120 degrees C for 30 minutes) on milk fat content. "The coefficients of variation for measurements of milk fat content were 0.7% and of fatty acids accounting for more than 0.09% of weight, 0.1-3.0%. Available fat content was 3.1+/-1.4 g/dl (mean +/- SD) in fresh human milk and 3.1+/-1.4 g/dl (not significant) in pasteurized human milk. Fat content declined to 2.7+/-1.1 g/dl ($p < 0.001$ vs. fresh) in sterilized human milk, because of increased fat adherence to the container surface after sterilization. The percentage composition of saturated, monounsaturated, and polyunsaturated fatty acids of the n-6 (C18:3, C20:2, C20:3, and C22:4) and the n-3 series (C18:3 C20:5, C22:5, and C22:6) was not affected by thermal treatment. Milk sterilization caused a slight decrease of linoleic (-0.7% vs. fresh milk; $p = 0.006$) and arachidonic (-2,6%; $p = 0.045$) acids." Authors concluded that "[p]asteurization of human milk does not influence fat content and composition, but sterilization may reduce available fat content by more than 10%, whereas there are only slight changes in fatty acid composition. [...] Therefore, if heat treatment is necessary in human milk to avoid microbial risks, pasteurization is preferable to sterilization in maintaining the available fat content and fatty acid composition."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Ford	1977	Examined the effect of heat treatments of graded severity on immunoglobulins, lactoferrin, lysozyme, vitamin B12-and folate-binder proteins, and lactoperoxidase in human milk. "Holder pasteurization (62.5 degrees C 30 minutes) reduced the IgA titer by 20%, and destroyed the small content of IgM and most of the lactoferrin. Lysozyme was stable to this treatment, but with an increase in temperature there was progressive destruction, to near 100% at 100 degrees C. The same was broadly true of the capacity of milk to bind folic acid and protect it against bacterial uptake; with vitamin B12 the binder was more labile at 75 degrees C than at 100 degrees C. The milk contained no detectable lactoperoxidase." Authors discussed the advantages and disadvantages of heat treatment and concluded that heat treatment "should be no more severe or prolonged than is required for the destruction of likely pathogens. For batch processing of small quantities of milk of small quantities of milk the holder process (62.5 [degrees] C 30 minutes) would seem to be the method of choice."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Friend	1983	Evaluated the effects of several methods of processing and storage on key enzymes, B vitamins, and lipid components of mature human milk. "Freezing and frozen storage had little effect on the enzymes of pooled samples of milk. Lactoperoxidase activity decreased from 36 in raw pooled samples to 17 in pooled samples slow frozen and stored for 3 months at -25 degrees C (P less than 0.05). Similarly, quick freezing and storage for 3 months significantly decreased the lactoperoxidase activity of pooled samples from 93 to 14 (P less than 0.05). Quick freezing and frozen storage tended to increase lipase activity although the changes were not significant. Freezing and frozen storage did not significantly affect the levels of biotin, niacin, and folic acid. Similarly, the total lipid fatty acid level and relative % of each fatty acid were not significantly different in the frozen samples as compared to the raw samples." Authors concluded that "slow freezing offers the same storage stability as quick freezing with much less effort and equipment and thus would be the method of choice for preserving the milk."		
Milk treatment	Primary study - in vitro	Gaffin	1983	"Pooled human breast milk is frequently heat treated before administration to neonates in order to reduce the risk of spreading infection. However, heating such milk by two different routine hospital procedures [pasteurisation - 63 degrees C for 20 minutes in a non-regulated water bath, temperature control by placement of hand on/off boiling plate by staff; boiling for approximately 20 minutes] totally inactivated anti-endotoxin antibodies present, thus greatly reducing the benefit of administering breast milk. Temperature-time parameters of the heat treatment of human breast milk were studied to determine the limits of anti-endotoxin IgG and IgA activities."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Garza	1982	"The effects of collection technique, storage container, and the duration and temperature of storage on selected nutrient concentrations in mature human milk were evaluated. Milk samples were collected during the fourth week of lactation from women 20-35 years of age by hand expression or suction. Greater volumes [mean 52, s.e.m. 7ml vs mean 27, s.e.m. 3ml suction vs manual resp; $p<0.10$] and fat concentrations [mean 3.7, s.e.m. 0.5g% vs mean 3.0, s.e.m. 0.5g% suction vs manual resp; $p<0.001$] were observed in milks collected by suction. Vitamin A, zinc, iron, copper, sodium [no data reported], and protein nitrogen [mean 220, s.d. 20mg/dl vs mean 210, s.d. 20mg/dl suction vs manual resp; no p value reported] concentrations were not affected by storage of milk in either pyrex or polypropylene containers for up to 24 h. The storage temperature had a significant effect on protein nitrogen and ascorbic acid concentrations. These findings indicate that collection methods and storage procedures used for comparatively brief periods will affect the concentrations of selected nutrients of mature human milk."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Goes	2002	Assessed the levels of "fat, protein, lactose, calcium, phosphorus, zinc, iron, copper, and vitamin A in processed mature milk samples (individual, n = 60, and pooled, n = 10) from a reference human milk bank in Brazil and assessed the effect of pasteurization followed by freezing on the nutrient composition and the pattern of zinc distribution in fractions (fat, whey, and casein) of milk samples (n = 15). RESULTS: Mean nutrient concentrations were within expected ranges in mature milk from healthy women, except fat, which was lower. Interindividual variability of nutrient concentrations was high (coefficient of variation, 21-62%) but reduced overall in pooled samples. Processing of milk samples did not affect the nutrient contents but did cause a significant shift ($P < 0.04$) in the relative distribution of zinc, with a decrease in the whey fraction and an increase in the fat fraction. CONCLUSIONS: Redistribution and possible alterations in the zinc-binding pattern during processing in human milk banks may reduce zinc bioavailability to the infant."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Hamprecht	2004	Evaluated "the virological and biochemical characteristics of freeze-storing breast milk at -20 degrees Celsius, compared it with traditional Holder pasteurization (30 min at 62.5 degrees Celsius), and a new short-term pasteurization (5 s at 72 degrees Celsius) based on the generation of a milk film. Both heat treatment procedures were able to destroy viral infectivity and pp67 RNA completely. Preliminary results showed short-term heat inactivation below 72 degrees Celsius was less harmful in reducing the activity of marker enzymes than Holder pasteurization. Freezing breast milk preserved the biochemical and immunologic quality of the milk; however, late viral RNA and viral infectivity was also preserved. Compared with viral DNA, CMV-RNA more directly reflects infectious CMV in human milk samples. Further studies are necessary to evaluate short-term heat treatment below 72 degrees Celsius as an effective tool for prevention of CMV transmission."		
Milk treatment	Primary study - in vitro	Henderson	1998	"Milk fatty acids, including the polyunsaturated long chain fatty acids essential for retinal function and brain development, are not affected by pasteurization (62.5 degrees C for 30 min). Milk lipases are completely destroyed by pasteurization, whereas amylase lost only 15% of initial activity. Thus, certain bioactive components are stable to pasteurization of donor milk and can benefit the recipient infants."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Hernandez	1979	Aimed to evaluate the effects of freezing and pasteurization on the bacterial-growth inhibiting activity of human milk. "Human breast milk samples were collected from lactating mothers, and aliquots were maintained at room temperature, frozen, and pasteurized. Samples were inoculated with 10 to 50 colony-forming units per milliliter (cfu/ml) of Escherichia coli or group B streptococcus, and incubated at 37 C. Quantitative growth was measured at eight and 24 hours. No inhibitory activity was demonstrated by control broth, commercial formula, and pasteurized breast milk, which had a rapid logarithmic growth to a maximum of 10(8) to 10(9) cfu/ml at 24 hours. Compared with these controls, fresh breast milk, fresh frozen breast milk, and breast milk frozen for 21 days demonstrated a significant inhibition of bacteria growth. A trend toward gradual loss of inhibiting activity was noted with prolonged freezing of breast milk. Although freezing may quantitatively decrease the amount of some breast milk host-defense factors, it cannot be assumed that comparable functional reductions will necessarily result." Authors concluded that "frozen breast milk is a potential alternative for feeding premature infants when fresh milk is not available."	AAP 1977	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Honour	1979	Assayed the bacteriostatic activity for milk-sensitive and milk-resistant indicator strains of Escherichia coli. "Activity is greatest in colostrum which is active directly against all strains of E. coli. One week after delivery of the baby, milk is active against the milk-sensitive strain and becomes active against the milk-resistant strain in the presence of physiological amounts of bicarbonate and iron-binding protein. This activity decreases within 2--4 days on keeping milk unheated at 4 degrees C but is preserved for at least 4 months and often up to 2 years in milk heated to 56 degrees C then stored at 4 degrees C or in milk frozen, unheated, at -28 degrees C provided it is not repeatedly thawed and frozen. Later lactation milks are usually indistinguishable in activity from 1-week post-partum milk but may be less stable on storage particularly if frozen. Lyophilization in vacuo preserves activity of early-lactation milk for at least 6 months. Heating milk to above 65 degrees C causes a progressive loss of activity which can be partially restored by adding bicarbonate and iron-binding protein. Iron abolishes the activity of milk and reduces that of colostrum."		
Milk treatment	Primary study - in vitro	Martinez-Costa	2007	"This study analyzed the bactericidal activity of human milk and how it is influenced by refrigerated storage. Nine samples of mature human milk were collected and divided into 3 aliquots. One was analyzed immediately, and the other 2 were refrigerated at 4 degrees C to 6 degrees C for 48 and 72 hours, respectively. All of the fresh samples exhibited bactericidal activity with an average value of 83.47% +/- 18.37%. Refrigeration for 48 hours did not cause significant modifications, whereas storage beyond 72 hours significantly lowered the degree of bacteriolysis versus fresh milk. In conclusion, human milk possesses bactericidal activity that remains stable during the first 48 hours of refrigerated storage, but it is significantly reduced beyond 72 hours."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Miranda	2004	"The aim of this study was to assess changes in glutathione peroxidase (GPx) activity and in the concentration of the lipid peroxidation marker, malondialdehyde (MDA), when human milk was kept refrigerated or frozen. Thirty-two human milk samples were assayed for GPx activity and MDA concentration. Samples were divided in three aliquot portions, the first to be immediately analysed, the second to be refrigerated at 4 degrees C and analysed 24 h thereafter, and the third to be frozen at -20 degrees C and assayed after 10 days. GPx activity was significantly decreased in refrigerated and in frozen milk, when compared to their control samples. MDA was increased only in refrigerated milk but not in frozen samples. Thus, freezing seems better than refrigeration in order to prevent lipid peroxidation in stored human milk samples."		No specific reference to donor milk banking.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Morera	1998	"The effect of various storage methods on the stability of the triacylglyceride fraction of human milk was evaluated. Samples were treated as follows: Group I--stored at -20 degrees C for 4 months, group II--heated for 1.5 min at 80 degrees C and stored at -20 degrees C for 4 months, group III--stored at -80 degrees C for 4 months and thawed rapidly at room temperature (25 degrees C) just before analysis and group IV--stored at -80 degrees C for 2 months, thawed rapidly at room temperature (25 degrees C), then stored at -80 degrees C for a further 2 months and finally thawed rapidly at 25 degrees C just before analysis. The absence of hydrolysis products in group II and group III indicated that these storage procedures were satisfactory even when samples were rapidly thawed for a short time (group IV). Only storage at -20 degrees C without previous heat treatment led to the hydrolysis of triacylglycerides and the appearance of free fatty acids (group I). On the other hand, the effect that freezing and thawing had over the lipolysis grade was studied. Samples were treated as follows: group V--stored at -20 degrees C for 2 months, thawed slowly at refrigerator temperature (5 degrees C), held at this temperature for one week and stored for a further month at -20 degrees C. Freezing and thawing activated lipolysis and increased the production of free fatty acids, monoacylglycerides and diacylglycerides. Milk samples were analyzed by reversed-phase HPLC with a ternary gradient of acetonitrile-dichloromethane-acetone and an evaporative light-scattering detector>"		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Orloff	1993	"Human milk was inoculated with human immunodeficiency virus type I (HIV-1) or with HIV-1-infected cells in volumes and containers typically used in human milk banks. The inoculated milk was pasteurized at 62.5 degrees C for 30 minutes in a water bath, i.e., conditions currently in use or proposed for human milk pasteurization. The process of HIV-1 inoculation and pasteurization effectively inactivated the infectivity of both cell-free HIV-1 and HIV-1-infected cells. No virus was recovered after the process, even after repeated subculturing in attempts to rescue the virus. Pasteurization reduced the infectious titer of cell-free HIV-1 and HIV-1-infected cells by more than 5 logs and 6 logs respectively. Human milk contains one or more components that inactivate HIV-1 but that are not toxic for the cells used to replicate virus. These components have not been identified, but physical and solubility properties are consistent with characteristics of lipids." Authors concluded that "[p]asteurisation coupled with donor screening should alleviate any concerns about the safety of banked human milk with respect to HIV-1 transmission."	CDC 1985	

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Raptopoulou-Gigi	1977	"After standard heat sterilisation IgA and lactoferrin were undetectable in milk samples. Pasteurisation also sterilised milk samples even after heavy artificial contamination and did not damage the proteins. Gamma-irradiation sterilised equally effectively but caused some denaturation of IgA and lactoferrin. Since most of the milk samples were sterile or had only light contamination with skin bacteria, there seems to be no need for routine sterilisation. If sterilisation is necessary, the method used should be chosen to minimise damage to milk proteins." "The standard sterilisation procedure [heating to 105 degrees C, freezing and thawing, repeating the cycle], gamma-irradiation [2.5 Mrads from a cobalt-60 source] , and pasteurisation [62.5 degrees C for 30 minutes] sterilised all the samples received. Pasteurisation also sterilised all the samples that were deliberately heavily contaminated with Staph aureus and E coli. The effect of the other procedures on these samples was not tested."		Although mean changes with sd were reported, no p values or statistical tests appear to have been applied.
Milk treatment	Primary study - in vitro	Rees	1987	"Pooled human milk samples received in the laboratory were tested for the presence of various enzymes using the APIZYM™ system. All raw milk samples contained detectable quantities of nine (distinct) enzymes [alk phos, esterase, est lip, lipase, leu aryl, acid phos, ppa, beta glucuron, and NAG] of the 19 represented on the strip." "Pasteurization by the Holder process (62.5 [degrees] C for 30 min) destroys the activity of alkaline phosphatase, lipase and N-acetyl [beta] glucosaminidase." Proposed methods of measuring the efficiency of the pasteurisation cycle used were: pasteurisation at 58 degrees C for 30 min; no NAG, alk phos detected. Pasteurisation at 62.5 degrees C for 30 min; no NAG, no alk phos detected.		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Roberts	1978	Paired samples of fresh breast milk were either pasteurised at 62 5°C for 30 minutes or untreated. Twelve paired samples were then inoculated at room temperature with an enteropathogenic Escherichia coli 0125 inoculum containing 105 organisms/ml. A further six paired samples were inoculated with the Oxford strain of Staphylococcus aureus. Bacterial growth was compared in raw and pasteurised milk by Miles and Misra counts after 14 hours' incubation at 37°C. All pasteurised samples were sterile before inoculation while raw milk samples invariably contained a variety of bacterial contaminants. To eliminate the effect of incidental bacterial contamination on growth of the inoculum raw milk was passed through a Seitz E K filter and shown to be bacteria free. Six paired samples treated in this way were then tested by the described method, an enterotoxigenic strain of Staph aureus (NCTC 10657) being used as the inoculated organism. Bacterial counts in raw and pasteurised samples were compared by paired t tests (table). Highly significant differences in bacterial growth were found with E coli [raw 7.5×10^4 vs pasteurised 5.5×10^4, $p < 0.001$] and Staph aureus [Oxford raw 4×10^4 vs pasteurised 1.8×10^7, $p < 0.001$]. Similar results were obtained with filtered milk. [Toxigenic Staph aureus raw 11×10^4 vs pasteurised 23×10^4, $p < 0.001$] [...] We conclude that unheated, compared with pasteurised, breast milk has bacterial growth inhibitory properties and that these may protect the neonatal gut against harmful bacterial colonisation. The need for careful and hygienic methods of milk collection in conjunction with bacteriological monitoring is clear."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Scott	1987	"The performance of the Axicare human milk pasteurizer was evaluated under different load conditions. The design criteria for pasteurisation specified that milk should be held at 63 degrees C for 30 min. The holding time at this temperature was insufficient if bottles of milk frozen at -20 degrees C were placed into the machine as directed, after the water-bath preheating phase. However, if the machine was loaded with frozen bottles before the whole cycle was commenced, adequate thawing and warming to holding temperature was achieved in sufficient time for satisfactory pasteurization. The pasteurizer gave consistent and adequate temperature and time conditions. The seals on three types of bottles tested tended to leak during the pasteurization cycle but no method of avoiding this problem was established."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Silvestre	2006	"Available lysine content is an indicator of protein quality and nutritional value of milk. Many studies have examined the effects of extraction, treatment and storage of human milk upon its components, though no references are found regarding the possible changes in milk quality as defined by its content in essential amino acids such as lysine. The present study investigates the available lysine content in human milk and the variations in lysine resulting from milk manipulation as follows: (a) Cold storage (refrigeration at 4 degrees C for 48 hours, and frozen for 15 days at - 20 degrees C); (b) Thermal treatment under conditions of low (Holder)(63 degrees C/30 minutes) and high pasteurization (75 degrees C/15 seconds). The results obtained show a decrease in milk lysine concentration after storage in both refrigerated and frozen samples [mean (sd) mg Lys/100ml fresh 161.34 (70.768); refrigerated 98.55 (39.191); frozen 94.75 (36.365); p=0.0037 and p=0.0310 vs fresh milk resp]. Pasteurization causes a highly significant loss of available lysine. The lysine losses were greater on applying low pasteurization versus the more gentle conditions of high pasteurization [mean (sd) mg Lys/100ml fresh 181.41 (86.318); low 127.53 (64.991); high 153.55 (74.502); p=0.0000015 and p=0.0000078 vs fresh milk resp; p=0.000015 low vs high]. CONCLUSIONS: While manipulation through cold storage or thermal treatment does not affect the protein content of human milk, its protein quality is modified [mean (sd) g protein/l fresh 12.70 (4.787); refrigerated 11.19 (4.975); frozen 11.74 (3.386); p=n.s. vs fresh milk resp]. When human milk must be subjected to hygienization, it is preferable to apply high temperature treatment (75 degrees C, 15 seconds) than habitual pasteurization (63 degrees C, 30 minutes) [mean (sd) g protein/l fresh 13.78 (6.836); low 12.49 (4.639); high 13.39 (5.4195); p=n.s. vs fresh milk resp]."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Silvestre	2008	"AIM: Pasteurization is the thermal treatment usually applied in milk banks to eliminate the risk of transmission of infectious agents. The aim of this study was to investigate the effect of heat processing upon the antioxidant properties of human milk. METHODS: Milk samples collected from 31 healthy women were subjected to two different pasteurization techniques: Holder pasteurization (63 degrees C for 30 min) and high pasteurization (75 degrees C for 15 sec) and oxidative stress markers (glutathione, glutathione peroxidase activity, malondialdehyde and total antioxidant capacity) were determined in comparison to fresh milk. RESULTS: Malondialdehyde concentration was the same in all samples [mean (sd) uM fresh 0.9 (0.5); Holder 0.8 (0.6); high 0.8 (0.5); $p>0.05$ vs fresh milk for both], while there was a decrease in glutathione concentration [mean (sd) uM fresh 7.74 (5.53); Holder 4.17 (3.24); high 5.78 (3.24); $p<0.05$ and $p>0.05$ vs fresh milk resp] and total antioxidant capacity [mean (sd) mMeq uric acid fresh 0.24 (0.16); Holder 0.08 (0.06); high 0.2 (0.14); $p<0.05$ and $p>0.05$ vs fresh milk resp] in milk samples subjected to thermal processing versus fresh milk samples. However, the drop in these parameters was seen to be significantly greater when applying Holder pasteurization. Both thermal treatments induced considerable and similar loss of glutathione peroxidase activity [mean (sd) mM/Lxmin fresh 17.7 (5.0); Holder 6.6 (5.4); high 6.7 (4.3); $p<0.05$ vs fresh milk for both]. CONCLUSION: Thermal processing of human milk implies a decrease in its antioxidant properties but, when necessary, high pasteurization should be the election method in terms of milk oxidative status."		SD assumed?

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Silvestre	2008	"An evaluation is made of the stability of overall human milk bactericidal capacity following 2 modalities of thermal pasteurization: 63°C/30 minutes and 75°C/15 seconds. Ten milk samples (mature milk) were analyzed. In each sample, the effect of both thermal treatments on bactericidal capacity against Escherichia coli was evaluated in relation to the capacity of fresh milk (control). All the samples analyzed possessed bactericidal capacity. Human milk pasteurization induced a significant loss of this capacity that was more pronounced after high-temperature treatment than after low-temperature processing. Untreated milk, low-pasteurized milk, and high-pasteurized milk yielded a reduction in E. coli growth of 70.10% [sd 8.14], 52.27% [sd 16.95], and 36.39% [sd 14.98, p<0.05 for all comparisons], respectively. In conclusion, human milk possesses antimicrobial activity that is lost in part as a result of thermal processing. Such bactericidal capacity is, moreover, better preserved by low-temperature, long-time pasteurization." Refrigeration results low pasteurization: mean (no sd reported - shown on graph only) 0 hours 52.27%; 48 hours 68.97%; 72 hours 52.56%; p=n.s. Refrigeration results high pasteurization: mean (no sd reported) 0 hours 36.4%; 72 hours 28.8%; p=n.s.		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Terpstra	2007	"The standard method used by North American milk banks is Holder pasteurization (63 degrees C for 30 minutes). The authors undertook an experiment to validate the effects of a high-temperature short-time (HTST) pasteurization process (72 degrees C for 16 seconds) on the bioburden of human milk. It was concluded that HTST is effective in the elimination of bacteria as well as of certain important pathogenic viruses." BVDV: after exposure to the pasteurization process for 4 or 8 seconds, no infectious virus was detectable. HAV: all time points tested detected infectious virus. HIV: after exposure to the pasteurization process for 4 or 8 seconds, no infectious virus was detectable. PPV: all time points tested detected infectious virus. PRV: after exposure to the pasteurization process for 4 or 8 seconds, no infectious virus was detectable. Total aerobic count: after 8 seconds, no viable bacteria could be detected. E coli: by 4 seconds, no viable E coli could be cultured. Staph aureus: no growth was detected after 12 seconds. S. agalactiae: by 4 seconds, no bacteria could be cultured from the treated milk. Authors concluded that "together with data obtained in a comparative experiment looking, among other things, at levels of IgA and other proteins thought to play a role in immune defense of the infant, indicating that HTST preserves more of the important milk protein than Holder pasteurization (manuscript in preparation) leads the authors to the conclusion that it may be the method of choice for the treatment of human milk. The major drawback of HTAT is that it is extremely expensive, prohibitively so if one cannot benefit from economies of scale."		No published paper identified re the IgA etc May 2009.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Van Zoeren-Grobbe	1987	"We investigated the effect of the composition of the storage container, Holder pasteurisation, and conditions during tube feeding on the concentration of selected vitamins in human milk. Though the fat soluble vitamins A [Mean (sd) micromol/l Polypropylene 1.32 (0.83); glass 1.39 (0.84)], D [Mean (sd) pmol/l Polypropylene 143 (64); glass 149 (59)], and E [Mean (sd) micromol/l Polypropylene 7.1 (2.8); glass 7.7 (3.4)] were not affected, the concentration of several water soluble vitamins decreased. The lower vitamin C concentration of milk stored in polypropylene containers compared with milk stored in glass containers (29%) was not significant [Mean (sd) micromol/l Polypropylene 141 (45); glass 174 (40)]. Holder pasteurisation significantly lowered the concentrations of vitamins C (36%), folacin (31%), and B6 (15%). [p<0.001]."		Results from tube feeding and phototherapy not presented.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Viazis	2007	"Banked human milk, processed using low-temperature/long-time or Holder pasteurization, inactivates pathogenic microorganisms but degrades important biochemical components. High-pressure processing kinetics favor inactivation of microorganisms with retention of biochemical activity and nutritional quality of foods. The effects of high-pressure processing (400 Mpa) and low-temperature/long-time pasteurization (62.5°C, 30 minutes) on total immunoglobulin A and lysozyme activity in human milk were investigated. Indirect modified enzyme-linked immunosorbent and a <i>Micrococcus lysodeikticus</i> turbidimetric assay were performed to measure immunoglobulin A immunoactivity and lysozyme activity, respectively. Pressure-treated samples retained significantly higher ($P < .05$) levels of immunoglobulin A [% retained at 30 mins 85.6; 60 mins 87.1; 90 mins 80.6; 120 mins 75.4] and lysozyme activity [% retained at 30 mins 106.9; 60 mins 96.3; 90 mins 96.3; 120 mins 95.8] compared to samples treated with low-temperature/ long-time pasteurization [% retained 52.1% and 60.5% resp]. These data suggest that high-pressure processing is a potential alternative to thermal pasteurization of human milk that can give greater retention of some bioactive components. Further research is needed to determine whether high-pressure processing can inactivate pathogens of concern in donor human milk."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Viazis	2008	"Low-temperature, long-time (LTLT) pasteurization assures the safety of banked human milk; however, heat can destroy important nutritional biomolecules. High-pressure processing (HPP) shows promise as an alternative for pasteurization of breast milk. The purpose of this study was to investigate the efficacy of HPP for inactivation of selected bacterial pathogens in human milk. Human milk was inoculated with one of five pathogens (10⁸ to 10⁹ CFU/ml), while 0.1% peptone solution solutions with the same levels of each organism were used as controls. The samples were subjected to 400 MPa at 21 to 31 degrees C for 0 to 50 min or to 62.5 degrees C for 0 to 30 min (capillary tube method) to simulate LTLT pasteurization. Tryptic soy agar and selective media were used for enumeration. Traditional thermal pasteurization resulted in inactivation (> 7 log) of all pathogens within 10 min. In human milk and in peptone solution, a 6-log reduction was achieved after 30 min of HPP for <i>Staphylococcus aureus</i> ATCC 6538. After 30 min, <i>S. aureus</i> ATCC 25923 was reduced by 8 log and 6 log in human milk and peptone solution, respectively. Treatments of 4 and 7 min resulted in an 8-log inactivation of <i>Streptococcus agalactiae</i> ATCC 12927 in human milk and peptone solution, respectively, while <i>Listeria monocytogenes</i> ATCC 19115 required 2 min for an 8-log inactivation in human milk. <i>Escherichia coli</i> ATCC 25922 was inactivated by 8 log after 10 min in peptone solution and by 6 log after 30 min in human milk. These data suggest that HPP may be a promising alternative for pasteurization of human milk. Further research should evaluate the efficacy of HPP in the inactivation of relevant viral pathogens."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Wardell	1981	"In a study of human milk collected for banking, heating at 62.5 degrees C for 30 min, and freezing and thawing resulted in hydrolysis of triglycerides. Freezing and thawing caused disruption of fat globules and a greater hydrolysis of triglycerides than did the heating process. There was a decrease in the percentage of the poly-unsaturated fatty acids linoleic acid (C18:2) and linolenic acid (C18:3) after freezing and thawing, and after heating, but the other fatty acids of human milk triglycerides were not affected. It is suggested that the availability of linoleic and linolenic acid in milk declines when these procedures are used in human milk banking."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Wardell	1984	"In a study of human milk obtained in the first month of lactation, lipase and esterase activity were assayed. Bile salt-stimulated lipase (BSSL) and bile salt-stimulated esterase (BSSE) activities in colostrum [mean (sd) units/ml 18.65 (4.4) and 23.9 (4.3) resp] were similar to corresponding enzyme activities in transitional milk [mean (sd) units/ml 17.5 (5.7) and 24.5 (12.1) resp] and in mature milk [mean (sd) units/ml 19.8 (5.6) and 24.95 (6.05) resp]. BSSL and BSSE were significantly (P less than 0.001) correlated to one another [correlation coefficient 0.834], which suggests that lipase and esterase activities in milk are due to the same enzyme. When milk was allowed to stand at room temperature, in a refrigerator, or subjected to freezing and thawing, wide fluctuations were observed in lipase and esterase activities, but there was no systematic tendency for enzyme activity to increase or decrease. Heating milk to various temperatures between 40-55 degrees C resulted in progressive loss of enzyme activity [Rate constant at 40.0 degrees C 1.32×10^{-5} k/s-1; 45.0 degrees C 7.83×10^{-5} k/s-1; 46.5 degrees C 3.00×10^{-4} k/s-1; 47.5 degrees C 4.33×10^{-4} k/s-1; 48.2 degrees C 9.00×10^{-4} k/s-1; 50.0 degrees C 3.00×10^{-3} k/s-1; 53.5 degrees C 1.13×10^{-2} k/s-1; 55.0 degrees C 3.17×10^{-2} k/s-1]. The activation energy for the process which inactivates the enzyme was found by linear regression to the Arrhenius plot to be 2×10^5 J X mole⁻¹. Our findings suggest that lipase and esterase activity in human milk which is donated to hospitals and stored frozen can make a valuable contribution to fat digestion in the newborn infant, but pasteurization destroys the enzyme."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Welsh	1979	"Semliki Forest virus (SFV), herpes simplex virus type 1 (HSV-1), coxsackievirus B4, and cytomegalovirus (CMV) were added to human milk, which was then subjected to treatments that approximated those required for the decontamination or storage of milk. Boiling was the only treatment that eliminated these viruses from the milk. Pasteurization (at 62.5 C for 30 min) did destroy CMV [no detectable CPE after 20 days], but the other viruses could still be detected. All of the viruses except HSV-1 were detectable after the contaminated milk samples had been stored at -15 C for 10 days. SFV, HSV-1, and CMV were also decreased by lipid antiviral activity, which was present in 78% of samples that were obtained on day 5 postpartum. Naturally excreted CMV was detected at the highest levels in milk that lacked this antiviral factor; this CMV also survived freezing for 10 days. Thus, whereas the lipid antiviral activity decreased the level of enveloped viruses, whether they were added to or naturally excreted into human milk, further reduction in the levels of these viruses required heat treatment."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Wills	1982	"Using the Oxford Human Milk Pasteuriser human milk was exposed to lower temperature and shorter time periods than employed in classical holder pasteurisation. Heating human milk at 62.5 degrees C for 5 min completely destroyed Escherichia coli, Staphylococcus aureus, and group B beta-haemolytic streptococci inoculated into the samples. Heating at 56.0 degrees C for 15 min destroyed over 99% of the inoculated organisms. The mean percentage remaining activity of certain antimicrobial proteins after heat treatment at 62.5 degrees C for 30 min, 62.5 degrees C for 5 min and 56 degrees C for 15 min were as follows: IgA 67, and 90%; lactoferrin 27, 59 and 91%; and lysozyme 67, 96 and 106%, respectively. These results suggest that human milk can be effectively pasteurised using less heat treatment than in classical holder pasteurisation. Lower temperature and shorter heat treatment also preserves substantially more of the activity of the antimicrobial proteins present in human milk."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Primary study - in vitro	Yamato	1986	"Peripheral blood lymphocytes from 2 normal individuals seronegative for human T-cell leukemia virus type I (HTLV-I) were co-cultured with HTLV-I-producing MT-2 cells that had been heated at 56 degrees for 30 min or exposed to 10,000 rad of X-irradiation. HTLV-I-induced lymphocyte transformation was consistently achieved by co-culture with irradiated MT-2 cells but not by co-culture with heated MT-2 cells. The heat treatment was found to be lethal to both MT-2 cells and the virus. [Viability % and mean reverse transcriptase activity (sd) cpm at 56 degrees C; 0 mins 100 and 3399 (164); 5 mins 66.3 and 915 (95); 10 mins 23.7 and 575 (18); 20 mins 0 and 441 (63); 30 mins 0 and 401 (42); 90 degrees C 10 mins 0 and 396 (68)]. These findings are discussed in terms of their potential clinical application for preventing the transmission of HTLV-I." Authors concluded that "heating at 56 [degrees] C for 30 min" or at 90 degrees for 10 mins "would be equally effective in [killing HTLV-1 infected lymphocytes]."		No p values or significance reported.
Milk treatment	Service description	Arnold	1999	"Occasionally the milk in the vat is agitated with a large gravy whisk to prevent separation of fat and uneven heating of components."		Goteborg milk bank Sweden
Milk treatment	Service description	Arnold	1999	"Milk is pasteurized in 5-20 liter batches at 63 [degrees] C for 30 minutes in a 30-liter stainless steel vat surrounded by a sleeve in which hot water or steam can circulate. This piece of commercial kitchen equipment is similar to a steam kettle. A domed clear lid allows a thermal probe to be inserted to monitor the temperature of the milk."		Goteborg milk bank Sweden
Milk treatment	Service description	Arnold	1999	"Emphasis in this milk bank is on a 'clean' product, not a sterile one; hence milk pasteurization occurs in an open system. All equipment is cleaned in a standard dishwasher."		Goteborg milk bank Sweden

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Service description	Arnold	1999	"All milk is pasteurized according to protocols and guidelines that are part of the public health law. The hospital infection control department inspects the milk bank and enforces the Health Ministry regulations. Pasteurization is at 60 [degrees] C for 30 minutes, with the 30-minute count beginning when the temperature of the milk reaches 57.9 [degree] C. The pasteurizer is a unique, specially designed and engineered two-chamber unit with a 20-liter (approximately 660-ounce) capacity. Specially manufactured bottles are placed in a rack, which is totally submerged in the heated chamber, brought to temperature and held there, and then transferred to the second compartment and submerged in chilled water to stop the heat reaction. The bottles for the pasteurizer hold 250cc and are triangular in cross section. This means they can be stacked on their sides in the freezer, wasting less space than round bottles and providing a more stable stack [...]. They are plastic, water tight, and are used only for human milk. If milk is contaminated with bacteria, then the milk is first brought to a boil, chilled, and then pooled and pasteurized as usual. Postpasteurization, bacteriological tests are done and milk is refrozen until it is dispensed and used."		Hvidovre milk bank Denmark
Milk treatment	Service description	Arnold	1999	"When heat treatment is complete, the vat is tilted and the milk is poured into a stainless steel milk pail through a funnel with a disposable sponge rubber filter at the bottom. This is intended to filter out any large contaminants, such as hair. A large rubber spatula is used to push fat through the filter. The milk is then poured into 'factory clean' polypropylene bottles which are used once."		Goteborg milk bank Sweden
Milk treatment	Service description	Asquith	1987	"All milk from donors with a history of herpes virus infection is pasteurized."		San Jose milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Service description	Asquith	1987	"Treatment, either by prolonged freezing at -20 [degrees] C (but not at -70 [degrees] C) or by pasteurization has been shown to inactivate cytomegalovirus (CMV)."	Friis 1982; Hayes 1972; Stagno 1980	San Jose milk bank US
Milk treatment	Service description	Balmer	1992	"These criteria are necessary because pasteurisation is ineffective if milk is heavily contaminated with micro-organisms."		Sorrento milk bank UK
Milk treatment	Service description	Balmer	1992	"The efficacy of pasteurisation is checked by including a test bottle in each batch. The test bottle is a 250 ml Winchester containing water in which a small bottle containing 5 ml of raw mil is submerged. After pasteurisation 0.2ml milk from that sample is inoculated on to two blood agar plates [...]. A batch of milk is not used until a report of no growth for this sample is received from the laboratory."	DHSS 1981	Sorrento milk bank UK
Milk treatment	Service description	Balmer	1992	"All acceptable milk is strained through sterile muslin to remove any hairs or bits of fluff from donor's clothes."		Sorrento milk bank UK
Milk treatment	Service description	Balmer	1992	"All milk should be at room temperature immediately before pasteurising because pasteurising is not effective if the temperature has to be raised considerably during the cycle."	Scott 1989	Sorrento milk bank UK
Milk treatment	Service description	Balmer	1992	"All milk is pasteurised at 56 [degrees] C for 30 minutes in a custom built pasteuriser (Scott Weston) and rapidly cooled to 10 [degrees] C at the end of the cycle. The model [...] is very similar to the Colgate Axicare CM80. The whole cycle (time and temperature) is recorded on a chart that is kept for reference."		Sorrento milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Service description	Balmer	1992	"Although heat treatment will kill most bacteria present in milk, the toxins produced by some bacteria are not necessarily destroyed by heat. It is therefore advisable to eliminate milk contaminated with any toxin producing organisms such as Escherichia coli and S aureus."		Sorrento milk bank UK
Milk treatment	Service description	Baum	1982	"If no growth is reported [from the sample of milk], the 39 bottles are transferred into a third freezer ready for use in the hospital."		John Radcliffe milk bank UK
Milk treatment	Service description	Baum	1982	"The milk is [...] decanted into specially designed screw-top bottles in preparation for pasteurisation (Fre-flow by Woolf Griptight [...]). When the pasteuriser indicates that the water bath has reached a pre-determined temperature, the rack of 40x100 ml bottles is submerged in the water, following which the automated pasteurisation cycle is completed. At the end of the cycle, when the milk has cooled to room temperature, 39 of the bottles are placed in the postpasteurisation freezer while one bottle is sent for bacteriology."		John Radcliffe milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Service description	Baum	1982	In the Oxford Human Milk Pasteuriser "milk is heated rapidly to a predetermined temperature, held at that temperature for a predetermined time and then cooled rapidly. Over the last two years using the settings of 62.5 [degrees] C with a holding time of 30 minutes, more than 95% of all milk samples handled in our bank have shown no bacterial growth on the postpasteurisation culture. However we recognise that in choosing the settings of 62.5 [degrees] C for 30 minutes we were taking the classical pasteurisation formula which was originally designed to eliminate tubercle from bovine milk. In recent experiments with the Oxford Human Milk Pasteuriser we have used a lower temperature and shorter time pasteurisation (56 [degrees] C with a holding period of 15 minutes) and shown that milk samples are rendered sterile with starting counts of 10 ⁷ organisms per ml of E. coli, Staph. Aureus and Group B [beta]-haemolytic streptococci."	Wills 1982	John Radcliffe milk bank UK
Milk treatment	Service description	Baum	1982	"Our recent experiments using the Oxford Human Milk Pasteuriser at 56 [degrees] C for 15 minutes have shown that the percentage survival of IgA, lactoferrin and lysozyme approaches 100%."	Wills 1982	John Radcliffe milk bank UK
Milk treatment	Service description	Bjorsten	1980	Reviewed evidence on treatment processes - including heat treatment. "Even mild heat treatment will inactivate some of these [antimicrobial and nutritional] factors. We therefore consider that holder pasteurisation should not be recommended as a safe and reproducible routine method for decontamination."	Anon 1977; Lloyd-Jones 1979; Lucas 1979; Gibbs 1977; Gothefors 1975; Ford 1977; Raptopoulou-Gigi 1977; Eyres 1978; Liebhaber 1977; Hernandez 1979	Narrative review.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Service description	Bjorsten	1980	Reviewed evidence on treatment processes - including storage. "We [...] conclude that breast milk contaminated with various bacteria can be safely stored at 4 [degrees] C and at 6 [degrees] C for at least 72 hours. Even longer storage periods at 6-8 [degrees] C would constitute a minimal risk for growth of potential pathogens." Freezing "neither decreases the content of live bacteria nor denatures milk proteins, although the cells present in milk are killed [...]. Thus the decision whether or not to freeze breast milk for storage or transportation seems to be mainly a practical question."	Gibbs 1977; Gothefors 1975; Ford 1977; Raptopoulou-Gigi 1977; Eyres 1978; Liebhaber 1977; own study	Narrative review.
Milk treatment	Service description	Cash	1981	"Two methods of milk treatment, heating and freezing, assure a bacteriologically acceptable product. While heating results in the lowest possible bacterial count, it also inactivates immunoglobulins and decreases the viability of leukocytes. In addition, heat alters milk lipids decreasing their intestinal absorption."	Paxon 1979; Ford 1977; Hernandez 1979; Williamson 1978	EOPC milk bank US
Milk treatment	Service description	Connor	1982	"Following this, specimens of the milk are obtained and cooling and freezing of the milk is carried out according to the procedure previously followed."		Enfield milk bank UK
Milk treatment	Service description	Connor	1982	"A thermostatically controlled water-bath has been acquired. The bottles are lowered on a rack into this bath, the water already having reached the pre-set temperature of 66 [degrees] C. Tests with a thermocouple have established that 15 minutes are required for the milk to reach this temperature. It was agreed to allow a holding time at 63 [degrees] C [to] 66 [degrees] C for 15 minutes (thus making the total immersion time 30 minutes)." This replaces the previous method of using hypochlorite solution.		Enfield milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Service description	Connor	1982	Reported outbreak of <i>Klebsiella oxytoca</i> in babies fed milk from the milk bank and babies fed formula milk. Main problems identified were: the lack of sterile feeding bottles (other than those for collection from mothers' homes); using a saucepan instead of the pasteurizer (as was broken); the instability of the storage containers when immersed in water and the lid not being watertight; increased handling of milk when splitting into smaller amounts. Actions were agreed and implemented to address these.		Enfield milk bank UK
Milk treatment	Service description	Dempster	1982	"Despite the fact that freezing appears to have a detrimental effect on breast milk, for practical reasons it is difficult to run a milk bank in Durban's climatic conditions without freezing the milk."	Paxson 1979; Robinson 1978; Gibbs 1977	Addington milk bank South Africa
Milk treatment	Service description	Fernandez	1993	"Earlier, the milk was used unprocessed (raw) if it satisfied the criteria suggested by Asquith. Today, in view of the rising incidence of AIDS in India, all containers of milk are subjected to heat treatment even if bacterial counts are low."	Asquith 1979	Bombay milk bank India. May not be directly relevant to the UK, but agreed to leave in with caveats in interpretation.
Milk treatment	Service description	Fernandez	1993	"Heat treatment of milk is carried out by the method recommended by the Mothers' Milk Bank of San Jose, California. Although most of the milk banks abroad use a conventional pasteurizer for heat treatment, the use of a geyser and shaker waterbath with thermostatic control that is locally available is found to be equally effective and helps to cut costs."	Asquith 1988	Bombay milk bank India. May not be directly relevant to the UK, but agreed to leave in with caveats in interpretation.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Service description	Greenwood Wilson	1951	"The entire supply from all donors is pasteurized by a simple process."		Cardiff milk bank Wales
Milk treatment	Service description	Hartmann	2007	"International best practice requires that donor human milk must be pasteurised (heated to 62.5 [degrees] C for 30 min) prior to being fed to recipients. The PREM Bank has committed to meeting this standard. All donor milk is pasteurised at 63.5 [+/-] 1.0 [degrees] C for 30 min in a custom built flow-through batch pasteuriser (Saurin Pty Ltd). The pasteuriser is temperature calibrated to +/- 1.0 [degrees] C therefore, this temperature range ensures a minimum of 62.5 [degrees] C is obtained."	UKAMB 2003; HMBANA 2005	PREM milk bank Australia
Milk treatment	Service description	Hoey	1980	"Over the past four years approximately 2500 low-birthweight babies have received frozen unpasteurised breast milk that has been thawed. No ill effects have been noted."		Salvation Army milk bank UK
Milk treatment	Service description	Hoey	1980	"All samples are cultured. Only those yielding Pseudomonas aeruginosa are pasteurised and the rest are pooled and deep frozen."		Salvation Army milk bank UK
Milk treatment	Service description	Hoey	1980	"We agree with Dr David Baum (18 October, p 1066) that great caution must be exercised in the administration of a breast milk bank. However, he states that pasteurisation "can preserve the majority of the antimicrobial factors" (our italics). Dr Bjorksten and his colleagues suggest that all the factors are preserved by freezing. Our experience suggests that pasteurisation is unnecessary, timeconsuming, and expensive."	Baum 1980; Bjorksten 1980	Salvation Army milk bank UK
Milk treatment	Service description	Kimball	1955	"Each morning the breast milk collected the previous day is removed from the refrigerator and poured together into a kettle. It is brought to a boil slowly and stirred gently and frequently. It is never allowed to reach a rolling boil, but by a slow heat is kept at 212 [degrees] F. for 3 minutes."		Evanston milk bank US

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Service description	McEnery	1978	"Boiling and even holder pasteurisation (62.5 [degrees] C for 30 minutes) destroys some of the immune properties of human milk. This is why we decided to keep each milk sample separate and use it intact without pasteurisation, provided that the bacterial count was low and non-pathogenic."	Ford 1976; Williamson 1978	Whipps Cross milk bank UK
Milk treatment	Service description	Omarsdottir	2008	"This study was designed to document current routines pertaining to breastmilk use for preterm infants in Sweden. METHODS: A questionnaire regarding breastmilk handling and routines was sent to all 36 neonatal units in Sweden in November 2006 and February 2007. RESULTS: Of the 36 participating neonatal units 27 had their own milk bank. [...] In 11 of the 36 neonatal units maternal milk was frozen to reduce the risk of cytomegalovirus transmission."		
Milk treatment	Service description	Omarsdottir	2008	"This study was designed to document current routines pertaining to breastmilk use for preterm infants in Sweden. METHODS: A questionnaire regarding breastmilk handling and routines was sent to all 36 neonatal units in Sweden in November 2006 and February 2007. RESULTS: Of the 36 participating neonatal units 27 had their own milk bank. [...] Donor milk was pasteurized in 22 milk banks [81%]." "In 18 of these milk banks, donor milk was heated to 62.5 [degrees] C for 30 minutes (Holder pasteurization), whereas in one of the milk banks, donor milk was heated to 72 [degrees] C for 30 minutes. In the three remaining milk banks, donor milk was heated for 15 seconds to 72 [degrees] C (two milk banks) and 73 [degrees] C (one milk bank) respectively."		
Milk treatment	Service description	Pedersen	1982	"Treatment procedures were originally decided upon from the procedures used with market milk. The overall qualities of WM, except for reduced vitamin-C content, were believed to be unchanged after heat treatment [...]."	MacPherson 1939	Fuglebakken milk bank Denmark

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Service description	Pedersen	1982	"Freshly milked WM, especially earlier, was used without heat treatment."		Fuglebakken milk bank Denmark
Milk treatment	Service description	Penc	1996	"If the purity of a batch is sufficient, an amount equal is defrosted, pasteurized, and taken to the ward for use."		Polish Mother's Memorial Hospital milk bank Poland
Milk treatment	Service description	Penc	1996	"Donor milk is always heat treated. Pasteurization is done in a constant temperature shaking water bath at 65 [degrees] C for 30 minutes."		Polish Mother's Memorial Hospital milk bank Poland
Milk treatment	Service description	Penc	1996	"Each pasteurized batch contains a control bottle for monitoring bacterial content after pasteurization."		Polish Mother's Memorial Hospital milk bank Poland
Milk treatment	Service description	Reid	1988	Survey of UK milk banks. Breast milk treated by heat 1; pasteurisation 15; no treatment (raw donor milk) 0; no treatment (raw maternal milk) 10; banks closed 2; no response 2.		Ninewells milk bank Scotland. Report of out-dated practice.
Milk treatment	Service description	Sauve	1984	"[...] and in seven centres it was pooled and pasteurized before use. A Holder method (62.7 [degrees] C for 30 minutes) was used in two centres and four used a Flash method (72.7 [degrees] C for 16 seconds). The method used was not specified in one instance."		Various milk banks Canada

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Service description	Siimes	1979	"We have relied on heat treatment as the most practical way of processing human milk and are encouraged by the data of Welsh and May indicating that most of the known antiviral and antibacterial factors are, in fact, relatively heat resistant at the temperatures generally used. We have used 60 [degrees] C for 10 minutes although the optimal conditions remain to be determined.	Welsh 1979	Helsinki milk bank Finland
Milk treatment	Service description	Springer	1997	"With modern screening methods, contamination of donor milk has been largely eliminated and boiling of milk is no longer necessary."		Leipzig milk bank Germany
Milk treatment	Service description	Tomalin	1983	"Pasteurisation is carried out at the unit by the nursing staff."		Kings College milk bank UK
Milk treatment	Service description	Tomalin	1983	"Early on it was found that boiling milk destroyed many of the nutrients. The policy now is to give raw milk where possible but only when tests have shown that it is consistently free of harmful bacteria. The unit believes that although pasteurised milk is safer, some components are destroyed and the full immunological value of the milk is only obtained from raw milk."		Kings College milk bank UK

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Service description	Tully	2000	"The milk is heat processed in glass to assure more even heat distribution and to prevent heat warping between the container and lid; UK milk banks use a commercially produced milk pasteurizer (Colgate Medical), which has specially designed plastic bottles that do not leak. With the shaking water bath pasteurizer, different milk banks use different containers, usually depending on the availability and cost. Some banks use recycled 2- or 3-ounce formula bottles, and some use canning jars sold for home canning use (Kerr, about \$2 per dozen 8-oz jars when bought in bulk.) These jars are made of a glass tempered to withstand the rapid heating and cooling process and to be reused. They can be returned to the milk bank for washing and reuse. The bottles and jars require new lids each time (about \$.50 per dozen for the canning jars and a little more for the caps for the formula bottles). A dishwasher with a hot rinse cycle (about \$500) is the most time-efficient way to clean the glassware used in processing and the jars or bottles. Some milk banks use the hospital's autoclaving facilities to sterilize glassware, but that is it not necessary."		HMBANA milk banks US & Canada

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Milk treatment	Service description	Tully	2000	"The Precision 50 shaking water bath (Fisher Scientific, about \$4000) will hold 200-224 ounces at a time, depending on the size and shape of the bottles of milk. Some milk banks use the Precision 25, which is smaller and a little less expensive, but obviously cannot process as much milk at one time. A temperature probe in a control bottle is used to monitor the temperature of the batch of milk during processing. Either an alarm thermometer or a recording thermometer can be used. A simple digital alarm thermometer is the least expensive (Fisher Scientific, about \$50). It is inserted through a rubber cork so the tip of the probe is at the center of the bottle. Water is used in the control bottle. The probe is on a long wire, which allows the thermometer to sit outside the water bath for easy monitoring during processing."		HMBANA milk banks US & Canada
Milk treatment	Service description	Tully	2000	"After it is heated to 62.5 [degrees] C and held there for 30 minutes (Holder pasteurization), it is quickly chilled in an ice slurry, labeled, and refrozen. A sample from the last jat prepared is taken for a postculture, which must report no growth at 2 days before it can be distributed."		HMBANA milk banks US & Canada
Milk treatment	Service description	Tully	2000	"Processing a batch of milk takes about 2 hours for the first load in the processor and [...] another 45 minutes to an hour for each additional load."		HMBANA milk banks US & Canada
Staff training	Narrative review	Bar-yam	2003	"Educate physicians, nurses, and other providers about the benefits of donor breastmilk."		
Staff training	Narrative review	Bar-yam	2003	"Work with local NICUs and doctors to identify and overcome barriers to using banked donor milk."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Staff training	Narrative review	Bar-yam	2005	"In communities where there are milk banks there are also public education campaigns to inform the community at large of the existence of the milk bank. There are also education campaigns for perinatal health professionals, neonatologists, obstetricians, pediatricians, midwives, nurses, social workers, and other so that they will know how the services work and how to refer both potential donors and recipients to the bank."	HMBANA 2005	US milk banks - relevant to UK?
Staff training	Narrative review	Simmer	2000	"Guidelines for the screening of donors and the pasteurisation and storage of donated milk are readily available from HM banking associations, but recommendations by professional bodies are few and some so not support the establishment of HM banks."	AAP 1980; Canadian Paediatric Society no date	
Staff training	Narrative review	Woo	2007	"[...] nurses need to know what to tell mothers about informal milk sharing." This can include purchasing/sharing milk via the internet.		
Staff training	Narrative review	Woo	2007	"[...] if a nurse had understood more about human milk banking, the conversation could have taken place, and [the bereaved mother - hypothetical] could have been comforted by knowing that her milk was helping other babies."		
Staff training	Narrative review	Woo	2007	"Despite [following HMBANA guidelines], healthcare providers do not yet seem aware of the safety of donated human milk. [...] Clearly, healthcare providers have a knowledge deficit regarding human milk banking."		

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Staff training	Opinion piece	Nommsen-Rivers	1997	Editorial on the occupational safety issues for staff handling human milk. Author discussed whether universal precautions apply to human milk, and focussed on the interpretation and application of these in the United States. The Centres for Disease Control guidelines state "Human breast milk has been implicated in perinatal transmission of HIV, and HbsAG has been found in the milk of mothers infected with HBV. However, occupational exposure to human breast milk has not been implicated in the transmission of HIV nor HBV infection to health care workers. Moreover, the health care worker will not have the same type of intensive exposure to breast milk as the nursing neonate. Whereas universal precautions do not apply to human breast milk, gloves may be worn by health care workers in situations where exposures to breast milk might be frequent, for example, in breast milk banking." Author argued that "[i]n most cases, common sense policies such as routine hand washing and thorough clean-up of any spills is all that is necessary. This includes the day care worker or NICU nurse that feeds an infant expressed breast milk. Milk that must be discarded can be safely disposed of down a sink drain. [...] Consistent with CDC guidelines, it would be prudent for those with more broad and intensive exposure to human milk, such as research laboratory workers and milk bank processors, to follow precautions such as covering exposed wounds and wearing protective gloves. [...] Where the threat of AIDS exists, fear may quickly overtake reason. Therefore, it is important for the lactation consultant to not only understand the current recommendations, but also to be an advocate for reasonable safety guidelines that do not hinder our efforts to promote, protect, and support breastfeeding."	CDC 1988	Refer to latest DH and UK guidance also. Mainly related to maternal milk handling.

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Staff training	Opinion piece	Williams	2007	"Despite these observations many neonatal paediatricians continue to cite concerns about the use of donor breast milk when mother's own is not available. Doubts primarily relate to two things: the nutritional quality of donor milk and the possibility that a recipient infant may acquire infection."	Lucas 1984; Gross 1983	
Staff training	Service description	Asquith	1987	"The drivers too, are initially trained and are kept current on MMB policies by attendance at regular in-service seminars."		San Jose milk bank US
Staff training	Service description	Asquith	1987	"All paid and volunteer workers at the MMB are barred from activities with any active illness or open lesions, and must submit a written release from a physician before resuming work."		San Jose milk bank US
Staff training	Service description	Cash	1981	"Education of the perinatal nursing staff regarding the breast milk bank is part of the orientation program for new personnel. The collection and storage procedure and a demonstration of the Lloyd-B pump are included. In addition, the procedure for feeding banked breast milk is discussed with the nursing staff of the intensive care nursery."		EOPC milk bank US
Staff training	Service description	Cash	1981	"An educational program emphasizing quality control is presented to all transports."		EOPC milk bank US
Staff training	Service description	Cash	1981	"The coordinator also serves as an educational resource person for the nursing staff regarding new research on the role of breast milk for the neonate."		EOPC milk bank US
Staff training	Service description	Penc	1996	"Some physicians also resisted the use of donor milk, a controversy that continues to this day."		Polish Mother's Memorial Hospital milk bank Poland

KCQ	Study	Author	Year	Conclusions	Reference(s)	Notes
Staff training	Service description	Tully	2001	"The milk banking system is organized from the national to the local level, with a training course for milk bank personnel, a registry of all those who have been certified [...]. Federal regulation now requires that all milk bank directors be certified [...]"		Brazilian milk banks Brazil

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Appendix 6 Donor milk banking – principles of quality

These are based on two key European Union directives related to the quality assurance processes for human tissue and blood establishments. See details in the Appendix to this document.

1 INTRODUCTION AND GENERAL PRINCIPLES

1.1 *Quality system*

- 1.1.1 Quality shall be recognised as being the responsibility of all persons involved in the processes of the donor milk bank with management ensuring a systematic approach towards quality and the implementation and maintenance of a quality system.
- 1.1.2 The quality system encompasses quality management, quality assurance, continuous quality improvement, personnel, premises and equipment, documentation, collection, testing and processing, storage, distribution, quality control, batch recall, and external and internal auditing, non-conformance and self-inspection.
- 1.1.3 The quality system shall ensure that all critical processes are specified in appropriate instructions and are carried out in accordance with the standards and specifications set out in these principles. Management shall review the system at regular intervals to verify its effectiveness and introduce corrective measures if deemed necessary.

1.2 *Quality assurance*

- 1.2.1 All donor milk banks shall be supported by a quality assurance function, whether internal or related, in fulfilling quality assurance. That function shall be involved in all quality-related matters and review and approve all appropriate quality related documents.
- 1.2.2 All procedures, premises, and equipment that have an influence on the quality and safety of donor milk shall be validated prior to

introduction and be re-validated at regular intervals determined as a result of these activities.

2 PERSONNEL AND ORGANISATION

- 2.1.1 A responsible person must be appointed having appropriate qualifications and responsibilities for quality as outlined below.
- 2.1.2 A donor milk bank must have an organisational structure and operational procedures appropriate to their activities; there must be an organisational chart which clearly defines accountability and reporting relationships.
- 2.1.3 Every donor milk bank must have access to a nominated medical registered practitioner to advise on and oversee the establishment's medical activities such as donor selection, review of outcomes of recipients or interaction as appropriate with clinical users.
- 2.1.4 Personnel in donor milk banks shall be available in sufficient numbers to carry out the activities related to the collection, testing, processing, storage and distribution of donor milk and be trained and assessed to be competent to perform their tasks.
- 2.1.5 All personnel in donor milk banks shall have up to date job descriptions which clearly set out their tasks and responsibilities. Donor milk banks shall assign the responsibility for processing management and quality assurance to different individuals and who function independently.
- 2.1.6 All personnel in donor milk banks shall receive initial and continued training appropriate to their specific tasks. Training records shall be maintained. Training programmes shall be in place and shall include good practice. The training programme must ensure and document that each individual:

- has demonstrated competence in the performance of their designated tasks;
- has an adequate knowledge and understanding of the scientific/technical processes and principles relevant to their designated tasks;
- understands the organisational framework, quality system and health and safety rules of the establishment in which they work, and
- is adequately informed of the broader ethical, legal and regulatory context of their work.

- 2.1.7 The contents of training programmes shall be periodically assessed and the competence of personnel evaluated regularly.
- 2.1.8 There shall be written safety and hygiene instructions in place adapted to the activities to be carried out and are in compliance with local policies.

3 PREMISES

3.1 *General*

- 3.1.1 Premises, including any designated collection facilities, shall be adapted and maintained to suit the activities to be carried out. They shall enable the work to proceed in a logical sequence so as to minimise the risk of errors, and shall allow for effective cleaning and maintenance in order to minimise the risk of contamination.

3.2 *Donor milk bank*

- 3.2.1 There shall be an area for confidential personal interviews with and assessment of individuals to assess their eligibility to donate. This area shall be separated from all processing areas.

3.3 *Donor milk testing and processing areas*

- 3.3.1 There shall be a dedicated laboratory area for testing that is separate from the donor milk processing area with access restricted to authorised personnel.

3.4 *Storage area*

- 3.4.1 Storage areas shall provide for properly secure and segregated storage of different categories of donor milk including quarantine and released materials.
- 3.4.2 Provisions shall be in place in the event of equipment or power failure in the main storage facility.

3.5 *Waste disposal area*

- 3.5.1 An area shall be designated for the safe disposal of waste, disposable items used during the collection, testing, and processing and for rejected donor milk.

4 EQUIPMENT AND MATERIALS

- 4.1.1 All equipment shall be validated, calibrated and maintained to suit its intended purpose. Operating instructions shall be available and appropriate records kept.
- 4.1.2 Equipment shall be selected to minimise any hazard to donors, personnel, or donor milk.
- 4.1.3 All critical equipment and technical devices must be identified and validated, regularly inspected and preventively maintained in accordance with the manufacturers' instructions. Where equipment or materials affect critical processing or storage parameters (e.g. temperature, microbial contamination levels), they must be identified and must be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects and to ensure that the critical parameters are maintained within acceptable limits at all times. All equipment with a critical measuring function must be calibrated against a traceable standard if available.
- 4.1.4 New and repaired equipment must be tested when installed and must be validated before use. Test results must be documented.
- 4.1.5 Maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment must be performed regularly and recorded accordingly.
- 4.1.6 Procedures for the operation of each piece of critical equipment, detailing the action to be taken in the event of malfunctions or failure, must be available.

- 4.1.7 Inventory records shall be retained for a period acceptable to and agreed with the competent authority.
- 4.1.8 When computerised systems are used, software, hardware and back-up procedures must be checked regularly to ensure reliability, be validated before use, and be maintained in a validated state. Hardware and software shall be protected against unauthorised use or unauthorised changes. The back-up procedure shall prevent loss of or damage to data at expected and unexpected down times or function failures.

5 DOCUMENTATION

- 5.1.1 Documents setting out specifications, procedures and records covering each activity performed by the donor milk bank shall be in place and kept up to date.
- 5.1.2 A document control procedure must be established to provide for the history of document reviews and changes and to ensure that only current versions of documents are in use.
- 5.1.3 Records shall be legible and may be handwritten, transferred to another medium such as microfilm or documented in a computerised system.
- 5.1.4 All records, including raw data, which are critical to the safety and quality of the donor milk shall be kept so as to ensure access to these data for at least 10 years after expiry date, use or disposal.
- 5.1.5 All significant changes to documents shall be acted upon promptly and shall be reviewed, dated and signed by a person authorised to perform this task.

6 DONOR MILK COLLECTION, TESTING AND PROCESSING

6.1 *Donor eligibility*

- 6.1.1 Procedures for safe donor identification, suitability interview and eligibility assessment shall be implemented and maintained. They shall take place before each donation and comply with the requirements set out in the NICE guidelines.
- 6.1.2 The donor interview shall be conducted in such a way as to ensure confidentiality.
- 6.1.3 The donor suitability records and final assessment shall be signed by a qualified health professional.

6.2 *Collection of donor milk*

- 6.2.1 The donor milk collection procedure shall be designed to ensure that the identity of the donor is verified and securely recorded and that the link between the donor and the donated milk is clearly established.
- 6.2.2 The containers used for the collection of donor milk and their processing shall be CE-marked. The batch number of the donor milk shall be traceable.
- 6.2.3 Donor milk handling procedures shall minimise the risk of microbial contamination.
- 6.2.4 Laboratory samples shall be taken at the time of donation and appropriately stored prior to testing.
- 6.2.5 The procedure used for the labelling of records, donor milk samples and batches, and laboratory samples with donation numbers shall be designed to avoid any risk of identification error and mix-up.
- 6.2.6 After milk collection, the containers shall be handled in a way that maintains the quality of the donor milk and at a storage and transport temperature appropriate to further processing requirements.

- 6.2.7 There shall be a system in place to ensure that each donation can be linked to the collection and processing system into which it was collected and/or processed.

6.3 *Laboratory testing*

- 6.3.1 All laboratory testing procedures shall be validated before use.
- 6.3.2 Each donation shall be tested in conformity with the requirements laid down in the NICE guidelines on the operation of donor milk banks.
- 6.3.3 There shall be clearly defined procedures to resolve discrepant results and ensure that donor milk samples from donors who have a repeatedly reactive result in a serological screening test for infection with the viruses mentioned in the NICE guidelines shall be excluded from therapeutic use and be disposed of. Appropriate confirmatory serological testing shall take place. In case of confirmed positive results, appropriate donor management shall take place including the provision of information to the donor and follow-up procedures.
- 6.3.4 There shall be data confirming the suitability of any laboratory reagents used in the testing of donor blood samples.
- 6.3.5 The quality of the laboratory testing shall be regularly assessed by the participation in a formal system of proficiency testing, such as an external quality assurance programme.
- 6.3.6 Blood group serology testing shall include procedures for testing specific groups of donors (e.g. those assessed as being at a higher risk).

6.4 *Processing and validation*

- 6.4.1 All equipment and technical devices shall be used in accordance with validated procedures.

- 6.4.2 The processing of donor milk shall be carried out using appropriate and validated procedures including measures to avoid the risk of contamination and microbial growth in the prepared batches.

6.5 *Labelling*

- 6.5.1 At all stages, all containers shall be labelled with relevant information of their identity. In the absence of a validated computerised system for status control, the labelling shall clearly distinguish released from non-released batches of donor milk.
- 6.5.2 The labelling system for the collected donor milk, intermediate and finished batches must unmistakably identify the type of content, and comply with the labelling and traceability requirements defined in the NICE guidelines.

6.6 *Release of donor milk*

- 6.6.1 There shall be a safe and secure system to prevent each batch of donor milk from being released until all mandatory requirements set out in the NICE guidelines have been fulfilled. Each donor milk bank shall be able to demonstrate that each batch has been formally released by an authorised person. Records shall demonstrate that before a batch of donor milk is released, all current declaration forms, relevant medical records and test results meet all acceptance criteria.
- 6.6.2 Before release, donor milk shall be kept administratively and physically segregated from released donor milk. In the absence of a validated computerised system for status control the label of either the sample or batch shall identify the release status in accordance with 6.5.1.
- 6.6.3 In the event that the final batch fails release due to a confirmed positive infection test result, in conformity with the requirements set out in Section 6.3.2 and 6.3.3, a check shall be made to ensure that other samples from the same donation and batches prepared from

previous donations given by the donor are identified. There shall be an immediate update of the donor record.

7 STORAGE AND DISTRIBUTION

7.1 General

- 7.1.1 The quality system of the donor milk bank shall ensure that storage and distribution requirements shall comply with the NICE guidelines.
- 7.1.2 Maximum storage time must be specified for each type of storage condition. The selected period must reflect among others possible deterioration of the donor milk and its component properties.
- 7.1.3 Critical transport conditions, such as temperature and time limit must be defined to maintain the required properties.
- 7.1.4 The container/package must be secure and ensure that the donor milk is maintained in the specified conditions. All containers and packages need to be validated as fit for purpose.
- 7.1.5 Where distribution is carried out by a contracted third party, a documented agreement must be in place to ensure that the required conditions are maintained.
- 7.1.6 Procedures for storage and distribution shall be validated to ensure donor milk quality during the entire storage period and to exclude mix-ups of milk from different donors. All transportation and storage actions, including receipt and distribution, shall be defined by written procedures and specifications.
- 7.1.7 Appropriate records of inventory and distribution shall be kept.
- 7.1.8 Packaging shall maintain the integrity and storage temperature of donor milk during distribution and transportation.

7.2 Final labelling for distribution

7.2.1 The primary donor milk container must provide:

- type of donor milk (if appropriate), identification number or code of the sample, and lot or batch number where applicable;
- identification of the donor milk bank;
- expiry date;
- when donor milk is known to be positive for a relevant infectious disease marker, it must be marked as: BIOLOGICAL HAZARD.

If any of the information above cannot be included on the primary container label, it must be provided on a separate sheet accompanying the primary container. This sheet must be packaged with the primary container in a manner that ensures that they remain together.

7.2.2 The following information must be provided either on the label or in accompanying documentation:

- date of distribution of the donor milk;
- biological determinations carried out on the donor and results;
- storage recommendations;
- instructions for opening the container, package, and any required manipulation/reconstitution;
- expiry dates after opening/manipulation;
- instructions for reporting serious adverse reactions and/or events as set out above.

7.3 *External labelling of the shipping container*

7.3.1 For transport, the primary container must be placed in a shipping container that must be labelled with at least the following information:

- identification of the originating donor milk bank, including an address and phone number;

- identification of the receiving organisation, including address and phone number;
- a statement that the package contains human donor milk and HANDLE WITH CARE;
- recommended transport conditions (e.g. keep cool, in upright position, etc.);
- safety instructions/method of cooling (when applicable).

8 CONTRACT MANAGEMENT

- 8.1.1 Tasks that are performed externally shall be defined in a specific written contract.

9 NON-CONFORMANCE

9.1 *Deviations*

- 9.1.1 Donor milk deviating from required standards set out in the NICE guidelines shall be released for use only in exceptional circumstances and with the recorded agreement of the prescribing physician and the donor milk bank manager.

9.2 *Complaints*

- 9.2.1 All complaints and other information, including serious adverse reactions and serious adverse events, which may suggest that defective donor milk batches have been issued, shall be documented, carefully investigated for causative factors of the defect and, where necessary, followed by recall and the implementation of corrective actions to prevent recurrence. Procedures shall be in place to ensure that the competent authorities are notified as appropriate of serious adverse reactions or serious adverse events in accordance with regulatory requirements.

9.3 *Recall*

- 9.3.1 There shall be personnel authorised within the donor milk bank to assess the need for batch recall and to initiate and coordinate the necessary actions.
- 9.3.2 An effective recall procedure shall be in place, including a description of the responsibilities and actions to be taken. This shall include notification to the competent authority.

- 9.3.3 Actions shall be taken within pre-defined periods of time and shall include tracing all relevant batches and, where applicable, shall include trace-back. The purpose of the investigation is to identify any donor who might have contributed to causing the recipient reaction and to retrieve available samples or batches from that donor, as well as to notify consignees and recipients of milk collected from the same donor in the event that they might have been put at risk.

9.4 *Corrective and preventive actions*

- 9.4.1 A system to ensure corrective and preventive actions on donor milk non-conformity and quality problems shall be in place.
- 9.4.2 Data shall be routinely analysed to identify quality problems that may require corrective action or to identify unfavourable trends that may require preventive action.
- 9.4.3 All errors and accidents shall be documented and investigated in order to identify system problems for correction.

10 SELF-INSPECTION, AUDITS AND IMPROVEMENTS

- 10.1.1 Self-inspection or audit systems shall be in place for all parts of the operations to verify compliance with the standards set out in the NICE guidelines. They shall be carried out regularly by trained and competent persons in an independent way according to approved procedures.
- 10.1.2 All results shall be documented and appropriate corrective and preventive actions shall be taken.

Appendix

10.2 *Directive 2006/86/EC of 24 October 2006 'implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells'. OJ, 25.10.2006*

ANNEX I

Requirements for accreditation, designation, authorisation or licensing of tissue establishments as referred to in Article 3

A. ORGANISATION AND MANAGEMENT

1. A responsible person must be appointed having qualifications and responsibilities as provided in Article 17 of Directive 2004/23/EC.
2. A tissue establishment must have an organisational structure and operational procedures appropriate to the activities for which accreditation/designation/authorisation/licensing is sought; there must be an organisational chart which clearly defines accountability and reporting relationships.
3. Every tissue establishment must have access to a nominated medical registered practitioner to advise on and oversee the establishment's medical activities such as donor selection, review of clinical outcomes of applied tissues and cells or interaction as appropriate with clinical users.
4. There must be a documented quality management system applied to the activities for which accreditation/designation/authorisation or licensing is sought, in accordance with the standards laid down in this Directive.

5. It must be ensured that the risks inherent in the use and handling of biological material are identified and minimised, consistent with maintaining adequate quality and safety for the intended purpose of the tissues and cells. The risks include those relating in particular to the procedures, environment, staff health status specific to the tissue establishment.
6. Agreements between tissue establishments and third parties must comply with Article 24 of Directive 2004/23/EC. Third party agreements must specify the terms of the relationship and responsibilities as well as the protocols to be followed to meet the required performance specification.
7. There must be a documented system in place, supervised by the responsible person, for ratifying that tissues and/or cells meet appropriate specifications for safety and quality for release and for their distribution.
8. In the event of termination of activities the agreements concluded and the procedures adopted in accordance with Article 21(5) of Directive 2004/23/EC shall include traceability data and material concerning the quality and safety of cells and tissues.
9. There must be a documented system in place that ensures the identification of every unit of tissue or cells at all stages of the activities for which accreditation/designation/authorisation/licensing is sought.

B. PERSONNEL

1. The personnel in tissue establishments must be available in sufficient number and be qualified for the tasks they perform. The competency of the personnel must be evaluated at appropriate intervals specified in the quality system.
2. All personnel should have clear, documented and up-to-date job descriptions. Their tasks, responsibilities and accountability must be clearly documented and understood.
3. Personnel must be provided with initial/basic training, updated training as required when procedures change or scientific knowledge develops and

adequate opportunities for relevant professional development. The training programme must ensure and document that each individual:

- (a) has demonstrated competence in the performance of their designated tasks;
- (b) has an adequate knowledge and understanding of the scientific/technical processes and principles relevant to their designated tasks;
- (c) understands the organisational framework, quality system and health and safety rules of the establishment in which they work, and
- (d) is adequately informed of the broader ethical, legal and regulatory context of their work.

C. EQUIPMENT AND MATERIALS

1. All equipment and material must be designed and maintained to suit its intended purpose and must minimise any hazard to recipients and/or staff.
2. All critical equipment and technical devices must be identified and validated, regularly inspected and preventively maintained in accordance with the manufacturers' instructions. Where equipment or materials affect critical processing or storage parameters (e.g. temperature, pressure, particle counts, microbial contamination levels), they must be identified and must be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects and to ensure that the critical parameters are maintained within acceptable limits at all times. All equipment with a critical measuring function must be calibrated against a traceable standard if available.
3. New and repaired equipment must be tested when installed and must be validated before use. Test results must be documented.
4. Maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment must be performed regularly and recorded accordingly.

5. Procedures for the operation of each piece of critical equipment, detailing the action to be taken in the event of malfunctions or failure, must be available.

6. The procedures for the activities for which accreditation/designation/authorisation/licensing is sought, must detail the specifications for all critical materials and reagents. In particular, specifications for additives (e.g. solutions) and packaging materials must be defined. Critical reagents and materials must meet documented requirements and specifications and when applicable the requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [1] and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices [2].

D. FACILITIES/PREMISES

1. A tissue establishment must have suitable facilities to carry out the activities for which accreditation/designation/authorisation or licensing is sought, in accordance with the standards laid down in this Directive.

2. When these activities include processing of tissues and cells while exposed to the environment, this must take place in an environment with specified air quality and cleanliness in order to minimise the risk of contamination, including cross-contamination between donations. The effectiveness of these measures must be validated and monitored.

3. Unless otherwise specified in point 4, where tissues or cells are exposed to the environment during processing, without a subsequent microbial inactivation process, an air quality with particle counts and microbial colony counts equivalent to those of Grade A as defined in the current European Guide to Good Manufacturing Practice (GMP), Annex 1 and Directive 2003/94/EC is required with a background environment appropriate for the processing of the tissue/cell concerned but at least equivalent to GMP Grade D in terms of particles and microbial counts.

4. A less stringent environment than specified in point 3 may be acceptable where:

(a) a validated microbial inactivation or validated terminal sterilisation process is applied;

(b) or, where it is demonstrated that exposure in a Grade A environment has a detrimental effect on the required properties of the tissue or cell concerned;

(c) or, where it is demonstrated that the mode and route of application of the tissue or cell to the recipient implies a significantly lower risk of transmitting bacterial or fungal infection to the recipient than with cell and tissue transplantation;

(d) or, where it is not technically possible to carry out the required process in a Grade A environment (for example, due to requirements for specific equipment in the processing area that is not fully compatible with Grade A).

5. In point 4(a), (b), (c) and (d), an environment must be specified. It must be demonstrated and documented that the chosen environment achieves the quality and safety required, at least taking into account the intended purpose, mode of application and immune status of the recipient. Appropriate garments and equipment for personal protection and hygiene must be provided in each relevant department of the tissue establishment along with written hygiene and gowning instructions.

6. When the activities for which accreditation/designation/authorisation or licensing is sought involve storage of tissues and cells, the storage conditions necessary to maintain the required tissue and cell properties, including relevant parameters such as temperature, humidity or air quality must be defined.

7. Critical parameters (e.g. temperature, humidity, air quality) must be controlled, monitored, and recorded to demonstrate compliance with the specified storage conditions.

8. Storage facilities must be provided that clearly separate and distinguish tissues and cells prior to release/in quarantine from those that are released and from those that are rejected, in order to prevent mix-up and cross-

contamination between them. Physically separate areas or storage devices or secured segregation within the device must be allocated in both quarantine and released storage locations for holding certain tissue and cells collected in compliance with special criteria.

9. The tissue establishment must have written policies and procedures for controlled access, cleaning and maintenance, waste disposal and for the re-provision of services in an emergency situation.

E. DOCUMENTATION AND RECORDS

1. There must be a system in place that results in clearly defined and effective documentation, correct records and registers and authorised Standard Operating Procedures (SOPs), for the activities for which accreditation/designation/authorisation/licensing is sought. Documents must be regularly reviewed and must conform to the standards laid down in this Directive. The system must ensure that work performed is standardised, and that all steps are traceable; i.e. coding, donor eligibility, procurement, processing, preservation, storage, transport, distribution or disposal, including aspects relating to quality control and quality assurance.

2. For every critical activity, the materials, equipment and personnel involved must be identified and documented.

3. In the tissue establishments all changes to documents must be reviewed, dated, approved, documented and implemented promptly by authorised personnel.

4. A document control procedure must be established to provide for the history of document reviews and changes and to ensure that only current versions of documents are in use.

5. Records must be shown to be reliable and a true representation of the results.

6. Records must be legible and indelible and may be handwritten or transferred to another validated system, such as a computer or microfilm.

7. Without prejudice to Article 9(2), all records, including raw data, which are critical to the safety and quality of the tissues and cells shall be kept so as to ensure access to these data for at least 10 years after expiry date, clinical use or disposal.

8. Records must meet the confidentiality requirements laid down in Article 14 of Directive 2004/23/EC. Access to registers and data must be restricted to persons authorised by the responsible person, and to the competent authority for the purpose of inspection and control measures.

F. QUALITY REVIEW

1. An audit system must be in place for the activities for which accreditation/designation/authorisation/licensing is sought. Trained and competent persons must conduct the audit in an independent way, at least every two years, in order to verify compliance with the approved protocols and the regulatory requirements. Findings and corrective actions must be documented.

2. Deviations from the required standards of quality and safety must lead to documented investigations, which include a decision on possible corrective and preventive actions. The fate of non-conforming tissues and cells must be decided in accordance with written procedures supervised by the responsible person and recorded. All affected tissues and cells must be identified and accounted for.

3. Corrective actions must be documented, initiated and completed in a timely and effective manner. Preventive and corrective actions should be assessed for effectiveness after implementation.

4. The tissue establishment should have processes in place for review of the performance of the quality management system to ensure continuous and systematic improvement.

ANNEX II

Requirements for the authorisation of tissue and cell preparation processes at the tissue establishments as referred to in Article 4

The competent authority shall authorise each tissue and cell preparation process after evaluation of the donor selection criteria and procurement procedures, the protocols for each step of the process, the quality management criteria, and the final quantitative and qualitative criteria for cells and tissues. This evaluation must comply at least with the requirements set out in this Annex.

A. RECEPTION AT THE TISSUE ESTABLISHMENT

Upon reception of procured tissues and cells at the tissue establishment, the tissues and cells must comply with the requirements defined in Directive 2006/17/EC.

B. PROCESSING

When the activities for which the accreditation/designation/authorisation/licensing is sought include processing of tissues and cells, the tissue establishment procedures must comply with the following criteria:

1. The critical processing procedures must be validated and must not render the tissues or cells clinically ineffective or harmful to the recipient. This validation may be based on studies performed by the establishment itself, or on data from published studies or, for well established processing procedures, by retrospective evaluation of the clinical results for tissues supplied by the establishment.
2. It has to be demonstrated that the validated process can be carried out consistently and effectively in the tissue establishment environment by the staff.
3. The procedures must be documented in SOPs which must conform to the validated method and to the standards laid down in this Directive, accordingly with Annex I(E), points 1 to 4.
4. It must be ensured that all processes are conducted in accordance with the approved SOPs.

5. Where a microbial inactivation procedure is applied to the tissue or cells, it must be specified, documented, and validated.

6. Before implementing any significant change in processing, the modified process must be validated and documented.

7. The processing procedures must undergo regular critical evaluation to ensure that they continue to achieve the intended results.

8. Procedures for discarding tissue and cells must prevent the contamination of other donations and products, the processing environment or personnel. These procedures must comply with national regulations.

C. STORAGE AND RELEASE OF PRODUCTS

When the activities for which the accreditation/designation/authorisation/licensing is sought include storage and release of tissues and cells, the authorised tissue establishment procedures must comply with the following criteria:

1. Maximum storage time must be specified for each type of storage condition. The selected period must reflect among others possible deterioration of the required tissue and cell properties.

2. There must be a system of inventory hold for tissues and/or cells to ensure that they cannot be released until all requirements laid down in this Directive have been satisfied. There must be a standard operating procedure that details the circumstances, responsibilities and procedures for the release of tissues and cells for distribution.

3. A system for identification of tissues and cells throughout any phase of processing in the tissue establishment must clearly distinguish released from non-released (quarantined) and discarded products.

4. Records must demonstrate that before tissues and cells are released all appropriate specifications are met, in particular all current declaration forms, relevant medical records, processing records and test results have been verified according to a written procedure by a person authorised for this task

by the responsible person as specified in Article 17 of Directive 2004/23/EC. If a computer is used to release results from the laboratory, an audit trail should indicate who was responsible for their release.

5. A documented risk assessment approved by the responsible person as defined in Article 17 of Directive 2004/23/EC must be undertaken to determine the fate of all stored tissues and cells following the introduction of any new donor selection or testing criterion or any significantly modified processing step that enhances safety or quality.

D. DISTRIBUTION AND RECALL

When the activities for which the accreditation/designation/authorisation/licensing is sought include distribution of tissues and cells, the authorised tissue establishment procedures must comply with the following criteria:

1. Critical transport conditions, such as temperature and time limit must be defined to maintain the required tissue and cell properties.
2. The container/package must be secure and ensure that the tissue and cells are maintained in the specified conditions. All containers and packages need to be validated as fit for purpose.
3. Where distribution is carried out by a contracted third party, a documented agreement must be in place to ensure that the required conditions are maintained.
4. There must be personnel authorised within the tissue establishment to assess the need for recall and to initiate and coordinate the necessary actions.
5. An effective recall procedure must be in place, including a description of the responsibilities and actions to be taken. This must include notification to the competent authority.
6. Actions must be taken within pre-defined periods of time and must include tracing all relevant tissues and cells and, where applicable, must include

trace-back. The purpose of the investigation is to identify any donor who might have contributed to causing the reaction in the recipient and to retrieve available tissues and cells from that donor, as well as to notify consignees and recipients of tissues and cells procured from the same donor in the event that they might have been put at risk.

7. Procedures must be in place for the handling of requests for tissues and cells. The rules for allocation of tissues and cells to certain patients or health care institutions must be documented and made available to these parties upon request.

8. A documented system must be in place for the handling of returned products including criteria for their acceptance into the inventory, if applicable.

E. FINAL LABELLING FOR DISTRIBUTION

1. The primary tissue/cell container must provide:

(a) type of tissues and cells, identification number or code of the tissue/cells, and lot or batch number where applicable;

(b) identification of the tissue establishment;

(c) expiry date;

(d) in the case of autologous donation, this has to be specified (for autologous use only) and the donor/recipient has to be identified;

(e) in the case of directed donations - the label must identify the intended recipient;

(f) when tissues and cells are known to be positive for a relevant infectious disease marker, it must be marked as: BIOLOGICAL HAZARD.

If any of the information under points (d) and (e) above cannot be included on the primary container label, it must be provided on a separate sheet accompanying the primary container. This sheet must be packaged with the primary container in a manner that ensures that they remain together.

2. The following information must be provided either on the label or in accompanying documentation:

- (a) description (definition) and, if relevant, dimensions of the tissue or cell product;
- (b) morphology and functional data where relevant;
- (c) date of distribution of the tissue/cells;
- (d) biological determinations carried out on the donor and results;
- (e) storage recommendations;
- (f) instructions for opening the container, package, and any required manipulation/reconstitution;
- (g) expiry dates after opening/manipulation;
- (h) instructions for reporting serious adverse reactions and/or events as set out in Articles 5 to 6;
- (i) presence of potential harmful residues (e.g. antibiotics, ethylene oxide etc).

F. EXTERNAL LABELLING OF THE SHIPPING CONTAINER

For transport, the primary container must be placed in a shipping container that must be labelled with at least the following information:

- (a) identification of the originating tissue establishment, including an address and phone number;
- (b) identification of the organisation responsible for human application of destination, including address and phone number;
- (c) a statement that the package contains human tissue/cells and **HANDLE WITH CARE**;

(d) where living cells are required for the function of the graft, such as stem cells gametes and embryos, the following must be added: "DO NOT IRRADIATE";

(e) recommended transport conditions (e.g. keep cool, in upright position, etc.);

(f) safety instructions/method of cooling (when applicable).

**10.3 *COMMISSION DIRECTIVE 2005/62/EC of 30
September 2005 implementing Directive 2002/98/EC
of the European Parliament and of the Council as
regards Community standards and specifications
relating to a quality system for blood establishments***

1. INTRODUCTION AND GENERAL PRINCIPLES

1.1. Quality system

- 1 Quality shall be recognised as being the responsibility of all persons involved in the processes of the blood establishment with management ensuring a systematic approach towards quality and the implementation and maintenance of a quality system.
- 2 The quality system encompasses quality management, quality assurance, continuous quality improvement, personnel, premises and equipment, documentation, collection, testing and processing, storage, distribution, quality control, blood component recall, and external and internal auditing, contract management, non-conformance and self-inspection.
- 3 The quality system shall ensure that all critical processes are specified in appropriate instructions and are carried out in accordance with the standards and specifications set out in this Annex. Management shall review the system at regular intervals to verify its effectiveness and introduce corrective measures if deemed necessary.

1.2. Quality assurance

- 1 All blood establishments and hospital blood banks shall be supported by a quality assurance function, whether internal or related, in fulfilling quality assurance. That function shall be involved in all quality-related matters and review and approve all appropriate quality related documents.
- 2 All procedures, premises, and equipment that have an influence on the quality and safety of blood and blood components shall be validated prior to

introduction and be re-validated at regular intervals determined as a result of these activities.

2. PERSONNEL AND ORGANISATION

1 Personnel in blood establishments shall be available in sufficient numbers to carry out the activities related to the collection, testing, processing, storage and distribution of blood and blood components and be trained and assessed to be competent to perform their tasks.

2 All personnel in blood establishments shall have up to date job descriptions which clearly set out their tasks and responsibilities. Blood establishments shall assign the responsibility for processing management and quality assurance to different individuals and who function independently.

3 All personnel in blood establishments shall receive initial and continued training appropriate to their specific tasks. Training records shall be maintained. Training programmes shall be in place and shall include good practice.

4 The contents of training programmes shall be periodically assessed and the competence of personnel evaluated regularly.

5 There shall be written safety and hygiene instructions in place adapted to the activities to be carried out and are in compliance with Council Directive 89/391/EEC ⁽⁴⁾ and Directive 2000/54/EC of the European Parliament and of the Council ⁽⁵⁾.

3. PREMISES

3.1. General

Premises including mobile sites shall be adapted and maintained to suit the activities to be carried out. They shall enable the work to proceed in a logical sequence so as to minimise the risk of errors, and shall allow for effective cleaning and maintenance in order to minimise the risk of contamination.

3.2. Blood donor area

There shall be an area for confidential personal interviews with and assessment of individuals to assess their eligibility to donate. This area shall be separated from all processing areas.

3.3. Blood collection area

Blood collection shall be carried out in an area intended for the safe withdrawal of blood from donors, appropriately equipped for the initial treatment of donors experiencing adverse reactions or injuries from events associated with blood donation, and organised in such a way as to ensure the safety of both donors and personnel as well as to avoid errors in the collection procedure.

3.4. Blood testing and processing areas

There shall be a dedicated laboratory area for testing that is separate from the blood donor and blood component processing area with access restricted to authorised personnel.

3.5. Storage area

- 1 Storage areas shall provide for properly secure and segregated storage of different categories of blood and blood components and materials including quarantine and released materials and units of blood or blood components collected under special criteria (e.g. autologous donation).
- 2 Provisions shall be in place in the event of equipment or power failure in the main storage facility.

3.6. Waste disposal area

An area shall be designated for the safe disposal of waste, disposable items used during the collection, testing, and processing and for rejected blood or blood components.

4. EQUIPMENT AND MATERIALS

- 1 All equipment shall be validated, calibrated and maintained to suit its intended purpose. Operating instructions shall be available and appropriate records kept.
- 2 Equipment shall be selected to minimise any hazard to donors, personnel, or blood components.
- 3 Only reagents and materials from approved suppliers that meet the documented requirements and specifications shall be used. Critical materials shall be released by a person qualified to perform this task. Where relevant, materials, reagents and equipment shall meet the requirements of Council Directive 93/42/EEC ⁽¹⁾ for medical devices and Directive 98/79/EC of the European Parliament and of the Council ⁽²⁾ for in vitro diagnostic medical devices or comply with equivalent standards in the case of collection in third countries.
- 4 Inventory records shall be retained for a period acceptable to and agreed with the competent authority.
- 5 When computerised systems are used, software, hardware and back-up procedures must be checked regularly to ensure reliability, be validated before use, and be maintained in a validated state. Hardware and software shall be protected against unauthorised use or unauthorised changes. The back-up procedure shall prevent loss of or damage to data at expected and unexpected down times or function failures.

5. DOCUMENTATION

- 1 Documents setting out specifications, procedures and records covering each activity performed by the blood establishment shall be in place and kept up to date.
- 2 Records shall be legible and may be handwritten, transferred to another medium such as microfilm or documented in a computerised system.

3 All significant changes to documents shall be acted upon promptly and shall be reviewed, dated and signed by a person authorised to perform this task.

6. BLOOD COLLECTION, TESTING AND PROCESSING

6.1. Donor eligibility

1 Procedures for safe donor identification, suitability interview and eligibility assessment shall be implemented and maintained. They shall take place before each donation and comply with the requirements set out in Annex II and Annex III to Directive 2004/33/EC.

2 The donor interview shall be conducted in such a way as to ensure confidentiality.

3 The donor suitability records and final assessment shall be signed by a qualified health professional.

6.2. Collection of blood and blood components

1 The blood collection procedure shall be designed to ensure that the identity of the donor is verified and securely recorded and that the link between the donor and the blood, blood components and blood samples is clearly established.

2 The sterile blood bag systems used for the collection of blood and blood components and their processing shall be CE-marked or comply with equivalent standards if the blood and blood components are collected in third countries. The batch number of the blood bag shall be traceable for each blood component.

3 Blood collection procedures shall minimise the risk of microbial contamination.

4 Laboratory samples shall be taken at the time of donation and appropriately stored prior to testing.

5 The procedure used for the labelling of records, blood bags and laboratory samples with donation numbers shall be designed to avoid any risk of identification error and mix-up.

6 After blood collection, the blood bags shall be handled in a way that maintains the quality of the blood and at a storage and transport temperature appropriate to further processing requirements.

There shall be a system in place to ensure that each donation can be linked to the collection and processing system into which it was collected and/or processed.

6.3. Laboratory testing

1 All laboratory testing procedures shall be validated before use.

2 Each donation shall be tested in conformity with the requirements laid down in Annex IV to Directive 2002/98/EC.

3 There shall be clearly defined procedures to resolve discrepant results and ensure that blood and blood components that have a repeatedly reactive result in a serological screening test for infection with the viruses mentioned in Annex IV to Directive 2002/98/EC shall be excluded from therapeutic use and be stored separately in a dedicated environment. Appropriate confirmatory testing shall take place. In case of confirmed positive results, appropriate donor management shall take place including the provision of information to the donor and follow-up procedures.

4 There shall be data confirming the suitability of any laboratory reagents used in the testing of donor samples and blood component samples.

5 The quality of the laboratory testing shall be regularly assessed by the participation in a formal system of proficiency testing, such as an external quality assurance programme.

6 Blood group serology testing shall include procedures for testing specific groups of donors (e.g. first time donors, donors with a history of transfusion).

6.4. Processing and validation

- 1 All equipment and technical devices shall be used in accordance with validated procedures.
- 2 The processing of blood components shall be carried out using appropriate and validated procedures including measures to avoid the risk of contamination and microbial growth in the prepared blood components.

6.5. Labelling

- 1 At all stages, all containers shall be labelled with relevant information of their identity. In the absence of a validated computerised system for status control, the labelling shall clearly distinguish released from non-released units of blood and blood components.
- 2 The labelling system for the collected blood, intermediate and finished blood components and samples must unmistakably identify the type of content, and comply with the labelling and traceability requirements referred to in Article 14 of Directive 2002/98/EC and Commission Directive 2005/61/EC (1). The label for a final blood component shall comply with the requirements of Annex III to Directive 2002/98/EC.
- 3 For autologous blood and blood components, the label also shall comply with Article 7 of Directive 2004/33/EC and the additional requirements for autologous donations specified in Annex IV to that Directive.

6.6. Release of blood and blood components

- 1 There shall be a safe and secure system to prevent each single blood and blood component from being released until all mandatory requirements set out in this Directive have been fulfilled. Each blood establishment shall be able to demonstrate that each blood or blood component has been formally released by an authorised person. Records shall demonstrate that before a blood component is released, all current declaration forms, relevant medical records and test results meet all acceptance criteria.
- 2 Before release, blood and blood components shall be kept administratively and physically segregated from released blood and blood components. In the

absence of a validated computerised system for status control the label of a unit of blood or blood component shall identify the release status in accordance with 6.5.1.

3 In the event that the final component fails release due to a confirmed positive infection test result, in conformity with the requirements set out in Section 6.3.2 and 6.3.3, a check shall be made to ensure that other components from the same donation and components prepared from previous donations given by the donor are identified. There shall be an immediate update of the donor record.

7. STORAGE AND DISTRIBUTION

1 The quality system of the blood establishment shall ensure that, for blood and blood components intended for the manufacture of medicinal products, the storage and distribution requirements shall comply with Directive 2003/94/EC.

2 Procedures for storage and distribution shall be validated to ensure blood and blood component quality during the entire storage period and to exclude mix-ups of blood components. All transportation and storage actions, including receipt and distribution, shall be defined by written procedures and specifications.

3 Autologous blood and blood components as well as blood components collected and prepared for specific purposes shall be stored separately.

4 Appropriate records of inventory and distribution shall be kept.

5 Packaging shall maintain the integrity and storage temperature of blood or blood components during distribution and transportation.

6 Return of blood and blood components into inventory for subsequent reissue shall only be accepted when all quality requirements and procedures laid down by the blood establishment to ensure blood component integrity are fulfilled.

8. CONTRACT MANAGEMENT

Tasks that are performed externally shall be defined in a specific written contract.

9. NON-CONFORMANCE

9.1. Deviations

Blood components deviating from required standards set out in Annex V to Directive 2004/33/EC shall be released for transfusion only in exceptional circumstances and with the recorded agreement of the prescribing physician and the blood establishment physician.

9.2. Complaints

All complaints and other information, including serious adverse reactions and serious adverse events, which may suggest that defective blood components have been issued, shall be documented, carefully investigated for causative factors of the defect and, where necessary, followed by recall and the implementation of corrective actions to prevent recurrence. Procedures shall be in place to ensure that the competent authorities are notified as appropriate of serious adverse reactions or serious adverse events in accordance with regulatory requirements.

9.3. Recall

- 1 There shall be personnel authorised within the blood establishment to assess the need for blood and blood component recall and to initiate and coordinate the necessary actions.
- 2 An effective recall procedure shall be in place, including a description of the responsibilities and actions to be taken. This shall include notification to the competent authority.
- 3 Actions shall be taken within pre-defined periods of time and shall include tracing all relevant blood components and, where applicable, shall include trace-back. The purpose of the investigation is to identify any donor who might have contributed to causing the transfusion reaction and to retrieve available

blood components from that donor, as well as to notify consignees and recipients of components collected from the same donor in the event that they might have been put at risk.

9.4. Corrective and preventive actions

- 1 A system to ensure corrective and preventive actions on blood component non-conformity and quality problems shall be in place.
- 2 Data shall be routinely analysed to identify quality problems that may require corrective action or to identify unfavourable trends that may require preventive action.
- 3 All errors and accidents shall be documented and investigated in order to identify system problems for correction.

10. SELF-INSPECTION, AUDITS AND IMPROVEMENTS

- 1 Self-inspection or audit systems shall be in place for all parts of the operations to verify compliance with the standards set out in this Annex. They shall be carried out regularly by trained and competent persons in an independent way according to approved procedures.
- 2 All results shall be documented and appropriate corrective and preventive actions shall be taken.