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

Full guideline

Draft for consultation, September 2009

This guideline was developed following the NICE short clinical guideline process. This document includes all the recommendations, details of how they were developed and summaries of the evidence they were based on.

Contents

Disclaimer

NICE clinical guidelines are recommendations about the treatment and care of people with specific diseases and conditions in the NHS in England and Wales.

This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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, for as long as mother and baby wish.

If a mother does not wish to express milk despite discussion with experienced staff and information regarding benefits to herself and her baby, or if she is not able to express sufficient milk, donor breast milk can be used.

A Health Technology Assessment (HTA) report entitled 'Breastfeeding promotion in special care and neonatal intensive care units; an evidence synthesis' is expected to be published in 2009. This report uses 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. [This report is not yet published - summary results will be added for the final guideline, if available].

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.

Person-centred care

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

Good communication between professionals and service users is essential. It should be supported by evidence-based written information tailored to the person’s needs. All information 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

Screening donors

- Follow the staged screening process outlined below when recruiting donors. This should be based on a balanced consideration of relative risk for the recipient population. [REC 1.2.4]
- Do not routinely repeat serological tests while the donor is donating milk. [REC 1.2.19]

Testing donor milk

- Before pasteurisation, test milk samples for bacterial contamination and discard if samples exceed a count of:
  - 10^5 colony forming units (CFU)/ml for total viable bacteria or
  - 10^4 CFU/ml for *Enterobacteriaceae* or
  - 10^4 CFU/ml for *Staphylococcus aureus*. [REC 1.2.51]
- 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. [REC 1.2.55]

Tracking and tracing

- At all stages, milk containers should be labelled clearly for identification (see recommendation 1.2.68). Labels should clearly distinguish released from non-released batches of donor milk. [REC 1.2.66]
- Only supply donor milk to hospitals or neonatal units that are willing to follow the tracking procedures for milk outlined by the milk bank. [REC 1.2.77]

Quality assurance and staff training

- Use HACCP principles in all quality assurance processes. [REC 1.2.80]

- All milk bank staff should have ongoing training relevant to their job, which should be 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. [REC 1.2.74]
- Train milk bank staff in HACCP principles, food hygiene and pasteurisation, and provide ongoing support so that practices reflect these principles. [REC 1.2.75]
- All donor milk prescribed in the NHS should be from milk banks that can demonstrate adherence to the NICE guidelines on the operation of donor milk banks. [REC 1.2.76]

1.2 List of all recommendations

Recruiting donors

1.2.1 When promoting breast milk donation aim to reach all potential donors.

1.2.2 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 public health
  - shops for new mothers, babies and children
- 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
  - breastfeeding support or related organisations
- articles in the media.

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

Screening and selecting donors

1.2.4 Follow the staged screening process outlined below when recruiting donors. This should be based on a balanced consideration of relative risk for the recipient population.

1.2.5 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) (http://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) (http://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.

1.2.6 Ask a potential donor about:

- her diet
  - Advise her that if she is following a strict exclusion diet (for example, a vegan diet without additional vitamin supplementation), she may not be eligible to donate milk.
- any exposure to passive smoke
  - Advise her that if she is exposed to high or sustained levels of passive smoke, for example if other members of her household smoke heavily, she may not be eligible to donate milk.
- any medication that she is taking
  - Advise her that if she is currently taking any medication or undergoing any other medical therapy, she may not be eligible to donate milk.
- any current or significant environmental or chemical exposure
  - Advise her that if she is exposed to high or sustained levels of environmental or chemical contaminants that can be expressed in breast milk, she may not be eligible to donate milk.
- any recent exposure to infection (including HIV 1 or 2, hepatitis B or C, HTLV I or II, syphilis, herpes, acute or chronic infections) or any recent medical intervention (for example, blood transfusions or vaccinations)
  - Advise her that she may not be eligible to donate milk depending on the assessment of risk and/or the results of subsequent tests.
  - Refer to guidance from the DH on the safety of recent vaccination when breastfeeding (www.dh.gov.uk/ for information on vaccinations).

1.2.7 If a potential donor is donating previously expressed breast milk, ask her to answer the screening questions for the period when the milk was expressed.

1.2.8 When screening potential donors, use a combination of informal interview and questionnaire and refer to medical sources if necessary (with consent).

1.2.9 Conduct the screening process with potential donors at a mutually acceptable time and place.

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

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

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

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

1.2.13 If a donor provides a one-off donation of milk, delay testing for 3 months (or sooner if local protocols allow). Quarantine her milk until the test results are known.

1.2.14 When milk banks request serological testing, laboratories should communicate clearly the results and recommended action.

1.2.15 Communicate test results to potential donors verbally, either in person at a follow-up appointment or by telephone (unless the donor prefers to receive them in writing). If appropriate, based on

local protocols, offer counselling and/or information on local support groups.

1.2.16 If a woman is eligible to donate milk after screening and serological testing, collect information from her using a systematic checklist to

- confirm that she is in good general health
- document the age and health of her baby.

1.2.17 Before accepting a donor's milk, obtain her consent for the processing and intended use of the donated milk.

1.2.18 Whilst a donor continues to donate, ask regularly about her general health and the exclusion criteria above. Advise her that if her status or circumstances change related to these, she should contact the milk bank immediately.

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

Training and supporting donors

1.2.20 Provide information to donors on milk bank requirements for their

- diet
- alcohol consumption
- caffeine consumption.

1.2.21 Provide all new donors with training, preferably face-to-face with additional information by telephone and in writing. Training should cover:

- collecting and expressing milk, including cleaning and using breast pumps and containers
- storing milk (including cooling and freezing)
- personal hygiene, including cleaning the hands and breasts
- labelling and documenting donated milk
- transporting donated milk (if needed).

1.2.22 Arrange training at a time and place suitable for both donor and trainer.

1.2.23 Provide ongoing, individualised support to all donors until no longer needed. This may include

- continued support for collecting of and maintaining lactation
- emotional support.

1.2.24 Offer additional support and information on milk collection to donors whose milk has significant or repeated bacterial contamination (see recommendation 1.2.51).

Stopping or suspending milk donations

1.2.25 Consider no longer accepting milk from donors who consistently supply

- milk that does not meet the microbiological criteria (see recommendation 1.2.51) despite support
- small amounts of milk.

1.2.26 Advise donors that if they develop a temperature or have contact with a viral exanthematous disease, to contact the milk bank to discuss suspending their milk donation.

1.2.27 Advise donors who begin taking any medication that they should contact the milk bank to discuss suspending or stopping their milk donation. Use appropriate reference sources (such as the British National Formulary) to determine whether a donor should continue to express milk for donation.

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

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

1.2.30 When defining how long to accept milk from donors who continue to be suitable, milk banks should take into account local considerations, such as the size of its recipient population and its current stock levels.

Expressing milk at home for donation

1.2.31 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.

1.2.32 Actively encourage donors to manually express milk; however pump-expressed milk should be accepted if donors prefer this method.

Handling milk at home

1.2.33 Advise donors that milk collected for donation should be frozen as soon as possible and no longer than 24 hours after expression.

1.2.34 Advise donors to:

- preferably freeze individual samples immediately or
- refrigerate samples collected over 24 hours if necessary (for example, because of storage capacity), and then freeze the batch.

1.2.35 Advise donors that expressed milk for donation can be stored before transport to the milk bank for up to:

- 2 weeks in the freezer compartment of a fridge or
- 3 months in a domestic freezer, at minus 18ºC or lower.

1.2.36 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 collecting breast milk.

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

1.2.38 Provide donors with the means to check and document their freezer temperature every day.

Handling milk during transportation

1.2.39 Critical transport conditions, such as temperature and time limit must be defined to maintain the frozen nature of the milk.

1.2.40 Milk should be transported in secure containers and packaging which maintain the milk in the necessary conditions.

1.2.41 If 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.

1.2.42 Milk banks should define in writing their procedures for transporting and storing milk samples. They should ensure these procedures maintain the quality of the milk and avoid errors in identifying

samples. Appropriate records of inventory and distribution should be kept.

1.2.43 Milk should be collected from donors using an agreed transport provider (preferably a medical courier). If needed, a member of staff from the milk bank could collect the milk. In cases where this is not possible, use appropriate monitoring processes such as sign out when leaving and sign in when arriving.

1.2.44 Collect milk from the donor's home or from other designated places, such as depots that have practices in place to monitor the freezers and maintain standards for quality control, storage and security. Similar processes should be in place in any location where the milk is stored.

Handling milk at the milk bank

1.2.45 Process all donated milk under hygienic conditions (a sterile environment is not necessary). Wear gloves at all times when handling donor milk.

1.2.46 Check that milk arriving at the milk bank is labelled correctly and in good condition, and transfer all samples immediately to the freezer.

1.2.47 Do not store:

- frozen milk samples direct from the donor in the same freezer as pasteurised samples
- refrigerated, thawed milk samples awaiting pasteurisation in the same refrigerator (or area, if using walk-in fridges) as thawed, pasteurised samples.

1.2.48 Store milk samples awaiting testing in the freezer for no longer than 3 months from the date of expression.

1.2.49 Discard milk samples from donors who do not meet selection criteria.

1.2.50 Before pasteurisation, thoroughly thaw the milk samples; keep them in the refrigerator and prevent them from reaching room temperature (they should not exceed 8ºC).

1.2.51 Before pasteurisation, test milk samples for bacterial contamination and discard if samples exceed a count of:

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

1.2.52 Milk banks should seek help from microbiology laboratories to investigate instances of significant or unusual contamination, for example by undertaking further bacterial tests.

1.2.53 When milk banks request bacterial tests, laboratories should communicate clearly the results and recommended action.

1.2.54 Pasteurise donated milk at 62.5ºC for 30 minutes.

1.2.55 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.

1.2.56 Discard pasteurised milk that has a total viable bacterial count of 10/ml or more.

1.2.57 After testing and pasteurising, cool milk samples to refrigerator temperature (4ºC or lower), then move them to the freezer and store for no longer than 3 months.

1.2.58 Process milk in containers made of food grade materials.

1.2.59 Containers and equipment should be cleaned and stored according to local protocols based on hazard analysis and critical control points (HACCP) principles.

Pooling donor milk

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

1.2.61 Do not pool:

- milk from different donors,

  or

- batches of pasteurised milk from the same donor.

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

Fortifying donor milk

1.2.63 Milk banks should not be responsible for adding anything to the milk. Fortifiers and other additives should be added only when the milk is about to be used.

Tracking and tracing

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

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

1.2.66 At all stages, milk containers should be labelled clearly for identification (see recommendation 1.2.68). Labels should clearly distinguish released from non-released batches of donor milk.

1.2.67 For each milk batch, keep the following records:

- About the donor:
  - medical records/NHS number/donor ID
  - consent
  - medical history
  - serology test results.
- About each container before pasteurisation:
  - donor identification number
  - 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 milk, or the disposal date of the milk, as appropriate.

1.2.68 Label each pasteurised container of milk with the following information:

- an identification number assigned by the milk bank that is unique to every container
- confirmation that it contains pasteurised donor breast milk
- an expiry date.

1.2.69 The receiving hospital or neonatal unit should keep a record of how the milk is used.

1.2.70 Keep any archived blood or milk samples for at least 11 years.

1.2.71 All records, including raw data, which are critical to the safety and quality of the donor milk should be kept so as to ensure access to these data for at least 30 years after expiry date, use or disposal.

Quality assurance

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

1.2.73 Regularly inspect all equipment used in 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.

1.2.74 All milk bank staff should have ongoing training relevant to their job, which should be 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.

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

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

1.2.77 Only supply donor milk to hospitals or neonatal units that are willing to follow the tracking procedures for milk outlined by the milk bank.

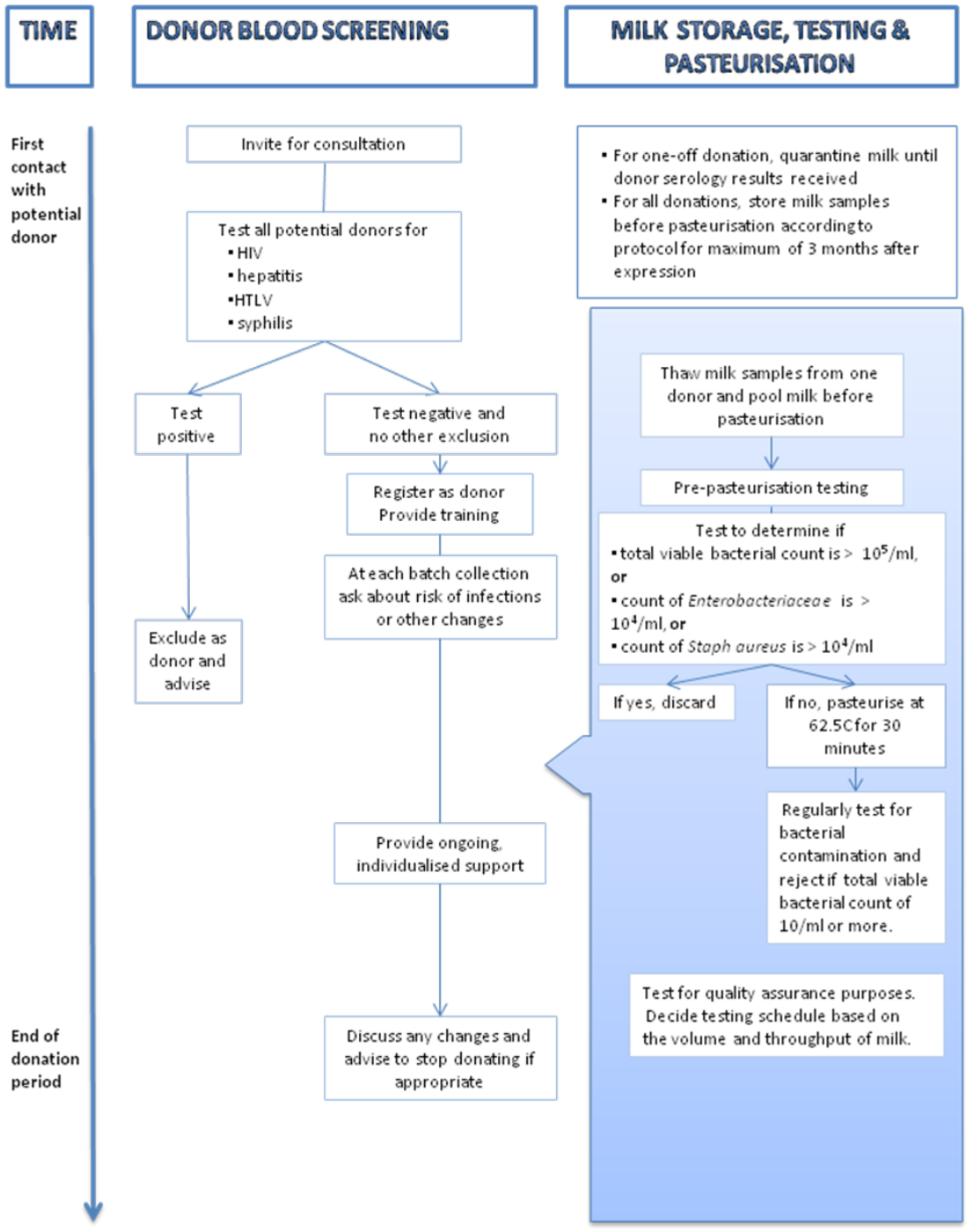
1.2.78 Milk banks should implement a quality control system that is followed by all staff and encompasses:

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

1 1.2.79 Milk banks should review their quality control system regularly.

2 1.2.80 Use HACCP principles in all quality assurance processes.

3 ## *1.3 Care pathway*



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1.4 Overview

1.4.1 Operating donor milk banks

Seventeen donor breast milk banks are currently in operation in the UK. These provide donor milk to babies, including preterm 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.

1.4.2 The NICE short clinical guideline programme

‘Donor breast milk banks: the operation of donor breast milk services’ (NICE clinical guideline XX) 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

1.4.3 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

See ‘The guidelines manual’ (2009) on the NICE website for more information on how NICE clinical guidelines are developed.

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] and 'Patient safety and reduction of risk of transmission of Creutzfeldt-Jakob disease [CJD] via interventional procedures' [NICE interventional procedure guidance 196]) 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, in order to place the final recommendations in context; it was not intended to be used as primary evidence. Survey questions were included on the following topics:

- 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.

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 full costing report and template 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] and 'Patient safety and reduction of risk of transmission of Creutzfeldt-Jakob disease [CJD] via interventional procedures' [NICE interventional procedure guidance 196]) 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'), 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; www.nice.org.uk/CG53) and 'Feverish illness in children' (NICE clinical guideline 47;www.nice.org.uk/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 in the relevant 'evidence to recommendations' sections below.

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 Recruiting donors

2.4.1 Evidence review

Thirty five of the 217 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 six milk banks in the UK, five in the US, two in Denmark, and one each in 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.

2.4.2 Evidence statements

2.4.2.1 Healthy mothers who are breastfeeding their own babies and have more milk than they need are suitable candidates for donating surplus milk.[1]

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

2.4.2.2 '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 milk.[2]

2.4.2.3 Surplus milk from mothers whose lactation is well established may be suitable for donor milk.[3]

2.4.2.4 Surplus milk from mothers who have expressed milk for their own babies in the neonatal intensive care unit may be suitable for donor milk.[4]

2.4.2.5 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 process.[5]

2.4.2.6 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*
  - *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 post-natal classes*
  - *breastfeeding mothers' support groups*

[2] Based on 1 position statement (Anon 1985) and 1 service description (Baum 1982).
[3] Based on 1 position statement (Anon 1985).
[4] Based on 1 service description (Arnold 1996).
[5] Based on 2 narrative reviews (Bar-Yam 2003; Bar-Yam 2005).

– *organisations such as the La Leche League or the National Childbirth Trust*

- *through mass media contact such as*

– *newspapers*

– *newsletters*

– *magazine articles*

– *TV*

– *radio.*[6]

2.4.2.7 *An active recruitment programme is needed because a continuous supply of new donors is required to maintain supplies.*[7]

2.4.2.8 *Recruitment of donors may be increased if the milk bank offers breastfeeding support and services to the donors.*[8]

2.4.2.9 *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.*[9]

2.4.2.10 *The need for donor milk should be explained in non-technical language.*[10]

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

- *peer support while breastfeeding*
- *the provision of milk only for babies of family members.*[11]

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

- *the presence of a 'significant other'*

[6] 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)
[7] Based on 1 narrative review (Holland 2006).
[8] Based on 1 primary study (Azema and Callahan 2003).
[9] Based on 1 primary study (Azema and Callahan 2003).
[10] Based on 1 primary study (Azema and Callahan 2003).
[11] Based on 1 narrative review (Holland 2006) and 1 primary study (Ighogboja et al. 1995).

- *no work outside the home*
- *fewer than three children*
- *a positive attitude towards breastfeeding even though they have experienced problems*
- *a desire to help others.*[12]

2.4.2.13 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 idea.*[13]

2.4.2.14 Ongoing education and motivation of women on postnatal wards may reduce concerns about donating milk and thus increase recruitment.[14]

2.4.2.15 The cultural beliefs and attitude of the healthcare professional discussing milk donation may influence the decision of the woman to donate.[15]

2.4.2.16 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 law.[16]

2.4.3 Evidence to recommendations

The GDG considered that any recruitment strategy should be broad, and not be targeted at any specific group of potential donors. Also, the milk bank should be able to recruit using a flexible approach that balances their

[12] Based on 1 primary study (Azema and Callahan 2003) and 1 service description (Baum 1982).
[13] Based on 1 narrative review (Holland 2006) and 2 primary studies (Egri-Okwaji et al. 1984; Ighogboja et al. 1995).
[14] Based on 1 service description (Fernandez et al. 1993).
[15] Based on 1 narrative review (Holland 2006) and 1 opinion piece (Modi 2006).
[16] Based on 1 narrative review (Holland 2006) and 1 opinion piece (Modi 2006).

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 any existing milk banks needing to increase their levels of recruitment, the suggested options will be a useful resource.

2.4.4 Recommendations

Recommendation 1.2.1

When promoting breast milk donation aim to reach all potential donors.

Recommendation 1.2.2

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 public health
    - shops for new mothers, babies and children
- 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
    - breastfeeding support or related organisations
- articles in the media.

Recommendation 1.2.3

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

2.5 Screening and selecting donors

2.5.1 Evidence review

Forty seven of the 217 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 seven milk banks in the UK, five in the US, two in Australia and Sweden, and one each in South Africa, China, India, Poland, Germany, and Denmark, also various milk banks in North America including Canada.

There was general agreement that screening and selection of donors were needed, but there was less agreement on the exact nature of the screening and selection. 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 DÃ³rea 2006) evaluated all 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.

2.5.2 Evidence statements

2.5.2.1 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 milk.[17]

2.5.2.2 *In the past, not all milk banks have screened potential donors, either by taking a history of past or current infection or by laboratory tests.*[18]

2.5.2.3 *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 screening.*[19]

2.5.2.4 *Women with HIV infection or at high risk of HIV infection should not donate breast milk.*[20]

2.5.2.5 *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 vaccination.*[21]

2.5.2.6 *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*

[17] Based on many reports and studies (Anon 1980; Anon 1995; Asquith et al. 1987; Hartmann et al. 2007; Kinsey 1984; Mortimer et al. 1988)).
[18] Based on 1 position statement (Anon 1985), 1 service description (McEnery and Chattopadhyay 1978).
[19] Based on 1 service description (Hartmann et al. 2007).
[20] Based on 1 narrative review (Boyes 1987), and 1 position statement (Anon 1995).
[21] Based on 1 position statement (Anon 1985).

- *low regional or local prevalence, which means that screening is undertaken only in potential donors from high-risk groups*
- *national screening recommendations.*[22]

2.5.2.7 Potential donors are asked about:

- *their general health and medical history (including acute or chronic infections, recent vaccinations, 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*
- *any exposure to CJD (for example, in the US 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 smoking.*[23]

2.5.2.8 Milk banks use the following tests or investigations when screening or selecting prospective milk donors:

- *general physical examination*

[22] 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).
[23] 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).

- *chest radiograph, PPD or tine test (for tuberculosis)*
- *blood test for HIV antibody test (for HIV, recommended by the Centers for Disease Control)*
- *blood tests for HBsAg and anti-HBc (for hepatitis)*
- *VDRL (for syphilis)*

2.5.2.9 The tests may differ in different milk banks depending on tests routinely undertaken during antenatal and perinatal assessment in local hospitals. [24]

2.5.2.10 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 woman.[25]

2.5.2.11 One milk bank asked potential donors to attend a follow-up appointment to receive the results of the blood test(s) in person.[26]

2.5.2.12 In one milk bank, the potential donor is given a form by the milk bank nurse at her first visit The form is similar to that given to blood donors) and 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 made.[27]

2.5.2.13 In one milk bank, blood is tested at the potential donor's home to minimise any inconvenience to the woman.[28]

2.5.2.14 Tests are repeated if a woman continues to donate 3 months after the date of the initial blood test.[29]

[24] 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).
[25] Based on 2 service descriptions (Balmer and Wharton 1992; Hartmann et al. 2007).
[26] Based on 1 service description (Hartmann et al. 2007).
[27] Based on 1 service description (Balmer and Wharton 1992).
[28] Based on 1 service description (Balmer and Wharton 1992).
[29] Based on 1 service description (Hartmann et al. 2007).

2.5.2.15 Various methods are used for collecting 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 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).*

2.5.2.16 Information is also collected by different members of staff, including the milk bank coordinator or the milk bank nurse.[30]

2.5.2.17 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 babies.[31]

2.5.3 Evidence to recommendations

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

[30] Based on 1 primary study (Almeida and DÃ³rea 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).
[31] Based on 2 narrative reviews (Anon 1987; Bromberger 1982).

some degree in the UK population (with local variation), are known to be transmitted via breast milk or breastfeeding, and have significant consequences if contracted. This risk of transmission needs to be balanced against the effects of pasteurisation 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 adequate 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 (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.

There was no conclusive evidence identified on test accuracies in order to quantitatively evaluate optimal testing strategies, as well as cost effectiveness of donor screening. However, after pasteurisation the risk of a baby contracting the serious diseases screened for above is very low (no cases of transmission of any of the screened conditions via pasteurised, donor milk were identified) so the 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 prior to 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.

2.5.4 Recommendations

Recommendation 1.2.4

Follow the staged screening process outlined below when recruiting donors. This should be based on a balanced consideration of relative risk for the recipient population.

Recommendation 1.2.5

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) (http://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) (http://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 1.2.6

Ask a potential donor about:

- her diet
    - Advise her that if she is following a strict exclusion diet (for example, a vegan diet without additional vitamin supplementation), she may not be eligible to donate milk.
- any exposure to passive smoke
    - Advise her that if she is exposed to high or sustained levels of passive smoke, for example if other members of her household smoke heavily, she may not be eligible to donate milk.
- any medication that she is taking
    - Advise her that if she is currently taking any medication or undergoing any other medical therapy, she may not be eligible to donate milk.
- any current or significant environmental or chemical exposure
    - Advise her that if she is exposed to high or sustained levels of environmental or chemical contaminants that can be expressed in breast milk, she may not be eligible to donate milk.
- any recent exposure to infection (including HIV 1 or 2, hepatitis B or C, HTLV I or II, syphilis, herpes, acute or chronic infections) or any recent medical intervention (for example, blood transfusions or vaccinations)
    - Advise her that she may not be eligible to donate milk depending

on the assessment of risk and/or the results of subsequent tests.

- Refer to guidance from the DH on the safety of recent vaccination when breastfeeding (www.dh.gov.uk/ for information on vaccinations).

Recommendation 1.2.7

If a potential donor is donating previously expressed breast milk, ask her to answer the screening questions for the period when the milk was expressed.

Recommendation 1.2.8

When screening potential donors, use a combination of informal interview and questionnaire and refer to medical sources if necessary (with consent).

Recommendation 1.2.9

Conduct the screening process with potential donors at a mutually acceptable time and place.

[See Donor consent for recommendation 1.2.10]

Recommendation 1.2.11

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

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

Recommendation 1.2.12

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

Recommendation 1.2.13

If a donor provides a one-off donation of milk, delay testing for 3 months (or sooner if local protocols allow). Quarantine her milk until the test results are known.

Recommendation 1.2.14

When milk banks request serological testing, laboratories should communicate clearly the results and recommended action.

Recommendation 1.2.15

Communicate test results to potential donors verbally, either in person at a follow-up appointment or by telephone (unless the donor prefers to receive them in writing). If appropriate, based on local protocols, offer counselling and/or information on local support groups.

Recommendation 1.2.16

If a woman is eligible to donate milk after screening and serological testing, collect information from her using a systematic checklist to

- confirm that she is in good general health
- document the age and health of her baby.

Recommendation 1.2.17

Before accepting a donor's milk, obtain her consent for the processing and intended use of the donated milk.

Recommendation 1.2.18

Whilst a donor continues to donate, ask regularly about her general health and the exclusion criteria above. Advise her that if her status or circumstances change related to these, she should contact the milk bank immediately.

Recommendation 1.2.19

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

2.6 Donor consent

2.6.1 Evidence review

Only 1 of the 217 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.

2.6.2 Evidence statements

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

2.6.2.2 One milk bank recorded donor consent as part of the donor's medical record.(Hartmann et al. 2007)[32]

2.6.3 Evidence to recommendations

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

[32] Based on 2 service descriptions (Hartmann et al. 2007; Penc 1996).

2.6.4 Recommendations

Recommendation 1.2.10

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

2.7 Training and supporting donors

2.7.1 Evidence review

Twenty nine of the 217 studies included in the review provided 51 evidence records. The studies contained:

- 17 service descriptions
- 5 narrative reviews
- 4 position statements
- 2 primary studies
- 1 primary study.

The publication dates ranged from 1955 to 2007.

The service descriptions reported practice in six milk banks in the UK, four in the US, two in Australia and Germany, and one each in South Africa, Sweden, Denmark and Canada.

There was general agreement that training and support for donors were needed, but there was less agreement on the exact content of the training and the level of support needed. Where 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 DÃ³rea 2006) evaluated all 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.

2.7.2 Evidence statements

2.7.2.1 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 maintenance. [33]

2.7.2.2 Frequent contact with and feedback from milk bank staff may help to maintain the commitment of donors to collecting as much high-quality milk as possible. [34]

2.7.2.3 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 appropriate. [35]

2.7.2.4 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 donations. [36]

2.7.2.5 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 cleaning of the hands and breasts.*

[33] Based on 1 narrative review (Bromberger 1982) and 1 position statement (Fernandez et al. 1990).
[34] Based on 1 service description (Asquith et al. 1987).
[35] Based on 1 service description (Asquith et al. 1987).
[36] Based on 2 service descriptions (Connor 1982; Davidson et al. 1979) and 1 position statement (Fernandez et al. 1990).

Such training can help to minimise bacterial contamination.[37]

2.7.2.6 One milk bank trained donors in the proper processes for administration of milk samples, including instructions on the appropriate labelling of milk.[38]

2.7.2.7 Two milk banks gave donors information on diet, and alcohol and caffeine consumption.[39]

2.7.2.8 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).[40]

2.7.2.9 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*
- *sterile bottles*
- *labels for donations.*[41]

2.7.3 Evidence to recommendations

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

[37] 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 DÃ³rea 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).
[38] Based on 1 service description (Asquith et al. 1987).
[39] Based on 2 service descriptions (Asquith et al. 1987; Cash and Giacoia 1981).
[40] 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).
[41] Based on 2 service descriptions (Asquith et al. 1987; Hartmann et al. 2007).

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 whilst ensuring that staff time is used efficiently (e.g. arrange telephone meeting when receiving samples and instead of face to face meetings where appropriate; plan training following routine milk collection or delivery to reduce travel and time requirements for staff etc).

2.7.4 Recommendations

Recommendation 1.2.20

Provide information to donors on milk bank requirements for their

- diet
- alcohol consumption
- caffeine consumption

Recommendation 1.2.21

Provide all new donors with training, preferably face-to-face with additional information by telephone and in writing. Training should cover:

- collecting and expressing milk, including cleaning and using breast pumps and containers
- storing milk (including cooling and freezing)
- personal hygiene, including cleaning the hands and breasts
- labelling and documenting donated milk
- transporting donated milk (if needed).

Recommendation 1.2.22

Arrange training at a time and place suitable for both donor and trainer.

Recommendation 1.2.23

Provide ongoing, individualised support to all donors until no longer needed. This may include

- continued support for collecting of and maintaining lactation
- emotional support.

Recommendation 1.2.24

Offer additional support and information on milk collection to donors whose milk has significant or repeated bacterial contamination (see recommendation 1.2.51).

2.8 Stopping or suspending milk donations

2.8.1 Evidence review

Twelve of the 217 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 four milk banks in the US, three in the UK and two in 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).

2.8.2 Evidence statements

2.8.2.1 One milk bank advised donors who supplied contaminated milk to stop donating milk.[42]

2.8.2.2 One milk bank advised donors who supplied milk with a low protein content to stop donating milk.[43]

2.8.2.3 One milk bank advised donors who supplied small amounts of milk (less than 2 ounces daily after a week's trial) to stop donating milk.[44]

2.8.2.4 In one study, donors taking prescription drugs for infections (anti-infection agents in 89.3% of 56 women and antimicrobial agents in 84.6% of 52 women) were advised to wait for 5 half-lives of the drug after the last ingested dose before they resumed collecting milk; in most cases, a washout period of 1 day was sufficient.[45]

2.8.2.5 One milk bank advised donors who had herpetic lesions to stop collecting milk while the lesions were present.[46]

[42] Based on 1 service description (Arnold 1999).
[43] Based on 1 service description (Arnold 1999).
[44] Based on 1 service description (Kimball et al. 1955).
[45] Based on 1 primary study (Hoppu et al. 1994).
[46] Based on 1 service description (Asquith et al. 1987).

2.8.2.6 One milk bank advised donors to stop collecting milk for 3 weeks after rubella vaccination.[47]

2.8.2.7 Two milk banks advised donors whose babies became ill to stop donating milk.[48]

2.8.2.8 Two milk banks advised donors who became ill to stop donating milk.[49]

2.8.2.9 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 projects.[50]

2.8.3 Evidence to recommendations

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 in 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.

There are many reference sources on drugs and breastfeeding; for example, the 'British national formulary' (BNF) has a specific section on this. However, any decision on whether a donor should suspend donation needs to 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;

[47] Based on 1 service description (Asquith et al. 1987).
[48] Based on 2 service descriptions (Balmer and Wharton 1992; Cash and Giacoia 1981).
[49] Based on 2 service descriptions (Cash and Giacoia 1981; McEnery and Chattopadhyay 1978).
[50] Based on 1 service description (Langerak and Arnold 1991).

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.

2.8.4 Recommendations

Recommendation 1.2.25

Consider no longer accepting milk from donors who consistently supply

- milk that does not meet the microbiological criteria (see recommendation 1.2.51) despite support
- small amounts of milk.

Recommendation 1.2.26

Advise donors that if they develop a temperature or have contact with a viral exanthematous disease, to contact the milk bank to discuss suspending their milk donation.

Recommendation 1.2.27

Advise donors who begin taking any medication that they should contact the milk bank to discuss suspending or stopping their milk donation. Use appropriate reference sources (such as the British National Formulary) to determine whether a donor should continue to express milk for donation.

Recommendation 1.2.28

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

Recommendation 1.2.29

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

Recommendation 1.2.30

When defining how long to accept milk from donors who continue to be suitable, milk banks should take into account local considerations, such as the size of its recipient population and its current stock levels.

2.9 Expressing milk at home for donation

2.9.1 Evidence review

Thirty nine of the 217 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 seven milk banks in the UK, four in the US, two in Denmark and one each in 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.

2.9.2 Evidence statements

2.9.2.1 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 milk.[51]

2.9.2.2 When drip milk is collected and combined with expressed milk, a considerable increase in energy and fat content is seen compared with drip milk alone.[52]

2.9.2.3 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 but would offer no advantage in terms of bacterial contamination (Carroll et al. 1980). [53]

2.9.2.4 Higher rates of bacterial contamination and lower energy and total fat content have been seen in milk expressed using pumps

[51] Based on 3 narrative reviews (Arnold 1997; Davies 1982; Williams and Pittard, III 1981), 3 primary studies (Almeida and DÃ³rea 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).
[52] Based on 1 narrative review (Davies 1982) and 1 primary study (Stocks et al. 1983).
[53] 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).

compared with milk expressed manually. Many milk banks therefore recommend that donors express milk manually.[54]

2.9.2.5 *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).*[55]

2.9.2.6 *One study noted a specific need to support donors when they stop expressing milk if their own baby has died.*[56]

2.9.3 Evidence to recommendations

All breastfeeding mothers are 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 manual expression 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.

[54] Based on 2 narrative reviews (Kinsey 1984; Williams and Pittard, III 1981), 1 position statement (Anon 1980), 4 primary studies (Almeida and DÃ³rea 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).
[55] 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).
[56] Based on 1 narrative review (Woo and Spatz 2007).

2.9.4 Recommendations

Recommendation 1.2.31

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 1.2.32

Actively encourage donors to manually express milk; however pump-expressed milk should be accepted if donors prefer this method.

2.10 Handling milk at home

2.10.1 Evidence review

Twenty six of the 217 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 seven milk banks in the UK, three in the US (one providing information from a number of milk banks across North America), two in Denmark, two in Australia and one each in 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.

2.10.2 Evidence statements

2.10.2.1 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 home.[57]

2.10.2.2 Good hygiene is important for all aspects of milk handling at a donor's home.[58]

2.10.2.3 Most milk banks provide donors with instructions on how milk should be stored before collection, and most recommend that milk 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).[59]

2.10.2.4 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 refrigerator.[60]

2.10.2.5 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. Also, the milk bank recommended that after an outbreak of infection caused by contaminated milk, milk should be refrigerated immediately after collection had been completed.[61]

2.10.2.6 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)

[57] Based on many references (see below); a specific example is from 1 service description (Pedersen 1982).
[58] Based on 1 narrative review (Davies 1982) 1 primary study (Minder et al. 1982), and 1 service description (Cash and Giacoia 1981).
[59] 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).
[60] Based on 1 service description (Lucas et al. 1979).
[61] Based on 1 service description (Beal et al. 1978) and 1 case report (Ryder et al. 1977).

for no longer than 24 hours before being transported to the milk bank.[62]

2.10.2.7 *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 bank.*[63]

2.10.2.8 *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 growth.*[64]

2.10.2.9 *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).*[65]

2.10.2.10 *Some milk banks do not allow donors to use containers other than those provided.*[66]

2.10.2.11 *Some milk banks instruct donors to pool milk collected over 24 hours.*[67]

[62] Based on 1 position statement (Gutierrez and de Almeida 1998).
[63] Based on 1 service description (Cash and Giacoia 1981).
[64] Based on 1 primary study (Murphy et al. 1982) and 2 service descriptions (Asquith et al. 1987; Pedersen 1982).
[65] 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).
[66] Based on 3 service descriptions (Cash and Giacoia 1981; Dempster 1982; Hartmann et al. 2007).
[67] Based on 3 service descriptions (Bjorksten et al. 1980; Radcliffe 1989; Tomalin 1983).

2.10.2.12 One milk bank instructed donors to express only once into autoclaved bottles, which were then stored in the refrigerator until collection.[68]

2.10.3 Evidence to recommendations

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; www.nice.org.uk/PH11), because of transportation to the milk bank and the use of donor milk for babies who 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 (that is, breast milk 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 −18ºC or lower) based on 'Improving the nutrition of pregnant and breastfeeding mothers and children in low-income households' (NICE public health guidance 11; www.nice.org.uk/PH11), but were modified to reflect the time needed at the milk bank to process the donated milk.

[68] Based on 1 service description (McEnery and Chattopadhyay 1978).

2.10.4 Recommendations

Recommendation 1.2.33

Advise donors that milk collected for donation should be frozen as soon as possible and no longer than 24 hours after expression.

Recommendation 1.2.34

Advise donors to:

- preferably freeze individual samples immediately or
- refrigerate samples collected over 24 hours if necessary (for example, because of storage capacity), and then freeze the batch.

Recommendation 1.2.35

Advise donors that expressed milk for donation can be stored before transport to the milk bank for up to:

- 2 weeks in the freezer compartment of a fridge or
- 3 months in a domestic freezer, at minus 18ºC or lower.

Recommendation 1.2.36

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 collecting breast milk.

Recommendation 1.2.37

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

Recommendation 1.2.38

Provide donors with the means to check and document their freezer temperature every day.

2.11 Transporting milk to the milk bank

2.11.1 Evidence review

Twenty-seven of the 217 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 eight milk banks in the UK, five in the US (one provided information from a number of milk banks across North America), two in Germany and one each in 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.

2.11.2 Evidence statements

2.11.2.1 Details of how milk should be handled during transport were reported only rarely.

2.11.2.2 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 refrigerated.[69]

2.11.2.3 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 firemen.[70]

2.11.2.4 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, boxes insulated with crumpled newspaper or packing beads, with dry ice if needed.[71]

[69] 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).
[70] 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).
[71] 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).

2.11.2.5 One milk bank stored collected milk at an intermediary, local depository before transporting it in bulk to the milk bank every 2 weeks.[72]

2.11.2.6 Periods between collections from donors differed; for example, one milk bank collected milk every 10 days, (Balmer and Wharton 1992), one once a week or at least within one month (Bjorksten et al. 1980), and one twice weekly (Connor 1982).[73]

2.11.3 Evidence to recommendations

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 (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:294:0032:0050:EN:PDF and http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:256:0041:0048:EN:PDF).

[72] Based on 1 service description (Baum 1982).
[73] Based on 4 service descriptions (Balmer and Wharton 1992; Bjorksten et al. 1980; Connor 1982; Davidson et al. 1979).

2.11.4 Recommendations

Recommendation 1.2.39

Critical transport conditions, such as temperature and time limit must be defined to maintain the frozen nature of the milk.

Recommendation 1.2.40

Milk should be transported in secure containers and packaging which maintain the milk in the necessary conditions.

Recommendation 1.2.41

If 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 1.2.42

Milk banks should define in writing their procedures for transporting and storing milk samples. They should ensure these procedures maintain the quality of the milk and avoid errors in identifying samples. Appropriate records of inventory and distribution should be kept.

Recommendation 1.2.43

Milk should be collected from donors using an agreed transport provider (preferably a medical courier). If needed, a member of staff from the milk bank could collect the milk. In cases where this is not possible, use appropriate monitoring processes such as sign out when leaving and sign in when arriving.

Recommendation 1.2.44

Collect milk from the donor's home or from other designated places, such as depots that have practices in place to monitor the freezers and maintain standards for quality control, storage and security. Similar processes should be in place in any location where the milk is stored.

2.12 Milk handling in general

2.12.1 Evidence review

Thirty-three of the 217 included studies provided 48 evidence records. The studies contained:

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

Publication dates ranged from 1953 to 2007.

Service descriptions reported practice in three milk banks in the US, two in the UK, and one each in 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.

2.12.2 Evidence statements

2.12.2.1 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 considered.[74]

2.12.2.2 Because all storage processes affect the nutritional and immunological qualities of milk, any processing should be the minimum required to achieve the required safety. [75]

2.12.2.3 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)*

[74] 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).
[75] Based on 1 narrative review (Narayanan 1989).

- *reduces the antioxidant activity of milk (but less so than freeze-thawing)*
- *increases levels of free fatty acids*
- *retains creamatocrit 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*[76]

2.12.2.4 Freezing milk:

- *affects the rate of lipolysis (and thus 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 creamatocrit values*
- *reduces the glutathione content (and thus the antioxidant activity)*
- *has no effect on malondialdehyde*
- *reduces bacteriostatic activity over time*
- *preserves bactericidal activity*
- *has no effect on immunological factors, such as IgA, IgM, and IgG (although one narrative review states that IgG and IgM are destroyed)*
- *allows bacterial growth in non-contaminated milk compared with refrigeration*

[76] 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)

- *increases bile salt-independent esterase activity*
- *increases lipase activity*
- *destroys, or markedly reduces, CMV infection*
- *does not destroy HIV*
- *does not destroy Semliki Forest virus*
- *does not destroy herpes simplex virus type 1*
- *does not destroy coxsackie virus*[77]

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.[78]

2.12.2.5 Hydrolysis of triglycerides occurs in milk frozen at -20°C, but not at -70°C.[79]

2.12.2.6 Freeze-thawing milk:

- *denatures HTLV-1*
- *increases cell loss*
- *has no effect on vitamin A levels*
- *decreases levels of vitamin C*
- *increases concentrations of free fatty acids*
- *reduces creamatocrit values*
- *activates lipolysis, and thus the levels of free fatty acids and glycerides*
- *does not cause unacceptable levels of bacterial growth in milk that had not been pasteurised*

[77] 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).
[78] Based on 1 meeting report (Silverman 1971), and 2 narrative reviews (Wight 2001; Williams and Pittard, III 1981).
[79] Based on 2 primary studies (Berkow et al. 1984; Bitman et al. 1983).

- *has no effect on lipoprotein lipase or bile salt-stimulated lipase*
- *reduces bacteriostatic activity.*

However, fast freeze-thawing may preserve more of the antibacterial and nutritional components of the milk, but may also require more effort and equipment.[80]

2.12.2.7 *Microwaving milk decreases 'anti-infective' properties.*[81]

2.12.2.8 *Lyophilising (freeze-drying) milk preserves bacteriostatic activity.*[82]

2.12.2.9 *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 feeding.*[83]

2.12.2.10 *Tocopherols appear to be stable when milk is stored after heating or freezing.*[84]

2.12.2.11 *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 acids.*[85]

2.12.2.12 *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*

[80] 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).
[81] Based on 1 narrative review (Wight 2001).
[82] Based on 1 primary study (Honour and Dolby 1979).
[83] Based on 1 narrative review (Williams and Pittard, III 1981).
[84] Based on 1 primary study (Moffatt et al. 1987).
[85] Based on 1 primary study (Luukkainen et al. 1995).

hydrolysis. However, the study also noted that different results had been seen in similar analyses.[86]

2.12.2.13 One primary study examining the effect of different storage processes on esterolytic activity concluded that storage in the freezer was the preferred method.[87]

2.12.2.14 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 sequestration.[88]

2.12.3 Evidence to recommendations

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

2.13 Handling milk at the milk bank

2.13.1 Evidence review

Forty-eight of the 217 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.

[86] Based on 1 primary study (Lepri et al. 1997).
[87] Based on 1 primary study (O'Connor and Walde 1985).
[88] Based on 1 primary study (Hegde and Vikyath 2007).

Service descriptions reported practice in ten milk banks in the UK, five in the US (one also described practice across milk banks in North America), two in Sweden, two in Australia, one each in 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. But 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.

2.13.2 Evidence statements

2.13.2.1 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 milk.[89]

2.13.2.2 Freezing is the most common method of storing pasteurised donor milk, although some milk banks refrigerate milk. [90]

2.13.2.3 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). [91]

2.13.2.4 A meeting report stated that after thawing, milk should not be refrozen. [92]

[89] See below. 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).
[90] 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).
[91] Based on 1 case report (Ryder et al. 1977).
[92] Based on 1 meeting report (Silverman 1971).

2.13.2.5 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 required. [93]

2.13.2.6 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. [94]

2.13.2.7 One narrative review stated that most milk banks limit storage to 3−4 months at below −7°C. [95]

2.13.2.8 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 months[96]

2.13.2.9 One milk bank recommends that freezers should not be self-defrosting, and should be monitored with a recording thermometer or a thermometer with an alarm.[97]

2.13.2.10 Pasteurisation is the most common method of treating donor milk, although some milk banks use 'raw' milk, when possible. [98]

2.13.2.11 One milk bank specifies that raw donor milk (unpasteurised, unfrozen) is used within 72 hours of collection. [99]

2.13.2.12 One milk bank stores milk by freeze-drying large volumes of donor milk. [100]

2.13.2.13 In the US, milk for pre-term babies is processed separately. [101]

[93] Based on 1 narrative review (Roy and Lescop 1979).
[94] 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).
[95] Based on 1 narrative review (Williams and Pittard, III 1981).
[96] Based on 1 position statement (Gutierrez and de Almeida 1998).
[97] Based on 1 service description (Tully 2000).
[98] Based on 8 service descriptions (Arnold 1996; Asquith et al. 1987; Balmer and Wharton 1992; Bjorksten et al. 1980; Hartmann et al. 2007; Hoey et al. 1980; Penc 1996; Tully 2000).
[99] Based on 1 service description (Springer 1997).
[100] Based on 1 service description (Springer 1997).

2.13.2.14 Two milk banks examine each container for appearance, taste, colour, or odour that could indicate spoilage or flavouring from the mother's diet that may affect safety or taste. [102]

2.13.2.15 One primary study found that there was a link between the presence of off-flavour milk and higher rates of micro-organisms. [103]

2.13.2.16 Similarly 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.[104]

2.13.2.17 One milk bank uses milk in rotation, with the oldest milk being used first. [105]

2.13.2.18 Handling of the milk at some milk banks is minimised to prevent contamination and procedures are carried out under sterile conditions or using sterilised equipment.[106]

2.13.2.19 One milk bank handles (pools and samples) all milk in a laminar flow cabinet using aseptic technique and all containers are commercially sterile. [107]

2.13.2.20 One milk bank transfers milk from breast pumps to reusable, non-sterile bottles, which are cleaned between uses in a dishwasher.

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[101] Based on 1 narrative review (Wight 2001).
[102] Based on 2 service descriptions (Asquith et al. 1987; Pedersen 1982).
[103] Based on 1 service description (Novak et al. 2008).
[104] 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).
[105] Based on 1 service description (Beal et al. 1978).
[106] Based on 3 service descriptions (Asquith et al. 1987; Kimball et al. 1955; Penc 1996).
[107] Based on 1 service description (Hartmann et al. 2007).

Other milk banks also report using dishwashers to clean equipment.[108]

2.13.2.21 One milk bank works in an open system, as they are not aiming for a sterile product. [109]

2.13.2.22 In the US (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 gloves. [110]

2.13.3 Evidence to recommendations

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 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 based on 'Improving the nutrition of pregnant and breastfeeding mothers and children in low-income households' (NICE public health guidance 11; www.nice.org.uk/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.

[108] Based on 3 service descriptions (Arnold 1999; Balmer and Wharton 1992; Tully 2000).
[109] Based on 1 service description (Arnold 1999).
[110] Based on 1 position statement (Anon 1995).

2.13.4 Recommendations

Recommendation 1.2.45

Process all donated milk under hygienic conditions (a sterile environment is not necessary). Wear gloves at all times when handling donor milk.

Recommendation 1.2.46

Check that milk arriving at the milk bank is labelled correctly and in good condition, and transfer all samples immediately to the freezer.

Recommendation 1.2.47

Do not store:

- frozen milk samples direct from the donor in the same freezer as pasteurised samples
- refrigerated, thawed milk samples awaiting pasteurisation in the same refrigerator (or area, if using walk-in fridges) as thawed, pasteurised samples.

Recommendation 1.2.48

Store milk samples awaiting testing in the freezer for no longer than 3 months from the date of expression.

Recommendation 1.2.49

Discard milk samples from donors who do not meet selection criteria.

Recommendation 1.2.50

Before pasteurisation, thoroughly thaw the milk samples; keep them in the refrigerator and prevent them from reaching room temperature (they should not exceed 8ºC).

Recommendation 1.2.51

Before pasteurisation, test milk samples for bacterial contamination and discard if samples exceed a count of:

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

Recommendation 1.2.52

Milk banks should seek help from microbiology laboratories to investigate instances of significant or unusual contamination, for example by undertaking further bacterial tests.

Recommendation 1.2.53

When milk banks request bacterial tests, laboratories should communicate clearly the results and recommended action.

Recommendation 1.2.54

Pasteurise donated milk at 62.5ºC for 30 minutes.

Recommendation 1.2.55

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.

Recommendation 1.2.56

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

Recommendation 1.2.57

After testing and pasteurising, cool milk samples to refrigerator temperature (4ºC or lower), then move them to the freezer and store for no longer than 3 months.

Recommendation 1.2.58

Process milk in containers made of food grade materials.

Recommendation 1.2.59

Containers and equipment should be cleaned and stored according to local protocols based on hazard analysis and critical control points (HACCP) principles.

2.14 Pooling donor milk

2.14.1 Evidence review

Thirty-eight of the 217 included studies provided 49 evidence records. Studies included

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

Publication dates ranged from 1951 to 2007.

Service descriptions reported practice in eight milk banks in the UK, four in the US (one also described practice across milk banks in North America), and one each in 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.

2.14.2 Evidence statements

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

2.14.2.1 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 recommended.[111]

2.14.2.2 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 donors[112]

[111] 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).

2.14.2.3 However, 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 great.[113]

2.14.2.4 One milk bank reported pooling all milk, although raw and pasteurised donations were pooled separately.[114]

2.14.2.5 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 may increase the risk of concentration of toxic substances excreted in the milk. [115]

2.14.2.6 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 use .[116]

2.14.3 Evidence to recommendations

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 vCJD transmission via donor milk. If new evidence shows that vertical transmission of vCJD can be ruled out or if a reliable test becomes available, this could be re-evaluated in any update of this guideline.

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[112] 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).
[113] Based on 1 meeting report (Silverman 1971).
[114] Based on 1 service description (Tomalin 1983).
[115] 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).
[116] Based on 1 opinion piece (Modi 2006).

2.14.4 Recommendations

Recommendation 1.2.60

Only pool pre-pasteurised milk from the same donor.

Recommendation 1.2.61

Do not pool:

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

Recommendation 1.2.62

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

2.15 Testing donor milk

2.15.1 Evidence review

Fifty-eight of the 217 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, and
- 1 opinion piece.

Publication dates ranged from 1951 to 2009.

Service descriptions reported practice in eight milk banks in the UK, five in the US (one also described practice across milk banks in North America), two each in Sweden (also one report across various milk banks), Finland, Australia, and Denmark, and one each in India, South Africa, Germany, Canada (also one report across various milk banks), 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.

2.15.2 Evidence statements

2.15.2.1 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 use.[117]

2.15.2.2 Although adequate pasteurisation destroys HIV in milk, most milk banks adopt a dual approach of pasteurisation and screening of donors in order to prevent any transmission of HIV through donor milk. Some may rely on pasteurisation only.[118]

2.15.2.3 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 (8–15% in pregnant women).[119]

2.15.2.4 Testing schedules may differ because of:

- *local disease prevalence*
- *local levels of specific contaminants*
- *storage procedures used*
- *costs, time and availability of tests*[120]

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

- *DDT concentrations*
- *levels of bacteria or infection*

[117] 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).
[118] Based on 1 opinion piece (Morley and Lucas 1993), and 2 narrative reviews (Oxtoby 1988; Van de et al. 1992).
[119] Based on 1 case report (Nduati et al. 1994).
[120] Based on 1 narrative review (Narayanan 1989), and 2 position statements (Anon 1980; Penc 1996).

- *CMV*
- *MRSA (methicillin-resistant Staphylococcus aureus)*
- *enteric pathogens*
- *organisms with the potential to be enteric pathogens*
- *non-pathogenic organisms*
- *bacillus species that are heat resistant*
- *dilution with water or cow's milk (especially when donors receive payment).*[121]

2.15.2.6 Some milk banks test for specific contaminants if the donor has a diagnosed infection such as mastitis.[122]

2.15.2.7 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.)*[123]

2.15.2.8 One case report describes an outbreak of Salmonella kottbus traced to contaminated donor milk from a single donor. [124]

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

- *rejection of raw milk that*

[121] 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).
[122] Based on 2 service descriptions (Asquith et al. 1987; Omarsdottir et al. 2008).
[123] Based on 1 meeting report (Silverman 1971), 3 narrative review (Oxtoby 1988; Roy and Lescop 1979; Williams and Pittard, III 1981), 1 position statement (Anon 1980), 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).
[124] Based on 1 case report (Ryder et al. 1977).

- *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 4,000 organisms/ml of Staphylococcus aureus*
- *exceeds 10^4 colony-forming units (CFU)/ml of normal skin flora*
- *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 bank.[125]

2.15.2.10 *It is not clear what effect of different organisms and different levels of contamination have on the recipient baby, and whether this differs according to the recipient group.* [126]

2.15.2.11 *One milk bank defined the microbiological criteria for accepting milk for pasteurisation:*

- *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*

[125] Based on 2 narrative reviews (Arnold 1997; Wight 2001), 1 position statement (Anon 1985), and 7 service descriptions (Arnold 1999; Balmer and Wharton 1992; Beal et al. 1978; Cash and Giacoia 1981; Dempster 1982; Langerak and Arnold 1991).
[126] Based on many references: specific examples include 1 narrative review (Narayanan 1989) and 1 opinion piece (Arnold et al. 1997).

(for example, Staphylococcus epidermis, Streptococcus viridans and diphtheroids)

- *milk is not used if it has more than 10^3 CFU/ml of Staphylococcus aureus, any gram negative rod (lactose-fermenting and Pseudomonas spp.), beta-haemolytic streptococci or Streptococcus faecalis.* [127]

2.15.2.12 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 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).*
- *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*

[127] Based on 1 service description (Balmer and Wharton 1992).

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 criteria.[128]

2.15.2.13 One milk bank used criteria that, in general, the pilot sample must contain no potential pathogens capable of producing heat-stable enterotoxins, no Enterobacteriacaea 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 unacceptable.[129]

2.15.2.14 One milk bank used criteria as follows:

- *If the sample contains less than 2.5 x 10^6 non-pathogenic organisms/l that aliquot of milk will be given to a baby without further processing.*
- *If there are between 2.5 x 10^6 and 1 x 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 1x10^9 organisms/l and grows Staphylococcus aureus or Pseudomonas, Klebsiella, or Proteus spp., or other enteropathogenic organisms is not fed to babies*[130]

2.15.2.15 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, Staphylococcus aureus, Escherichia coli, Klebsiella spp.,*

[128] Based on 1 service description (Davidson et al. 1979).
[129] Based on 1 service description (Hartmann et al. 2007).
[130] Based on 1 service description (McEnery and Chattopadhyay 1978).

Pseudomonas aeruginosa, 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 acceptable.*[131]

2.15.2.16 One milk bank used criteria as follows:

- *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 use.[132]

2.15.2.17 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 sepsis.[133]

2.15.2.18 Milk banks also test

- *the fat, protein or lactose content*
- *the carbohydrate or caloric content*
- *the acidity*
- *the sodium levels*

[131] Based on 1 service description (Tully 1999).
[132] Based on 1 service description (Sauve et al. 1984).
[133] Based on 1 primary study (Botsford et al. 1986).

- *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 raw*[134]

2.15.2.19 Not all milk banks routinely test both before and after pasteurisation. For example, one milk bank reported testing samples after pasteurisation four times a year, and one tests 1 in 40 bottles after pasteurisation.[135]

2.15.2.20 Not all milk banks routinely test and in one survey, seven milk banks were reported to use no defined standards or to test routinely.[136]

2.15.2.21 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 donations.[137]

2.15.2.22 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 contamination.[138]

2.15.3 Evidence to recommendations

Questions addressed by the GDG focused on the following areas:

[134] Based on 2 narrative reviews (Davies 1982; Williams and Pittard, III 1981), 3 position statementd (Anon 1985; Fernandez et al. 1990; Gutierrez and de Almeida 1998), 5 primary studies (Almeida and DÃ³rea 2006; Lindemann et al. 2004; Spencer and Hull 1981; Wojcik et al. 2009; Wright and Feeney 1998), and 12 service descriptions (Arnold 1999; Balmer and Wharton 1992; 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).
[135] Based on 2 service description (Arnold 1999; Tomalin 1983).
[136] Based on 1 survey of services (Sauve et al. 1984).
[137] Based on 2 service descriptions (Arnold 1999; Bjorksten et al. 1980).
[138] Based on 1 service description (Bjorksten et al. 1980).

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

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 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 cytomegalovirus (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 for CMV of potential donors.

As regards 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 *Staphylococcus aureus* and *Escherichia 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 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 *Staph aureu*s 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 prior to 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. Any testing after pasteurisation that will rarely change the decision to supply milk (only if the equipment fails and the pasteurisation process was therefore not followed) and even carries a risk of introducing contamination (if not conducted in appropriate conditions) is unlikely to positively change recipient outcomes and thus unlikely to be worth the additional spending.

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 minimum requirements of testing, and milk banks could exceed this if this was indicated.

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.

2.15.4 Recommendations

See Handling milk at the milk bank

2.16 Treating donor milk

2.16.1 Evidence review

Ninety-six of the 217 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, and
- 1 meeting report.

Publication dates ranged from 1951 to 2008.

Service descriptions reported practice in eight milk banks in the UK , three in the US (one also described practice across milk banks in North America), two in Denmark, one each in Sweden (also one report across various milk banks), India, South Africa, Germany, Canada and North America (two reports across various milk banks), 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.

2.16.2 Evidence statements

2.16.2.1 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 considered.[139]

2.16.2.2 The majority of reviews recommend the use of Holder pasteurisation rather than sterilisation, and most milk banks support and follow this recommendation. [140]

2.16.2.3 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 expensive.[141]

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

2.16.2.4 Storing milk at 23°C (room temperature):

- *has no effect on vitamin A levels*

[139] 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).
[140] Based on many references: specific examples include 8 narrative reviews (Bromberger 1982; Davies 1982; Kinsey 1984; Oxtoby 1988; Roy and Lescop 1979; Simmer 2000; Tully et al. 2001; Wight 2001), 1 opinion piece (Modi 2006), 2 position statements (Anon 1980; Anon 1985), 1 primary study (Lucas and Roberts 1979), and 1 service description (Arnold 1999).
[141] 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).

- *reduces levels of vitamin C.*[142]

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

- *has no effect on IgG, IgA or IgM*
- *destroys HIV*
- *destroys HTLV-1-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).*[143]

2.16.2.6 Heating milk to 62.5–63°C for 30 minutes (Holder pasteurisation):

- *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, IgM*
- *has no effect on gangliosides or glycoconjugates*

[142] Based on 2 primary studies (Honour and Dolby 1979; Rechtman et al. 2006).
[143] Based on 2 narrative reviews (Eglin and Wilkinson 1987; Ogundele 2000), and 2 primary studies (Wills et al. 1982; Yamato et al. 1986).

- *reduces lactoferrin*
- *reduces C3 complement*
- *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 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 virus.*[144]

2.16.2.7 Heating milk to above 65°C causes a progressive loss of bacteriostatic activity.[145]

2.16.2.8 Heating milk to 72°C for 10 seconds destroys CMV.[146]

2.16.2.9 Heating milk to 75°C for 15 seconds:

- *decreases lysine concentrations*
- *kills listeria innocua*
- *destroys CMV*
- *decreases levels of glutathione peroxidase*
- *reduces bactericidal activity.*[147]

2.16.2.10 Heating milk to 90°C for 10 minutes destroys HTLV-1.[148]

[144] 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).
[145] Based on 1 primary study (Honour and Dolby 1979).
[146] Based on 1 narrative review (Stagno 2002).
[147] 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).

2.16.2.11 Other pasteurisation methods include heat treatment at 56°C, 62°C, 65.6°C or 65°C, and for different times (most commonly 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 minutes.[149]

2.16.2.12 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 content.*[150]

2.16.2.13 One milk bank reported autoclaving milk at 100°C for 5 minutes.[151]

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

- *IgA and IgG*
- *lactoferrin and alpha-1 trypsin.*[152]

2.16.2.15 One primary study showed that pasteurisation followed by freezing caused redistribution of zinc, but did not affect other nutrients.[153]

2.16.2.16 One primary study showed that high-pressure processing retained higher levels of IgA and lysozyme compared with Holder pasteurisation.[154]

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[148] Based on 1 primary study (Yamato et al. 1986).
[149] Based on 3 service descriptions (Arnold 1996; Asquith et al. 1987; Balmer and Wharton 1992), and 1 primary study (Lloyd-Jones et al. 1979).
[150] Based on 1 narrative review (Ogundele 2000), and 2 primary studies (Fidler et al. 1998; Raptopoulou-Gigi et al. 1977).
[151] Based on 1 service description (Langerak and Arnold 1991).
[152] Based on 1 primary study (Raptopoulou-Gigi et al. 1977).
[153] Based on 1 primary study (Goes et al. 2002).
[154] Based on 1 primary study (Viazis et al. 2007).

2.16.3 Evidence to recommendations

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 micro-organisms 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 the Quality assurance section) 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.

2.16.4 Recommendations

See Handling at the milk bank

2.17 Fortifying donor milk

2.17.1 Evidence review

Twenty-one of the 217 included studies provided 38 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 one milk bank each in the US, Sweden (one also across various milk banks) 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.

2.17.2 Evidence statements

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

2.17.2.1 The aim of fortification was generally understood to be a match of the nutritional content of the milk to the recipient baby.[155]

2.17.2.2 Some safety concerns about the effects of fortification, specifically on the osmolality of the milk and on host defence properties, were expressed.[156]

2.17.2.3 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 considerably.[157]

2.17.2.4 One milk bank reported routine supplementation, but no further details were reported. [158]

2.17.2.5 A survey of milk banks indicated that all neonatal units enriched donor milk, either based on nutritional analysis or blindly.[159]

[155] Based on 1 narrative review (Anon 1987) and 1 service description (Arnold 1999).
[156] Based on 1 opinion piece (Braune 1982), 1 position statement (Anon 1985), and 1 primary study (Santiago et al. 2005).
[157] Based on 1 narrative review (Anon 1987) and 2 opinion pieces (Braune 1982; Modi 2006).
[158] Based on 1 service description (Langerak and Arnold 1991).
[159] Based on 1 service description (Omarsdottir et al. 2008).

2.17.2.6 One author noted that milk banks in the UK do not determine the nutritional content of breast milk.[160]

2.17.3 Evidence to recommendations

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 recommendations therefore emphasise this.

2.17.4 Recommendations

Recommendation 1.2.63

Milk banks should not be responsible for adding anything to the milk. Fortifiers and other additives should be added only when the milk is about to be used.

2.18 Disposing of donor milk

2.18.1 Evidence review

Eight service descriptions from the 217 included studies provided 12 evidence records. Publication dates ranged from 1978 to 2007.

Service descriptions reported practice in three milk banks in the UK, two in Australia, one each in the US, Finland and South Africa.

2.18.2 Evidence statements

2.18.2.1 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 described.[161]

2.18.2.2 One milk bank reported that contaminated milk (as measured by agreed criteria) was retained for use in research.[162]

[160] Based on 1 opinion piece (Modi 2006).
[161] 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).
[162] Based on 1 service description (Asquith et al. 1987).

2.18.2.3 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).[163]

2.18.3 Evidence to recommendations

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

2.18.4 Recommendations

No specific recommendations were made.

2.19 Quality assurance

2.19.1 Evidence review

No references made explicit reference to quality assurance.

2.19.2 Evidence statements

2.19.2.1 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.

2.19.3 Evidence to recommendations

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.

- Directive 2006/86/EC of 24 October 2006 'implementing Directive 2004/23/EC of the European Parliament and of the Council as regards

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

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 (www.food.gov.uk/foodindustry/regulation/hygleg/hygleginfo/foodhygknow/) to identify critical points in processes and design appropriate measures to prevent errors.

2.19.4 Recommendations

Recommendation 1.2.72

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

Recommendation 1.2.73

Regularly inspect all equipment used in 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.

[See also Staff Training]

Recommendation 1.2.76

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

Recommendation 1.2.77

Only supply donor milk to hospitals or neonatal units that are willing to follow the tracking procedures for milk outlined by the milk bank.

Recommendation 1.2.78

Milk banks should implement a quality control system that is followed by all staff and encompasses:

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

Recommendation 1.2.79

Milk banks should review their quality control system regularly.

Recommendation 1.2.80

Use HACCP principles in all quality assurance processes.

2.20 Tracking and tracing

2.20.1 Evidence review

Forty-six of the 217 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 seven milk banks in the UK (also one across milk banks), seven in the US (two also described practice across milk banks in North America), two each in Denmark, Australia and Sweden (one various), one each in India, Germany, Finland, Poland and Brazil (various).

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.

2.20.2 Evidence statements

2.20.2.1 There was general agreement that a system of administration of milk samples, including tracking and tracing, was needed. However, different milk banks used different systems. [164]

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

2.20.2.3 Even where administration systems were in place, procedures were not always followed.[165]

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

- *a registry of 'raw' milk donors*

[164] 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).
[165] Based on 1 case report (Ryder et al. 1977).

- *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*
- *record of recipient use, either individual baby or other organisation.*[166]

2.20.2.5 *It is generally accepted that, whichever system is used, adequate resources (money, staff, equipment, etc.) are needed to implement an effective and efficient administration system.*[167]

2.20.2.6 *A report from a meeting recommended that contingency samples should be frozen before treatment and archived for 'investigational purposes which may arise.'*[168]

2.20.2.7 *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 milk.*[169]

[166] 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).
[167] Based on 3 narrative reviews (Bromberger 1982; Lording 2006; Weaver 2001) and 1 service description (Tully 2000).
[168] Based on 1 meeting report (Silverman 1971).
[169] Barriers based on 1 narrative review (Lording 2006).

2.20.2.8 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 send to the local health authorities.*
- *All milk samples should be marked with the name, date and time of collection.*[170]

2.20.2.9 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*

[170] Based on 1 position statement (Gutierrez and de Almeida 1998).

- *consent*
- *product used.*[171]

2.20.3 Evidence to recommendations

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.

No guidelines on the archiving of donor milk samples or critical information were found. The GDG referred to the Royal College of Pathologists' guidelines, which state that records need to be kept for no less than 30 years (paragraph 51, page 12), and that archived blood samples need to kept for at least 11 years (paragraph 66, page 14) (www.rcpath.org/resources/pdf/g031_retentionstorageofrecords_oct06.PDF).

[171] Based on 1 service description (Hartmann et al. 2007).

2.20.4 Recommendations

Recommendation 1.2.64

Track milk from the donor through to the recipient hospital.

Recommendation 1.2.65

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

Recommendation 1.2.66

At all stages, milk containers should be labelled clearly for identification (see recommendation 1.2.68). Labels should clearly distinguish released from non-released batches of donor milk.

Recommendation 1.2.67

For each milk batch, keep the following records:

- About the donor:
    - medical records/NHS number/donor ID
    - consent
    - medical history
    - serology test results.
- About each container before pasteurisation:
    - donor identification number
    - 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 milk, or the disposal date of the milk, as appropriate.

Recommendation 1.2.68

Label each pasteurised container of milk with the following information:

- an identification number assigned by the milk bank that is unique to every container
- confirmation that it contains pasteurised donor breast milk
- an expiry date.

Recommendation 1.2.69

The receiving hospital or neonatal unit should keep a record of how the milk is used.

Recommendation 1.2.70

Keep any archived blood or milk samples for at least 11 years.

Recommendation 1.2.71

All records, including raw data, which are critical to the safety and quality of the donor milk should be kept so as to ensure access to these data for at least 30 years after expiry date, use or disposal.

2.21 Staff training

2.21.1 Evidence review

Ten of the 217 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 two milk banks in the US, various milk banks in Brazil (one report) and one in Poland.

2.21.2 Evidence statements

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

2.21.2.2 Two narrative reviews stated that healthcare professionals did not have a full understanding of the benefits of milk donation or the process of milk banking.[172]

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

- *hygiene*
- *quality control*

[172] 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).

- *collection and storage procedures*
- *an update on research on the role of breast milk for the neonate.*[173]

2.21.2.4 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 certified.[174]

2.21.3 Evidence to recommendations

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.

2.21.4 Recommendations

Recommendation 1.2.74

All milk bank staff should have ongoing training relevant to their job, which should be 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.

Recommendation 1.2.75

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

[173] Based on 2 service descriptions (Asquith et al. 1987; Cash and Giacoia 1981).
[174] Based on 1 service description (Tully 2001).

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, new 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 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) 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/CGXXfullguideline). [Note: these details will apply to the published full guideline.]

Quick reference guide

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

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N1XXX). [Note: these details will apply when the guideline is published.]

‘Understanding NICE guidance’

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

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N1XXX). [Note: these details will apply when the guideline is published.]

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/PH11
- Postnatal care. NICE clinical guideline 37 (2006). Available from www.nice.org.uk/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.

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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.

[Name; style = Unnumbered bold heading]
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8.4 Declarations

8.4.1 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).

8.4.2 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.

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