Quick reference guide

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Donor breast milk banks

The operation of donor breast milk bank services

NICE clinical guideline 93
Developed by the Centre for Clinical Practice at NICE
About this booklet
This is a quick reference guide that summarises the recommendations NICE has made to the NHS in Donor breast milk banks: the operation of donor breast milk bank services (NICE clinical guideline 93).

Who should read this booklet?
This quick reference guide is for donor breast milk bank staff, healthcare professionals who care for babies who receive donor breast milk, and organisations who are considering starting a donor breast milk bank.

Who wrote the guideline?
The guideline was developed by the Centre for Clinical Practice at NICE following the short clinical guideline process. The Centre worked with an independent group of healthcare professionals (including consultants, GPs and nurses), representatives for mothers and babies, and technical staff, who reviewed the evidence and drafted the recommendations. The recommendations were finalised after public consultation.

For more information on how NICE clinical guidelines are developed, go to www.nice.org.uk

Where can I get more information about the guideline?
The NICE website has the recommendations in full, reviews of the evidence they are based on, a summary of the guideline for women who are donating, or who would like to donate, breast milk or for anyone interested in breast milk donation, and tools to support implementation (see inside back cover for more details).

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, and informed by the summary of product characteristics of any drugs they are considering.

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.
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>4</td>
</tr>
<tr>
<td>Key to terms</td>
<td>4</td>
</tr>
<tr>
<td>Key priorities for implementation</td>
<td>5</td>
</tr>
<tr>
<td>Recruiting donors</td>
<td>6</td>
</tr>
<tr>
<td>During the period of donation</td>
<td>8</td>
</tr>
<tr>
<td>Collection of donor milk and transport to the milk bank</td>
<td>10</td>
</tr>
<tr>
<td>Processing donor milk at the milk bank</td>
<td>11</td>
</tr>
<tr>
<td>Tracking and tracing donor milk</td>
<td>13</td>
</tr>
<tr>
<td>Quality assurance</td>
<td>14</td>
</tr>
<tr>
<td>Further information</td>
<td>15</td>
</tr>
</tbody>
</table>

### Person-centred care

Treatment and care should take into account individual needs and preferences. Good communication is essential, supported by evidence-based information, to allow informed decisions about care. Follow Department of Health advice on seeking consent if needed. If agreed, families and carers should have the opportunity to be involved in decisions about treatment and care.
Introduction

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

If, after discussion with experienced staff, a mother is unable to express sufficient milk or does not wish to express milk for a baby unable to feed at the breast, donor breast milk can be used. Donor breast milk banks provide donor milk for babies, including preterm babies and babies with growth restriction.

This short clinical guideline aims to improve the safety of donor milk by making recommendations on the safe and effective operation of donor milk banks. Donor milk banks should follow the recommendations in this quick reference guide for all donor breast milk that is used in the NHS.

Key to terms

**Donor breast milk** Breast milk expressed by a mother that is then processed by a donor milk bank for use by a recipient who is not the mother’s own baby. No payment is given for the donated milk.

**Donor milk depot** Any place where donor milk can be stored before transfer to the milk bank. The depot can be run by the milk bank (for example, when donors are from wide geographic areas) or by volunteers.

**Drip milk** Milk that is passively collected from one breast while the baby feeds at the other.

**Hazard Analysis and Critical Control Point (HACCP)** Further information can be found on the Food Standards Agency website (see www.food.gov.uk).
Key priorities for implementation

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

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

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

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

* These recommendations can be found in both the full guideline and the NICE guideline at www.nice.org.uk/guidance/CG93
**Donor breast milk banks**

**Recruiting donors**

Promoting the donation of breast milk
- Target as many potential donors as possible using a variety of channels (see boxes 1 and 2).
- Use clear, non-technical language.
- Include the stage 1 screening questions on page 7 in recruitment material so that potential donors can self-screen for these criteria.

Box 1. Direct referrals or recommendations by:
- current and previous donors
- staff at neonatal intensive care units
- paediatricians assessing babies’ progress
- health visitors (or other healthcare professionals providing postpartum care)
- childbirth educators
- organisers and attendees of prenatal and postnatal classes
- breastfeeding mothers’ support groups and organisations.

Box 2. Written information and other activities
- Provide written information to be left in:
  - GP surgeries
  - antenatal clinics and postnatal wards
  - volunteer and other organisations working in maternity and childbirth
  - children’s or Sure Start centres
  - maternity shops.
- Features in the media.

Screening and selecting donors
- Follow the stepped screening process detailed on page 7.
- Conduct the screening interview (see both stage 1 and 2 screening questions on page 7) at a mutually acceptable time and place, either face-to-face or by telephone.
- If a potential donor is donating previously expressed breast milk, ask her to answer the screening questions on the opposite page for the period when the milk was expressed.

At first contact: explain that serological testing (see page 7) is mandatory to reduce the risk of passing on infections. Obtain informed consent before testing.

- Perform all serological testing at enrolment. Do not rely on antenatal test results.
- Before accepting a donor’s milk, obtain her consent for its processing and intended use. Advise her that, once donated, the milk will not be returned to her.

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Footnotes for screening diagram on page 7:
1 Recommended alcohol levels for breastfeeding mothers. See www.dh.gov.uk for information on alcohol and breastfeeding.
2 See www.hpa.org.uk for information on the risk of CJD.
3 Ensure that all tests are carried out in laboratories with clinical pathology accreditation (CPA), and that results are communicated clearly and can be interpreted appropriately. Blood samples received from donors should be archived by the laboratory.
4 See www.dh.gov.uk for guidance on the safety of recent vaccination when breastfeeding.
Screening questions to ask the potential donor: stage 1

- Does she:
  - currently smoke or use nicotine replacement therapy?
  - regularly drink more than 1 to 2 units of alcohol once or twice a week?¹
  - use, or has she recently used, recreational drugs?
- Has she ever tested positive for HIV 1 or 2, hepatitis B or C, human T-lymphotropic virus (HTLV) type I or II, or syphilis?
- Is she at increased risk of Creutzfeldt–Jakob disease (CJD)?²

NO to all of these questions

Conduct a further interview and serological testing to assess possible risks to babies receiving the donor breast milk.

YES to any of these questions

Advise that she is not eligible to donate milk.

Screening questions to ask the potential donor: stage 2 – assessment of risk

Ask questions about:
- her health and that of her baby
- any recent exposure to infection (including HIV 1 or 2, hepatitis B or C, HTLV I or II, syphilis, herpes, or acute or chronic infections) – further testing may be needed
- any recent medical intervention (for example, exposure to diagnostic radioactive isotopes)⁴
- any medication she is taking, or medical treatment she is having
- any exposure to passive smoke (for example, do other members of her household smoke heavily?)
- any significant environmental or chemical exposure (for example, contamination of the local water supply): is she exposed to high or sustained levels of contaminants that can be expressed in breast milk?

Refer to medical sources, with consent, if necessary.

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

Use the information given to make a balanced decision about the woman’s eligibility to donate based on possible risks to recipients and/or the results of subsequent serological testing.

Serological testing³

Test for:
- HIV 1 and 2
- hepatitis B and C
- HTLV I and II
- syphilis.

Test negative

Give test results either in person or by telephone (unless the woman prefers to receive them in writing). If needed, offer further help and support based on local protocols, including information on counselling and local support groups.

Test positive

Exclude from donating
During the period of donation

While a donor continues to donate milk:

- ask regularly about her general health and the screening exclusion criteria on page 7
- advise her to contact the milk bank immediately if her status or any circumstances change that may affect her answers to the screening questions on page 7
- do not routinely repeat serological tests.

Training and support for donors

Provide all new donors with:

- training (see table 1)
- ongoing support according to their individual needs until no longer required. This may include:
  - information and ongoing support on milk bank requirements for their diet and alcohol consumption
  - continued support for collecting expressed milk and maintaining lactation
  - emotional support.

<p>| Table 1. Training to be provided for all donors |</p>
<table>
<thead>
<tr>
<th>Where and when</th>
<th>Topics to be covered</th>
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<tr>
<td>Preferably face-to-face giving additional information by telephone and in writing. Conduct at a time and place that is suitable for both donor and trainer.</td>
<td>Hand washing and the importance of this. Good personal hygiene. Collecting and expressing milk, including cleaning and using breast pumps and containers. Storing donated milk (including cooling and freezing). Labelling donated milk and documenting storage conditions. Transporting donated milk (if needed).</td>
</tr>
</tbody>
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If a woman’s milk has significant or repeated microbial contamination, offer additional support and information on milk collection.

Advice to give donors on expressing and handling milk at home

Method of expression

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

- Advise donors to collect expressed milk rather than ‘drip’ milk.

Collection of donor milk

Advise donors that:

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

- collection containers should be used according to instructions provided by the milk bank.
Storage of donor milk

Advise donors that:

- milk collected for donation should be frozen as soon as possible to maintain its nutritional and microbiological quality and that it should be kept frozen
- if necessary (for example, because of storage capacity), they can refrigerate expressed milk they collect over 24 hours and then freeze the batch
- frozen expressed milk should be transported to the milk bank (see page 10) as soon as possible
- if necessary, expressed milk can be stored before transport to the milk bank (see page 10) for up to 3 months in a domestic freezer at −18°C or lower
- if they do not have access to a freezer at their home, they may be able to access freezers for milk storage at local donor milk depots or children's centres
- if they have any concerns about storage conditions or freezer temperatures, they should discuss these with the milk bank.

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

Stopping donations

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

- milk that does not meet the microbiological criteria given on page 12
- small amounts of milk.

When to advise donors to contact the milk bank to discuss suspending or stopping their milk donation

- If they develop a fever or have contact with a viral exanthematous disease.
- If they begin taking any medication*.
- If they develop lesions or infections of the breast (including mastitis or herpes).

* Refer to appropriate reference sources, such as the British national formulary for children, the Drugs and Lactation Database (LactMed; www.toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT), or the UK Drugs in Lactation Advisory Service (www.ukmicentral.nhs.uk/drugpreg/guide.htm).

If a donor is stopping their milk donation, provide them with as much advice and support as they need.

Consider the size of the recipient population, the milk bank's stock levels, and the preferences of the donor when discussing how long a woman can donate milk.
Collection of donor milk and transport to the milk bank

Collection of donor milk
- Collect from either the donor’s home, or from donor milk depots that monitor freezers and maintain standards for quality control. Ensure that similar processes are in place in any location where the milk is stored.
- Where possible use an agreed transport provider (ideally a medical courier) or a member of staff from the milk bank.
- Donors may sometimes deliver their own milk to the milk bank or depot, in which case they should also follow the milk bank’s requirements for transport.

Transport of donor milk
- Define critical transport conditions, including temperature and time limit, to ensure that the donor milk remains frozen.
- Define in writing the milk bank’s procedures for transporting and storing donor milk. Ensure that these procedures maintain the quality of the milk and allow accurate identification of samples.
- Transport in secure, tamper-evident containers and packaging.
- Keep records of inventory and distribution.
- If a contracted third party is used for transport, ensure that a documented agreement is in place to maintain the conditions needed.
- Use consistent monitoring processes, including recording the journey time.
Processing donor milk at the milk bank

- Process all donated milk under hygienic conditions (a sterile environment is not necessary).
- Practise good hand hygiene and wear gloves when handling donor milk.
- Keep all donor milk in containers made of food grade materials.
- Discard milk from donors who do not meet the selection criteria (see the stepped screening process on page 7).
- Seek help from microbiological laboratories to identify and investigate significant or unusual contamination.
- Do not add anything to the donated milk.
Donor breast milk banks

Processing donor milk at the milk bank

Receiving donated milk
- Check milk:
  - is labelled correctly with the donor’s name and date of expression
  - is still frozen
  - has not been tampered with.
- Transfer immediately to the freezer.

Storing donated milk
- Store pasteurised and unpasteurised milk in separate freezers and fridges.
- Store milk awaiting pasteurisation in the freezer (at −20°C) for no longer than 3 months from the date of expression.
- Only pool pre-pasteurised milk from the same donor.
- Do not pool milk from different donors.

Testing donated milk
- Thoroughly thaw the milk, keeping it at less than 8°C.
- Do not store milk in the fridge for longer than 24 hours.
- Test a sample from each batch of pooled milk for microbial contamination.
- Ensure that laboratories communicate test results clearly, and that they provide comments that can be interpreted appropriately.

Do samples exceed:
- $10^5$ colony-forming units (CFU)/ml for total viable microorganisms or
- $10^4$ CFU/ml for Enterobacteriaceae or
- $10^4$ CFU/ml for Staphylococcus aureus?

Pasteurise milk at 62.5°C for 30 minutes in a human milk pasteuriser.

After pasteurisation
- Rapidly cool milk to 4°C or lower, remove one bottle for testing (see below) if appropriate, then move the remainder of the batch to the freezer; store for no longer than 6 months after the date of expression.
- Do not open the lid of pasteurised milk unless it is to test the milk; discard any bottles opened for testing.
- Do not pool batches of pasteurised milk from the same donor.

Testing pasteurised donor milk
- Regularly test pasteurised milk for microbial contamination. Base the testing schedule on volume and throughput of milk. Test:
  - either at least once a month or every 10 cycles, whichever comes first, and
  - whenever new processes, equipment or staff are introduced, or if there are concerns about any part of the process.
- Discard pasteurised milk that has a total viable microbial count of 10 CFU/ml or more.
Donor breast milk banks

Tracking and tracing donor milk

- Track milk from the donor through to the recipient hospital.
- When tracking and monitoring donor milk processing, include freezer temperatures, pasteurisation processes and stock control.
- Clearly label all donor milk containers; clearly identify milk that is ready to be used.
- For pasteurised donor milk, label each container with:
  - a unique identification number
  - confirmation that the milk has been pasteurised
  - instructions to keep frozen and use within 24 hours of defrosting
  - an expiry date (no later than 6 months from expression).

<table>
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<tr>
<th>Records to be kept for each donor milk batch¹</th>
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| **About the donor** | NHS number/donor ID.  
|                   | Consent.  
|                   | Relevant medical history.  
|                   | Serological test results.  
| **Before pasteurisation** | For each container:  
|                   | donor ID  
|                   | tests undertaken  
|                   | test results.  
| **After pasteurisation** | For each container:  
|                   | samples that make up the batch  
|                   | the batch number  
|                   | tests undertaken  
|                   | test results  
|                   | details of pasteurisation, including date.  
| **About the milk** | Hospital or neonatal unit that receives the milk, or date of disposal.  

¹ Keep all records (including raw data) that are critical to the safety and quality of the donor milk for at least 30 years after the expiry date, use or disposal. These records are confidential.

- Only supply donor milk to hospitals or neonatal units that agree to comply with the tracking procedures for milk outlined by the milk bank.
- The hospital or neonatal unit should keep a record of how the donor milk is used. They should document for each bottle of milk:
  - the condition of the milk when it arrives after transport
  - the storage conditions
  - the baby's name, NHS number and date of birth, and the date administered
  - the batch number and the date the milk was used in the patient record of each baby.
Quality assurance

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

- Implement a quality control system that is followed by all milk bank staff. This should cover:
  - collecting, testing, processing, storing and transporting milk
  - personnel, required documentation, premises and equipment
  - batch recall, external and internal auditing, non-conformance to processes and self-inspection
  - continuous quality improvement.

- Review the quality control system regularly.

Equipment used in handling and processing donor milk

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

- Validate, calibrate and maintain all equipment; keep records of this.

- Use equipment according to the manufacturer’s instructions.

- Regularly inspect all equipment; follow the manufacturer’s instructions.

- If equipment could affect temperature or contamination levels, ensure that it has sensors and alarms so that constant conditions can be maintained.

Training of milk bank staff

- Conduct ongoing training for all milk bank staff that is relevant to their job; record this training.

- Cover good practice and ensure 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
  - is trained in HACCP principles, food hygiene and pasteurisation.

- Provide ongoing support so that practices reflect HACCP principles.
Donor breast milk banks

Further information

Ordering information
You can download the following documents from www.nice.org.uk/guidance/CG93

- A quick reference guide (this document) – a summary of the recommendations for healthcare professionals.
- ‘Understanding NICE guidance’ – a summary for patients and carers.
- The full guideline – all the recommendations, details of how they were developed, and reviews of the evidence they were based on.

For printed copies of the quick reference guide or ‘Understanding NICE guidance’, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk and quote:

- N2094 (quick reference guide)
- N2095 (‘Understanding NICE guidance’).

Implementation tools
NICE has developed tools to help organisations implement this guidance (see www.nice.org.uk/guidance/CG93).

Related NICE guidance
For information about NICE guidance that has been issued or is in development, see www.nice.org.uk

Published


Updating the guideline
This guideline will be updated as needed, and information about the progress of any update will be available at www.nice.org.uk/guidance/CG93