

Appendix 4 Survey of donor milk banks in the UK

Rationale for the survey

During the scoping work for this guideline it was clear that the evidence base for the operation of donor milk bank services was very limited. We considered that an assessment of current service provision and issues, through a structured survey, would be a useful addition to the published literature. The survey should cover:

- rates of donation and use of donor breast milk
- costs of service provision
- descriptions of models of service provision
- perceived problems with current services
- results of completed audits, and
- further information or research to support the development of services.

As this guideline was not intended to develop ‘true’ service guidance (that is, where the level of need is assessed and guidance is given on how this need should be met), we wanted to be sure that the information collected would directly inform the recommendations. However, we were clear from the outset that the survey would not be considered during the drafting of the recommendations (that is, the survey was not considered as primary evidence) but would be used to focus our questions at the initial stages and to compare the final draft recommendations to current practice and highlight areas where change was required.

Developing the survey

The survey was developed by the guideline technical team and questions were framed based on existing guidelines and other surveys of donor milk banks, primarily the UKAMB milk bank surveys (personal communication; UKAMB 2008). The drafts were discussed and piloted with 2 GDG members (GW and NM), and members of other teams within NICE, including the Implementation Support and Costings teams. The survey was then revised, as appropriate, and a final version agreed. A copy of the final version with the covering letter can be seen at the end of this Appendix.

Methods

The survey was sent to 17 milk banks in the UK, and non-responders were followed-up both by letter and by telephone, if required. Results were collated and a basic analysis undertaken. We designed the survey simply to describe current practice, not to allow detailed analysis comparing responses with any factor associated with the milk bank.

Results

The summary results were presented to the GDG at two points in the development of the guideline

- results on priorities for the guidelines (section 6 in the questionnaire), perceived problems (section 9) and areas where more information or research is needed (section 10) were presented at meeting 1, and
- the summary results for all sections were presented at meeting 3, after all recommendations had been agreed for consultation.

Overall, 13/17 milk banks returned completed questionnaires (a 76% response rate). Many responses are very detailed with lots of supporting documentation.

Demographic data

The respondent milk banks were from a wide geographical area, and were hosted in different ways (these included neonatal intensive care units, special care baby units, women's and children's services, health visiting services, paediatrics and neonatal medicine). Some milk banks were linked to specific services or units, whilst others were not. Funding arrangements also differed, but the majority of milk banks were funded wholly through the NHS; two milk banks received only 10-12.5% of their funding from the NHS. In one milk bank, the remaining funding was provided through charitable donations. The length of time that the milk banks had been running ranged from 5 years to 70 years.

Current service provision and delivery

The range of responses can be seen in Table 1 below.

Table 1 Level of service provision in 2008-9

	Minimum	Maximum	Median
How many babies in your attached neonatal unit received donor breast milk?	35	234	73.5
How many women donated milk?	7	139	48
How many new donor women were recruited?	11	161	73
How much milk (in litres) was collected?	15.4	1940	209
How much milk (in litres) was pasteurised?	13.5	1740	205.5
How much milk (in litres) was disposed of?	1.9	599	49.9
How much milk (in litres) was received from other milk banks?	0	2	0
How much milk (in litres) was transported to other milk banks?	0	2	0
How much milk (in litres) was received from other hospitals?	0	365	0
How much milk (in litres) was transported to other hospitals?	0	818	34.5
How many babies in other neonatal units received donor breast milk from your unit?	0	65	14

Other caveats to the figures presented include one milk bank reported some responses for 9 months only, one reported figures for 2007 as more recent data were not available, and one reconfigured services during 2008 so figures were not complete.

Most milk banks did not charge local units for the provision of milk (because the funding often is provided through the local unit), however, one milk bank charges £40 per litre.

Most milk banks charged other units between £100 and £150 per litre, as a contribution to costs, but again one charged £40 per litre. As well as providing other units, most milk banks provided to other services, including community services.

Staffing and organisation

Milk banks operated using a variety of staffing structures. Very few milk banks employed full time members of staff; if they did, the types of role included donor

screening, milk bank assistant, and manager. Most roles were part-time, and some milk banks supported employed staff with volunteers.

There was a range of staff/roles involved; some could be considered as 'expert' roles, and some 'general'. Examples of role descriptions included:

- consultant
- pasteuriser
- counsellor
- nursery nurse
- administration.

Donor recruitment

Most milk banks (11/13) reported that they actively recruit donors. Examples of some methods included through antenatal classes and wards, local magazines, or a milk bank website. Some milk banks (2/13) reported using leaflets and other promotional material, and 'word of mouth'.

Most milk banks (7/11) followed the UKAMB guidelines on recruitment, whilst some (3/11) did not. Although some milk banks reported not following the UKAMB guidelines, one interpretation of this could be that they followed most of the recommended process, but adapted them for local circumstances.

Donor screening

Most milk banks used a mixed approach with different strategies being used at different points in the process – for example, an initial screen via telephone, with a more in-depth interview face-to-face.

Table 2 Screening process for donor women

How do you ask screening and/or selection questions to donor women?		
Verbally, face-to-face	12 did (1 mostly)	1 missing response
Verbally, by telephone	10 did (1 mostly)	3 missing responses
By written questionnaire with no support from a milk bank member of staff	4 did not 1 rarely – followed up with phone call	8 missing responses
By written questionnaire with support from a milk bank member of staff	8 did (1 only if by post)	5 missing responses

Most milk banks (11/13) did not rely on the results of relevant antenatal tests, and tested at the time of screening for donation.

The majority of milk banks (9/12) followed the UKAMB guidelines on screening; some (3/12) did not. Reasons given for not following the guidelines were that repeat screening during donation was not done (however, this UKAMB recommendation was specified as 'ideally').

Donor stopping

Most milk banks (12/13) provided information on stopping (temporarily or permanently) to donors; in many cases, this was both written and verbal information and was mainly on medication use. Some milk banks (2/13) used the relevant UKAMB leaflets. However, it is known that more milk banks adapt the UKAMB information to their local needs.

Some milk banks (2/13) suggested that mothers should stop donating when their baby is a defined age (6 or 12 months).

All milk banks (12/12) followed the UKAMB guidelines.

Expressing milk for donation

All milk banks (11/11) followed the UKAMB guidelines. The provision of information on expression differed; some (4/11) milk banks specified using the UKAMB leaflets for donors, others verbally, including by telephone.

Milk storage at home

Most milk banks (11/13) followed UKAMB guidelines; however some (2/13) did not, and reasons given were that home freezer temperatures or freezers on wards (if providing a one-off donation) temperatures were not monitored. A range of support was provided; this included the provision of thermometers, daily recording sheets, and general information.

Milk transportation

Most milk banks (11/13) followed UKAMB guidelines on the transport of donor milk. A range of methods of temperature monitoring were reported, with some milk banks using simple thermometers, and one milk bank reported using 'warm milk' temperature recorders.

Milk storage at the milk bank

Most milk banks (12/13) followed UKAMB guidelines; one milk bank did not, but followed detailed protocols including audio and visual alarms on freezers, twice-daily monitoring and recording. As expected, a range of processes was described. However, most milk banks monitored freezer temperatures once or twice a day, and milk was stored, when stated, at -20 to -21 degrees C.

Testing donor milk

All milk banks (13/13) followed UKAMB guidelines, with some variation in pre- and post-testing; one milk tested random samples, whilst two milk banks tested all batches. No milk bank reported different pre- and post-testing schedules.

Pasteurising donor milk

All milk banks (13/13) followed UKAMB guidelines on treating donor milk. When specified, all milk banks used Holder pasteurisation. There was some variation in the equipment used, but all models had monitoring and recording facilities. In addition to the in-built monitoring feature, one milk bank reported checking temperatures with a probe.

Pooling milk

No milk bank (0/13) pooled milk between donors.

Fortifying donor milk

Donor milk from most (7/12) milk banks was reported as being fortified; however, we did not ask how much of each donor milk banks' milk was fortified. If done, all donor milk would be fortified after pasteurisation.

Archiving samples of donor milk

Few milk banks (3/13) archived samples of milk, and two followed UKAMB guidelines. Reasons given for not archiving included a lack of storage space or equipment, a lack of rationale from the microbiological perspective (for example, if a serum sample is retained), and a lack of evidence.

Disposing of donor milk

A range of methods of disposal was reported, but most milk banks used the same processes as for general clinical waste.

Table 3 Disposing of donor milk

Do you have a process for disposing of donor breast milk?		
Raw milk?	8 did	1 missing response 1 not known
Pasteurised milk?	8 did	1 missing response 1 not known
Milk that does not meet acceptance criteria?	9 did	1 missing response 1 not known

Information recording¹

Milk banks reported various approaches to obtaining consent from the donors from structured, informed consent to verbal, implicit consent (however this was reported as being changed). Consent was stored mainly in hard copy.

All milk banks had processes for tracking and tracing within the milk bank, and between the milk bank and the receiving hospital; however, these differed. Most reported information recording being manual and storage being in hard copy.

¹ Although we asked for information on consent for use of donor milk by the recipient's parent or carer, we have not reported the information here as this is not considered the responsibility of the donor milk bank.

Staff training

All milk banks provided staff training; this included food handling, clinical skills, phlebotomy, breastfeeding support training, pasteurisation, UKAMB support training, general orientation to the milk bank process, and ongoing development.

Information provision²

Most milk banks used UKAMB leaflets, or local leaflets, to provide information to donors or potential donors. See also other sections for specific information provision.

Priorities for the NICE guideline

It should be emphasised that the rankings were not used to exclude areas to be covered in the guideline, but to ensure that we focussed on those areas considered most important by the milk banks themselves.

² Although we asked about the information provided to a potential recipient's parent or carer, we have not reported the information here as this is not considered the responsibility of the donor milk bank.

Table 4 Ranking of priorities

	Median ranking*	Highest ranking	Lowest ranking	Order of priority
Donor recruitment and selection	3	1	5	Important
Collection, storage, and handling of donor breast milk	2	1	5	Important
Administration of the service, including tracking and tracing of donor breast milk	2	1	5	MOST important
Training of staff	3	2	5	LESS important
Information for donors and parents/carers of babies receiving donor breast milk	4	1	5	LEAST important

*1 being the most important and 5 being the least important

Perceived problems with current services

Reported themes were:

- Personal opinion amongst HCP and wider perception as to its benefits
- Lack of funding
- Milk bank needs to be a dedicated job, not part of another job
- Lack of facilities (storage, preparation areas)
- Lack of standard training, which impact on staff recruitment
- Practical challenges of milk collection and transport
- Lack of statutory guidelines
- Lack of coordinated effort to meet wider needs
- Concerns over the robustness of record keeping, including track back from recipient units

- Lack of time and/or staff (both nursing and administrative)
- Dependence on 'good-will' of staff and volunteers
- Recruitment of donors
- Link with microbiological expertise and support

Suggestions to address perceived problems

Reported themes were:

- Development of a NICE Guideline
- Support with funding, including a proper ring-fenced budget
- More staff, both nursing and administrative
- Recognition of the vital service provided
- Research work to demonstrate the cost effectiveness of using DBM in intensive care of the newborn situations, for example in the reduction of NEC
- Dedicated hours for milk bank staff, with job descriptions
- Education of all staff involved in milk banking
- Standardised 'paper trail' to be used by all milk banks, either with computerised/electronic dedicated tracking systems and records or simple computerised forms/data
- Standard training package, with further qualification(s) on management/administration issues.
- More milk collection depots in the community with coordinated local/regional transport systems
- Set up a national service with government funding with regional centres covering the whole country not necessarily within a hospital setting, but with the correct staff & facilities & funding to run a national service

Other information or research needed

Reported themes were:

- Analysis of safety and benefit for recipient babies in different circumstances
- Analysis of milk and how this relates to fortification

- Clear guidelines by NICE, that are cost effective and consider costs (with funding provided if needed)
- DoH support to ensure milk banks are following best practice, with local and national monitoring
- Equitable access for all babies, not dependent on opinions of HCP caring for them
- Coordination between milk banks

Conclusions

Milk banks operate services in different ways but the majority are following the existing UKAMB guidelines.

Acknowledgements

We would like to thank all those who responded to the survey, and we appreciate how much time this would have taken. The results have been extremely useful in the development of the NICE guidelines and helped to ensure that the final recommendations are relevant to current milk banking practice in the UK.

Letter to milk bank managers

Dear

The National Institute for Health and Clinical Excellence (NICE) has been asked to develop a short clinical guideline on the operation of donor breast milk bank services. As part of the work for this guideline, we would like to understand the how existing milk bank services work and the level of service that they provide. This will then enable the Guideline Developers to write practice recommendations that are relevant to current practice in donor breast milk banking.

Please find enclosed a questionnaire asking about how your milk bank services are being operated, and what information you feel you would need to develop the service in future. This questionnaire has been sent to all UK milk banks, and any response is entirely voluntary.

We anticipate that this will take approximately 1 hour to complete.

All results will be confidential, and will be anonymised and summarised in the final report. We will inform you when the draft guideline (which will include the results of the survey) is on the NICE website and we encourage you to register as a stakeholder, through your host organisation. Please see the NICE website for how to register as a stakeholder (www.nice.org.uk).

When completed, please return the survey in the pre-paid envelope **by Monday 6th April 2009** to

Kathryn Chamberlain
National Institute for Health and Clinical Excellence
Level 1A, City Tower
Piccadilly Plaza
Manchester M1 4BD
Tel: 0161 870 3110 | Fax: 0845 003 7785

If you have queries on any aspect of the questionnaire or the guideline, please do not hesitate to contact Kathryn (Kathryn.chamberlain@nice.org.uk).

Yours sincerely

Tim Stokes

Associate Director

Kathryn Chamberlain

Project Manager



NICE questionnaire on donor breast milk services

When completed, please return **Monday 6th April 2009** in the pre-paid envelope to

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NICE questionnaire on donor breast milk services

The National Institute for Health and Clinical Excellence (NICE) is developing a short clinical guideline on the operation of donor breast milk bank services. As part of this work, we are conducting a survey of existing milk bank services to

- a) determine current practices in donor breast milk banking, and
- b) gain information needed for future practice.

We would very much appreciate if you could complete the questionnaire about your donor breast milk bank service. The information it provides will be an essential part of developing NICE guideline recommendations that are relevant to current practice in donor breast milk banking. All responses will be anonymised in the final report.

Details of your milk bank

Name of donor breast milk bank	
Host organisation – for example, district general hospital	
Department of host organisation with responsibility for the milk bank	
Are your services attached to any specific neonatal/specialist services? If so, which one(s)?	
Approximately how much of your funding in percentage terms is from your NHS Trust?	%
Approximately how much of your funding in percentage terms is charity-based?	%
How long has the milk bank been established?	

Current service provision and design

1 In your milk bank in 2008

If you do not know, please answer 'Not known'

- | | | |
|-----|---|--|
| 1.1 | How many babies in your attached neonatal unit received donor breast milk? | |
| 1.2 | How many women donated milk? | |
| 1.3 | How many new donor women were recruited? | |
| 1.4 | How much milk (in litres) was collected? | |
| 1.5 | How much milk (in litres) was pasteurised? | |
| 1.6 | How much milk (in litres) was disposed of? | |
| 1.5 | How much milk (in litres) was received from other milk banks? | |
| 1.6 | How much milk (in litres) was transported to other milk banks? | |
| 1.7 | How much milk (in litres) was received from other hospitals? | |
| 1.8 | How much milk (in litres) was transported to other hospitals? | |
| 1.9 | How many babies in other neonatal units received donor breast milk from your unit? | |

Please add any comments or clarifications on the responses above.

2 In your milk bank, how many full-time equivalent members of staff are you currently funded to employ?

If possible, please provide a detailed breakdown – for example, the numbers of staff by grade, job title, and hours worked.

3.3 How do you ask screening and/or selection questions to donor women?

Please check all those which apply.

Verbally, face-to-face

Verbally, by telephone

By written questionnaire **with no** support from a milk bank member of staff

By written questionnaire **with** support from a milk bank member of staff

Other (please give details)

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3.4 What processes do you have to validate information provided by donor women?

For example, do you repeat tests that were undertaken antenatally?

Could you please attach any documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

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3.5 Do you provide information to donor women on when to stop donation, either temporarily or permanently? Yes/No

If yes, please attach any written documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

Do you advise donor women on when to stop donation (temporarily or permanently) as recommended in the UKAMB 2003 guidelines? Yes/No
Please add any additional detail, if needed, in the box below.

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3.6 What information do you give to donor women on expressing milk?

Could you please attach any relevant documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

Is the information you give to donor women on expressing milk consistent with that recommended in the UKAMB 2003 guidelines? Yes/No
Please add any additional detail, if needed, in the box below.

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3.7 How do you recommend that donor breast milk should be stored?

Could you please attach any documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

Do you advise donors to follow the UKAMB 2003 recommendations on how to store milk **at home**?

Yes/No

Please add any additional detail, if needed, in the box below.

For example, what are the minimum standards for the freezer at the donor's home, and how do you monitor these?

Do you follow the UKAMB 2003 recommendations on how to store milk **during transportation**?

Yes/No

Please add any additional detail, if needed, in the box below.

For example, how are samples stored during transportation, and how do you monitor these?

Do you follow the UKAMB 2003 recommendations on how to store milk **at the milk bank**?

Yes/No

Please add any additional detail, if needed, in the box below.

For example, what are the minimum standards for the freezer at the milk bank, and how do you monitor these?

3.8 How you test donor breast milk?

Where appropriate, please attach any documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

Do you test milk as recommended in the UKAMB 2003 guidelines?

Yes/No

Please add any additional detail, if needed, in the box below.

For example, what bacteriological/microbiological tests do you do? How do you record the results? What criteria, related to the testing, do you use to reject milk?

3.9 How you treat donor breast milk?

This relates to the heat treatment, not the fortification of milk.

Where appropriate, please attach any documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

Do you treat donor breast milk as recommended in the UKAMB 2003 guidelines?

Yes/No

Please add any additional detail, if needed, in the box below.

For example, what pasteurisation process do you use – method of pasteurisation, equipment used? How do you cool the milk? How do you audit the process of treatment?

3.10 Do you pool donor breast milk from different donor women? Yes/No

If yes, please attach any documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

3.11 Do you fortify donor breast milk? Yes/No

If yes, do you do this before or after heat treatment or pasteurisation?

Before/after

Please summarise any additional information in the box below.

3.12 Do you archive samples of donor breast milk? Yes/No

If yes, please attach any documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

Do you archive samples of donor breast milk as recommended in the UKAMB 2003 guidelines?

Yes/No

Please add any additional detail, if needed, in the box below.

For example, how long do you store samples for? What are these kept for?

3.13 Do you have a process for disposing of donor breast milk?

Where available, please attach any documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

Raw milk?

Yes/No

Pasteurised milk?

Yes/No

Infected milk?

Yes/No

Please add any comments or clarifications on the responses above.

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3.14 How do you record and store information on

The consent to donate donor breast milk?

The consent to use donor breast milk?

Tracking and tracing donor breast milk <u>within</u> the milk bank?

Tracking and tracing donor breast milk <u>between</u> the milk bank?

4 What training do the following receive?

Donor breast milk bank staff
Other staff working with mothers and babies who may benefit from, or who are receiving, donor breast milk
Other staff working with potential donors

5 What information is provided to the following?

Please attach any relevant documentation (either as hard copy or in an electronic version as appropriate). If no written documentation is available, please summarise in the box below.

Parents or carers of babies receiving donor breast milk
Donors and potential donors

6 What areas of service provision should we focus on in the NICE short guideline on the operation of donor breast milk bank services?

Please rank the following five areas in order, with 1 being the most important and 5 being the least important.

	Rank in order (1 to 5)
Donor recruitment and selection	
Collection, storage, and handling of donor breast milk	
Administration of the service, including tracking and tracing of donor breast milk	
Training of staff	
Information for donors and parents/carers of babies receiving donor breast milk	

7 Do you have any recent, completed audit information?

If so, and you are willing to share the information, please attach any audit information to the questionnaire (if the information is in an electronic format, please email to Kathryn.Chamberlain@nice.org.uk).

Further information or research

8 In your milk bank

8.1 Are you able to estimate how much a litre of donor breast milk costs to produce? Yes/No

If yes, would you be willing for us to contact you at a later date to get more details?

Yes/No

8.2 How much do you charge **your local** neonatal unit for donor milk?

8.3 How much do you charge **other** neonatal units for donor milk?

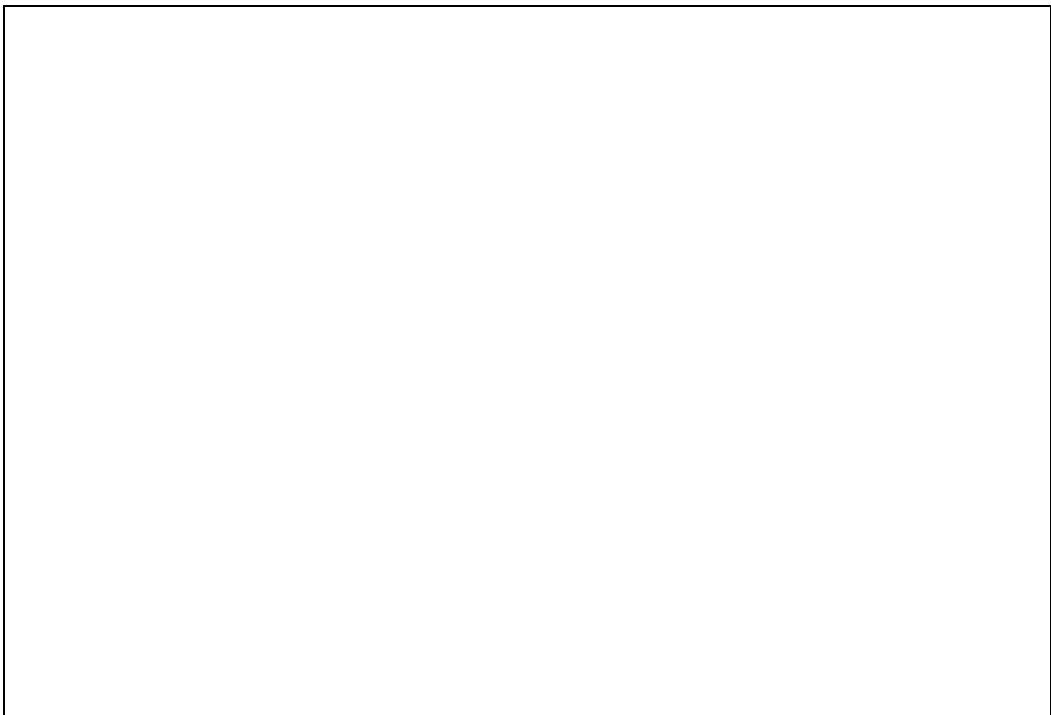
8.4 Do you supply anyone other than neonatal units with donor milk? Yes/No

If so, what sort of service do you supply to (for example, paediatric intensive care, surgical, oncology)?

9a What are your perceived problems with current services?



9b How could these problems be addressed?



10 What information or research would you need to develop your service in the future?



Thank you for taking the time and effort to complete this questionnaire.