National Institute for Health and Clinical Excellence

Donor breast milk banks

Guideline Consultation Comments Table

08 September 2009 – 06 October 2009

Type	Stakeholder	Order No	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Association of Breastfeeding Mothers	2.00	37		Recommendation 1.2.12 I am unclear what evidence the Committee have replied on in deciding to perform all screening tests at the time of enrolment. Using antenatal tests would increase the attractiveness of milk donation for many would-be donors.	The GDG considered it vital to repeat any antenatal tests to ensure the safety of the milk; also not all tests are done antenatally.
SH	Association of Breastfeeding Mothers	2.01	38		Recommendation 1.2.18 Interviews, or informal discussions, where the would-be donor feels that her milk may be rejected, are very emotive. It is suggested that such discussions should not take place within the donor's home. It is noted that some of the documented evidence included milk bank staff visiting the donor's home and making general observations, including as to the level of hygiene. (page 34 line 10-11). This would seem intrusive.	The interview can take place at any site as agreed with the potential donor and the interviewer. The evidence statements reflect the evidence reviewed, and the GDG agreed that such actions should not be recommended in this guideline.
SH	Association of Breastfeeding Mothers	2.02	45	19	An excellent guide is Thomas Hale "Medications and Mother's Milk" 2008 (13th ed)	We have recommended that milk banks should refer to up-to-date sources of information and have provided web links. However, other sources such as this could be used. UPDATE: We have only referenced the BNF-C but recognise that other sources could be used.
SH	Association of Breastfeeding Mothers	2.03	46	6 – 7	The NICE guidelines note but do not condone the practice of asking a mother to cease donations at a certain age such as 12 months.	We have not made recommendations on the age of the donor's baby as this would be more appropriate in a guideline on the indications for the use of donor breast milk.
SH	Association of Breastfeeding Mothers	2.04	46		The immune boosting qualities associated with regression milk are particularly strong. There may be circumstances where this is especially appropriate for the recipient baby.	However, we are not making recommendations on which babies should receive this milk. This may be an area that would be covered in a guideline on the indications for donor breast milk.
SH	Association of Breastfeeding Mothers	2.05	46	10, 11, 12, 13	This appears to be a pragmatic compromise and we hope that there will be more research to provide more evidence to base recommendations upon.	And this would be more appropriately covered in a guideline on the indications for donor breast milk.
SH	Association of Breastfeeding Mothers	2.06	47		Recommendation 1.2.25 While it may be appropriate to cease accepting milk from mothers whose milk does not meet microbiological or quantity criteria, such would-be donors may need emotional support as this is an emotive subject, and we hope that they would receive such support as per recommendation 1.2.29 which applies to mothers who are stopping of their own violition.	We have recommended support at two points relevant – post testing and ongoing if the milk does not meet the microbiological criteria. So we would expect this support to be provided as you suggest.
SH	Association of Breastfeeding Mothers	2.07	47		Recommendation 1.2.26 While milk from ill mothers may be inappropriate for vulnerable infants it may not be contra-indicated for all infants, depending on the extent and nature of the illness. The milk bank should be sensitive to this issue and match the milk to the	And this would be more appropriately covered in a guideline on the indications for donor breast milk. We also have specified that any illness should be

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					recipient without unnecessarily discarding milk.	discussed with the milk bank for a full consideration (the donor would not meet the criteria for good general health, so should raise this with the milk bank)
SH	Association of Breastfeeding Mothers	2.08	47		Recommendation 1.2.27 The use of Thomas Hale "Medications and Mother's Milk" (2008) 13th ed has been found to be especially useful.	We have recommended that milk banks should refer to up-to-date sources of information and have provided web links. However, other sources such as this could be used. UPDATE: We have only referenced the BNF-C but recognise that other sources could be used.
SH	Association of Breastfeeding Mothers	2.09	47		Recommendation 1.2.27 While milk from mothers taking medications may not be appropriate for vulnerable infants, it may not be contra-indicated for all infants, depending on the nature of the drug taken. The milk bank should be sensitive to this issue, and match the milk to the recipient without unnecessarily discarding milk.	We have specified that any medication should be discussed with the milk bank for a full consideration .
SH	Association of Breastfeeding Mothers	2.10	54		Recommendation 1.2.36 The practicalities of expressing milk for donation mean that mothers may find it hard to always use pre-approved collection containers. We hope that the milk banks would find a range of containers acceptable, as the evidence cited a variety of different collection containers.	We have recommended that milk should be in containers acceptable to the milk bank – this does not necessarily need to be pre-approved.
SH	Association of Breastfeeding Mothers	2.11	54		Recommendation 1.2.38 If there are automated methods of checking and documenting freezer temperature, these would be preferable to ease the administrative burden on donating mothers. Additionally, arrangements need to be put in place for holiday periods when the donor is not physically present to document freezer temperature.	We accept that documentation of the freezer temperature may be a burden, but is part of the quality assurance needed to ensure the 'safest' milk being delivered to the milk bank. We would expect that this would be discussed with the milk bank and appropriate arrangements put in place.
SH	Association of Breastfeeding Mothers	2.12	90	5, 6, 7	Disposal of donated milk via the clinical waste system is obviously necessary at times, however, it seems that this is a big waste when so many babies are routinely fed formula. Ideally milk banks would release such milk for general use before considering disposing of it.	We have made specific recommendations on when donor milk should be discarded. The GDG did not consider milk from donors who were not suitable to recruit or milk that did not meet microbiological standards to be appropriate to use.
SH	Association of Breastfeeding Mothers	2.13	99	17	We agree that there is limited high-quality evidence on this subject, and would be glad for further research to aid better practice in milk banking.	…
SH	Association of Medical Microbiologists	4.00	7 8 9	23-26 20-29 13-25	We agree with the advice given in the section for screening and selection of donors	Thanks…
SH	Association of Medical Microbiologists	4.01	11 12	10-14 1-11	We agree with the advice given for when to stop or suspend milk donation	Thank you…
SH	Association of Medical Microbiologists	4.02	14	14-16	We recommend that a statement is included that good hand hygiene should be carried out both before and starting working in the milk bank and prior to wearing and after discarding gloves.	We have added this to the recommendation.

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SH	Association of Medical Microbiologists	4.03	15	8-12	We suggest advice is given on sampling and what volume should be tested. We agree with the guidance on when to discard the milk.	The GDG considered that no specific guidance on the method of sampling was needed. If milk banks were uncertain, they should ask the laboratory for guidance.
SH	Association of Medical Microbiologists	4.04	15	13-17 19-27	We agree with the advice given here concerning investigation of significant or unusual contamination, and that laboratories should communicate clearly the results and recommended action.	Noted with thanks…
SH	Association of Medical Microbiologists	4.05	16	1-2	We agree with the advice given here that pasteurised milk that has a total viable bacterial count of 10/ml or more should be discarded.	We have clarified that this should be CFU/ml
SH	Association of Medical Microbiologists	4.06	18	9	We agree that archived blood samples should be kept for 11 years but would like clarification concerning which milk samples should be stored and where. It is likely that many of the laboratories that do the testing do not have adequate storage facilities at present. There would be resource implications.	This now refers to blood only.
SH	Association of Medical Microbiologists	4.07	18	10-12	We agree with this guidance that records should be kept for at least 30 years	…
SH	Breastfeeding Network, The	8.00	General		We welcome a guideline in this area. We generally feel that this is a good piece of work though it could have been stronger on the benefits and importance of donor milk. It would have been useful to see the World Health Organisation (2003) Global Strategy for Infant and Young Child Feeding mentioned as it highlights the ranking of donor milk. The next best thing to being fed mother's own milk at the breast or her own expressed milk. See this paragraph below. http://whqlibdoc.who.int/publications/2003/9241562218.pdf **Exercising other feeding options** 18. The vast majority of mothers can and should breastfeed, just as the vast majority of infants can and should be breastfed. Only under exceptional circumstances can a mother's milk be considered unsuitable for her infant. For those few health situations where infants cannot, or should not, be breastfed, the choice of the best alternative – expressed breast milk from an infant's own mother, breast milk from a healthy wet-nurse or a human-milk bank, or a breast-milk substitute fed with a cup, which is a safer method than a feeding bottle and teat – depends on individual circumstances.	The Introduction has been revised; this reference however has not been added as the GDG consider the introduction to clearly state that donor milk can be used. However it should be noted that we did not review the evidence on the benefits of donor breast milk.
SH	Breastfeeding Network, The	8.01	5	32	It would be useful to have *Hazard Analysis and Critical Control Point* written in full at the first abbreviation.	Added
SH	Breastfeeding Network, The	8.02	6	20	We are pleased to see *1.2.2 When promoting the donation of breast milk, aim to reach as many 20 potential donors as possible through a variety of channels, 21 including:* And in particular using a variety of channels	Thank you…
SH	Breastfeeding Network, The	8.03	7	8	We are pleased to see recommendation of use of easy language	Thanks…

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SH	Breastfeeding Network, The	8.04	7	27	Pleased to see this included: *Include this information in recruitment material so that potential donors can self-screen for these criteria.*	Thanks…
SH	Breastfeeding Network, The	8.05	8	15	We feel there needs to be more clarity on what constitutes significant environmental or chemical exposure. As it stands it could be seen as ambiguous since many potential donors may not know their exposure levels. Perhaps giving some examples would help.	We have clarified what we mean by exposure and added an example..
SH	Breastfeeding Network, The	8.06	11	10	It would be useful to give an explanation of the following:- Consider no longer accepting milk from donors who consistently supply small amounts of milk.	The GDG considered it not possible nor appropriate to define this as would depend on factors specific to each milk bank –for example, current stock levels, costs of processing milk etc…
SH	Breastfeeding Network, The	8.07	12	2	Suggest using terms which the lay public are able to understand. Many lay members may not be familiar with the term *viral exanthematous disease*.	This version is for healthcare professionals – the Understanding NICE guidance will use terms for a lay audience.
SH	Breastfeeding Network, The	8.08	12	11	Where it mentions herpes it would be helpful to clarify if it just means active lesions on the breasts or herpes infection on any other part of the body. Would a woman with herpes simplex with an active lesion on her lip also be required to suspend her collection or just on the breast area where it would come in to direct contact?	This has been clarified to mean lesions on the breast only.
SH	Breastfeeding Network, The	8.09	13	8	It would be useful if there could be an explanation of why there is a maximum storage time of 3 months for a domestic freezer. Other guidance suggests this should be 6 months. If it is because the milk is defrosted and pasteurised after 3 months and then re-frozen it would be useful for this to be mentioned.	We have noted that there are differences between milk for donation and milk for a mother's own baby – in this case, we have recommended a shorter storage time to ensure the 'freshest' and 'highest quality' milk getting to the milk bank before processing (which both affects the composition and takes time).
SH	Breastfeeding Network, The	8.10	15	1	It would be useful if there could be an explanation of why there is a maximum storage time of 3 months for a domestic freezer. Other guidance suggests this should be 6 months. If it is because the milk is defrosted and pasteurised after 3 months and then re-frozen it would be useful for this to be mentioned.	We have noted that there are differences between milk for donation and milk for a mother's own baby – in this case, we have recommended a shorter storage time to ensure the 'freshest' and 'highest quality' milk getting to the milk bank before processing (which both affects the composition and takes time).
SH	Breastfeeding Network, The	8.11	17	4	We welcome inclusion of the following statement:- *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.*	We have revised this, but maintained the intent.
SH	Breastfeeding Network, The	8.12	90	5	We welcome inclusion of the following statement:- *Donor milk should be disposed of in the same way as any other clinical waste*	Thanks…
SH	British Dietetic Association	9.00	10	17	Giving advice about diet without elaboration is too vague and open to incorrect advice being given. Suggest add in 'using guidance issued by the Food Standards Agency on diet and breastfeeding' www.eatwell.gov.uk	We have clarified that these recommendations are specifically for donors and the requirement of the donor milk bank. UPDATE: In addition, the question on diet has been removed.
SH	British Dietetic Association	9.01	10	26	Was consideration given to the use of nipple or skin creams? These can contain chemicals that may not be desirable and may also contain bacteria if been in use over a	The GDG considered that any advice on use of skin creams would be the same as that for a

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					long period of time.	mother expressing milk for her own baby; however, if there was ongoing significant contamination, this may be something that would be discussed with the donor.
SH	Bromley Hospitals NHS Trust (now South London Healthcare)	12.00	50	1	1.2.32 Nearly all donors use breast pumps and pressure to hand express could put many potential donors off donating. This seems an unfair request to ask of donors who are taking time out most days to donate to their local milk bank.	We do recommend that milk from donors who use pumps is acceptable.
SH	Bromley Hospitals NHS Trust (now South London Healthcare)	12.01	54	1	1.2.38 Most domestic freezers do not have freezer temperature gauges and it would be costly to provide every donor with a fridge/freezer thermometer. If milk has been contaminated at home this would be picked up during the pre-pasteurisation screening.	We have revised the recommendation but is part of the quality assurance needed to ensure the 'safest' milk being delivered to the milk bank.
SH	Bromley Hospitals NHS Trust (now South London Healthcare)	12.02	57	1	1.2.43 Donors at our milk bank deliver the milk themselves, it would not be possible for milk bank staff to collect milk and not affordable to provide medical couriers.	We do recommend that it is preferable to collect the milk, but that other options are available.
SH	Bromley Hospitals NHS Trust (now South London Healthcare)	12.03	57	1	1.2.44 This would be a costly process and all milk collected from donors is pre-pasteurisation so any contamination should be picked up at testing.	We do recommend that it is preferable to collect the milk, but that other options are available.
SH	Bromley Hospitals NHS Trust (now South London Healthcare)	12.04	67	1	1.2.46 Should say that "containers are in good condition"	We have recommended that the milk is checked for state (that is, is frozen) and has not been tampered with. This would include checking that the containers are in good condition.
SH	Bromley Hospitals NHS Trust (now South London Healthcare)	12.05	67	1	1.2.50 Do we need to state how long the milk can be kept defrosted before pasteurisation. Our pre-past samples have to be incubated for 24 hours, plus time needed for sample to be processed and results reported. Would a guideline of 48 hours from defrosting to pasteurisation be reasonable?	We have added in a time limit for this.
SH	Bromley Hospitals NHS Trust (now South London Healthcare)	12.06	68	1	1.2.55 Surely every batch processed should be tested post pasteurisation. This would be at the end of each cycle of the pasteuriser.	This was discussed fully by the GDG and the recommendation is to test regularly, but not after each cycle.
SH	Bromley Hospitals NHS Trust (now South London	12.07	71	1	1.2.61 Do not need "batches of pasteurised milk from the same donor".	We have left this in to clarify that pooling should only occur within donors before pasteurisation.

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	Healthcare)					
SH	Bromley Hospitals NHS Trust (now South London Healthcare)	12.08	98	1	1.2.70 Many hospitals have their own protocols for the storage of serology samples. Due to storage issues it is unlikely that samples could be stored for this length of time. This would require a huge investment in specialised freezers and also tracking of samples. Also to store milk samples one would have to insure that the samples were not contaminated before freezing as this could potential pose a hazard to other samples stored.	We have revised the recommendation to refer to blood samples only.
SH	Department of Health	18.00	General		We are happy with this service guideline, but consider that it could be potentially difficult for a bank to go through it systematically. We feel that it may be helpful to provide a checklist for banks based on this.	We have fed these comments back to the Implementation team who will consider these when developing tools to support banks implementing these guidelines.
SH	Department of Health	18.01	5	32	Reference is made to HACCP, and it is also referred to later (for example, in *1.2.59*). In our opinion, some explanation of this early on would be helpful for people who do not run milk banks, and who may be unaware of what it means in this context. We believe that a mention in abbreviations could prove to be inadequate.	We have added both in the abbreviations and a brief explanation in the Glossary with a link to the FSA website for further information
SH	Department of Health	18.02		1.2.2	Regarding the recruitment of donors, could you please consider adding Children's Trusts/Local Authority settings, e.g. children's/ sure start centres.	These have been added.
SH	Department of Health	18.03		1.2.57	Could you please clarify whether there is any guidance relating to cooling following pasteurisation i.e. that is, does the milk go straight into a fridge? If so, is that fridge solely for cooling, and how soon after should freezing occur?	We have added clarification on the cooling post pasteurisation.
SH	Imperial College Healthcare NHS Trust	26.00	5	14	We do not agree milk which tests positive for staph aureus even at less than 10^4 CFU/ml should be given to babies following pasteurisation as this process does not remove bacterial toxin that may be present in the milk. We note the GDG recognition on page 81 lines 22-24 that *" the recommendations should specify the minimum requirements of testing, and milk banks could exceed this if this was indicated."* This statement implies that this section (page 5 line 14) and recommendation 1.2.51 (page 15 line 8) should state that these are minimum requirements.	We recognise that this is a less stringent acceptance level than previously recommended. The GDG did discuss this fully and the rationale is documented in the Evidence to Recommendations section (including that for *Staph aureus*). We have also revised the sentence on minimum recommendations as this is not the intention.
SH	Imperial College Healthcare NHS Trust	26.01	5	28	We agree milk should not be supplied to hospital not following tracking procedures however this guideline does not define what they should be or how they will be monitored. Instead it says they should follow tracking procedures as outlined by the local milk bank. This recommendation is inadequate. Currently milk banks ask hospitals receiving donor milk to track and record which baby receives milk however we have no way of knowing if they do this. These recipient hospitals are in different NHS Trusts and therefore not accountable to the Trust which hosts the milk bank. The milk banks can therefore not be held accountable for "policing" the use of donor milk in recipient hospitals. The guideline therefore needs to be more specific about what the responsibilities of the recipient hospitals are, namely:	We have added in most of the suggested information. However the GDG wanted to emphasise the responsibility of the recipient hospital to document and retain records, as for other products such as blood.

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					• For each bottle of milk to record the name, NHS number and DOB and date administered for each baby who received the milk and return a copy to the milk bank within 1 week of its use. • In the individual patient record of each baby who receives donor milk to record the batch number of that bottle and the date the milk was used. • To monitor and record the condition of all donor milk on arrival following transport. • To monitor and record the storage conditions for all donor milk. • To regularly provide written evidence of good practice and compliance with the local milk bank guidelines to the milk bank manager.	
SH	Imperial College Healthcare NHS Trust	26.02	6	13	The use of the word *"prescribed"* is inappropriate. Donor milk is not a drug, a blood product nor an IV administered fluid, it therefore is not prescribed. A drug/product that is prescribed must be written on a prescription chart and signed by a register doctor or nurse/midwife who has received specific trained and is authorised by their employing trust. No evidence is provided in section 2.19 as to why the word *"prescribed"* has been chosen. Suggested alternative wording; *"All donor milk administered to patients cared for within the NHS should be from milk banks……."*	We have revised the wording to 'administered'
SH	Imperial College Healthcare NHS Trust	26.03	25	24	Recruiting donors –evidence statements. We agree with these and section 2.4.3, both are well written and supports the recommendations 1.2.1, 1.2.2 and 1.2.3	Thank you…
SH	Imperial College Healthcare NHS Trust	26.04	34	18	Screening and selecting donors – evidence to recommendations. We agree there is no consensus in the evidence reviewed and support the GDG's attempt to define appropriate screening and selection process for donors. Sections 2.5.2 and 2.5.3 generally support the recommendations listed under 2.5.4 but not conclusively.	And the discussions of the GDG when making the recommendations are documented in the evidence to recommendations section, with further details in Appendix 3.
SH	Imperial College Healthcare NHS Trust	26.05	8	12	Using the *words "currently taking **any** medication……., she may not be eligible to donate milk"* is misleading and not evidence based. Is the GDG suggesting women who take for instance salbutamol by inhaler on an irregular basis should be discourage from donating? As it stands it's a very negative statement that could deter potential donors. It would be more appropriate to say; *"advise her that if she is currently any type of medication or undergoing any other medical therapy, she will need to discuss this in more detail with the milk bank so that her eligibility to be a milk donor can be further assessed."*	We do recommend that if taking any medication, this should be discussed with the milk bank staff.
SH	Imperial College Healthcare NHS	26.06	9	13	This recommendation -1.2.11 is supported by the paragraph on page 35, lines 7-13.	This rationale has been added to the section 2.6.4

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	Trust				However the screening programs for blood and tissue donation also screen for CMV and a preterm baby will receive blood specifically donated by CMV negative donors. If the GDG do not wish to include CMV serology testing in this recommendation then the reason for this omission should be clearly documented in this paragraph on page 35, lines 7-13; the current reference does not provide sufficient evidence. Information is given later in section 2.15.3. page 79 lines 17-22 which does explain why testing may not be required.	
SH	Imperial College Healthcare NHS Trust	26.07	64	1	In fact by the time the baby receives the milk there will have been 3 complete cycles of freeze thaw as well as pasteurisation which will affect the quality of the milk. More research is required to enable a reduction in these multiple phases and reduce the degradation that currently is inherent in the processing methods.	We have made research recommendations that the process of donor milk handling and its effects on the composition of the milk should be evaluated.
SH	Imperial College Healthcare NHS Trust	26.08	67	1	2.13.4 Recommendations. Inclusion of all recommendations 1.2.45 to 1.2.54 together here is misleading as much of the evidence the GDG reviewed etc appears later in the document in sections 2.14 to 2.16	We have checked the recommendations and moved as appropriate.
SH	Imperial College Healthcare NHS Trust	26.09	17	1	Recommendation 1.2.62 This not just about pooled milk and would fit better if placed between 1.2.54 and 1.2.55	This has been moved
SH	Imperial College Healthcare NHS Trust	26.10	79	20	It should be clearly identified in section 1.2 that prevention of CMV transmission via donor milk is reliant on adequate pasteurisation, freezing and storage and that this is the reason CMV serology screening of the donors is not recommended.	A further sentence has been added.
SH	Imperial College Healthcare NHS Trust	26.11	81	22	*"It was recognised that the recommendations should specify the minimum requirements of testing, and milk banks could exceed this if this was indicated."* This recognition is buried deep in the document in section 2.15.3. As this statement is very relevant to the GDG recommendations for donor serology screening, the selection of milk suitable for use following pasteurisation based on levels of bacterial contamination and post pasteurisation testing; a statement in both sections 1.1 under the heading "testing donor milk" (page 5 line 9-23) and 1.2.11 should note that these are minimum requirements.	These are not intended as minimum recommendations (the wording here has been revised) but are criteria as determined and agreed based on expert consensus (there was a lack of high-quality evidence on which to base the recommendation); however, any guideline recommendations are only recommendations.
SH	Imperial College Healthcare NHS Trust	26.12	17	4	Fortifying donor milk – agree	Thanks…
SH	Imperial College Healthcare NHS Trust	26.13	90	10	The whole of section 2.19 is out of sequence with the list of recommendation in section 1.2. Again making the whole document difficult to read. Section 2.19 should follow Section 2.20	We will check the order and revise as appropriate before final publication/
SH	Imperial College Healthcare NHS Trust	26.14	19	6	SEE COMMENT 3 The use of the word *"prescribed"* is inappropriate. Donor milk is not a drug, a blood product nor an IV administered fluid, it therefore is not	We have revised the wording to 'administered'

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					prescribed. A drug/product that is prescribed must be written on a prescription chart and signed by a register doctor or nurse/midwife who has received specific trained and is authorised by their employing trust. No evidence is provided in section 2.19 as to why the word *"prescribed"* has been chosen. Suggested alternative wording; *"All donor milk administered to patients cared for within the NHS should be from milk banks……."*	
SH	Imperial College Healthcare NHS Trust	26.15	19	9	SEE COMMENT 2 We agree milk should not be supplied to hospital not following tracking procedures however this guideline does not define what they should be or how they will be monitored. Instead it says they should follow tracking procedures as outlined by the local milk bank. This recommendation is inadequate. Currently milk banks ask hospitals receiving donor milk to track and record which baby receives milk however we have no way of knowing if they do this. These recipient hospitals are in different NHS Trusts and therefore not accountable to the Trust which hosts the milk bank. The milk banks can therefore not be held accountable for "policing" the use of donor milk in recipient hospitals. The guideline therefore needs to be more specific about what the responsibilities of the recipient hospitals are, namely: • For each bottle of milk to record the name, NHS number and DOB and date administered for each baby who received the milk and return a copy to the milk bank within 1 week of its use. • In the individual patient record of each baby who receives donor milk to record the batch number of that bottle and the date the milk was used. • To monitor and record the condition of all donor milk on arrival following transport. • To monitor and record the storage conditions for all donor milk. • To regularly provide written evidence of good practice and compliance with the local milk bank guidelines to the milk bank manager.	We have added in most of the suggested information.
SH	Imperial College Healthcare NHS Trust	26.16	92	2	Tracking and tracing section 2.20 While this is important, the evidence base used to support some of the recommendations is very weak but has significant resource implications which have not been explored by	We note throughout the limited nature of the evidence. We also recognise the importance of this area of processing. The GDG did consider the resource implications, and we made

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					the GDG.	recommendations on the type of information to be retained, not the methods (that is, whether paper or electronic) of collection. We will also feed these comments back to the Implementation Team.
SH	Imperial College Healthcare NHS Trust	26.17	18	9	What is the definition of an achieved blood or milk sample? Is it intended each milk bank decides this locally? If so make this clear, if not then define. The document quoted on page 96 line 13 is out of date. The updated version (copy attached) publishes by the RCPath in August 2009 states on page 26 section 127. ***"Separated serum or plasma, stored for transfusion purposes*** …… *Archived blood donor samples should be stored by blood services for* ***at least 3 years****, and preferably longer if it is practicable, in order to facilitate 'look-back' exercises.* If the recommendation here is at least 3 years; why did the GDG recommend at least 11 years? As the blood for the serological testing of potential donors is not sent to the blood transfusion service from analysis but to hospital based laboratories it will be processed according to page 19 section 74. of the attached document: *"Plasma and serum* *Keep for 48 hours after the final report has been issued by the laboratory. If there is a requirement to store for longer, specimens that have been centrifuged but not separated should be separated to prolong stability."* While we may be able to argue for 3 years storage, it is highly unlikely take hospital based laboratories will keep these samples for longer. Milk samples – what are they being keep for? Unless this is defined how does one argue for resource to provide storage? Milk has not been defined as a blood product or tissue, if classification as the former it would require storage for at least 3 years and the later it would require disposal after initial analysis.	Thank you for the updated reference. This now refers to blood only. We have also recommended that current guidance from the Royal College of Pathologists is followed. UPDATE: reference to the RCPath guidance has been removed.
SH	Imperial College Healthcare NHS Trust	26.18	18	7	This recommendation is too weak SEE COMMENT 2 We agree milk should not be supplied to hospital not following tracking procedures however this guideline does not define what they should be or how they will be monitored. Instead it says they should follow tracking procedures as outlined by the local milk bank. This recommendation is inadequate.	We have added in most of the suggested information. However the GDG wanted to emphasise the responsibility of the recipient hospital to document and retain records, as for other products such as blood.

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					Currently milk banks ask hospitals receiving donor milk to track and record which baby receives milk however we have no way of knowing if they do this. These recipient hospitals are in different NHS Trusts and therefore not accountable to the Trust which hosts the milk bank. The milk banks can therefore not be held accountable for "policing" the use of donor milk in recipient hospitals. The guideline therefore needs to be more specific about what the responsibilities of the recipient hospitals are, namely: • For each bottle of milk to record the name, NHS number and DOB and date administered for each baby who received the milk and return a copy to the milk bank within 1 week of its use. • In the individual patient record of each baby who receives donor milk to record the batch number of that bottle and the date the milk was used. • To monitor and record the condition of all donor milk on arrival following transport. • To monitor and record the storage conditions for all donor milk. • To regularly provide written evidence of good practice and compliance with the local milk bank guidelines to the milk bank manager.	
SH	Imperial College Healthcare NHS Trust	26.19	99	13	We support the research recommendations outlined in section 3	Thank you
SH	La Leche League GB	86.00	1.2.2	20	At present publicity is done by volunteers. Whose will be the responsibility to pubilcise the need for donors Publicity without the infrastructure to arrange collection/transport will not be v worthwhile	We would consider recruitment as part of the role of the milk bank with the support of volunteers as needed. We also consider collection and transport to be part of donor breast milk handling, and have made recommendations in these areas.
SH	La Leche League GB	86.01	1.2.41	23	Needs to state what happens if a group of donors together share transporting to bank / depot – does this come under the definition of contracted	This would not be 'contracted' but any transportation arrangements should follow the relevant recommendations.
SH	La Leche League GB	86.02	1.2.44	8	There could be publicity for possible depots to come forward, eg depots in large hospitals in areas without a bank, and hospitals undergoing new building work could be asked to provide for a depot/bank. This would help remove a barrier for many women that live too far away from the bank to drop off milk.	This is an issue of implementation – we have fed this comment to the Implementation Team.
SH	La Leche League GB	86.03	1.2.46	17	Consider tamperproof seals	We have added that the milk bank should check that the milk has not been tampered with.
SH	La Leche League GB	86.04	1.2.57	3	Consider tamperproof seals	We have added in 'tamper evident' at other points in the guideline
SH	La Leche League GB	86.05	*2.4.2.16*	9	Should efforts be made to involve the Islamic community in discussion of these issues so that there is understanding on both sides on any restrictions that there are on receipt of milk. While obviously strict anonymity must take place is there a place for ensuring that any rules on milk kinship are not broken	We would anticipate, as with other healthcare, the beliefs and preferences of the individual would be taken into account, and confidentiality maintained.
SH	La Leche League	86.06	General		Until collection/transport arrangements are in place in an area mothers with a low	The recommendations allow for different

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	GB				income will not be as able as other mothers to volunteer as donors because of the cost of taking milk o the nearest bank - income should not be a barrier	approaches to collecting milk and do not restrict to donors transporting their own milk. Local arrangements should consider who their donors are and what support (including support with transport) they need.
SH	La Leche League GB	86.07	General		Where potential donors have low levels of fluency in written/spoken English, efforts should be made to produce publicity that will reach them and to provide mothers with the support they need to be enabled to donate their milk	All NICE guidance is produced with the underlying principle that "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." This is stated in the Person Centred Care section. Local arrangements should consider who the donors/potential donors are and what information (including different formats, for example language or other needs) they require.
SH	Medicare Colgate Ltd	31.00	General		We are very concerned after reading the draft guidelines to find that the 'Pasteurisation Process Methodology' which is core to safe treatment of donor milk has not been tabled more comprehensively. None of the important safety features are addressed. These need to be part of the risk assessment for safe treatment of human donor milk. **Therefore very clear guidance needs to be tabled for this serious issue**.	We have discussed this part of the guideline in depth with the Guideline Development Group. We have also considered your comments, along with other stakeholder comments, and responded in detail below.
SH	Medicare Colgate Ltd	31.01	15	18	1.) **The Heating Process** The Draft Guideline describes the heating process of 30 minutes @ 62.5 °C (page 15 section 1.2.54) needs to include a tolerance of + or - 0.5 °C as currently technology for pasteurisation equipment cannot fulfil such exact criteria. **2.) Omission of rapid cooling process** There is no mention of the required rapid cooling process which is an integral part of the treatment process. 'Any delay in cooling encourages the growth of heat resistant organisms' * quote from the National Dairy council advice team. As previously recommended by the Department of Health in their publication *' Collection and Storage of Human Milk'* . This document has been omitted from the references. This reference has been part of the Guidelines from the Royal College of Paediatrics published in 1993 & 1999 and when it clearly advised of the cooling rate of 3.75 °C per minute with a final temperature of 10°C before transferring to a freezer. And also part of the UKAMB guidelines. Although other references which highlight the importance of rapid cooling as part of the pasteurisation process are tabled in the new proposed NICE guidelines i.e.	Heating – we have recommended both the pasteurisation time and temperature and the need to ensure that equipment is fit for purpose. NICE guidelines do not specify the details of quality assurance the functioning of equipment. Cooling – we have added in that rapid cooling is required.

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					Gibbs JH, Fisher C.Bhattacharya S,JD Baum (1977) Drip Milk its composition, collection & pasteurisation. Early Human Development 1977: *Quote : 'Rapid cooling of both water bath & milk.* *And 'Human Milk Banking at Sorrento Maternity Hospital ,Birmingham.* *Archives of Disease in Childhood April 1992.* *Quote: Milk is rapidly cooled to 10 ° C a the end of the cycle* *Department of Health & Social Security HMSO 1981- ' Collection and Storage of Human Milk'* *Quote : after holding (the heating process) the milk temperature should be reduced to 25 °C within 10minutes.*	
SH	Medicare Colgate Ltd	31.02	16	3	**How do Milk Banks achieve cooling to 4 °C.** Section 1.257 page 16) states after testing and pasteurising, cool milk samples to refrigerator temperature 4° C or lower. However no indication is given that this needs to be integral to the pasteurisation process. It needs to be very clearly tabled how Milk Banks can achieve a milk temperature of 4 °C prior to placing the milk into the fridge. As some milk banks use equipment where final milk temperature after the pasteurisation is around - 25 °C. Some of the pasteurisation equipment currently used at some UK Milk Banks is not able to cool the milk temperature down in the required time of 10 minutes to 25 °C. This equipment cools with tap water and the best final milk temperature according to the manufacturers own details on their literature nowhere near fulfils the criteria of 10° C . Cooling to 4° C with tap water is certainly not possible. Tap water cooling is uncontrolled cooling as water temperatures vary from season to season and from hospital to hospital.	Cooling – we have added in that rapid cooling is required. UPDATE: Based on the evidence, the GDG did not consider that they could recommend a particular method (see also comparable recommendations on thawing pre pasteurisation). The recommendation therefore focuses on the need to cool to a temperature of 4 degrees or lower before freezing. Evidence statements have also been added to support this.
SH	Medicare Colgate Ltd	31.03	16	6	**Bottles used & Water Levels in the Pasteuriser** All pasteurisers currently used operate with a water bath. The water levels are pre set by the manufacturer for a certain type and size of bottle height. The cycle time is also pre set according to material of bottle i.e. glass, PP, HD etc. This is water level issue may not be very clearly understood by many staff using pasteurisation equipment. If there is a change in size and type of bottles used this has a serious safety impact. If bottles are changed to a smaller size than the pre set level, the bottles are then submerged during the heating cycle and also during the cooling cycle when there is a risk of tank water entering into the submerged bottles. If bottles are of larger size than the pre set water level then not all the milk content might	We have recommended that staff should follow the manufacturer's instructions and should be trained in pasteurisation, if appropriate to their role.

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					be covered during heating cooling and there is a risk that bottles do not receive full treatment.	
SH	Medicare Colgate Ltd	31.04	17	10	**Proof of treatment :** This needs to be obtained for the core temperature of the milk. Some UK Milk Banks currently only measure and record the water bath temperature which varies considerably on the cooling cycle from the actual core temperature of the milk. Pasteurisation data verification needs to be able to show the actual milk temperatures for both heating and cooling to give confidence that successful treatment has been carried out. Proof of treatment for both the heating cycle at 62.5 °C for 30 minutes and cooling cycle from 62.5°C to 25° C in 10 minutes with a resultant temperature of 10° C is vital for a safe end product. Where there is only proof of the heating cycle there is a window of opportunity for a human error risk factor. Therefore there is no evidence when the bottles where transferred from the pasteuriser to the fridge or freezer.	We have made several recommendations on the need to use equipment that is fit for purpose and the need to maintain and calibrate such equipment. We have also made recommendation s on the monitoring of critical processes, such as pasteurisation and cooling.
SH	Medicare Colgate Ltd	31.05	18	14	**Independent validation of pasteurisers** As pasteurisers are not classified as a medical device but catering equipment there are no strict criteria in place for pasteuriser manufacturers to adhere to. It is currently left to the individual manufacturer to decide on the operation criteria of the pasteuriser. As price of the equipment plays an important role there is a risk that short cuts could be taken. Hospitals have not the necessary equipment to test that all position (i.e. 36 nests) in the pasteuriser heat and cool to the required criteria. All pasteurisers should be validated prior to being taken into operation at a Milk Bank by an independent testing house with a test certificate to confirm the claims made by the manufacturer actually match the required performance.	We have noted in the guideline that there are no NHS standards for human milk pasteurisers. Milk banks are then given guidance on the whole process of handling donor milk (which needs to be considered as a whole process, as each step relies on the effectiveness of other steps) including the monitoring and maintenance of the equipment and its functioning. We would not anticipate that milk banks should need to validate equipment before purchasing, but that the post pasteurisation testing would be increased (as recommended) to ensure that the equipment is functioning and staff are able to use it as instructed.
SH	Medicare Colgate Ltd	31.06	20	2	HACCP will not cover the pasteurisation criteria as they have no data for Human Milk treatment. HACCP do not cover methodology.	However, HACCP does cover the application of the recommendations in donor milk processing.
SH	Medicare Colgate Ltd	31.07	79	30	'Adequate pasteurisation' needs to be qualified	This has been clarified.
SH	Medicare Colgate Ltd	31.08	81	27	Proof of treatment for both the heating cycle at 62.5 °C for 30 minutes and cooling cycle from 62.5°C to 25° C in 10 minutes with a resultant temperature of 10° C is vital for a safe end product. Where there is only proof of the heating cycle there is a window of opportunity for a human error risk factor. Therefore there is no evidence when the bottles where transferred from the pasteuriser to the fridge or freezer.	We have added further clarification on the cooling post pasteurisation.
SH	Medicare Colgate Ltd	31.09	87	11-16	**Independent validation of pasteurisers** As pasteurisers are not classified as a medical device but catering equipment there are no strict criteria in place for pasteuriser manufacturers to adhere to.	We have noted in the guideline that there are no NHS standards for human milk pasteurisers. Milk banks are then given guidance on the whole process of handling donor milk (which needs to be considered as a whole process, as each step

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					Fit for purpose is not sufficient guidance, no specific criteria is mentioned in the Quality Assurance section. As previous recommendations in the draft guidelines do not clearly define the heating & cooling criteria. It is currently left to the individual manufacturer to decide on the operation criteria of the pasteuriser. As price of the equipment plays an important role there is a risk that short cuts could be taken. Hospitals have not the necessary equipment to test that all position (i.e. 36 nests) in the pasteuriser heat and cool to the required criteria. All pasteurisers should be validated prior to being taken into operation at a Milk Bank by an independent testing house with a test certificate to confirm the claims made by the manufacturer actually match the required performance.	relies on the effectiveness of other steps) including the monitoring and maintenance of the equipment and its functioning. We would not anticipate that milk banks should need to validate equipment before purchasing, but that the post pasteurisation testing would be increased (as recommended) to ensure that the equipment is functioning and staff are able to use it as instructed.
SH	Medicare Colgate Ltd	31.10	87	5-10	No mention of the cooling process. What is the recommended pasteurisation process ? There a two types of treatment currently used in UK Milk Banks. One type does not fulfil the cooling criteria within 10 minutes to 25°with further cooling to 10°C as an integrated part of the pasteurisation process (Tap water cooled pasteurisers) The other type does fulfil the cooling criteria within 10 minutes to 25°C with further cooling to 10°C as an integrated part of the pasteurisation process. (Pasteurisers equipped with a chiller for refrigerated cooling)	We have added further clarification on the cooling process. However, based on evidence, it was not possible to recommend any specific method of achieving cooled milk.
SH	Medicare Colgate Ltd	31.11	90	17-19	This is not strictly true, The below listed papers clearly make reference to the quality assurance process of rapid cooling. The below listed papers are not 'Medical Literature' but published studies which have been peer reviewed. *Gibbs JH, Fisher C,Bhattacharya S,JD Baum (1977) Drip Milk it's composition, collection & pasteurisation.Ealry Human Development 1977:* *Quote : 'Rapid cooling of both waterbath & milk with a final temperature of 10°C* *And 'Human Milk Banking at Sorrento Maternity Hospital ,Birmingham.* *Archives of Disease in Childhood Aprill 1992.* *Quote: Milk is rapidly cooled to 10 C a the end of the cycle* *Department of Health & Social Security HMSO 1981- ' Collection and Storage of Human Milk'* *Quote : after holding (the heating process) the milk temperature should be reduced to 25C within 10minutes.*	Although they make reference to the specifics of cooling, they are describing the process that they use, not an evaluation of the effectiveness of that approach. The GDG therefore made recommendations based on the evidence and expert consensus as documented in the full guideline and the Appendices.

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SH	Medicare Colgate Ltd	31.12	92	1	It needs to be mentioned that Infection Control and Medical Physics Departments need to be consulted on any purchase of capital equipment. Operating criteria should not be left to the manufacturer to decide These need to be clearly defined in the' fit for purpose section' for pasteuriser guidance. The user needs to guide the manufacturer not vice versa.	We would anticipate that all organisations have a policy for the procurement of all capital equipment that includes confirmation by all relevant departments within the organisation that it is fit for purpose before an order is placed
SH	Medicare Colgate Ltd	31.13	103- 120	General	Why was this importance reference omitted from the references ? *Department of Health & Social Security HMSO 1981- ' Collection and Storage of Human Milk'* *Quote : after holding (the heating process) the milk temperature should be reduced to 25 °C within 10minutes.*	We reviewed more recent guidance (for example UKAMB guidelines of 2003) that have superceded this. However, many of the included studies have referenced this, so the content of the guidelines is represented in the guideline (see the full evidence reports in Appendix 5) although not cited as a source in the full guideline. During the validation process, this reference has now been added.
SH	Medicare Colgate Ltd	31.14	90	20-24	There are existing quality assurance guidelines from a number of European, Australian and US Guidelines : see below **United States of America – 2007** Guidelines for the Establishment and Operation of a Donor Human Milk – Human Milk Banking Association of North America "*Chilling & Storage – Following heat processing, the milk should be rapidly cooled"* **Australia – 2007** Best Practice Guidelines for the Operation of a Donor Human Milk Bank in an Australian NICU – B.T.Hartmann, W.W.Pang, A.D.Keil, P.E.Hartmann & K.Simmer *"The efficacy of any pasteuriser is dependent on both the pasteurising temperature and hold time and the time taken to heat and subsequently cool product"* **Germany -1998** Leitlinie für die Einrichtung und zur Arbeitsweise von Frauenmilchbanken – Liepzinger Universitätsverlag "*After heating the milk is rapidly cooled"* **Italy – 2002** Linee Guida perLa costituzione e l'organizzazione di una Banca del Latte Umano Donato "*The final phase of the pasteuriser cycle cools the milk rapidly to 10°C"* **Austria – 1998** Institut für Milchhygiene & Milchtechnology Veterinärmedizinische Universität Wien – Prof. Dr. Hans Asperger - Extract from the 'Draft Guidelines 16/12/98' "*Rapid Cooling of Milk – immediately after heat treatment the milk must be cooled with refrigerated water (as part of the pasteurisation process) to 4°C"*	We reviewed both the guidelines and the underlying evidence. The GDG made recommendations based on the evidence and expert consensus as documented in the full guideline and the Appendices.

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SH	Medicare Colgate Ltd	31.15	91	1-10	It should not be left to the individual milk banks to identify the critical points in processes and design appropriate measures to prevent errors . The main reason for Guidelines must to give guidance and to ensure uniformity of treatment. Especially as the test regime for treat donor milk will be relaxed in the proposed new guidelines. Less testing means less cost however this can only be safe if every milk bank has the same process protocol.	We have made recommendations on the process of handling donor breast milk – but each milk bank will need to develop and minor procedures to implement these.
SH	Medicare Colgate Ltd	31.16	General		There are also paediatric dietetics departments which treat donor human milk and are not classified as a Milk Bank, these have not been identified in this guideline title 'Donor Breast Milk Bank'	The guidelines are relevant to those services where the complete process of handling donor breast milk is undertaken (from recruitment to releasing pasteurised milk for use). Throughout, the emphasis is on the safety of the milk and the processing of this milk should only be done in those units able to demonstrate adherence to these guidelines.
SH	National Childbirth Trust	35.00	4		Prefer stronger start to Introduction vis: "Breastfeeding is a source of complete nutrition that changes to meet each infant's growing needs, and confers active immunity to disease. The use of breastmilk substitutes is detrimental to the health and development of the infant and child, and to the health of the mother."	We consider the Introduction to outline the use of donor breast milk (accepting that we have not systematically reviewed the evidence for this as not part of the remit of this guideline). The aim of the guideline is to describe best practice with the aim of safety, so healthcare professionals and parents/carers of recipients can be assured of the safety of the donor milk, when handled according to these guidelines.
SH	National Childbirth Trust	35.01	4	Insert after line 6	Expand introduction to point out the value of breastmilk for babies in neonatal care – see HTA review for instance. This would help to put the guideline in context. Also there is some evidence that the presence of a breastmilk bank on site supports breastfeeding for premature and sick babies: "A recent unpublished study at Guy's and St Thomas' Hospital in London found that the establishment of a donor human milk bank was associated with a substantial increase in the provision of maternal breastmilk to infants with a birth weight of less than 1500 g at the time of discharge. Fifty per cent of infants received breastmilk at discharge before the milk bank opened, whereas 78% received breastmilk on discharge 18 months after their milk bank opened (Dr Camilla Kingdon, St Thomas' Hospital and Association for Milk Banking, personal communication, 2008).	The HTA report has now been published and the results updated accordingly.
SH	National Childbirth Trust	35.02	4	7	ADD words in italics for clarity and reorder: If a mother does not wish to express milk *for a baby unable to feed at the breast* despite information regarding benefits to herself and her baby and discussion with experienced staff	This clause has been added.
SH	National Childbirth Trust	35.03	4	10-17	Will be updated noting: "Donor milk would become cost-effective given improved	This report has now been published and the results updated accordingly.

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					mechanisms for its provision."	
SH	National Childbirth Trust	35.04	5	27	Released and non-released should be added to the Glossary when prepared	We have revised this to clarify and removed these terms.
SH	National Childbirth Trust	35.05		32	Add HACCP to abbreviations list	This has been added.
SH	National Childbirth Trust	35.06	7	13-14	"This should be based on a balanced consideration of relative risk for the recipient population. " Users of the guideline will need further elucidation of this point; the recipient population may not be known at the time the users are recruited and there is limited evidence to assess relative risk.	This has been removed.
SH	National Childbirth Trust	35.07	8	Whole page	We do not disagree with the information, but potential donors need to be encouraged and this information will need to be put in a more positive way when screening donors in practice.	We will feedback this comment to the Implementation Team.
SH	National Childbirth Trust	35.08	10	17-19	Information on diet should stress that the babies who receive the donated milk are particularly vulnerable. It is important not to perpetuate the idea that a breastfeeding mother must attain very high dietary standards at all times, otherwise her baby will suffer. This can lead women to change to formula feeding to the detriment of their own and their babies' health.	We have clarified that these recommendations are specifically for donors and the requirement of the donor milk bank. UPDATE: In addition, the question on diet has been removed.
SH	National Childbirth Trust	35.09	12	6-7	More detailed, appropriate information from a specialist source such as: UK Drugs in Lactation Advisory Service www.ukmicentral.nhs.uk/drugpreg/guide.htm	This has been added.
SH	National Childbirth Trust	35.10	40	14	*Donors can be supervised at home (for example, by health visitors) while collecting and storing donations.* Although women who donate to milk banks may be more relaxed or less prudish than the majority, it is possible that the idea of being supervised while collecting milk would put donors off. Is this really the practice described in the papers mentioned?	The evidence statements reflect the evidence reviewed, and the GDG agreed that such practice should not be recommended in this guideline.
SH	National Childbirth Trust	35.11	49	13	All breastfeeding mothers *should be* given clear information on how to express milk for their own babies. This recommendation, which is part of the Baby Friendly Initiative standards, has not been rolled out successfully across the whole country, therefore it should not be assumed that women are given information on how to express.	We will feed this comment back to the Implementation Team.
SH	National Childbirth Trust	35.12	60	Probably 17-19	Logically, following Page 59 line 1-2, add: • *reduces the antioxidant activity of milk*	The evidence is specific to freeze-thawing.
SH	National Childbirth Trust	35.13	64	5	*in the UK the recommended period for storing frozen milk is 3 months.* Needs to be clarified whether this is after pasteurization – ie it may have been stored for up to three months in a domestic freezer before transport to the milk bank.	This has been clarified.
SH	National Childbirth Trust	35.14	65	1-2	There is a possibility that dishwashers may leave residues – such as salt or other potentially harmful chemicals – on the containers.	The evidence statements reflect the evidence reviewed, and the GDG agreed that such practice should not be recommended in this guideline.
SH	National Childbirth Trust	35.15	89	7	We can understand the guidelines not including information on fortification with artificial milk fortifier but this is mentioned as a possibility, whereas enhancing the composition of mother's own milk – which the HTA report on breastfeeding promotion in neonatal units points out " offers an apparently simple solution" to the problem of increasing nutrient supply to premature or growth restricted babies.	This is noted as important, and maternal milk is outside the remit of this guideline.
SH	National Childbirth	35.16	98	15 -17	This would seem to be an argument for extending training for all healthcare professionals	And we would anticipate that all healthcare

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	Trust				who may be in contact with parents of premature babies particularly concerning the benefits of human breastmilk including donor milk .	professionals who handle or use donor breast milk should be aware of the process; however the indications of donor milk are outside the remit of this guideline.
SH	National Childbirth Trust	35.17	101	5	Research on the viability of enhancing the nutrient content, particularly the energy content of human milk in the UK would enable tailored nutritional support to some of the most vulnerable and growth restricted babies. This is carri4ed out in some other countries and should be investigated in this country to determine the barriers, benefits and possible risks. We believe this is a more important research area than some mentioned in the list, such as donor attitudes.	The remit of these research recommendations is as for the practice recommendations – that is the process of handling donor breast milk. However we do note the need to link any research with health outcomes in the recipient population(s).
PR	NETSCC	79.00			**1.1 Are there any important ways in which the work has not fulfilled the declared intentions of the NICE guideline (compared to its scope – attached)**	…
PR	NETSCC (Ref 1)	79.01	General		In my opinion, the guideline fulfils the declared intentions.	Thank you…
PR	NETSCC (Ref 2)	79.02	General		The scope suggested that while it would not be possible to use the QALY as the outcome measure, the guidelines would be based on evidence of cost-effectiveness and that analyses would be undertaken 'as appropriate'. In particular it appeared that the intention was to consider the relative costs and relative safety of different approaches. No cost or cost-effectiveness analyses whatsoever was undertaken.	Thank you, your comment has been noted.
PR	NETSCC (Ref 2)	79.03	General		The lack of evidence does not appear to have been recognized in the scope.	The aim of the Scope is to identify the areas to be covered in the guideline – not to make judgements on the evidence before the full guideline development processes for identifying and assessing evidence have been completed. However, the technical team were aware that high-quality evidence would be lacking, and therefore different approaches were used to support the recommendations in the absence of such evidence (see section 2.1).
PR	NETSCC	79.04			**2.1 Please comment on the validity of the work i.e. the quality of the methods and their application (the methods should comply with NICE's Guidelines Manual available at http://www.nice.org.uk/page.aspx?o=guidelinesmanual).**	…
PR	NETSCC (Ref 1)	79.05	General		I believe the methods are high quality, rigorous, and well documented.	Thank you…
PR	NETSCC	79.06			**3.1 How far are the recommendations based on the findings? Are they a) justified i.e. not overstated or understated given the evidence? b) Complete? i.e. are all the important aspects of the evidence reflected?**	…
PR	NETSCC (Ref 2)	79.07	24	14	The document emphasises that given the weak evidence available many of the recommendations were based on consensus methods. It is stated that full details of the methods used are presented in appendix 3. This appendix is not included.	All appendices were available on the website…
PR	NETSCC (Ref 1)	79.08	General		In my opinion, the recommendations are justified by the findings.	Thank you…
PR	NETSCC (Ref 2)	79.09	25	25	Under the subheading 'evidence statements' a list of random statements from individuals are made about for example the relative merits of milk donation. This section is completely unclear, no context is given. For example, it is unclear what research	We have added in the questions being addressed in each section. The methods are described in the Appendix 2.

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					question is being addressed, what research methods were used to gather the views, and no effort was made to help the reader interpret the 'evidence' presented.	
PR	NETSCC (Ref 1)	79.10	79	1-4	I wonder if a statement about the decision to pasteurise the donor breast milk would be helpful, prior to a consideration of the appropriate pasteurisation conditions, and pre- and post-tests? I think the decision to pasteurise is probably an appropriate one, given the need to first assure the recipient's safety, but it is possible that the potential benefits associated with raw breast milk may be lost through this process. This point might also be brought out in the recommendations and discussion. I was pleased to see it alluded to within the future research section (P100).	A rationale for this has been added (from Appendix 3 on the development of the recommendations)
PR	NETSCC (Ref 2)	79.11	29	General	No details were provided on the review methods used, e.g. how were the 217 studies identified. Are studies published from 1951 relevant?	The details were in Appendix 2 (available on the website)
PR	NETSCC	79.12			**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.**	…
PR	NETSCC (Ref 1)	79.13	General		I also wondered if it was appropriate to make a comment about the use and appropriateness of incentives (financial or otherwise) to motivate donor recruitment.	There is no intention that donors should be paid for provision of donor milk. This has been clarified in the guidelines.
PR	NETSCC	79.14			**3.2 Are any important limitations of the evidence clearly described and discussed?**	…
PR	NETSCC (Ref 1)	79.15	General		There was very little in the way of health economics and/or statistical issues to comment on.	Noted…
PR	NETSCC (Ref 2)	79.16	General		There is little evidence to support any of the recommendations.	From the outset, it was clear that there was little high-quality evidence to support practice. We have therefore used various methods to ensure a robust set of recommendations, even in the absence of high-quality evidence. We have also made research recommendations which we anticipate will support any update of these guidelines in the future.
PR	NETSCC (Ref 1)	79.17	General		Yes, in several places and in the research recommendations.	…
PR	NETSCC (Ref 2)	79.18	General		There is no attempt to root the guidelines based on effectiveness or cost-effectiveness.	We would disagree with this assessment. From the outset, it was clear that there was little high-quality evidence to support practice. We have therefore used various methods to ensure a robust set of recommendations, even in the absence of high-quality evidence.
PR	NETSCC (Ref 2)	79.19	23	13	Guidelines should be rooted in evidence on effectiveness, cost and cost-effectiveness. The commentary suggests that there was insufficient evidence on input parameters for a cost-effectiveness model. They then suggest though that information on costs will be available for the final report. This is rather unsatisfactory. It is this draft report that I am being asked to review and it would be better if what cost and cost-effectiveness evidence the team had been able to assemble was presented here rather than subsequently.	The costings report for all NICE guidance is published either at or after publication of the final guidance. The costings report does not form part of the evidence base for decision making. UPDATE: A costing statement will be produced.
PR	NETSCC	79.20			**4.1 Is the whole report readable and well presented? Please comment on the**	…

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					overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.	
PR	NETSCC (Ref 2)	79.21	General		Perhaps the report should be more 'up front' about the assumption that as a society we may wish to minimise the risks from donated milk (as with blood) with relatively little concern for the costs than for guideline areas where adverse consequences might be viewed 'less severely)?	Thank you for your comment, we agree with the need to be transparent and upfront about any implicit assumptions employed in an analysis or evidence based guidelines. We do, however, believe that the guideline document states clearly that there was a strong sense within the committee and during scoping consultation that risk minimisation to the recipient will be the central focus of this guideline. Maximising safety comes at a cost, and we have worked hard to ensure that recommendations on donor milk bank services that deliver milk whilst observing the best possible safety standards will not exceed opportunity costs acceptable to society.
PR	NETSCC (Ref 2)	79.22	General		This is a difficult area in which to provide evidence based guidelines. I think this should be more clearly acknowledged. I also wonder whether the authors should be more selective in the guidelines they issue. The document includes 80 guidelines many of which are not 'evidence based'.	This is acknowledged in the section on how the guidelines were developed (Section 2.1). In addition, NICE guidelines are based on the 'best available evidence' acknowledging therefore that there are areas where guidance is needed, even if 'best evidence' is not available. The 'evidence to recommendations' sections also document why the recommendations were made, in the absence of high-quality evidence, and why they were considered important.
PR	NETSCC (Ref 2)	79.23	23	4	The authors highlight that they have undertaken a survey that collected potentially important information on the costs of services and that this was included in appendix 4. This appendix is not included.	All appendices were available on the website…
PR	NETSCC (Ref 1)	79.24	General		The report is readable and well presented. The style facilitates an understanding of how the recommendations have been reached from the evidence.	Thank you…
PR	NETSCC (Ref 2)	79.25	24	16	The report asserts that is was not possible to construct an economic model but that costs and benefits were considered. This is a rather contradictory statement. No justification is given and no further elaboration is provided.	We separated individual decision areas where resource implications were most likely to be an issue (e.g. donor testing). The GDG was then presented with and considered likely downstream costs and effects for when considering other evidence, as presented in the individual guidelinechapters. We did not construct a formal decision analytic framework, but aided the GDG with information to ensure that cost effectiveness has been transparently considered when making recommendations for the NHS.

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PR	NETSCC (Ref 2)	79.26	30	General	There is no justification for the recommended screening approach which will lead to massive increases in the costs. Information on the costs of the different tests is readily available and could have been considered. I would have also thought that a crude projection of the cost-effectiveness of different strategies could have been made.	Thank you for your comment. We have done what we thought was necessary as well as appropriate. We will also be providing appropriate costing tools to support milk banks when implementing this guidance, which will include figures and projections of different strategies. UPDATE: A costing statement will be produced.
PR	NETSCC (Ref 1)	79.27	General		I have identified a number of small 'typos' and suggested changes for consideration. These are outlined in section 5.	Thank you – and these have been actioned as documented.
PR	NETSCC (Ref 2)	79.28	29	120	It is completely unclear as to whether there is any evidence to justify the resources required to follow the recommendation of promoting breast milk donation with the aim to recruit 'all possible donors'. For example, an alternative strategy would be to focus efforts on population subgroups where relatively 'high yield' may be anticipated	We have revised this to 'as many potential donors as possible'.
PR	NETSCC	79.29			**4.2 Please comment on whether the research recommendations, if included, are clear and justified.**	…
PR	NETSCC (Ref 2)	79.30	34	10	The authors state that: "Screening incurs an extra cost, but in this context this was considered necessary". No information is presented on even what the additional cost might be let alone what the benefits might be to allow any form of evidence-based assessment as to whether the benefits justified the costs.	We agree that in a different situation more complex work may have added value in reducing decision uncertainty. This was a challenging area given the lack of robust evidence, and we have done what we thought was necessary as well as appropriate.
PR	NETSCC (Ref 2)	79.31	98	4	Each recommendation starts with a similar summary of the number of studies that were available and the type of study. The reader is given little contextual information to help interpret the strength and usefulness of the evidence assembled. No information is presented on how the studies were identified and the relative quality of the different studies identified (see for example the evidence review on staff training)	The details of the review process were documented in the Appendices. The limited evidence base is also noted at the beginning of the guideline, where we also outline the different ways we aimed to try to work with such evidence.
PR	NETSCC (Ref 1)	79.32	General		I think the research recommendations were clear and justified.	Thank you…
PR	NETSCC (Ref 2)	79.33	General		The authors cite a forthcoming HTA study that includes a health economics model. I would urge the team to find out whether useful evidence will be available from this study and if so to amend their guidance accordingly. Certainly it would be more sensible to delay the publication of this report so that this evidence (if useful) could be included.	The HTA summary has now been added to the report. We were also aware of this work during development and worked with the authors to share work as appropriate.
PR	NETSCC (Ref 2)	79.34	35	General	It is stated that the probability of a baby contracting a serious disease following screened pasteurised donor milk is very low, and then an assertion is made that this implies that the benefits from a screening and pasteurizing strategy would be high. This is unsupported as no evidence is presented as to what the probability of a serious disease could be in the absence of a screening and pasteurization strategy. i.e. it is the size of the incremental benefits versus the incremental costs which is important.	Thank you for your comment. As stated above, we accept that there could have been more scope for de novo work to be carried out, but due to the constraints we were subjected to we have focused on providing the GDG with information on the likely downstream costs and effects that are associated with the respective recommendations. This was a particular challenge given the paucity of data in this area, and formal consensus

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						methods have played an important role for this particular guideline.
PR	NETSCC (Ref 2)	79.35	100	3	The authors provide research recommendations but the justification for them is unclear given that the whole area appears devoid of evidence. For example, they state: "our expectation is that, once any risks of donor milk banking are minimised, new research can be undertaken to evaluate the benefits of donor 3 milk, and to identify the recipient babies who would benefit most." I would have thought that given there is no strong evidence on which strategy to minimize risk is most appropriate, an important first step would be to undertake research comparing the risks of serious disease following different approaches..	The remit of these research recommendations is as for the practice recommendations – that is the process of handling donor breast milk. However we do note the need to link any research with health outcomes in the recipient population(s).
PR	NETSCC	79.36			**Please make any additional comments you want the NICE Guideline Development Group to see, feel free to use as much or as little space as you wish.**	…
PR	NETSCC (Ref 1)	79.37	7	1.2.5	For clarification, this information relies on self report?	Yes but is checked with the potential donor before recruiting her,
PR	NETSCC (Ref 1)	79.38	9	1.2.13	"If a donor provides a one-off donation of milk, delay testing for 3 months (or sooner if local protocols allow)." I'm not sure I understand the need to delay? Is this to allow time for possible seroconversion subsequent to viraemia at the time of donation?	The recommended testing strategy is now the same for ongoing and one-off donations.
PR	NETSCC (Ref 1)	79.39	11	1.2.23	"continued support for collecting of and maintaining lactation" I'm not sure this makes sense as it stands – is there a word missing? Does it need rewording?	This has been corrected to clarify that is about 'collecting milk'.
PR	NETSCC (Ref 1)	79.40	13	1.2.35	At this stage, I don't think it has been made clear that donors will need to monitor their freezer temperature – this comes in at 1.2.38.	This is part of the training so donors will be aware of their responsibility for this.
PR	NETSCC (Ref 1)	79.41	13	1.2.38	What should happen if donors don't collect the data (i.e. missing data) or they fail?	This is part of their responsibility in donating, and they should be informed of this and supported as appropriate. We have also added in guidance on what to do if there are concerns about the freezer temperatures.
PR	NETSCC (Ref 1)	79.42	15	1.2.50	Consider rewording the following: "keep them in the refrigerator and prevent them from reaching room temperature (they should not exceed 8ºC)" to "keep them in the refrigerator and do not allow them to exceed 8°C". Note that there is a big difference between 8°C and room temperature (18-21°C).	This has been revised.
PR	NETSCC (Ref 1)	79.43	15	1.2.52	How would significant or unusual contamination be detected?	We have rephrased this – but the visual inspection at the lab would identify significant or unusual contamination.
PR	NETSCC (Ref 1)	79.44	27	2.4.2.11	I'm not sure I understand this bullet point. Could it be reworded?	This has been revised.
PR	NETSCC (Ref 1)	79.45	30	6	Extra full stop	Corrected
PR	NETSCC (Ref 1)	79.46	30	10-11	This section is in note form and the reader is left a little confused about North America, the USA and Canada. This is also the case in other similar sections on evidence review e.g. p 82 lines 14-18..	The wording of these sections has been revised.
PR	NETSCC (Ref 1)	79.47	33	2.5.2.12	Missing full stop, extra bracket.	Corrected

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PR	NETSCC (Ref 1)	79.48	39	9-10	Should this read 3 primary studies?	We have checked and corrected these
PR	NETSCC (Ref 1)	79.49	39	21	Is this author name correct?	This has been corrected.
PR	NETSCC (Ref 1)	79.50	44	2.8.24	I'm not sure I understand the distinction between anti-infection agents and antimicrobial agents here.	This has been checked and revised.
PR	NETSCC (Ref 1)	79.51	55	2.11.2.2	Note form	This has been revised,
PR	NETSCC (Ref 1)	79.52	59	23-24	It doesn't seem intuitive that treatment would reduce bacteriostatic activity but preserves bactericidal activity.	This has been revised to reflect the inconsistency in the reviewed literature.
PR	NETSCC (Ref 1)	79.53	59	28-29	I don't understand the statement: "Freezing milk… allows bacterial growth in non-contaminated milk compared with refrigeration"	This has been clarified.
PR	NETSCC (Ref 1)	79.54	60	3	Remove word 'infection'.	Removed
PR	NETSCC (Ref 1)	79.55	72	23	Replace 'levels of bacteria or infection' with 'levels of microorganisms'?	Revised to 'levels of bacteria'
PR	NETSCC (Ref 1)	79.56	73	4-6	This might need further clarification, as it seems slightly vague to me. Could 'organisms with the potential to be enteric pathogens' and 'non-pathogenic organisms' be replaced with the term 'indicator organisms' since presumably that is their purpose – to indicate that a pathogen might be present? Could 'bacillus species that are heat resistant' be replaced by 'heat resistant *Bacillus* spp. that can form spores'?	These have been revised
PR	NETSCC (Ref 1)	79.57	74	9 and 12	Presumably they won't be tested for all pathogens?! This might need clarifying.	But they would reject any milk with bacterial growth of any kind.
PR	NETSCC (Ref 1)	79.58	74	14	Is this CFU per mL?	The paper states CFU?
PR	NETSCC (Ref 1)	79.59	74	11 and 13	These two values are very different! The value in line 13 is less stringent than the pre-pasteurisation levels – can this be correct?	These reflect the different criteria used in different milk banks so are not consistent.
PR	NETSCC (Ref 1)	79.60	77	4	Preferable to what?	Checked the paper and this is as quoted – so have left as is.
PR	NETSCC (Ref 1)	79.61	84	9	Full stop after bacteria genus 'letter' e.g. E. coli.	Added
PR	NETSCC (Ref 1)	79.62	85	4	Full stop after bacteria genus 'letter' e.g. E. coli.	Added
PR	NETSCC (Ref 1)	79.63	84	22	Capital letter on Listeria (also page 85 line 19)	Revised
PR	NETSCC (Ref 1)	79.64	85	7	Give the acronym in full?	Added
PR	NETSCC (Ref 1)	79.65	97	Rec 1.2.67	The third bullet is missing "For each pasterised container…"	This has been corrected
PR	NETSCC (Ref 2)	79.66	General		I found this report a very difficult one to review since so little evidence is available. In particular the lack of evidence collated on the relative costs of the different strategies was particularly concerning. While such projections would obviously be highly uncertain I would have thought coming up with some 'ballpark' figures would have been helpful. As it stands the guidelines presented have little or no supporting evidence.	Thank you for this comment. We agree that it was a challenging area for an evidence based guideline considering the evidence base. We have done what we thought was necessary as well as appropriate. We will also be providing a costing

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						statement (as appropriate) to support milk banks when implementing this guidance, which will include figures and projections of different strategies.
SH	NHS Sefton	85.00	General		NHS Sefton welcomes the opportunity to comment on the draft guidance for Donor Breastmilk Banks. The guidance is highly important and offers families a much due choice for their pre term baby whilst affirming that breastmilk is the best form of nutrition and encourages exclusive breastfeeding for the first six months of an infant's life. North Mersey PCT's have been working collaboratively to use the principles of social marketing to identify staff and public perceptions of breastfeeding. The findings of this work will similarly inform the implementation of this guidance in relation to recruitment and support of donors.	Thank you for these comments. We will also feed this back to the Implementation Team.
SH	NHS Sefton	85.01	4	7, 8, 9	This statement could mislead - Need to clarify how the distribution of milk is prioritised for pre-term and poorly babies and emphasise that it is not available as an easy option choice for those who do not wish to breastfeed but want 'designer milk'.	This guideline does not cover indications for the use of donor breast milk. However, the Introduction does describe some circumstances where donor breast milk may be used. This sentence has been clarified to clarify some examples where donor breast milk may be considered.
SH	NHS Sefton	85.02	6	23	Mindful of the literacy needs of many and also the reluctance of some to pick up a leaflet that may have breastmilk in the title, we would suggest where available, the use of other digital signage/customer information systems in settings like G.P surgeries/antenatal clinics/shops that permits key messages to be visual and heard.	Noted and all information should be in formats appropriate to the audience – this is a key principle of any information in the NHS so has not been specified in the recommendations.
SH	NHS Sefton	85.03	7	17	Include link to NHS stop smoking services at www.dh.gov.uk or advise those selecting donors to provide brief intervention on smoking and breastfeeding.	Although important, this is not considered the key role of the donor milk bank.
SH	NHS Sefton	85.04	10	19	Include information on exposure to second hand smoke.	We have a recommendation that women should be asked about passive smoking.
SH	NHS Sefton	85.05	10	21	Consider short DVD using present donor testimonials to address those with literacy needs.	We have not specified how information should be delivered in all circumstances; we will feedback this suggestion to the Implementation Team for consideration.
SH	NHS Sefton	85.06	17	14	Include definitions of released and non released in glossary	These terms have been removed in the process of revision.
SH	NHS Sefton	85.07	20	1.3 Care pathway	Include brief intervention on algorithm so it reads 'exclude as donor and provide relevant brief intervention or signpost to services'.	We have removed the care pathway, but as for all NICE guidance, a Quick Reference Guide will be produced.
SH	NHS Sefton	85.08	28		The implementation of workplace policies that support women to express and store breastmilk after returning to work would improve likelihood of donating.	And although this is important, it is outside the remit of this guideline. We will feed this comment back to the Implementation Team also.
SH	NHS Sefton	85.09	29	2.4.4	See comment 3 Mindful of the literacy needs of many and also the reluctance of some to pick up a leaflet	See response to comment previously

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					that may have breastmilk in the title, we would suggest where available, the use of other digital signage/customer information systems in settings like G.P surgeries/antenatal clinics/shops that permits key messages to be visual and heard.	
SH	NHS Sefton	85.10	34	14	In support of this, labelling of breastmilk should include duration of breastfeeding/expressing by donor.	We have not made recommendations on the duration of breastfeeding as this would be more appropriate in a guideline on the indications for the use of donor breast milk.
SH	NHS Sefton	85.11	36	2.5.4	See recommendation 4	See response to previous comment
SH	NHS Sefton	85.12	40	14	Supervision of donors can be undertaken by breastfeeding peer supporters/ family support workers where available. Look beyond Health Visitors for supervision or consider skill mix within the service for sustainability.	Noted, however, the GDG did not wish to recommend supervision as such, but wanted to ensure that donors are supported as they need. We have not specified who should do this, but that the milk bank should ensure that women are supported.
SH	NHS Sefton	85.13	41	5	Every contact should be seen as a health promoting opportunity.	And we anticipate that there will be ongoing dialogue between the donor and the milk bank.
SH	NHS Sefton	85.14	41	7	Include cost benefit analysis here.	It is not clear to what this refers?
SH	NHS Sefton	85.15	43	2.7.4 Rec. 1.2.20	See recommendation 5	See response previously
SH	NHS Sefton	85.16	47	2.8.4 Rec.1.2.29	The development of donor peer support or an Infant feeding support services could sustain the level of advice and support for those stopping milk donations. Consider physical and emotional impact.	We have made several recommendations on the need to support the donor; this could be via different routes as you suggest. We will also feed this comment back to the Implementation Team.
SH	NHS Sefton	85.17	54	2.10.4	Include labelling of milk in these recommendations	We do recommend that donors are trained in the handling of donor milk at home including labelling.
SH	NHS Sefton	85.18	97	2.20.4	Consider in Rec. 1.2.67 collecting duration of breastfeeding/expressing on donor records for the purpose of matching age appropriate milk in light of changes in constituents with age.	We have recommended that that age of the donor's baby should be documented.
SH	NHS Sefton	85.19	98	13, 15	Action needs to be extended to include all staff working with pregnant and lactating women. Healthcare professionals still need to improve their understanding of the benefits of breastmilk ahead of benefits of donation and so it should be recommended that donation and the process of banking be incorporated into any mandatory/non mandatory breastfeeding training. PCT's should actively involve partner agencies in training and vice-versa.	We will feed these comments back to the Implementation Team.
SH	NHS Sefton	85.20	99	2.21.4	Action needs to be extended to include all staff working with pregnant and lactating women. Healthcare professionals still need to improve their understanding of the benefits of breastmilk ahead of benefits of donation and so it should be recommended that donation and the process of banking be incorporated into any mandatory/non mandatory breastfeeding training. PCT's should actively involve partner agencies in training and vice-versa.	We will feed these comments back to the Implementation Team.
SH	NHS Sheffield	45				…
SH	Norfolk and	83.00	17	5-7	Agree not the place of the milk bank but there needs to be formal guidance on	This guideline is for donor milk banks, so the

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	Norwich University Hospital NHS Trust		88	12-13	fortification, ie how fortified for specific types/categories of recipients at the clinical site.	recommendation is specific to the handling of donor milk at the milk bank.
SH	Norfolk and Norwich University Hospital NHS Trust	83.01	83 100	11-19 11-24	More research needed re efficacy of high temperature/short time processing to assess the option that eliminates key bacteria and viruses whilst preserving nutritional and immunological constituents. How can guidance be formatted prior to such work?	We have made research recommendations on the need to evaluate the effect of handling donor breast milk, and specifically refer to the newer processes such as high pressure treatment.
SH	Norfolk and Norwich University Hospital NHS Trust	83.02	87	1-4	Agree	…
SH	Oxford Radcliffe Hospitals NHS Trust	49.00	9	19	What is the rationale for requiring blood tests from donors at the point at which they offer the first donation of milk, rather than using antenatal blood tests? What evidence is there that pregnant women who are negative to HIV, Hep B etc at 12 weeks gestation acquire these infections during their pregnancy, or shortly after birth? There are cost implications for milk banks, which currently rely just on antenatal tests, of switching to additional testing of new donors. There are also cost effectiveness issues in relation to testing for any factor that is rare in the population from whom milk is being received, especially if it would be inactivated by pasteurisation. There are potentially counselling implications for testing donors for conditions not normally screened for antenatally. If milk banks test for Hep C, sometimes they are going to find it – and someone is going to have to deal with it.	The GDG considered that all serological tests should be undertaken to minimise the risk of transmission – this is particularly important when taken in the overall context of the recommendation not to repeat these tests during donation. The cost implications were considered and discussed in the Evidence to recommendations section. Counselling and support are recommended in line with local protocols.
SH	Oxford Radcliffe Hospitals NHS Trust	49.01	9 (20	21 3)	If there is no requirement for repeat /routine blood tests during the time that a mother is donation milk, what is the rationale for quarantining "one–off "donations and waiting three months before asking them to have the battery of blood tests? Why would there be any need to be more worried about sero-conversion in someone providing a one-off donation than in a "regular" donor? This has considerable implications for tracing one-off" donors and getting blood tests arranged if they live "out of area" (and are simply leaving the milk that they expressed when their babies were admitted to a regional Neonatal unit for care). There are also cost and space implications of storing milk for that length of time (3 months). There is also the possibility that emotional distress will be caused to mothers who have donated their milk because their baby has died – if they are contacted to have a blood test three months later - even if they have been warned that this will be necessary.	The recommended testing strategy is now the same for ongoing and one-off donations.
SH	Oxford Radcliffe	49.02	10	7	Obviously donors have to give informed consent for serological testing, but what consent	The GDG considered important that donors

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	Hospitals NHS Trust				is required for the process of handling their milk? What does this mean?	should be aware of the use that their donated milk may be put to, and consent to this.
SH	Oxford Radcliffe Hospitals NHS Trust	49.03	10	19	Why is caffeine consumption listed in 1.2.20 (page 10 and 43) and not in 1.2.5 (page 7 and page 36)?	This has been removed from all sections after discussion with the GDG.
SH	Oxford Radcliffe Hospitals NHS Trust	49.04	12 (47)	4	This seems to be suggesting that if a medication can safely be taken by a breastfeeding woman, it might be permissible for her also to donate milk to the milk bank whilst taking the medication. This seems to be a step backwards. For some time now, milk banks have been telling mothers that if they are taking any prescription medication (apart from named exceptions) they should not donate until the medication was cleared from their system – 5 half lives. The rationale for this was that even if the drug was AAP approved, it was not thought wise to give sick babies a "cocktail" of even traces of medication – since they would inevitably receive milk from more than one donor. Is it now thought that this poses no risk?	We have recommended that the donor should discuss any medication with the donor milk bank and the decision to stop or suspend donation should be made at that point. We will also raise this issue with the Implementation Team – there may be some support or further information that could be provided to maintain an up-to-date list of named medications.
SH	Oxford Radcliffe Hospitals NHS Trust	49.05	13	16	Is the suggestion that milk banks provide all donors with thermometers for their freezer? Where is the evidence that this is necessary? There are considerable cost implications to asking milk banks to do this. How accurate would the thermometer provided need to be? How would it be calibrated / tested? How often? If the milk is not kept frozen, because the freezer is failing, surely none of the other food in the freezer will be frozen either and it will be quite obvious to the donor.	This has been revised to ensure that the freezers are monitored, but there is no requirement for the milk bank to provide thermometers. The application of HACCP principles should also be applied to storage at the home, and guidance given to donors.
SH	Oxford Radcliffe Hospitals NHS Trust	49.06	20	3	This care pathway needs clarifying – it seems to suggest that the decision to pasteurise can be made on the basis of microbiology results. This would mean that the thawed milk would have to be stored for at least 48 hours.	We have removed the care pathway, but as for all NICE guidance, a Quick Reference Guide will be produced.
SH	Oxford Radcliffe Hospitals NHS Trust	49.07	5	28	Milk banks may receive assurance from the unit to which they are providing the milk that they will follow a tracking / recording procedure, but there is no way in which they can easily monitor or enforce the procedure. It is unreasonable to expect that they will even try. The NICE guidance should operate to the point at which the milk leaves the milk bank, and not beyond it. If the milk is safe for preterm babies to drink, it will be safe for anybody.	This has been revised to reflect this. However, we have added in further guidance on the type of information that a milk bank may request from the recipient hospital.
SH	Royal College of Midwives	55.00	General		The Royal College of Midwives welcomes the opportunity to comment on the draft of this important guideline.	Thank you.
SH	Royal College of Midwives	55.01	4	6	Information regarding the importance of mothers expressing their own milk for their own babies may be useful. The document goes straight from breastfeeding to donor milk. You may wish to refer to the RCM Infant Feeding: a resource for health care professionals and parents	The MCN Expert Report was used during the development of this guideline (key reference in the NICE guideline on maternal and infant nutrition) where appropriate, as was other relevant

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					published by the Royal College of Midwives Trust, September 2009 and MCN consultation (2007) Expert Report – Handling and storage of expressed breast milk http://www.nice.org.uk/nicemedia/pdf/MCN_Expert_Report-Handling_and_storage_of_expressed_breast_milk.	information on expressing milk for a mother's own baby. However, it should be emphasised that the focus was on donor milk and direct extrapolation from maternal milk was not always possible or appropriate.
SH	Royal College of Midwives	55.02	4 24	10 1	It would appear more appropriate to wait for the publication of this report before publishing the guideline, in the acknowledged context that 'for most topics, there was limited or no high-quality evidence'.	This report has now been published and the results updated accordingly. However, it does not provide evidence on the operation of donor milk banks, but evidence on the need for such banks when operated efficiently.
SH	Royal College of Midwives	55.03	16 and 45	6 11-17	There is no mention of Bisphenol A in containers for storing milk.	We have specified that food-grade plastic should be used.
SH	Royal College of Midwives	55.04	12 And 26	19 1	The two statements in these sections about 'drip milk' seem to contradict each other.	The GDG did not recommend the acceptance of drip milk as there is evidence that composition of drip milk is different– please see the relevant Evidence to Recommendations section for details. However, the evidence statements reflect the practice of some milk banks.
SH	Royal College of Midwives	55.05	12 45	6 19	It has been suggested that BNF information is not always accurate, and can be limited. Medications in Mother's milk, and The Breastfeeding Network's 'Drugs in Breastmilk' factsheets may be helpful.	We have revised this to the BNF-C and the UK Drugs in Lactation Advisory Service. UPDATE: We refer only to the BNF-C in the Evidence to Recommendation section.
SH	Royal College of Midwives	55.06	35	1-2	More discussion of the evidence on the risk of HIV/Hep B transmission via breastmilk would be helpful here – there are no references cited.	Reference to the HPA and one other reference have been added
SH	Royal College of Midwives	55.07	35	28	The RCM is pleased to see this proposal for 'stepped' screening , where self assessment is recommended prior to the formal testing stage.	Thank you
SH	Royal College of Midwives	55.08	97	1	It would be useful to develop a nationwide system of tracking the milk eg using a barcode with unique identifier	Noted and this area of processing is vital; however we made recommendations on the type of information to be retained, not the methods (that is, whether paper or electronic) of collection. We will also feed these comments back to the Implementation Team.
SH	Royal College of Midwives	55.09	98	1	A retrospective randomised screening system could facilitate an effective audit trail.	We will feed these comments back to the Implementation Team.
SH	Royal College of Midwives	55.10	General		The RCM is concerned that commissioning (and by implication payment) should not be involved in the provision of donor milk.	There is no intention that donors should be paid for provision of donor milk. This has been clarified in the guidelines.
SH	Royal College of Nursing	56.00	General	General	The RCN welcomes this guideline.	Thank you.
SH	Royal College of Nursing	56.01	General	General	There is nothing in the document which runs contrary to our experience and practice, however as NICE guidelines go the "evidence" seems elderly and quite weak. Sadly there are no large major RCTs to reliably validate much of the practice. At best this can	Noted, and we agree with your summary. From the outset, it was clear that there was little high-quality evidence to support practice.

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					be regarded as current practice which will hopefully evolve and refine as research supports changes to the guidelines. The recommendations are based on current best practice and are supported by the collective weight of the evidence however poor we currently have. So as such is valuable as a starting point.	We have therefore used various methods to ensure a robust set of recommendations, even in the absence of high-quality evidence. We have also made research recommendations which we anticipate will support any update of these guidelines in the future.
SH	Royal College of Nursing	56.02	General	General	We recognise that there is a paucity of good research based work in this area and we would like to make a call for further research to underpin these recommendations.	We have also made research recommendations which we anticipate will support any update of these guidelines in the future.
SH	Royal College of Nursing	56.03	General	General	There should be a lot of focus on Implementation of the guidelines i.e. collaborating working and who should be involved to enable a successful implementation.	We have fed these comments back to the Implementation team who will consider such collaboration when developing tools and strategies to support banks implementing these guidelines.
SH	Royal College of Nursing	56.04	General	General	It would be helpful to identify opportunities for joint working with Midwives.	See comment above on collaboration.
SH	Royal College of Nursing	56.05	General	General	Post natal follow up and involvement of primary care services is essential.	NICE Clinical Guideline 37 gives guidance on postnatal care, and healthcare professionals would be expected to refer to this as appropriate. We have also fed this comment back to the Implementation Team.
SH	Royal College of Nursing	56.06	General	General	This Document is mostly for Neonatal nurses and Bacteriologists, there is little reference in the main document to the Midwives' role, though lots of references are to Milk Nurses.	We would expect this guidance to be appropriate for all staff involved in the handling of donor breast milk – this may be a range of staff, including midwives. As with many clinical guidelines, we have not made recommendations specific to the job title of any particular healthcare professional, but have tried to aim these at the roles that any healthcare professional may undertake in the process of donor milk handling. We will also feedback this comment to the Implementation Team.
SH	Royal College of Obstetricians and Gynaecologists	57			This organisation replied and said they had no comments to make	…
SH	Royal College of Paediatrics and Child Health	58.00	General	General	The College notes that the guidance document covers the topic well.	Thank you…
SH	Royal College of Paediatrics and Child Health	58.01	General	General	The College thinks that the guideline, which outlines a standardised and safe process, will inspire confidence in both mothers who donate their milk and mothers whose infants are receiving it.	Thank you…
SH	Royal College of	58.02	General	General	The lack of a really good evidence base means that the guideline developers have taken	Thank you…

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	Paediatrics and Child Health		(evidence base)		great pains over this. The College notes that they did a very good job in comprehensively assessing the available evidence and describing how they achieved consensus of expert views (and also where there was no consensus). The available evidence and guidelines from around the world have been examined in great detail and the guidance provided is clear and logical. There are obviously many only partially answered questions in this field, which only ongoing research can answer.	We have also made research recommendations which we anticipate will support any update of these guidelines in the future.
SH	Royal College of Paediatrics and Child Health	58.03	General	General	The College notes it is helpful to see that the group recognises that this area of health care suffers from being relatively small scale and therefore clarity about the need for staff training and audit of procedures is emphasised.	And this is an area that we have highlighted as key priorities for implementation.
SH	Royal College of Paediatrics and Child Health	58.04	General	General	The College agrees that it is correct to view breast milk in the same way as other human tissue and to use the same standards as those applied to blood donation.	And we aimed to make reference to other best practice in areas of donation, such as blood, where appropriate.
SH	Royal College of Paediatrics and Child Health	58.05	General (benefits of EBM)	General	The College notes that the tone of the guideline is very prescriptive and sets out long lists of exclusions, rather than long lists of those who are eligible for donor milk. The restrictions are important but a little vague. We recommend that the guideline be more positive about the benefits to babies from donor expressed breast milk (EBM). It is not just that mothers do not want to express but just as often they are too sick themselves or simply are not able to. We would like to see the guideline re-assure that EBM is safe to use.	We have clarified the exclusions in response to this and other comments. We consider the Introduction to outline the use of donor breast milk (accepting that we have not systematically reviewed the evidence for this as not part of the remit of this guideline). The aim of the guideline is to describe best practice with the aim of safety, so healthcare professionals and parents/carers of recipients can be assured of the safety of the donor milk, when handled according to these guidelines.
SH	Royal College of Paediatrics and Child Health	58.06	General	General	The College recommends that the guideline include information about the use of EBM, so that it is clear that the production and availability of EBM make it a precious resource that cannot be used freely. The College notes that EBM should be used for infants where there are clinical indications for its use, and only where the balance of benefit has been fully assessed by the Health Care team and the parents.	We acknowledge that this is an important area, however the indications and use of donor milk were outside the remit of this guideline.
SH	Royal College of Paediatrics and Child Health	58.07	General	General	The College recommends that the guideline include a statement about ensuring that neonatal networks understand the need for donor breast milk banks, and that siting in one place may avoid duplication and deliver better economies of scale.	The guidelines are focussed on the operation of donor milk banks (that is, the handling of milk) not the configuration of those services in local areas. We will feedback these comments to the Implementation Team
SH	Royal College of Paediatrics and Child Health	58.08	5	12	First line total viable bacteria is not exclusive of the next two named. We recommend that it should first read Enterobacteriaceae, then Staphylococcus aureus, then "all other bacteria".	The GDG consider the recommendation to follow logically from a general count, through to specifics.
SH	Royal College of Paediatrics and Child Health	58.09	5	15	The College would like clarification on whether the recommendation is to regularly test pasteurised milk for bacterial contamination after pasteurisation and before banking, or whether to get samples from the bank to test regularly.	The recommendation is to test milk regularly post pasteurisation.
SH	Royal College of Paediatrics and	58.10	6	18	The College notes that 1.2.1 and 1.2.2 are contradictory. Should the promotion of breast milk donation aim to reach all potential donors or as many as possible?	These two recommendations have been clarified and merged – but the aim is to reach 'as many as

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	Child Health					possible'
SH	Royal College of Paediatrics and Child Health	58.11	12	19	The College was surprised that evidence is now sufficient to indicate that hand expression is strongly to be preferred, and that it is noted as more hygienic. We note that many mothers find it more comfortable initially, but would expect that once lactation is established a woman should be given a choice between hand and pump.	Evidence did support hand expression (higher fat and lower bacterial contamination) and this is in line with guidance for mothers expressing their own milk (See NICE clinical guideline 37 on post natal care). However, we do recommend that donors may prefer to use a pump and this is acceptable.
SH	Royal College of Paediatrics and Child Health	58.12	16	2	The College would like clarification on what is meant by "10/ml".	We have clarified that this should be CFU/ml
SH	Royal College of Paediatrics and Child Health	58.13	13 14 15 16 51 53 54 66 67-68	2 22 6 3 10,13,18,22 2 Table 10 Table	The College would like clarification on the recommendation that expressed breast milk be refrigerated within 24 hours of expressing. We would like to see evidence of the bacterial content of milk kept unrefrigerated up to 24 hours after expressing.	We have noted that there are differences between milk for donation and milk for a mother's own baby – in this case, the risk is not bacterial but changes in the nutritional and immunological composition and an aim to get the 'freshest' and 'highest quality' milk to the milk bank for processing.
SH	Royal College of Paediatrics and Child Health	58.14	45 and 94	12 and 3	The College notes that many mothers are prescribed straightforward drugs, antibiotics, etc., and recommends that the guideline list the most prescribed drugs.	We have recommended that milk banks should refer to up-to-date sources of information. We will also feed this comment back to the Implementation Team.
SH	Scottish National Blood Transfusion Service (SNBTS)	84.00	7	25	Should the relevant risk factors for CJD (eg recipients of human pituitary derived hormones, dura mater, blood transfusion, organ or tissue graft, **or** classified as 'at risk for public health purposes' following surgery or donating blood) be specified? Is a history of blood transfusion (post-1980) to be regarded as a contraindication to milk donation as it is for both blood and tissue donors?	We have included a cross reference to the HPA website to ensure accurate and current information on CJD.
SH	Scottish National Blood Transfusion Service (SNBTS)	84.01	9	13	It should state that the virology testing of blood samples must be carried out by CPA or MHRA accredited laboratories using assays that have been approved for donor screening (as opposed to clinical diagnostic testing where less sensitive assays may be used). The United Kingdom Blood Transfusion Services produce a list of approved assays for donor screening in the UK. The use of nucleic acid testing would markedly reduce the length of the 'window period' for any potential infections which may be missed by only using serological testing. Whilst not justifiable if the policy of repeat serological testing and quarantining of donations were to be adopted, the use of nucleic acid testing should be seriously considered when this is not the case. The small number of donors involved and the large number of donations per donor would make the cost of this additional testing per donation almost negligible.	We have added a recommendation on the need to use accredited laboratories and we consider that such labs would then use the appropriate test for purpose.
SH	Scottish National Blood Transfusion Service (SNBTS)	84.02	9	19 & 21	There is an inconsistency in the proposals for testing blood samples of donors for markers of viral infection which would result in dual standards.	The recommended testing strategy is now the same for ongoing and one-off donations.

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					• For 'one-off' donation milk it is proposed to delay testing for 3 months and quarantine any donations until the test results are known. *This testing protocol can be regarded as the gold standard as it ensures that there is no risk of 'window period' infection and all donations are confirmed to be virology negative before they are released for use.* • For other (regular) donors the proposal is for testing at the time of enrolment with no further testing or quarantining of the donations. *This testing protocol may miss 'window period' 'infections which could be present at the time of testing and will not pick up any future infections which could occur whilst still donating milk. It can not confirm that all donations are virology negative before they are released for use.* If it is believed that the risk of 'window period' infection, or subsequent infection, is so low (and with the additional benefits of pasteurisation) that no additional testing is required of the regular donors then the one-off donors should also be tested at the time of enrolment, rather than delaying for 3 months, allowing the donations to be available for use once the test results were available.	
SH	Scottish National Blood Transfusion Service (SNBTS)	84.03	13	8	The recommendations allow for breast milk to be stored for 3 months in a domestic freezer at -18ºC or lower. A recent paper (May 2007) "Domestic food practices in New Zealand freezer survey" prepared on behalf of the New Zealand Food Safety Authority monitored the air temperature of 39 domestic freezers using data loggers. Only 28% operated at a mean temperature of -18ºC or lower, with 68% operating with a mean temperature between -13 and -18ºC and 4% with a mean temperature of only -12ºC. The maximum temperature for these freezers ranged from –11.5 to –15.2ºC. Storage in domestic freezers is by far the weakest part of the "cold chain" and should be kept to the minimum practical period. Ideally this should be no more than 2 weeks but operationally no more than 4 weeks may be more realistic.	We have recommended that milk should be transported to the milk bank as soon as possible because of these concerns. We have also added in guidance to donors to contact the milk bank if there are concerns about the performance of their freezer.
SH	Scottish National Blood Transfusion Service (SNBTS)	84.04	13	16	This is a very vague statement as it does not specify what piece of equipment should be used to check freezer temperatures nor how the documented temperatures should be used. The only piece of equipment that would provide continuous monitoring of the freezer would be a data logger. The opposite end of the spectrum would be to obtain a once a day daily reading from a validated thermometer. As the minimum and maximum temperature may vary by several degrees throughout the day, the recorded temperature may not provide an accurate reflection depending on what time of day it was taken. If monitoring shows the temperature of the freezer to be warmer than -18 ºC (eg -15 ºC) what action should be taken regarding the milk? The longer the milk is stored in this domestic freezer the more important this question becomes.	We accept there will be variation, but a judgement on risk will need to be made. This should be done as part of the HACCP assessment of storage at the home, and guidance given to donors. We have also advised that donors should contact the milk bank if there are concerns about the freezer performance.
SH	Scottish National Blood Transfusion Service (SNBTS)	84.05	16 20	5 4	This states that milk can be stored for no longer than 3 months after pasteurisation. This states that milk can be stored for a maximum of 3 months from expression before pasteurisation. Together these statements allow a maximum storage period of 6 months from the time of expression, of which 3 months can be in an uncontrolled domestic freezer. This is consistent with	We have revised this recommendation so that the expiry date is 6 months post expression. We have also recommended that donors should transport the milk to the milk bank as soon as possible, because of the concern over domestic freezers.

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					NICE PH11 "Maternal and child nutrition" which allows maternal expressed breast milk to be stored for up to 6 months in a domestic freezer at -18ºC or lower. As it is the maximum storage period of 6 months that is important, there is no scientific reason why the milk can not be stored following pasteurisation until 6 months after the date of expression. For example, if the milk is pasteurised 1 month after expression then it should be allowed a maximum 5 month storage period following pasteurisation. This should encourage minimizing the storage period in the donor's domestic freezer and allow a longer shelf life for the pasteurised donor milk, thus both improving the quality of the milk and reducing any wastage due to milk passing it's expiry date. Where milk is pooled for pasteurisation then the date of expression for the oldest bottle contributing to the pool should be used to determine the expiry date of that batch of milk. Where milk is not pooled the actual date of expression should be used to determine the expiry date for each individual bottle.	
SH	United Kingdom Association for Milk Banking	74.00	4	4	Suggest omit 'for as long as mother and baby wish' as this weakens the recommendation. WHO recommend 'breastfeeding up to two years and beyond'.	This has been removed.
SH	United Kingdom Association for Milk Banking	74.01	4	7	Because of limited supplies, donor milk is not available for all babies but only for those who are sick and preterm – this line infers that any mother not wishing to breastfeed/express milk could ask for donor milk. Is this what is intended?	This guideline does not cover indications for the use of donor breast milk. However, the Introduction does describe some circumstances where donor breast milk may be used. This sentence has been clarified to clarify some examples where donor breast milk may be considered.
SH	United Kingdom Association for Milk Banking	74.02	5	13/14	Are these minimum recommendations? On what basis is this recommendation made? How much additional milk would be available for use if this is adopted (rather than no pathogenic organisms as per current recommendation) – does this incur any additional risk for any recipient population group eg extremely preterm/sick infants?	These are not intended as minimum recommendations but are criteria as determined and agreed based on expert consensus (there was a lack of high-quality evidence on which to base the recommendation); however, any guideline recommendations are only recommendations.
SH	United Kingdom Association for Milk Banking	74.03	5	18	What is the evidence based rationale for this? It appears to be an arbitrary recommendation that may compromise safety given the importance of the pasteurisation process.	We recognise that this is a change in practice – please see the Evidence to Recommendations section for the reasons for this. The GDG discussed this fully and do not consider it to compromise safety if the testing is part of the whole process of donor milk banking as recommended in the guidelines.
SH	United Kingdom Association for Milk Banking	74.04	5	28	Hospital trusts will be required to sign up in advance to agree to comply with the tracking recommendation to ensure that recipients are not denied milk because the recommended procedures are not in place. There are training implications here for any Trust using donor milk.	We will raise this with the Implementation Team.
SH	United Kingdom Association for Milk Banking	74.05	6	13	'prescribed'? Suggest more appropriate terminology.	We have revised the wording to 'administered'

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SH	United Kingdom Association for Milk Banking	74.06	7	7	Delete 'articles' as this suggests written media only	Have revised to 'features'
SH	United Kingdom Association for Milk Banking	74.07	8	22	This implies that only a recent blood transfusion is of interest – would any blood transfusion post 1980 still be a contraindication to donating?	We have removed this example here as this related to the risk of CJD not the transfusion itself.
SH	United Kingdom Association for Milk Banking	74.08	9	21	3 months from when and why 'sooner if local protocols allow' – does this refer to the use of more sensitive serology testing in which case should it be stated here?	The recommended testing strategy is now the same for ongoing and one-off donations.
SH	United Kingdom Association for Milk Banking	74.09	10	26	'breasts'? At this point suggest limit to 'personal hygiene' to ensure there is no suggestion that breasts need to be cleaned prior to each expression.	This has been revised as suggested.
SH	United Kingdom Association for Milk Banking	74.10	11	15	Need to specify a volume – small is too subjective. In some instances small amounts of milk may be valuable. Consider removing and leaving up to individual milk banks.	The GDG considered it not possible nor appropriate to define this as would depend on factors specific to each milk bank –for example, current stock levels, costs of processing milk etc… The intention is to leave this decision with the milk bank.
SH	United Kingdom Association for Milk Banking	74.11	13	2	Preferably store milk on the top shelf of a fridge rather than lower shelves so that nothing drips on to the bottle and contaminates it or take measures to prevent containers of milk being contaminated.	Such details would be covered through the HACCP protocol and should be included in the training for donors (covered by storage and freezing of milk).
SH	United Kingdom Association for Milk Banking	74.12	15	5-7	Clarify that the 8 deg C does not refer to the refrigerator temperature but to the temp of the milk at any time during testing and handling prior to pasteurisation.	This has been revised.
SH	United Kingdom Association for Milk Banking	74.13	15	18	Suggest it will be helpful to outline in greater detail the full requirements of the pasteurisation process (including the evidence if available for cooling requirements and submersion/non submersion of bottles)	We have added in that rapid cooling is required. No evidence for submersion was identified, but we have recommended that all milk should be pasteurised in equipment made for pasteurising human milk and that this equipment is fit for purpose.
SH	United Kingdom Association for Milk Banking	74.14	15	19	This is a very important point and milk banks will require help in determining their testing schedule. Clarification would be required on volume and throughput but on what evidence would it be based.	We have recommended how often this should be done, but milk banks can test more often depending on their volume and throughput (and this will be a local decision).
SH	United Kingdom Association for Milk Banking	74.15	16	1	Are the tests in routine use this sensitive?	We have clarified that this should be CFU/ml
SH	United Kingdom Association for Milk Banking	74.16	16	9	Ensure that there is an adequate printout from the pasteuriser to show that the correct time and temperature have been reached during the pasteurisation process.	This would form part of the monitoring of the equipment functioning, and is covered in the recommendations on quality assurance.
SH	United Kingdom Association for	74.17	17	6/7	Suggest omit 'Fortifiers ....used'. It is unnecessary given the previous sentence.	This has been removed

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	Milk Banking					
SH	United Kingdom Association for Milk Banking	74.18	17	28	Print out from pasteuriser for each batch processed.	This would be covered by records to be kept.
SH	United Kingdom Association for Milk Banking	74.19	18	9	Which samples and at what temperature?	This now refers to blood only. We have also recommended that current guidance from the Royal College of Pathologists is followed. UPDATE: reference to the RCPath guidance has been removed.
SH	United Kingdom Association for Milk Banking	74.20	29	5	See previous comment (7) Delete 'articles' as this suggests written media only	We have revised this to 'features'
SH	United Kingdom Association for Milk Banking	74.21	36	Rec 1.2.6	'Advise her.....donate milk' – suggest replace with a more positive statement that will not deter potential donors	We have revised this recommendation to emphasise the health of the donor, but also these are criteria that will be discussed with the donor, not use as self-screening criteria.
SH	United Kingdom Association for Milk Banking	74.22	47	1	Need to specify a volume – small is too subjective. See previous comment (11) Need to specify a volume – small is too subjective. In some instances small amounts of milk may be valuable. Consider removing and leaving up to individual milk banks.	See response to comment previously
SH	United Kingdom Association for Milk Banking	74.23	54	1	Preferably store milk on the top shelf of a fridge rather than lower shelves so that nothing drips on to the bottle and contaminates it.	Such details would be covered through the HACCP protocol and should be included in the training for donors or staff as appropriate.
SH	United Kingdom Association for Milk Banking	74.24	57	Rec 1.2.39	What time limit – is this to be defined?	Such details would be covered through the HACCP protocol as the time limit would differ depending on the containers used for example.
SH	United Kingdom Association for Milk Banking	74.25	64	16 and ref 98	Remove Balmer and Wharton 1992 from reference number 98 – this paper does not say that 'raw milk is used when possible'.	These references have been checked and revised. Removed this reference as was cited in error.
SH	United Kingdom Association for Milk Banking	74.26	66	18	Repetition of 'based on'	Revised
SH	United Kingdom Association for Milk Banking	74.27	73	7	The issue of paying donors is not mentioned except that mothers might dilute the milk if they were paid. We urge that there be a recommendation that donors are not paid for their milk in UK as this may detract from self exclusion and/or the provision of too much milk by 'donors'.	We have added this to the Introduction and the definition of donor breast milk.
SH	United Kingdom Association for Milk Banking	74.28	78		Remove Balmer and Wharton from reference number 134 – there is no reference to the use of 'raw milk' in this paper.	This has been removed
SH	United Kingdom Association for Milk Banking	74.29	80	11-16	Does this take into account the extremely vulnerable nature of some recipients? Also '(because.....processing)' is not very clear	The GDG discussed this fully and although indications for use of donor breast milk are not within the remit of this guideline, they considered the criteria to be appropriate for all recipients.

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						However, in certain circumstances, milk banks may wish to apply stricter criteria.
SH	United Kingdom Association for Milk Banking	74.30	80	29 - 30	Confidence in the safety of the milk is extremely important both to recipient parents and milk bank staff. Whilst it is acknowledged that it is impractical to test all bottles, a once per pasteurisation testing regime does quickly identify if there is a general problem with the pasteuriser which could otherwise go unrecognised and lead to the administration of milk that is unsuitable. In turn this could lead to less confidence in donor milk.	The GDG discussed this fully – and there was a counter-argument that testing each cycle could lead to a false sense of security as not each bottle would be tested and the risk of opening bottles once pasteurised could introduce bacteria. They therefore agreed on the testing schedule recommended.
SH	United Kingdom Association for Milk Banking	74.31	81	2-7	Unclear	This has been revised to clarify.
SH	United Kingdom Association for Milk Banking	74.32	81	9-10	What is the minimum and what evidence is it based on?	This is the principle and the minimum is defined in the recommendation. The rationale for the criteria is documented in the evidence to recommendations section.
SH	United Kingdom Association for Milk Banking	74.33	81	14-16	If cost saving is not driving this recommendation, see comment 29 Preferably store milk on the top shelf of a fridge rather than lower shelves so that nothing drips on to the bottle and contaminates it or take measures to prevent containers of milk being contaminated.	Such details would be covered through the HACCP protocol and should be included in the training for staff as appropriate.
SH	United Kingdom Association for Milk Banking	74.34	81	17	Does this refer to testing under any circumstances ie even if opened in laminar flow cabinet. This is wasteful of milk.	Yes – we have recommended that any milk opened post pasteurisation should be discarded.
SH	United Kingdom Association for Milk Banking	74.35	81	20-21	See comment 14 Suggest it will be helpful to outline in greater detail the full requirements of the pasteurisation process (including the evidence if available for cooling requirements and submersion/non submersion of bottles)	We have added more detail on the cooling process, but the issue of submersion will depend on the type of human milk pasteuriser used.
SH	United Kingdom Association for Milk Banking	74.36	81	24	What would the indications be?	The GDG discussed this fully and indications for use of donor breast milk are not within the remit of this guideline; however they considered the criteria to be appropriate for all recipients. However, in certain circumstances, milk banks may wish to apply stricter criteria.
SH	United Kingdom Association for Milk Banking	74.37	81	28	'Should' but is this sufficiently rigorous.	The GDG considered it to be safe, if the recommendations on storage and handling post pasteurisation were followed.
SH	United Kingdom Association for Milk Banking	74.38	89	Rec 1.2.63	As per previous comment (17) Ensure that there is an adequate printout from the pasteuriser to show that the correct time and temperature have been reached during the pasteurisation process.	See response to previous comment
SH	United Kingdom Association for	74.39	99	Rec 1.2.74	These draft guidelines, whilst overall to be welcomed, will lead to an increase in the training requirements of staff due to the added complexity of some of the	We will feed these comments back to the Implementation Team.

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	Milk Banking				recommendations and the suggested need for local protocols in places. UKAMB recommends that the training of staff in milk banks needs to be consistent, rigorous and auditable. Attention will need to be addressed urgently to the training needs of milk banks staff and all health professionals involved in the handling and use of donor milk.	
SH	Welsh Assembly Government	75			This organisation responded and said they had no comments to make	…
SH	Western Health and Social Care Trust	77.00	5	1.1	Post pasteurisation testing ~ we have always tested every batch, this often reveals rod bearing bacillus when a donor has got slack and has switched to using a dish washer for sterilising.	We recognise that this is a change in practice – please see the Evidence to Recommendations section for the reasons for this. We also emphasise the need to control the temperature post pasteurisation as this will inhibit growth of any bacillus (which unless allowed to grow poses no risk to the recipient). Spore-bearing bacteria (which would not be destroyed by pasteurisation) should be detectable in the pre-pasteurisation samples – presence of spore-bearing bacteria would be 'unusual contamination' that should be investigated.
SH	Western Health and Social Care Trust	77.01	5	9	Should each bottle not be tested regardless of time due to social changes in a donor life style i.e. hospital to home and the added pressure of home life.	We have revised this to clarify that all milk will be tested before pasteurisation.
SH	Western Health and Social Care Trust	77.02	5	24	Home babies ~ this also brings into question staffing rota's in hospital settings i.e. temporary staff, this cannot be assured to adhere to unit policy on donor tracking as they maybe unfamiliar with this procedure.	The responsibility of the recipient hospital or unit is to train any staff handling or using donor breast milk in the processes required.
SH	Western Health and Social Care Trust	77.03	6	10	All staff should hold a valid food hygiene certificate ~ ours all have level 3 "supervising food safety in catering".	We have recommended that all staff should be trained in food handling if part of their role.
SH	Western Health and Social Care Trust	77.04	8	1.2.6	Environtmental or chemical exposure ~ such as ? and how this needs explaining/filtering (donor record sheet) N. Ireland Blood Transfusion Service could not help us with this.	We have clarified what we mean by exposure and added an example..
SH	Western Health and Social Care Trust	77.05	8	29	We should be asking about tissue transplants? ~ we have had two rejects this year with corneal transplants.	The risk related to transplants is CJD risk and ongoing medication – both of which are covered in the recommendations
SH	Western Health and Social Care Trust	77.06	9	1.2.10	What consent form? We have our own basic one but others use NHS Operation Consent Forms.	We do not specify a form, but any testing should be after getting informed consent in accordance with local protocols as for any other serological testing.
SH	Western Health and Social Care Trust	77.07	9	1.2.7	If the Donors already expressed her milk ~ she will not have been checking the freezer temperature just that her freezer is freezing well.	Have clarified that she will be asked also about the state of the milk and its storage.
SH	Western Health and Social Care Trust	77.08	9	1.2.12	Seems to contraindicate 1.2.13	The recommended testing strategy is now the same for ongoing and one-off donations.

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SH	Western Health and Social Care Trust	77.09	11	10	This is not always a viable option, due to their social standing i.e. run a breast feeding support group ~ you are in danger of losing other potential donors in that group due to negativity.	We have phrased the recommendation to allow for the milk bank to make such decisions locally.
SH	Western Health and Social Care Trust	77.10	11	15	Agree that donors should have a minimum donation of 12 – 15 bottles – before any tests are done.	The recommendations have now been changed to recommend testing at recruitment –no minimum donation before tests are done was specified either in the draft or in this final version..
SH	Western Health and Social Care Trust	77.11	15	1.2.50	Should we be temperature probing? ~ if so how should the probe be safely cleaned ~ cross contamination problems etc…	Details of how temperature should be monitored would be part of the agreed HACCP protocol in the milk bank
SH	Western Health and Social Care Trust	77.12	15	1.2.55	It throws up the occasional rod bearing bacilli	We recognise that this is a change in practice – please see the Evidence to Recommendations section for the reasons for this. We also emphasise the need to control the temperature post pasteurisation as this will inhibit growth of any bacillus (which unless allowed to grow poses no risk to the recipient).
SH	Western Health and Social Care Trust	77.13	15	8	Regardless of count ~ should all milk containing bacterial contamination not be destroyed?	We recognise that this is a less stringent acceptance level than previously recommended. The GDG did discuss this fully and the rationale is documented in the Evidence to Recommendations section.
SH	Western Health and Social Care Trust	77.14	16	3	Where does the post check pasteurising come in here? ~ before putting in the fridge or after ?	The recommendation on this has been clarified to specify the timing of the testing.
SH	Western Health and Social Care Trust	77.15	17	1.2.62	So you have pasteurised Colostrum ~ it will be used in 10 – 20 ml lots ~ can it not be opened under a laminar flow in a septic condition rather than a nursery with risk of more infection.	This guideline is relevant to the handling of donor breast milk, not maternal colostrum.
SH	Western Health and Social Care Trust	77.16	32	2.5.2.7	Ireland does not accept mothers that were in the U.K., Isle of Man or Channel Islands for one year between 1980 – 1996.	The evidence statements reflect the information from the reviewed papers.
SH	Western Health and Social Care Trust	77.17	48	8	Drip milk is also higher in coliforms	These statements reflect the evidence in the reviewed papers.
SH	Western Health and Social Care Trust	77.18	52	11	Is this still recommended as evidence has shown washing in a sterilised liquid is not as clean as fairy detergent? Also they do not mention bags within the group of containers.	The evidence statements reflect the evidence reviewed, and the GDG agreed that such practice should not be recommended in this guideline.
SH	Western Health and Social Care Trust	77.19	81	19	End donor pasteurised samples are retained for 11 years	We have revised the recommendation on archiving to refer to blood samples only.

These stakeholder organisations were approached but did not respond:

Ace Intermed Limited
Association of Catholic Nurses of England and Wales
BHF Care & Education Research Group, University of York
Birmingham Womens NHS Trust
BLISS - the premature baby charity
British National Formulary (BNF)
British Society of Paediatric Gastroenterology, Hepatology & Nutrition (BSPGHAN)
Cambridge University Hospitals NHS Foundation Trust (Addenbrookes)
Commission for Social Care Inspection
Connecting for Health
Countess of Chester Hospital NHS Foundation Trust
Department for Communities and Local Government
Department of Health, Social Security and Public Safety of Northern Ireland
Devon PCT
East Lancashire Hospitals Trust
Gloucestershire PCT
Guys and St Thomas NHS Trust
Healthcare Commission
Heart of England Acute Trust
King's College Acute Trust
Kingston Hospital NHS Trust
Lactation Consultants of Great Britain
Luton & Dunstable Hospital NHS Foundation Trust
Medicines and Healthcare Products Regulatory Agency (MHRA)
Medway NHS Trust
Mother and Infant Research Unit
National Forum of LSA Midwifery Officers (UK)
National Patient Safety Agency (NPSA)
National Perinatal Epidemiology Unit
National Public Health Service - Wales
National Treatment Agency for Substance Misuse
NHS Clinical Knowledge Summaries Service (SCHIN)
NHS Plus
NHS Purchasing & Supply Agency
NHS Quality Improvement Scotland
North Trent Neonatal Network
North West Infant Feeding Co-ordinators Group
Nottingham University Hospitals NHS Trust
Pennine Acute Hospitals NHS Trust
PERIGON Healthcare Ltd
Public Health Group North West
Queen Mary's Hospital NHS Trust (Sidcup)
Royal College of General Practitioners
Royal College of Pathologists
Royal Devon and Exeter NHS Foundation Trust
Royal Society of Medicine
SACAR
Scottish Intercollegiate Guidelines Network (SIGN)

Sheffield Children's NHS Foundation Trust
Sheffield PCT
Sheffield Teaching Hospitals NHS Foundation Trust
Social Care Institute for Excellence (SCIE)
Social Exclusion Task Force
Southampton University Hospitals NHS Trust
SPECIAL CARE BABY FUND (CHARITY)
St George's Healthcare NHS Trust
St Richards Hospital
UNICEF Baby Friendly Initiative
Welsh Scientific Advisory Committee (WSAC)
Womens Health and Reproduction Research Group at King's College London