Appendix 3 Methods of guideline development

See ‘The guidelines manual’ (2009) at www.nice.org.uk/GuidelinesManual for more information on how NICE clinical guidelines are developed.

Background

Extrapolation from other evidence

From the initial scoping work, it was clear that there were many areas where there is limited or no high-quality evidence. One solution was to extrapolate from evidence in other areas. In this case, there was a wealth of evidence related to breastfeeding that could inform the development of recommendations on donor milk. For example, on the question of transmission of HIV through milk, we searched for evidence on transmission via donor milk, and as no evidence was identified, we extrapolated from current UK guidance on breastfeeding for HIV-positive mothers.

We also referred to other relevant NICE or DH guidance, and health and safety guidance as appropriate.

Formal consensus development

Most GDGs are able to reach agreement through informal consensus. However, when combined with the need for such detailed service guidance, the lack of high-quality evidence, and the large number of potential recommendations, we considered there was a role for the use of formal consensus development.

An example of the use of formal consensus development in a NICE clinical guideline can be seen in ‘Feverish illness in children: assessment and initial management in children younger than 5 years’ (NICE clinical guideline 47) A detailed description is given in appendix A of the full guideline (http://www.nice.org.uk/nicemedia/pdf/CG47Guidance.pdf).

Methods of formal consensus development

Usually, where good evidence exists, a GDG can reach consensus through informal methods; however, formal consensus methods are increasingly being used to develop clinical guidelines. (Murphy et al. 1998)

Formal consensus methods are those in which the structure, process and output are explicit from the outset. Three main approaches have been used in the health field

- the Delphi method
- the nominal group technique (NGT)
- the consensus development conference (Murphy et al. 1998).

A modified version of the Delphi method – the RAND method – is often used in guideline development. This involves several stages including the mailing of questionnaires, elicitation of private decisions, formal feedback of group choices, face-to-face contact, structured interaction, and an explicit aggregation method. (Murphy et al. 1998)

Cues and clinical scenarios

In the RAND process, cues are defined as 'factors which influence clinical decision making', and these are used as dimensions (or indications) that group members are asked to take into account when making their decisions. (Murphy et al. 1998; Raine et al. 2005) Cues are used to develop and refine clinical scenarios which are then rated by the group. This guideline does not lend itself easily to the development of cues (because interventions for a specific condition or indications for using an intervention are not within the remit). Even if it were possible to define cues for one topic area, these would not be relevant for other topics. Therefore, we considered that if the aim of the cues is to systematically describe all the possibilities that may occur, we could explore the 'extremes' and range of possible options through the ratings of recommendations which reflect these. The recommendations and their ratings can be seen below.

Choosing and preparing the scientific evidence

A review of identified evidence was provided to the GDG members at least one week before the meeting. The evidence reports were presented in tables, summarising the included studies, with quotes where appropriate. Evidence statements summarising the body of evidence were also provided to the GDG before the meetings.

At the meetings, the GDG were asked to discuss the evidence and to agree the evidence statements, with any revisions as agreed.

Rating the recommendations

The GDG were asked to rate the draft recommendations on the scale below. We did not ask the GDG to rate these via a postal questionnaire, but did this at the meeting, keeping individual responses anonymous.

1	2	3	4	5	6	7	8	9	Don't know
Strongly disagree		Somewhat disagree		Uncertain		Somewhat agree		Strongly agree	

The rating was repeated for a second round. It should be noted however, that although two or more rating rounds are likely to result in some convergence of individual judgments, it is unclear whether this increases the accuracy of the group decision. (Murphy et al. 1998)

Structuring the interaction

After the initial rating (round 1) results, both individual and summary results were revealed to the GDG and a discussion held about each recommendation that did not achieve consensus. This discussion was facilitated by the Chair as would other GDG discussions, adopting the ground rules specified in chapter 3 of 'The guidelines manual' (2009) (section 3.1, box 3.2).

Synthesising individual judgements

We adopted an explicit definition of ‘agreement’ based on the median of the ratings to determine the decision, with a measure of strength of consensus. The more demanding this measure of strength of agreement, the more anodyne the results will be; either no statements will qualify or those that do will be of little interest (Murphy et al. 1998).

The GDG decision on a recommendation was:

- AGREE where the median >6
- DO NOT AGREE where the median <4
- NOT SURE where the median 4–6.

The measure of consensus stated that there was a group consensus if at least 75% of the responses lay in any one range, and there was group uncertainty if this range lay in the 4–6 response. So if 75% of GDG responses:

- lay in 1–3 then DO NOT AGREE
- lay in 7–9 then AGREE
- otherwise, NOT SURE.

This is the same method as applied in the NICE clinical guideline on feverish illness. However, we also calculated a measure of consensus as described in the RAND manual.(Brook 1994) This measure, ‘D9R’ considers all ratings and if at least one rating falls in the 1–3 (do not agree) range and at least one falls in the 7–9 range (agree), then there is considered to be a lack of consensus.

We planned to discuss any recommendation that did not achieve consensus based on either criteria. In practice, the GDG tended to discuss all recommendations regardless of consensus. If a recommendation did not achieve consensus (on either measure), members who had rated against the majority were asked if they wanted to explain why they had done so, and a full discussion of the recommendation then ensued, with revisions made to the wording as agreed. If the recommendation did achieve consensus, GDG

members often still discussed it, and made minor revisions to the recommendation.

All recommendations, rating results and a summary of the discussions can be seen below.

Summary of process

- Informal consensus methods to agree evidence statements
- Formal consensus methods to develop recommendations.
  GDG members:
  - rated the recommendations privately
  - returned responses for analysis and pooling
  - received the pooled results, individual ratings and their position compared with others (at all points, individual results were kept confidential unless identified by the person themselves)
  - discussed all recommendations, with a focus on those for which group consensus was not achieved
  - re-rated recommendations
  - made minor revisions to recommendations, with a focus on those for which group consensus was not achieved.

References

Brook RH (1994) The RAND/UCLA appropriateness method. In: McCormick KA, Moore SR, Siegel RA, editors. *Clinical practice guidelines development: methodology perspectives.* Rockville, MD: US Department of Health and Human Services, p

Murphy MK, Black NA, Lamping DL et al. (1998) Consensus development methods, and their use in clinical guideline development. Health Technol.Assess. 2: i-88.

Raine R, Sanderson C, Black N (2005) Developing clinical guidelines: a challenge to current methods. BMJ 331: 631-3.

Recommendations and the ratings

Round 1 – donor recruitment

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	GDG considerations	Recommendation for Round 2
R1a	Recruit donor women from any of the following groups: • mothers early in lactation (usually 'drip milk')	3	5	3	0	0	Do not agree	No consensus	Consensus	There was some discussion about the timing of recruitment. This may include the early recruitment of women who have lost their babies. The mother's preference should be respected. The discussion included whether this was about selection or recruitment. It was agreed that the issue was about when women should be approached about donating milk, so the word 'donor' was revised to 'potential donor' throughout. The general agreement was to recommend a broad recruitment strategy, but with some specific groups named, such as bereaved mothers (see recommendations below). See R2 which covers all these groups.	…
R1b	• mothers whose lactation is well-established	9	0	0	8	0	Agree	Consensus	Consensus	See R2 which covers all these groups.	…
R1c	• mothers whose infant has died.	8.5	0	0	8	0	Agree	Consensus	Consensus	See R2 which covers all these groups.	…
R2	Recruit donor women from any mother who has surplus breast milk.	9	0	1	7	0	Agree	Consensus	Consensus	There has been a minor word change to reflect recruitment, rather than selection.	Recruit potential donor women from any mother who has surplus breast milk.

R3	Do not use surplus milk from mothers who have expressed milk for their own babies in the NICU.	1.5	8	0	0	0	Do not agree	Consensus	Consensus	It was agreed that the revised recommendation should be a positive one on the use of surplus milk.	Use surplus milk from mothers who have expressed milk for their own babies in the NICU.
R4	Consider using surplus milk from mothers who have expressed milk for their own babies in the NICU only if milk from other donors is not sufficient to meet demand.	2	7	1	0	0	Do not agree	Consensus	Consensus	See recommendation R3.	…
R5	Do not actively recruit donor women.	1	7	1	0	0	Do not agree	Consensus	Consensus	Revised recommendation to be positive recommendation on active recruitment.	Actively recruit donor women.
R6a	Recruit potential donors through a variety of channels.This can include • providing written information packs to be left in o doctors' offices	8.5	0	0	8	0	Agree	Consensus	Consensus	There was general discussion about the variety of methods that could be used to recruit potential donors. The approach of each milk bank will depend on local circumstances, including level of funding and need to recruit. General recommendations were therefore agreed, with a broad strategy overall. It was decided that minor revisions made to wording should be less specific about the details of how the information should be provided (e.g. the removal of packs in R6a-d).	Recruit potential donors through a variety of channels.This can include • providing written information to be left in o doctors' offices o hospitals (sometimes provided to mothers in the perinatal period) o volunteer or health-related organisations working in public health o infant, children and maternity shops
R6b	• providing written information packs to be left in o hospitals (sometimes provided to mothers in the perinatal period)	9	0	0	8	0	Agree	Consensus	Consensus	Merged with R6a	…
R6c	• providing written information packs to be left in o volunteer or health-related organisations working in public health	8.5	0	1	7	0	Agree	Consensus	Consensus	Merged with R6a	…

R6d	• providing written information packs to be left in o infant, children and maternity shops	8	0	3	4	1	Agree	No consensus	Consensus	Merged with R6a	…
R6e	• or through direct referrals or recommendation from o donor women	9	0	0	8	0	Agree	Consensus	Consensus		• or through direct referrals or recommendation from o donor women o staff at the NICUs o attending paediatricians when assessing the progress of the infant o health visitors (or other healthcare professionals providing post-partum care) o childbirth educators o organizers and attenders of pre- or post-natal classes o nursing mothers' groups o breast feeding support or related organisations
R6f	• or through direct referrals or recommendation from o staff at the NICUs	9	0	0	8	0	Agree	Consensus	Consensus	Merged with R6e.	…
R6g	• or through direct referrals or recommendation from o attending paediatricians when assessing the progress of the infant	9	0	0	7	1	Agree	Consensus	Consensus	Merged with R6e.	…

R6h	• or through direct referrals or recommendation from o health visitors (or other healthcare professionals providing post-partum care)	8.5	0	0	8	0	Agree	Consensus	Consensus	Merged with R6e.	…
R6i	• or through direct referrals or recommendation from o childbirth educators	8.5	0	0	8	0	Agree	Consensus	Consensus	Merged with R6e.	…
R6j	• or through direct referrals or recommendation from o organizers and attenders of pre- or post-natal classes	9	0	0	8	0	Agree	Consensus	Consensus	Merged with R6e.	…
R6k	• or through direct referrals or recommendation from o nursing mothers' groups	9	0	0	8	0	Agree	Consensus	Consensus	Merged with R6e.	…
R6l	• or through direct referrals or recommendation from o organisations, such as the La Leche League, or the National Childbirth Trust	9	0	0	8	0	Agree	Consensus	Consensus	The recommendation was made more general, with the removal of specific organisations (in line with NICE policy on recommendations). It was noted, however, that the 'Understanding NICE Guidance' would include some named organisations. Merged with R6d.	…

R6m	• or through mass media contact, such as o newspaper	8	1	0	6	1	Agree	Consensus	No consensus	The recommendation was revised to reflect that it refers to publicity for the donor milk bank and its work – it is not a paid advertisement. There was agreement that any mass publicity or advertising would need to be balanced with increased workload, and that it should be focused to try to limit interest. There was also a question about whether donors recruited in this way would be as informed as others. Overall, donor breast milk is a public health issue, and so it does need to be in the public domain. Anecdotally, such publicity may work better at local rather than national level, and there are good reports from experience in local areas. All strategies were deemed to be appropriate, depending on local circumstances. And as with any strategy, the confidentiality and wishes of any potential donor or donor would need to be respected.	• or through mass media contact, such as o newspaper articles o newletters o magazine articles o TV and radio o internet
R6n	• or through mass media contact, such as o newsletters	9	0	1	6	1	Agree	Consensus	Consensus	Merged with R6m.	…
R6o	• or through mass media contact, such as o magazine articles	8	0	1	6	1	Agree	Consensus	Consensus	Merged with R6m.	…

R6p	• or through mass media contact, such as o TV	8	1	1	6	0	Agree	Consensus	No consensus	Merged with R6q Again this refers to publicity for the donor milk bank and its work – it is not a paid advertisement. Merged with R6m.	…
R6q	• or through mass media contact, such as o radio	8	1	1	6	0	Agree	Consensus	No consensus	Although the evidence did not refer to the use of the internet (owing to the age of the publications), this was agreed to be a valuable area for recruitment and general publicity. Merged with R6m.	…
R7a	Provide other services to encourage donor women • such as breastfeeding support	8	1	2	5	0	Agree	No consensus	No consensus	There was agreement that support and other services could be given as needed, but that this was not the key role of the milk bank. Also, donors should not be given access to services that would not otherwise be available to them, because this would breach all principles of donation. Recommendations will be made on the ongoing support needed by donor women, but not the provision of additional services to 'encourage' donors. It was decided to remove this recommendation because of the principle of donation.	…
R7b	• other relevant services	6	1	3	3	1	Uncertain	No consensus	No consensus	See above.	…
R8	When recruiting donor women, aim to reach all women through a broad strategy with no targeting.	7	2	2	4	0	Agree	No consensus	No consensus	The wording was revised to make a general statement on the need for a broad strategy See also R1a.	When recruiting potential donor women, aim to reach all women, including mothers whose baby has died, through a broad strategy.

R9a	Target women who • do not work in the health or social sectors	5	2	4	2	0	Uncertain	No consensus	No consensus	In the situation where there are limited resources, is there a principle that one needs to focus on those groups where recruitment is likely to more successful? Often, there is a perception about a 'type' of donor, but there are many exceptions. So a broad approach should be used, within resources. The provision of clear, accurate information then allows women to select themselves. There was agreement that all lactating women have a right to be considered as potential donors, and therefore any strategy should be broad and not target specific groups based on attitudes or beliefs. See R8.	…
R9b	Target women who • have a positive attitude to breastfeeding	8	1	0	7	0	Agree	Consensus	No consensus	See above.	…
R9c	Target women who • express the 'need to help others'	7.5	1	0	7	0	Agree	Consensus	No consensus	See above.	…
R9d	Target women who • have support and time to donate milk.	8	1	1	6	0	Agree	Consensus	No consensus	See above.	…
R10a	Communicate the need for donor milk banking, and the process in clear, non-technical language, • using either written or verbal communication.	9	0	0	8	0	Agree	Consensus	Consensus	The GDG agreed some revised wording.	Communicate the need for donor milk banking, and the process in clear, non-technical language, using either written and/or verbal communication.
R10b	• using written information alone.	3.5	4	1	3	0	Uncertain	No consensus	No consensus	See above.	…

R10c	• using verbal communication alone.	3.5	4	2	2	0	Uncertain	No consensus	No consensus	See above.	…
R11	Do not elicit the beliefs and attitudes of the potential donor in any discussion of donor milk banking.	2	4	2	1	1	Do not agree	No consensus	No consensus	Although there may be different cultural beliefs and attitudes to donor-milk banking, there was general agreement that, by using a broad strategy with clear information, any women, regardless of religion, socioeconomic class etc., would have access to information and could decide, with support from milk-bank staff if needed, whether she wished to be considered as a potential donor.	…

Round 1 – donor screening and selection

Due to the complexity, the level of technical detail, and the importance of this area, the GDG requested that each recommendation be discussed in full regardless of the consensus ratings.

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	Corrections made to ratings post meeting	GDG considerations	Recommendation for Round 2

SS1	Follow an agreed screening process when selecting donors. This should be based on a balanced consideration of relative risk for the infant and aim to minimise bacterial contamination. •	8	1	1	5	1	Agree	No consensus	No consensus		The GDG noted that health economic considerations are very relevant to the screening and selection process. There is also a need to consider the National Blood and Transplant recommendations and practice in this area. It was also noted that the aim of screening and selection is not simply to minimise contamination. Agreed wording of revised recommendation. Overall, the recommendations were revised to reflect • Which ones would make a donor be refused? • Which would result in delay? • Which would not be picked up in a history? • Which ones are screened for by questioning and then followed up by testing? • Which can be self-excluded for? It is also important to recognise that most infections can be ruled out at the initial blood test, but seroconversion may result in a false negative. Any information requested should be used when making the decision to accept a donor, and should not be collected without clear justification and use.	Follow an agreed screening process when selecting donors. This should be based on a balanced consideration of relative risk for the infant.

SS2	Do not screen potential donors.	1	8	0	0	0	Do not agree	Consensus	Consensus		See above.	…
SS3a	Collect information from prospective donors on: • their general health and medical history (including acute or chronic infections, recent vaccinations, blood transfusions)	9	0	0	8	0	Agree	Consensus	Consensus		All of the following recommendations need to be clear about the difference between the risk of and the exposure to the various infectious diseases. Where appropriate, this was revised as agreed. There was agreement that there should be balance between asking specific questions with providing information to women on screening and selection (allowing them to self-screen) and then the taking of a comprehensive medical history by a trained person.	Collect information from prospective donors on: • their general health and medical history (including acute or chronic infections, recent vaccinations, blood transfusions)
SS3b	• the age, health, and nutritional status of their baby	9	0	0	7	1	Agree	Consensus	Consensus			• the age, health, and nutritional status of their baby
SS3c	• diet history and nutritional intake	7	0	2	6	0	Agree	No consensus	Consensus	**Corrected is A-CON-CON		• diet history and nutritional intake
SS3d	• any exposure to HIV	9	0	1	7	0	Agree	Consensus	Consensus		Revised to clarify risk of exposure.	• the risk of exposure to HIV
SS3e	• any exposure to toxoplasmosis	9	1	2	5	0	Agree	No consensus	No consensus		Most people are exposed to toxoplasmosis often without their knowledge, so to use this as a screening question is neither sensitive or specific. Although there is clear evidence that toxoplasmosis is a risk to the fetus during pregnancy, there is no evidence on the risk of toxoplasmosis for babies. Agreed to remove.	….

SS3f	• any exposure to tuberculosis	9	1	1	6	0	Agree	No consensus	No consensus	**Corrected is A-CON-NoCON	The GDG discussed the role of the milk bank in identifying communicable diseases such as TB. Specifically, most TB is acquired in childhood (in the UK) which then leads then to clinically silent disease. When pulmonary TB presents, the risk of transmission is primarily through coughing. If a donor has clinically silent TB then her milk may be infected, but pasteurisation would destroy this. Symptomatic TB should be identified through the existing public health systems. Agreed to remove.	…
SS3g	• any exposure to syphilis	9	0	2	6	0	Agree	No consensus	Consensus	**Corrected is A-CON-CON	Revised to clarify risk of exposure.	• the risk of exposure to syphilis
SS3h	• any exposure to hepatitis	9	0	1	7	0	Agree	Consensus	Consensus		Revised to clarify risk of exposure.	• the risk of exposure to hepatitis

SS3i	• any exposure to rubella	6.5	1	3	4	0	Agree	No consensus	No consensus		Rubella is one of many viral infections, and it is not clear why screening and selection would specify rubella alone. If a mother was infected with rubella, this would not be a reason to refuse her as a donor, but would just delay any donations until she was clear of infection. The GDG agreed therefore that this would be covered in a general recommendation to screen for any exposure to infection and a detailed history – see revised recommendation and SS3a above on current infection.	• any recent exposure to infectious diseases
SS3j	• any exposure to herpes	8	0	3	5	0	Agree	No consensus	Consensus			• any exposure to herpes
SS3k	• any exposure to CMV	6	3	1	3	1	Uncertain	No consensus	No consensus		Most people will not know they have been exposed to CMV so not a useful screening question. Also proper treatment of any infected milk will destroy CMV. Agreed to remove..	…
SS3l	• any exposure to CJD	8	0	3	5	0	Agree	No consensus	Consensus		The GDG agreed to refer to DH guidance on the risk of CJD and the advice that if the woman is identified as being at increased risk of CJD, she should not donate breast milk.	• any public health risk of CJD (**TO ADD cross reference to DH guidance)
SS3m	• medication use	9	0	0	8	0	Agree	Consensus	Consensus			• medication use
SS3n	• any medical treatment (other than medication use)	8.5	0	2	6	0	Agree	No consensus	Consensus	**Corrected is A-CON-CON		• any medical treatment (other than medication use)

SS3o	• any exposure to pollutants	5	2	5	1	0	Uncertain	No consensus	No consensus		The GDG were not clear which pollutants would be screened for. Also, this was not considered to be highly relevant to the UK, as there are clear standards of health and safety that are adhered to. Where there may be specific situations (for example, water contamination, or chemical fires) these will covered by the environmental health/public health laboratory response and information from these and the Health Protection Agency as appropriate should be sought. However, it was noted that such instances are rare, but that milk banks should know of processes to follow in the event of such exposure.	**TO ADD rec on communication in the event of chemical exposure?
SS3p	• any occupational exposure to chemicals	7	0	2	5	1	Agree	No consensus	Consensus		The GDG did not consider this to be highly relevant to the UK, as there are clear standards of health and safety that are adhered to and any woman who works with chemicals harmful during pregnancy should receive a full risk assessment through occupational health services. Agreed to remove.	…
SS3q	• the presence of diarrhoea	6.5	1	3	4	0	Agree	No consensus	No consensus		This would be identified through a comprehensive history as recommended in SS3a above.	…

SS3r	• symptoms of other recurrent infections	8.5	1	1	6	0	Agree	No consensus	No consensus	**Corrected is A-CON-NoCON	This would be identified through a comprehensive history as recommended in SS3a above.	…
SS3s	• alcohol intake	9	0	0	8	0	Agree	Consensus	Consensus		…	• alcohol intake
SS3t	• smoking	9	0	0	8	0	Agree	Consensus	Consensus		…	• smoking
SS3u	• 'recreational' drug use	9	0	0	8	0	Agree	Consensus	Consensus		…	• 'recreational' drug use
SS4	If donations of previously expressed breast milk are to be accepted, do not screen donors.	1	7	0	0	1	Do not agree	Consensus	Consensus		…	…
SS5	If donations of previously expressed breast milk are to be accepted, screen donors as usual; questions relating to the use of prescription medication, smoking and alcohol consumption etc. should be answered retrospectively.	9	1	0	7	0	Agree	Consensus	No consensus		…	If donations of previously expressed breast milk are to be accepted, screen donors as usual; questions relating to the use of prescription medication, smoking and alcohol consumption etc. should be answered retrospectively.
SS6a	Use the following tests or investigations for screening or selecting prospective milk donors: • general physical examination	3	4	1	2	1	Do not agree	No consensus	No consensus		The GDG were not clear as to the purpose of a physical examination and did not consider it a useful addition to a comprehensive medical history and appropriate testing. Agreed to remove.	…
SS6b	• chest radiograph, PPD, or tine test (for tuberculosis)	3	6	1	0	1	Do not agree	Consensus	Consensus		See SS3f on TB screening.	…
SS6c	• HTLV-III and HIV antibody test (for HIV)	9	0	1	6	1	Agree	No consensus	Consensus	**Corrected is A-CON-CON	Revised to reflect out-dated use of HTLV. Also current tests.	• HIV 1 & 2 antigen/antibody test

SS6d	• HBsAg and anti-HBc blood test (for hepatitis)	9	1	2	4	1	Agree	No consensus	No consensus		Revised to reflect current testing processes for hepatitis. If adequate treatment processes are followed, the pasteurisation of milk will destroy any infection, so only need to test for surface antigen. However, the GDG agreed to test as for other human products, such as blood, to minimise any risk from hepatitis. Although rates of hepatitis C are low in the UK, higher rates are seen in other countries and/or ethnic groups. However, even if the donor has hepatitis C, she is unlikely to excrete this in her milk and therefore testing for this may not be cost effective because adequate treatment can destroy the infection. However, recent data suggests that treatment of milk may not be as effective as thought (see recommendations on treatment) and concerns over hepatitis transmission are often cited as reasons for not using donor milk.	• HBsAg and anti-HBc blood test , anti hep c antibodies (for hepatitis)
SS6e	• VDRL (for sexually transmitted diseases, specifically syphilis))	9	0	1	6	1	Agree	No consensus	Consensus	**Corrected is A-CON-CON	Revised to reflect current testing processes for sexually transmitted diseases.	• a test for anti-treponemal antibodies (for sexually transmitted diseases, specifically syphilis)

SS7	Test for those conditions to be screened and results communicated according to local protocols.	6	1	3	3	1	Uncertain	No consensus	No consensus		There was general agreement that this guideline should make specific recommendations on how testing should be undertaken and results communicated, whilst recognising both national best practice for human donated products and local practice. See recommendations below on the process of testing.	…
SS8	All tests should be performed at the time of enrolling for donor milk banking.	7.5	0	3	5	0	Agree	No consensus	Consensus		The timing of testing also depends on the nature of the donation – for example, some donations are one-off donations and as such testing at the time of donation may not reflect the health state at the time of donation. Recommendation therefore on the need to test at 3 months, allowing time for the appropriate testing and treatment of the milk and any seroconversion of the donor.	All tests should be performed at the time of enrolling for donor milk banking, even where results from antenatal tests are available. Delay testing for 3months if a donor provides a one off donation.
SS9	Do not repeat tests routinely undertaken during antenatal and perinatal assessment unless the history indicates possible infection or exposure after the initial tests have been done.	1	5	0	2	1	Do not agree	No consensus	No consensus		See SS10.	…
SS10	Do not repeat any tests routinely undertaken during antenatal and perinatal assessment.	1	6	0	1	1	Do not agree	Consensus	No consensus		There was general agreement that results from antenatal tests should not be used and this was added to SS8 above.	…

SS11	Do not test for any other condition or infections, even if clinically suspicious.	3	5	2	0	1	Do not agree	No consensus	Consensus		The GDG agreed that the role of the milk bank is not to provide general healthcare to women, so should not be requesting any tests other than those recommended above specific to the donation of milk.	…
SS12a	Consider other tests as appropriate, based on some or all of the following: • the use of effective treatment processes to eliminate the specific contamination	7	1	2	4	1	Agree	No consensus	No consensus		There was general agreement that this guideline should make specific recommendations on how testing should be undertaken and results communicated, whilst recognising both national best practice for human donated products and local practice. See recommendations above on the process of testing.	…
SS12b	• local testing/screening protocols during the antenatal period	4	3	2	2	1	Uncertain	No consensus	No consensus		As above.	…
SS12c	• regional or local prevalence; where appropriate, consider screening only in donors from high risk groups	2	6	1	1	0	Do not agree	Consensus	No consensus		As above.	…
SS12d	• other national screening recommendations.	9	0	0	7	1	Agree	Consensus	Consensus		As above.	…
SS13	Testing is mandatory, and as such no explanation or consent from the donor is required.	2.5	7	1	0	0	Do not agree	Consensus	Consensus		See SS14.	…

SS14	Explain the reasons for testing to every mother when she first contacts the milk bank about donating milk (to minimise risks to the recipient baby) and seek informed consent before testing.	9	0	0	8	0	Agree	Consensus	Consensus		The mandatory nature of testing is important, and has been added to this recommendation as agreed in the GDG.	Testing is mandatory. Explain the reasons for testing to every mother when she first contacts the milk bank about donating milk (to minimise risks to the recipient baby) and seek informed consent before testing.
SS15	Communicate the results of all tests.	9	0	1	7	0	Agree	Consensus	Consensus		Merged with the mode of communication below – see SS17a.	…
SS16	Communicate the results of any positive tests.	9	1	0	7	0	Agree	Consensus	No consensus		See SS16.	
SS17a	Communicate the results of tests • in person at a follow-up appointment. Where appropriate, offer counselling and/or information on local support groups.	6	2	2	4	0	Uncertain	No consensus	No consensus		There was general agreement that the communication of all test results needs to be both woman focused and in accordance with local protocols. Recommendations therefore reflect the need to balance the preference of the woman and adherence to local testing protocols.	Communicate all results of tests verbally, either in person at a follow-up appointment or via a telephone call, or in writing depending on the preference of the woman and in accordance with local protocols. Where appropriate and in accordance with local protocols, offer counselling and/or information on local support groups.
SS17b	Communicate the results of tests • verbally, through a telephone call. Where appropriate, offer counselling and/or information on local support groups.	4	4	2	2	0	Uncertain	No consensus	No consensus		See SS17a.	…

SS17c	Communicate the results of tests • verbally, either in person at a follow-up appointment or via a telephone call depending on the preference of the woman. Where appropriate, offer counselling and/or information on local support groups.	6	2	2	4	0	Uncertain	No consensus	No consensus		See SS17a.	…
SS17d	Communicate the results of any tests • in writing. Where appropriate, offer counselling and/or information on local support groups.	5	2	3	3	0	Uncertain	No consensus	No consensus		See SS17a.	…
SS18	Inform women who are positive for HIV infection that they are able to donate breast milk.	1	7	1	0	0	Do not agree	Consensus	Consensus		Revised for clarification.	Inform women who are positive for HIV infection that they are unable to donate breast milk.
SS19	Inform women who have received live rubella vaccination that they should never donate breast milk.	1	7	1	0	0	Do not agree	Consensus	Consensus		The GDG agreed to cross refer to the DH guidance on vaccination, and have revised the recommendation appropriately. Current guidance is that breastfeeding is not a contraindication to" routine immunisation" and that where additional precautions are required – "refer to the relevant chapter for further information":	Refer to guidance from the DH on the safety of recent vaccination in breastfeeding for women who are potential donors (**TO ADD cross reference to Green Book)
SS20	Inform women who have received live rubella vaccination not to donate breast milk near the time of their vaccination.	7	1	1	5	1	Agree	No consensus	No consensus		See also SS20.	Inform women who have received live vaccinations not to donate breast milk in the month prior of their vaccination.

SS21a	All tests should be undertaken, • if possible, at the woman's home.	3	5	2	1	0	Do not agree	No consensus	No consensus		The GDG agreed that it was not appropriate to make recommendations on where testing should be undertaken.	…
SS21b	• where possible, in the setting preferred by the potential donor.	7.5	1	0	7	0	Agree	Consensus	No consensus		See above.	…
SS22	Do not repeat any tests whilst the woman continues to donate milk.	1.5	6	2	0	0	Do not agree	Consensus	Consensus		The GDG acknowledged that repeated testing would increase safety. Some services retest at 3 months and then release the frozen 3 months-old milk. A balance between testing (for example, many donors may need to be tested to identify one case of infection) and treatment (even if the donor and her milk are infected, proper treatment will destroy the infection in the milk) needs to be achieved. Logistically the storage of milk for 3 months would increase costs but also risk of mistaken administering of milk. **TO ADD HE when considered Revised to ensure that no seroconversion has occurred.	Do not repeat any tests whilst the woman continues to donate milk. When donation stops repeat tests 3 months after stopping.
SS23	Repeat tests if women continue to donate for more than 3 months from the date of the initial blood test.	5	1	5	2	0	Uncertain	No consensus	No consensus		See SS22.	…
SS24	Repeat tests if women continue to donate for more than 6 months from the date of the initial blood test.	5	1	5	2	0	Uncertain	No consensus	No consensus		See SS22.	…

SS25a	Collect information for screening using the most up-to-date source. This may include • from healthcare records including o routine health data from different healthcare professionals, such primary care providers and paediatricians	5	2	5	1	0	Uncertain	No consensus	No consensus		The GDG considered that any recommendation on healthcare records was not appropriate.	…
SS25b	• from healthcare records including o information from visits to healthcare professionals, such as gynaecologists and paediatricians, arranged by the milk bank if appropriate	5	2	5	1	0	Uncertain	No consensus	No consensus		See above.	…
SS25c	• from the donor o by questionnaire	8	1	1	6	0	Agree	No consensus	No consensus	**Corrected is A-CON-NoCON	Revised as agreed.	Collect information for screening using the most up-to-date source. This may include • from the donor • by interview
SS25d	• from the donor o by interview	8.5	0	1	7	0	Agree	Consensus	Consensus		See above.	…
SS26a	If possible, the questionnaire and/or interview should be conducted • in the potential donor's home.	6	2	3	3	0	Uncertain	No consensus	No consensus		Again, the preference of the woman should be considered if possible.	If possible, the questionnaire and/or interview should be conducted at a place suitable to both parties.
SS26b	• at the milk bank.	6	1	4	3	0	Uncertain	No consensus	No consensus		See above.	…

SS27a	All questionnaires and/or interviews should be conducted • in the potential donor's home.	3	5	2	1	0	Do not agree	No consensus	No consensus	**Mistyped one response - no effect on result. Corrected in spreadsheet	See SS26a.	…
SS27b	• at the milk bank.	3	5	2	1	0	Do not agree	No consensus	No consensus	**Mistyped one response - no effect on result. Corrected in spreadsheet	See SS26a.	…
SS28	No one approach will cover all information necessary and a variety of approaches is recommended. Where possible, information should be confirmed by other sources or additional history taking and/or testing.	6.5	3	1	4	0	Agree	No consensus	No consensus		The GDG did not consider this recommendation to be specific or helpful, so it was removed.	…
SS29	If information is not available, just leave blank.	2.5	6	2	0	0	Do not agree	Consensus	Consensus		The GDG did not consider this recommendation to be specific or helpful, so it was removed.	…

Round 1 – donor training and support

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	GDG considerations	Recommendation for Round 2
TS1a	Train donors in the proper techniques for • milk collection and expression, including the use of pumps and containers and their cleaning	9	0	0	9	0	Agree	Consensus	Consensus	Agreed no changes needed.	Train donors in the proper techniques for • milk collection and expression, including the use of pumps and containers and their cleaning
TS1b	• milk storage, including the cooling and freezing of milk	9	0	0	9	0	Agree	Consensus	Consensus	Agreed no changes needed	• milk storage, including the cooling and freezing of milk
TS1c	• personal hygiene, including cleaning of the hands and breasts	9	0	0	9	0	Agree	Consensus	Consensus	Agreed no changes needed	• personal hygiene, including cleaning of the hands and breasts
TS1d	• administration of milk donations, such as the labeling of stored samples.	9	0	0	9	0	Agree	Consensus	Consensus	Agreed no changes needed	• administration of milk donations, such as the labeling of stored samples.
TS2a	Provide information to donor women on intake of • diet	8	1	1	6	1	Agree	No consensus	No consensus	The wording was revised to clarify that this is about information on continued exclusions – for example, when a woman may be following a strict vegan diet without supplements. This is more about general advice on dietary intake for breastfeeding, not a dietary recommendation.	Provide information to donor women on • diet
TS2b	• alcohol	9	0	0	9	0	Agree	Consensus	Consensus	Revised wording for clarity.	• alcohol consumption
TS2c	• caffeine	9	0	0	9	0	Agree	Consensus	Consensus	Revised wording for clarity.	• caffeine consumption

TS3a	Provide training through • written information alone	3	8	1	0	0	Do not agree	Consensus	Consensus	Any strict recommendation on either verbal or written information may give rise to practical problems, in terms of provision of information. The wording was revised to allow flexibility and to meet the needs of the donor.	Provide training verbally, which may be face-to-face or over the telephone, with appropriate supplementary information to be given to the donor.
TS3b	• face-to-face, with supplementary written information	8	0	0	9	0	Agree	Consensus	Consensus	See TS3a.	…
TS3c	• face-to-face alone	3	5	4	0	0	Do not agree	No consensus	Consensus	See TS3a.	…
TS4a	Provide training • on discharge from hospital	5	3	3	3	0	Uncertain	No consensus	No consensus	By specifying the timing of training, this would result in it being suitable for some donors, but not for all. Also the ideal timing and setting would be at a time/place of mother's preference, but this may not always be possible. The GDG revised the wording to reflect these concerns.	Provide training at a time and place suitable for both parties.
TS4b	• at a time and place suitable for the donor	7	0	2	7	0	Agree	Consensus	Consensus	See TS4a.	…
TS4c	• after milk samples are accepted	3	8	1	0	0	Do not agree	Consensus	Consensus	See TS4a.	…
TS5	Provide ongoing support to all donor women,	8	0	1	8	0	Agree	Consensus	Consensus	There was general agreement that support should be provided to all women with the option to opt-out when no longer needed.	Provide ongoing support to all donor women until no longer required.
TS6	Only provide ongoing support to donor women who have specifically requested it.	3	5	3	1	0	Do not agree	No consensus	No consensus	See TS5.	…
TS7a	Support should include • continued support for the collection and milk and the maintenance of lactation	8	0	1	8	0	Agree	Consensus	Consensus	There was much discussion about the exact definition of support because little, if any, detail was reported in the included studies. In practice, support can range from a simple thank-you through to full support for the woman in whichever way she needs. The wording was revised to reflect this.	Support may include • continued support for the collection of milk and the maintenance of lactation • emotional support.

TS7b	• psychological support.	7	2	2	5	0	Agree	No consensus	No consensus	As above, it was not clear exactly what was meant by psychological support. The role of the milk bank is primarily about support for continued donation, not breastfeeding alone, although obviously there may be a significant overlap. Also, there may be very specific support needs – for example, if a woman who has lost her baby wishes to continue to express, support should be available to support her decision. The term 'emotional support' may be better as psychological support may not always be needed. Merged with TS7a above.	…
TS8a	Provide contact and feedback • only to those donors who request it	3	6	3	0	0	Do not agree	No consensus	Consensus	As with support, there was much discussion on the definition of contact and feedback. Although the evidence reported one milk bank that did feed back quality and quantity to each donor, the GDG did not consider that this was enough to recommend it in this guideline. There was also the possibility of such feedback having negative impact, both on the donor (e.g. if she feels under pressure) and on the milk bank (in terms of time). The GDG considered that contact and feedback was about thanking the donor, feeding back any problems with the milk, and periodic enquiry about progress – but that any contact and feedback should be tailored to the individual donor's needs.	Provide ongoing, individualised contact and feedback to all donors
TS8b	• to all donors	8	0	1	8	0	Agree	Consensus	Consensus	See TS8a.	…
TS8c	• after each collection	5	4	4	1	0	Uncertain	No consensus	No consensus	See TS8a.	…

TS9a	Contact and feedback should include • amount of milk collected	5	1	5	2	1	Uncertain	No consensus	No consensus	See TS8a. Such feedback may discourage small donations. Current practice differs: • Some milk banks provide a certificate for the period of donation. • Some donors may enquire on an individual basis. • Some donors may not be interested in the amount donated. • Some donors track their own amounts. The GDG agreed that the most important point was that a milk bank knows the amount and quality of the milk donated, not necessarily the mother unless requested.	…
TS9b	• quality of milk collected	6	1	4	4	0	Uncertain	No consensus	No consensus	See TS8a. Where there are implications for a mother's own baby, the GDG agreed that the issue of quality would need to be fed back to the mother; however, it would need to be based on clear guidelines and evidence. Other than in such specific cases, it may not be helpful to feed back routinely – it would depend on what is meant by quality.	…

TS10a	When collecting milk samples from the donor's home, • make a formal assessment of any changes in the home environment that may require additional support or intervention from the milk bank staff.	4	4	3	2	0	Uncertain	No consensus	No consensus	Although one milk bank reported assessment of this kind as part of their practice, the GDG considered it to be unnecessary if clear, comprehensive screening processes were in place, with good training and support. Change in the home environment would not be easy to assess, not all women would be visited at home, and there is no evidence-based link to the quality of milk. It could also be viewed as inappropriate – an invasion of privacy. Any changes in lifestyle will be covered in the screening and selection/stopping recommendations. The GDG agreed not to make any recommendations in this area.	…
TS10b	• enquire, informally, about any changes in the home environment that may require additional support or intervention from the milk bank staff.	7	2	2	5	0	Agree	No consensus	No consensus	See TS10a.	…

TS11a	Supervise • all domiciliary milk collection	3	6	2	1	0	Do not agree	No consensus	No consensus	As above, the definition of supervise was not clear and may differ in the included studies (although few details were reported). The GDG considered that, if 'supervise' meant watching women collect the milk, then they would not want to recommend supervision. However, if 'supervision' was about provision of additional advice or training, then there was general support. It was noted that it would not be appropriate to encourage women to continue to donate milk if it were continually being rejected on bacteriological criteria. The GDG therefore recommended additional information and support if bacterial contamination were significant and repeated, noting that this information and support could range from a simple intervention (e.g. reminding them of processes to be followed) through to a more involved intervention (e.g. repeated training).	Offer additional information and support on domiciliary milk collection if bacterial contamination is significant and repeated.
TS11b	• domiciliary milk collections where possible	3	6	1	2	0	Do not agree	No consensus	No consensus	See TS11a.	…
TS11c	• domiciliary milk collections if bacterial contamination is significant and repeated.	8	0	3	6	0	Agree	No consensus	Consensus	See TS11a.	…

Round 1 – donor stopping

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	GDG considerations	Recommendation for Round 2
S1a	Do not continue to accept milk from donors who supply • contaminated milk	4	4	4	0	0	Uncertain	No consensus	Consensus	The GDG interpreted 'contaminated' to mean milk that does not meet the bacteriological standards. This draft recommendation was based on one study where donors were 'dismissed' if they were not able to provide 'clean' milk. The GDG considered those circumstances in which a milk bank would wish to ask a donor not to continue to collect milk; any recommendation would therefore need to cover most, if not all, circumstances. Also, it is not clear whether a donor should be asked to stop donating or to suspend donation for a defined time. In practice, few donors return once they have suspended donation. It was also recognised that some mothers will always supply milk that does not meet the bacteriological standards, while others will need some support or simple intervention to prevent this happening. However, there is also the issue of whether and how to communicate the underlying concern to the mother. Based on limited evidence, it is not clear that bacteriological contamination is a safety issue for babies, but the balance of risks and benefits may differ for donor milk in recipient babies; therefore, the bacteriological standards applied to donated milk may be stricter than those that would be applied to milk for a mother's own baby.	Consider no longer accepting milk from donors who supply • milk that does not meet the microbiological criteria despite support
S1b	• milk with a low protein content	4.5	2	2	2	2	Uncertain	No consensus	No consensus	Routine measurement of protein content is not done, so the recommendation was removed.	…

S1c	• small amounts of milk (less than 2 ounces daily after a week's trial).	3	5	2	1	0	Do not agree	No consensus	No consensus	Although the draft recommendation specifies a small amount, the GDG considered that, in practice, it may not be possible to define this; and if a milk bank needs milk then small amounts may be accepted. Also a week's trial is not generally sufficient. The issue of resources was important, and the GDG considered that, if milk banks are to be financially accountable, then it may not be cost effective to collect very small amounts as a matter of routine. However, this may average across a milk bank if other donors provide larger amounts. In principle, the GDG agreed that it is legitimate and appropriate to consider not processing small amounts, particularly if they area one-off donations or from a long distance away. The definition of 'small' will therefore depend on local circumstances.	• small amounts of milk

S2a	Advise women that • if they become ill, they can continue to donate milk.	3	6	2	0	0	Do not agree	Consensus	Consensus	The GDG revised the wording to define 'ill'. The GDG also discussed whether it was relevant if a baby became ill, and it was felt to be relevant only where there was clear evidence that the baby's illness came from the mother. The GDG agreed therefore that the mother is the focus of this recommendation. The concern over the illness will also depend on the treatment processes used for the milk, because many infections are destroyed with adequate processing. If a mother has chicken-pox, the virus will be in the milk but after pasteurisation the risk will be minimised for both the recipient and the staff handling the milk. Milk-bank staff may also need to consider the issue of illness retrospectively, because women may donate milk that has been stored. Other considerations may be the physical effects of any illness (for example, not being able to get out of bed) and the implications for milk collection.	Advise women that if they develop a temperature or have contact with other exanthema, to contact the milk bank to discuss temporary suspension of milk donation.
S2b	• if their baby becomes ill, they can continue to donate milk.	3	5	2	1	0	Do not agree	No consensus	No consensus	See S2a.	…
S3	Advise donor women who are taking short courses of medication for infection that they should stop collecting milk for donation.	7	1	2	5	0	Agree	No consensus	No consensus	The GDG agreed that it was the responsibility of the donor to inform the milk bank if she were taking any medication, and it was then the responsibility of the milk bank to advise on any action to be taken, including temporary suspension of donation.	Advise donor women who begin taking medication that they should inform the milk bank to discuss temporary suspension of milk donation.
S4	Advise donor women who are taking short courses of antimicrobial medication that they should stop collecting milk for donation.	7	0	3	5	0	Agree	No consensus	Consensus	See S3.	…

S5	Advise donor women who are taking short courses of medication that they should wait for 5 half-lives of the drug after the last ingested dose; in most cases, a wash-out period of 1 day will be sufficient.	5.5	2	5	1	0	Uncertain	No consensus	No consensus	See S3.	…
S6a	Advise donor women that they should temporarily discontinue to collect milk for donation if • they have herpetic lesions	8	0	2	4	2	Agree	No consensus	Consensus	The GDG discussed whether herpes infection should be considered a risk. Recurrent cold sores are localised, and the virus may not appear in milk; the risk may come from contamination after expression, not viral material in the milk. As discussed before, the risk of any infection in the milk depends on the treatment processes used. The recommendation was reworded to include breast infections or lesions. In these circumstances, there are many risks including risk to the mother with damage to the skin from the pump, or blood in the milk. The recommendation was also expanded to include any changes in the colour or consistency of the milk. As with the use of medication, the recommendation was reworded to emphasise that women should inform the milk bank, with the milk bank then advising on any action to be taken. Milk banks work in a climate of trust – but more monitoring and checking is appropriate. So any donor who becomes unable to meet the initial recruitment criteria should contact the milk bank for advice.	Advise donor women that they should inform the milk bank if • they have any breast lesions or infection (including mastitis) such as herpes to discuss temporary suspension of milk donation • they have any changes in the colour or consistency of the milk • they have had any vaccination • they no longer meet the initial recruitment criteria
S6b	• they have had a recent rubella vaccination (a minimum of 3 weeks before they can start to donate again).	8	1	0	4	3	Agree	No consensus	No consensus	See S6a.	…

S7a	Advise donor women that they should discontinue to collect milk for donation if • they have herpetic lesions	5	3	1	3	1	Uncertain	No consensus	No consensus	See S6a.	…
S7b	• they have had a rubella vaccination in the past month.	3	4	1	1	2	Do not agree	No consensus	No consensus	See S6a.	…
S8a	Advise donors who are taking medication for a period of time that they should • stop collecting milk for donation	5	2	3	3	0	Uncertain	No consensus	No consensus	See S3.	…
S8b	• they may continue to express, and any milk that contains contraindicated medication should be labelled and will be used for research projects	4.5	3	4	1	0	Uncertain	No consensus	No consensus	See S3. Milk banks do not need to register as tissue banks but, if milk were being collected for research, then they would need to register. Research governance now would not allow the collection of milk in this way.	…

S9	NEW									The issue of when donors should be advised to stop expressing milk for donation was raised. Although there is general advice on how long breastfeeding should be continued, when to stop is still the decision of the mother. For milk donation, it may be appropriate to ask donors to stop when their own baby reaches a certain age. This age would depend on the target population of the milk bank – generally, the main recipient population is pre-term babies, so it may be appropriate to restrict donation according to the age of the baby. The recipient population will differ by milk bank. The reason for such a criterion is based on evidence that suggests that levels of zinc in breast milk decrease over time; 'more mature' milk may therefore not be suitable in nutritional composition for pre-term babies. Should donors who become pregnant be advised to stop donating? There is no evidence on this, and, based on the experience of the GDG, mothers will stop by choice. As in all milk donation, there is a need to respect the mother's decision if she wishes to continue to donate, but there may be implications for the mother because, by accepting the milk, there is an implicit support of that process..It was agreed, therefore, not to make a recommendation on this.	Local policies should be set up to define when donors should be advised to stop donating milk based on the age of their own baby, and this should be based on the recipient population.

Round 1 – milk expression

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	Corrections made post meeting	GDG considerations	Recommendation for Round 2

MExp1a	Advise donors to • collect both expressed milk, and drip milk.	4	4	3	1	0	Uncertain	No consensus	No consensus		Generally, although drip milk (as part of a donation) would be accepted, there was concern expressed about advising a donor to collect drip milk exclusively and accepting drip milk exclusively because of the low energy content. There may be some rare occasions, where exclusive drip milk would be needed. If drip milk is mixed with expressed milk, although this may improve the energy content when compared to drip milk alone, there was concern that the expressed milk would then be 'diluted'. Anecdotally, women who are collecting drip milk are 'good' lactators, and produce large amounts of milk. A key issue was that of advising donors – so that drip and expressed milk could be collected but kept separately. Further advice is then needed on the mixing of drip and expressed milk – and this should be based on the recipient. The GDG considered that there was a balance to be reached between reinforcing the view that donor milk is 'not good' but without ruling out the 'rare' use of drip milk – as there are circumstances when drip milk would be used. Any storage and processing recommendations need also to apply to drip milk as well.	Advise donors to collect expressed milk; however for donors who do produce drip milk they should be advised to collect and keep it separate from expressed milk.

MExp1b	• keep the drip milk and expressed milk separate.	6	2	3	3	0	Uncertain	No consensus	No consensus		See MExp1a above	…
MExp2	Advise donors to collect only expressed milk.	7	0	3	5	0	Agree	No consensus	Consensus		See MExp1a above	…
MExp3a	Advise donors to • discard the first 5 ml of expressed milk.	4	3	2	2	1	Uncertain	No consensus	No consensus		There is evidence of higher levels of bacteria in first few mls of expressed milk, but it is not clear how much milk should be discarded nor levels of bacterial contamination that would be accepted (see also recommendations on testing). The GDG agreed therefore that, because of the adequate testing and treatment of donor milk, and discarding is not widespread, that no recommendation should be made. However, if donors are consistently provided milk with high levels of contamination that they should be supported as recommended previously.	…
MExp3b	• discard the first 10 ml of expressed milk.	3	4	3	0	1	Do not agree	No consensus	Consensus		See MExp3a above	…
MExp3c	• discard the first 15 ml of expressed milk.	3	5	2	0	1	Do not agree	No consensus	Consensus		…	…
MExp3d	• discard the first 20 ml of expressed milk.	3	5	2	0	1	Do not agree	No consensus	Consensus		…	…
	Advise donors to express milk										…	

MExp4a	• using hand expression alone.	2.5	7	0	1	0	Do not agree	Consensus	No consensus		The GDG considered that the evidence showed hand expression was preferable, but that milk expressed by pump was acceptable if the donor was unable to, or did not wish to hand express. Costs of providing pumps were discussed, but most mothers purchase or have access to pumps if required.	Actively encourage donors to hand express milk however pump expressed milk is acceptable.
MExp4b	• using hand breast pumps alone.	3	6	0	1	1	Do not agree	No consensus	No consensus	**Corrected is CON-No CON	See MExp4a above	…
MExp4c	• using electric breast pumps alone.	3	6	0	1	1	Do not agree	No consensus	No consensus	**Corrected is CON-No CON	See MExp4a above	…
MExp4d	• preferably using hand expression, but using pumps if the donor prefers.	4.5	4	1	3	0	Uncertain	No consensus	No consensus		See MExp4a above	…
MExp4e	• using any method of expression preferred by the donor	8	1	0	7	0	Agree	Consensus	No consensus		See MExp4a above	…
MExp5a	Provide advice and support on stopping expressing milk to • all donors.	7	2	0	6	0	Agree	No consensus	No consensus	**Corrected is CON-No CON	The GDG agreed that this is part of the role of the donor milk bank service; any donor who requires support when stopping expressing milk should have access to advice and support as needed.	Provide advice and support on stopping expressing milk to donors as required.
MExp5b	• donors until no longer required.	7	2	1	4	1	Agree	No consensus	No consensus		See MExp5a above	…
MExp5c	• donors whose baby has died.	9	0	1	6	1	Agree	No consensus	Consensus	**Corrected is CON- CON	It was agreed that these donors need support, but it was not necessary to specify these in the recommendation.	…

Round 1 – milk handling at home

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	Corrections made post meeting	GDG considerations	Recommendation for Round 2
MHHome1	Advise donors that they should handle expressed milk for donation as they would milk for their own baby.	5	3	2	3	8	Uncertain	No consensus	No consensus		It was generally agreed that the handling of donor milk is not as for maternal milk and recommendations were revised as below.	…
MHHome2a	Advise donors that expressed milk for donation should • be allowed to reach room temperature before freezing or refrigerating.	2	8	0	0	8	Do not agree	Consensus	Consensus		Expressed milk for donation should be frozen/refrigerated immediately.	Advise donors that expressed milk for donation should • should be refrigerated or frozen immediately after collection
MHHome2b	• not be left uncovered.	8.5	0	0	8	8	Agree	Consensus	Consensus		Open containers should no longer be used – see also the recommendations on containers to be used.	• not be left uncovered.
MHHome3a	Advise donors that, before transport to the milk bank • all milk expressed for donation should be frozen.	7.5	0	2	6	8	Agree	No consensus	Consensus	**Corrected to CON-CON	Some people do bring fresh milk so would not want to rule this out, but the majority of donor milk will be received at the milk bank in a frozen state.	Advise donors that, before transport to the milk bank • all milk expressed for donation should be frozen.
MHHome3b	• all milk expressed for donation should be refrigerated.	2	5	1	2	8	Do not agree	No consensus	No consensus		See MHHome3a above.	• all milk expressed for donation should be refrigerated.

MHHome3c	• all milk expressed for donation should be frozen, unless milk is being transported to the milk bank on a daily basis. In this case, milk can be refrigerated.	8	0	2	6	8	Agree	No consensus	Consensus	**Corrected to CON-CON	See MHHome3a above.	• all milk expressed for donation should be frozen, unless milk is being transported to the milk bank on a daily basis. In this case, milk can be refrigerated.
MHHome4a	Advise donors to • refrigerate each collected sample individually	6	0	5	3	8	Uncertain	No consensus	Consensus		The British Dietetic Association guidelines for mothers expressing milk on neonatal units for their own baby recommend that milk can be refrigerated for upto 48 hours before use, but if the milk is going to be frozen, it should be frozen immediately. However, there are different issues for the storage and handling of milk for donation. For example, milk stored at 4 degrees or less will have increased lipolysis over time (upto 48 hours), but the levels will not be enough to reject the milk. In addition milk for donation is going to be pasteurized, so such strict storage conditions (related to bacterial contamination) may not be necessary. The GDG queried why if the donor has access to a freezer, would she not freeze the milk.	Advise donors to • freeze milk as soon as possible.

MHHome4b	• freeze each collected sample individually	4.5	2	4	2	8	Uncertain	No consensus	No consensus		The GDG had a preference for freezing individual samples immediately, but based on practical considerations, it was accepted that samples could be pooled over 24 hours then frozen. Donors should store expressions separately at home but this will mean more containers and more administration. There is no cost impact around the use of additional containers as any new expression still needs to be into a new container.	• it is preferred that milk is collected as individual samples, however if mother finds it necessary then pool.
MHHome4c	• refrigerate collected samples over 24 hours, then freeze the pooled collection	7	1	2	5	8	Agree	No consensus	No consensus		There are significant practical issues of storing lots of containers in a fridge with other items and the refrigerator being opened often. Freezers may be more stable. The risk of pooling at home is related to handling of the containers more (for example, opening the container to add the new sample) and cross contamination. However, the GDG recognized that pragmatically, women may need to pool their milk.	• refrigerate collected samples within 24 hours, then freeze the milk
MHHome4d	• freeze collected samples over 24 hours, by adding each new sample to the frozen or freezing pool	4	4	1	3	8	Uncertain	No consensus	No consensus		See MHHome4a-c	…
MHHome4e	• refrigerate collected samples over 2 days, then freeze the pooled collection	3	5	1	2	8	Do not agree	No consensus	No consensus		See MHHome4a	…

MHHome4f	• freeze collected samples over 2 days, by adding each new sample to the frozen or freezing pool	3	4	3	1	8	Do not agree	No consensus	No consensus		See MHHome4a	…
MHHome4g	• refrigerate collected samples over 1 week, then freeze the pooled collection	1	8	0	0	8	Do not agree	Consensus	Consensus		See MHHome4a	…
MHHome4h	• freeze collected samples over 1 week, by adding each new sample to the frozen or freezing pool	2	5	3	0	8	Do not agree	No consensus	Consensus		See MHHome4a	…
MHHome5a	Advise donors that expressed milk for donation can be stored for • up to 1 days in the main part of a fridge, at 4ºC or lower before transport to the milk bank.	7	1	0	6	8	Agree	No consensus	No consensus	**Corrected to CON-No CON	As for above, the key issues are around practical considerations of handling and storing, but also degradation of nutrients, for example, and larger fat globules. The GDG referred to the NICE PH11 guidance on storage of maternal milk , but because of the extended period of storage at the milk bank, there was a need to recommend lower temperatures and shorter times than recommended for maternal milk.	Advise donors that expressed milk for donation can be stored for • up to 1 day in the main part of a fridge, at 4ºC or lower before transport to the milk bank.
MHHome5b	• up to 2 days in the main part of a fridge, at 4ºC or lower before transport to the milk bank.	3	4	1	2	8	Do not agree	No consensus	No consensus		See MHHome5a	…
MHHome5c	• up to 3 days in the main part of a fridge, at 4ºC or lower before transport to the milk bank.	3	5	2	0	8	Do not agree	No consensus	Consensus		See MHHome5a	…

MHHome5d	• up to 4 days in the main part of a fridge, at 4ºC or lower before transport to the milk bank.	3	6	1	0	8	Do not agree	No consensus	Consensus	**Corrected to CON-CON	See MHHome5a	…
MHHome5e	• up to 5 days in the main part of a fridge, at 4ºC or lower before transport to the milk bank.	2	7	0	0	8	Do not agree	Consensus	Consensus		See MHHome5a	…
MHHome5f	• up to 2 days in the freezer compartment of a fridge before transport to the milk bank.	4.5	3	1	2	8	Uncertain	No consensus	No consensus		See MHHome5j	…
MHHome5g	• up to 5 days in the freezer compartment of a fridge before transport to the milk bank.	3.5	3	2	1	8	Uncertain	No consensus	No consensus		See MHHome5j	…
MHHome5h	• up to 1 week in the freezer compartment of a fridge before transport to the milk bank.	4.5	3	2	1	8	Uncertain	No consensus	No consensus		See MHHome5j	…
MHHome5i	• up to 10 days in the freezer compartment of a fridge before transport to the milk bank.	3	4	2	0	8	Do not agree	No consensus	Consensus		See MHHome5j	…
MHHome5j	• up to 2 weeks in the freezer compartment of a fridge before transport to the milk bank.	4	3	2	1	8	Uncertain	No consensus	No consensus		There was a recognition that some women may not have access to a separate freezer, and though not ideal, milk for donation can be stored in a freezer compartment of a refrigerator, but the recommended period of storage is much shorter than for a separate freezer. See MHHome5p.	• up to 2 weeks in the freezer compartment of a fridge before transport to the milk bank preferable at -18 but in some circumstances can be stored in this

MHHome5k	• up to 5 days in a domestic freezer , at minus 18ºC or lower before transport to the milk bank.	2.5	6	1	1	8	Do not agree	No consensus	No consensus	**Corrected to CON-CON	See MHHome5p	…
MHHome5l	• up to 1 week in a domestic freezer, at minus 18ºC or lower before transport to the milk bank.	2.5	5	1	2	8	Do not agree	No consensus	No consensus		See MHHome5p	…
MHHome5m	• up to 2 weeks in a domestic freezer, at minus 18ºC or lower before transport to the milk bank.	2.5	5	1	2	8	Do not agree	No consensus	No consensus		See MHHome5p	…
MHHome5n	• up to 1 month in a domestic freezer, at minus 18ºC or lower before transport to the milk bank.	6.5	2	2	4	8	Agree	No consensus	No consensus		See MHHome5p	…
MHHome5o	• up to 2 months in a domestic freezer, at minus 18ºC or lower before transport to the milk bank.	5.5	1	5	2	8	Uncertain	No consensus	No consensus		See MHHome5p	…

MHHome5p	• up to 3 months in a domestic freezer, at minus 18ºC or lower before transport to the milk bank.	7	1	3	4	8	Agree	No consensus	No consensus		Again, the GDG were guided by the NICE PH11 recommendations on storage of maternal milk. A shorter storage time was recommended because, practically, donations need to be tested and pasteurised within 3 months of expression – but this is based on the capacity of the milk bank not the evidence on storage. The recommended storage time of 3 months at home plus a maximum of 3 months to process at the milk bank is therefore consistent with the PH11 guidance of 6 months total storage. The GDG considered that the optimal storage location for the milk is at the milk bank, recognizing the better equipment and explicit processes, so donors should be encouraged to transport the donations to the milk bank as soon as possible. See also the recommendations on transportation.	• up to 3 months in a domestic freezer, at minus 18ºC or lower. Take into account the time needed by the milk bank to process it. Get it to the milk bank asap
MHHome5q	• up to 4 months in a domestic freezer, at minus 18ºC or lower before transport to the milk bank.	2	5	2	0	8	Do not agree	No consensus	Consensus		See MHHome5p	…
MHHome5r	• up to 5 months in a domestic freezer, at minus 18ºC or lower before transport to the milk bank.	1	6	1	0	8	Do not agree	No consensus	Consensus	**Corrected to CON-CON	See MHHome5p	…

MHHome5s	• up to 6 months in a domestic freezer, at minus 18ºC or lower before transport to the milk bank.	1	6	1	0	8	Do not agree	No consensus	Consensus	**Corrected to CON-CON	See MHHome5p	…
MHHome6a	Advise donors to collect expressed milk for donation in • any container they can find	1	8	0	0	8	Do not agree	Consensus	Consensus		See MHHome6e	Advise donors to collect expressed milk for donation in
MHHome6b	• aluminium jugs	1	7	1	0	8	Do not agree	Consensus	Consensus		See MHHome6e	…
MHHome6c	• plastic bottles or jars	3	4	0	3	8	Do not agree	No consensus	No consensus		See MHHome6e	…
MHHome6d	• glass bottles or jars	3	4	0	3	8	Do not agree	No consensus	No consensus		See MHHome6e	…
MHHome6e	• containers provided by the milk bank	9	0	0	8	8	Agree	Consensus	Consensus		The GDG agreed that donors should be provided with containers from the milk bank.	• containers provided by the milk bank
MHHome6f	Only accept donations that are in containers provided by the milk bank.	3	5	2	1	8	Do not agree	No consensus	No consensus		If donations are collected in hospital then the mother will be provided with appropriate containers from there. When mothers express milk for their own baby at home, they often use other container such as bags. The GDG agreed donations should only be accepted in containers designed for the collection of milk.	Only accept donations that are in containers provided by the milk bank however for one-off donations containers specifically designed for the collection of breast milk
MHHome7a	Advise donors that, before used, collection containers should be • washed in cold, soapy water	1	6	1	1	8	Do not agree	No consensus	No consensus	**Corrected to CON-No CON	See MHHome7g	Advise donors that, before used, collection containers should be
MHHome7b	• washed in hot, soapy water	4	4	1	3	8	Uncertain	No consensus	No consensus		See MHHome7g	…

MHHome7c	• sterilized using sterilizing fluid	6	3	1	3	8	Uncertain	No consensus	No consensus		See MHHome7g	…
MHHome7d	• sterilized by heating in the oven	3	4	1	2	8	Do not agree	No consensus	No consensus		See MHHome7g	…
MHHome7e	• cleaned as they would clean the bottles for feeding their own baby	5	3	3	2	8	Uncertain	No consensus	No consensus		See MHHome7g	…
MHHome7f	• washed in the dishwasher, if possible	5	3	2	2	8	Uncertain	No consensus	No consensus		See MHHome7g	…
MHHome7g	• used as received from the milk bank	9	0	0	8	8	Agree	Consensus	Consensus		The milk bank should provide sterile containers for one-off use. This ensures, not only, that the container is sterile, and that the material is suitable – for example, plastics may react to different heat processes and leaching of plasticisers may be increased. Practically, the use of a standard bottle also makes handling easier within the milk bank. Milk banks need to demonstrate that the quality of the milk is the highest – so there is a need to discard and refuse some milk – and donors should therefore be advised that they should follow the instructions from the milk bank.	• used as received from the milk bank

Round 1 – milk handling at the milk bank 1

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	Corrections made post meeting	GDG considerations	Recommendation for Round 2
MHMB1a	Process **all** milk under sterile conditions.	3	6	1	1	1	Do not agree	No consensus	No consensus		See MHMilkBank1b	…
MHMB1b	Process **all** milk under hygienic conditions, that may not necessarily be sterile.	8	0	2	7	0	Agree	Consensus	Consensus		There was a general agreement that a balance needed to struck between treatment and the effect of such processing on the milk.	Process **all** milk under hygienic conditions, that may not necessarily be sterile.
MHMB2a	On receipt at the milk bank, • thaw any frozen samples.	3	5	1	2	1	Do not agree	No consensus	No consensus		See MHMilkBank2d	On receipt at the milk bank,
MHMB2b	• allow all samples to reach room temperature.	2.5	8	0	0	1	Do not agree	Consensus	Consensus		See MHMilkBank2d	…
MHMB2c	• refrigerate all samples.	3	7	0	2	0	Do not agree	Consensus	No consensus		See MHMilkBank2d	…
MHMB2d	• freeze all samples.	8	0	0	7	2	Agree	Consensus	Consensus		This is based on the previous recommendations that donors should provide frozen or refrigerated samples.	• freeze all samples.

MHMB2e	• refrigerate those samples which are to be used **raw**, if meet testing criteria.	5	2	1	2	4	Uncertain	No consensus	No consensus		The GDG recognized that, although raw milk may be used in rare circumstances and only under the supervision of the prescribing physician, in general milk banks would not be processing raw milk. Recommendations were therefore made only for milk to be treated.	…
MHMB3	On receipt at the milk bank, • process milk for use in pre-term babies (that is, milk from the appropriate stage of lactation) separately.	6	3	1	4	1	Uncertain	No consensus	No consensus		As the guideline is not covering indications for the use of milk, this recommendation was not considered relevant and removed.	…
MHMB4	Store frozen samples direct from the donor in the same freezer as pasteurized samples.	1	9	0	0	0	Do not agree	Consensus	Consensus		…	Do not store frozen samples direct from the donor in the same freezer as pasteurized samples.
MHMB5	Store refrigerated samples direct from the donor in the same fridge as thawed, pasteurized samples.	1	9	0	0	0	Do not agree	Consensus	Consensus		…	Do not store refrigerated samples direct from the donor in the same fridge as thawed, pasteurized samples.
MHMB6	Store milk to be used **raw** in the same fridge as samples to be pasteurised.	1	8	0	0	1	Do not agree	Consensus	Consensus		…	Do not store milk to be used **raw** in the same fridge as samples to be pasteurised.

MHMB7a	Examine samples from the donor for • appearance (including the presence of blood)	8	1	1	7	0	Agree	Consensus	No consensus		It is important to check the samples visually, but there is no evidence on how any discolouration or other factor (taste, odour) relates to any risks. Colour – appearance, can indicate some specific situations, such as medication being taken. But generally, the GDG agreed that a visual inspection to exclude obvious 'wrong' samples should be made.	Examine samples from the donor for • appearance
MHMB7b	• taste	1	8	1	0	0	Do not agree	Consensus	Consensus		See MHMilkBank7a	…
MHMB7c	• colour	7.5	2	1	5	1	Agree	No consensus	No consensus		See MHMilkBank7a	…
MHMB7d	• odour	3	5	3	1	0	Do not agree	No consensus	No consensus		See MHMilkBank7a	…
MHMB8a	Discard samples which • appear to contain contaminants	8	2	1	6	0	Agree	No consensus	No consensus		See MHMilkBank8e	Discard samples which
MHMB8b	• taste unusual	1	4	2	0	3	Do not agree	No consensus	Consensus		See MHMilkBank8e	…
MHMB8c	• are an unusual colour	6	2	5	2	0	Uncertain	No consensus	No consensus		See MHMilkBank8e	…
MHMB8d	• smell unusual	5.5	3	3	2	1	Uncertain	No consensus	No consensus		See MHMilkBank8e	…
MHMB8e	• on examination, raise any safety concerns	8	1	0	8	0	Agree	Consensus	No consensus		See MHMilkBank7a	• on examination, raise any safety concerns
MHMB9	Discard samples from • donors who subsequently fail to meet selection criteria	9	1	0	8	0	Agree	Consensus	No consensus		…	Discard samples from • donors who subsequently fail to meet selection criteria

MHMB10a	Discard samples stored, **post expression and prior to testing** • in the refrigerator for 1 day	1.5	7	0	1	1	Do not agree	Consensus	No consensus		The GDG agreed that these should be linked to the storage periods defined in the Milk Handling at Home section.	Accept samples stored, **post expression and prior to testing** in the refrigerator for upto 1 day
MbHMB10c	• in the refrigerator for 2 days	2	7	0	0	2	Do not agree	Consensus	Consensus		On discussion, the GDG agreed to link these to the storage periods defined in the Milk Handling at Home section.	…
MdHMB10e	• in the refrigerator for 3 days	7	2	0	5	2	Agree	No consensus	No consensus		See MHMilkBank10a	…
MfHMB10g	• in the refrigerator for 4 days	7	1	1	5	2	Agree	No consensus	No consensus		See MHMilkBank10a	…
MHMB10h	• in the refrigerator for 5 days	7	1	1	5	2	Agree	No consensus	No consensus		See MHMilkBank10a	…
MHMB10i	• in the freezer for 1 week	1	7	0	0	2	Do not agree	Consensus	Consensus		See MHMilkBank10a	…
MHMB10j	• in the freezer for 2 weeks	1	7	0	0	2	Do not agree	Consensus	Consensus		See MHMilkBank10a	…
MHMB10k	• in the freezer for 1 month	1	7	0	0	2	Do not agree	Consensus	Consensus		See MHMilkBank10a	…
MHMB10l	• in the freezer for 2 months	1.5	7	1	0	1	Do not agree	Consensus	Consensus		See MHMilkBank10a	…
MHMB10m	• in the freezer for 3 months	2	7	0	0	2	Do not agree	Consensus	Consensus		See MHMilkBank10a	• in the freezer for upto 3 months
MHMB10n	• in the freezer for 4 months	7	1	2	4	2	Agree	No consensus	No consensus		See MHMilkBank10a	…
MHMB10o	• in the freezer for 5 months	7	1	1	5	2	Agree	No consensus	No consensus		See MHMilkBank10a	…
MHMB10p	• in the freezer for 6 months	7	1	1	5	2	Agree	No consensus	No consensus		See MHMilkBank10a	…
MHMB11a	Discard samples stored, **post expression and prior to using raw** • in the refrigerator for 1 day	1.5	4	0	0	5	Do not agree	No consensus	Consensus		(Not making recommendations on the handling of raw milk)	…

MHMB11b	• in the refrigerator for 2 days	2	5	0	0	4	Do not agree	No consensus	Consensus	1-3 4 D/K 5	(Not making recommendations on the handling of raw milk)	…
MHMB11c	• in the refrigerator for 3 days	7	2	0	3	4	Agree	No consensus	No consensus	1-3 1 D/K 5	(Not making recommendations on the handling of raw milk)	…
MHMB11d	• in the refrigerator for 4 days	7	2	0	3	4	Agree	No consensus	No consensus	Median 7.5 1-3 1 D/K 5	(Not making recommendations on the handling of raw milk)	…
MHMB11e	• in the refrigerator for 5 days	7	2	0	3	4	Agree	No consensus	No consensus	Median 7.5 1-3 1 D/K 5	(Not making recommendations on the handling of raw milk)	…
MHMB12	Before selecting for testing, always choose the 'newest' samples first.	3	6	1	0	2	Do not agree	No consensus	Consensus	Median 2 1-3 7 4-6 0 CON-CON	The milk bank should operate a method of stock control, and the GDG agreed that this would be covered through general quality assurance. No recommendation was therefore made.	…
MHMB13	Thaw samples for testing when a donor has been shown to meet the selection criteria (that is when the results of any serological testing are available).	8	3	1	5	0	Agree	No consensus	No consensus	1-3 4 4-6 0	The process of testing differs depending on whether a one-off donation or ongoing. Please see therefore the recommendations on testing batches later.	…
MHMB14a	Thaw samples by • using a hot water bath (manual)	3	5	1	2	1	Do not agree	No consensus	No consensus	4-6 0 7-9 3	See MHMilkBank14d	Thaw samples by

MHMB14b	• heating in a microwave	1.5	7	1	0	1	Do not agree	Consensus	Consensus	Median 1 1-3 8 4-6 0	See MHMilkBank14d	…
MHMB14c	• running under a hot tap	2	7	1	0	1	Do not agree	Consensus	Consensus	1-3 8 4-6 0	See MHMilkBank14d	…
MHMB14d	• using a hot water bath (electric)	2.5	5	0	3	1	Do not agree	No consensus	No consensus	4-6 1 7-9 2	The various options for defrosting were discussed. There are advantages of defrosting at a monitored temperature, although frozen milk can be thawed in a refrigerator or by leaving it out at room temperature. If milk is stored at very low temperatures (-35°) it will take longer to defrost and also the size of the bottles has an impact.	• using a temperature controlled environment such as a water bath (electric) or refrigerator
MHMB14e	• leaving in the refrigerator	7.5	1	1	6	1	Agree	No consensus	No consensus	Median 8 4-6 0 7-9 7 CON-No CON	See MHMilkBank14d	• leaving in the refrigerator

MHMB14f	• leaving out to reach room temperature	3	5	0	3	1	Do not agree	No consensus	No consensus		However, there are guidelines that say that the milk shouldn't be at room temperature for longer than a certain length of time; in general the period at which milk is kept at an uncontrolled temperature should be minimised.	• leaving out to reach room temperature

MHMB15a	**Before pasteurisation**, test • all samples	7.5	3	0	5	1	Agree	No consensus	No consensus		Every donation should be tested, but donations from a single donor can be pooled (see previous recs on Milk Handling at Home) and the batch tested. Although this means that larger amounts may have to be discarded, this is balanced with lower costs as testing every donation is very expensive, but testing by batch (1-2l) is less costly. The aim of testing pre-pasteurisation tests is for levels of contamination but testing post pasteurisation is to check the effectiveness of the process. (See also recs on testing post-pasteurisation)	**Before pasteurisation**, test • all samples but this should be done in batches
MHMB15b	• a random selection of samples	5	4	0	4	1	Uncertain	No consensus	No consensus		See MHMilkBank15a	…
MHMB15c	• samples only once a week	2	6	1	0	2	Do not agree	No consensus	Consensus		See MHMilkBank15a	…
MHMB15d	• samples only twice a month	2	6	0	1	2	Do not agree	No consensus	No consensus		See MHMilkBank15a	…
MHMB15e	• only the first sample received from a donor	1	7	0	0	2	Do not agree	Consensus	Consensus		See MHMilkBank15a	…

MHMB15f	• the first three samples received from a donor	1	7	0	0	2	Do not agree	Consensus	Consensus		See MHMilkBank15a	…
	Before pasteurisation, test samples for the following:											**Before pasteurisation**, test samples for the following:
MHMB16a	• environmental or other contaminants	3.5	3	3	0	3	Uncertain	No consensus	Consensus		In general, the GDG agreed that in the UK, it is not necessary to test for such contaminants.	…
MHMB16ai	o DDT concentrations	3.5	3	2	1	3	Uncertain	No consensus	No consensus		This is not a routine test.	…
MHMB16aii	o water	2	5	1	0	3	Do not agree	No consensus	Consensus		This test was mainly recommended in those milk banks where donors were paid, to check for dilution.	…
MHMB16aiii	o cow's milk	2	4	1	0	4	Do not agree	No consensus	Consensus		This test was mainly recommended in those milk banks where donors were paid, to check for dilution.	…

MHMB16bi	• viral infection	4	4	2	2	1	Uncertain	No consensus	No consensus		The GDG discussed which viruses could be tested for and agreed not to test for viruses in milk based on the likelihood of contamination and the prevalence (minimized through the recommended donor screening process). In addition, pasteurisation destroys or inactivates the viruses so no pre-pasteurisation check was recommended.	…
MHMB16bii	o CMV	3	5	1	3	0	Do not agree	No consensus	No consensus		See MHMilkBank16bi	…
MHMB16biii	o MRSA	4.5	3	2	3	1	Uncertain	No consensus	No consensus		See MHMilkBank16bi	…
MHMB16biv	o HIV	3	5	1	3	0	Do not agree	No consensus	No consensus		See MHMilkBank16bi	…
MHMB16bv	o Semliki Forest virus	3	5	1	1	2	Do not agree	No consensus	No consensus		See MHMilkBank16bi	…
MHMB16bvi	o herpes simplex virus	3	5	0	3	1	Do not agree	No consensus	No consensus		See MHMilkBank16bi	…
MHMB16bvii	o coxsackie virus	3	5	1	2	1	Do not agree	No consensus	No consensus		See MHMilkBank16bi	…
MHMB16bviii	o HTLV-1	3	5	0	4	0	Do not agree	No consensus	No consensus		See MHMilkBank16bi	…
MHMB16bix	o hepatitis B	4.5	4	1	3	1	Uncertain	No consensus	No consensus		See MHMilkBank16bi	…
MHMB16bx	o hepatitis C	4.5	4	1	3	1	Uncertain	No consensus	No consensus		See MHMilkBank16bi	…

MHMB16ci	• bacterial contamination	9	0	0	8	1	Agree	Consensus	Consensus		As with viruses, milk banks need to check for specific indicator bacteria.	• bacterial contamination
MHMB16cii	o enteric pathogens	9	1	0	7	1	Agree	Consensus	No consensus		See MHMilkBank16ci	o enteric pathogens
MHMB16ciii	o pathogens with the potential to be enteric	9	1	1	6	1	Agree	No consensus	No consensus		See MHMilkBank16ci	o pathogens with the potential to be enteric
MHMB16civ	o non-pathogenic organisms	7.5	3	0	5	1	Agree	No consensus	No consensus		See MHMilkBank16ci	o non-pathogenic organisms
MHMB16cv	o coliform bacteria	8.5	0	0	8	1	Agree	Consensus	Consensus		See MHMilkBank16ci	o coliform bacteria
MHMB16cvi	o saprophytic bacteria	8	1	2	4	2	Agree	No consensus	No consensus		See MHMilkBank16ci	o saprophytic bacteria
MHMB16cvii	o heat resistant bacillus	8	1	1	7	0	Agree	Consensus	No consensus		See MHMilkBank16ci	o heat resistant bacillus
MHMB16cviii	o from mastitis	8	1	2	4	2	Agree	No consensus	No consensus		See MHMilkBank16ci	o from mastitis
MHMB16cix	o Salmonella Kottbus	9	1	0	6	2	Agree	No consensus	No consensus		See MHMilkBank16ci	o Salmonella Kottbus
MHMB16cx	o normal breast flora	5	4	0	4	1	Uncertain	No consensus	No consensus		See MHMilkBank16ci	o normal breast flora
MHMB16cxi	o commensal skin flora	4	4	1	3	1	Uncertain	No consensus	No consensus		See MHMilkBank16ci	o commensal skin flora
MHMB16cxii	o Staph epidermis	8	3	0	4	2	Agree	No consensus	No consensus		See MHMilkBank16ci	o Staph epidermis
MHMB16cxiii	o Staph aureus	9	0	1	6	2	Agree	No consensus	Consensus		See MHMilkBank16ci	o Staph aureus
MHMB16cxiv	o Staph albus	8.5	1	1	4	3	Agree	No consensus	No consensus		See MHMilkBank16ci	o Staph albus
MHMB16cxv	o viridans streptococci	9	1	0	5	3	Agree	No consensus	No consensus		See MHMilkBank16ci	o viridans streptococci
MHMB16cxvi	o diphtheroids	9	1	0	5	3	Agree	No consensus	No consensus		See MHMilkBank16ci	o diphtheroids
MHMB16cxvii	o gram-negative rod	9	0	1	4	4	Agree	No consensus	Consensus		See MHMilkBank16ci	o gram-negative rod
MHMB16cxviii	o haemolytic streptococci	9	1	0	6	2	Agree	No consensus	No consensus		See MHMilkBank16ci	o haemolytic streptococci
MHMB16cxix	o Strep faecalis	9	1	0	6	2	Agree	No consensus	No consensus		See MHMilkBank16ci	o Strep faecalis
MHMB16cxx	o Pseud spp	9	1	1	5	2	Agree	No consensus	No consensus		See MHMilkBank16ci	o Pseud spp

MHMB16cxxi	o Proteus spp	9	1	0	5	3	Agree	No consensus	No consensus		See MHMilkBank16ci	o Proteus spp
MHMB16cxxii	o Enterobacteriecaea	9	0	0	7	2	Agree	Consensus	Consensus		See MHMilkBank16ci	o Enterobacteriecaea
MHMB16cxxiii	o enterococci	9	1	0	5	3	Agree	No consensus	No consensus		See MHMilkBank16ci	o enterococci
MHMB16cxxiv	o Klebsiella	9	1	0	5	3	Agree	No consensus	No consensus		See MHMilkBank16ci	o Klebsiella
MHMB16cxv	o E coli	9	0	0	8	1	Agree	Consensus	Consensus		See MHMilkBank16ci	o E coli
MHMB16cxvi	o listeria	9	1	0	7	1	Agree	Consensus	No consensus		See MHMilkBank16ci	o listeria
MHMB16di	• nutritional factors	5	3	2	3	1	Uncertain	No consensus	No consensus		Testing for nutritional composition, if done, should be post pasteurization.	…
MHMB16dii	o fat	5	4	3	2	0	Uncertain	No consensus	No consensus		See MHMilkBank16di	…
MHMB16diii	o caloric value (energy)	5	3	3	3	0	Uncertain	No consensus	No consensus		See MHMilkBank16di	…
MHMB16div	o carbohydrate	5	4	3	2	0	Uncertain	No consensus	No consensus		See MHMilkBank16di	…
MHMB16dv	o protein	4	4	4	1	0	Uncertain	No consensus	No consensus	Median 5 1-3 3 7-9 2	See MHMilkBank16di	…
MHMB16dvi	o lactose	4	4	4	1	0	Uncertain	No consensus	No consensus		See MHMilkBank16di	…
MHMB16dvii	o vitamins	3	5	3	1	0	Do not agree	No consensus	No consensus		See MHMilkBank16di	…
MHMB16dviii	o minerals	3	5	3	1	0	Do not agree	No consensus	No consensus		See MHMilkBank16di	…
MHMB16dix	o sodium	4	4	4	1	0	Uncertain	No consensus	No consensus		See MHMilkBank16di	…
MHMB16dx	o zinc	4	4	4	1	0	Uncertain	No consensus	No consensus		See MHMilkBank16di	…
MHMB16dxi	o immunologic factors	4	4	4	1	0	Uncertain	No consensus	No consensus		See MHMilkBank16di	…
MHMB16dxii	o enzyme activity	3	5	3	1	0	Do not agree	No consensus	No consensus		See MHMilkBank16di	…

MHMB16e	• acidity	4	3	3	1	2	Uncertain	No consensus	No consensus	Median 3 1-3 4 D/K 1 DO NOT AGREE	Some countries use acidity as an indirect indicator for bacteria. But acidity could also be a chemical contaminant rather than bacterial contamination. When bacterial testing is being done, acidity gives no added information. Acidity may affect the acceptability of the milk; if this was caused by bacteria then the bacteria would be destroyed during pasteurization but the pH may have shifted and affect acceptability but there is no clear evidence on the effect on the recipient baby – some view that acidified donor milk (yoghurt) would not have any problems for the baby.	• acidity
	Discard **samples for raw use** that contain										(Not making recommendations on the handling of raw milk)	…
MHMB17a	• organisms other than normal breast flora or commensal skin flora	7	2	1	4	2	Agree	No consensus	No consensus		(Not making recommendations on the handling of raw milk)	…

MHMB17b	• gram negative bacteria	5	3	0	3	3	Uncertain	No consensus	No consensus		(Not making recommendations on the handling of raw milk)	…
MHMB17c	• ≥10,000 organisms/ml Staph epidermis	3	4	1	0	4	Do not agree	No consensus	Consensus		(Not making recommendations on the handling of raw milk)	…
MHMB17d	• ≥4,000 organisms/ml Staph aureus	6	2	2	2	3	Uncertain	No consensus	No consensus	Median 6.5 4-6 1 7-9 3 AGREE	(Not making recommendations on the handling of raw milk)	…
MHMB17e	• ≥10^4 CFU/ml of normal skin flora	3	4	1	1	3	Do not agree	No consensus	No consensus	4-6 0 7-9 2	(Not making recommendations on the handling of raw milk)	…
MHMB17f	• pathogens	7	2	0	3	4	Agree	No consensus	No consensus		(Not making recommendations on the handling of raw milk)	…
MHMB17g	• coliform bacteria	5	3	0	3	3	Uncertain	No consensus	No consensus	Median 8	(Not making recommendations on the handling of raw milk)	…

MHMB18	Discard **samples for pasteurisation** that contain										Lower levels of any bacterial contamination are acceptable as pasteurisation would destroy these, but there some that are important organisms–for example, staph aureus – that release toxins that would remain even if the organisms are destroyed. Also, if there were high levels of contamination, then the resultant contamination may remain at an unacceptable level (pasteurization destroys logarithmically, so effectiveness depends on the starting level) . The Dairy industry test for fewercontamintants, but this is not being fed to 23 week old babies. The GDG recognized the need to assume that the main recipients are preterm, sick but that may not be the case. Key to these recommendations is the confidence in the pasteurisation process.	Discard **samples for pasteurisation** that contain

MHMB18a	• any organisms	1	7	0	0	2	Do not agree	Consensus	Consensus		See MHMilkBank18	• any organisms
MHMB18ai	• ≥10^2 CFU/ml of any organisms	1.5	5	1	0	3	Do not agree	No consensus	Consensus		See MHMilkBank18	• ≥10^2 CFU/ml of any organisms
MHMB18aii	• ≥10^3 CFU/ml of any organisms	1.5	5	1	0	3	Do not agree	No consensus	Consensus		See MHMilkBank18	• ≥10^3 CFU/ml of any organisms
MHMB18aiii	• ≥10^4 CFU/ml of any organisms	3	5	1	1	2	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^4 CFU/ml of any organisms
MHMB18aiv	• ≥10^5 CFU/ml of any organisms	2.5	4	1	1	3	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^5 CFU/ml of any organisms
MHMB18av	• ≥10^6 CFU/ml of any organisms	6	2	1	3	3	Uncertain	No consensus	No consensus		See MHMilkBank18	• ≥10^6 CFU/ml of any organisms
MHMB18bi	• any skin commensals	1	6	1	0	2	Do not agree	No consensus	Consensus		See MHMilkBank18	• any skin commensals
MHMB18bii	• ≥10^2 CFU/ml of skin commensals	1	6	0	0	3	Do not agree	No consensus	Consensus		See MHMilkBank18	• ≥10^2 CFU/ml of skin commensals
MHMB18biii	• ≥10^4 CFU/ml of skin commensals	2	5	1	0	3	Do not agree	No consensus	Consensus		See MHMilkBank18	• ≥10^4 CFU/ml of skin commensals
MHMB18biv	• ≥10^5 CFU/ml of skin commensals	2	4	1	1	3	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^5 CFU/ml of skin commensals
MHMB18bv	• ≥10^6 CFU/ml of skin commensals	3.5	3	1	2	3	Uncertain	No consensus	No consensus		See MHMilkBank18	• ≥10^6 CFU/ml of skin commensals
MHMB18biv	• ≥10^6 CFU/ml of skin commensals	6	2	1	3	3	Uncertain	No consensus	No consensus		See MHMilkBank18	• ≥10^6 CFU/ml of skin commensals
MHMB18ci	• any Staph aureus	4	3	1	2	3	Uncertain	No consensus	No consensus		See MHMilkBank18	• any Staph aureus
MHMB18cii	• ≥10^2 CFU/ml of Staph aureus	4.5	3	0	3	3	Uncertain	No consensus	No consensus		See MHMilkBank18	• ≥10^2 CFU/ml of Staph aureus
MHMB18ciii	• ≥10^4 CFU/ml of Staph aureus	7	2	0	3	4	Agree	No consensus	No consensus		See MHMilkBank18	• ≥10^4 CFU/ml of Staph aureus
MHMB18civ	• ≥10^5 CFU/ml of Staph aureus	7	2	0	3	4	Agree	No consensus	No consensus		See MHMilkBank18	• ≥10^5 CFU/ml of Staph aureus
MHMB18cv	• ≥10^6 CFU/ml of Staph aureus	7	2	0	3	4	Agree	No consensus	No consensus		See MHMilkBank18	• ≥10^6 CFU/ml of Staph aureus
MHMB18civ	• ≥10^6 CFU/ml of Staph aureus	7	2	0	3	4	Agree	No consensus	No consensus		See MHMilkBank18	• ≥10^6 CFU/ml of Staph aureus
MHMB18di	• any gram-negative rod bacteria	4.5	3	0	3	3	Uncertain	No consensus	No consensus		See MHMilkBank18	• any gram-negative rod bacteria
MHMB18dii	• ≥10^2 CFU/ml of any gram-negative rod bacteria	1.5	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^2 CFU/ml of any gram-negative rod bacteria
MHMB18diii	• ≥10^4 CFU/ml of any gram-negative rod bacteria	2	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^4 CFU/ml of any gram-negative rod bacteria

MHMB18div	• ≥10^5 CFU/ml of any gram-negative rod bacteria	2	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^5 CFU/ml of any gram-negative rod bacteria
MHMB18dv	• ≥10^6 CFU/ml of any gram-negative rod bacteria	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• ≥10^6 CFU/ml of any gram-negative rod bacteria
MHMB18div	• ≥10^6 CFU/ml of any gram-negative rod bacteria	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• ≥10^6 CFU/ml of any gram-negative rod bacteria
MHMB18ei	• any haemolytic streptococci	5	3	1	3	2	Uncertain	No consensus	No consensus		See MHMilkBank18	• any haemolytic streptococci
MHMB18eii	• ≥10^2 CFU/ml of any haemolytic streptococci	1.5	3	1	0	5	Do not agree	No consensus	Consensus		See MHMilkBank18	• ≥10^2 CFU/ml of any haemolytic streptococci
MHMB18eiii	• ≥10^3 CFU/ml of any haemolytic streptococci	2	3	1	0	5	Do not agree	No consensus	Consensus		See MHMilkBank18	• ≥10^3 CFU/ml of any haemolytic streptococci
MHMB18eiv	• ≥10^4 CFU/ml of any haemolytic streptococci	2	3	1	0	5	Do not agree	No consensus	Consensus		See MHMilkBank18	• ≥10^4 CFU/ml of any haemolytic streptococci
MHMB18ev	• ≥10^5 CFU/ml of any haemolytic streptococci	3	2	1	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^5 CFU/ml of any haemolytic streptococci
MHMB18eiv	• ≥10^6 CFU/ml of any haemolytic streptococci	3	2	1	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^6 CFU/ml of any haemolytic streptococci
MHMB18fi	• any Strep faecalis	5	3	1	3	2	Uncertain	No consensus	No consensus		See MHMilkBank18	• any Strep faecalis
MHMB18fii	• ≥10^2 CFU/ml of Strep faecalis	1.5	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^2 CFU/ml of Strep faecalis
MHMB18fiii	• ≥10^3 CFU/ml of Strep faecalis	1.5	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^3 CFU/ml of Strep faecalis
MHMB18fiv	• ≥10^4 CFU/ml of Strep faecalis	2	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^4 CFU/ml of Strep faecalis
MHMB18fv	• ≥10^5 CFU/ml of Strep faecalis	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• ≥10^5 CFU/ml of Strep faecalis
MHMB18fiv	• ≥10^6 CFU/ml of Strep faecalis	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• ≥10^6 CFU/ml of Strep faecalis
MHMB18gi	• any heat-resistant bacteria	5	3	1	3	2	Uncertain	No consensus	No consensus		See MHMilkBank18	• any heat-resistant bacteria
MHMB18gii	• ≥10^2 CFU/ml of any heat-resistant bacteria	3	3	0	2	4	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^2 CFU/ml of any heat-resistant bacteria
MHMB18giii	• ≥10^3 CFU/ml of any heat-resistant bacteria	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• ≥10^3 CFU/ml of any heat-resistant bacteria
MHMB18giv	• ≥10^4 CFU/ml of any heat-resistant bacteria	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• ≥10^4 CFU/ml of any heat-resistant bacteria
MHMB18gv	• ≥10^5 CFU/ml of any heat-resistant bacteria	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• ≥10^5 CFU/ml of any heat-resistant bacteria
MHMB18giv	• ≥10^6 CFU/ml of any heat-resistant bacteria	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• ≥10^6 CFU/ml of any heat-resistant bacteria

MHMB18hi	• any Pseudomonas	7	3	0	4	2	Agree	No consensus	No consensus		See MHMilkBank18	• any Pseudomonas
MHMB18hii	• ≥10^2 CFU/ml of Pseudomonas	1.5	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^2 CFU/ml of Pseudomonas
MHMB18hiii	• ≥10^3 CFU/ml of Pseudomonas	1.5	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^3 CFU/ml of Pseudomonas
MHMB18hiv	• ≥10^4 CFU/ml of Pseudomonas	2	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^4 CFU/ml of Pseudomonas
MHMB18hv	• ≥10^5 CFU/ml of Pseudomonas	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• ≥10^5 CFU/ml of Pseudomonas
MHMB18hiv	• ≥10^6 CFU/ml of Pseudomonas	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• ≥10^6 CFU/ml of Pseudomonas
MHMB18ji	• any Klebsiella	4.5	3	0	3	3	Uncertain	No consensus	No consensus		See MHMilkBank18	• any Klebsiella
MHMB18jii	• ≥10^2 CFU/ml of Klebsiella	1.5	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^2 CFU/ml of Klebsiella
MHMB18jiii	• ≥10^3 CFU/ml of Klebsiella	1.5	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^3 CFU/ml of Klebsiella
MHMB18jiv	• ≥10^4 CFU/ml of Klebsiella	2	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^4 CFU/ml of Klebsiella
MHMB18jv	• ≥10^5 CFU/ml of Klebsiella	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• ≥10^5 CFU/ml of Klebsiella
MHMB18jiv	• ≥10^6 CFU/ml of Klebsiella	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• ≥10^6 CFU/ml of Klebsiella
MHMB18ki	• any Proteus	4.5	3	0	3	3	Uncertain	No consensus	No consensus		See MHMilkBank18	• any Proteus
MHMB18kii	• ≥10^2 CFU/ml of Proteus	1.5	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^2 CFU/ml of Proteus
MHMB18kiii	• ≥10^3 CFU/ml of Proteus	1.5	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^3 CFU/ml of Proteus
MHMB18kiv	• ≥10^4 CFU/ml of Proteus	2	3	0	1	5	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^4 CFU/ml of Proteus
MHMB18kv	• ≥10^5 CFU/ml of Proteus	4	2	0	2	5	Uncertain	No consensus	No consensus		See MHMilkBank18	• ≥10^5 CFU/ml of Proteus
MHMB18kiv	• ≥10^6 CFU/ml of Proteus	7	1	0	2	6	Agree	No consensus	No consensus		See MHMilkBank18	• ≥10^6 CFU/ml of Proteus
MHMB18li	• any entero-pathogenic bacteria	7.5	2	0	4	3	Agree	No consensus	No consensus		See MHMilkBank18	• any entero-pathogenic bacteria
MHMB18lii	• ≥10^2 CFU/ml of any entero-pathogenic bacteria	2	2	0	1	6	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^2 CFU/ml of any entero-pathogenic bacteria
MHMB18liii	• ≥10^3 CFU/ml of any entero-pathogenic bacteria	3	2	0	1	6	Do not agree	No consensus	No consensus		See MHMilkBank18	• ≥10^3 CFU/ml of any entero-pathogenic bacteria

MHMB18liv	• ≥10^4 CFU/ml of any entero-pathogenic bacteria	7	1	0	2	6	Agree	No consensus	No consensus		See MHMilkBank18	• ≥10^4 CFU/ml of any entero-pathogenic bacteria
MHMB18lv	• ≥10^5 CFU/ml of any entero-pathogenic bacteria	7	1	0	2	6	Agree	No consensus	No consensus		See MHMilkBank18	• ≥10^5 CFU/ml of any entero-pathogenic bacteria
MHMB18liv	• ≥10^6 CFU/ml of any entero-pathogenic bacteria	7	1	0	2	6	Agree	No consensus	No consensus		See MHMilkBank18	• ≥10^6 CFU/ml of any entero-pathogenic bacteria

Round 1 – milk handling at the milk bank 2

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	Corrections made post meeting	GDG considerations	Recommendation for Round 2
MHMB19	Discard **samples for pasteurisation** that contain										It was agreed that samples should not tested for environmental contaminants or viruses, so these recommendations all fell.	Discard **samples for pasteurisation** that contain
MHMB19ai	• environmental or other contaminants	6.5	1	2	3	2	Agree	No consensus	No consensus		See MHMB19	…
MHMB19aii	o DDT concentrations	6	1	3	3	1	Uncertain	No consensus	No consensus		See MHMB19	…
MHMB19aiii	o water	5	3	3	2	0	Uncertain	No consensus	No consensus		See MHMB19	…
MHMB19aiv	o cow's milk	5	3	2	3	0	Uncertain	No consensus	No consensus		See MHMB19	…
MHMB19bi	• viral infection	6	2	1	2	3	Uncertain	No consensus	No consensus		See MHMB19	…
MHMB19bii	o CMV	4.5	4	1	3	0	Uncertain	No consensus	No consensus		See MHMB19	…
MHMB19biii	o MRSA	3	5	0	2	1	Do not agree	No consensus	No consensus		See MHMB19	…
MHMB19biv	o HIV	7	3	0	4	1	Agree	No consensus	No consensus		See MHMB19	…
MHMB19bv	o Semliki Forest virus	3	4	1	1	2	Do not agree	No consensus	No consensus		See MHMB19	…
MHMB19bvi	o herpes simplex virus	4	4	1	3	0	Uncertain	No consensus	No consensus		See MHMB19	…
MHMB19bvii	o coxsackie virus	5.5	2	2	2	2	Uncertain	No consensus	No consensus		See MHMB19	…
MHMB19bviii	o HTLV-1	6	3	1	3	1	Uncertain	No consensus	No consensus		See MHMB19	…
MHMB19bix	o hepatitis B	7.5	3	0	5	0	Agree	No consensus	No consensus		See MHMB19	…
MHMB19bx	o hepatitis C	7.5	3	0	5	0	Agree	No consensus	No consensus		See MHMB19	…

MHMB20	Pasteurise, or heat treat for	1	2	0	0	6	Do not agree	No consensus	Consensus		Pasteurisation is commonly used, and milk banks have considerable experience with this treatment process. The GDG considered whether they could recommend a variety of methods depending on the aims of treatment – for example, best bacterial safety whilst preserving most qualities.	Pasteurise, or heat treat for – give some variations on this
MHMB20a	• 56.0 degrees C for 30 minutes	1	4	0	0	4	Do not agree	No consensus	Consensus		See MHMB20	…
MHMB20b	• 57.5 degrees C for 30 minutes	1	4	0	0	4	Do not agree	No consensus	Consensus		See MHMB20	…
MHMB20c	• 56.0 degrees C for 33 minutes	1	4	0	0	4	Do not agree	No consensus	Consensus		See MHMB20	…
MHMB20d	• 57.5 degrees C for 33 minutes	1	4	0	0	4	Do not agree	No consensus	Consensus		See MHMB20	…
MHMB20e	• 62.0 degrees C for 30 minutes	2	4	0	0	4	Do not agree	No consensus	Consensus		See MHMB20	…
MHMB20f	• 62.5 degrees C for 5 minutes	3	5	0	0	3	Do not agree	No consensus	Consensus		See MHMB20	…

MHMB20g	• 62.5 degrees C for 30 minutes	8	1	0	5	2	Agree	No consensus	No consensus		There is a need to balance the temperature and the time. It may be appropriate to recommend a lower temperature to preserve the immunological components, but this may impact on the defined threshold for discarding milk. If the temperature is lower, then the time may need to be extended.	• 56 or 57 (+ or -) degrees C for 30 minutes
MHMB20h	• 63.0 degrees C for 30 minutes	7	1	0	4	3	Agree	No consensus	No consensus		See MHMB20	…
MHMB20i	• 65.0 degrees C for 30 minutes	3	2	0	1	5	Do not agree	No consensus	No consensus		See MHMB20	…
MHMB20j	• 72.0 degrees C for 10 seconds	5	1	1	1	5	Uncertain	No consensus	No consensus		See MHMB20	…
MHMB20k	• 72.0 degrees C for 15 seconds	5	1	1	1	5	Uncertain	No consensus	No consensus		See MHMB20	…
MHMB20l	• 90.0 degrees C for 10 minutes	2	2	1	0	5	Do not agree	No consensus	Consensus		See MHMB20	…
MHMB20m	• 100.0 degrees C for 5 minutes	1	2	1	0	5	Do not agree	No consensus	Consensus		See MHMB20	…
	Alternatively, treat using											Alternatively, treat using
MHMB21a	• heating to 105.0 degrees C, then freeze-thawing	2	3	0	0	5	Do not agree	No consensus	Consensus		The Dairy industry is using this method increasingly, but currently there is little evidence in its use in donor milk banks and it requires a high capital investment.	• heating to 105.0 degrees C, then freeze-thawing (RESEARCH REC – to be moved)

MHMB21b	• high-pressure	4.5	2	1	1	4	Uncertain	No consensus	No consensus		See MHMB21a	• high-pressure (RESEARCH REC – to be moved)
MHMB22a	**After treatment**, test • all samples	4.5	3	0	3	2	Uncertain	No consensus	No consensus	Median 2 7-9 2 D/K 3 **Corrected to Do not agree – NO con – NO con	Routine post pasteurisation also can check that samples have not been contaminated through leakage into the bottles and may identify some specific contamination.	**After treatment**, test • all samples

MHMB22b	• a random selection of samples	8	2	0	5	1	Agree	No consensus	No consensus	7-9 6 D/K 0 **Corrected to Agree – Con – NO con	A accurate pasteurisation log with some indicative testing should be enough to be confident that the process has worked. Testing should be done to check that the pasteurisation process has worked so levels of alkaline phosphatase and other indicator tests (bacterial) should be measured both routinely (as part of a defined quality control programme), and after any changes in the process, if there is any suspicion of problem or for a specific reason. The timing of the quality control testing should be based on volume and throughput.	• a random selection of samples
MHMB22c	• samples only once a week	1	4	1	0	3	Do not agree	No consensus	Consensus		The timing of the quality control testing should be based on volume and throughput.	• samples only once a week

MHMB22d	• samples only twice a month	1	4	0	1	3	Do not agree	No consensus	No consensus		The timing of the quality control testing should be based on volume and throughput.	• samples only twice a month
MHMB22e	• samples four times a year	1	5	0	0	3	Do not agree	No consensus	Consensus		The timing of the quality control testing should be based on volume and throughput.	• samples four times a year
MHMB22f	• 1 in 40 bottles	1	3	2	0	3	Do not agree	No consensus	Consensus		The timing of the quality control testing should be based on volume and throughput.	• 1 in 40 bottles
MHMB23	**After treatment**, test samples for										Testing should be done to check that the pasteurisation process has worked so levels of alkaline phosphatase and other indicator tests (bacterial) should be measured.	**After treatment**, test samples for
MHMB23a	• environmental or other contaminants	1	4	1	1	2	Do not agree	No consensus	No consensus		See MHMB23	…
MHMB23ai	o DDT concentrations	1	4	1	1	2	Do not agree	No consensus	No consensus		See MHMB23	…
MHMB23aii	o water	1	4	1	1	2	Do not agree	No consensus	No consensus		See MHMB23	…
MHMB23aiii	o cow's milk	1	3	1	1	3	Do not agree	No consensus	No consensus		See MHMB23	…
MHMB23bi	• viral infection	1	5	0	0	3	Do not agree	No consensus	Consensus		See MHMB23	…
MHMB23bii	o CMV	1	5	0	0	3	Do not agree	No consensus	Consensus		See MHMB23	…
MHMB23biii	o MRSA	1	5	0	0	3	Do not agree	No consensus	Consensus		See MHMB23	…
MHMB23biv	o HIV	1.5	5	0	1	2	Do not agree	No consensus	No consensus		See MHMB23	…

MHMB23bv	o Semliki Forest virus	1.5	5	0	1	2	Do not agree	No consensus	No consensus		See MHMB23	…
MHMB23bvi	o herpes simplex virus	1.5	6	0	0	2	Do not agree	No consensus	Consensus	**Corrected to Do not agree – CON – CON	See MHMB23	…
MHMB23bvii	o coxsackie virus	1.5	5	0	1	2	Do not agree	No consensus	No consensus		See MHMB23	…
MHMB23bviii	o HTLV-1	1.5	5	0	1	2	Do not agree	No consensus	No consensus		See MHMB23	…
MHMB23bix	o hepatitis B	2	5	1	0	2	Do not agree	No consensus	Consensus		See MHMB23	…
MHMB23bx	o hepatitis C	2	5	1	0	2	Do not agree	No consensus	Consensus		See MHMB23	…
MHMB23ci	• bacterial contamination	8	1	0	6	1	Agree	No consensus	No consensus	**Corrected to Agree – CON – CON	See MHMB23	…
MHMB23cii	o enteric pathogens	7.5	2	0	4	2	Agree	No consensus	No consensus		See MHMB23	…
MHMB23ciii	o pathogens with the potential to be enteric	7.5	2	0	4	2	Agree	No consensus	No consensus		See MHMB23	…
MHMB23civ	o non-pathogenic organisms	8	2	0	3	3	Agree	No consensus	No consensus		See MHMB23	…
MHMB23cv	o coliform bacteria	7.5	1	0	5	2	Agree	No consensus	No consensus		See MHMB23	…
MHMB23cvi	o saprophytic bacteria	8	2	0	3	3	Agree	No consensus	No consensus		See MHMB23	…
MHMB23cvii	o heat resistant bacillus	7.5	2	0	4	2	Agree	No consensus	No consensus		See MHMB23	…
MHMB23cviii	o from mastitis	2.5	4	0	2	2	Do not agree	No consensus	No consensus		See MHMB23	…
MHMB23cix	o Salmonella Kottbus	7.5	2	0	4	2	Agree	No consensus	No consensus		See MHMB23	…
MHMB23cx	o normal breast flora	2	5	0	2	1	Do not agree	No consensus	No consensus		See MHMB23	…
MHMB23cxi	o commensal skin flora	3	4	0	3	1	Do not agree	No consensus	No consensus		See MHMB23	…
MHMB23cxii	o Staph epidermis	5.5	3	0	3	2	Uncertain	No consensus	No consensus		See MHMB23	…
MHMB23cxiii	o Staph aureus	7.5	2	0	4	2	Agree	No consensus	No consensus		See MHMB23	…
MHMB23cxiv	o Staph albus	8	2	0	3	3	Agree	No consensus	No consensus		See MHMB23	…

MHMB23cxv	o viridans streptococci	8	2	0	3	3	Agree	No consensus	No consensus		See MHMB23	…
MHMB23cxvi	o diphtheroids	8	2	0	3	3	Agree	No consensus	No consensus		See MHMB23	…
MHMB23cxvii	o gram-negative rod	8	2	0	3	3	Agree	No consensus	No consensus		See MHMB23	…
MHMB23cxviii	o haemolytic streptococci	7.5	2	0	4	2	Agree	No consensus	No consensus		See MHMB23	…
MHMB23cxix	o Strep faecalis	7.5	2	0	4	2	Agree	No consensus	No consensus		See MHMB23	…
MHMB23cxx	o Pseud spp	7	2	1	3	2	Agree	No consensus	No consensus		See MHMB23	…
MHMB23cxxi	o Proteus spp	8	2	0	3	3	Agree	No consensus	No consensus		See MHMB23	…
MHMB23cxxii	o Enterobacteriecaea	7.5	1	0	5	2	Agree	No consensus	No consensus		See MHMB23	…
MHMB23cxxiii	o enterococci	8	2	0	3	3	Agree	No consensus	No consensus		See MHMB23	…
MHMB23cxxiv	o Klebsiella	8	2	0	3	3	Agree	No consensus	No consensus		See MHMB23	…
MHMB23cxv	o E coli	8	2	0	5	1	Agree	No consensus	No consensus		See MHMB23	…
MHMB23cxvi	o listeria	8	2	0	5	1	Agree	No consensus	No consensus		See MHMB23	…
MHMB23di	• nutritional factors	5	2	2	2	2	Uncertain	No consensus	No consensus	4-6 3 7-9 0 D/K 3 **Corrected to Uncertain – NO Con – Con	See MHMB23	…
MHMB23dii	o fat	5	2	3	2	1	Uncertain	No consensus	No consensus		See MHMB23	…
MHMB23diii	o caloric value (energy)	5	2	3	2	1	Uncertain	No consensus	No consensus		See MHMB23	…
MHMB23div	o carbohydrate	5	2	3	2	1	Uncertain	No consensus	No consensus		See MHMB23	…
MHMB23dv	o protein	5	2	3	2	1	Uncertain	No consensus	No consensus		See MHMB23	…
MHMB23dvi	o lactose	5	2	4	1	1	Uncertain	No consensus	No consensus		See MHMB23	…
MHMB23dvii	o vitamins	5	2	4	1	1	Uncertain	No consensus	No consensus		See MHMB23	…

MHMB23dviii	o minerals	5	3	3	1	1	Uncertain	No consensus	No consensus		See MHMB23	…
MHMB23dix	o sodium	5	3	3	1	1	Uncertain	No consensus	No consensus		See MHMB23	…
MHMB23dx	o zinc	5	3	3	1	1	Uncertain	No consensus	No consensus		See MHMB23	…
MHMB23dxi	o immunologic factors	5	2	4	1	1	Uncertain	No consensus	No consensus		See MHMB23	…
MHMB23dxii	o enzyme activity	5	2	3	1	2	Uncertain	No consensus	No consensus	4-6 4 D/K 1	See MHMB23	…
MHMB23e	• acidity	3.5	2	1	1	4	Uncertain	No consensus	No consensus		See MHMB23	…
MHMB23f	• alkaline phosphatase	5	2	2	2	2	Uncertain	No consensus	No consensus	1-3 1 D/K 3	See MHMB23	…
	Discard **samples after treatment** that contain											Discard **samples after treatment** that contain
MHMB24a	• any organisms	9	1	1	3	3	Agree	No consensus	No consensus	Median 7 1-3 2 D/K 2	**TO BE COMPLETED	…
MHMB24ai	• ≥10^2 CFU/ml of any organisms	8	2	0	3	3	Agree	No consensus	No consensus		**TO BE COMPLETED	…
MHMB24aii	• ≥10^3 CFU/ml of any organisms	8	1	0	4	3	Agree	No consensus	No consensus		**TO BE COMPLETED	…
MHMB24aiii	• ≥10^4 CFU/ml of any organisms	8	1	0	5	2	Agree	No consensus	No consensus		**TO BE COMPLETED	…
MHMB24aiv	• ≥10^5 CFU/ml of any organisms	9	1	0	4	3	Agree	No consensus	No consensus		**TO BE COMPLETED	…
MHMB24av	• ≥10^6 CFU/ml of any organisms	9	1	0	4	3	Agree	No consensus	No consensus		**TO BE COMPLETED	…
MHMB24bi	• any skin commensals	8	1	1	4	2	Agree	No consensus	No consensus		**TO BE COMPLETED	…
MHMB24bii	• ≥10^2 CFU/ml of skin commensals	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24biii	• ≥10^4 CFU/ml of skin commensals	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24biv	• ≥10^5 CFU/ml of skin commensals	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24bv	• ≥10^6 CFU/ml of skin commensals	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24biv	• ≥10^6 CFU/ml of skin commensals	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24ci	• any Staph aureus	8.5	0	1	5	2	Agree	No consensus	Consensus		**TO BE COMPLETED	…

MHMB24cii	• ≥10^2 CFU/ml of Staph aureus	8	0	0	4	4	Agree	No consensus	Consensus	Median 9 7-9 4 D/K 5	**TO BE COMPLETED	…
MHMB24ciii	• ≥10^4 CFU/ml of Staph aureus	9	0	0	3	5	Agree	No consensus	Consensus	7-9 4 D/K 4	**TO BE COMPLETED	…
MHMB24civ	• ≥10^5 CFU/ml of Staph aureus	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24cv	• ≥10^6 CFU/ml of Staph aureus	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24civ	• ≥10^6 CFU/ml of Staph aureus	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24di	• any gram-negative rod bacteria	8.5	1	0	5	2	Agree	No consensus	No consensus		**TO BE COMPLETED	…
MHMB24dii	• ≥10^2 CFU/ml of any gram-negative rod bacteria	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24diii	• ≥10^4 CFU/ml of any gram-negative rod bacteria	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24div	• ≥10^5 CFU/ml of any gram-negative rod bacteria	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24dv	• ≥10^6 CFU/ml of any gram-negative rod bacteria	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24div	• ≥10^6 CFU/ml of any gram-negative rod bacteria	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24ei	• any haemolytic streptococci	8.5	0	1	5	2	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24eii	• ≥10^2 CFU/ml of any haemolytic streptococci	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24eiii	• ≥10^3 CFU/ml of any haemolytic streptococci	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24eiv	• ≥10^4 CFU/ml of any haemolytic streptococci	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24ev	• ≥10^5 CFU/ml of any haemolytic streptococci	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24eiv	• ≥10^6 CFU/ml of any haemolytic streptococci	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24fi	• any Strep faecalis	8	0	1	6	1	Agree	No consensus	Consensus	**Corrected to Agree – CON - con	**TO BE COMPLETED	…
MHMB24fii	• ≥10^2 CFU/ml of Strep faecalis	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24fiii	• ≥10^3 CFU/ml of Strep faecalis	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…

MHMB24fiv	• ≥10^4 CFU/ml of Strep faecalis	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24fv	• ≥10^5 CFU/ml of Strep faecalis	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24fiv	• ≥10^6 CFU/ml of Strep faecalis	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24gi	• any heat-resistant bacteria	9	1	0	4	3	Agree	No consensus	No consensus		**TO BE COMPLETED	…
MHMB24gii	• ≥10^2 CFU/ml of any heat-resistant bacteria	7.5	0	2	2	4	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24giii	• ≥10^3 CFU/ml of any heat-resistant bacteria	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24giv	• ≥10^4 CFU/ml of any heat-resistant bacteria	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24gv	• ≥10^5 CFU/ml of any heat-resistant bacteria	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24giv	• ≥10^6 CFU/ml of any heat-resistant bacteria	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24hi	• any Pseudomonas	9	0	1	4	3	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24hii	• ≥10^2 CFU/ml of Pseudomonas	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24hiii	• ≥10^3 CFU/ml of Pseudomonas	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24hiv	• ≥10^4 CFU/ml of Pseudomonas	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24hv	• ≥10^5 CFU/ml of Pseudomonas	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24hiv	• ≥10^6 CFU/ml of Pseudomonas	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24ji	• any Klebsiella	9	0	1	4	3	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24jii	• ≥10^2 CFU/ml of Klebsiella	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24jiii	• ≥10^3 CFU/ml of Klebsiella	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24jiv	• ≥10^4 CFU/ml of Klebsiella	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24jv	• ≥10^5 CFU/ml of Klebsiella	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24jiv	• ≥10^6 CFU/ml of Klebsiella	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…

MHMB24ki	• any Proteus	9	0	1	4	3	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24kii	• ≥10^2 CFU/ml of Proteus	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24kiii	• ≥10^3 CFU/ml of Proteus	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24kiv	• ≥10^4 CFU/ml of Proteus	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24kv	• ≥10^5 CFU/ml of Proteus	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24kiv	• ≥10^6 CFU/ml of Proteus	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24li	• any entero-pathogenic bacteria	8.5	0	0	6	2	Agree	No consensus	Consensus	**Corrected to Agree – CON - con	**TO BE COMPLETED	…
MHMB24lii	• ≥10^2 CFU/ml of any entero-pathogenic bacteria	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24liii	• ≥10^3 CFU/ml of any entero-pathogenic bacteria	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24liv	• ≥10^4 CFU/ml of any entero-pathogenic bacteria	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24lv	• ≥10^5 CFU/ml of any entero-pathogenic bacteria	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB24liv	• ≥10^6 CFU/ml of any entero-pathogenic bacteria	9	0	0	3	5	Agree	No consensus	Consensus		**TO BE COMPLETED	…
	Discard **samples after treatment** that contain										**TO BE COMPLETED	…
MHMB25ai	• environmental or other contaminants	6	1	1	2	4	Uncertain	No consensus	No consensus		**TO BE COMPLETED	…
MHMB25aii	o DDT concentrations	6	1	2	2	3	Uncertain	No consensus	No consensus		**TO BE COMPLETED	…
MHMB25aiii	o water	3	2	2	0	4	Do not agree	No consensus	Consensus		**TO BE COMPLETED	…
MHMB25iv	o cow's milk	4	2	0	2	4	Uncertain	No consensus	No consensus		**TO BE COMPLETED	…
MHMB25bi	• viral infection	8.5	1	1	6	0	Agree	No consensus	No consensus	**Corrected to Agree – CON – no con	**TO BE COMPLETED	…
MHMB25bii	o CMV	8	1	1	5	1	Agree	No consensus	No consensus		**TO BE COMPLETED	…
MHMB25biii	o MRSA	8	1	1	5	1	Agree	No consensus	No consensus		**TO BE COMPLETED	…

MHMB25biv	o HIV	8	1	0	6	1	Agree	No consensus	No consensus	**Corrected to Agree – CON – no con	**TO BE COMPLETED	…
MHMB25bv	o Semliki Forest virus	8	1	0	6	1	Agree	No consensus	No consensus	**Corrected to Agree – CON – no con	**TO BE COMPLETED	…
MHMB25bvi	o herpes simplex virus	8	1	0	6	1	Agree	No consensus	No consensus	**Corrected to Agree – CON – no con	**TO BE COMPLETED	…
MHMB25bvii	o coxsackie virus	8	1	0	6	1	Agree	No consensus	No consensus	**Corrected to Agree – CON – no con	**TO BE COMPLETED	…
MHMB25bviii	o HTLV-1	8	1	0	6	1	Agree	No consensus	No consensus	**Corrected to Agree – CON – no con	**TO BE COMPLETED	…
MHMB25bvix	o hepatitis B	8	1	1	5	1	Agree	No consensus	No consensus		**TO BE COMPLETED	…
MHMB25bx	o hepatitis C	8	1	1	5	1	Agree	No consensus	No consensus		**TO BE COMPLETED	…
MHMB26a	Discard samples stored, **<u>post expression and post testing and treating</u>** • in the refrigerator for 1 day	1	4	1	0	3	Do not agree	No consensus	Consensus	7-9 1 D/K 2 **Corrected to Do not agree – no Con –NO con	…	Discard samples stored, **<u>post expression and post testing and treating</u>** • in the refrigerator immediately after pasteurisation and should be put in the freezer as soon as it has cooled to fridge temperature
MHMB26b	• in the refrigerator for 2 days	4	3	0	3	2	Uncertain	No consensus	No consensus		See MHMB26a	…

MHMB26c	• in the refrigerator for 3 days	5	3	0	3	2	Uncertain	No consensus	No consensus		See MHMB26a	…
MHMB26d	• in the refrigerator for 4 days	5	3	0	3	2	Uncertain	No consensus	No consensus		See MHMB26a	…
MHMB26e	• in the refrigerator for 5 days	7	3	0	4	1	Agree	No consensus	No consensus		See MHMB26a	…
MHMB26f	• in the freezer for 1 week	1.5	4	0	2	2	Do not agree	No consensus	No consensus		See MHMB26a	…
MHMB26g	• in the freezer for 2 weeks	1.5	4	0	2	2	Do not agree	No consensus	No consensus		See MHMB26a	…
MHMB26h	• in the freezer for 1 month	1	5	0	1	2	Do not agree	No consensus	No consensus		See MHMB26a	…
MHMB26i	• in the freezer for 2 months	1	5	0	1	2	Do not agree	No consensus	No consensus		See MHMB26a	…
MHMB26j	• in the freezer for 3 months	2	4	0	2	2	Do not agree	No consensus	No consensus		This links with the maximum of 3 months in the donor's home freezer to sum to a total of 6 months.	• in the freezer for 3 months
MHMB26k	• in the freezer for 4 months	2	4	0	2	2	Do not agree	No consensus	No consensus		See MHMB26a	…
MHMB26l	• in the freezer for 5 months	2	4	0	2	2	Do not agree	No consensus	No consensus		See MHMB26a	…
MHMB26m	• in the freezer for 6 months	7	3	0	4	1	Agree	No consensus	No consensus		See MHMB26a	…
MHMB27	Refrigerate samples for use.	2	5	2	1	0	Do not agree	No consensus	No consensus		See MHMB26a	…
MHMB28	Freeze samples for use.	8.5	1	0	7	0	Agree	Consensus	No consensus		See MHMB26a	…
MHMB29	Freeze-dry samples for use.	5	1	3	0	4	Uncertain	No consensus	Consensus		See MHMB26a	…
MHMB30	Before selecting for use, always choose the 'newest' samples first.	2	6	2	0	0	Do not agree	No consensus	Consensus	**Corrected to Do not agree – CON - con	…	Before selecting for use, generally choose the 'oldest' batches first.
MHMB31a	Milk should be processed using containers made of • glass	6	3	1	3	1	Uncertain	No consensus	No consensus		Concerns expressed about glass containers included the risk of chipping or cracking.	Milk should be processed using containers made of • glass

MHMB31b	• plastic	3	4	2	1	1	Do not agree	No consensus	No consensus		Concerns expressed about plastic containers included the risk of chipping or cracking. Also, not all plastic is food grade grade and polycarbonate contains bisphenol A.	• plastic
MHMB31c	• food-grade plastic	7	1	1	5	1	Agree	No consensus	No consensus		**TO BE COMPLETED	• food-grade plastic
MHMB31d	• any material that can withstand the necessary hot and cold temperatures	2	6	0	1	1	Do not agree	No consensus	No consensus	**Corrected to Do not agree – CON – no con	**TO BE COMPLETED	• any material that can withstand the necessary hot and cold temperatures
MHMB31e	• stainless steel	4	2	2	1	3	Uncertain	No consensus	No consensus		**TO BE COMPLETED	• stainless steel
	Containers and equipment should be											Containers and equipment should be
MHMB32a	• washed in cold, soapy water	1	6	0	1	1	Do not agree	No consensus	No consensus	**Corrected to Do not agree – CON – no con	See MHMB32e	…
MHMB32b	• washed in hot, soapy water	1	4	1	2	1	Do not agree	No consensus	No consensus		See MHMB32e	…
MHMB32c	• sterilized using sterilizing fluid	1	5	1	1	1	Do not agree	No consensus	No consensus		See MHMB32e	…
MHMB32d	• sterilized by heating in an oven	1	5	1	1	1	Do not agree	No consensus	No consensus		See MHMB32e	…
MHMB32e	• sterilized by autoclaving	8	0	0	7	1	Agree	Consensus	Consensus		…	• sterilized by autoclaving
MHMB32f	• disposed of after one use	5	2	1	2	3	Uncertain	No consensus	No consensus		See MHMB32e	…
MHMB32g	• washed in the dishwasher, if possible	2.5	3	3	0	2	Do not agree	No consensus	Consensus		See MHMB32e	…

MHMB33	Wear gloves at all times when handling donor milk.	9	1	1	6	0	Agree	No consensus	No consensus	**Corrected to Agree – CON – no con	Gloves are important to minimise contamination of the milk. Usual hospital practice is to change gloves between procedures and local infection control protocols should be followed.	Wear gloves at all times when handling donor milk. (TO Look at how often change the gloves & protective clothing in general. Infection control guideline?)

Round 1 – milk pooling

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	GDG considerations	Recommendation for Round 2
MPool1	Pool **raw** milk within donors (that is, milk from the same donor).	7.5	3	0	5	1	Agree	No consensus	No consensus	…	Pool **raw** (pre treated) milk within donors (that is, milk from the same donor).
MPool2	Pool **raw** milk between donors (that is, milk from different donors).	1	8	0	0	1	Do not agree	Consensus	Consensus	…	Do not pool **raw** milk between donors (that is, milk from different donors).
MPool3	Pool **treated** milk within donors (that is, milk from the same donor).	5.5	2	3	3	1	Uncertain	No consensus	No consensus	There are theoretical advantages to pooling (dilution of contaminants, more uniformity of milk etc) but because of tracking back, there is a widespread concern about pooling between donors. In the UK context of CJD and other as yet un-recognised risks, then there are justificable reasons not to pool. A general principle should be that donor exposure is limited for any recipient baby so that would automatically preclude pooling between donors. Ideally, milk banks should not pool the treated milk as this would involve opening containers and this could introduce contamination. But there may be occasions at feeding, where small amounts would be pooled post treatment.	Do not pool **treated** milk within donors (that is, milk from the same donor). Would be some occasions where may need to pool treated milk
MPool4	Pool **treated** milk between donors (that is, milk from different donors).	1	7	1	0	1	Do not agree	Consensus	Consensus	…	Do not pool **treated** milk between donors (that is, milk from different donors).
MPool5	Pool **all** milk within donors (that is, milk from the same donor).	1.5	5	2	1	1	Do not agree	No consensus	No consensus	Milk banks should never pool treated and untreated milk as would be completely illogical.	…

MPool6	Pool **all** milk between donors (that is, milk from different donors).	1	7	1	0	1	Do not agree	Consensus	Consensus	…	Do not pool **all** milk between donors (that is, milk from different donors).

Round 1 – fortification of donor milk

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	GDG considerations	Recommendation for Round 2
MFort1	Fortify all milk routinely.	The GDG agreed not to rate these recommendations as complete consensus and recommendations not relevant to this guideline.								Milk banks should not fortify milk as part of the processing of donor milk. Fortification of carbohydrates and proteins – when mixed with milk - increases osmolality over time and therefore should be added immediately before feeding. If a milk bank acts as a milk kitchen, then fortification would be done, but this is not within the process of milk banking. If milk is to be fortified this should only be done immediately prior to delivery – also the fortifiers may not be sterile, so again need to be done at the point of delivery, according to the manufacturers. The GDG did not recommend routine compositional testing as part of the process of milk banking, so fortification can only be prescribed by the neonatologists for the individual baby. In principle, milk banks should not be involved in adding anything to the milk, and to limit contamination, pasteurised bottles should not be opened until the point of feeding.	Donor breast milk, if fortified or other additives, should only be done so immediately prior to feeding. Do not open the lid until the point of delivery (feeding) this includes fortification or other additives.
MFort2	Fortify milk to match the content of the milk to the recipient.										(Milk Banks should not be responsible for adding anything to the milk)
MFort3	Fortify milk to match the nutritional content of the milk to the recipient.										…
MFort4	Fortify milk to match the immunological content of the milk to the recipient.										…
MFort5	Fortify milk without an analysis of the content of the milk.										…
MFort6	Fortify milk without a nutritional analysis of the content of the milk.										…
MFort7	Fortify milk without an immunological analysis of the content of the milk.										…

Round 1 – track and trace

See also the chapter on quality assurance principles for donor milk banking.

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	Changes made post meeting	GDG considerations	Recommendation for Round 2
MTrackTrace1	Do not systematically monitor milk samples so they can be tracked and traced.	1	8	0	0	1	Do not agree	Consensus	Consensus		There are two aims of the administration of milk samples • stock control • traceability If there was a barcoding system, this would do both tracking and tracing, and stock control. Currently this monitoring is done manually. And therefore we need to ensure that the track and trace and the QA documentation are linked and that there is a minimum of duplication of effort…	Monitor milk samples so they can be tracked and traced.
MTrackTrace2	Track and trace milk samples.	9	0	0	8	1	Agree	Consensus	Consensus		…	Track and trace milk samples.
MTrackTrace3	Track and monitor milk processing.	9	0	0	8	1	Agree	Consensus	Consensus		…	Track and monitor milk processing.

	Maintain and monitor the following:										…	Monitoring would include: freezer temperatures, pasteurisation, stock control
MTrackTrace4a	• a registry of 'raw' milk donors	9	0	0	8	1	Agree	Consensus	Consensus		(Not making recommendation on the use of 'raw' milk)	…
MTrackTrace4bi	• donor record	9	0	0	8	1	Agree	Consensus	Consensus		…	• donor record
MTrackTrace4bii	o medical record/NHS number	9	0	0	8	1	Agree	Consensus	Consensus		…	o medical record/NHS number
MTrackTrace4biii	o consent	9	0	0	8	1	Agree	Consensus	Consensus		…	o consent
MTrackTrace4biv	o medical history questionnaire	9	0	0	8	1	Agree	Consensus	Consensus		…	o medical history questionnaire
MTrackTrace4bv	o pathology results	9	0	1	7	1	Agree	Consensus	Consensus		…	o pathology results
MTrackTrace4ci	• labeling of each sample	9	0	0	6	3	Agree	No consensus	Consensus		…	• labeling of each sample Labeling pre/post pasteurisation: • Unique ID – each bottle should have one • That it is DBM • Batch number • Expiry date
MTrackTrace4cii	o donor identity	9	1	0	7	1	Agree	Consensus	No consensus		…	o donor identity (name or unique ID)
MTrackTrace4ciii	o details of medication (if taken)	6.5	2	2	4	1	Agree	No consensus	No consensus		…	…
MTrackTrace4civ	o date of expression	9	1	0	7	1	Agree	Consensus	No consensus		…	o date of expression
MTrackTrace4cv	o date of collection	9	1	1	6	1	Agree	No consensus	No consensus		…	…
MTrackTrace4cvi	o date of deposit	9	1	1	6	1	Agree	No consensus	No consensus		…	…
MTrackTrace4cvii	o date of bacteriologic clearance	9	2	0	6	1	Agree	No consensus	No consensus		…	…

MTrackTrace4cviii	o expiry date	9	0	0	8	1	Agree	Consensus	Consensus		…	
MTrackTrace4di	• testing log	9	1	0	5	3	Agree	No consensus	No consensus		…	• testing log
MTrackTrace4dii	o nutritional analysis	1	5	1	1	2	Do not agree	No consensus	No consensus		…	…
MTrackTrace4diii	o tests undertaken	9	0	0	8	1	Agree	Consensus	Consensus		…	o tests undertaken and results thereof
MTrackTrace4div	o results of testing before pasteurisation	9	0	1	7	1	Agree	Consensus	Consensus		…	…
MTrackTrace4dv	o results of testing after pasteurisation	9	0	1	7	1	Agree	Consensus	Consensus		…	…
MTrackTrace4ei	• labeling of each pool	9	0	0	6	3	Agree	No consensus	Consensus	7-9 5 D/K 4	…	…
MTrackTrace4eii	o between different donors	9	1	0	2	6	Agree	No consensus	No consensus	Median 5 7-9 5 D/K 7 **Corrected to Uncertain – No con – No con	…	…
MTrackTrace4eiii	o within individual donors	9	0	0	6	3	Agree	No consensus	Consensus	7-9 5 D/K 4	…	…
MTrackTrace4fi	• pasteurization undertaken	9	0	0	7	2	Agree	Consensus	Consensus		…	• pasteurization undertaken
MTrackTrace4fii	o details of the pasteurisation	9	0	1	7	1	Agree	Consensus	Consensus		…	o date of the pasteurisation
MTrackTrace4gi	• record of recipient use	9	0	0	6	3	Agree	No consensus	Consensus		…	• record of recipient use
MTrackTrace4gii	o sample(s) used	9	0	0	8	1	Agree	Consensus	Consensus		…	o sample(s) used
MTrackTrace4giii	o consent	9	0	1	7	1	Agree	Consensus	Consensus		…	o consent

MTrackTRace5	NEW recommendation										Record of recipient use should be documented in the patient's notes. The duty of care should be documented, at dispensing level (as with blood products)/. It is therefore the responsibility of the receiving hospital to document fully the recipient information (full audit trail).	It is the receiving hospital's responsibility to document the recipient
MTrackTRace6	NEW recommendation										…	Archiving samples – in line with blood bank milk banks should archive samples for look back and should consider working with blood banks – get advice from tissue banking – clinical expert: transfusional haematologist
MTrackTRace7	NEW recommendation										…	Each aliquot needs to be identified within an individual process and individual batch: At every key stage of the process Milk banks must be able to track back
MTrackTRace8	NEW recommendation										…	Records keeping: Data needed for full traceability shall be kept for a least 30 years and preferably up to ?

Round 1 – transportation

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	GDG considerations	Recommendation for Round 2

MHTrans1a	Transport milk for donation • refrigerated	6	3	3	3	0	Uncertain	No consensus	No consensus	The GDG recognized that they will accept refrigerated milk in some cases, so it does need to be transported, but frozen milk is preferred. Two issues are relevant here – the state and temperature and whether donations are transported by the designated 'carrier' from the milk bank or by the donor. It was recognized that processes used in tissue transportation would be expensive and may not be appropriate for donor milk– but the principle should be that there is demonstrable adherence to processes and that temperatures are monitored. Again, this links closely with the decisions made on pastuerisation, as if the recommended pasteurisation temperature is lowered, then we would need to be even more confident in the safety and monitoring during other stages – such as transport. Temperature is a surrogate marker and measuring only on receipt is not enough. Options include measurement and monitoring by probe. A good practice principle should be that the temperature should be stable – if arrives thawed should then be processed immediately – if reached ambient temp and only in 2 hours, then would process. As new services will be set up, we need to make sure that knowledge and practice are communicated.	Transport milk for donation Temperature should be kept stable (leave frozen and arrive frozen)

MHTrans1b	• frozen	9	0	0	9	0	Agree	Consensus	Consensus	After this discussion, the GDG agreed that only frozen milk should be accepted – this is because of the lack of evidence on transportation and the lack of good practice. So any donations should leave the donor's home frozen, arrive frozen at the milk bank, be labelled, and be frozen at any point. The consequences of moving to frozen milk alone are not substantial in the UK, and would improve the confidence in the safety. Some minimal amounts will be refused, and only those women who do not have access to any freezing facilities will not be able to donate.	• Milk which was previously frozen but arrives thawed should be processed
MHTrans1c	• at ambient temperature	1	8	1	0	0	Do not agree	Consensus	Consensus	See MHTrans1b	• Good practice principles should be adhered to
MHTrans1d	• in the state received	5	3	3	3	0	Uncertain	No consensus	No consensus	See MHTrans1b	• Label the milk with what state the milk was in when transported (frozen)
MHTrans2a	Transport milk from the donor's home • by air	5	2	1	2	4	Uncertain	No consensus	No consensus	Any mode of collection is acceptable as long as the recommended process is followed and monitored– so that the milk bank can be confident that quality is maintained.	Transport milk • by an appropriate means ensuring a temperature stable environment

MHTrans2b	• by package or parcel couriers	7.5	1	0	3	5	Agree	No consensus	No consensus	See MHTrans2a	…
MHTrans2c	• by taxi	6	2	1	2	4	Uncertain	No consensus	No consensus	See MHTrans2a	…
MHTrans2d	• using a designated milk bank vehicle	8	0	0	5	4	Agree	No consensus	Consensus	See MHTrans2a	…
MHTrans2e	• using a Trust or other car	8	0	1	4	4	Agree	No consensus	Consensus	See MHTrans2a	…
MHTrans2f	• any appropriate means.	9	1	1	7	0	Agree	Consensus	No consensus	Could transport using a 'responsible' person or system. May need additional guidance Need to ensure that the process is followed – so that quality is maintained.	• When transporting from a milk bank transport the milk in a frozen state
MHTrans3	Accept donations delivered by the donor, or her representative (partner, family member).	8	0	0	9	0	Agree	Consensus	Consensus	Any mode of collection is acceptable as long as the recommended process is followed and monitored– so that the milk bank can be confident that quality is maintained.	Accept donations delivered by the donor, or her representative (partner, family member).
MHTrans4	Employ a member of staff (not a nurse) to collect the milk.	7.5	0	0	8	1	Agree	Consensus	Consensus	Any mode of collection is acceptable as long as the recommended process is followed and monitored– so that the milk bank can be confident that quality is maintained.	Employ a member of staff (not a nurse) to collect the milk. Designated and agreed transport preferably a Medical courier, in cases where this is not possible, should use appropriate actions such as sign out when leaving and sign in when arriving
MHTrans5	Use volunteers to collect the milk.	7	1	0	8	0	Agree	Consensus	No consensus	See MHTrans3-4	…
MHTrans6	Employ a nurse to collect the milk.	6	4	1	4	0	Uncertain	No consensus	No consensus	See MHTrans3-4	…
MHTrans7	Collect the milk from the donor's home.	9	1	0	8	0	Agree	Consensus	No consensus	…	Collect the milk from the donor's home.

MHTrans8	Collect the milk from other designated places, such as a local grocery store.	5	3	2	4	0	Uncertain	No consensus	No consensus	…	Collect the milk from other designated places, such as a depot, which have practices in place to monitor the freezers and maintain the standards for quality control, storage and security.
MHTrans9a	Transport the milk in • styrofoam containers	8	0	2	5	2	Agree	No consensus	Consensus	…	Transport the milk in • styrofoam containers. British standard for cool boxes – look at this
MHTrans9b	• cooler boxes	8	0	2	5	2	Agree	No consensus	Consensus	See MHTrans9b	…
MHTrans9c	• tin pails	1	9	0	0	0	Do not agree	Consensus	Consensus	See MHTrans9b	…
MHTrans9d	• boxes insulated with crumpled newspaper	2	8	0	0	1	Do not agree	Consensus	Consensus	See MHTrans9b	…
MHTrans9e	• boxes packed with dry ice	8	0	2	5	2	Agree	No consensus	Consensus	See MHTrans9b	…
MHTrans9f	• any container that will maintain the milk at the appropriate temperature	9	1	2	6	0	Agree	No consensus	No consensus	See MHTrans9b	…
	Collect the milk										Collect the milk
MHTrans10a	• at least every day	2	9	0	0	0	Do not agree	Consensus	Consensus	See MHTrans10h	…
MHTrans10b	• at least every 2 days	3	8	0	1	0	Do not agree	Consensus	No consensus	See MHTrans10h	…
MHTrans10c	• at least every 5 days	3	8	1	0	0	Do not agree	Consensus	Consensus	See MHTrans10h	…
MHTrans10d	• at least every week	3	7	1	1	0	Do not agree	Consensus	No consensus	See MHTrans10h	…
MHTrans10e	• at least every 10 days	3	7	1	1	0	Do not agree	Consensus	No consensus	See MHTrans10h	…
MHTrans10f	• at least every 2 weeks	3	7	1	1	0	Do not agree	Consensus	No consensus	See MHTrans10h	…

MHTrans10g	• at least every month	7	3	1	5	0	Agree	No consensus	No consensus	See MHTrans10h	…
MHTrans10h	• as agreed with the donor	9	1	0	8	0	Agree	Consensus	No consensus	…	• as agreed with the donor (see in first set of recs) but at least within 3 months
MHTrans11	NEW recommendation									…	Processes should be put in place to ensure tamper evidence. Similar processes should be in place where the milk is stored. Fridges should meet the standards.

Round 1 – consent

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	GDG considerations	Recommendation for Round 2
Consent1	Obtain consent from each donor prior to accepting any donation.	9	0	0	9	0	Agree	Consensus	Consensus	It was not clear what consent means in this situation – is it implicit that consent on use is in the act of donation?	…
Consent2	Consent should include									There was general agreement that consent should be sought.	Obtain consent from donors before accepting milk, for:
Consent2a	• serological testing of the donor	9	0	0	9	0	Agree	Consensus	Consensus		• serological testing of the donor
Consent2b	• microbiological testing of donated milk	9	0	0	9	0	Agree	Consensus	Consensus		• microbiological testing of donated milk
Consent2c	• use of donated milk.	9	1	1	7	0	Agree	Consensus	No consensus	The GDG considered the model of tissue donation where donors generally make consent for 'any reasonable use' but additional consent is needed in 'rare' circumstances. For example, some milk donors may not wish their donations to be used in adults. The key is for milk banks to know the recipient population and therefore donors can give informed consent to that use.	• use of donated milk (the milk bank should explain clearly the intended use of the milk)
Consent3	[Milk banks should] Obtain consent from the recipient or their representative prior to use.	9	2	0	7	0	Agree	Consensus	No consensus	This was not considered to be the role of the milk bank – no recommendation was therefore made.	…

Consent4	Destroy records of consent after a donor stops donating.	1	8	1	0	0	Do not agree	Consensus	Consensus	The GDG agreed not to make a recommendation on this.	…

Round 1 – quality assurance

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	GDG considerations	Recommendation for Round 2
QA1	Follow quality assurance processes as agreed locally.	7	1	1	7	0	Agree	Consensus	No consensus	The GDG considered this wording to be too vague and consistency across milk banks is needed. Agreed to remove.	…
QA2	All persons involved in the processes of the donor milk bank should recognize the need for quality assurance with management ensuring a systematic approach towards quality and the implementation and maintenance of a quality system.	9	0	0	8	1	Agree	Consensus	Consensus	…	Milk banks should implement and maintain an agreed quality control system for processing milk which is followed by all staff.
QA3	Encompass quality management, quality assurance, continuous quality improvement, personnel, premises and equipment, documentation, collection, testing and processing, storage, distribution, quality control, batch recall, and external and internal auditing, non-conformance and self-inspection in any quality processes.	9	0	0	9	0	Agree	Consensus	Consensus	…	A quality control system for milk banks should encompass: • collection, testing, processing, storage and distribution • personnel, documentation, premises and equipment • batch recall, external and internal auditing, non-conformance and self-inspection • Continuous quality improvement.

QA4	Ensure that all critical processes are specified in appropriate instructions and are carried out in accordance with the standards and specifications set out in these principles. Management shall review the system at regular intervals to verify its effectiveness and introduce corrective measures if deemed necessary.	9	0	0	9	0	Agree	Consensus	Consensus	…	Milk banks should review their quality control system regularly and amend it if needed. Milk bank staff should be given clear written instructions to help them follow the system.
QA5	Use HACCP principles in any quality assurance process.	9	0	0	8	1	Agree	Consensus	Consensus	The Australian donor milk guidelines use HACCP as do the Italian guidelines… HACCP principles are general principles of safety used in food handling, so the concepts should not be new to staff trained in food handling. There was general support for the application of HACCP in milk banking as another process to ensure the safe handling and processing of donor milk.	Use HACCP principles in any quality assurance process agreed locally

Round 1 – test and treat

	RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	GDG considerations	Recommendation for Round 2
TT1	Advise women who test positive for HIV, hepatitis, or HPV that they should not donate milk.	9	0	0	9	0	Agree	Consensus	Consensus	…	Advise women who test positive for HIV, hepatitis, or HPV that they should not donate milk.
TT2	Test milk before treatment for any bacterial contamination, and discard if • total viable bacterial count is greater than 10^5/ml, or • count of Enterobacteriaceae is greater than 10^4/ml, or • count of Staph aureus is greater than 10^4/ml.	9	1	0	6	2	Agree	No consensus	No consensus	The general principle adopted was that contaminated milk from the mother is OK and safe, but this is more difficult to justify from a non-maternal source so stricter acceptance levels should be applied. The GDG noted however, that any acceptance criteria are arbitrary. The specified micro-organisms will be destroyed at the recommended treatment temperature. If levels of *Staph aureus* are very high, (above 10^5/ml) toxigenic problems may arise and therefore a lower level was specified; this is also consistent with food levels. Enterobacteriaceae – *salmonella, e coli* etc – may sometimes be pathogenic but will be destroyed by pasteurisation. There was general acceptance that a combination of TBC and a count of those which are recognised to be problematic in food borne illness would be appropriate (reflecting important contamination rather than simply poor processing).	Test milk before pasteurisation for bacterial contamination and discard it if: • total viable bacterial count is greater than 10^5/ml, or • count of Enterobacteriaceae is greater than 10^4/ml, or • count of Staph aureus is greater than 10^4/ml.
TT3	Microbiology labs should undertake further bacterial tests, as appropriate, if there is any concern about significant or unusual contamination.	9	0	0	9	0	Agree	Consensus	Consensus	…	Microbiology labs should undertake further bacterial tests if there is concern about significant or unusual contamination.

TT4	Cross refer to recommendation on supporting donors if consistently high levels of contamination.	9	0	0	9	0	Agree	Consensus	Consensus	…	Offer support to donors whose milk has consistently high levels of contamination (see recommendation XX).
TT5	Pasteurise milk for donation at 62.5 degrees C for 30 minutes.	9	0	0	8	1	Agree	Consensus	Consensus	…	Pasteurise milk for donation at 62.5 degrees C for 30 minutes.
TT6	Test milk post pasteurisation regularly. The testing schedule should be determined by the milk bank based on the volume and throughput of milk pasteurised.	9	0	1	8	0	Agree	Consensus	Consensus	The GDG raised concerns that if a failure of equipment was not noticed, then babies may be being fed milk with pathogens – this was not an acceptable risk to the baby and to milk banking in general. It was counter-argued that currently only one bottle per cycle is tested so testing in this way may not pick up a problem if there is a problem with the pasteuriser. However, if a full quality assurance process is in place, with appropriate monitoring post pasteurisation this would be the most effective and efficient way to ensure that the processed milk is safe.	Regularly test pasteurised milk for bacterial contamination. Milk banks should decide their testing schedule based on the volume and throughput of milk. Testing should occur: • either at least once a month or every 10 cycles, depending on which comes first, **and** • on an ad-hoc basis if any new processes, equipment or staff are introduced, or if there are concerns about any part of the process.
TT7	Test post pasteurisation either at least once a month, or every 10 cycles, depending on which comes first.	9	2	0	6	1	Agree	No consensus	Consensus	Added to TT6	…
TT8	Test on an ad-hoc basis if any new processes, equipment , or staff are introduced, or there are concerns about any part of the process.	9	1	1	7	0	Agree	Consensus	Consensus	Added to TT6	…
TT9	Discard any batch that has a total viable bacterial count of 10/ml or more post pasteurisation.	9	0	0	7	2	Agree	Consensus	Consensus	…	Discard milk that has a total viable bacterial count of 10/ml or more post-pasteurisation.

Round 1 – staff training

Recommendations were not rated for this section – we agreed to develop recommendations to address the training needs based on the final recommendations. These recommendations, although not rated, were circulated to the GDG and revisions made as appropriate.

Round 2 – all recommendations

For the final recommendations, including editorial changes (some of which are included in this version), please see the recommendations in the NICE guideline.

RECOMMENDATION	Median	1-3	4-6	7-9	D/K	Rec based on median	Consensus based on 75% rule	Consensus based on D9R	Evidence to recommendations	RECOMMENDATION post round 2 discussion
1.1 Donor recruitment									…	…
1.1.1 Aim to reach all potential breast milk donors including mothers who have surplus breast milk.	9	1	0	8	0	Agree	Consensus	No consensus	Agreed to remove final clause.	Aim to reach all potential breast milk donors.
1.1.2 Actively recruit donors through a variety of channels. This can include: • providing written information to be left in: ◊ GP surgeries ◊ antenatal clinics and postnatal wards ◊ volunteer or health-related organisations working in public health ◊ infant, children and maternity shops • through direct referrals or recommendations from: ◊ donors ◊ staff at Neonatal Units	9	1	0	8	0	Agree	Consensus	No consensus	There was some concern that mass media could be expensive and may not result in any increase in suitable donors. Refined to make clearer. The GDG viewed that this list may be helpful for new milk banks or those banks for whom recruitment is problematic.	Actively recruit donors through a variety of channels. This can include: • providing written information to be left in: o GP surgeries o antenatal clinics and postnatal wards o volunteer or health-related organisations working in public health

◊ attending paediatricians when assessing the progress of the infant ◊ health visitors (or other healthcare professionals providing postpartum care) ◊ childbirth educators ◊ organisers and attendees of pre- or post-natal classes ◊ nursing mothers' groups ◊ breastfeeding support or related organisations • through mass media contact, such as ◊ Newspaper,magazine articles, newsletters, and other written information ◊ TV and radio ◊ The Internet										o infant, children and maternity shops • through direct referrals or recommendations from: o donors o staff at Neonatal Units o attending paediatricians when assessing the progress of the infant o health visitors (or other healthcare professionals providing postpartum care) o childbirth educators o organisers and attendees of pre- or post-natal classes o nursing mothers' groups o breastfeeding support or related organisations • through features or article in the mass media

1.1.3	Use clear, non-technical language in any recruitment material or activities, to communicate the need for donor milk banking, and the process.	9	0	0	9	0	Agree	Consensus	Consensus	Revised to reflect usage of milk and process of operation.	Use clear, non-technical language in any recruitment material or activities, to communicate the purposes for which donor milk is used, and the process.
1.2	***Donor screening & selection***										
1.2.1	Follow the screening process outlined below when selecting donors. This should be based on a balanced consideration of relative risk for the infant.	9	1	0	6	2	Agree	No consensus	No consensus	Revised to note that the risk is about the recipient population, not the mother's own baby.	Follow the screening process outlined below when selecting donors. This should be based on a balanced consideration of relative risk for the recipient population.
1.2.2	Collect information from prospective donors on: • general health and medical history (including acute or chronic infections, recent vaccinations, blood transfusions) • the age and health of their baby • diet history and nutritional intake • The risk of (1) exposure to HIV (2) exposure to syphilis (3) exposure to hepatitis • any recent exposure to infectious diseases • any exposure to herpes • any public health risk of CJD (**TO ADD cross reference to DH guidance)	9	1	0	7	1	Agree	Consensus	No consensus	Information should be collected in a systematic way. However, there is variation in what information is collected and how this is collected. The purpose of collecting this information is to exclude some potential donors. The GDG agreed to allow the technical to restructure these recommendations to allow self-screen, screen with support, and screen during donation The criterion on the age/health of baby was removed as it	Collect information from prospective donors using a systematic checklist to confirm that she is in good general health and that none of the exclusions listed below apply. Exclude from donation women who: • Currently smoke or use NRT • Recent or current recreational drug use • Tested positive to (screening e.g HIV, hepatitis) • At public health risk for CJD(add link) The following should be discussed and may

	• medication use • any medical treatment (other than medication use) • **TO ADD rec on communication in the event of chemical exposure? • alcohol intake • smoking • ?substance misuse/'recreational' drug use									was not clear how this relates to milk safety and composition (but there may be some components, such as zinc, which change in significant levels) – so this was removed.	be excluded: • Alcohol intake – check DH guidance • Exclusion diets • Passive smoking • medication (as there are some that will exclude you from being a donor) • environmental or chemical exposure • risk factors including needle stick injuries, life style factors, tattoos etc etc Refer to guidance from the DH on the safety of recent vaccination in breastfeeding for women who are potential donors (www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917).
1.2.3	If donations of previously expressed breast milk are to be accepted, screen donors as usual; screening questions should be answered retrospectively.	9	1	0	8	0	Agree	Consensus	No consensus	…	If donations of previously expressed breast milk are to be accepted, screen donors as usual; screening questions should be answered retrospectively.

1.2.4	Use the following tests for screening prospective milk donors: • HIV 1 & 2 antigen/antibody test • HBsAg and anti-HBc blood test , anti hep c antibodies (for hepatitis) • HPVL • a test for anti-treponemal antibodies (for sexually transmitted diseases, specifically syphilis)	9	0	1	8	0	Agree	Consensus	Consensus	Related to hepatitis C– the initial screening will exclude those at recent high risk, and then a good history would exclude more. The current prevalence is low and therefore it is not clear that additional testing for hepatitis C is needed –other than the antibody test.	Use the following tests for screening prospective milk donors: • HIV 1 & 2 antigen/antibody test • HBsAg and anti-HBc blood test , anti hep c antibodies (for hepatitis) • HTLV 1 & 2 • a test for anti-treponemal antibodies (for sexually transmitted diseases, specifically syphilis)
1.2.5	Perform all tests at the time of enrolling for donor milk banking, even where results from antenatal tests are available. Delay testing for 3 months if a donor provides a one-off donation during which time their milk should be quarantined.	9	0	1	8	0	Agree	Consensus	Consensus	This 3 months is based on the seroconversion over this period.	Perform all tests at the time of enrolling for donor milk banking, even where results from antenatal tests are available. Delay testing for 3 months (or sooner if local protocols allow) if a donor provides a one-off donation during which time their milk should be quarantined.
1.2.6	Explain that testing is mandatory and the reason for testing (to minimise risks to the recipient baby) to every mother when she first contacts the milk bank about donating milk and seek informed consent before testing.	9	0	0	9	0	Agree	Consensus	Consensus	…	Explain that testing is mandatory and the reason for testing (to minimise risks to the recipient population) to every mother when she first contacts the milk bank about donating milk and seek informed consent before testing.
1.2.7	Communicate all test results verbally, either	9	0	0	9	0	Agree	Consensus	Consensus	…	Communicate all test results verbally, either

	in person at a follow-up appointment or via a telephone call, or in writing depending on the preference of the woman and in accordance with local protocols. Where appropriate and in accordance with local protocols, offer counselling and/or information on local support groups.										in person at a follow-up appointment or via a telephone call, or in writing depending on the preference of the woman and in accordance with local protocols. Where appropriate and in accordance with local protocols, offer counselling and/or information on local support groups.
1.2.8	Inform women who are positive for HIV infection that they are unable to donate breast milk.	9	1	1	7	0	Agree	Consensus	No consensus	…	See 1.2.2
1.2.9	Refer to guidance from the DH on the safety of recent vaccination in breastfeeding for women who are potential donors (www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917).	9	0	0	9	0	Agree	Consensus	Consensus	…	See 1.2.2
1.2.10	Inform women who have received live vaccinations that they should not donate breast milk in the month after their vaccination.	9	2	0	7	0	Agree	Consensus	No consensus	DELETE as covered in 1.2.9 above	…
1.2.11	Do not repeat tests while the woman continues to donate milk. When donation stops repeat tests 3 months after stopping.	5.5	2	2	2	3	Uncertain	No consensus	No consensus	The risk is that if screened initially, the donor may seroconvert in the window between testing and conversion. Some milk banks quarantine the milk	Do not routinely repeat tests while the woman continues to donate milk.

										until it can be proven that this is not the case. If the testing system is improved, this period can be reduced to days (and it takes this long to express in milk) – however, there is a cost implication. The time period therefore depends on the tests used. However, it was agreed that additional testing is not required if adequate pasteurization is done.	
1.2.12	Collect information for screening from the donor, as well as from medical sources if necessary, using a combination of informal interview and questionnaire	9	1	0	8	0	Agree	Consensus	No consensus	…	Collect information for screening from the donor, referring to medical sources if necessary (with consent from the prospective donor), using a combination of informal interview and questionnaire
1.2.13	If possible, the questionnaire and/or interview should be conducted at a place suitable to both parties.	9	2	0	7	0	Agree	Consensus	No consensus	…	If possible, the questionnaire and/or interview should be conducted at a mutually acceptable time and place.
1.3	***Donor Training and Support***										
1.3.1	Train donors in the proper techniques for	9	0	0	9	0	Agree	Consensus	Consensus	…	Train donors in the importance of and

	• milk collection and expression, including the use of pumps and containers and their cleaning • milk storage, including the cooling and freezing of milk • personal hygiene, including cleaning of the hands and breasts • administration of milk donations, such as the labelling of stored samples.										proper techniques for • milk collection and expression, including the cleaning and use of pumps and containers • milk storage, including the cooling and freezing of milk • personal hygiene, including cleaning of the hands and breasts • labelling and documentation of milk donations • transportation of donations
1.3.2	Provide information to donor women on • diet • alcohol consumption • caffeine consumption	9	1	1	7	0	Agree	Consensus	No consensus	…	Provide information to donor women on milk bank requirements for their • diet • alcohol consumption • caffeine consumption
1.3.3	Provide donors with training, either face-to-face or by telephone, and offer supplementary written information. • Arrange training at a time and place	9	0	0	8	1	Agree	Consensus	Consensus	…	Provide donors with training, either face-to-face or by telephone, and offer supplementary written information. Arrange training at a time and place

	suitable for both donor and trainer.										suitable for both donor and trainer.
1.3.4	Provide ongoing support to all donors until no longer required. Support may include • continued support for the collection of milk and the maintenance of lactation • emotional support.	9	0	0	9	0	Agree	Consensus	Consensus	…	Provide ongoing individualised support to all donors until no longer required. Support may include • continued support for the collection of milk and the maintenance of lactation • emotional support.
1.3.5	Provide ongoing, individualised contact and feedback to all donors.	9	1	0	8	0	Agree	Consensus	No consensus	DELETE, as added to 1.3.4	…
1.3.6	Offer additional information and support on domiciliary milk collection if bacterial contamination is significant and repeated.	9	0	0	9	0	Agree	Consensus	Consensus	…	Offer additional information and support on milk collection if bacterial contamination is significant and repeated.
1.4	***Donor stopping***										
1.4.1	Consider no longer accepting milk from donors who supply • milk that does not meet the microbiological criteria despite support • small amounts of milk	9	0	1	8	0	Agree	Consensus	Consensus	It is not possible to define 'small' as is dependent on the milk bank, and its throughput.	Consider no longer accepting milk from donors who supply • milk that does not meet the microbiological criteria despite support • small amounts of milk
1.4.2	Advise women that if they develop a	9	0	0	9	0	Agree	Consensus	Consensus	…	Advise women that if they develop a

	temperature or have contact with other exanthema, to contact the milk bank to discuss temporary suspension of milk donation.										temperature or have contact with other exanthema, to contact the milk bank to discuss temporary suspension of milk donation.
1.4.3	Advise donors who begin taking medication that they should contact the milk bank to discuss temporary suspension of milk donation.	9	0	0	9	0	Agree	Consensus	Consensus	…	Advise donors who begin taking medication that they should contact the milk bank to discuss suspension or cessation of milk donation. (add the list of medication/treatments)
1.4.4	Advise donors to contact the milk bank if they: • have breast lesions or infection (including mastitis) such as herpes, to discuss temporary suspension of milk donation • have seen changes in the colour or consistency of the milk • have had vaccinations • no longer meet the initial recruitment criteria.	9	0	0	9	0	Agree	Consensus	Consensus	…	Advise donors to contact the milk bank if they: (merge some of the recs e.g. develop a temp) • have breast lesions or infection (including mastitis, herpes) to discuss temporary suspension of milk donation • no longer meet the initial recruitment criteria.
1.4.5	Local policies should be set up to define when donors should be advised to stop donating milk based on the age of their own baby; this should be based on the age of recipient population.	9	1	2	5	1	Agree	No consensus	No consensus	This is a practical issue- and milk banks should decide this for themselves.	Local policies should be set up to define when donors should be advised to start and stop donating milk based on local practical considerations.

1.5	***Milk expression at home for donation***										
1.5.1	Advise donors to collect expressed rather than drip milk for donation; if donors do produce drip milk, advise them to keep it separate from expressed milk.	9	0	0	9	0	Agree	Consensus	Consensus	…	Advise donors to collect expressed rather than drip milk for donation.
1.5.2	Actively encourage donors to hand-express milk; however pump-expressed milk should be accepted if donors prefer this method.	9	0	0	8	1	Agree	Consensus	Consensus	…	Actively encourage donors to hand-express milk; however pump-expressed milk should be accepted if donors prefer this method.
1.5.3	Provide advice and support on stopping expressing milk to donors as required.	9	0	0	8	1	Agree	Consensus	Consensus	…	Provide advice and support on stopping expressing milk to donors as required.
1.6	***Milk handling at home***									…	
1.6.1	Advise donors that all expressed milk for donation should:										Advise donors that all expressed milk for donation should:
	• be frozen immediately after expression	8	2	1	5	1	Agree	No consensus	No consensus	…	• be frozen as soon as possible but within 24 hours after expression
	• not be left uncovered.	9	0	0	9	0	Agree	Consensus	Consensus	DELETE as would be covered in hygiene training	…
1.6.2	Advise donors to: • freeze individual samples **or** • refrigerate samples collected over 24 hours if necessary (for example, because of storage capacity), then	9	0	0	7	2	Agree	Consensus	Consensus	…	Advise donors to: • freeze individual samples or • refrigerate samples collected over 24 hours if necessary (for example,

	freeze the batch.										because of storage capacity), then freeze the batch.
1.6.3	Advise donors that expressed milk for donation can be stored for: • up to 2 weeks in the freezer compartment of a fridge before transport to the milk bank **or** • up to 3 months in a domestic freezer, at minus 18ºC or lower.	9	0	0	9	0	Agree	Consensus	Consensus	…	Advise donors that expressed milk for donation can be stored for: • up to 2 weeks in the freezer compartment of a fridge before transport to the milk bank or • up to 3 months in a domestic freezer, at minus 18ºC or lower.
1.6.4	Advise donors that expressed milk can only be accepted by the milk bank if it has been collected and stored in containers provided by the milk bank. For one-off donations, the milk should be in containers specifically designed for the collection of breast milk.	9	1	0	8	0	Agree	Consensus	No consensus	…	Advise donors that expressed milk can only be accepted by the milk bank if it has been collected and stored in containers provided by or acceptable to the milk bank. For one-off donations, the milk should be in containers specifically designed for the collection of breast milk.
1.6.5	Advise donors that collection containers should be used as received from the milk bank.	8.5	0	1	7	1	Agree	Consensus	Consensus	…	Advise donors that collection containers should be used according to instructions from the milk bank.
1.7	***Milk handling at the milk bank***										
1.7.1	Process all milk under hygienic conditions (a full sterile environment is not necessary).	9	0	0	9	0	Agree	Consensus	Consensus	…	Process all milk under hygienic conditions (a sterile environment is not necessary).

1.7.2	On receiving milk at the milk bank, transfer all samples immediately to the freezer.	9	1	0	7	1	Agree	Consensus	No consensus	…	On receiving milk at the milk bank, check to ensure they are labeled correctly and in good condition, then transfer all samples immediately to the freezer.
1.7.3	Do not store: • frozen samples direct from the donor in the same freezer as pasteurised samples. • refrigerated samples direct from the donor in the same fridge as thawed, pasteurised samples.	9	0	0	9	0	Agree	Consensus	Consensus	REMOVE refrigerated as only accepting frozen milk, and reworded to show that raw and treated milk would not be mixed.	Do not store: • frozen samples direct from the donor in the same freezer as pasteurised samples. • refrigerated raw samples in the same fridge as thawed, pasteurised samples.
1.7.4	Examine samples from the donor for appearance, and discard any samples which raise safety concerns.	8.5	0	1	7	1	Agree	Consensus	Consensus	There is a perception that appearance does indicated quality – however, this is not evidence based. But gross changes in colour and solid contaminants may raise concerns but it was not possible to define these, so it was agreed to remove the recommendation.	…
1.7.5	Discard samples from donors who subsequently fail to meet selection criteria.	9	0	1	8	0	Agree	Consensus	Consensus	…	Discard samples from donors who subsequently fail to meet selection criteria.
1.7.6	Store samples awaiting testing in the	9	0	0	6	3	Agree	No consensus	Consensus	Milk needs to be used within 6 months of	Store samples awaiting testing in the freezer for no longer than 3 months from

	freezer for no longer than 3 months.									expression (stored in a freezer) and this should be pasteurized at 3 months at the latest after expression. One-off donations are pasteurized immediately (this then allows 3 months for testing) – stock control is therefore paramount.	the date of expression.
1.7.7	Thaw samples by: • using a temperature-controlled environment such as a water bath (electric) or refrigerator	8	1	1	6	1	Agree	No consensus	No consensus	…	Milk should be completely thawed before pasteurization but should not be allowed to reach room temperature (above 8 degrees). This is best achieved by placing in the refrigerator.
	• leaving in the refrigerator	8	1	1	6	1	Agree	No consensus	No consensus	…	…
	• leaving out to reach room temperature.	8	2	1	5	1	Agree	No consensus	No consensus	…	…
1.7.8	Before pasteurisation, test all samples in batches.	9	0	1	7	1	Agree	Consensus	Consensus	Some milk banks test all samples then test before batching – others do this the other way round. All milk should be tested before pasteurisation, but it will differ by milk bank whether it is more cost effective to treat each sample and batch	Before pasteurisation, test the milk

										only those which pass or batch up then discard a whole batch if failed.	
SEE section below on testing and treating											
1.7.9	After testing and treating, store milk batches immediately in the refrigerator. Move batches to the freezer as soon as fridge temperature is reached, and store for up to 3 months. • in the refrigerator immediately and move to the freezer as soon as fridge temperature is reached • in the freezer for up to 3 months.	8	0	2	7	0	Agree	Consensus	Consensus	The principle adopted was that milk should be cooled before removal from the pasteurizer (below 10 degrees) but there is no clear evidence for this. However, if milk can be cooled as soon as possible, then the growth of spores should be minimized.	After testing and pasteurising, cool the milk to refrigeration temperature (4 degrees) . Move batches to the freezer as soon as fridge temperature is reached, and store for up to 3 months. • in the refrigerator immediately and move to the freezer as soon as fridge temperature is reached • in the freezer for up to 3 months.
1.7.10	When selecting milk for use, generally choose the oldest batches first.	9	0	0	9	0	Agree	Consensus	Consensus	Agreed to delete	…
1.7.11	Milk should be processed using containers made of • glass • plastic • food-grade plastic • any material that can withstand the necessary hot and cold temperatures • stainless steel.	7.5	1	1	2	5	Agree	No consensus	No consensus	…	Milk should be processed using food grade materials.

1.7.12	Containers and equipment should be sterilized by autoclaving.	9	1	2	4	2	Agree	No consensus	No consensus	This should be by following HCAPP principles – see quality assurance section	Containers and equipment should be cleaned and stored according to local HACCP principles. (?remove and have a section on the HCAPP principles)
1.7.13	Wear gloves at all times when handling donor milk.	9	0	0	9	0	Agree	Consensus	Consensus	…	Wear gloves at all times when handling donor milk.
Pooling of milk											
1.7.14	Pool all pre-treated milk derived from the same donor. Do not pool: • milk from different donors • batches of treated milk from the same donor.	9	0	1	6	2	Agree	No consensus	Consensus	…	Only pool all pre-pasteurised milk derived from the same donor. Do not pool: • milk from different donors • batches of treated milk from the same donor.
Milk fortification											
1.7.15	Do not open the lid of batches of treated milk until the point of delivery (feeding); this includes when adding fortifiers or other additives.	9	0	2	7	0	Agree	Consensus	Consensus	…	Do not open the lid of batches of treated milk until the point of delivery (feeding);
1.7.16	Milk banks should not be responsible for adding anything to the milk.	9	0	1	8	0	Agree	Consensus	Consensus	…	Milk banks should not be responsible for adding anything to the milk. Fortifiers and other additives should only be added at the

											point of delivery.
Tracking and tracing											
1.7.17	Monitor milk samples so they can be tracked and traced.	9	1	1	7	0	Agree	Consensus	No consensus	…	…
1.7.18	Track and trace milk samples.	9	1	0	8	0	Agree	Consensus	No consensus	Tacking should stop at delivery but there need to be information processes to facilitate and allow track back if needed. If milk banks are supplying their own unit, the tracking and tracing circle would be complete. But this would not be the case in the supply of milk to external units.	…
1.7.19	Track and monitor milk processing, including freezer temperatures, pasteurization processes, and stock control.	9	0	0	8	1	Agree	Consensus	Consensus	…	Ensure traceability by tracking the milk from the donor through to the recipient hospital. Track and monitor milk processing, including freezer temperatures, pasteurization processes, and stock control.
1.7.20	Document the following information about each sample: • donor records	9	0	0	9	0	Agree	Consensus	Consensus	…	Document the following information about each sample:

	– medical record/NHS number – consent – medical history questionnaire – pathology results – labelling of each sample • testing log, including tests undertaken and their results • pasteurisation details, including date of the pasteurisation • record of recipient use – sample(s) used – consent										• donor records • medical record/NHS number • consent • medical history questionnaire • pathology results • labelling of each sample • testing log, including tests undertaken and their results • pasteurisation details, including date of the pasteurisation • record of receiving unit
1.7.21	Label each container (either a sample or a batch) with the following information: – an identification number that is unique to every bottle – a statement that it contains donor breast milk – batch number – expiry date – donor identity (name or unique	9	1	1	5	2	Agree	No consensus	No consensus	…	Label each pasteurised container with the following information: • an identification number that is unique to every bottle • a statement that it contains pasteurised donor breast milk • expiry date.

	identification number) – date of expression.										
1.7.22	It should be the receiving hospital's responsibility to document the recipient use.	9	0	0	9	0	Agree	Consensus	Consensus	…	It should be the receiving hospital's responsibility to document the recipient use.
1.7.23	Archiving samples – in line with blood bank milk banks should archive samples for look back and should consider working with blood banks – get advice from tissue banking – clinical expert: transfusional haematologist	9	0	1	6	2	Agree	No consensus	Consensus	The GDG asked the technical team to cross refer to relevant guidance for the transfusion service or other relevant sources. This was done and revised for the final guideline.	See NICE recommendations
1.7.24	There should be a process to identify each aliquot within any individual process and individual batch.	9	0	0	9	0	Agree	Consensus	Consensus	…	There should be a process to identify each aliquot within any individual process and individual batch. Change wording to reflect the suggestion
1.7.25	At every stage of the process, milk banks should be able to track back to the donor or donors for each sample or batch.	9	0	0	9	0	Agree	Consensus	Consensus	…	…
1.7.26	Data needed for full traceability should be kept for at least 30 years and preferably up to XX.	8.5	0	1	5	3	Agree	No consensus	Consensus	The GDG asked the technical team to cross refer to relevant guidance for the transfusion service or other relevant sources. This was done and revised for the final guideline.	See NICE recommendations

1.8	***Milk handling during transportation***										
1.8.1	Transport frozen milk by an appropriate means to ensure a temperature-stable environment.	9	0	0	9	0	Agree	Consensus	Consensus	…	Whenever transporting frozen milk by an appropriate means to ensure a temperature-stable environment.
1.8.2	Label the milk with its initial state (which should be frozen) when collected	8.5	1	2	5	1	Agree	No consensus	No consensus	The aim is to ensure that the collected milk is frozen and has been handled according to the agreed process, labeled and documentation is provided from the donor on amount, first and last dates.	. Provide donor with means to make daily checks on the freezer temperature and be able to document this. All samples are labelled, dates etc.
1.8.3	Donations that are delivered to the milk bank should be delivered either by the donor herself or a representative, for example a partner or family member.	8.5	0	2	6	1	Agree	No consensus	Consensus	REMOVE	…
1.8.4	If needed, use a member of staff (not necessarily a nurse) to collect the milk. Alternatively, use a designated and agreed transport provider, preferably a medical courier. In cases where this is not possible, should use appropriate actions such as sign out when leaving and sign in when arriving.	9	0	0	9	0	Agree	Consensus	Consensus	…	If needed, use a member of staff (not necessarily a nurse) to collect the milk. Alternatively, use a designated and agreed transport provider, preferably a medical courier. In cases where this is not possible, should use appropriate actions such as sign out when leaving and sign in when arriving.
1.8.5	Collect the milk from the donor's home.	8	1	0	8	0	Agree	Consensus	No consen	COMBINED with below, allowing	…

									sus	anywhere suitable for the donor	
1.8.6	Collect the milk from other designated places if necessary, such as a depot that has practices in place to monitor the freezers and maintain standards for quality control, storage and security.	9	0	0	9	0	Agree	Consensus	Consensus	…	Collect the milk from the donor's home or from other designated places if necessary, such as a depot that has practices in place to monitor the freezers and maintain standards for quality control, storage and security. Similar processes should be in place where the milk is stored. Freezers should meet the standards
1.8.7	Transport the milk in styrofoam containers that meet the relevant British standards.	9	0	0	8	1	Agree	Consensus	Consensus	Link to relevant blood standard – and would allow for large enough quantities to be transported.	Transport the milk in containers fit for purpose that meet the relevant British standards. (check what is used for transporting blood – need to maintain temperature and hygiene) Processes should be put in place to ensure tamper evidence
1.8.8	Agree with the donor a suitable time to collect the milk, but this should be within 3 months of its expression.	8.5	0	0	8	1	Agree	Consensus	Consensus	REMOVE	…
1.8.9	Processes should be put in place to ensure tamper evidence. Similar processes should be in place where the milk is stored. Fridges should meet the standards.	9	0	0	8	1	Agree	Consensus	Consensus	REMOVE	…
1.9	***Donor consent***										

1.9.1	Obtain consent from donors before accepting milk, for:									…	Before accepting her milk, obtain consent from the donor, for:
•	serological testing of the donor	9	0	0	9	0	Agree	Consensus	Consensus	…	• serological testing
•	microbiological testing of donated milk	9	0	1	8	0	Agree	Consensus	Consensus	…	• the processing and intended use of the donated milk.
•	use of donated milk (the milk bank should explain clearly the intended use of the milk)	9	0	1	8	0	Agree	Consensus	Consensus	…	…
1.10	***Testing and treating donor milk***										
1.10.1	Advise women who test positive for HIV, hepatitis, or HPV that they should not donate milk.	9	0	0	8	1	Agree	Consensus	Consensus	See rec 1.2.2	…
1.10.2	Test milk before treatment for any bacterial contamination, and discard if • total viable bacterial count is greater than 10^5/ml, or • count of Enterobacteriaceae is greater than 10^4/ml, or • count of Staph aureus is greater than 10^4/ml.	9	0	2	6	1	Agree	No consensus	Consensus	…	Before pasteurisation, test the milk for bacterial contamination and discard if the: • total viable bacterial count is greater than 10^5/ml, or • count of Enterobacteriaceae is greater than 10^4/ml, or • count of Staph aureus is greater than 10^4/ml.
1.10.3	Microbiology labs should undertake further bacterial tests, as appropriate, if there is any concern about significant or unusual contamination.	9	0	1	8	0	Agree	Consensus	Consensus	…	Microbiology labs should undertake further bacterial tests if there is any concern about significant or unusual contamination.
NEW											When milk banks request bacterial tests, laboratories should communicate the results clearly in terms of values,

											interpretation and recommended action.
1.10.4	Cross refer to recommendation on supporting donors if consistently high levels of contamination.	9	0	0	9	0	Agree	Consensus	Consensus	…	Offer support to donors whose milk has consistently high levels of contamination (see recommendation XX).
1.10.5	Pasteurise milk for donation at 62.5 degrees C for 30 minutes.	9	0	0	9	0	Agree	Consensus	Consensus	…	Pasteurise milk for donation at 62.5 degrees C for 30 minutes.
1.10.6	Test milk post pasteurisation regularly. The testing schedule should be determined by the milk bank based on the volume and throughput of milk pasteurised.	9	2	0	7	0	Agree	Consensus	No consensus	It was recognized that this recommendation would set a minimum testing schedule, and that milk banks could decide to test more frequently. Any testing schedule should be determined on throughput – recognising that if there is a failure, milk will need to be discarded. The key point of control is the functioning of the equipment – so calibration and checking is key. Manufacturers should also be able to state the tolerance – deviations may not be important but they should be known.	Regularly test pasteurised milk for bacterial contamination. Milk banks should decide their testing schedule based on the volume and throughput of milk. Testing should occur: • either at least once a month or every 10 cycles, depending on which comes first, and • on an ad-hoc basis if any new processes, equipment, or staff are introduced, or if there are concerns about any part of the process.

										Also training in the use of any critical equipment is important.	
1.10.7	Test post pasteurisation either at least once a month, or every 10 cycles, depending on which comes first.	9	2	0	6	1	Agree	No consensus	Consensus	See 1.10.6	…
1.10.8	Test on an ad-hoc basis if any new processes, equipment , or staff are introduced, or there are concerns about any part of the process.	9	1	1	6	1	Agree	No consensus	Consensus	See 1.10.6	…
1.10.9	Discard any batch that has a total viable bacterial count of 10/ml or more post pasteurisation.	9	0	0	8	1	Agree	Consensus	Consensus	…	Discard milk after pasteurisation that has a total viable bacterial count of 10/ml or more.
1.11	***Quality assurance and staff training***										
NEW										…	All equipment shall be validated, calibrated and maintained to suit its intended purpose. Operating instructions shall be available and appropriate records kept.
NEW										…	All critical equipment and technical devices must be identified and validated, regularly inspected and preventively maintained in accordance with the manufacturers' instructions. Where equipment or materials affect critical processing or storage parameters (e.g. temperature, microbial

										contamination levels), they must be identified and must be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects and to ensure that the critical parameters are maintained within acceptable limits at all times. All equipment with a critical measuring function must be calibrated against a traceable standard if available.
NEW									…	All donor milk prescribed in the NHS should be from milk banks that are part of the overall structure and governance of the linked hospitals/trust.
NEW									…	Only provide donor milk to recipient hospitals who are willing to follow the procedures for tracking use as defined by the supplying milk bank.
1.11.1	Milk banks should implement and maintain an agreed quality control system for processing milk which is followed by all staff.	9	0	0	9	0	Agree	Consensus	Consensus	…	Milk banks should implement and maintain an agreed quality control system for processing milk which is followed by all staff.
1.11.2	A quality control system for milk banks should encompass: • collection, testing, processing, storage and	9	0	0	9	0	Agree	Consensus	Consensus	…	A quality control system for milk banks should encompass: • collection, testing, processing, storage

	distribution • personnel, documentation, premises and equipment • batch recall, external and internal auditing, non-conformance and self-inspection • Continuous quality improvement.										and distribution • personnel, documentation, premises and equipment • batch recall, external and internal auditing, non-conformance and self-inspection • continuous quality improvement.
1.11.3	Milk banks should review their quality control system regularly and amend it if needed. Milk bank staff should be given clear written instructions to help them follow the system.	9	0	0	9	0	Agree	Consensus	Consensus	…	Milk banks should review their quality control system regularly. Milk bank staff should be given clear written instructions to help them follow the system.
1.11.4	Use HACCP principles in any quality assurance process agreed locally	9	0	0	8	1	Agree	Consensus	Consensus	…	Use HACCP principles in any quality assurance process.
NEW										…	All personnel in donor milk banks shall receive initial and continued training appropriate to their specific tasks. Training records shall be maintained. Training programmes shall be in place and shall include good practice. The training programme must ensure and document that each individual: • has demonstrated competence in the performance of their designated tasks; • has an adequate knowledge and understanding of the

			scientific/technical processes and principles relevant to their designated tasks; • understands the organisational framework, quality system and health and safety rules of the establishment in which they work, and • is adequately informed of the broader ethical, legal and regulatory context of their work. If part of their role, train staff in the principles of HACCP, food hygiene, and pasteurisation. Provide continued training and support to ensure that practice reflects these principles.