National Institute for Health and Clinical Excellence

Donor breast milk banks
Scope Consultation Table
18 November – 16 December 2008

Type	Order No	Stakeholder	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	1	Ace Intermed Limited		This organisation was approached but did not respond	
SH	2	Association of Breastfeeding Mothers		This organisation was approached but did not respond	
SH	3	Association of Catholic Nurses of England and Wales		This organisation was approached but did not respond	
SH	4	Association of Medical Microbiologists		This organisation was approached but did not respond	
SH	5	BHF Care & Education Research Group, University of York		This organisation was approached but did not respond	
SH	6	Birmingham Womens NHS Trust		This organisation was approached but did not respond	
SH	7.01	BLISS - the premature baby charity	general	Donor breast milk must be equally available to all premature and sick babies who could benefit from its use (i.e. when there is no or insufficient maternal breast milk available). Not all neonatal units have access to DBM either because of geographic access (and no arrangements in place with existing donor milk banks) or because of prevailing medical opinion. Bliss acknowledges that producing a NICE guideline on the operation of donor breast milk bank services will help to assure the safety and consistency of donor breast milk and so make DBM a more trusted and chosen alternative to formula milk when there is insufficient maternal breast milk. Any recommendations as to how this could be made more widely available to all neonatal units would be welcomed.	Noted. Based on information from the DH and at the Stakeholder workshop, the guideline aims to cover the process of donor milk banking, not the indications for use. We will not be making recommendations on which milk should be used for which babies. We do not disagree that the use of donor milk is an important question, but it will not be addressed in these guidelines.
SH	7.02	BLISS - the premature baby charity	2a	The Department of Health asked NICE to develop a guideline on the use of donor breast milk in pre term babies for use in the NHS in England and Wales, so it would be a missed opportunity if some mention of the uses of DBM were not discussed in the guideline.	See response above…
SH	7.03	BLISS - the premature baby charity	3b	This section acknowledges that there are significant nutrient and non nutrient benefits to using DBM. Again it would be a missed opportunity if the guideline could not address this in some way, even if as part of context and acknowledging where there are limitations in studies and available evidence.	See response above. Re the national model, this is outside our remit, but we would anticipate that the final guidelines will provide information for new milk

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				Bliss recognises that most DBM in the UK is targeted towards premature babies, most commonly as an adjunct to the babies' maternal breast milk, while the mothers' breast milk supply is being established or as a stand alone alternative to formula if no maternal breastmilk is available, particularly in babies at risk of developing Necrotising Enterocolitis. Addressing use of DBM, even if as part of the background to the guideline, would be a valuable starting point to direct future work that is currently outside the scope of this guideline. e.g. a) research programmes for DBM b) current use and guidance on which babies benefit most c) a national model for donor milk banks	banks to be established, and then local services can develop their links as appropriate for local and wider needs.
SH	7.04	BLISS - the premature baby charity	3c	The HTA report may yield information that can usefully be built upon in terms of future recommendations, so Bliss is glad to see that the guideline will refer to this as applicable, particularly in the role of DBM in supporting the establishment of lactation in mothers of premature babies whose babies are offered DBM.	This will be a key reference for this guideline, and cited as appropriate, within the remit of this guideline.
SH	7.05	BLISS - the premature baby charity	3d	The safety aspects of DBM are sometimes cited by medical colleagues (along with insufficient evidence on benefits) as reasons why they may not actively promote DBM as an alternative to formula milk for some premature or sick infants. Bliss would welcome a guideline which addresses the safety of DBM, ashelping to produce a safe and consistent product (that can reliably be tracked and traced). This will help to make DBM be seen as a viable alternative for feeding sick and premature babies by a larger number of clinical practitioners.	Thank you for this, and the provision of recommendations to support a safe and consistent product are the focus of this guideline
SH	7.06	BLISS - the premature baby charity	4a	Bliss acknowledges that although preterm babies are the main recipients for DBM, both preterm and sick babies (especially some post operative groups of infants) receive donor breast milk, so the guideline should refer to infant and not just premature infants an identified in 2a. However, under 4.1.1a are you interested in infants who currently receive DBM ? It would be helpful to clarify why they get it and typical volumes and length of time – if only for illustrative purposes. However, this information may not be readily available; it could be useful to highlight what information is not readily available.	See also response above re indications. In addition as part of this guideline, we will be assessing the volume of milk processed through a brief survey of donor milk services, but we will not be asking for detailed information on volumes and periods of use for individual babies.
SH	7.07	BLISS - the premature baby charity	4.3.1	Under recruitment it would be helpful to look at geographic selection and how milk banks raise awareness for recruitment and if they work with neonatal units outside of their geographic area, have they	We anticipate that this will be discussed during the development of the guideline.

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				developed a working relationship to both recruit donors and distribute milk.	
SH	7.08	BLISS - the premature baby charity	4.3.1.c	Tracking and tracing is an important issue and again will make wide spread use of donor milk more attractive as milk can be used with confidence knowing that there are effective systems for sourcing donor and recipient, preferably without relying on retracing paper trails, which may be time consuming and depends upon good record management.	We anticipate that this will an important focus of this guideline and will be discussed in detail during the development of the guideline.
SH	7.09	BLISS - the premature baby charity	4.3.1f	Bliss welcomes any work on information for parents to ensure awareness raising, accurate and sensitive information and particularly indicating how DBM is used as an adjunct while establishing mothers' own milk supply.	Thank you and this is considered important, but as noted above, we will not be providing detailed recommendations on the information for parents on indications for donor milk.
SH	7.10	BLISS - the premature baby charity	4.3.2	Bliss acknowledges that limited control studies are available, and that this poses problems in terms of inclusion of indications for use of DBM in the guideline. However, it would be helpful to acknowledge what DBM is used for and where there is or isn't evidence, even if this only forms part of the context or background.	There will be an introduction section which will put the guideline recommendations in context.
SH	7.10	BLISS - the premature baby charity	4.5	Under economic aspects would it be possible to look at potential cost savings in terms of economies of scale if alternative models were available . For example, rather than each milk bank adopting their own methods of tracking and tracing or testing for prions, would a national model make better economic sense and what indications would this suggest for milk banking in the future?	Noted, and as above, a national model would be outside the remit of this guideline. However, where evidence permits, the costs of different models of services will be examined and considered.
SH	8	Breastfeeding Network, The		This organisation responded after the consultation period and we were unable to take their comments into account	
SH	9	British Dietetic Association		This organisation was approached but did not respond	
SH	10	British National Formulary (BNF)		This organisation was approached but did not respond	
SH	11	British Society of Paediatric Gastroenterology, Hepatology & Nutrition (BSPGHAN)		This organisation was approached but did not respond	
SH	12	Bromley Hospitals NHS Trust		This organisation was approached but did not respond	
SH	13	Cambridge University Hospitals NHS Foundation Trust (Addenbrookes)		This organisation was approached but did not respond	
SH	14	Commission for Social Care Inspection		This organisation was approached but did not respond	
SH	15	Connecting for Health		This organisation was approached but did not respond	

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SH	16	Countess of Chester Hospital NHS Foundation Trust		This organisation was approached but did not respond	
SH	17	Department for Communities and Local Government		This organisation was approached but did not respond	
SH	18	Department of Health		This organisation was approached but did not respond	
SH	19	Department of Health, Social Security and Public Safety of Northern Ireland		This organisation was approached but did not respond	
SH	20	Devon PCT		This organisation was approached but did not respond	
SH	21.00	East Lancashire Hospitals Trust	2a	Could this guideline not include availability of donor milk for postnatal wards – for those few occasions where a baby is hypoglycaemic or hypernatraemic?	The Scope does not define any restrictions on the use of donor milk, and does not address indications for the use of donor milk.
SH	21.01	East Lancashire Hospitals Trust	4b	Transitional care unit could include transitional care on a postnatal ward?	Noted (this wording has been amended) and the intention is to produce a guideline on the process of operating a donor milk bank, not where the milk should be used.
SH	21.02	East Lancashire Hospitals Trust	Appendix A	How could donor milk be used to help sustain breastfeeding on the postnatal ward for those babies who are hypoglycaemia or have more than 10% weight loss (whilst mother is assisted to establish as milk supply)? Is this beneficial to outcomes?	We are defining a process for milk banking not the use/indications. The Scope does not define any restrictions on the use of donor milk, and does not address indications for the use of donor milk.
SH	21.03	East Lancashire Hospitals Trust	Appendix B	Why just preterm babies? Could involve term babies?	Following comments at the stakeholder meeting, the Scope was drafted so that no restrictions on the use of donor milk are intended. However, the guideline will define the process for donor milk banking not the use/indications.
SH	21.04	East Lancashire Hospitals Trust	4.3.2	Feel it would actually be good / helpful to include indications of donor milk, use	Noted. Based on information received from the DH and at the Stakeholder workshop, this short clinical guideline will specifically address the process of donor milk banking, not the indications for use. A short clinical guideline on the indications for use could logically follow on from guidance on the process for donor milk banking and stakeholders are welcome to suggest this as a suitable topic for NICE to consider at: http://www.nice.org.uk/getinvolved/suggestato

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SH	78.00	Glasgow Caledonian University	4.3.1 b	Each/separate expressed quantity of milk must be timed and dated to allow for culture and sensitivity testing pre pooling. This will not be required if pasteurisation reaches a high enough temperature to eradicate potential contaminants. Pooling should be by gestational age, i.e. 26 weeks,30 weeks, 34 weeks and 37 weeks. Pre-term milk does not have the same level of constituents.	Noted and we will consider the evidence and GDG expertise on this as documented in section 4.3.1b.
SH	78.01	Glasgow Caledonian University	General/ 4.5	It has unclear what effect pasteurisation will have on immunoglobulin levels, posing the question: " What are the costs and benefits of this process?".	As outlined in the revised section 4.5, this may be an area where economic evaluation may be useful. As with all clinical guidelines, a protocol will be prepared by the health economist in conjunction with the GDG to ensure the appropriate analyses are conducted to inform the recommendations.
SH	78.02	Glasgow Caledonian University	4.3.1 d	Level of staff competence must be considered. Should there be a national regulatory body, or good practice guidelines to monitor this?	This will be considered in 4.3.1 (e) – training & competencies. However, we would not expect to make detailed recommendations on the how competencies would be regulated or monitored.
SH	22	Gloucestershire Hospitals NHS Foundation Trust	General	My colleagues and I feel that the guideline should include indications for the use of donor breast milk. Otherwise, it seems fine.	Noted. Based on information from the DH and at the Stakeholder workshop, the guideline aims to cover the process of donor milk banking, not the indications for use.
SH	23	Guys and St Thomas NHS Trust		This organisation was approached but did not respond	
SH	24	Healthcare Commission		This organisation was approached but did not respond	
SH	25	Heart of England Acute Trust		This organisation was approached but did not respond	
SH	26	Imperial College Healthcare NHS Trust		This organisation was approached but did not respond	
SH	27	King's College Acute Trust		This organisation was approached but did not respond	
SH	28	Kingston Hospital NHS Trust		This organisation was approached but did not respond	
SH	80.00	La Leche League Great Britain	3a)	Breast milk is not 'best', it is normal and necessary. It provides normal health outcomes for infants in the short, medium and long term. Artificial milk does not.	Noted. The statement that "breast milk is the best nourishment for babies …" is an accepted phrase in common usage and is not inconsistent with the view that "breast milk is normal and necessary.

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SH	80.01	La Leche League Great Britain	3b)	Again this section normalises artificial feeding in its language. Suggest something like '…donor breast milk can be used. It provides significant nutrient and non-nutrient qualities. Artificial milk can be used if donor milk is not available – although it has the disadvantage of not providing immune factors. ' – wording not necessarily as suggested here, but change of emphasis is needed.	Thank you for this comment.
SH	29	Lactation Consultants of Great Britain		This organisation was approached but did not respond	
SH	30	Luton & Dunstable Hospital NHS Foundation Trust		This organisation was approached but did not respond	
SH	31.00	Medicare Colgate Ltd	Section 3 - f	Concern over adequate pasteurisation methodology – Currently pasteuriser methodology varies from pasteuriser to pasteuriser and from Milk Bank to Milk Bank. Regulation of pasteuriser methodology should be defined similar to Autoclave Methodology irrespective of pasteuriser manufacturer. This needs to be clearly regulated by the new guidelines according to published reference papers. The last reference papers published were : The Department of Health Paper :' The Collection & Storage of Human Milk'(1981) and the Royal College of Paediatrics Guidelines for the establishment and operation of Human Milk Banks in the UK.(1999) The Royal College of Paediatrics Guidelines defined rapid cooling as a reduction in temperature of 3.75 degrees Celsius per minute. Both cite the Gibbs,J.H Fisher,C.Bhattacharya,Goddard and J.D Baum, 1977 paper Published in 'Early Human development, 1,227-245 Both the fore mentioned papers recommend heating to 62.5 holding for 30 minutes followed by rapid cooling from 62.5C to 25C within 10 minutes, followed by further cooling to 10C. The S.Williamson, J.H Hewitt, E. Finucane, H.R Gamsu paper ' Organisation of bank of raw and pasteurised human milk for neonatal intensive care' British Medical Journal Feb 1978, 1, 393-396 Referred to tap water cooling but due its inadequacy Prof Harold	Noted and we anticipate that this will be discussed in detail during the development of the guideline. Thank you also for the references.

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				Gamsu at King' s College hospital subsequently followed the 'Baum methodology' for controlled cooling. Subsequent Guidelines by UKAMB were less precise in their guidelines in respect of cooling. There are number of UK Milk Banks who operate pasteurisers with tap water cooling which cannot fulfil this important criteria. If the cooling process from 62.5C to 25 C takes longer than the recommended time span there is a risk of re-growth of bacteria. Full proof of treatment of the milk data for both heating and rapid cooling to 10 C is required. (some equipment currently used can only provide water bath temperature, this does not indicate core milk temperature). There is a significant difference during the cooling process between water bath temperature and actual core milk temperature. If the water bath temperature shows 15 C the core milk temperature is likely to be still around 25 C, too hot to be placed into a refrigerator. Tap water cooled pasteurisers cannot always fulfil the final cooling criteria of 10C. Tap water temperatures cannot be controlled or measured and vary significantly during winter , summer, time of day , location etc. Tap water cooling requires considerable amounts of water which is also an environmental issue. Hospitals using controlled cooling will all show identical treatment profiles for the entire cycle, uncontrolled (e.g tap water) will have varying results not only within their hospital but also at other hospitals.	
SH	31.01	Medicare Colgate Ltd	Section 4.3.1 - b	There is currently no clear guide to the suitability of storage containers for breast milk to be pasteurised. As this is not clearly defined, there is no uniform	Noted and we anticipate that this will be discussed in detail during the development of the guideline.

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				methodology in place with regard to submerging during the heating process. Evidence based data shows that if the containers are not fully submerged during the heating process any droplets present in the screw top of the container might not receive the same treatment as the rest of the milk.(Steriliser Consultants, Report on the affect of water level when pasteurising Human Milk 13 Aug. 02) The main reason quoted for not submerging is the fear of water ingress into the containers during the heating process, either if bottles are not leak proof or if the screw lid is not tightened sufficiently. Pasteuriser containers need to be of a construction to fully eliminate this risk. Containers for pasteurisation of human milk need to be fitted with a hermetic Seal (like Milk is sealed the retail sector) prior to being placed into the pasteuriser. Thus eliminating the risk of water ingress and fulfilling the necessity of fully submerging the feed during the pasteurisation process. Foil seal bottles are available from the NHS Supply Chain.	
SH	32	Medicines and Healthcare Products Regulatory Agency (MHRA)		This organisation was approached but did not respond	
SH	33	Medway NHS Trust		This organisation was approached but did not respond	
SH	34	Mother and Infant Research Unit		This organisation was approached but did not respond	
SH	35.00	National Childbirth Trust	General	We recognise that this document has been narrowed since the original draft, and strongly recommend that the scope returns to the original, wider remit. We suggest that the remit from the DH –the use of donated human breastmilk – does logically include examination of the evidence base on which babies are most at risk if given formula milk. If indications are not considered at this stage, there will continue to	Noted. Based on information from the DH and at the Stakeholder workshop, the guideline aims to cover the process of donor milk banking, not the indications for use. We will not be making recommendations on which milk should be used for which babies. We do not disagree that the use of donor milk

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				be widespread inequality in provision, with babies who need breastmilk, and whose mothers are either too ill or otherwise unable to provide their own milk, suffering through lack of a readily available supply of donor milk. Section 3b recognises that there are 'significant nutrient and non-nutrient benefits to breastmilk'; it is by no means universally accepted that there is insufficient evidence to develop guidelines on the subject. The Health Technology Assessment (HTA) report referred to in 3 also recognises that there are measurable health risks if babies are not fed breastmilk. In some cases it is difficult to distinguish the separate influences of mother's milk and donated milk, but the Cochrane review found eight relevant trials. Although consideration of the evidence may take more time initially, the research has been considered recently and it would • save time in the long run • clarify the further research that needs to carried out and • improve care and equity for some of the sickest, smallest babies in the meantime.	is an important question, but it will not be addressed in these guidelines.
SH	35.01	National Childbirth Trust	**Guideline title**	We urge NICE to revert to the original title The use of donated human breastmilk	We consider the agreed title to accurately reflect the aims of the guideline.
SH	35.02	National Childbirth Trust	General	We believe that in addition to looking at the operational side of milk banks, NICE guidelines regarding the evidence base for Milk banks and recommendations of best practice in relation to the provision of donor milk are necessary. In addition, costs cannot be adequately considered without inclusion of the health costs to babies, to families and to the NHS of morbidity and mortality, due to lack of breastmilk.	Noted, and we have revised the section on health economics to reflect this. But as above, the focus of this guideline is operation of milk banks, not indications for use of milk.
SH	35.03	National Childbirth Trust	2 a)	NCT believes the remit should be widened to include vulnerable term babies - low birth weight, immuno-compromised and post-surgery (gut for example) babies. There are disadvantages in considering only premature babies in isolation, rather than including sick term babies, who need neonatal care or similar, such as cardiac care and sometimes require donor	Noted. Based on information from the DH and at the Stakeholder workshop, the guideline aims to cover the process of donor milk banking, not the indications for use. We will not be making recommendations on

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				milk. These full term babies who are very sick or have surgery sometimes do not thrive on formula milk, cannot tolerate it or would recover more rapidly and safely with human milk. Whether the guidelines cover safety aspects, procedures and good practice only or also include indications for the use and recommendations for further research and development of a donor milk service, these babies need to be taken into account.	which milk should be used for which babies. We do not disagree that the use of donor milk is an important question, but it will not be addressed in these guidelines.
SH	35.04	National Childbirth Trust	3a)	It is more accurate to quote the WHO recommendations for continuing breastfeeding for at least 2 years, to accurately encompass the desire for mothers to continue beyond six months if they choose to do so. e.g. "The **World Health Organization** recommends that infants should be exclusively breastfed for the first 6 months of life. Breastfeeding should continue for at least 2 years with weaning foods added at 6 months of age".	We have quoted the UK recommendations on continued feeding.
SH	35.05	National Childbirth Trust	3 a) and 3 b)	This sentence does not display an awareness of the risks of formula milk. There is a danger in using statements like 'best nourishment' and 'benefits' of breastmilk. Our default position is that breastfeeding or breastmilk is the most appropriate form of nourishment for all but a very few babies, taking into account evolution and the evidence base. In view of the uphill struggle there is to protect and support breastfeeding, it is better to be honest and talk about the risks of formula milk rather than the benefits of breastmilk. Inverting reality by referring to the benefits of breastfeeding, becomes even more misleading if using percentages, Thus if a study found a "25% decrease" in breast cancer rates among women who were breastfed as babies, using breastfed health as the norm instead, would mean an approximately 33% increase in breast cancer rates among women who were formula fed. (see "Watch Your Language"[1]) This is particularly relevant when discussing evidence with health professionals who have, in the past, seen preterm formula milk as easier and better then human milk. Maybe some emphasis should be given to the fact that it would not simply be for optimum nourishment in the preterm (or sick) infant, but could actually save lives in situations where the baby was too ill to digest artificial milk, fighting a bug or where the artificial milk would put undue strain on its system. In this instance it could perhaps be	We have reworded this section, and this is intended as a brief introduction to the topic, rather than a comprehensive review of the evidence.

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				referred to as having lifesaving applications in the preterm and sick child. [1] Wiessinger D. Watch Your Language! *Journal of Human Lactation*, 1996,Vol. 12(1); 1-4. Available at: http://www.bobrow.net/kimberly/birth/BFLanguage.html	
SH	35.06	National Childbirth Trust	3b	This sentence is the wrong way around. 'Where a mother does not wish to or is not able to express sufficient milk for her baby, donor breast milk can be used' It is ironic that the naturally evolved substance could be described as an 'alternative' to the synthetic substance. Throughout history, the main alternative to mother's milk was another mother's milk.	We have revised this sentence.
SH	35.07	National Childbirth Trust	Add After 3c	Breastfeeding has an important role to play in reducing health inequalities. For example, babies of mothers in low income groups are up to 50% less likely to be breastfed than those born to mothers in the highest income groups, but these babies are more likely to be born preterm. However, provision of donor milk bank services may be lower in areas of higher social deprivation.	Noted and all NICE guidelines have a commitment to addressing such inequalities – as noted above, we are not recommending which babies should receive milk, but we would anticipate effective implementation and support of the final guidelines to address this…
SH	35.08	National Childbirth Trust		It is currently unclear which babies need breastmilk the most. However, there is no evidence in this country that mothers are less likely to express their own milk because there is donor milk available in the unit. Rather the availability and value placed on donor milk seems to encourage more women to express. In addition the expertise developed by staff in supporting women to express milk, for their own or other babies, tends to help mothers of premature or sick to continue breastfeeding or expressing for longer.	We will not be making recommendations on which milk should be used for which babies. We do not disagree that the use of donor milk is an important question, but it will not be addressed in these guidelines.
SH	35.09	National Childbirth Trust	3e	In the absence of guidelines on which babies need donor milk the most, it is unlikely that 'Local needs will determine how services are commissioned to implement the guideline recommendations' It is probable that some human milk banks will continue, but there is a possibility that, if the safety recommendations require additional staff time, expensive equipment or more restriction on donors, some may close down. This would be to the detriment of both the babies who need the milk in those areas and those in other areas where no donor milk is yet available as well as future research.	Such issues will be a key part of the implementation processes that will support the final guideline.
SH	35.10	National Childbirth Trust	4.1	Is there any provision of donor milk from the private sector, can it be bought or sold? Does the guideline also need to cover this	NICE clinical guidelines make recommendations to and for the NHS, not the

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				possibility?	private sector.
SH	35.11	National Childbirth Trust	4.1.1, 4.1.2	We would like to include those families who wish to receive donor milk but for whom there is none available or they don't have access to any. Part of the operational procedures should be to determine who has access to donor milk, and how these patients are prioritised, as provision is very uneven across the country – and across the UK - at present. If access to life saving drugs were at issue, there would be headline news on the issue.	We anticipate that this issue of access (in principle) will be discussed during the development of the guideline, but as noted above, we are not recommending who should receive donor milk as priorities.
SH	35.12	National Childbirth Trust	4.1.1	Add in the possibility of having Mothers' Milk 'Depots' – which provide a central collection point, outside the donor mother's home, and before collection by the milk bank itself. They provide a way of collecting from donors spread over an otherwise unmanageable geographical area, and should be encouraged. These need guidelines and protocols just as milk banks do, and presently there are none.	We anticipate that any recommendations on storage etc would be relevant to such depots.
SH	35.13	National Childbirth Trust	4.1.1. c)	Should this include the babies of women who donate breastmilk?. There is no mention of maximum or minimum daily donation amounts.	We refer only to 'infants who receive donor milk'. We will be considering the information given to donor women.
SH	35.14	National Childbirth Trust	4.1.1d	What responsibility is there to provide donor milk if a parent or carer requests it for their baby? Is this something that should be covered?	Indications for breast milk are not included (and therefore we will not be reviewing the responsibility to provide milk).
SH	35.15	National Childbirth Trust		It is not clear if there would be any recommendations/advice about the physical space that might be needed for a milk bank	As this would link to level of provision, this will not be covered.
SH	35.16	National Childbirth Trust	4.1.1 f)	Guidance needed on remuneration and incentives to donors, (in some other countries people are paid) to clarify and improve consistency e.g.fuel for collectors, or if costs are incurred in attending for blood tests. (although perhaps this is included in the reference to administration?)	We will be guided by the evidence and GDG expertise on this area (we are reviewing processes of recruitment). We will also refer to any national guidance, if available, on this issue.
SH	35.17	National Childbirth Trust	4.1.2	Babies who do not receive donor milk should be considered in the cost calculations. The previous draft noted: ' Preterm babies fed donor breastmilk have a lower risk of NEC compared to formula fed infants'	Any cost calculations will be based on all relevant information.
SH	35.18	National Childbirth Trust	4.2	As above, re private sales, is there any access to breastmilk for sale via the internet etc. that needs monitoring??	NICE clinical guidelines make recommendations to and for the NHS, not the private sector.
SH	35.19	National Childbirth Trust	4.3.1a)	added in italics: "relevant lifestyle factors, such as smoking status and alcohol *and caffeine* intake")	This is not intended to be comprehensive, but an indication of the factors we will be

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					considering.
SH	35.20	National Childbirth Trust	4.3.1a)	Need to include the age of the baby? ie the time post partum before which the mother should start donating or stop.	We anticipate that this issue will be discussed during the development of the guideline.
SH	35.21	National Childbirth Trust	4.3.1 b) and appendix a	Seems unbalanced not to include fortification if safety is the priority as there are risks associated with any additions to human milk, including Enterobacter sakazakii, salmonella, and other organisams as well as the risk of non-human milk proteins, for instance. How should these risks be explained to parents of babies who are considered suitable to receive fortified donor milk?	We will be reviewing the process of fortification, but not what the milk should be fortified with.
SH	35.22	National Childbirth Trust	4.3.1 b) and Appendix A	Again, collection by / transport to / storage at / retrieval from Mothers Milk Depots or similar facilities should be included in the guidelines.	We anticipate that any recommendations on these areas would be relevant to such depots.
SH	35.23	National Childbirth Trust	4.3.1b)	Add Hygiene practices	We have not added this, but we will be focussing on the hygiene and safety issues of these.
SH	35.24	National Childbirth Trust	4.3.1 e)	Should it be "... working with *donors and* potential donors"? (added in italics)	This has been added…
SH	35.25	National Childbirth Trust	4.3.1f)	Should include training for donors, e.g. use of and cleaning breast pumps, hand washing technique, hygiene practices etc.	We would expect information to include any training as needed.
SH	35.26	National Childbirth Trust	4.3.2a)	Very important that indications for the use of donor breastmilk are covered by this guidance. Leaving this until further research is carried out and clinicians agree on it, will mean that some human milk banks are under threat, new ones are unlikely to open, leaving babies vulnerable to infections and other risks of formula milk.	Noted. Based on information from the DH and at the Stakeholder workshop, the guideline aims to cover the process of donor milk banking, not the indications for use. We will not be making recommendations on which milk should be used for which babies. We do not disagree that the use of donor milk is an important question, but it will not be addressed in these guidelines.
SH	35.27	National Childbirth Trust	4.4.	We agree tracking and traceability are important, but consideration should be given to organising the processing and distribution of donated human milk more efficiently by an organisation such as the national blood service. Recruitment of donors and collection of milk from suitably screened volunteers could continue to be carried out by the current system, or a more geographically even network of milk depots.	Such recommendations would be outside the Scope of this guideline. However, we would anticipate that these guidelines could be used to develop new services where such services do not already exist.
SH	35.28	National Childbirth Trust	4.5	Published evidence on the health-related quality of life of the infant	This section has been revised to clarify how

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				receiving donor breastmilk and the mother or parent/carer and family, including any related psychosocial issues. Again indications for the use of donor milk must be included for this to make sense, and it would be a vital output. In addition the proportion of babies who are discharged from hospital breastfeeding and continue to breastfeed would be a valuable measure.	health economics will be used in this guideline.
SH	35.29	National Childbirth Trust	Appendix A	Regarding training – could include training for potential donors in hygiene practices and expressing milk.	We would expect recommendations on what training potential donors would need.
SH	35.30	National Childbirth Trust	Appendix A	What factors should influence which babies receive donor breastmilk? Which babies should receive donor milk as a priority? What are the short and long term risks of fortifier? Which babies should receive fortified milk?	We will not be making recommendations on which milk should be used for which babies. We do not disagree that the use of donor milk is an important question, but it will not be addressed in these guidelines.
SH	35.31	National Childbirth Trust		As part of the expressing at home question, perhaps there should be something on the equipment used / whether or not the milk bank should provide / monitor it to ensure its safety / suitability?	We would anticipate that monitoring of any practices would be discussed during the development of this guideline, and we will also work closely with the Implementation Team to ensure that this is undertaken.
SH	36	National Forum of LSA Midwifery Officers (UK)		This organisation was approached but did not respond	
SH	37	National Patient Safety Agency (NPSA)		This organisation was approached but did not respond	
SH	38.00	National Perinatal Epidemiology Unit	General and 4.4 and 4.5	I attended the scoping workshop in Manchester and therefore I am aware that the scope has changed from "the use of human donor milk" to "the operation of donor breast milk bank services". I think that both questions are important and it would be logical to include them in the same scope. There has already been a Cochrane review on the use of donor breast milk in preterm babies, and it would not take the NICE team very long to update this review and include it in the same NICE guideline. If the scope of this guideline does not include an assessment of the potential benefits and harms of donor milk then I think it will be difficult to assess the key outcome measures (4.4 a)) – how can the safety of donor milk (which presumably means things like an	Noted. Based on information from the DH and at the Stakeholder workshop, the guideline aims to cover the process of donor milk banking, not the indications for use. We do not disagree that the use of donor milk is an important question, but it will not be addressed in these guidelines. We also acknowledge the difficulties therefore in assessing effectiveness and have revised the outcomes and section 4.5 to reflect and clarify these.

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				extremely low risk of CJD) be assessed without looking at other risks such as necrotising enterocolitis, infection and growth. Similarly, I think that the QALYs (4.5) for the infant will be meaningless unless they include all of the potential outcomes.	
SH	38.01	National Perinatal Epidemiology Unit	4.3.1 b)	In the second bullet point, I would add the words "in the hospital setting" since this applies to units which receive donor milk, but do not have a milk bank: "storage of donor milk at home, during transportation, at the milk bank and in the hospital/clinic setting, including refrigeration …"	We have not added this, and would anticipate that local guidance on storage for any milk in the hospital setting would be followed.
SH	39	National Public Health Service - Wales		This organisation was approached but did not respond	
SH	40	National Treatment Agency for Substance Misuse		This organisation was approached but did not respond	
SH	41	NHS Clinical Knowledge Summaries Service (SCHIN)		This organisation was approached but did not respond	
SH	42	NHS Plus		This organisation was approached but did not respond	
SH	43	NHS Purchasing & Supply Agency		This organisation was approached but did not respond	
SH	44	NHS Quality Improvement Scotland		This organisation was approached but did not respond	
SH	45	NHS Sheffield		This organisation was approached but did not respond	
SH	46	North Trent Neonatal Network		This organisation was approached but did not respond	
SH	47	North West Infant Feeding Co-ordinators Group		This organisation was approached but did not respond	
SH	48	Nottingham University Hospitals NHS Trust		This organisation was approached but did not respond	
SH	49.00	Oxford Radcliffe Hospitals NHS Trust	4.3.1a	Relevant medical history to include blood transfusion since 1980?	This was not intended to be an exhaustive list, but we anticipate that this will be discussed during the guideline development.
SH	49.01	Oxford Radcliffe Hospitals NHS Trust	4.3.1a	Any limit to the age of the prospective donor's baby at the time of the first donation?	This was not intended to be an exhaustive list, but we anticipate that this will be discussed during the guideline development.
SH	49.02	Oxford Radcliffe Hospitals NHS Trust	4.3.1a	Will reasons for stopping permanently include the age the baby has reached?	This was not intended to be an exhaustive list, but we anticipate that this will be discussed during the guideline development.
SH	49.03	Oxford Radcliffe Hospitals NHS Trust		Given the importance of human milk to preterm babies perhaps no limit should be put on the two above.	We will be guided by the evidence and the GDG on these issues.

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SH	49.04	Oxford Radcliffe Hospitals NHS Trust	4.3.1a	The word "potential" has been used in relation to the screening of donors. Any suggestion that donors should be rescreened at intervals whilst they are donating would require a robust risk benefit analysis, as this would have huge resource implications in terms of follow–up (particularly for one-off donations from women who then leave the area) and of milk storage and "shelf life" of already pasteurised milk.	Noted and if such a strategy were to be recommended, this would be based on a robust synthesis of the evidence, and appropriate modelling following the principles of NICE guideline development.
SH	49.05	Oxford Radcliffe Hospitals NHS Trust	4.3.1b	Will "expression" thus exclude the donation of dripped milk?	We have revised this to specify 'collection' of milk
SH	49.06	Oxford Radcliffe Hospitals NHS Trust	4.3.1b	A robust risk benefit analysis needs to take place around any recommendation to archive samples of milk or blood, which would consume time, power/fuel, space and money. What can be learnt from NBTS?	Agreed, and we will be looking to established national policies on such issues, where appropriate.
SH	49.07	Oxford Radcliffe Hospitals NHS Trust	4.3.1b	Tracking and tracing systems need to take account of the fact that milk may leave the unit where is has been processed. It may go into the community where the use electronic tracking systems may not be possible or to other units where electronic systems are incompatible. A simple form of tracking may be more universalisable.	Noted and we anticipate that this will be discussed during the development of the guideline.
SH	49.08	Oxford Radcliffe Hospitals NHS Trust	4.3.1b	Transportation considerations need to include transport out, as well as to, the processing unit if units supply other hospitals.	Noted and we anticipate that this will be discussed during the development of the guideline.
SH	49.09	Oxford Radcliffe Hospitals NHS Trust	Appendix A	Donors are currently, and should in the future, be recruited by any means possible. Word of mouth, posters in Children's Centres and healthcare facilities, in any relevant written given to a pregnant woman or mother, by the health professionals providing care for the new mother who has a good milk supply. Increasing the number of donors needs to take place after capacity has been built into the existing and future milk banks. Religious and ethnic and cultural differences between donors should be largely irrelevant. It is difficult to see what bearing they might have on the recruitment criteria, but it has had to made clear in the past that donors cannot place restrictions on the recipients of their milk. If milk kinship is a cultural factor, that is likely to affect the willingness of a mother to donate, or have her child receive donated milk.	Thank you for this information
SH	49.10	Oxford Radcliffe Hospitals NHS Trust	Appendix A	The criteria for the suitability of a mother to donate milk should be as unrestrictive as is compatible with safety. The most important factor is that a donor is feeding her own well and growing baby.	Thank you for this information, and we anticipate that this will be discussed during the development of the guideline.

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SH	49.11	Oxford Radcliffe Hospitals NHS Trust	Appendix A	Initial screening – there are cost effectiveness considerations to repeating blood tests that were done during pregnancy prior to milk donation. There are also cost effectiveness issues in relation to testing for any factor that is rare in the population from whom milk is being received, especially if it would be inactivated by pasteurisation. What do NBTS screen for each time?	
SH	49.12	Oxford Radcliffe Hospitals NHS Trust	Appendix A	See 5 above in relation to re-screening	…
SH	49.13	Oxford Radcliffe Hospitals NHS Trust	Appendix A	See 7 above in relation to archiving	…
SH	49.14	Oxford Radcliffe Hospitals NHS Trust	Appendix A	The question relating to the pooling of milk could be taken as asking if milk from several mothers should be put together (which would be a retrograde step for the UK) or whether each individual bottle of milk from a single donor should be treated singly. The arguments for and against are set out in the 2003 UKAMB document. One option is considerably more expensive and time consuming than the other. "Contaminated milk" can sometimes be used for other purposes, depending on the contaminant and the post pasteurisation result.	Thank you, and we although we have not specified this, we are focussing on the pooling of milk from a single donor.
SH	49.15	Oxford Radcliffe Hospitals NHS Trust	Appendix A	Donors should be told exactly what their blood is to be screened for, if new tests are required, and what category of recipient the milk is likely to be used for (mostly pre-term and sick babies). Recipients should know that milk donors are as "safe" as blood donors, that they are feeding their own child and that additionally milk is microbiologically tested, pasteurised and re-screened. All milk banks will have their own version of this. The consent recipient's next of kin should be recorded in the recipient's notes. The same should apply to the giving of formula (or milk fortifiers that are cows' milk derived).	Thank you for this information, and we anticipate that this will be discussed during the development of the guideline.
SH	49.16	Oxford Radcliffe Hospitals NHS Trust	Appendix A	Training and competencies:- Staff who are handling milk should have done a basic food handling / food safely course as a minimum. Registered nurses or midwives could be assumed to have covered asepsis as part of their training, but all staff should have supervised practice to start with. All staff need to be trained in what ever system of documentation is put in place. Staff who are working with mothers who are receiving or may benefit from donor milk should be enthusiastic and knowledgeable about the importance of human milk to pre-term babies, and be conversant with the eligibility and screening of donors an the system of milk	Thank you for this information, and we anticipate that this will be discussed during the development of the guideline.

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				processing in their milk bank. Staff working with potential donors should know who to advise them to contact, and possibly be able to supply registration form to those expressing interest.	
SH	50.00	Pennine Acute Hospitals NHS Trust	General	I strongly feel that a guideline should indicate which babies donor milk can be used for as this could be used to influence Trusts to purchase donor milk	Noted. Based on information from the DH and at the Stakeholder workshop, the guideline aims to cover the process of donor milk banking, not the indications for use. We will not be making recommendations on which milk should be used for which babies. We do not disagree that the use of donor milk is an important question, but it will not be addressed in these guidelines
SH	50.01	Pennine Acute Hospitals NHS Trust	General	I agree with East Lancs re indication that donor milk should be available for infants that are term but have medical indications for supplements	As above
SH	50.02	Pennine Acute Hospitals NHS Trust	General	I also agree with East Lancs comments that donor milk should be used on transitional care wards if mothers milk is unavailable	As above
SH	50.03	Pennine Acute Hospitals NHS Trust	General	I feel that the document should strengthen the difference between formula milk and breastmilk by 'normalising' breastmilk and identifying the risks of formula milk	We have reworded this section from the consultation version, and this is intended as a brief introduction to the topic, rather than a comprehensive review of the evidence. However, we do state that breast milk is the best nutrition and that donor milk is an option (rather than formula) where maternal milk is not sufficient or available.
SH	51	PERIGON Healthcare Ltd		This organisation was approached but did not respond	
SH	52	Public Health Group North West		This organisation was approached but did not respond	
SH	53	Queen Mary's Hospital NHS Trust (Sidcup)		This organisation was approached but did not respond	
SH	54	Royal College of General Practitioners		This organisation was approached but did not respond	
SH	55	Royal College of Midwives		This organisation was approached but did not respond	
SH	56	Royal College of Nursing		This organisation was approached but did not respond	
SH	57	Royal College of Obstetricians and Gynaecologists		This organisation was approached but did not respond	

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SH	58.00	Royal College of Paediatrics and Child Health	2.a	The mention of "use" is open to misinterpretation. The subsequent paragraphs (esp 3.c which refers to "…service guidance on the operation of donor breast milk banks") clarify that the guidance to be developed in fact relates to the safe collection, processing and storage of donor milk – rather than its appropriate "use". We agree that adherence to appropriate guidance in this area is a fundamental aspect of clinical governance and patient safety.	Noted and this is the wording as in the DH remit – however, based on information from the DH and at the Stakeholder workshop, we have interpreted the remit as you outline.
SH	58.01	Royal College of Paediatrics and Child Health	3.b	Add to "a mother does not wish" "despite discussion with experienced staff and information regarding benefits to herself and her baby". In the same paragraph it must be explicitly stated that although there are nutrient and non-nutrient benefits of donor breast milk, these benefits remain less than mother's own breast milk. Relevant guidance on encouraging and supporting mother when relevant to continue to try to provide own milk must be referenced in final guidance rather than throw baby out with bathwater. Availability of DBM does not mean healthcare professionals are off the hook on this one.	Added in as suggested.
SH	58.02	Royal College of Paediatrics and Child Health	3.c	Add "neonatal" before special and intensive care	Added in as suggested.
SH	58.03	Royal College of Paediatrics and Child Health	3.e	Suggest delete sentence: *"There are currently no UK guidelines on the establishment and operation of breast milk banks".* These sentences are a bit of a non sequitur. Whilst the UKAMB guidelines need updating, they are still the ones which most UK banks follow having been reviewed by the RCPCH Quality of Practice Committee.	Noted and we have revised this to clarify.
SH	58.04	Royal College of Paediatrics and Child Health	4.2.b	Suggest: *"Special care baby units, neonatal units, transitional care units and other settings such as paediatric wards and paediatric surgical units that require access to donor breast milk".*	Revised (we have considered that 'wards' includes 'surgical units', noting also that the list is not intended to be comprehensive)...
SH	58.05	Royal College of Paediatrics and Child Health	4.3.1.b	Suggest*: "collection of donor milk"* as some donor milk is dripped rather than expressed	Revised...
SH	58.06	Royal College of Paediatrics and Child Health	4.3.2.a	Indications must be considered orrisk-benefit and cost benefit analyses cannot be considered (see below).	However, this is a guideline on the process of donor milk banking, not the clinical or cost effectiveness of donor milk banking – as defined in section 4.4a, 'risks' refers to the minimisation of risk and this has been reworded.
SH	58.07	Royal College of Paediatrics and Child Health	4.4.a	What is the comparator against which "risk" will be evaluated: TPN or formula? Will the risks associated with these treatments also be established? Or will feeding with the mother's own milk be used as a	As defined in section 4.4a, 'risks' refers to the minimisation of risk and this has been reworded.

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				base case (despite the fact this is not in practice substituted by donor milk).	
SH	58.08	Royal College of Paediatrics and Child Health	4.5	It is not really clear how this can be done in the light of 4.3.2.a. and our comments on 4.4.a above. How could the health costs saved through use of donor breastmilk be quantified without firstly describing the indications for its use and, secondly, estimating the incidence and prevalence of complications related to the use of formula or extended parenteral nutrition as alternative nutrient sources? Will the NPEU systematic review data (subsequently published in Boyd et al's paper *Arch. Dis. Child. Fetal Neonatal Ed.* 2007;92:F169-F175) be applied here? We find this confusing. If it is not (as stated elsewhere) the intention to cover clinical efficacy, you will surely have to limit the assessment to economic costs of providing donor milk rather than its cost-effectiveness?	This section has been revised to clarify the role of health economics in the development of this particular guideline.
SH	58.09	Royal College of Paediatrics and Child Health		Add potential accreditation, commissioning and charging arrangements.	We anticipate that accreditation may be a principle that the GDG would consider. However, we would not expect to make detailed recommendations on the content of any accreditation scheme or how it would be regulated. Commissioning and charging are topics that, if considered appropriate, would be dealt with by Implementation or Commissioning teams in NICE.
SH	58.10	Royal College of Paediatrics and Child Health	Appendix A	The question "How long can donor breastmilk be stored?" should be added.	Noted and added.
SH	58.11	Royal College of Paediatrics and Child Health	General	The operation of donor breast milk banks should be included.	We have drafted the Scope to cover the operation of a donor milk bank, that can then be interpreted and implemented to meet local need.
SH	58.12	Royal College of Paediatrics and Child Health	General	The College supports the fact that the model is the donation of blood (in safety terms anyway).	Noted with thanks.
SH	58.13	Royal College of Paediatrics and Child Health	General	It is a very sensible first step to focus on ensuring that current milk banks are operated appropriately and safely, so the College would agree with the general remit of the draft.	Noted with thanks.
SH	58.14	Royal College of Paediatrics and Child Health	4.3.1 c	The guideline should emphasise that this is really important - to ensure that all milk samples are appropriately coded and trackable -	Noted. We will be guided by the evidence and the expertise of the GDG, but have specified

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				probably using some sort of bar-code system	that this is an area that will be covered.
SH	58.15	Royal College of Paediatrics and Child Health	4.3.2 9b	Mother's own milk is not to be included in the scope - but given that incidents of wrong milk being given to babies is not uncommon, I wonder if the question of bar-coding ALL milk samples should be considered - to try and avoid these errors.	Noted and this is obviously an important area and recommendations may be similar if not the same, but we have been tasked with a guideline on donor milk, not maternal milk.
SH	58.16	Royal College of Paediatrics and Child Health	General	The College hopes that the evidence whether just preterm mothers should donate for preterm babies will be considered.	Noted. Based on information from the DH and at the Stakeholder workshop, the guideline aims to cover the process of donor milk banking, not the indications for use. In this case, we will not be making recommendations on which milk should be used for which babies.
SH	58.17	Royal College of Paediatrics and Child Health	Appendix A	Under Appendix A, development of a standardised consent form for parents / guardians of infants receiving donor breast milk, with the relevant risks / benefits highlighted should be included.	We consider the principles of consent are covered in 4.3.1c. However, it is not within the remit of this guideline to provide a specific form for use across the NHS.
SH	59	Royal College of Pathologists		This organisation was approached but did not respond	
SH	60	Royal Devon and Exeter NHS Foundation Trust		This organisation was approached but did not respond	
SH	61	Royal Society of Medicine		This organisation was approached but did not respond	
SH	62	SACAR		This organisation was approached but did not respond	
SH	63	Scottish Intercollegiate Guidelines Network (SIGN)		This organisation was approached but did not respond	
SH	64	Sheffield Children's NHS Foundation Trust		This organisation was approached but did not respond	
SH	65	Sheffield PCT		This organisation was approached but did not respond	
SH	66	Sheffield Teaching Hospitals NHS Foundation Trust		This organisation was approached but did not respond	
SH	67	Social Care Institute for Excellence (SCIE)		This organisation was approached but did not respond	
SH	68	Social Exclusion Task Force		This organisation was approached but did not respond	
SH	69	Southampton University Hospitals NHS Trust		This organisation was approached but did not respond	
SH	70	SPECIAL CARE BABY FUND (CHARITY)		This organisation was approached but did not respond	
SH	71	St George's Healthcare NHS Trust		This organisation was approached but did not respond	

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SH	72	St Richards Hospital		This organisation was approached but did not respond	
SH	73	UNICEF Baby Friendly Initiative		This organisation was approached but did not respond	
SH	74.00	United Kingdom Association for Milk Banking	3d	In each case there is a requirement to balance any safety concerns against risks associated with use of the alternatives ie parenteral nutrition and/or formula.	Noted…
SH	74.01	United Kingdom Association for Milk Banking	3e	More recently published guidelines for donor milk banking in Europe (Italy published in 2006, Switzerland due for publication in 2009) are based on the UKAMB guidelines and will provide a useful comparison. Local needs – currently local needs and use of donor milk are unclear and largely undocumented.	Thank you for this information.
SH	74.02	United Kingdom Association for Milk Banking	4.3.1b	As a growing number of donors provide milk previously expressed and stored (on a NICU, PICU, SCBU, home etc) attention needs to be given to the importance of retrospective screening particularly with medication, alcohol, drug use.	Noted and we anticipate that this will be discussed during the development of the guideline.
SH	74.03	United Kingdom Association for Milk Banking	4.3.1c	Consideration given to centralisation of records given the number of babies who transfer between hospitals (and milk banks) on donor breastmilk	Noted and we anticipate that this will be discussed during the development of the guideline.
SH	74.04	United Kingdom Association for Milk Banking	4.3.1d	Consideration given to levels of staffing to allow for supervision, sign offs and cover.	Noted. Without an assessment of local need (which is outside the Scope of this guideline), we will not be able to recommend specific staffing levels. However, such issues may be raised during the development of the implantation tools to support this guideline.
SH	74.05	United Kingdom Association for Milk Banking	4.3.1f	Leaflets from UKAMB are available for review	Thank you for this information.
SH	74.06	United Kingdom Association for Milk Banking	4.3.2a	Without discussion of indications, local needs (3e) cannot be determined	Noted, and this guideline focuses on the operation of donor milk services. However, assessment of local need may be raised during the development of the implantation tools to support this guideline.
SH	74.07	United Kingdom Association for Milk Banking	4.3.2b	A recommendation may be useful regarding the possibility of such milk being later donated to a milk bank.	We will be guided by the evidence and the GDG expertise on this…
SH	74.08	United Kingdom Association for Milk Banking	4.5	Clinical effectiveness and cost effectiveness: in the absence of recommendations for clinical use and lack of information regarding current use and the extent of the use of donor milk how will this be determined?	We have revised this section to clarify.

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SH	74.09	United Kingdom Association for Milk Banking	Appendix A	Should donor breastmilk be analysed for macro nutrients?	We will be guided by the evidence and the GDG expertise on this…but may be outside the Scope as is related then to the indications for donor milk.
SH	75	Welsh Assembly Government		This organisation responded and said they have no comments to make.	Noted with thanks
SH	76	Welsh Scientific Advisory Committee (WSAC)		This organisation was approached but did not respond	
SH	77	Womens Health and Reproduction Research Group at King's College London		This organisation was approached but did not respond	