NICE National Institute for Health and Care Excellence

Appendix A: Stakeholder consultation comments table

2018 surveillance of Donor milk banks: service operation (2010)

Consultation dates: 29 May to 11 June 2018

Do you agree with the proposal not to update the guideline?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
Royal College of Nursing	Yes	Not at this time in light of there being no new evidence to support updating.	Thank you for your response.
Royal College of Paediatrics and Child Health	Yes	There has not been much more recent evidence presented either	Thank you for your response.
Hearts Milk Bank CIC	No	Whilst time frames are provided for storage of milk prior to freezing (Rec 1.2).38 page 53 and for frozen milk prior to pasteurisation (both of which differ from other internationally published guidelines including the 2018 Human Milk Banking Association of North America guideline www.hmbana.org), there is currently no guidance as to the timeframe between thawing and pooling (and pre	Thank you for your comments. Responses to each individual point are provided below. **Timeframe between thawing and pooling** Unfortunately we are unable to view the Human Milk Banking Association of North America guideline as it is not freely available.

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		pasteurisation testing) of milk and subsequent pasteurisation. There is large variability between 'immediately' and 'within 24 – 48 hours'. This may impact on the nutritional quality of the milk. It may also mean that the bacteriological sampling is not representative of the milk when it starts the pasteurisation process. Transporting milk to and from the milk bank – donor milk is now being increasingly transported over long distances including on occasions internationally. There is a need for clearer guidance on conditions and safe time frames, (Rec 2.12 .44 – 47) including recommendations regarding provision of volunteer services for both raw and pasteurised donor milk as this is now widespread and has impacted greatly on both the recruitment of donors and the provision of donor milk throughout the UK in recent years. Whilst the voluntary organisations have codes of practice and can be expected to adhere to high standards as they originally developed to transport blood and other emergency health products, specific practical recommendations could be included in the guidelines to aid these organisations, inform training requirements and help to ensure milk banks are utilising safe and optimal transport conditions. Duties of care of milk bank staff – the duties of care to the recipients are widely addressed through all the safety recommendations within the guideline however milk banks also have a duty of care to the donors including all women excluded from donating as a result of not meeting the NICE	No evidence was identified during guideline development or through this surveillance review on the timeframe between thawing and pooling of milk and subsequent pasteurisation to inform guidance in this area at this time. **Transporting milk to and from the milk bank** Guidance on transportation of milk was based on European Union directives related to the transportation of blood and tissue. These have not changed since the guideline was developed. The guideline recommends that all donor milk administered in the NHS should be from milk banks that can demonstrate adherence to the NICE guidance on the operation of donor milk banks. This guidance would apply to voluntary organisations if they are operating milk banks supplying the NHS. **Duties of care of milk bank staff** Thank you for raising the issue of duty of care to milk donors. However, as the focus of the guideline is on service delivery and the use of human donor breast milk in preterm babies, it is not within

		recommendations (eg maternal medications, alcohol intake, milk storage times, nicotine use). Recommendations should be considered for inclusion that address the risk that being excluded from a milk donation programme may impact on the mother's decisions regarding breastfeeding her own infant. (Ref Ensuring Safety in Donor Human Milk Banking in Neonatal Intensive Care Ben T. Hartmann. Clin Perinatol 44 (2017) 131–149) Duties of care to bereaved mothers are of especial importance – ensure use of appropriate recruitment literature, access to appropriate location and services for serology testing etc	the scope to include recommendations for people not involved in the service. Specific recommendations around breastfeeding are covered in NICE's guideline on postnatal care.
		There are currently increasing levels of informal sharing of milk in the UK and in addition human milk can be purchased via the internet. Human milk acquired in these ways by parents is likely to be being used to feed infants on neonatal units. This was not widespread in 2009. Whilst the guideline recommends that 'All donor milk administered in the NHS should be from milk banks that can demonstrate adherence to the NICE guidance on the operation of donor milk banks (Rec 1.7) the inclusion of further background discussions that highlight the potential risk of donor milk from safe sources not being available would inform and be of value to clinicians.	**Informal sharing of milk** This guideline focuses on identifying the optimal configuration of a milk bank service including recruitment, assessment and selection of donor women. As such, the guideline offers best practice advice on the operation of donor breast milk bank services. Informal sharing of milk and sourcing donor milk products via other routes beyond donor milk banks is beyond the scope of the guideline.
		There is an increasing global commercialisation of human milk (www.prolacta.com, www.medolac.com, www.internationalmilkbank.com , www.neolacta.com, www.ambrosia.com) including human milk that is	**Global commercialisation of human milk**

		purchased from mothers in one country for sale to families in another country. There are concerns surrounding the payment for human derived tissues and fluids Ref: The Gift Relationship: From Human Blood to Social Policy by Richard M Titmuss eds Ann Oakley, John Ashton LSE Books Human milk which has been paid for and sold from outside the UK does not currently meet the NICE recommendations, particularly with reference to not pooling milk between mothers CG93 Rec 1.56 Only pool pre-pasteurised breast milk from the same donor. 1.57 Do not pool breast milk from different donors, Such human milk and human milk products are currently in use in neonatal units in Europe including currently as part of research trials in hospitals in England.	Thank you for raising this issue. We are not aware of the use of commercial milk products in the UK. NICE's guideline on donor milk banks provides guidance on the operation of donor breast milk bank services. This includes guidance on recruiting, screening and selecting donors with a focus on ensuring that milk for donation reaches the donor milk bank as soon as possible to ensure the highest quality before processing. It is not within the scope of the guideline to make recommendations on use of commercial products within the NHS.
		The desirability of bar code tracking systems to enhance traceability should be reviewed. ICCBBA (the International Council for Commonality in Blood Banking Automation (www.iccbba.org) published ISBT128 Standard Labelling of Milk Banking Products in 2016. The use of ISBT128 coding should be considered for inclusion as a recommendation when bar coding tracking systems are in use in milk banks.	**Bar code tracking systems** The purpose of the ISBT128 Standard Labelling of Milk Banking Products document is to help facilities and software developers design appropriate ISBT 128 labels for human milk banking products. However, the guideline focuses more on the information that should be recorded as standard. During guideline development, tracking and tracing of milk samples was considered to be the most important function of any administration system used in a milk bank, and the committee were keen to make detailed recommendations on the principles to follow and the information to be collected. The

			guideline recommends that at all stages, donor milk containers should be labelled clearly for identification as there is no evidence on the most effective and efficient tracking and tracing system to use.
		There are widely varying practices in general between milk banking operations however these are particularly noteworthy around the bacteriological testing of donor milk (both before and after pasteurisation). These differences lead to widely varying discard rates of donor milk and so impact on the availability of donor milk in the UK. The results of the European Milk Bank Association's Working Group on 'Guidelines in use in Milk Banks in Europe' is expected to be published later this year (www.europeanmilkbanking.com) However these differences in recommendations also exist between the UK and North America as well as more globally (SeePATH. Strengthening Human Milk Banking: A Global Implementation Framework. Version 1.1. Seattle, Washington, USA: Bill & Melinda Gates Foundation Grand Challenges initiative, PATH; 2013,)	**Bacteriological testing of donor milk** We are not aware of variations in practice between milk banking operations around the bacteriological testing of donor milk (both before and after pasteurisation). NICE's guideline on donor milk banks provides guidance on the operation of donor breast milk bank services in the NHS and this may differ from guidelines and approaches taken in other countries due to different methods for developing guidelines. Through the surveillance review, no new evidence was identified which suggested NICE guideline CG93 should be updated.
		Are the alcohol intake recommendations from the Department of Health / NHS for alcohol intake in pregnancy and when breastfeeding (https://www.nhs.uk/conditions/pregnancy-and-baby/breastfeeding-alcohol/) wholly relevant for breastmilk donation? According to current recommendations it is considered safe to have 2 units of alcohol twice a week but not a single unit 5 times a week …	**Alcohol intake** The UK Chief Medical Officers' Low Risk Drinking Guidelines published in 2016 do not specifically focus on women who are breastfeeding. The current guideline is in line with information on NHS Choices which states: it's recommended that breastfeeding mothers have no more than one or two units of alcohol once or twice a week. The hyperlink in the current recommendation 1.12 will be replaced with a hyperlink to the NHS Choices website which

		even though donors are advised to leave sufficient time after alcohol for there to be none in their milk. In addition many parents follow an alcohol free diet and expect donors to do the same. This should be reviewed to ensure most relevant recommendation is being provided There is a need for a recommendations in place for Department of Health/NHS England etc to advise all milk banks of travel implications in the event of newly recognised viral or other infections globally e.g. Zika	includes more detailed information on alcohol intake when breastfeeding. **Recommendations for Department of Health and Social Care / NHS England** Thank you for your comment. It is not in NICE's remit to make recommendations for government bodies.
Bournemouth University	No	The following comments are predominantly based around the results of review we have recently completed on milk banking practices in the U.K. ("Exploring human milk banking practices in the U.K. including provision of nutritional advice/information – especially with respect to omega-3 and omega-6 fatty acids" IRAS project ID: 205068). We had a response rate of 93% (14 of the 15 active milk banks), and are currently extending this internationally. We will be submitting the results for publication to a peer reviewed journal, but they have been presented at the 4th International European Milk Bank Association Congress Glasgow (2017), and the 13th International Congress of the International Society for the Study of Fatty Acids and Lipids (2018).	Thank you for your comment and for highlighting the review you have developed. Unfortunately, as this is unpublished work we are unable to consider the results in this surveillance review. However, we will add the review details to our event tracker and consider any impact on the guideline when published. However, we have considered the individual studies cited below: • Turoli, Testolin, Zanini, Bellù R.(2004): Determination of oxidative status in breast and formula milk. Acta Paediatr. 93(12):1569-74 – *This study is outside the surveillance search dates.* • Bertino,Giribaldi, Baro, Giancotti, Pazzi, Peila, Tonetto, Arslanoglu, Moro, Cavallarin, Gastaldi, (2013): Effect of prolonged refrigeration on the lipid profile, lipase activity, and oxidative status of human milk. J Pediatr Gastroenterol Nutr. 56(4): 390–396 – *This study reported that prolonged refrigeration (up to 96 hours) did not affect the fatty acid composition of breast milk, and preserved both its overall oxidative status and the*

		The main comments relate to issues around storage and transport conditions and how these negatively impact on the quality of the milk. Although the milk banks complied with the NICE guidelines, there is now a large body of evidence indicating milk should be stored at the lowest possible temperature for the shortest possible time, as polyunsaturated fatty acids in milk are highly prone to damage be oxygen (lipid peroxidation) and sub-optimal conditions lead to the generation of toxic peroxides and also decrease the nutritional content of the milk. We are currently producing a review of the effects of storage conditions on human milk and would be happy to provide further references, but for initial background: Turoli, Testolin, Zanini, Bellù R.(2004): Determination of oxidative status in breast and formula milk. Acta Paediatr. 93(12):1569-74 Bertino,Giribaldi, Baro, Giancotti, Pazzi, Peila, Tonetto, Arslanoglu, Moro, Cavallarin, Gastaldi, (2013): Effect of prolonged refrigeration on the lipid profile, lipase activity, and oxidative status of human milk. J Pediatr Gastroenterol Nutr. 56(4): 390–396 Elisia I, Kitts, (2013): Differences in vitamin E and C profile between infant formula and human milk and relative susceptibility to lipid oxidation. Int J Vitam Nutr Res. 83(5):311-9.	*activity of human milk lipolytic enzymes. No impact on the guideline is anticipated as it currently recommends that donors should be advised that expressed milk collected for donation should be frozen as soon as possible to maintain the nutritional and microbiological quality of the milk.* • Elisia I, Kitts, (2013): Differences in vitamin E and C profile between infant formula and human milk and relative susceptibility to lipid oxidation. Int J Vitam Nutr Res. 83(5):311-9. – *This study is comparing the nutrient composition of formula milk with human milk which is not directly applicable to NICE guideline CG93 which focuses on the operation of donor breast milk bank services.* • Miranda, Muriach, Almansa, Jareño, Bosch-Morell, Romero, Silvestre (2004): Oxidative status of human milk and its variations during cold storage. BioFactors 20: 129-137. – *This study is outside the surveillance search dates.* • van Zoeren-Grobben, Moison, Ester, Berger HM (1993): Lipid peroxidation in human milk and infant formula: effect of storage, tube feeding and exposure to phototherapy. Acta Paediatr. 82(8):645-9. – *This study is outside the surveillance search dates.*

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		Miranda, Muriach, Almansa, Jareño, Bosch-Morell, Romero, Silvestre (2004): Oxidative status of human milk and its variations during cold storage. BioFactors 20: 129-137. van Zoeren-Grobben, Moison, Ester, Berger HM (1993): Lipid peroxidation in human milk and infant formula: effect of storage, tube feeding and exposure to phototherapy. Acta Paediatr. 82(8):645-9. **Handling donor milk at home: 1.38** This recommendation needs to be amended, as currently the recommendation does not define temperature and time limits for transport only "frozen as soon as possible". Our results indicate wide variability in practices, which may negatively impact on the milk quality. Four milk banks recommend that milk should be frozen immediately, six recommend immediate freezing as best practice, but allow storage in the fridge for 24 hours, and four recommend storing in the fridge for 24 hours before freezing. Although these are all within the current guidelines, we suggest that the guidelines should be amended based on the literature to state that the milk must be frozen immediately. **Handling donor milk at home: 1.40**	**Handling donor milk at home: 1.38** Thank you for your comment. The current guidance provides a framework for donors to work within depending on their circumstances and availability of storage capacity to freeze expressed milk. We didn't identify any evidence through the surveillance review to indicate that specific timeframes for freezing donor milk could be added to the recommendation. **Handling donor milk at home: 1.40** The current recommendation allows for some flexibility as expressed milk can be used after being frozen for up to 3 months in a domestic freezer. No new evidence was identified through the surveillance review to indicate that specific timeframes for freezing donor milk could be added to the recommendation.

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		Although all within the guidelines, there is wide variability in practice with regards storage at home. 10 milk banks allow storage for up to three months before transport, three between one to two months and for one month or less. The time-limit should be informed by the evidence and limited to less than one month. **Handling donor milk during transportation: 1.44** This recommendation needs to be amended, as currently it does not define temperature or time limits for transportation only "to ensure that donor milk remains frozen during transport". This lack of clarity has led to wide variability in practices. Our result show that two milk banks have 30 minute time limits for transportation, three have one hour limits, one has two hours, two have four hours, one has five hours, and five milk banks have no time limits. As dry ice is not provided for transportation the stability of the milk cannot be guaranteed, particularly on the longer journeys in hot weather conditions. We suggest that there needs to be a defined maximum time-limit for transportation, and recommendations that milk should be transported on dry ice to ensure it remains frozen on the	**Handling donor milk during transportation: 1.44** Thank you for your comment, this recommendation was based on European Union directives related to the transportation of blood and tissue aiming to ensure that milk collected from a donor's home should be frozen and remain frozen during transport to the milk bank. No evidence was identified through the surveillance review to enable further detail about temperature and time limit for transport of donor milk to be added to the recommendation.

		longer journeys, as occurs between milk banks and hospitals. **Handling donor milk at the milk bank: 1.53** This recommendation states that storage at milk banks should be at -20°C for no longer than three months. It has been shown that to preserve the antioxidant capacity of milk temperatures much lower than this is required (e.g. Akdag, Sari, Dizdar, Uras, Isikoglu, Erel, Dilmen (2014): Storage at -80°C preserves the antioxidant capacity of preterm human milk. J Clin Lab Anal. 28(5):415-8), and therefore we recommend storing should be for short time-frames at the lowest possible temperature, ideally -80°C.	**Handling donor milk at the milk bank: 1.53** Thank you for highlighting the study by Akdag et al. Although this study suggests that freezing preterm human milk at -80°C preserves the antioxidant capacity, it doesn't indicate that freezing milk at -20°C has any detrimental impact on the safety or quality of the milk. Similarly, no evidence was identified through the surveillance review to indicate that the recommendation to store donor milk awaiting pasteurisation in the freezer at the milk bank (at −20°C) for no longer than 3 months from the date of expression should be updated.

Do you have any comments on areas excluded from the scope of the guideline?

Stakeholder	Overall response	Comments	NICE response
Royal College of Nursing	Yes	We would agree that amendments are required i.e. Recommendations 1.12 (see pages 4-5) of the guideline	Thank you.
Royal College of Paediatrics and Child Health	No answer	No comments provided	Thank you.

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Hearts Milk Bank CIC	Yes	Yes At the time the guideline was published the recipients of donor human milk from UK milk banks were almost exclusively preterm infants being cared for on neonatal units. The use of DHM for cardiac, post gut surgery and other term infants was minimal. Whilst this generally remains the case there is a growing use of donor milk by sick term infants and by healthy infants whose mothers are unable to lactate (undergoing cancer treatment, post mastectomy, HIV positive, using medications contraindicated for breastfeeding. (Hearts Milk Bank: developing the 'bank with a difference' Infant , Volume 14, Issue 3, 2018. CCG funding is made available in some cases to facilitate the use of DHM for such infants however it has been inconsistent. Having standard recommendations that don't take into account the wide variability in maturity, health and age of recipients means that potentially large volumes of human milk are discarded (potentially unnecessarily) or donors not recruited. However given that the vast majority of recipient infants remain those born very preterm / very low birth weight should consideration be given to optimising donor milk or prioritising donor milk best suited to this population. This includes the diet of donors especially with regard to intake of essential fatty acids – Rec 1.2.13 suggests asking questions about a donor's health (to confirm that she is in good general health).	Thank you for your comment. However, indications for the use of donor breast milk is an area outside the scope of this guideline which focuses on the operation of donor breast milk bank services and selection of donors. It's not clear how variability of recipients would impact on recruitment of donors. The guideline recommendations aim to promote the donation of breast milk as widely as possible whilst the screening and selection process recommended in the guideline is vital to ensure the safety of the donated milk.
Bournemouth University	Yes	**Handling donor milk at the milk bank**	Thank you for your comment. A timeframe between pooling milk and pasteurisation is noted in the guideline which recommends (1.56) pooling pre-pasteurised breast milk from the same donor and

		There is currently no guidance as to the timeframe between pooling of milk and pasteurisation. 11 milk banks report immediately pasteurising after pooling and microbial testing, whereas, one stores at 4°C for 24 hours and one refreezes and stores at -20°C for two days before thawing again for testing. The thawing and refreezing during this process has the potential to negatively impact the quality of the milk by releasing free fatty acids, which are more susceptible to lipi peroxidation. Importantly, the increases in free fatty acids are most likely attributed to an enzyme which increases activity during low temperature storage (Mehta, Jones, Hamosh (1982): Lipases in preterm human milk: ontogeny and physiologic significance. J Pediatr Gastroenterol Nutr. 1982;1(3):317-26). Since these enzymes are destroyed by pasteurisation, we suggest that there should be a new recommend to minimise pre-pasteurisation storage times and immediately pasteurise after microbiological testing. **Handling donor milk at the milk bank** There are currently no recommendations regarding limiting of photooxidation of milk. The long chain polyunsaturated fatty acids and other lipid compounds in milk are highly prone to lipid peroxidation and are light sensitive. Milk banks tend to use freezers with glass doors to reduce the time it takes to search for milk with the door open. We suggest a new recommendation to cover glass freezer	(1.55) that donor milk should be thawed before testing and pasteurising and kept in the refrigerator for no longer than 24 hours. The recommendations on handling donor milk at the milk bank indicate that milk may be frozen if stored ahead of pasteurisation, would be thoroughly thawed for pasteurisation and then frozen again for storage purposes. Unfortunately we cannot consider the study suggested by the stakeholder as it published outside the surveillance period and was available during guideline development. During development of recommendations, the evidence was not clear about which storage methods are least damaging to the nutritional and immunological components of donor milk. No evidence was identified through the surveillance to add to that considered in development of the guideline. Thank you for noting the risk of potential photooxidation of the donor milk. No evidence on this was identified through the surveillance review however, we will note this issue and investigate again at the next surveillance review.

		doors to decrease light exposure, and also cover milk when out of the freezer on the bench. **Screening and selecting donors** There needs to be strong recommendations in place for the Department of Health to advise all milk banks in the event of newly recognised viral or other infections e.g. Zika virus. **Screening and selecting donors** The nutritional content of human milk is highly responsive to maternal dietary intake, and we would like to recommend exclusion of specific donors at high risk of deficiency, where dietary intake is suboptimal, for example those following vegan diets deficient in long-chain omage-3 fatty acids. **Training and supporting donor** Further to the previous point, although no specific recipient groups are addressed within the guideline the known recipients in the UK are almost exclusively preterm infants and their specific needs should be taken into account when using donor milk. Specifically, recommendations around donors' diets should be explored given the desirability of a mixed diet that includes oily fish, which would of course benefit all recipients, but especially preterm infants. Human milk is highly responsive to levels of omega-3 fatty acid intake, and preterm infants are at risk for omega-3 fatty	Thank you for raising this. It is no longer within NICE's remit to make recommendations for government bodies. However, recommendation 1.13 states that when screening and selecting donors, the woman should be asked about any recent exposure to infection and this could include Zika virus. Thank you. The guideline already recommends (1.13) that potential donors should confirm they are in good health. Additionally, PH11: Maternal and child nutrition includes guidance for breastfeeding mothers including a recommendation to advise mothers that a healthy diet is important for everyone and that they do not need to modify their diet to breastfeed. No evidence was identified through the surveillance review to suggest there is an impact of specific diets on nutrient content of human milk. However, based on your feedback we will add a cross-referral from CG93 to PH11: Maternal and child nutrition. Indications for the use of donor breast milk is an area outside the scope of this guideline which focuses on the operation of donor breast milk bank services and selection of donors. The study by De Rooy, although focusing on the importance of polyunsaturated fatty acids in preterm babies, doesn't include human milk donations as a source of omega-3 fatty acid intake so it's applicability to the guideline is unclear. No evidence was identified through the surveillance review to suggest there is an impact of specific diets on nutrient content of human milk. However, we will monitor this area again at the next surveillance review of the guideline.

		acid deficiency e.g. De Rooy, Hamdallah, Dyall (2016): Extremely preterm infants receiving standard care receive very low levels of arachidonic and docosahexaenoic acids. Clin Nutr. 36(6): 1593-1600 Our review found that currently 11 of the milk banks do not offer nutritional guidance, and three offer only general advice. Finally, while indications, advantages and use of donor breast milk is *per se* not within the scope of this guidance, it is important that this is reviewed urgently as well. Unlike many other developed nations we seem to lack a clear national guidance on this. For example: https://www.milkbankontario.ca/research-and-resources/evidence-for-the-use-of-donor-milk/	Topic experts highlighted in the surveillance review that one of the greatest limitations of NICE guideline CG93 is a lack of clinical guidance on aspects related to who should receive donor milk, what are the benefits and harms of this intervention, and the management of the donors. These aspects are not covered in the scope of CG93. This will be added to the issue log of PH11: Maternal and child nutrition which is going to be updated, so this aspect could be considered in the scoping phase of the update.
Do you have any comments on equalities issues?			
Stakeholder	**Overall response**	**Comments**	**NICE response**

Royal College of Nursing	Yes	All seem appear appropriate	Thank you for your response.
Royal College of Paediatrics and Child Health	No answer	No comments provided	Thank you.
Hearts Milk Bank CIC	Yes	There have been no studies published on equality issues with regard to ethnicity, race, religion etc of donors in the UK however UK milk banks would attest to there being a lack of diversity amongst donors, especially amongst donors recruited from mothers of non hospitalised infants. In addition consideration should be given to the impact of the British Association of Perinatal Medicine (www.bapm.org) document 'Resolution on the Use of Donor Human Milk for Muslim Infants included in A Framework for Practice: the use of donor human expressed breast milk in newborns. 2016.	Thank you. The guideline aims to be inclusive in recruiting donors and provides guidance on using a variety of channels to reach as many potential donors as possible (1.9). This recommendation will be amended to include internet and social media. Indications for the use of donor breast milk is an area outside the scope of this guideline which focuses on the operation of donor breast milk bank services and selection of donors. However, the document cited (Resolution on the Use of Donor Human Milk for Muslim Infants included in A Framework for Practice: the use of donor human expressed breast milk in newborns. 2016) will be added to the issue log of PH11: Maternal and child nutrition which is going to be updated, so this aspect could be considered in the scoping phase of the update.
Bournemouth University	No	No comments provided	Thank you.