

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Centre for Clinical Practice

Review of Clinical Guideline (CG93) – Donor breast milk banks: the operation of donor milk bank services

Background information

Guideline issue date: 2010

Review: 2012 ([first review](#))

National Collaborating Centre: Internal Clinical Guideline Programme

Review recommendation

- The guideline should not be updated at this time.

Factors influencing the decision

Literature search

1. Through an assessment of abstracts from a systematic literature search, new evidence was identified that related to the following clinical areas within the guideline:
 - Service descriptions (whole guideline)
 - Recruitment, assessment and selection of donor women
 - Recruiting donors
 - Serological testing of potential donors.
 - Collection, storage and handling of donor breast milk
 - Testing and treatment of donor milk, including pasteurisation

2. No new evidence was identified in these areas which would invalidate the current guideline recommendations.
3. Initial intelligence gathering, qualitative feedback from other NICE departments, the views expressed by the Guideline Development Group, and the systematic literature search indicated that there were no additional clinical areas that required further focused literature searches.
4. New evidence was identified which directly answered 1 research recommendation in the original guideline relating to:
 - The process of handling donor milk: What is the effect of the process of milk banking on the nutritional and immunological components of donor milk? The new evidence detailed the consequences on immunological and nutritional components however often failed to detail microbial consequences of the treatment in the abstracts (summarised in table 1). The GDG noted that the pasteurisation method needed to balance safety with the destruction or reduction in the nutritional and immunological components of donor milk.

Guideline Development Group and National Collaborating Centre perspective

5. A questionnaire was distributed to GDG members, the National Collaborating Centre and the milk bank service providers to consult them on the need for an update of the guideline. Nine responses were received with all respondents highlighting that there was no new evidence related to the guideline that supports or contradicts current guideline recommendations or any interventions that have become more cost-effective or are likely to become more cost-effective. However, 5 respondents suggested partial updates looking at practice issues around
 - Exclusion criteria for donors
 - (IVF medication

- **variant** Creutzfeldt Jakob disease (CJD) risk stratification via the Health Protection Agency website)
- Defrosting conditions for donor milk
- Cooling temperatures for pasteurised donor milk
- Staff training.

No variations or substantial changes to management, costs or organisation of care recommended by the current guidelines were reported. Nor were there any reports of any new national policies or audits or efficacy or safety concerns about the recommended practice.

Implementation and post publication feedback

6. In total 19 enquiries were received from post-publication feedback, of which all were routine.
7. Feedback from the NICE implementation team indicated that the guideline was well received and has elevated the profile and importance of milk banks within the NHS. This has enabled management buy-in and ensured appropriate staff training and funding of such a “special” service. However, others stakeholders have commented that if unsupported or underfunded then milk banks struggle to implement the guideline due to lack of resources, low service profile and lack of competent staff.
8. In summary, no new evidence was identified through post publication enquiries or implementation feedback that would indicate a need to update the guideline.

Relationship to other NICE guidance

9. NICE guidance related to CG93 can be viewed in [Appendix 1](#).

Summary of Stakeholder Feedback

Review proposal put to consultees:

The guideline should be not updated at this time.

10. In total 11 stakeholders commented on the review proposal recommendation during the two week consultation period. The table of stakeholder comments can be viewed in [Appendix 2](#).

11. Eight stakeholders agreed with the review proposal and 1 stakeholder disagreed and 2 offered no opinion on the proposal.

12. Stakeholders commented that:

- They would like further clarity on the eligibility of donors with regard to
 - risk of CJD /vCJD
 - Smoking status
 - Medication use

Through the review of the guideline no evidence was found in these areas that would invalidate current recommendations and it was concluded that these topics do not need to be updated at this time.

- In addition, the requested reviews on storage times for donor breast milk, methods of thawing donor breast milk and the efficacy of different methods of pasteurisation. Through the review of the guideline no evidence was found in these areas that would invalidate current recommendations and it was concluded that these topics do not need to be updated at this time.

Anti-discrimination and equalities considerations

13. No evidence was identified to indicate that the guideline scope does not comply with anti-discrimination and equalities legislation.

Relationship to quality standards

14. This topic may potentially inform upcoming Quality Standard NHS healthcare topics.

15. This topic is not currently related to a published quality standard or a quality standard in development

Conclusion

16. The guideline should not be considered for an update at this time.

Mark Baker – Centre Director
Sarah Willet– Associate Director
Katy Harrison– Technical Analyst

Centre for Clinical Practice
27 November 2012

Appendix 1

The following NICE guidance is related to CG93:

Guidance	Review date
PH11 Maternal and child nutrition. NICE public health guidance 11 (2008)	July 2014
CG37 Postnatal care (2006)	July 2015.

There are 4 topics on the NICE quality standards topic library that have been referred that may have overlap with CG93:

Premature birth. Quality Standard

Parenteral nutrition in neonates. Quality Standard

Failure to thrive. Quality standard

Development follow-up pre-term babies. Quality standard

Appendix 2

National Institute for Health and Clinical Excellence
CG93 Donor breast milk banks

Guideline Review Consultation Comments Table

22 October – 5 November 2012

<i>Type</i>	<i>Stakeholder</i>	<i>Agree?</i>	<i>Comments</i> Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	Response
SH	British HIV Association	Yes	The issues relating to the screening of potential donors for HIV, and the treatment of donor milk to destroy HIV are covered in the original guideline and there does not appear to be any new evidence to change these recommendations.	N/A	N/A	Thank you for your comment.
SH	Department of Health		Thank you for the opportunity to comment on the review for the update of the above clinical guideline. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.			Thank you for your comment.
SH	La Leche League Great Britain	Yes, no update needed at present	Hope that the new evidence can be added for reference			Thank you for your comment.
SH	Medicare Colgate Ltd		No further comments			Thank you for your comment.

CG93 Donor breast milk banks Review Decision – December 2012

Type	Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	Response
SH	Royal College of General Practitioners	Yes (JA)				Thank you for your comment.
SH	Royal College of General Practitioners	Yes (MM)		I feel that the comment “providing leaflets in GP surgeries “ does not go far enough. Milk bank providers need to provide clear concise information to GPs on screening. Women who choose to donate breast milk go to a great deal of trouble to provide this service and it is essential that , where providers advise a woman to be screened at her GP surgery, that the GP is provided with the relevant information. In practice this does not always happen. (MM)		Thank you for your comment. The guideline provides information that is aimed at all healthcare professionals on screening and selection of donors.
SH	Royal College of Midwives	Yes	The RCM agrees with the proposal not to update the guideline as this time, in the context of the literature search			Thank you for your comment.

CG93 Donor breast milk banks Review Decision – December 2012

Type	Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	Response
			that found no new evidence that would change the recommendations.			
SH	Royal College of Nursing	Yes	We have nothing further to add. The proposal that the guideline should not be considered for an update at this time, seems sensible.			Thank you for your comment.
SH	Royal College of Obstetricians and Gynaecologists	Yes				Thank you for your comment.
SH	Royal College of Paediatrics and Child Health	Yes	We are pleased to see that the effects of pasteurization and freezing on immunological properties are increasingly being recognized.	The original document did not adequately elaborate which donors who have had IVF therapy should or should not be excluded. This is now a frequent issue for Milk Banks to address and causes a lot of concern amongst women who are potential donors. It would be very helpful to have clearer and more comprehensive	No	Thank you for your comment. The guideline currently recommends that a balanced decision on the eligibility should be made by healthcare professional recruiting the donor and take into account any current medication or recent medical intervention. The guideline does not

CG93 Donor breast milk banks Review Decision – December 2012

Type	Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	Response
				guidance on donors who have had IVF, particularly, as the drugs now used in IVF have changed		aim to be prescriptive and as such does not list all procedures or medications that an individual may be on.
SH	Royal College of Pathologists	Yes in general	<p>Should update advice on vCJDCJD risk stratification with link or reference to DH 'Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection: Part 4' 2010, as well as HPA.</p> <p>Should clarify what 'testing positive for hepatitis B and C' means – HBsAg positive required, not anti-HBc with HBsAg negative for example, and is HCV antibody enough or is HCV PCR needed?</p>			<p>Thank you for your comment.</p> <p>The document suggested for inclusion covers infection control procedures for taking samples from individuals who have a high risk of vCJD. As such it is outside the scope of the guideline as these individuals would not be eligible to be donors.</p> <p>The interpretation of test results to clarify the donors serological</p>

Type	Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	Response
						suitability for donation is part of the healthcare professionals role. The guideline is not designed to be prescriptive or replace clinical expertise.
SH	United Kingdom Association for Milk Banking	No	Milk bank staff have requested greater clarity with regard to defining which mothers are at increased risk of CJD. There is disparity between the HPA and the National Blood Service particularly around having received a blood transfusion and having received fertility treatments.			Thank you for your comment. The guideline recommends the use of the HPA risk stratification scheme. The National blood Service guidance details who should donate blood and does not give advice on the level of risk for vCJD. No further evidence was identified during the process on donor risk and CJD/vCJD.
SH	United Kingdom		Milk bank staff have requested greater clarity with regard to the medications (including herbal medications) that exclude a			Thank you for your comment.

CG93 Donor breast milk banks Review Decision – December 2012

Type	Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	Response
	Association for Milk Banking		mother (including temporarily) from donating her breastmilk. Whilst it is understood that the guideline does not determine or offer guidance on whom the recipients should be, in practice, which medications would be acceptable for different categories of recipients would be very useful.			The provision of a list of all possible medications has not been provided within the guideline as the guideline is not intended to be prescriptive and replace clinical judgement. The guideline recommends that health professionals refer to a suitable medical source to determine if current medication is a contraindication to milk donation.
SH	United Kingdom Association for Milk Banking		Milk bank staff and microbiology laboratory staff would benefit from a clearer identification and classification of the types of bacteria and the levels of bacteria that are acceptable in donor breastmilk prior to pasteurisation eg in tabular form.			Thank you for your comment. Your comments will be retained for future consideration.
SH	United Kingdom Association for		Donors often go away for weekends and holidays at short notice. Milk bank staff have requested guidance on whether the absence of daily temperature recordings should always			Thank you for your comment. The

CG93 Donor breast milk banks Review Decision – December 2012

Type	Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	Response
	Milk Banking		automatically preclude the acceptance of the frozen breastmilk.			recommendations with NICE clinical are for guidance. However, the guideline makes a series of recommendations relating to processing and storage of donor breast milk based on the best available evidence.
SH	United Kingdom Association for Milk Banking		Is there a need for a review of the storage times for donor breastmilk (in the fridge and freezer) and methods of thawing breastmilk in the light of Pseudomonas outbreaks on neonatal units in 2011 and 2012?			Thank you for your comment. No new evidence related to milk storage was identified that would change the current recommendations within the guideline.
SH	United Kingdom Association for Milk Banking		Guidance would be welcomed on the efficacy of different methods of pasteurisation including hot water, hot air, different methods of cooling and final temperatures achieved.			Thank you for your comment. No new evidence related to different pasteurisation processes was

CG93 Donor breast milk banks Review Decision – December 2012

Type	Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	Response
						identified that would change the current recommendations within the guideline.
SH	United Kingdom Association for Milk Banking		Tracking and traceability: can the guidance include a statement related to the only coding standard that should be adopted in any electronic breastmilk banking system is ICCBBA ISBT 128.			Thank you for your comment. The guideline makes numerous recommendations on the tracking and traceability of donor breast milk. The use of a coding standard is down to the preference of individual milk banks.
SH	United Kingdom Association for Milk Banking		Advice is requested on when is an ex smoker accepted as being a non smoker in terms of recruitment as a milk donor.			Thank you for your comment. The guideline states that only current smokers should not be considered eligible as donors.

