

National Institute for Health and Clinical Excellence

Donor breast milk banks – Pre-publication check  
Guideline Consultation Comments Table  
30 November – 14 December 2009

Type	Stakeholder	Order No	Section No	Page No	Error reported	Response
SH	Department of Health	1.00			<p>Thank you for the opportunity to comment on the pre-publication check of factual errors for the above clinical guideline.</p> <p>I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.</p>	Noted with thanks
SH	Glasgow Caledonian University	2.00			I can see no need for further alterations.	Noted with thanks
SH	La Leche League GB	3.00			Did not find any errors	Noted with thanks
SH	Medicare Colgate Ltd	4.00	1.2 – Quality Assurance Section	Page 7	<p><b>Quality assurance :</b> 1.2 states There is no NHS standard for Human Milk Pasteurisers.</p> <p>This is factually incorrect</p> <p>There is a Guidance from the 'Department of Health' :</p> <p>'Collection &amp; Storage of Human Milk' Report of a working party on human milk banks, panel on child nutrition, committee on medical aspects of food policy (see attached extract)</p> <p>This report states in Appendix IV ' after heating the milk temperature should be reduced to 25°C within 10 minutes.</p> <p>This methodology has been practised by all milk</p>	This is guidance published in 1981 that would now not be considered as an NHS standard (and this particular point is preceded with 'it is suggested'). In addition this has been superceded by many documents since publication, including the UKAMB 2003 guidelines.

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					banks and pasteuriser manufacturers over the past 20 years and has become an international standard with the exception of a few UK Milk Banks who have adopted uncontrolled tap water cooling in recent years.	
SH	Medicare Colgate Ltd	4.01	1.2.61 Handling Milk at the Milk Bank	Page18	<p><b>Handling Milk at the Milk Bank</b></p> <p>1.2.61 states: ' Pasteurise donated milk at 62.5 C for 30 minutes in a human milk pasteuriser'</p> <p>Factually omitted is the rapid cooling requirement</p> <p>Described as reducing the temperature from 62.5 to 25 C within 10 minutes with continuous cooling now suggested to 4 C. (Technical note : all temperatures should have a + or - 0.5 ° C tolerance)</p>	We have recommended rapid cooling in a following recommendation. We have also added in an evidence statement (2.14.3.11) on cooling post pasteurisation reported in the literature.
SH	Medicare Colgate Ltd	4.02	1.2.65 Handling Milk at the Milk Bank	Page 19	<p>1.2.65</p> <p><i>States 'after testing and pasteurising, rapidly cool the milk to a temperature of 4 °C or lower, then move to a freezer'</i></p> <p>Factually incorrect Testing should not delay the cooling process and should be carried out after cooling.</p> <p>A delay through waiting for testing could cause re- growth of bacteria in the milk.</p>	This recommendation has been revised to address this concern.
SH	Medicare Colgate Ltd	4.03	2.17.3.6 Evidence Statement	Page 100	<p><b>Evidence statement</b></p> <p>2.17.3.6</p> <p>States : Heating Milk to 62.5. °C for 30 minutes ( Holder Pasteurisation)</p>	This has been removed for clarity.

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					<p>Factually incorrect</p> <p>Definition of ' Holder Pasteurisation'</p> <p>The English standard definition of holder pasteurisation is that the milk shall be retained at a temperature for at least 30 minutes and to be immediately cooled to a temperature not more than 12 C.  ( See attached extract from <i>The Journal of Hygiene, Vol.33.No1 ( Jan 1933)</i>  <i>'Milk Pasteurisation as a technical problem.</i></p>	
SH	Medicare Colgate Ltd	4.04	2.17.4 Evidence of Recommendations	Page 103	<p><b>Evidence to recommendations</b></p> <p>2.17.4 states</p> <p>'Equipment should be fit for purpose'</p> <p>Definition of what is fit for purpose is required.</p> <p>Equipment needs to perform to a scientifically proven methodology as stated in the definition for holder pasteurisation. Specifically fulfilling the Department of Health Guideline on rapid cooling,</p> <p>Recent History</p> <p>A recent independent study carried out by an NHS authorised testing house on the performance of pasteurisation equipment on behalf of the Greater Glasgow &amp; Clyde Health Board and at Countess of Chester NHS Foundation Trust both used uncontrolled cooling.</p> <p>A full comparison test was made with a pasteuriser with controlled cooling and the test summary showed that uncontrolled cooling</p>	Thank you for your comment. However, your comment relates to an issue other than a factual error. Therefore we cannot respond to it

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					<p>failed the UKAMB guidelines ( now withdrawn).</p> <p>Consequently Glasgow has changed to controlled cooling equipment for their Donor Human Milk Bank.</p> <p>Notes :</p> <p>At the NICE consultation meeting on the 18<sup>th</sup> September 09 this information was again made available to the committee and the potential hazard was supported by the representative from the Royal College for Paediatrics, Prof. Andrew Wilkinson.</p>	
SH	National Childbirth Trust	5.00	2.10.4	58	<p>"All breastfeeding mothers are given clear information on how to express milk for their own babies." This is true only in maternity facilities accredited by the Baby Friendly Initiative or well on the way to achieving BFI status. This covers fewer than half the units and birth centres in England and no evidence is provided for the statement. We suggest it is changed to: All breastfeeding mothers <i>should be</i> given clear information on how to express milk for their own babies.</p>	This has been revised as suggested.
SH	Royal College of Nursing	6.00	2.1	23	<p><i>First paragraph is a repetition from 1.42 on page 22</i></p>	Thank you for your comment. However, your comment relates to an issue other than a factual error. Therefore we cannot respond to it
SH	Royal College of Nursing	6.01	1.2.38-1.2.43	74	<p><i>These paragraphs appear to repetition from 1.2.44-1.2.49 on page 63</i></p>	Thank you for your comment. However, your comment relates to an issue other than a factual error. Therefore we cannot respond to it
SH	Royal College of Paediatrics and Child Health	7.00			<p>Thank you for inviting the Royal College of Paediatrics and Child Health to do a pre-publication check for factual errors on the guideline on donor breast milk banks.</p>	Noted with thanks

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					We do not have any comments on this check. We look forward to its final publication as well as the response table to the stakeholder comments on the draft guideline.	
SH	United Kingdom Association for Milk Banking	8.00	1.2.58	17	Rather than referring to total viable bacteria, change to total viable microbial count . This is to include fungal micro organisms which may contribute to the total count. Please change other references to total viable bacteria to total viable microbial count throughout the document.	This has been corrected throughout.
SH	United Kingdom Association for Milk Banking	8.01	1.2.59	18	Instead of bacterial testing refer to microbial testing	This has been corrected throughout.
SH	United Kingdom Association for Milk Banking	8.02	1.2.63	18	Suggest microbial rather than bacterial	See response above
SH	United Kingdom Association for Milk Banking	8.03	1.2.64	19	As above	See response above
SH	United Kingdom Association for Milk Banking	8.04	2.6.4	41	Seroconversion rate of 15%. Is this correct?	<a href="http://www.chiva.org.uk/presentations/dontforget/pdf/Tookey-DFC.pdf">http://www.chiva.org.uk/presentations/dontforget/pdf/Tookey-DFC.pdf</a> based on the National Audit of Perinatal Transmission of HIV in England 2002 to 2005 (details <a href="http://nwww.esussexaiou.nhs.uk/docs/specialised/VerticaltransmissionFullreportOctober2007.pdf">http://nwww.esussexaiou.nhs.uk/docs/specialised/VerticaltransmissionFullreportOctober2007.pdf</a> )
SH	Western Health and Social Care Trust	9.00			<p>Recommendation 1.2.40 Freezer @ -18o or lower</p> <p>Recommendation 1.2.54 Freezer @ - 20o</p> <p>Why the difference in temperature?</p> <p>Chartered Institute for Environmental Health states</p>	<p>1.2.40 Temperature is consistent with the NICE guidance on maternal and infant nutrition <a href="http://www.nice.org.uk/nicemedia/pdf/PH011guidance.pdf">http://www.nice.org.uk/nicemedia/pdf/PH011guidance.pdf</a></p> <p>1.2.54 Temperature is consistent with the FSA guidance on infant feeds in hospital</p>

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					-18oC+ - 25oC for Freezers	<a href="http://www.food.gov.uk/multimedia/pdfs/publication/babypowdertoolkit1007">http://www.food.gov.uk/multimedia/pdfs/publication/babypowdertoolkit1007</a>