Questions for discussion

Guideline title

- Does the proposed guideline title of *'Milk banks: guidelines on the operation of donor milk bank services for preterm babies'* reflect the aims and purpose of the proposed guideline?

Population

- Are we correct in our definitions of the groups to be included?
- Key clarification needed is on the use of preterm – should we add growth restricted and low birth weight babies, seriously ill babies?

Healthcare setting & services

- Have we included all relevant Healthcare settings?
- Are there any other settings that need specifying – for example, where a mother may be at home but the baby is still in hospital?

Clinical Management

- Any comments on the areas to be covered?
- Are there any areas where existing guidelines on maternal breastfeeding would be appropriate – for example, are there any specific issues related to expression of milk for donor women compared to mothers?
- Should we be including the question on fortification/engineering of milk?

- Are there specific issues for the groups covered – ie preterm babies?
- Any comments on the areas not to be covered?

Recommendations

- Even just considering evidence based recs from the UKAMB guidelines, there are at least 40 (overall approx 100 recs) – in a short clinical guideline, we usually have no more than 20 recs.
  Are there any areas that we should be focussing on?
- How detailed should the recommendation be – for example, in the UKAMB the recommendations are very detailed, and are almost protocols for the operation of a milk bank – what are the expectations for this guideline?

Key Outcome Measures

- How can the safety of donor milk be assessed?
  Many studies are simply testing samples of milk for infection or difference in composition – how can we be sure that we get evidence that makes a real difference to the health of the baby?
- What are the long-term safety concerns related to donor milk – CJD, any others?

Health Economics

- Any initial thoughts on where a health economic approach will be most useful

GDG Composition

- Neonatologist x 2 - ?academic, ?access to milk bank, ?no access to milk bank
- Neonatal nurse x 2 - ?academic, ?access to milk bank, ?no access to milk bank
- Midwife x 2 - ?academic, ?community,?specialist in breast feeding
- Health visitor with experience of supporting donors/mothers of preterm babies
- PH physician with interest/expertise in infant nutrition/breastfeeding uptake
- Pharmacist/pharmacologist
- Microbiologist with special interest
- Manager/director of a milk bank
- Commissioner of relevant services
- Relevant professional with expertise in donor related issues
- ?safety of donor tissue/products
- Lay member x 2

Searching for Evidence

- What is the expected level/amount of evidence that we are likely to find?
- Can we restrict solely to donor milk, or will we need to refer to studies on maternal milk?
- Where would this not be appropriate?
- Have the processes used in milk banks changed over time – if so, would it be appropriate to determine a publication date cut-off?
- Are there any countries with very well developed milk bank services that we should look for any 'grey'/corroborative evidence?

Comments

Group	Section	Comment
A	1. Title	General agreement for the title: "Milk banks: guidelines on the operation of donor milk bank services".
A	1. Title	2nd suggestion "Milk banks: guidelines on donor milk bank services" (general to include clinical indicators as well as operation)
A	1. Title	Some members were disappointed that the scope does not cover indicators of donor milk provision. However, others thought that the safety issues should be addressed first (in this guideline) and be followed up by a separate guideline on clinical indications. Perhaps a research recommendation on clinical indicators could be added to this guideline to ensure that evidence is available.
A	1. Title	Should the guideline be limited to babies at risk of NEC – general disagreement. Also, should not be limited to preterm – post-

Group	Section	Comment
		op babies, unwell full term babies etc should be covered.
A	1. Title	Guidance on donor milk banking – Needs 3 separate guidelines to address the following issues: • This guideline 1. is donated milk a safe product? Next… • 2. Which babies should the donated milk be given to? • 3. Calculating need based on clinical indications and distribution models
B	1. Title	Focus on operational aspects. Indications for who receives DBM done as a separate piece of work.
C	1. Title	Preterm babies wording – milk is suitable for older more mature babies Use wording - Sick babies? Suggest that preterm is taken out or add preterm AND sick babies
A	2. Population	Group felt that the guideline should focus on the quality and safety of the milk rather than focusing on the specific population. Babies/pre-term should be 'infants'.
A	2. Population	New suggestions (4 groups): Infants who receive donated milk Mothers of babies receiving donated breast milk Women who donate breast milk Staff involved in the collection, storage and handling of donor breast milk banks
A	2. Population	4.1.2 – to be removed as unnecessary 4.2b – take out 'pre-term' babies. 4.2b – take out specialist settings – hospital settings instead 4.2c – add 'or in hospital' to the end of the statement.

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		Healthy full term babies, adults and older children could be included to make their exclusion explicit.
B	2. Population	Remove 'pre-term' – focus on indications for who should receive DBM in a separate piece of work. Population would become 'all'
C	2. Population	Prefer the term preterm AND sick babies (evidence is poor for all groups) 4.1.1. b) mothers who do not provide sufficient breast milk… 4.1.1. c) women who donate breast milk As a 'regular' donor Those who have stored milk for their own baby and have left it behind or whose babies have died
A	3. Settings	Happy with settings
B	3. Settings	Use term 'neonatal unit' and other special settings requiring access to DBM.
C	3. Settings	4.2 c) community services. Expand definition and look at what happens currently. Babies rarely receive DBM at home. Health visitors can and it would be good to support these groups but they aren't included currently. Milk will be supplied to these groups in some cases. Untapped resource. Again, remove preterm and refer to babies. How to say no to mothers who would like to use it if their babies do not fit into the guidelines if it's available? Include short term use (if milk available)? Surgery units? Don't want to exclude groups Matter of prioritisation
A	4. Clinical management	Recruitment of donors not included.
A	4. Clinical	Worries that low socioeconomic groups and ethnic minorities may be accidentally overlooked/excluded from the guideline.

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	management	Also – religious/cultural issues regarding donation – e.g. Muslims, Jehovah's witnesses etc. Issues of how to recruit and select these groups should be included Would the guideline disadvantage these religious/cultural groups? Would Muslim or Jewish women for example allow donations from non-Muslim and non-Jewish donors etc.
A	4. Clinical management	Blood transfusion is a reason for the exclusion of milk donors (may be covered in the screening process)
A	4. Clinical management	Donators may need to stop donating temporarily and permanently
A	4. Clinical management	International variability – different countries have different screening criteria. E.g. should an overview of other countries screening criteria be included?
A	4. Clinical management	Fortification – what exactly is meant by this? e.g. vitamins, phosphate, sodium etc. Adding fortifiers can affect the safety and quality of milk (e.g. when to add the fortifier, how quickly to store milk/re-freeze milk after fortifiers have been added etc) "The addition and timing of nutritional supplements including commercial fortifiers" – suggestion for rewording. Consideration of lacto-engineering without fortification – e.g. changing fat levels (lowering or increasing) etc.
A	4. Clinical management	Should national quality standards be included in the guideline – common standards for all milk donor banks. E.g. using a national accreditation tool
A	4. Clinical management	Distribution (e.g. transportation) of donor breast milk should be included. How should the milk be packed? Who should distribute it (commercial transportation or health service transportation?)
A	4. Clinical management	Tracking and tracing donated milk should be specifically highlighted in the guideline. Which donor's milk went to which baby? Which baby received milk from which donator? This practice is not currently standardised. Blood bank processes could be applied to milk banks.
A	4. Clinical	Suggestion that clinical indicators should be added which babies should receive milk?

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	management	
A	4. Clinical management	Mother's own milk – transportation should be of an equal standard to donated milk?
A	4. Clinical management	The guideline should identify gaps in the knowledge and seeks solutions or propose research recommendations.
B	4. Clinical management	4.3.1 a – how long would you expect women to donate milk? 4.3.1 b – fortification should be removed 4.3.1 c – split into 2 sections. Stock management which may include prioritisation of milk for each baby and issuing of milk. Tracking and recording what baby receives. System for recording availability. Distribution and transport. 4.3.1 d – ok as it is 4.3.1 e – training for people recruiting donors (health visitors, community midwives etc) 4.3.1 f – include HCP too, esp community and primary care.
B	4. Clinical management	4.3.2 – remove c) Children and adults not included.
C	4. Clinical management	Always want to encourage maternal breast feeding, there are only specific times when this is not recommended.
C	4. Clinical management	Annual inspections from environmental health (food as well as body tissue – bodily fluids covered under separate criteria in terms of handling). Involvement from infection control. This may not be true of all DBM providers. Be aware of regulations that will be applied. Disposal etc Food standards agency and Environmental health agency
C	4. Clinical management	Safety issues with left over milk

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C	4. Clinical management	Donors - Issues with immunisation (e.g. flu), toxoplasmosis
C	4. Clinical management	Age of mother's babies who are donating is an issue
C	4. Clinical management	Tracking systems – through from donor to recipient baby should be in place
C	4. Clinical management	fortification/engineering of milk? Not who gets it but how it's done – practically and safety (FSA guidelines?).
C	4. Clinical management	4.3.2. c) full-term healthy babies?
C	4. Clinical management	Additionally: Milk should not be pooled between donors in the UK Other countries do (those countries that don't have a problem with CJD)
C	4. Clinical management	Positive serology – counselling for women whose serology comes back positive for XX. This is rare, most are false positives. Testing – mothers should be informed of the results appropriately e.g. face to face.
C	4. Clinical management	Explanation of procedure to donor women.
A	5. Recommendations	Overarching recommendations – not too prescriptive/detailed as donor milk services work very differently However, where there is strong evidence, more detailed instruction would be acceptable The NICE guideline should be more descriptive than the UKAMB guideline
A	5. Recommendations	Agreements on safety standards (e.g. temperature) must be prescriptive and followed by all services

Group	Section	Comment
B	5. Recommendations	No specific comments
C	5. Recommendations	No specific comments
A	6. Key outcomes	Know which babies have received donated milk. Also know which donor their milk has come from. Ensure that all UK milk banks confirm to codes of practice – process outcome If clinical indicators are not included in the guideline then neither should clinical outcomes. Key processes must be adhered to consistently – adherence to prescriptive recommendations Accreditation/quality assurance of milk bank services – it is difficult to ensure that processes are followed outside of the direct service (e.g. donating mothers). Audit, tracking, tracing is essential Point c on quality of life should be taken out as it is not relevant – the key outcomes are about processes not clinical/health related issues. Info for patients the importance of mothers own breast milk must be emphasised. Mothers should not be encouraged to rely upon donated milk once the need for donated milk has passed. This should also be added to the training of those involved in milk banks. The provision of mothers own milk should be encouraged where appropriate alongside donor breast milk.
B	6. Key outcomes	Remove 4.4c
C	6. Key outcomes	Look at the alternative – formula comes from cows milk. Evidence of transmission of CJD – none. Ensure no harm is being done. Ensure infections not transmitted. Detection of inappropriate donors. Rates of detection in donor women.

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		Rescreening of women donating every three months. Ensure breast feeding is supported as well.
A	7. Health economics	The recommendations of the guideline could be v. expensive – some donor milk banks may not survive if demand/milk supply was to greatly increase. In addition, safety and delivery etc measures could be very expensive (equipment, resources, etc) If the recommendations are expensive but robust and useful – the general thought was that they should be followed. The donor milk services would probably need to change – perhaps regional provision, rather than small independent banks. A research recommendation in the guideline could be to ask milk banks for costs of specific processes. This would provide useful cost data. The guideline should consider different supply and distribution models for milk banks (e.g. no milk banks, centralisation of milk banks, regional milk banks, independent milk banks etc). Costing of the tracking and tracing would be useful.
B	7. Health economics	storage and monitoring of freezer temp. Tracking systems, manual vs automated Foil sealing bottles transport
C	7. Health economics	Per day cost of babies in neo natal unit – in for shorter time periods Supporting mothers to go home breast feeding Fewer illnesses in those breast fed Earlier introduction of donor milk compared with formula to preterm babies – quicker move to step down care – fewer nurses Prevention of NEC – NNT available Current service provision doesn't make economic sense.
A	8. GDG	Infection control nurse

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		Infant/neonatal feeding specialist and/or Midwife x 2 – a midwife is potentially a duplication of neonatal nurse Health visitor has been removed PH physician with interest/expertise in infant nutrition/breastfeeding uptake Dr Carol Campbell – useful for this role. Pharmacist/pharmacologist – co-opted expert instead of an GDG member Microbiologist with special interest could get rid of if there was a blood bank manager. Could be a co-opted member instead of a GDG member Blood bank manager Dietician BLISS would like to be involved as consultees but not necessarily GDG members
B	8. GDG	Neonatologist x 2 ?academic - N ?access to milk bank - Y ?no access to milk bank - N Neonatal nurse x 2 ?academic ?access to milk bank - Y ?no access to milk bank - N Midwife x1 -Y ?academic ?community ?specialist in breast feeding Health visitor with experience of supporting donors/mothers - Y

Group	Section	Comment
		PH physician with interest/expertise in infant nutrition/breastfeeding uptake - N Pharmacist/pharmacologist - N Microbiologist with special interest – Y Virologist Manager/director of a milk bank - Y Commissioner of relevant services - Y Relevant professional with expertise in donor related issues - Y safety of donor tissue/products - Y Lay member x 2 – Y Need someone who accesses a milk bank but doesn't have one on site, either because they're donating or because they're accessing (hub and spoke).
C	8. GDG	Microbiologist with special interest Expertise in pasteurisation /sterilisation Manager/director of a milk bank should be more? Lay member x 2 – donors and parents (separate) Specialist in breast feeding – not midwives Newly formed and existing milk bank representation Dietitian Representatives of different methods of pasteurisation – expertise in pasteurisation Environmental health rep
A	9. Evidence	Not just donor milk – also general breast milk The field changes rapidly – e.g. the guideline should be updated in 3-5 years

Group	Section	Comment
		Grey literature – all EU countries milk banks in different ways (some pool milk, some don't pasteurise). Not sure useful how international grey literature would be.
B	9. Evidence	Not covered explicitly – but some relevant comments throughout
C	9. Evidence	Not covered explicitly – but some relevant comments throughout