Reviewer’s report

Title: Feasibility and safety of setting up a donor breastmilk bank in a neonatal prem unit in a resource limited setting: An observational, longitudinal cohort study.

Version: 1 Date: 28 February 2011

Reviewer: Ben Hartmann

Reviewer’s report:

Minor Essential Revisions

1. Could the authors please describe the donor screening, bacterial screening and pasteurisation methods/practices of the NGO run milk bank? It is not clear whether these are identical to those briefly described for the in-house milk bank.

2. The authors report that assessment of the bacterial content of pasteurised donor milk consisted of microbiological culture from a 5ml aliquot of the first sample of pasteurised expressed breastmilk of each donor, however, they report only 30 samples were assessed from 35 donors. Why was the collection incomplete?

3. Also can the authors compare their post pasteurisation sampling regime and that recently reported by a US milk bank (see Landers and Updegrove 2010 Breastfeeding Medicine 5(3):117-121) - these authors found 7% of batches grew Bacillus sp. after pasteurisation. Would the post pasteurisation regime used during this feasibility and safety assessment study adequately control this infrequently encountered risk? The authors may also note that some dairy literature suggests that 'flash' pasteurisation increases Bacillus spore activation above that encountered with 'holder' pasteurisation. Given obvious need for a cost effective pasteurisation method - this issue may need to be addressed by a change in post pasteurisation screening regime.

4. This study assesses the safety of human milk banking by limited bacterial screening of post pasteurised donor milk and by assessment of adverse events associated with both formula and donor milk feeding. Unfortunately, with regard to the latter (as recognised by the authors) they were unable assess differences as the number who received donor milk was too small - and confounded by possible reverse causality. Given these limitations I believe the authors should not assert as a conclusion of the study that "it is possible to safely supply pasteurized donor breastmilk in a resource poor setting in South Africa". It is possibly too broad a statement given the investigations undertaken. The safety of milk banking is determined by the protocols employed by the milk bank and the quality management practices of the milk bank. This is one of the greatest successes of milk banking in Brazil - a practical demonstration that a commitment to proper quality management of the process as a whole (not just occasional safety checks and procedures) does not require enormous resources.
This may require that the authors reword the second objective of the study to "Secondly, to evaluate two aspects of the safety providing donor milk ..." or similar.

I must add that I regard these as minor revisions as there is existing literature regarding the bacterial safety of donor milk post pasteurisation. There is also a long history of donor milk banking with few reports of adverse events. In addition the risks of milk banking must be evaluated in the context of the risks of not milk banking.

5. This is a very well written and edited manuscript. One small spelling error/typo noted. Page 6 final sentence of section titled "Methodology for microbiology" "indentified" should read "identified".

6. Re: reference 11. I was unable to find a copy of the "Guidelines of the Human Milk Banking Association of South Africa" refered to on the weblink provided.

Discretionary Revisions

7. The authors point out that a reasonably large proportion of the eligible infants during the study period did not receive donor milk and that this may have been partly due to a lack of acceptance by staff. Could they suggest or offer comment on the implications of this for any future group looking to attempt a similar project. ie. could staff education/training prior to establishment be beneficial to its acceptance?

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests