Author's response to reviews

Title: Perinatal mortality in rural Burkina Faso: A prospective community-based cohort study.

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Version: 2 Date: 21 June 2010

Author's response to reviews: see over
Responses to Reviewer's report

Title: Perinatal mortality in rural Burkina Faso: A prospective community-based cohort study.
Version: 1 Date: 4 May 2010
Reviewer: Sabine Gies

Below please find our comments and answers to each of the comments/questions.

Major

1) Methods - Selection of participants and sample size
The sample of 900 women was enrolled from a total of 1162 identified pregnancies. Of these, 21 declined but it is not stated how many did not fulfil the inclusion criteria.

Five women did not meet the inclusion criteria and were excluded: 3 had given birth over 1 week before enrollment, one woman was found to have a mental handicap interfering with her involvement and another woman was later found to have a false pregnancy.

This information is now added in the manuscript (page 9, Results section, paragraph 1)

Were the 241 women not enrolled different from those enrolled?

This was a monthly random sampling process and data were collected only among women selected (randomly) for follow-up. We only had age and parity for a subsample of those who were not enrolled and there was no difference for these two characteristics. The aim of the overall random sampling process was to obtain a sample of women representative of all eligible women. We have no particular reason to think that they were different from their enrolled peers.

Enrolment was over a one year period but how were numbers distributed over this period?

The average number of pregnant women identified per month was 97, the average monthly enrollment was of 75 women. Globally, there was an even distribution over the 12 months. But it is worth noting that the average number of women included per month was of 4 per village as stated in the paper (page 5 methods section, paragraph 3).

Were the numbers related to village size?

Yes, there was a small variation of cluster size (median of 1200) and therefore the number of women enrolled varied slightly with the size of the cluster (village), as outlined in Table 2.

2) Methods - Type of intervention of the main study
It would be helpful to have some more information regarding the peer-support for exclusive breast-feeding apparently implemented in 12 of the 24 clusters.

This information is included in an overall paper from the PROMISE EBF-trial which is currently being written up for publication. Because of this as well as to maintain the focus of the current paper, we do not here elaborate on the intervention. But most of the information is available on the www.clinicaltrials.gov ClinicalTrials.gov Identifier: NCT00397150. A brief summary for the reviewer’s information: The main PROMISE-EBF study was a cluster-randomised trial based on individual peer-counselling for exclusive breastfeeding. The peer-counsellors (2-5 per villages) were village women selected by their own community and trained by experts in lactation and breastfeeding. All pregnant and lactating women in the intervention villages were offered home visits by a peer-counsellor irrespective of whether they were selected for data collection or not. The intervention did not focus on the promotion of health service use or health education in general but rather on advice and practical support such as why breast milk is important, when to start breastfeeding, how to put the baby to the breast. There was only one antenatal visit and 6 post-partum visits.

Was this intervention individual or community-based?

Please see above.

When did it start?

Please see above

By whom was it conducted?

Please see above

3) Analysis
   a) Although one would not expect exclusive breast feeding to have a direct impact on stillbirth, there could well be an impact of the intervention (or increased attention to pregnant women and delivery) on early neonatal death. The intervention arm should therefore be presented in Table 1. Also in Table 2, the allocation of villages to intervention arms would be helpful.

   We agree with the reviewer assumption and did indeed assess the effect of the intervention on early neonatal death but there was no significant difference. We prefer not to address this in the current paper, both because this was not a PROMISE-EBF outcome (which was EBF prevalence and diarrhea) and because the current paper reports on a cohort study of perinatal mortality nested into the EBF trial. Including the study arm will require the presentation of the baseline table of the the main EBF-trial and will indirectly disclose findings from the main trial paper. For the reviewer’s information, there was no major difference between the two study arms for baseline characteristics presented in Table 1.

   b) Including nulliparous women in the variable “history of previous perinatal death” seems not correct to me. While I agree that previous death is a high risk factor for PNM, this can only be assessed in parous women and therefore cannot be included
in the same multivariable model. I suggest correcting the figures in Table 1 and removing the variable from Table 2 and maybe present a separate model excluding nulliparae.

We agree, and corrections have been made now both in Table 1 and Table 3 and the suggested model is added.

c) Were tests for interactions between variables performed, i.e. between the number of antenatal visits and season of birth, place of birth and distance to the nearest health centre?

Yes, tests of interactions were performed. ANC visit only varied with parity [see added at page 9, section results, paragraph 2]. Health facility delivery varied with distance to nearest health centre [page 10, results section, paragraph 2] and with parity (now added at page 10, results section, paragraph 2). However, no interaction of health facility delivery and distance to nearest health facility or parity was found on PNM. Table 3 adjusted both for ANC visit and season of delivery accounting for any interaction between these covariates.

4) Discussion
a) Paragraph 2 – Prospective studies are rare but there is one conducted on malaria prevention in rural Burkina Faso (Boromo) that also reports on miscarriage and stillbirth (Gies et al, Malaria Journal 2008).

This is a relevant paper, which we now have referred to in the revised manuscript [see page 14, section discussion, paragraph 1]. It describes a study conducted in Boromo Health District (Burkina Faso) which focused on the effect of a community promotion of IPT-p on uptake of SP and on maternal and placental parasitemiae and provide data on fetal losses.

b) Paragraphs 9 and 11 – I think that the issue of maternal malaria is not sufficiently broadly discussed and the last sentence of paragraph 11 does not appear correct to me. Women delivering during the dry season are very likely to have been exposed to malaria during the first pregnancy trimester which falls into the rainy or early post-rainy season known to be high malaria transmission periods. So the high risk of primi- and secundigravidae could still (partly) be explained by malaria, especially if malaria prevention was insufficient in the present study. Moreover, the Boromo study showed a significant effect of season of delivery on the uptake of antenatal services including IPTp-SP (Gies et al, AJTMH 2009). This should be taken into account in the discussion.

We agree that this could have been stated more clearly and emphasize that our paragraph 9 does not oppose to the reviewer’s opinion. The paragraph is now revised for more clarity at page 17, section discussion, paragraph 1.

Paragraph 11 focuses on the seasonal pattern of PNM as observed in our study and looked at potential explanations bearing in mind that the rainy season is that of the recrudescence of malaria transmission in this area. The effect of malaria on pregnancy is reported to be higher during the first and last trimester and among pauciparae women (Steketee et al, AJTMH, 1996). Most of our study participants
were rather multigravidae (67% with at least 2 previous births) and therefore we could expect the adverse effect of malaria to be smaller for these mothers. So our last sentence is consistent with this assumption. For clarity, the sentence has been changed at page 17, section discussion, paragraph 3.

Minor
5) Table 1
The three administrative areas are not referred to in the methods section

We agree, this is done now in study site description, at page 5 section methods, paragraph 2.

6) Discussion – paragraph 3
Almost 30% of delivering women not having attended ANC is extremely low and in contrast with published health system statistics. ANC is free of charge in Burkina Faso since 2003 and in my experience, most women attend ANC at least once. Is there any explanation for this extremely low attendance in Banfora?

Our findings are consistent with the national (DEP/MS-BF, 2009, INSD, 2008) and international publications of the use of health services in Burkina Faso (UNICEF, SOWC 2009). Seventy-two percent of women had at least one ANC and this falls in the range of the most recent data from Burkina Faso and UNICEF. If the reviewer refers to the Boromo study, it should be noticed that there are several differences between the two areas:
- The proportion of women living <5km to the nearest health facility (HF) was 73% in Boromo vs. 48% in Banfora
- The study population: 56% were primigravidae in Boromo vs 17% in Banfora
- Multigravidae in rural areas have a lower probability of having ANC visit or delivering in health facility compared to primigravidae as confirmed in this study (page 9, Results section, paragraph 3, and page 10, paragraph 2).
- The EBF-trial did not promote the use of health services and IPTp was not effective at the time of the study as mentioned.
- Finally, some cultural features such as the power structure between the genders may be another reason contributing to a lower proportion of ANC attendance as compared to Boromo.
- Talking from personal experience, although the Ministry of Health in Burkina declared ANC free of charge in 2003, the reality on the ground is different, because as a physician myself I am aware of different strategies used by the local health staff to take money from ANC attendants.

Discretionary
7) Introduction - paragraph 3 and Discussion – paragraph 6
Paucity of reliable data is deplored in the introduction but then WHO estimates are confirmed in the discussion, so apparently they were not that unreliable?

We did not find any contradiction here. This is a comparison with DHS data that provide national average and are based on recalls. The DHS design differs definitely from the prospective, community-based cohort study that we carried out. It is commonplace to compare new data to existing reports especially with DHS reports that give national average, although carrying a high potential for recall bias.