Author's response to reviews

Title: Lessons learned from a demonstration program to sustainably reduce the burden of anaemia and hookworm in women in Yen Bai Province, Viet Nam.

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Author's response to reviews: see over
Lessons learned from implementing a demonstration program to reduce the burden of anaemia and hookworm in women in Yen Bai Province, Viet Nam.

Tran Q Phuc, Seema Mihrshahi, Gerard J Casey, Luong B Phu, Nong T Tien, Sonia R Caruana, Tran D Thach, Antonio Montresor and Beverley A Biggs

Dear Editor,

We have replied to the editorial and reviewer comments as outlined below and made some changes to the manuscript. We thank the editorial board and the reviewers for their useful comments on the manuscript and hope you find the accompanying changes satisfactory.

Yours sincerely

Dr. Beverley Ann Biggs

Editorial Board comments:

Major points:

1. Extensive editing down of the process is needed. The authors should summarize and highlight the most important aspects of this section.

This has been addressed and the word count reduces from 5315 to 3893.

2. More details on the numbers for each part of this program is needed: i.e. patients involved at each step.

The numbers of participants in surveys has been added throughout the manuscript and numbers have been provided with percentages when given. For example, most of the information about numbers of survey participants can be found in Figure 1.

Minor Points:

1. How often do the village workers visit the women: do they come once a week, once a month? Under distribution strategy "the VHR receive meds once a mos" but it is not explicit here how often they then see the women.

The sentence ‘VHWs would then distribute the tablets on a monthly basis to the WRA in their village.’ has been added to the first paragraph of this section. There were no other formal visits for distribution however the community educational meetings were used for IEC activities as mentioned in the Discussion.

2. "A baseline survey of anaemia and hookworm prevalence was undertaken to identify the prevalence and nature, magnitude, and severity of the diseases in the two project districts [31]" Are these the exact two districts Yen Binh and Tran Yen, and when was this study performed?
Yes these are the exact districts. The baseline survey was conducted in November 2005. The first sentence of paragraph 1, page 6 has been amended as follows:

‘In November 2005 a baseline survey of anaemia and hookworm prevalence was undertaken in Tran Yen and Yen Binh districts’

Have there been any other interventions from the time of that study to what has been reported here?
No there were no other interventions during the study period.
The following sentence has been added to paragraph 1, page 9.

‘No other interventions were initiated in Tran Yen or Yen Binh during the period November 2005, when the baseline survey was conducted, to May 2006 when the WIFS/deworming intervention commenced.’.

3. "regular visits by the district's Centres for Preventive Medicine personnel to the"-can you define regular (q mos?-i.e. be explicit)

‘Regular..’ has been replaced with ‘approximately monthly…’ as these visits were not on a set timetable but on an as needed basis. However it was agreed by the planning staff members that these visits occurred on average at least once per month.

4. was there ever a lack of supply or interruption in medications

No there was no interruption during the 12 month trial period. The following sentence has been added to paragraph 1, page 10.

‘The surveys also reported that there were no interruptions in supply of tablets over the period of the intervention.’

5. full compliance with iron tablets was 69% and partial compliance a further 16%: can you give us the actual numbers of patients as well

The numbers have been added in brackets after the percentages, ie. ‘ full compliance (taking all tablets as scheduled) with iron tablets was 69% (191/276) and partial compliance (taking some but not all tablets) a further 16% (43/276) after sixteen months of the intervention.’

6. how was compliance measured? Was everyone studies interviewed? If not what percent were?

The following amendment has been made in paragraph 1, page 10.

‘In the first survey 253 women, of whom 58 had taken part in the baseline survey, were interviewed using a structured questionnaire, and the second survey included 256 women, of whom 38 had taken part in the baseline survey.’

Informed consent must also be documented. Manuscripts may be rejected if the editorial office considers that the research has not been carried out within an ethical framework, e.g. if the severity of the experimental procedure is not justified by the value of the knowledge gained.
The following sentence has been added to paragraph 1, page 6:

‘For this and all other surveys informed consent was documented prior to enrolment.’

Referee 1.

1. The WRA referred to in the manuscript does not include the full range (ie. 15 to 49) and so it should be specified that it refers to women between the ages of 16 and 45.

The age range for WRA is now defined in ‘Methods and Results, section 2, Situation analysis – Formative research’

2. All instances referring to the micronutrient supplement should say iron-folic acid and not iron-folate, as it is the folic acid form which would be in the supplement.

Corrected throughout document.

3. ‘Ferrous’ should be ‘ferrous’.

Corrected throughout document

4. On page 6, the reference #29 is incorrect…it should be reference #27…Authors should review all references and ensure that the citation in the text matches what is in the reference list.

Reference corrected. All references checked and corrected as necessary.

5. Early on in the Methods section…which should really be renamed Methods and Results, as results are incorporated into this section (which is allowable here given the programmatic nature of the manuscript)…there should be a concise description of the organization administrative structure of governance level (ie. village, commune, district, province)

The section has been renamed in the abstract and the body of the manuscript. The Results and Discussion section has been renamed Discussion. The following sentence has been added to paragraph 2, page 5.

‘Governance in the province is by provincial civil committees (People’s Committee, Communist Party Committee) and service departments (eg Department of Health Services etc), through their district and commune counterparts, to the village and hamlet level.’

6. On page 9, top, it is unclear what is considered a ‘high’ prevalence of hookworm. Why are the results of the published baseline survey not reported here?

The Personal Communication reference has been deleted and the baseline survey results moved to the ‘Methods and Results, Development and planning, Situation analysis-formative research section’ as follows:

‘In November 2005 a baseline survey of anaemia and hookworm prevalence was undertaken to identify the prevalence and nature, magnitude, and severity of the diseases in
the two project districts of Tran Yen and Yen Binh (Pasricha, 2008 #8704). Demographic and socio-economic data from this survey is presented in Table 1. The prevalence of anaemia (Hb<120g/L) was 37.5% (131/349) and the prevalence of iron deficiency (ferritin <15µg/L) was 23.1% (81/349). Hookworm infection was present in 78.2% (261/334) of women, although heavy infection was uncommon (6.29%, 21/334). These results demonstrated that an anaemia and hookworm control intervention would benefit the population and it was decided to proceed with a WIFS and deworming intervention that targeted a total of approximately 50,000 WRA in two districts, and if successful to scale up to a province-wide program.

Subsequent sub-sections of “Implementation of the project” have been renumbered accordingly.

7. The published baseline survey contains NO date. This omission should be corrected in the current manuscript by specifying the year in which the baseline survey was carried out. The date should also appear in Table 1.

The following phrase ‘In November 2005 …’ has been added to the first sentence of the results report paragraph 1, page 6 and also added to the heading of Table 1.

8. VHW should probably always be referred to as VHWs. Should the ‘commune health worker’ on page 14 be a VHW?

VHWs has been standardised throughout the manuscript. On page 9 ‘commune health worker’ is the correct designation’. These health workers are the next level up from VHW.

9. ‘Tablets’ should be used throughout and ‘capsules’ removed.

Standardised as ‘tablets’ throughout the manuscript.

10. What is the justification for observing women for 30-minutes post-administration of tablets (page 14)? If this was to observe any side effects, then a longer period would probably have been better. (Do you expect side effects to occur within 30 minutes?)

This was not to detect side-effects but to ensure that the women swallowed their tablets without vomiting, now page 10.

The phrase ‘…to ensure vomiting did not prevent consumption of the tablet’ has been added to the final sentence of this paragraph.

11. Definitions for full compliance and partial compliance are needed (page 15).

Definitions have been inserted in brackets after each term as follows (now page 11):

‘ full compliance (taking all tablets as scheduled) with iron tablets was 69% (191/276) and partial compliance (taking some but not all tablets) a further 16% (43/276) after sixteen months of the intervention.’

12. Page 16…it is helpful to say that ‘…anaemia prevalence had fallen from 37.5% to 19.5% and hookworm prevalence form 78.2? to 25.2%’…Is this correct?
Yes it is correct and this change has been made (now page 11).

13. On page 16, add July 2006 after ‘...first compliance survey’...

This has been added (now page 11):

14. On page 17, para 1, it is unclear if it was the VHWs or the women who reported ‘...an inadequate understanding...’. Please clarify.

The paragraph (page 11-12) has been amended as follows:

‘VHWs requested a more comprehensive collection of educational materials to use in IEC activities. The materials developed included a set of nine posters, five for hookworm and four for anaemia, with photos and simple messages on one side and questions and answers for discussion on the reverse side. The messages placed more emphasis on the causes and health consequences of anaemia and hookworm disease for both women and newborns and the benefits to both of treating and controlling these diseases. Further information was made available for broadcasting over the village loudspeaker system.’

15. On page 17, para 1 line 3 from bottom...specify September 2007 as the 16-month monitoring survey.

The date has been inserted in brackets, now page 14.

16. Table 1 needs to be cited in the text. (I could not find it.)

The reference to Table 1 has been inserted in the paragraph summarising the baseline survey paragraph 1, page 6.

17. On page 20, the situation of treating pregnant women is discussed. In my opinion, there needs to be a stronger consideration of inadvertent deworming treatment of girls and women in the first trimester of pregnancy...This demonstration study may not have collected the necessary data to determine how many women would have been so treated...but it should be recommended that other programs should incorporate a follow-up mechanism of some sort to ascertain if any woman who, subsequent to deworming, becomes pregnant (at what date, etc.)...This would be a very valuable source of this type of data, currently unavailable. Perhaps it would also be appropriate to include advice regarding local hospitals adding a column to a birth registry to indicate whether women being admitted for delivery had had deworming in the previous x months.

The following sentence and supporting references have been added to this paragraph of the discussion.

“However, in order to reduce the potential for inadvertent treatment of women in the first trimester of pregnancy participating in mass deworming programs the two questions ‘Are you pregnant?’ and ‘When was your last menstrual period?’ should always be asked prior to administration. {Gyapong, 2003; WHO, 2006}.

The authors share the concern of the reviewer regarding inadvertent treatment of pregnant women. During the planning and development stage we worked closely with WHO. The latest
working document from WHO (Preventive chemotherapy in human helminthiasis, Coordinated use of anthelminthic drugs in control interventions: a manual for health professionals and programme managers. 2006 WHO, Geneva,) in Section 5.2.2 (page 13) states “Several studies have failed to find a statistically significant difference in the occurrence of congenital abnormalities between babies born to women treated with single dose mebendazole or albendazole during pregnancy and those born to untreated women (with refs).” In the same section it also states “These studies include approximately 6000 documented exposures to mebendazole, but the documented exposure to other anthelminthic drugs is much lower (approximately 50-200).”

The authors wholeheartedly agree with the reviewer that any new data on the outcomes of inadvertent deworming treatment of pregnant women would be very valuable. Unfortunately, in the resource-poor settings where such a population-based preventive health program is most needed, extensive follow up is rarely possible. None the less, although the program administration has been fully transferred to the provincial authorities we will discuss with them the feasibility of adding a column to a birth registry to indicate whether women being admitted for delivery had had deworming in the previous 9 months and assist in developing a monitoring/reporting methodology in cases of inadvertent deworming in pregnancy. As additional information for the editors and reviewer, a study of approximately 168 births in our core districts (Tran Yen and Yen Binh) and 295 births in two similar districts of the same province, prior to the expansion of the program, identified a significantly higher birth weight in our core districts. This study (the report of which has been submitted elsewhere) was conducted over some 6 months. During this time hospital staff in our core districts did not report any change in birth outcomes since the start of the WIFS/deworming program.

18. On page 21, the origin of the iron supplements is detailed, but not the albendazole. This should be added.

The sentence ‘Albendazole is provided by WHO as part of their ongoing program of deworming in Vietnam.’ has been added in this paragraph now page 15.

19. In Table 2, page 32 the 2nd and 3rd box…the word ‘sustainability’ should be replaced by ‘implementation’…These incentives clearly influenced the implementation of the current program. Whether this is sustainable or not is a different issue. For this reason, the word ‘sustainable’ should be removed from the title.

The suggested changes have been made.

20. Figure 1. Additional lines need to reflect the 4 deworming cycles…December 2006 should be added to indicate the mid-term review. May 2007-March 2008 should be added to the WIFS continued in 2 pilot districts box. WRA needs to be specified as 16-45 years of age.

Lines for deworming noted as black. ‘Mid-term review’ box added. ‘May 2007 – March 2008’ added to appropriate box. Definition of WRA added to footnote.

Reviewer 2

1) Minor Essential Revisions
1. The Manuscript is too long. Especially Methods (situation analyses section) needs to be reduced.
The manuscript in total has been shortened including the Situation Analysis section as requested.