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To the Editors
The Implementation Science Editorial Team

Dear Editors,

RE: Author's response to reviews: MS: 1484341573102056 – “Translating global recommendations on HIV and infant feeding to the local context: The development of culturally sensitive counselling tools in the Kilimanjaro Region, Tanzania”

I refer to your letter dated 14th June, 2006 regarding reviewers' comments on the manuscript referred to above.

I am delighted to inform you that we have now completed revising our manuscript in light of the reviewers' valuable comments and concerns. We thank them both for their constructive contributions to this article. We have tried to shorten the revised manuscript text as concise as possible given the description nature of this article. The word count for the text is now: **6,056 words** excluding the abstract, acknowledgement, references. We have ensured that our revised manuscript conforms to the journal style, English edited and files correctly formatted.

Please, find below the point-by-point description of the changes which have been made, responses to specific questions raised as well as explanations where changes have not been made. Page numbers are attached to each comment.

The **title, abstract and authors'** details have been modified accordingly.

Reviewer 2 – Simon Lewin

1. ***“The purpose of the study section seems to include several study aims”***. We have considered this concern and appreciated his suggestion that the broad aim of the study is to improve infant feeding counselling, while the others are more specific objectives. The corrections have been made in the manuscript. *(See page 2 first paragraph of the abstract and page 4 paragraph 2.)*

2. ***“Confusion regarding the difference between job aids as described in the paper and decision aids”***. The study described in this paper is part of a larger operations research project to test the impact of job aids on counsellors’ performance and mother’s compliance with recommended infant feeding practices. As stated in the paper, “job aids have gained status in health promotion as a cost-effective way to improve the *performance* of service providers, such as nurses, and are often defined as tools that reduce guesswork, minimize reliance on memory and promote compliance with standards.” We actually define decision aids as a sub-category or specific type of “client-oriented job aid, used to guide patients through a series of steps, giving them personalized information and/or helping them clarify their values and risk exposure in the context of health-related options.” Given that the integrated set of counselling tools described in this paper serve a double purpose (1) to help service providers counsel, and 2) to help mothers both make an informed choice of infant feeding method and practice that choice effectively), we feel strongly that it is most appropriate to use the overall title of “job aids”. Furthermore, for purposes of consistency in reporting on this first phase research and subsequently on the larger research question, we feel that it is best to use only one description of the integrated set of counselling tools, but clarify their dual use. We have decided to refer to them throughout the paper as “job aids”.

3. ***“The concern that O’Connor review on decision aids is not discussed in this paper as it provides rigorous synthesis of the evidence on the effectiveness of these interventions”***. The concern is valuable and appreciated; however, given that our major focus of this article is specifically on the development process and not of the effectiveness of the intervention, we have decided to discuss it in the up-coming

article on the effectiveness of the intervention in relationship to both counselors and mothers.

4. ***“The concern if a published reference no. 22 could be found on this issue?”*** The concern was taken into consideration and searched for it again. But, as it was a conference poster presentation in 1997, which was accessed, February 2003 at: http://www.who.int/dap-icium/posters/3F3_TXTF.html the page could not be found and due to the modification made to the text, this reference is no longer part of the manuscript text.

5. ***“The planning process where the authors appear to give the impression that theory based intervention planning may lead to more effective intervention”.*** In our opinion there is no opposition between developing theory based interventions whilst at the same time conducting evaluations designs that include measurements of important outcomes (Oxman et al., 2005; Hardeman et al., 2005). Actually it has been acknowledged that the characteristics of being theory- and evidence based distinguish effective school based interventions from those that were ineffective. According to Eccles (2005) a-theoretical transfer of research findings into intervention practices that is not theory based can be slow and like a haphazard process, which in addition fails to build on existing knowledge. In the present article we have noted the well documented work on changing behaviour through enhancing self efficacy as predicted by Social Cognitive Theory (SCT). Other techniques that have been shown to be effective are cognitive change techniques used in research on persuasive communication, and instigated by the TTM (Michie and Abraham, 2004; Hardeman et al 2002). (See page 19 last paragraph and page 20.)

6. ***“Please explain how these theories added value to the process”.*** Theories to identify psychological determinants for health behaviour other than the SCT, have generally not generated behaviour change interventions based on well specified, empirically supported educational techniques. For simplicity and to keep it short (as considerable reduction in the total number of words was requested), we removed the elaboration likelihood and goal setting theories and kept SCT which adds value to the process in that it not only specifies the relationship between beliefs and behaviour but also provides educational principles or techniques, for instance, on how to enhance

self efficacy. Those techniques have been widely applied and found to generate behaviour change. Moreover, the behaviour change methods suggested for this study are among those included in the list of 19 change methods suggested by Hardeman et al., 2000, commonly used in behaviour change programs.

References

Oxman AD et al. Variance and dissent. The OFF theory of research utilization. *Journal of Clinical Epidemiology* 2005;58:113-116.

Hardeman W et al. Application of the theory of planned behaviour in behaviour change interventions: a systematic review. *Psychology and Health* 2002; 17: 123-158

Michie S, Abraham C. Interventions to change health behaviours: evidence based or evidence inspired? *Psychology and Health* 2004;19: 29-49

7. ***“Provide a little more detail on how policy makers, technical experts etc. were involved in the development of the intervention”***. More details are now described under the sub-heading – **Using a participatory approach-** (*in page 7*). “Strategic participation and consensus building between all major stakeholders was seen as critical to the process of developing the intervention, in order to ensure its social and cultural relevance and scale-up. Policy makers, technical experts, service providers and clients were involved in various phases of the process. HIV-positive mothers, local community members and nurse-counsellors responsible for the day-to-day running of the PMTCT programme participated in the formative research and in the field testing of draft materials. Members of the national consultative group responsible for developing guidelines on HIV/IF and other national and international technical experts provided technical guidance during the planning process as well as during the materials’ design/adaptation of technical content and images from existing generic materials. A broad participation in the technical review of draft materials was achieved through electronic correspondence and the simultaneous transfer of digital graphic files to reviewers via the internet.”

8. **“Further information on formative research methods”**. The information on who conducted the interviews, how interview quality was maintained, selection of the respondents for both the individual interviews and focus groups and how the data was

analysed are now described in the manuscript. (See page 7 last paragraph, page 8 and 9.)

9. **Formative research results:** *“did not get a sense of a range of views from different stakeholder groups and different communities in some section”*. The groups are now reflected under their views in all sections of the formative research results. (See page 9, 10, 11 & 12 of the manuscript.)

10. *“Commercial infant formula: It is not clear whether???* *the first paragraph of this section is based on data from interviews/focus groups or is a summary of contextual information”*. We appreciated the comment and rewritten the section on infant formula. (See page 10 paragraph 3 of the manuscript).

11. **Rationale for the focus on job aids:** *“Further explanation of why this health service focus was chosen would be useful”*. It is described in details now in (page 15 paragraph 2).

12. *“A comment on the extent to which the brochures would be accessible to people with low levels of literacy and, indeed, whether that was a consideration in this setting”*. This concern has been taken into consideration. A more comprehensive explanation is now provided. The paper now describes the fact that Kilimanjaro Region has a well functioning health care system extending into the rural periphery. Informants reported a high trust in health care professionals and antenatal attendance is very high. Antenatal clinic hence represents an arena to access to the majority of pregnant women in the region. Most people can read and write and can make use of written material in Swahili. Swahili is a common language that the population in general understands and speaks well. The formative research findings indicated that people were hungry of more information and the technical reviewers (national and international) encouraged us to incorporate more information. Key messages were based on the needs identified during formative research and field testing of the draft materials. Also great care was taken to balance the amount of text being presented with illustrations that clearly communicated many of these key messages visually. (Is described in page 15 and 16 of the manuscript.)

13. ***“Was the text of the brochures also pre-tested with members of local communities?”*** This concern is very important, but, given the limited time and the fact that a study of the effectiveness of the materials was to follow immediately. The text was not pre-tested separately, but was assessed as part of the draft materials as described in the manuscript (*in page 8 paragraph 2, under field testing*).

14. **Abstract:** ***“The first sentence under results is rather clumsy and needs to be re-written”***. We agreed with this useful concern and the whole abstract has been re-written. (*See page 2 of the manuscript.*)

15. ***“Acronyms should be explained”*** The concern has been taken into consideration and all used acronyms in the manuscript are now defined and explained.

Discretionary Revisions

16. ***5th paragraph: please specify the focus of the Nairobi study”***. The focus has been specified in the manuscript in (*page 4 paragraph 1*).

17. **The suggestion to change the wording of the sentence in the purpose of the study** has now been changed and the sentence modified. (*See page 4 paragraph 2 of the manuscript.*)

18. The term **“methods”** is now used instead of **“methodology”**. (*See page 5 in the manuscript*).

19. The concern was taken into consideration and the belief that only breast milk beyond three months of baby’s age is not sufficient, based on current international infant feeding guidelines. (*See page 10 paragraph 1*).

20.a. ***“The reference to a traditional provider-client situations”***. Reference has been included in the rewrite.

20.b ***“More discussion: “Nurses identified a range of factors underlying better dialogue between providers and consumers ---- work by Rachel Jewkes and by***

Peterse in South Africa. Rather than focusing on underlying dialogue, we have decided to emphasize the importance of interpersonal communication and counselling skills in the text.

21. ***“The inclusion of the brochure on the expression and heat treatment of breast milk seems to run contrary to the underlying philosophy of the intervention”***. This concern has been taken into consideration in the rewrite to more fully explain the rationale for including this feeding method in the integrated set of job aids. “The feasibility and acceptability of expressed and heat-treated breast milk was also discussed during focus groups and interviews. Community participants stated that this option seemed too time-consuming to be a practical alternative to breastfeeding. Several mentioned that expression of breast milk was strongly associated with stillbirths, infant deaths or pre-term births (FGDs and interviews). Nurse counsellor ‘informants’, however, argued that hospital staff used to teach hand expression as part of normal breastfeeding counselling under the Baby Friendly Hospital Initiative in the 1980s, and agreed that it was important to provide information to mothers on this technique. When specifically queried, they acknowledged that heat treatment of expressed breast milk might be successfully used for a short period during the transition from exclusive breastfeeding to exclusive replacement feeding to reduce the risks associated with ‘mixed feeding’. We totally agree with the reviewer that this method run contrary to the underlying philosophy of the intervention – so the brochure has been removed in this article.

22. ***“The language that suggest that the infant feeding counselling toolkit was added at the last minute”***, was not the intended meaning, it was planned on the basis of the gaps noted from the formative research findings, it was to mean that the toolkit was developed last in the order of sequence. The explanation of the infant feeding ‘tool box’ has now been re-written. (See page 18 paragraph 3)

23. **Counselling card on relative risk: *“Further information on why this particular graphical approach was chosen”*** We appreciated the suggestion and the reason for choosing this approach has been added in the text. (See page 18 paragraph 2.)

Reviewer 1 – Alison Jenkins

1. ***“Proof-reading and formatting table 1 & 2 to be more readable, and numerous small typos”***. -This important feedback has been taken into consideration in rewriting the text. The tables have been revised to read more clearly and are now formatted (*See table 1 and 2 in pages 22 and 23 of the manuscript.*) The revised manuscript has been edited by the English editor.

2. ***“Further elaboration on how exactly the study addresses the limitations of postnatal follow up”***. The counselling materials meant to be used as a reference during counselling session (a counselling job aid) and as take-home reference materials for mothers (a mother’s job aid), to remind them of how to perform the task. Ideally, the health system should offer (allow/encourage?) the opportunity for follow up counselling, but in the situation, follow up is rare or non-existent. Mothers often do not return to the clinic prior to giving birth, post partum check-up are rare and home visits are non-existence. The materials are meant to serve as a job aid or reminder aid (a memory jogger) outlining the appropriate steps to take to comply with the recommended standards or performance (*explained throughout the text*).

3. ***“Pre-test of the materials need to be included in the methods section”***. We appreciated the reviewer’s suggestion and the pre-testing of the materials is now included in the methods section. (*See page 8 paragraph 2 of the manuscript.*)
 - b) ***“More clarification of the composition of the focus groups”***. We appreciated and agreed with the reviewer’s suggestion. More detailed information on the composition of the focus groups and selection criteria has been explained in (*page 7 and 8 of the manuscript*).

3. ***“Further description on the participatory approach for dissemination of findings and initial consensus building. Since the buy-in and participation of the appropriate national authorities is of particular importance, this warrants further description”***. This important point has been taken into consideration. (*See the description on page 7*

paragraph 1 and page 14 paragraphs 4 & 5 and also in page 15 paragraph 1 of the manuscript.)

Discretionary Revisions

4. ***“Would prefer to see gender-sensitive terminology (prevention of parent to child HIV transmission – PPTCT) used throughout”***. Indeed we do agree with the reviewer on this issue. PMTCT is not a good concept because it draws the attention to the mother as the embodiment of risk and a threat to the baby, while ignoring the role of the father both as a potential risk to both mother and child and as a necessary partner in preventing transmission to mother and baby. However, since our intervention is done through the standard intervention programme which carries the name of PMTCT in Tanzania as elsewhere, we find it complicated and potentially confusing to the readers if we call it by another name, like PPTCT. However, the concept of PMTCT needs to be discussed and we will do it elsewhere in a paper that discusses impact and policy implications of the intervention.

5. ***“The staff shortages and associated lack of time to counsel properly, even for nurses adequately trained in infant feeding counselling, be included as the barrier to the provision of informed infant feeding choices in the background section”***. The suggestion was appreciated and agreed. It has been included in the background section page 4 paragraph 1.

6. ***“ Counselling staff complement relative to antenatal bookings at KCMC clinic, as well as the existence/frequency of community mobilization activities or research projects related to HIV prevention conducted in that area for context.”***
In the Kilimanjaro region, only one community mobilization organization conducts outreach activities, known as - Kiwakukki . This group does not provide any kind of follow-up counseling or support services related to infant feeding, however. Antenatal counseling on infant feeding was also not a factor at KCMC. Little or no concerted infant feeding counselling was going on in the hospital. No other infant feeding counseling or IEC materials were available at KCMC.

7. ***“ There is a reference to identifying program objectives but it is uncertain how these relate to performance and learning objectives”***. This uncertainty might be attributed to mismatch of concepts. With program objectives we actually mean the performance objectives and learning objectives. *(Please see corrections at page 6 in the revised manuscript.)*

8. ***“The issue of disclosure in the methodology section should be addressed explicitly within the potential individual and environmental determinants affecting infant feeding practices; disclosure within the core and extended family and within communities will all influence a mother’s ability to make informed choices about infant feeding”***. More attention and description is given to the complex issues surrounding disclosure and confidentiality in the rewrite of the manuscript. *(See pages 6, 10, 12 and 20.)*

This is the end of the comments raised by the reviewers and once again we thank you very much and all the reviewers for their time and very valuable, constructive comments which, we believe have improved the quality of this article.

Yours sincerely,

Sebalda Leshabari

The corresponding author