

Re: # BMJ-2018-048110

"Increasing male engagement in Prevention of Mother-to-Child Transmission of HIV: What works in sub-Saharan Africa?"

Dear Dr. Veitch,

Many thanks for the prompt review of our submission with the above title, part of an intended BMJ collection focusing on PMTCT (VT). We have now revised the submission and include point by point responses to the reviewers' and editors' comments, as detailed below.

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#### EDITORIAL COMMENTS:

\*Please replace the Summary section with 3-5 Key Messages (at the end of the article)

Authors' response: We have done so accordingly; the Summary Section has now been deleted and Key Messages placed at the end of the article.

\*Please include a Standfirst at the beginning of the article, the following example may be used (or other published Analysis articles) for reference -

<https://na01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.bmj.com%2Fcontent%2F363%2Fbmj.k4513&data=02%7C01%7Cmuktar.aliyu%40vumc.org%7Cfcf3fddfec04a4072cd08d6900cc93f%7Cef57503014244ed8b83c12c533d879ab%7C0%7C1%7C636854781938797951&sdata=KiWRiATyC6twNPHmcQXD3OuKFX39H%2FC4Fwskz2qEog8%3D&reserved=0>. The Standfirst is the short summary text at the beginning reading "XYZ and colleagues describe ABC..."

Authors' response: We have attended to this with a standfirst statement located before the author byline.

\*Overall the article as submitted is very clear and well written, but a concern that the editors had is that it reads somewhat like a Minireview or an overview, rather than fitting well into the Analysis section of the journal. For this, a clear argument or perspective needs to be presented by the authors, with some novel insight rather than aiming to summarise the field as a whole. We also felt, in line with this, that it wasn't clear what the authors were aiming to contribute beyond the pre-existing systematic reviews.

\*We acknowledge that for the authors to address this, and to address the reviewers' perspectives, which are to a certain degree pulling in different directions, is something of a challenge. (And to remain within the 2000 word limit).

\*However, a refocus may be needed whereby it is important to consider what are the specific intended goals of the piece, rather than a summary of the evidence base and overall field. This may enable the authors to consider how to work with the reviewers' points without losing focus and the major points they are aiming to make. The editors felt that some of the key strengths of the article submitted are the existing elements focusing on limitations, evidence gaps and research agenda. One possibility is to make those components more explicit so that a more directed article can emerge.

Authors' response: Thank you for the very helpful suggestions. We have reworked the paper as follows:

- We have more explicitly noted the influence (direct or indirect) of gendered socio-cultural norms on male partner involvement in VT in SSA. This information is also included in the Key Messages.
- Increased discussion of limitations, evidence gaps and research questions by way of lack of standardized definition and guidance on optimal amount of male involvement, lack of rigorous RCTs, evidence from multi-combination interventions and cost-effectiveness analyses
- Discussed the promising psychosocial approach of trained peer-to-peer male support
- Updated the "Key questions for future research" box

\*We do not expect the authors to incorporate all of the reviewers points within a resubmitted article since to do so may involve them going well beyond word count and also expanding beyond the specific focus of their piece. However we do expect the authors to bear in mind each point individually and

consider how/whether to address in a refocused piece, and to comment in a point by point how they have addressed them. Some points could be answered with the use of boxes/tables rather than within the text per se. One reviewer's point however that some assertions are not well evidenced, should certainly be addressed thoroughly.

Authors' response: We have taken note of the suggestions and have outlined our revisions in the bulleted list above, as well as updating the "key questions for research" box and added supporting citations.

\*Regarding terminology (raised by one reviewer). In other papers in the series, we are using VT rather than PMTCT, and would guide the authors to do this. This would entail defining VT early on, and here the authors can state the equivalence with MTCT.

Authors' response: We have defined VT in the introduction and replaced MTCT with VT throughout the article.

\*In part of the article, there is something of a repetition where the paper discusses bundled interventions (the Nigerian trial) twice, in two separate sections. This could be tidied up a bit to ensure a cleaner flow and also to save word count slightly to expand on other elements.

Authors' response: We have taken out the sentence that discusses the Nigeria trial in the context of apportioning the impact of different components of a bundled intervention.

\*Box 1: this is useful but could benefit from further contextualisation or detail about how these proposals have been arrived at. Presenting this as a research agenda may imply that it's been derived from a broad consensus of the community, but it's not clear how the agenda items were obtained. This could be framed more as "key unanswered questions" or "key questions for research"? Some detail could also be added either in text or in the box about how these were derived by the authors, or citations to prior work which reveals these as key questions (eg SRs identifying major evidence gaps, or qualitative work indicating what participants/patients/researchers think important).

Authors' response: We agree. We have reframed the Box title to reflect "key questions for further research". We have also added supporting citations to the box.

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#### REVIEWERS' COMMENTS:

Reviewer: 1

Recommendation:

Comments:

The paper is very relevant and useful to patients/carers and beyond. As it is beneficial health outcomes to the family too. It is timely and addresses a key area that has a significant impact on the progress and potential success in ending the vertical transmission of HIV. The questions addressed in the paper are very relevant to patients and carers.

Authors' response: We thank the reviewer for this observation.

One of the topics that could be explored further is the issue of Health Care Provider attitudes being a barrier to male partner involvement. It would be helpful to include recommendations as to how this can be addressed, or share examples of good practice. This is because there is a really good focus on enablers from the male point of view though not so much addressing the HCP angle.

Authors' response: Because of word limit constraints we are unable to explore this important issue in detail. However, this point is now included in box 1 under "Key unanswered research questions". We have also alluded to the need to include health care providers trained in providing services to men in the "what changes national governments need to adopt" section thus: "While acknowledging the need to adapt to sociocultural context, evidence suggests that interventions should target three key factors: (1) community VT education, particularly addressing norms regarding male participation in maternal services; (2) community-based counseling of male partners to encourage and support maternal ANC attendance; and (3) the availability of trained health providers, private space and couples-based counseling and testing services within health facilities..."

It would also be helpful to have a recommendation on how to address the barrier of Government policies that fail to prioritise or accommodate male involvement.

Authors' response: We have added a sentence to the pertinent paragraph (changes that national programs need to institute), thus: "Governments should support male engagement initiatives by enabling structural and policy changes, including prioritizing the funding and implementation of such initiatives..."

It would also be good to further highlight the importance of Community and Community Leaders' meaningful involvement in suggesting or recommending enablers to address the barrier of prevention of vertical transmission teachings which are in conflict with socio economical and cultural norms.

Authors' response: We agree with this suggestion. We have now included a sentence to that effect in the paragraph that discusses changes that national HIV programs need to institute. "Governments should support male engagement initiatives by enabling structural and policy changes, including prioritizing funding and implementation of such initiatives. Public policies should also promote the engagement of community leaders as change agents to address socioeconomic and cultural norms that impede VT prevention."

The interventions suggested and guidance given can be readily taken up by patients/carers, particularly where there are robust structures in place to reach those patients/carers who may not be so motivated or who have additional challenges/barriers that prevent them from being involved.

Authors' response: We thank the Reviewer for the comment.

The outcome measures described/measured in the study are important to patients/carers.

The paper is timely and very relevant. The recommendations/interventions/guidance is clear and can be incorporated into in-country systems.

Authors' response: Thank you.

Re: Further strengthening. The authors could consider using language that is less stigmatising towards mothers living with HIV. So for instance, using terms such as Vertical Transmission of HIV instead of Prevention of Mother to Child Transmission, as this term tends to place the onus, blame and responsibility on the mother alone. Another term they might consider using is Ending... rather than Elimination of... See a couple of suggested references below:

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[https://na01.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.unaids.org%2Fsites%2Fdefault%2Ffiles%2Fmedia\\_asset%2F2015\\_terminology\\_guidelines\\_en.pdf&data=02%7C01%7Cmuktar.aliyu%40vumc.org%7Cfcf3fdffeca04a4072cd08d6900cc93f%7Cef57503014244ed8b83c12c533d879ab%7C0%7C1%7C636854781938797951&sdata=BJUKLYsEFnr4C52sgzKVCUryO9PsIFzpiX3ybQKia5w%3D&reserved=0](https://na01.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.unaids.org%2Fsites%2Fdefault%2Ffiles%2Fmedia_asset%2F2015_terminology_guidelines_en.pdf&data=02%7C01%7Cmuktar.aliyu%40vumc.org%7Cfcf3fdffeca04a4072cd08d6900cc93f%7Cef57503014244ed8b83c12c533d879ab%7C0%7C1%7C636854781938797951&sdata=BJUKLYsEFnr4C52sgzKVCUryO9PsIFzpiX3ybQKia5w%3D&reserved=0)

Authors' response: We agree with the suggestion and have now replaced "PMTCT" with "prevention of vertical transmission" throughout the paper. We have also substituted "elimination of MTCT" with "ending VT".

The involvement of patients/carers in the study does not seem to be clearly mentioned. If there was, it is not very explicit. And if they were involved, it is important to outline this, as well as how and at what level/stage they were involved. A key way of improving this is meaningfully involving patients/carers throughout the life-cycle of the study and in particular involving them as co-authors-where this is possible. (It maybe well be that they were involved, however, this is not very clear on reading the paper. It will be helpful to clarify or at least highlight this).

Authors' response: We appreciate the suggestion. Carers or patients were not involved in the writing of this analysis paper. As an analysis paper there was no original data collection involved in the preparation of this manuscript.

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Reviewer: 2

Recommendation:

Comments:

Reviewer feedback

LENGTH: Article is within the recommended length. However, the introduction exceeds the recommended word limit.

Authors' response: We were not aware of a word limit for the introduction section. We have now cut down on the length of the section.

PRESENTATION: Short title not provided. The single italicised sentence doesn't convey the key message of the paper.

The body of the text is well broken into subheadings

Authors' response: A short title is now provided. The standfirst statement (single italicized statement) has been edited accordingly to convey the key message. A bulleted "key message" section has also been provided at the end of the manuscript.

EVIDENCE BASE

Overall impression:

The topic is suitable to stimulate discussion, raise debate and air controversies. However, there are some important comments they authors should consider in order to make the paper more relevant to a general readership.

Introduction:

1-Some of the statements are not backed by references. The authors should reference the first two statements. In the second sentence, the authors make mention of compelling evidence. Where's the compelling evidence coming from? From systematic reviews? RCTs? The two studies that have been referenced at the end of the 3rd sentence are cohort studies in which case enough adjustments for confounders were not made. Authors should either remove the word "compelling" or make sure more studies with quality evidence are referenced.

Authors' response: We have edited the sentences and removed the word "compelling". The first sentence is based on conclusions from the UNAIDS Lancet Commission Working Group Discussion Paper "Envisioning "The end of AIDS": Challenges and prospects", accessible here:

<http://www.thelancet.com/pb/assets/raw/lancet/misc/unaid-discussion1.pdf>. We are already over the suggested limit for number of references.

Challenges in studying male partner involvement:

In this section, the authors raised some very strong points to support their case but, in some instances, not enough evidence was given to support their claim.

Firstly, the first challenge in male partner involvement should be the varying definitions of male partner involvement. Authors should have argued here that many definitions of male partner involvement lack the consideration of the intersectionality theory/approach which considers male partner involvement as an intersection of social norms, systemic forces and power dynamics. In addition, many definitions of male partner involvement don't consider the temporal variation of male partner involvement over time. Male partner involvement should be seen as dynamic and changing over time. In general, authors should have mentioned that in order to plan interventions that work, a deeper understanding of male partner involvement is needed. There's a study that has been conducted in Burkina Faso on this and will be published anytime soon.

Authors' response: We appreciate the points raised. We allude the point regarding male partner involvement as the intersection of norms, systemic forces and power dynamics in the "Varied socio-cultural contexts, including gender roles and power dynamics" paragraph: "Different sociocultural contexts and norms within and between countries highlight difficulties in generalizing specific male involvement approaches in SSA. These variations include gender roles, social expectations and traditions in reproduction and childcare, cultural systems such as family structures (including polygamous unions), and the role of the extended family in reproductive decision-making.<sup>9</sup> "

We have also included text on temporal variation of male partner involvement with time in the "Measurement challenges" paragraph thus: "Other challenges include the absence of a definition for an

ideal “level” of male partner engagement and failure to account for the temporal variation of male partner involvement over time.”

One challenge in male partner involvement that the authors didn't mention is the lack of robust studies on the impact of male partner involvement on the uptake of PMTCT services. There are very few RCTs and even when cohort studies are published, there isn't adjustment for confounders. These challenges ultimately affect the quality of findings even when systematic reviews are conducted. Furthermore, the lack of uniformity in the studies introduce a lot of heterogeneity, making it difficult to reliably pool the findings together in a meta-analysis.

Authors' response: We thank the reviewer for the suggestion. This information is now included in the first 2 sentences of the section 'Evidence from systematic reviews and meta-analyses' thus: "There is a lack of robust studies (such as RCTs) on the impact of male partner involvement on the uptake of VT prevention services. Study heterogeneity also makes it challenging to reliably pool findings in meta-analyses."

In page 6 line 45-46, the authors should provide more evidence to support their claim that unitary interventions are “unrealistic”.

Authors' response: We have deleted the sentence.

Bundled interventions: The authors failed here to mention that there might be some evidence to support the effectiveness of bundled interventions, but no robust cost-effectiveness analysis has been conducted to factor in the cost component. In many settings in sub-Saharan Africa, we can't overlook the cost of interventions as well.

Authors' response: We agree with the reviewer. We have added a sentence to that effect in the section that discusses findings from individual studies thus: "The dearth of cost-effectiveness analyses, however, limits conclusions regarding the cost-effectiveness of these bundled interventions".

In the "Research Questions" paragraph we also mention the importance of cost-effectiveness analyses: "Lastly, cost-effectiveness analyses of community and clinical interventions are essential to justify the efficient use of increasingly limited PEPFAR, Global Fund, or national health system funds."

Unintended effects: Good argument here. However, they failed to mention that in some cases, the expectations of women can be somehow contradictory, given their concern regarding their loss of privacy if men were allowed into their space. This controversy is important to stimulate discussion on how pre and post-natal care can be re-organized.

Authors' response: Thank you for the suggestion. We have now weaved that point in to the second sentence in the paragraph as follows: "Some women may fear loss of privacy or autonomy if men crossed into their "space". These women may be most comfortable managing their care independently, while others benefit from partner support."

#### Available evidence from individual studies

The authors presented a good case on the use of bundled interventions that integrate male partner involvement. However, they didn't mention how the use of community health workers, male champions and other community liaison officers can impact these bundle interventions.

Authors' response: This point is now included as the last sentence in the pertinent paragraph thus: "The use of community liaison officers e.g., community health workers and male champions can also impact the effectiveness of bundled interventions."<sup>14</sup>

Page 8, lines 35-50. The authors should explain why they singled out community education and sensitization. Community education and sensitization and usually part of a bundle of community interventions.

Authors' response: We agree that community education and sensitization are usually part of a bundle of community intervention. However, the bundled interventions that integrate male partner involvement we described in the first paragraph (under "findings from individual studies") are not solely community interventions (they include for example task shifting, point-of-care diagnostics). A separate paragraph that focuses on community education and sensitization was therefore warranted.

#### Evidence from systematic reviews and meta-analyses

Page 9, lines 5-6. The authors have mentioned that more rigorous analyses of male partner involvement are needed but didn't explain why. There was no critical appraisal of the studies by Brusamento et al and Takah et al.

Authors' response: We acknowledge the lack of formal critical appraisal of the studies mentioned. Whereas we agree that this is useful information, strict word limits for this type of article constrain our ability to provide the requested information. A formal critical appraisal of the studies would extend the length of our submission beyond 1800-2000 words.

The authors also missed a systematic review published by Manjate et al.

Here is the link

<https://na01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpubmed%2F26726756&data=02%7C01%7Cmuktar.aliyu%40vumc.org%7Cfc3fddfeca04a4072cd08d6900cc93f%7Cef57503014244ed8b83c12c533d879ab%7C0%7C1%7C636854781938797951&sdata=YiR9NRTxue7qSpDK9xcuYZv75p9Wk8d3MTM%2B3kczRpg%3D&reserved=0>

Authors' response: Thank you. Although constrained by the citation limits we have now included this review in the section that discusses systematic reviews, thus: "A systematic review of 28 articles from SSA found that whereas few papers addressed the perceived role of men in VT services, the majority included considerations of barriers and enablers to male participation.<sup>24</sup>"

We have also cited the paper in pertinent parts in Table 1.

#### CONTRIBUTORS and SOURCES:

Sources of information used in preparing the manuscript were not stated.

Authors' response: We have indicated in the introduction section that this is a narrative review based on our analysis of contemporary published literature on the topic.

#### BOXES/TABLES/FIGURES: Good

Authors' response: Thank you.

REFERENCES: More than 20 references used. No need to include the "dio" in the Vancouver style.

Authors' response: We have taken out all digital object identifiers in the paper. We removed a reference but then had to add the Manjato Cuco paper referred to above.

Ref #18: The journal title isn't italicised.

Authors' response: Done.

KEY MESSAGE BOX: Authors should include a message box with 2-4 "take home" messages.

Authors' response:

We have added a message box to the manuscript.

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Reviewer: 3

Recommendation:

Comments:

This analysis piece argues that suboptimal performance of PMTCT programs in sub-Saharan Africa (SSA) is related to suboptimal male involvement in the cascade of ANC and post-natal care. While the idea to improve male partner involvement in PMTCT programs itself is not novel, the authors provide a useful summary of the literature, and important suggestions for how to increase male involvement going forward.

Authors' response: Thank you.

Nevertheless, the analysis can be improved by addressing the following issues:

Introduction:

1) The argument hinges on the assumption that increasing male involvement will improve all steps of the PMTCT cascade, but there was only one sentence in the introduction describing this literature, with only 2 references covering all the following domains: increasing in HIV testing, ART initiation and

adherence, HIV communication and prevention, decreases in new infant HIV infections, and increases in HIV-free infant survival. I suggest that they bolster their review of the beneficial impacts of male involvement in PMTCT by providing a little more specificity in the introduction when the concept is first introduced.

Authors' response: We acknowledge the points raised by the reviewer. We endeavor to address all suggestions. However, as pointed out by Reviewer 2, our original introduction section was too long, and we are constrained by the number of citations allowed (max = 20) and the word limit associated with this article type (1800-2000 words). We note that any bolstering of the introduction section will be at the expense of other changes suggested by the reviewers.

2) Additionally, more nuance can be provided as to the type of "male involvement" referred to in the introduction. For instance, there is likely a difference between a partner agreeing that their pregnant partner should go to ANC clinic, versus accompanying them to visits, encouraging testing and uptake of ART and actively supporting ART adherence. This point is alluded to later when they describe "varying definitions of male involvement" but should be brought up early so that the reader knows what is meant by "male involvement" from the outset.

Authors' response: We agree with the point raised by the Reviewer. However, as an Analysis paper we are severely constrained by the word limit (1800-2000 words) and the maximum number of citations (20). Nevertheless, we have now mentioned this point in the introduction section thus: "Variability of male partner engagement definitions and strategies, coupled with wide differences in socio-cultural contexts, complicate the translation of research into policy and practice."

Challenges in studying male partner involvement in PMTCT

3) In the section on "low background involvement of males in antenatal care", the authors focus on ANC clinic attendance only, but not the involvement of males in other steps in the PMTCT cascade.

Authors' response: The antenatal care setting serves as the first point of contact with HIV services for many women. Most definitions for male involvement in PMTCT programming relate on the role of men during the antenatal period, e.g., accompanying the partner to the ANC or providing support to enable the woman attend ANC. We have now added a sentence to the section that mentions the importance of listed barriers to other steps in the PMTCT cascade thus: "These factors similarly limit male involvement in subsequent steps of the VT prevention cascade..."

4) In the section on "Varied socio-cultural contexts, including gender roles and power dynamics", it is not clear whether the authors are referring to differences in socio-cultural issues between settings, or on socio-cultural issues that may be relevant to many settings. The arguments can be clarified here.

Authors' response: Thank you for the question. We were referring to differences in sociocultural norms within and between settings. We have edited the relevant sentence to clarify the point: "Different sociocultural contexts and norms within and between countries highlight difficulties in generalizing specific male involvement approaches in SSA."

5) Section on "varying definitions of male involvement", when the authors discuss "the ideal level of male partner involvement", is there any evidence on what that ideal level is, and whether it is different according to the different steps along the cascade of care?

Authors' response: To our knowledge, there is no consensus as to what constitutes the "ideal" level of male partner involvement. We alluded to this point in the relevant section thus: "Other challenges include the lack of data on the ideal "level" of male partner engagement..."

6) In the section on "Male partner involvement strategies as a component of bundled interventions:" The first sentence (page 7, line 20) is not clear as written, and should be reworded.

Authors' response: The sentence has been reworded to read "Male engagement activities are increasingly being integrated into VT prevention programs as components of bundled interventions.10"

7) Line 37 on page 7: What type of "male partner involvement" increased as per discussion on varying definition of male partner involvement"?

Authors' response: Audet et al. 2016 defined male engagement as "partner accompaniment to ANC services at least one time during the pregnancy". This detail is now provided.

8) Section on “unintended effects”: Have some or all of the unintended effects described in this section been demonstrated in studies, or are these more hypothetical concerns?

Authors’ response: The effects described have been demonstrated in other studies. Please refer to the relevant citations (Lodenstein et al., 2018; Tokhi et al., 2018; Peneza et al., 2018).

Available evidence from individual studies:

9) It would be helpful if the authors describe what type of male involvement was included in each of the interventions presented. This is done in some but not all of the studies discussed.

Authors’ response: We appreciate the suggestion. We have edited the relevant text accordingly.

What changes do national HIV/PMCTC programs need to institute?

Authors’ response: Additional details have now been added to this section, in line with recommendations by Reviewer #1.

10) While the authors make some important and helpful recommendations here, since this is the heart of the analysis, I believe this section can be further expanded and enriched with more detailed recommendations.

Authors’ response: We have now added more detail within the constraints imposed by the word limits in this type of article.

Conclusion:

11) I think an expanded discussion of next steps in research can be helpful here or in the previous section (perhaps expanding some of the ideas listed in Box 1).

Authors’ response: We have re-written the conclusion section to clearly articulate the future research directions needed to effectively engage male partners in eliminating VT. We have also expanded Box 1 so readers can easily identify topics with little published research and added in supporting citations.

Thank you for the opportunity to revise and resubmit this submission. We look forward to hearing from you.