Author's response to reviews

Title: Enhancing quality and integrity in biomedical research in Africa: An international call for greater focus, investment and standardisation in capacity strengthening for frontline staff

Authors:

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Author's response to reviews: see over
On behalf of the authors, I wish to take this opportunity to sincerely thank you for taking time to review this manuscript. The authors took time to respond to each and every comment and suggestion raised by the reviewers. In addition, the authors considered the additional editorial requests to focus on the minor essential revisions proposed by the three reviewers based on previous correspondence regarding the precise nature of the article type. The revised manuscript with track changes has been attached together with a point by point response to the reviewers’ comments.

We do hope that the editor will consider the revised manuscript positively.

Yours faithfully,
1. **Responses to Reviewer 1 comments (Paul Wenzel W Geissle)**

- The paper’s main point, that fieldworkers have a key role in ascertaining the ‘integrity’ of research, both in terms of data quality and in terms of acceptability and sustainability of research is very important and in agreement with much recent social science work on medical research in Africa. The latter could be referenced slightly more broadly beyond the author’s colleagues.

  **Response:** More references have been added to support this point, including reference numbers 7 to 9.

- The point that this ‘expanded role’ and the fieldworker’s careers deserve more attention, also in terms of training, is well taken. This is a big problem, both in terms of career progression, and in terms of single-employer labour markets. However, I find the paper does not yet make as convincing case for the need to ‘standardise’ training and certification as it could do. In my view, the strongest argument in favour of this is the resulting inter-site mobility of field staff, and thus the opening of a broader labour market, transforming frontline staff from what they used to be – locally collected temporary ‘assistants’ – into an expert professional group with greater career opportunities and also with greater bargaining powers. This aspect could be developed a bit more. This relates to a key aspect of the fieldworker problem, namely that so far FWs have had very specific and short-term skills, that did not qualify them for anything beyond a particular study or site, and left largely dependent upon a localized collaboration (and external funds). Recognising their key role and giving certified training would partly make them more generally employable and thus less dependent upon one single, temporary employer. The author does make reference to this aspect on p.8, but this political could be emphasized more.

  **Response:** We agree with the reviewer that this point could be emphasized more and have edited the manuscript under the section ‘Develop common areas of a core curriculum for field worker capacity building to enhance quality of training processes’ on page 11 to include the following sentences: A particular importance of this form of collaboration is in supporting multi-site studies that are increasingly common within Africa. Common areas for training could include knowledge about basic biology, research approaches and methods, research ethics and research regulatory frameworks. Common skills include those for data
collection and documentation and – critically – ‘soft’ skills such as respectful communication, and being aware of and managing ethical challenges and issues in practice.

At the same time, some flexibility across such a joint curriculum would be important given differences in context across sites.

- However, the big ‘elephant in the room’ that the paper does not explicate (and I do think it should, in order to make sense) is the underlying economic inequality that constitutes what sometimes is described as ‘frontline’. This ‘front’ is, ultimately, not science vs. lay, or global vs. local, but resource rich vs. poor. And the FWs are caught in between, bearing the brunt of the ethical and political and economic consequences of this underlying structural form of overseas medical research. I.e it’s not just about ethics, and a somewhat erroneous positioning of FWs ‘at the bottom of the pile’ that good training could rectify, but about real inequalities in which FWs indeed are at the bottom, or rather somewhere stuck in-between far down and the very bottom. While added technical knowledge and standardised curricula would not solve this underlying issue, I think the paper would gain much by spelling out that this is where much of the FW conundrum comes from. And while the interventions proposed here will improve some things, ‘frontline staff’ will still have to struggle with these basic structural challenges.

Response: Again we agree with the reviewer that this is an important point that should be recognised in the manuscript, although the analysis and strategies we set out in the paper are aimed directly at structural issues that we feel can be directly addressed in the short term. A sentence has been added on page 7/8 under the section ‘FWs roles and training needs which states: In doing this, they play a central role within some of the poorest communities in rural Africa role as the frontline of often very well resourced international research institutions, creating tensions in understanding researchers’ and their own responsibilities to respond to important unmet needs within communities, and how this should be done. In doing so, their positions reflect a different and wider ‘frontline’ generated by global forms of structural inequity increasingly seen as an important ethical issue in international health research.

- Finally a small point regarding the 4th recommendation, p.8: I think this recommendation could be subsumed under the previous ones, as it does not seem to add much, unless one would discuss here more the actual ‘broader vision’ that is needed, concerning the challenge of implementing scientific field research in a field of inequality

Response: We agree with the reviewer about the two points being linked, and have now merged these recommendations.
2. **Responses to Reviewer 2 comments (Joseph Ochieng)**

- **Can the co-authors be listed with their contact information unless the journal has a limit on the number of authors to be listed?**
  
  Response: We have taken the strategy of including the names of conference participants at the end of the article instead of listing all the participants, as the number is huge.

- **The abstract does not contain the results section which would help a reader to understand at a glance what the manuscript is about. Please include a results section in the abstract.**

- **Additionally, the abstract does not have conclusions rather a discussion. This needs to be rectified.**

- **The methods section describes what happened during the workshop but falls short of explaining how the workshop discussions were analysed to form results for this manuscript. What type of analysis was used and how was the data analysed?**

- **It is important to know if the data collection methods had any limitations.**

- **The manuscript does not have a section to discuss results. Rather it reports findings from the workshop and recommendations by the workshop participants. It would be good to discuss these findings and recommendations which I think can be grouped together as results.**

To respond to all these comments together, and many of those of reviewer 3, we believe the main issue is a misunderstanding about the type of article we are hoping to publish. We hope that the manuscript will be published as an opinion piece in the correspondence section of the journal, and not as a research article. For this reason we have not followed the formatting normally used in a research article, including that:

- **We have not presented methods in detail. Rather the letter describes consensus developed during the workshop through a series of information sharing and participatory activities that are now explained in more detail in the revised version under sections background to workshop and workshop activities on page 3 to 6.**

- **We do not include a formal section on study limitations but have included a sentence on possible limitations as part of the discussion.**

- **The results and recommendations are presented under separate headings as outputs of the workshop, as advised by the reviewer.**

  **It would also be good to have a link or an appendix in the methods section which would link the list of the participants to the methods section. This would solve the issue of listing the participants in the methods section.**

  Response: The description of participants given under the methods section was meant to give an overview of the range of participants who attended the workshop, rather than a detailed list. An appendix of all the workshop participants grouped according to countries they represent is available on page 14.

- **Authors' contributions appear twice as line 182 and line 196. In line 199, For the first time in the manuscript initials of some authors appears which is confusing. These initials need to be linked to names already mentioned in the manuscript.**

  Response: This has been corrected.
3. **Responses to Reviewer 3 comments (Tracey Chantler)**

- *I enjoyed reading this article and think that it covers a very important topic and makes some timely and appropriate recommendations. However I do not think that the content should be presented in the format of a research paper. It would be better to present this either as an opinion piece or a workshop review with a call for action.*

- *Are the data sound? Key points are highlighted, although it is not clear how these have been elected, for example was this part of a ranking exercise during the workshop? It is also not usual to include references in the findings section of a research paper (another reason why I think this paper should not be published as a research paper but rather as an opinion piece or similar). Actually this ‘findings from the workshop section’ is more a resume of discussions from the workshop that are collated in key points and recommendations.*

- Please see our responses above to reviewer 2, concerning formatting of this manuscript as correspondence and not as a research article.

- The introduction provides an overview of an important topic and highlights the need to pay closer attention to the role of fieldworkers in biomedical research and more specifically to their training needs. The article does not describe a research project hence there is not a defined research question. Instead it summarises deliberations from a workshop on the role of fieldworkers in biomedical research in Africa. This part of the paper could have been improved by providing some examples of some of the challenges field workers face in their work.
  
  **Response:** This was addressed by editing the second paragraph under the introduction section and added some of the examples FWs experience on page 7

- Are the methods appropriate and well described? Details are provided about the workshop but it is not clear how data was collected or collated from the workshop activities, and it would have been good to find out more about the different sessions that were run as part of this workshop and how participants were involved in leading, facilitating and contributing to these sessions
  
  **Response:** A more detailed description was given under the workshop activities in line with the reviewers recommendations

- Some of the points that are highlighted need more explanation. E.g.: “There is a lack of standardisation of approaches to fieldworker capacity building across different research projects at individual institutions. This fragmentation has the potential to affect data integrity and cause confusion among participating communities”
  
  **Response:** The sentence was edited and a detailed description given under the section *Fieldworker’s roles and training needs. The following sentences were added to make the section clearer:* There was recognition that these are complex roles that include balancing of institutional roles and guidelines against the community expectations and fieldworkers’ personal interests. In this way, fieldworkers continuously make independent decisions on how to apply ‘ethical principles’ in reality. Examples of the ethical challenges fieldworkers
were reported to face include dealing with silent refusals\textsuperscript{11} (participants who may not openly refuse to participate in research but indirectly avoid key study procedures), dealing with increasing demands for study benefits from community members who may or not necessarily be study participants and how to deal with study participants who may genuinely be in need of support which the study cannot offer\textsuperscript{9,12,13}

- \textit{Are the discussion and conclusions well balanced and adequately supported by the data?} There is not a separate discussion it is included in the findings part. The recommendations read well but I think they could be better grounded by a more detailed description of the challenges fieldworkers face in the findings section.  
  \textbf{Response:} This has been addressed by the addition of examples of challenges, as described in our responses to the reviewers earlier comment (above).

- \textit{Are limitations of the work clearly stated? No, these are not discussed.}  
  \textbf{Response:} Although this is not a research article, we have added a sentence on possible limitations in our discussion.