Author's response to reviews

Title: Capacity Mapping Of National Ethics Committees In The Eastern Mediterranean Region

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Author's response to reviews: see over
Editorial Board Member's comments:

I have reviewed the revised version of this submission without having read its original content. The authors appear to have accommodated the first reviewer's comments, but only minimally to have responded to those of the second and third reviewers. Their cover letter explains why the authors cannot answer some of the third reviewer's questions, but should include this inability as a limitation to the information provided in their text. I believe that the second and third reviewers would be surprised and dismayed to see this revised version published, since it seems to have all but ignored their thoughtful comments. The authors might be asked to return to their text, and to respond more fully to reviewers' comments, including those that address limitations to their data. Further, they should explain whether their own study received ethics committee approval, without which its publication may be difficult to approve.

Authors' Response: We have included below our original responses to the 2nd and 3rd reviewers and have indicated our revised responses to several of their original comments. We would like to emphasize the following: 1) we now include a more detailed explanation of the limitations of our study, please see pages 9 and 10; and 2) regarding prior ethics committee review, our response to this query was detailed in our original response to the third reviewer.

II. Response to Reviewer: Henk ten Have

This is an interesting overview of the ethical infrastructure in the WHO-EMRO countries.

Reviewer Comment 1. One basic issue concerns the definition of National Bioethics Committee (NBC). There are several definitions with the effect that classification and identification of NBCs is different, for example among WHO and UNESCO. In this article it seems that the focus is on National Research Ethics Committees. Since the questionnaire has been distributed through the WHO Offices and the Ministries of Health, this explains the focus on Research Ethics Committees. It also explains the focus of the activities. It should be explained what has been regarded as a National Bioethics Committee and the difficulties of identifying bodies as such.

Response 1: We appreciate this comment by the reviewer. Originally, our paper was focused on National Research Committees. For example, our Introduction emphasized the importance of research ethics capacity. However, this was a misplaced focus on our part, since the survey that was distributed asked about National Ethics Committees.

Accordingly, we have redirected the focus of the paper on National Ethics Committees (see rewritten Introduction). To be sure, many of the items on the survey tool did inquire about research ethics activities, but it also had items regarding ethics activities in general.
Finally, we would like to point out that although the survey was sent to WHO Country Offices in each Member State of the EM region, these offices were told to distribute the survey to a relevant individual in the Ministries of Health or the Ministry of Higher Education so that a “wide net” can be cast for the most appropriate individual to complete the survey.

Reviewer Comment 2. The section on activities refers to documents used. It is not clear whether these documents are self-reported or whether a list has been provided in the questionnaire. It explains why important international documents such as the Universal Declaration on Bioethics and Human Rights are missing.

Response 2. The reviewer refers to documents used in the review of research proposals. The survey tool provided a list of documents from which respondents were to make a choice.

Reviewer Comment 3. Page 9: important references are missing here since only the UNESCO website is mentioned without explicit details. In the medical ethics literature (for example the Journal of Medical Ethics), articles have been published concerning specific activities such as ethics education.

Response 3: We have provided more details and references regarding UNESCO activities, as well as the other ethics capacity programs in ethics in the EM and Arab Regions.

Reviewer Comment 4. In Table 2 the reference to ‘religious’ and ‘community member’ is vague. What is exactly meant by this; what kind of person?

Response 4. The reviewer raises an important issue. The survey tool did not provide a list of categories for members; respondents wrote in their own categories and several used the terms “religious” and “community member”. Future research should focus on obtaining more details regarding types of members from the lay public.

REVISED RESPONSE: In response to this query, we now mention that the vagueness of listing a “community member” is a limitation of our study. Please refer to pages 9 and 10.
III. Response to Reviewer: Adnan Hyder

Thank you for sharing this paper with us. We believe that academic papers are needed on the issue of research ethics and ethical review processes in the Middle Eastern region. However, the paper needs more work and we hope that the comments below, and those inserted in the attached annotated paper (in green), will help you revise it and develop it further.

Reviewer Comment 1: The introduction section is lacking in a good review of the empirical work in this area; please add a paragraph that briefly covers the empirical efforts globally in evaluating NBC and IRBs. Also regional literature on ethics and research ethics has not been covered – please add many more references that now exist form the region (Ahmad A et a; Jafarey A et al; Moazam F et al; Bhutta Z et al; etc).

Response to 1: We appreciate this comment from the reviewer and have added the paper by Bhutta and colleagues. We do not feel, however, that the content of the articles by the other mentioned authors are relevant to the topic discussed in this paper. We also have not discovered any references regarding the evaluation of National Ethics Committees. We do mention the one study by Kirigia and colleagues regarding capacity mapping of National Research Committees in Africa (ref # 9).

Revised Response: We now mention additional papers that describe some of the medical and research ethics issues faced by countries in the EM Region. Please see references 2-5 and 12. We also mention a paper focused on the evaluation of research ethics committees (see REF 13). Also, we now mention another paper that describes characteristics of NECs in the EM Region (see REF 15).

Reviewer Comment 2: Ethical approval for your paper: which IRB approved this study in the region? It seems that at least one NBC or IRB should have approved this study itself? If not, why was this not done?

Response to 2: This study was considered an internal quality improvement activity of EMRO/WHO and was not considered to be research involving obtaining information about human subjects. Indeed the assessment of the IRB at the University of Maryland was as follows: “[the protocol] does not involve the interaction, intervention, collection of identifiable information about living individuals and therefore is not a human subject research project and does not require IRB oversight”. Accordingly, the study was given exempt status from the IRB.
Reviewer Comment 3: A fundamental issue is that the “respondent” needs to be defined for this survey. Was it one person from the NBC? An individual from the MOH? Was the survey discussed first in a committee? What happened when there were disagreements? An associated issue is that this affects the validity of the survey and needs to be addressed in the methods and the discussion section. We do not know what we are reading as data without a clear understanding of who is responding, how did they get to the response, and what were the limitations.

Response to 3: The reviewer raises an important issue. This is discussed in the paper on page 9, para 2. Also, as mentioned in the Methods Section, the WHO Country Office was instructed to distribute the survey to a relevant individual in the Ministry of Health or the Ministry of Higher Education. We do not have information on the identities of the individuals who completed the survey.

REVISED RESPONSE: We now give an expanded statement regarding this important limitation of our study. See pages 9/10.

Reviewer Comment 4: You need to review the results section carefully; many of the numbers do not add up? Or if we are reading them incorrectly, then you need to present it with greater clarity.

Response to 4: We thank the reviewer for this comment and we have made the necessary corrections.

Reviewer Comment 5: Did you ask about the laws and legislation that allowed for the existence of the NBC?

Response to 5: A question regarding this issue was not included in the survey.

REVISED RESPONSE: We now mention our neglect in asking for this information (as well as other types of information) as being a limitation to our study. See pages 9 and 10.

Reviewer Comment 6: The discussion section needs more work to be focused and organized. You are making some claims which neither seem to originate from the results nor are they referenced? Please review carefully and focus on highlighting your results and revise the section.

Response to 6: We appreciate this comment from the reviewer. We have re-organized the Discussion Section.

Reviewer Comment 7: The tables at the end can also be reduced; you can just describe the results in the text for those tables with 2 or 3 rows.
Response to 7: We have eliminated Table 7 and have described the data in the text. All other tables now include 4 or more rows of data.

Reviewer’s comments inserted in the attached annotated paper (in green

We thank the reviewer for his comments in the paper and we have incorporated many of the suggested changes.