Author’s response to reviews

Title: Aflatoxin Exposure in Children Age 6 – 12 Years: A Study Protocol of a Comparative Randomized Cross-sectional Study in Kenya, East Africa

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Version: 1 Date: 02 Sep 2019

Author’s response to reviews:

Our point-to-point response to the reviewers’ comments are listed as following:

For Reviewer reports:

“Editor: The manuscript received mixed reviews. There are many comments on language and structure. Please dedicate time to a thorough review and proofread”.

Response: Thank you for comments. The manuscript has been thoroughly reviewed and edited according to the reviewers’ comments.

For Reviewer #1:

“Strengths: The role of aflatoxins in causing disease and their effects on the outputs (micronutrient deficiency, immune suppression and growth impairment) are important areas of research. The impact of aflatoxins on human disease is clear”.

Response: Thanks for these positive comments.

“Weaknesses: There are several cofounders that affect the outputs listed above that cannot be separated from aflatoxin exposure in this study: poverty, rainfall, ethnicity and possibly ambient temperature (although temperature details not given for Makueni county)”.

Response: We conducted a five-part questionnaire carefully designed to control for confounding variables, including poverty and or socioeconomic status as indicated on page 11.
The study protocol was designed to control for differences in ethnicity since Makueni County is home to the Bantu group of Kamba ethnicity, while Siaya County is home to the Nilotes of Luo ethnicity. Moreover, the choice of Makueni and Siaya as study sites is to control for differences in weather conditions, because Makueni is classified as semi-arid region while Siaya experience tropical climate. Makueni County’s ambient temperature ranges between 18 and 24 degrees Celsius in the cold season and between 24 and 33 degrees Celsius in the hot season. These changes have been added on pages 6 and 7 in the revised manuscript.

“It is not clear how this study advances significantly on that provided in ref 21”.

Response: Reference 21 (reference 25 on revised manuscript) provides an overview of the extent of aflatoxin exposure among adults between the ages of 15 and 64 years. To date, there’s no data on aflatoxin exposure in children between the ages of 6 to 12 years despite reports that link aflatoxin exposure to adverse health outcomes in children. Our study is aimed at fulfilling this data gap and to inform policy makers on the importance of early interventions.

“There is no randomization in the study, despite this being in the title”.

Response: Schools were randomly selected per constituency at the county levels whereas participants enrolled in the study were randomly selected using Kish Grid Method to avoid selection bias. Reference 21 (now Ref 25) informed selection of Makueni and Siaya Counties as study sites.

“There are many typographical errors which make the article difficult to read. Indeed much of the discussion is written in the second person”.

Response: The manuscript has been thoroughly revised and edited appropriately.

For Reviewer #2:

“Dear Authors, this paper is very comprehensive and overall reads well. However, there is confusion with the tense, in some sections it is written as the study has already been conducted and in other sections it is written as though the study is yet to start, can you please check and update accordingly”.

Response: Thank you for comments. Fieldwork and data collection at this time have been completed, however laboratory analyses are ongoing. The manuscript has been updated accordingly.

“Few minors edits:
Page 6 line 113 - 'minimal risk, randomized, multi-Centre, cross-sectional and school-based' does not match with Page 6 123 ' the study design is a school based cross sectional study’”?

Response: The use of words such as ‘minimal risk’ was meant to convey the nature of the study, while ‘multi-center’ used to mean that recruitment is done in two different counties. We have resolved to limit use of these words to avoid confusion. Initial page 6 line 113 have been deleted from manuscript and a better description of the study design incorporated on page 6 in the revised manuscript.

“Page 17, line 326 - Is windy the correct word here?”

Response: The word ‘windy’ has been replaced by the word ‘prolonged’ in the revised manuscript on
“Page 19 line 381 - suggest change to 'the study administrators are not ethically allowed to contact participants in the future’?”

Response: The suggested change has been incorporated into the manuscript on page 17 in the revised manuscript.

“Page 19, line 383 - please include why May, June July may not guarantee high aflatoxin exposure, is this because the weather is drier?”

Response: We expect aflatoxin exposures to be high in May, June and July because during these months, it tends to be rainy, humid, and most farmers have a surplus of harvested grains from the earlier season which are highly susceptible to aflatoxin contamination. Nonetheless, factors such as community education programs to promote aflatoxin awareness, diet diversification and food security in some regions where study participants were recruited may be associated with decreased aflatoxin exposures. This information has been added on page 17 in the revised manuscript.

For Reviewer #3:

“Very well written and detailed article, just some suggestions to make it more readable”:

Response: Thank you for taking time to read and provide feedback for our manuscript.

“1) Figure 2 can be redrawn using a consort diagram template”.

Response: Figure 2 have been redrawn using the consort diagram template in the revised manuscript.

“2) Discussion can be made more concise by reducing some explanation about logistics”.

Response: In discussion, detailed explanation on logistics has been truncated. Original discussion had 8 paragraphs while the revised manuscript has 3 paragraphs on the discussion section as shown on pages 15 and 16 of revised manuscript.

Taken together, we have responded to the reviewers’ comments, and we hope that our revised manuscript could satisfy the reviewer and the editor. We look forward to your reconsideration of our revised manuscript.