Author’s response to reviews

Title: The validity of the Patient Health Questionnaire-9 to screen for depression in patients with type-2 diabetes mellitus in non-communicable diseases clinics in Malawi

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Author’s response to reviews:

Dear Editor,

Please find with this letter our revised manuscript entitled:

““The validity of the Patient Health Questionnaire-9 to screen for depression in patients with type-2 diabetes mellitus in non-communicable diseases clinics in Malawi”

Thanks to the reviewers for their thoughtful comments, which have improved the quality of our manuscript. We have amended the submission according to these comments. Please find below a detailed response and description of the changes made.

We look forward to hearing from you.

Sincerely

Michael Udedi
Tesfa Dejenie Habtewold (Reviewer 1):

I have read the manuscript with great interest. This is a very relevant study given that only few psychometric tools are validated in Africa and it is worthwhile to publish it.

Before publication, I would like to recommend you to add some description of the importance of validation study either in the introduction or discussion section.

Response: Thank you so much for your suggestion, this has been addressed in the discussion section, lines 222 to 226 on page 9

In addition, what is the difference between table 2 and 3?

Response: Thank you so much, Table 2 is for any depression thus either minor or major depression while table 3 is for identification of major depression only

why you choose to validate PHQ 9? Why not BDI or CIDI or others?

Response: Thank you so much, this was already in the text in lines 77-79 on page 3.

“We chose the PHQ-9 for this study because it has shown to be effective in other settings and brief, which is compatible with Malawian health care setting workload”.

Furthermore the PHQ-9 incorporates the DSM criteria into a brief measure of depression such that the questions of the PHQ-9 are easily understood and that time to administer and score is minimal.

BDI’s reliance on physical symptoms such as fatigue in participants scores may be inflated due to symptoms of the illness rather than of depression in patients with concomitant physical illness.

The limitation of HADS questionnaire in the diagnosis of depression or depressive symptoms associated with chronic illnesses, is that the symptoms of chronic illnesses confounds the test scores
I am also not convinced by your choice of cut-off point >= 9; please elaborate.

Response: Thank you so much for your question; this has been elaborated in the method section line 160-164;

The ROC curve analysis was used to choose cut-points for the PHQ-9 scale. Two different cut-points were used, and the diagnostic ability was assessed by a number of statistics at each of these points. The best combination of sensitivity and specificity was found to be at a cut-point of 9 or higher.

Phillip J. Tully, Ph.D. (Reviewer 2)

Good succinct abstract and clear rationale in introduction - a generally nicely written paper and validation study. Acknowledgment of similar PHQ studies in other African countries. Independent back translation.

Perhaps the diagnoses of major and minor depression with SCID could be moved from the analyses section.

Response: Thank you so much for your suggestion, this has been moved to criterion validity

No reference is given for the SCID.

Response: Thank you so much the reference of SCID has been given in line 118 on page 5

Was the study under-powered based on the calculation of 80% sensitivity versus actual sensitivity?

Response: Thank you so much the study was not underpowered
What method was used to determine optimal cut-off's (e.g. Youden index?). Some mention is made in the results and should be described in the methods "gave the best combination of sensitivity and specificity in detecting either minor or major depression."

Response: Thank you so much the ROC curve analysis was used to choose cut-points for the PHQ-9 scale.

This has been described in methods section, lines 160-164 on page 7

The OCC is not described in the methods.

Response: Thank you so much the information has been described in the methods section in line 168 on page 7

No flow chart is provided regarding how many persons were approached and ineligible or unavailable for the study.

Response: Thank you so much the information has been described in the results in line 179-180 on page 7

The depression prevalence by SCID is high, even for a diabetes sample. Could the authors provide a comparison of their prevalence data against other diabetes samples from LMIC’s?

Response: Thank you so much the comparison has been done in line 240-242 on page 9 and now reads

The rate of depression in this study is comparable to rates of depression in other LMICs such as 46% in South Africa, 40% in Iraq, 32% in Egypt, 15% to 30% in Nigeria, 14. 7% to 43% in Pakistan, 43% to 70% in Iran, 27% to 63% in Mexico [31] and 39.73% in Ethiopia [32].

The qualifications of the research assistants were not stated

Response: Thank you so much, this has been addressed in line 142 on page 6