Author’s response to reviews

Title: Cost effectiveness analysis of a cluster randomized culturally-tailored, community-health worker home-visiting diabetes intervention versus standard care in American Samoa

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Author’s response to reviews:


Introduction: We are grateful for the positive comments from the reviewers and here respond point by point to their critical suggestions. We edited the reviewers’ comments to focus on their concerns and suggestions and our responses. We present the three reviewers’ comments in order of each of their points. We used Track Changes in Word to show the new text and new citations in the submitted revised manuscript.

Reviewer #1: Comment 1. My comments for improvement refer essentially to some aspects of reporting, which seems incongruent or haphazard at instances (I provide some examples below). I also did not find the mention or citation to an appropriate reporting guideline (e.g. https://www.equator-network.org/reporting-guidelines/recommendations-for-reporting-cost-effectiveness-analyses/), which can be part of the reasons for the mentioned above.

The examples of issues with the reporting, or for which improvements are specifically suggested, are as it follows:

* The Abstract and the respective sections of the paper do not always match in content: e.g. the first element of the Results in the full paper equates to the Methods section in the abstract. Elements of the Conclusions of the abstract are not represented in the
Conclusions of the paper. A comprehensive revision of congruence must be performed with such regards.

Authors’ reply: Thank you for these helpful ways to clarify and make the manuscript more concise. We edited the revision to be more consistent, especially regarding presenting material in the correct section of the manuscript.

Rev #1, comment 2: The Results section in the full paper take too long to come to the main result, i.e. the ones reported in results of the Abstract. I’d recommend an inverse reporting approach - beginning with the main result and, eventually, provide then information on the underlying components.

Authors’ reply: We accepted your helpful suggestions and presented the main findings first and then the constituent results.

Rev #1, comment 3: It is immediately awkward to observe citations in the Results of an original research paper. Likely the underlying content pertains to the Methods (that in the first paragraph - as in the Abstract) or in the Methods or Discussion (that of the last paragraph), depending on whether you define different levels of thresholds upfront (in the Methods) or you do that a posteriori (in the Discussion) after sticking to only one in the Methods. Either reporting approach seems better than the current.

Authors’ reply: We agree and edited the ms. accordingly. Thank you.

Rev #1, comment 4: It is also immediately awkward to observe a Conclusion starting with "Future studies". Overall the Results and Conclusions would benefit from a more incisive approach. With such regards, for example the Introduction and Methods do a better job.

Authors’ reply: We agree and edited the ms. accordingly. Thank you.

Rev#1, comment 5: A minor issue: redundant language in the Abstract, results section: "increase of 0.05 QALYs gained." Either only 'increase of' or only 'gained'.

Authors reply: We agree and edited as suggested.

Reviewer #2: Thank you very much for providing an opportunity to review an interesting manuscript by Huang and co-authors. The manuscript reads well and based on my expertise, I have few comments and suggestions to authors below:
Rev #2, comment 1: Since this study is focused on CHW versus standard care, I would ask authors to elaborate on CHW intervention more clearly in the methods section. Why is it culturally tailored? I don't seem to find the answers. It would be good to extract some information in this manuscript for readers to quickly get an idea of what that intervention looks like?

Authors’ reply: We added a bit more detail but mainly provided additional citations to our prior publications about the concept, process of developing the cultural tailoring, and the intervention itself. We wanted to keep close to the word limit of the journal and decided that our prior papers had much information that curious readers can consult for the deeper details.

Rev #2, comment 2: As this study delves into the cost effectiveness, I would urge authors to depict all the cost analyzed in tables for more clarity in the methods section rather than in paragraphs. That would also reduce the length of the manuscript and may provide quick glimpse to readers about how and what costs were included in the study?

Authors’ reply: We provide the detailed medical system costs in Supplementary Table 1.

Rev #2, comment 3: In the methods section, line 9-14: could you update the latest WHO survey data. It looks a bit outdated. Alternatively, you could present a trend since 2004 till the date that will give readers a broader knowledge.

Authors’ reply: The WHO STEPS data for American Samoa are the latest systematic adult survey data. Since little systematic data is known we choose not to speculate about temporal trends since 2004 in the manuscript.

Rev #2: comment 4: Page 12-13: Please clarify were the QALY estimates were based on the results from a cross-sectional study from Thailand?

Authors’ reply: Yes. This is stated clearly in the manuscript in Methods, now the second paragraph of p.13 of the revised ms.

Rev 2, comment 5: page 13. Please clarify QALYs variation in states in Japan, how did you adjusted for Samoa study? Please break the sentence and try to make it clear?

Authors’ reply: We assume the reviewer is asking about the use of utility weights in Japan for the sensitivity analysis. If so, here is our response. Variation in QALYs for Japan was a less conservative relationship between HbA1c and QALYs, which we used only for the sensitivity analysis, and are not themselves relevant for American Samoa. We chose the Thailand value for our base case as it was both more conservative, and we believe it to be the best available approximation for the association of HbA1c changes and QALYs.
Reviewer #3, comment 1: This is an interesting and useful study that contributes to our knowledge and understanding of the cost-effectiveness (and, to a certain extent, the clinical outcomes) associated with a CHW-led model of care for Polynesian patients with T2DM. The paper seems to relate strongly to the US health system and previous experience in US health care settings; T2DM and poor clinical outcomes contribute disproportionately to health care costs in other Pacific Island countries (PIC) (Ref Anderson et al. The costs and affordability of drug treatments for type 2 diabetes and hypertension in Vanuatu. Pacific Health Dialog Volume 19: Number 2: 1). This paper will potentially of great interest to health decision-makers in those settings, who are looking at ways of reducing the cost burden of care for patients with NCDs; it would therefore be helpful if the overall messages could be contextualised to address Pacific health systems and population health settings more directly.

Authors’ Reply: We agree that the Pacific region has a formidable challenge to provide health services to its population during this cardiometabolic disease emergency. We do appreciate this and added the Anderson et al reference and another paper to broaden the appeal.

Reviewer #3, comment 2: The ABSTRACT does not stand alone as a summary of the paper as it does not accurately capture all of the most relevant findings and lessons from the study - it probably needs to be re-written. For example, in the Background, CHW interventions CAN improve T2DM care but are not guaranteed to.

Authors reply: We edited the sentence accordingly, thank you.

Rev #3, comment 3: It is incompletely demonstrated that the DCAS study 'improved clinical outcomes' as the study has not been designed to quantify risk and rate of progression towards specific clinical outcomes like ischaemic heart disease, cerebrovascular disease, chronic renal insufficiency requiring peritoneal or haemodialysis, retinal pathology or peripheral vascular disease and neuropathy requiring amputation; it is also not clear how directly the CHW-managed interventions addressed progression towards these end points (noting also that the period of intervention may be too short to influence these outcomes to a measurably significant degree).

Authors reply: We agree and edited the sentence to state that it improved HbA1c levels. Thank you.

Rev #3, comment 4: The subjects were '269 American Samoans DIAGNOSED WITH T2DM',

Authors’ reply: We edited the sentence following your suggestion. (Total N was 268). Thank you.

Rev #3, comment 5: it is not clear what 'clinical utilization ... data'
Authors’ reply: We describe this in the body of the Methods. We tried to keep the abstract concise and assume curious readers will read the main text.

Rev #3, comment 6: and the ICER 'from a societal perspective' mean as these terms are very general.

Authors’ reply: We revised this with more detail and definition in the body of the Methods following your suggestion. Thank you.

Rev #3, comment 7: If using 2012 USD, it is important to include the dates of the study (enrolment, process, measurement of outcomes).

Authors’ reply: We added the dates in the abstract as requested. Thank you.

Rev #3, comment 8: and it is not clear why a willingness-to-pay threshold of USD 50,000 per QALY gained has been selected for comparison.

Authors’ reply: This justification is provided in the revised Methods section.

Some of these comments flow through to the main body of the paper, although some of the information missing from the Abstract is generally available there.

Rev #3, comment 9: In the INTRODUCTION, a stronger orientation towards similar PIC contexts (as noted above) would be relevant and helpful. The issue is not only that the populations are 'medically-underserved' but that a healthy diet is now more difficult to maintain than in more 'traditional' times when high fat, high salt imported foods and sugar-sweetened beverages were not such a prominent part of the diet, and patterns of physical activity have also changed.

Authors’ reply: we added more concise detail on the nutrition and NCD transitions and cite the Anderson et al paper. Thank you.

Rev #3, comment 10: It would also be useful to describe what is meant by 'usual care'.

Authors’ reply: We felt constrained by word limits so cite our prior papers about the intervention. We hope readers wanting to know more will consult those.

Rev #3, comment 11: The Introduction should note that, due to already established pathology and end-organ disease, there will inevitably be physician and clinical care costs for patients that
the CHWs are not able to keep out of hospital and this may be expected to erode the outcome measures due to the relatively short time frame of the intervention (as noted in the Discussion).

Authors’ reply: We appreciate this point and added this view to the limitations in Discussion. Thank you!

Rev #3, comment 12: It would be useful to provide some background information on health service utilisation among T2DM and/or NCD patients as poor compliance with care is a major contributor towards poor clinical outcomes and the need for more costly tertiary interventions in many PICs.

Authors’ reply: Although we agree, there is no systematic data on this in American Samoa so we are forced to not include such a statement.

Rev #3, comment 13: The Introduction should also include some background on the American Samoa health system and health financing, including the cost burden associated with diabetes and other NCDs - some of this may be brought up from paragraph 1 of the Methods.

Authors’ reply: We cite some key reports on American Samoa already and do not have the space to describe the wider region.

Rev #3, comment 14: As noted above (Abstract), the willingness-to-pay threshold of USD 50,000 per QALY gained is plausible but needs some more detail about how and why it was selected (if possible).

Authors’ reply: Please see our revised detail in Methods about this.

Rev #3, comment 15: To say ‘the samples were balanced at baselines’ is an unusual expression; this should be stated more clearly (e.g. there was no significant difference in demographic or risk factor characteristics between the intervention and control populations, other than cigarette smoking which was higher in the intervention arm ... something like that).

Authors’ reply: We revised this. Thank you.

Rev #3, comment 16: The paragraph describing the LIMITATIONS of the study could also pick up some of the observations made in this review.

Authors’ reply: We revised this. Thank you.
Rev #3, comment 22: The CONCLUSIONS could be focused more strongly on recommendations that can be addressed to health decision makers (including in relation to models of care in other PICs).

Authors’ reply: We revised this. Thank you.