Author’s response to reviews

Title: What do the implementation outcome variables tell us about the scaling-up of the antiretroviral treatment adherence clubs in South Africa? A document review

Authors:
Ferdinand Mukumbang (mukumbang@gmail.com)
Zaida Orth (zaidaorth@gmail.com)
Brian van Wyk (bvanWyk@uwc.ac.za)

Version: 2 Date: 14 Feb 2019

Author’s response to reviews:
What do the implementation outcome variables tell us about the scaling-up of the antiretroviral treatment adherence clubs in South Africa? A document review
Ferdinand C. Mukumbang1, Zaida Orth1, and Brian van Wyk1

Dear Editor,

We want to thank you for considering our manuscript for possible publication in your journal. We are also grateful for the comments provided by the reviewers to improve the quality of our manuscript. In this letter, we provide a response to the points and comments made by the reviewers explicating how we addressed them and if not why.

Reviewer #1:

This is a useful study that can contribute to improving the implementation of a program for the benefit of PLHIV. The intention to use the concepts of science implementation is commendable and appropriate for this study.

This study presents a strategy for the delivery of ART and retention of PLHIV in treatment. The publication of this study could serve as an example for other actors involved in the management of LPHIV. The AC model has been very well described in its practical implementation. In addition, the study has the merit of assessing the implementation for an expanding program in the country using science implementation methods and concepts. There is a well-researched bibliography on the subject in the context of South Africa.
To improve the easy understanding of the study of the results to be shared, it is of major importance to:

Query 1: Review the title and clearly mention the implementations outcomes studied and make the link with the ACs

Response: We thank the reviewer for this observation. While we agree that having the elements of the implementation framework enlisted in the title could be appropriate we thought that doing so would make the title cumbersome and would impact on its readability. To this end, we decided to review the title to: What do the implementation outcome variables tell us about the scaling-up of the antiretroviral treatment adherence clubs in South Africa? A document review

Query 1: Provide comparisons between other models of ART delivery and AC

Response: It would have been great to provide a comparison of the adherence clubs to the other models such as quick pick-ups at the pharmacy. However these other differentiated ART delivery models have not received so much buy-in and implementation support as the adherence clubs in the South African context. This would make comparison a bit tricky.

Query 3: Clearly state the research question that will better define the scope of the study and the choice of method

Response: We thank the reviewer for this observation. The research question has thus been specified. What do the implementation outcome variables tell us about the scaling-up of the antiretroviral treatment adherence clubs in South Africa?

Query 4: The use of validated frameworks for intervention evaluation, such as RE-AIM or PRECEDE-PROCEED, would help to better systematise the choice of study variables and the correlations between them in order to better explain the results obtained. Select the parts of the framework that can be adapted to the data already collected.

Response: We thank the reviewer for these suggestions. The implementation outcome variables were selected over other exiting implementation frameworks such as RE-AIM and PRECEDE-PROCEED because they encompass the full range of concepts now thought to be involved in the implementation of innovations in health care. Bennet et al. [23] demonstrated the role and feasibility using of the implementation outcome variables when the employed them to conceptualise information from reviewed project documents from three countries to address questions regarding the scalability and sustainability of innovations.”

Query 5: Harmonise the objective of the study in the summary in the introduction
Response: Thank you for your suggestion. We have done that by removing the heading “The rationale for this review”.

Query 5: Adapt the data analysis according to the framework that will be used

Response: Considering that we have maintained the implementation outcome variables that we originally adopted, we have retained our analysis according to the implementation framework.

Query 6: Better describe the results in addition to the tables

Response: Thank you for your suggestion.

Query 7: The citation of some references was incomplete (1, 3, 7, 10, 11, 37, 41, 43), as well as the duplication of reference 18 at 23.

Response: Thank you for your suggestion. We have addressed these issues related to the references.

Reviewer #2:

The article treats a topic of interest, on a changed model of care for ART that will be useful for many actors in health and HIV care.

The methodology used is also interesting.

Query 1: It could be useful to provide a bit more information on how each of the dimensions is obtained, as this is not immediately clear to those unfamiliar with the methodology.

Response 1: We agree with the review. We have addressed this deficiency by improving the paragraphs thus: We have added the following sentence in the methods section to address this query. “We followed a thematic framework synthesis approach [22] by adopting the implementation outcome variables described by Peters et al. [19] – acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, coverage, and sustainability. The implementation outcome variables assess how well implementation has occurred regarding the intentional actions to deliver health services [19]. The implementation outcome variables were selected over other exiting implementation frameworks such as RE-AIM and PRECEDE-PROCEED because they encompass the full range of concepts now thought to be involved in the implementation of innovations in health care. Bennet et al. [23] demonstrated the role and feasibility using of the implementation outcome variables when the employed them to conceptualise information from reviewed project documents from three countries to address questions regarding the scalability and sustainability of innovations.”
Query 2: Also it's less clear how the relative weight of the various dimensions will work out. Certain dimensions might be more important, depending on the context and the ambitions of the programme and there might be tradeoffs to take into account. Eg coverage might be in tension with sustainability or costs. In particular in the methodology the fidelity aspect is in particular useful but the reasons for/origin of the difference in implementation is not specified much. It could be interesting to see how the changes are originating from internal pressure to fit with the existing (health or supply) system or rather further improvements based on better results in patient outcomes.

Response 2: We definitely agree with review that depending of the context some of the dimensions would be more important than others and that tradeoffs are therefore certain to happen. Nevertheless our study intended to capture how the adherence club programme has performed under each outcome variable to comprehensively capture its success with regard to national rollout.

Query 3: Inclusion and comparison with other models or alternative ways of organising ART pick up, applied outside South Africa would have been useful, as this would offer a larger range of possible approaches. Now the article focuses only on options that 'fit' or are acceptable to the South African system.

Response 3: Indeed, the adherence club has shown effectiveness and suitability in the Western Cape Province were the intervention was originally piloted. However, the success seen in the Western Cape Province has not been successfully replicated in the other eight provinces of South Africa. This information formed the backdrop of the study to assess how the implementation is taking place on a national level.

Query 4: In the description and discussion on the adherence club programme, there is some confusion between clinical visits and clinic visits. Normally there are no clinical care acts in the club appointments. This is a key element in experiences outside South Africa.

Response 4: We agree with the reviewer. Thank you for pointing that out. We have changes the clinical visit to adherence support visits.

Query 5: Also it would be useful to specify or go deeper into the aspect of how reducing the burden on patients by reducing frequency, waiting times etc is approached.

Response 5: We acknowledge the value of the insights shared by the reviewer. We have addressed the issue of more information on how reducing the burden on patients by reducing frequency and waiting times is approached thus: “As highlighted by Grimsrud et al. [30], the current ART pharmacy guidelines in South Africa require ART scripts to be written every six months. Although national policy allows three-month dispensing, there is great variation between provinces and individual facilities. In the standard AC medication pickup, patients receive a maximum of two months’ supply. Nevertheless, to support ART patients who most
commonly migrate over the Christmas holiday period, most clinics have resorted to provide four month’s ART supply, dispensed as two two-monthly supplies to align with national policy [30]. Data are limited on how long ART dispensing intervals should be to optimize retention in care. A comparison of outcomes among AC members who received two-month ART (normal standard of care) to four-month ART showed no difference in defaulting or viral suppression between groups [30].”

Query 6: The fact that club activities can take up to 1h30 or more seems not such a big reduction in time consuming activity; also the frequency of the contacts seems not so much reduced. To say it is better adapted to ‘lifestyle needs’ is for me confusing, as this seems to indicate a choice by the patients and not a choice for the health system to be less burdensome because excessive/non-justified demand on patients’ time.

Response 6: We appreciate the insights of the reviewer. The context of 1h30 being a reduction in time is that an average time spent to collect medication during a regular visit for a non-club patient is usually 6 hours. This is divided between the time spent at the reception for their files to be drawn, to the see a clinician and to collect their medication from the usually congested pharmacies. The adherence club could fit around the lifestyle of the patient in the sense that they can continue with other activities of the day without significantly disrupting their programme, such as going to work.

Query 7: As far as my information goes, there might be also some legal restrictions to the roll out of ART clubs outside the health centres; as it is legally required for a nurse or medical staff to transport medicines outside the health centre.

Response 7: We that the reviewer for pointing out this important issue. We have addressed it by adding the following sentence. “Potential legal restrictions to the roll out of ART clubs outside the healthcare facilities have been highlighted especially regarding medication dispensing, as it is legally required for a nurse or medical staff to transport medicines outside the healthcare facilities. To overcome this challenge, according to McGregor et al. [32] a new cadre of low-level pharmacy workers has also been approved to address legal grey areas in terms of dispensing ART off-site for the community-based and home-based AC models.”

Query 8: Also it would be interesting to see how the number of patients per club influences the roll out, organisation and logistics of clubs per health centre.

Response 8: We acknowledge the value of the insights shared by the reviewer. Because we conducted a document review, we could not find any document that could respond to these aspects of the implementation of that adherence clubs.

Query 9: These elements could be interesting to develop in the discussion part.
In fact now there is hardly any discussion, which would provide interesting insights on policy options and future ambitions of changing/improving effectiveness and efficiency of the programme.

Response 9: We acknowledge the lack of discussion around these points. We have therefore develop these points under the heading Policy implications and recommendations.

Potential legal restrictions to the roll out of ART clubs outside the healthcare facilities have been highlighted especially regarding medication dispensing, as it is legally required for a nurse or medical staff to transport medicines outside the healthcare facilities. To overcome this challenge, according to MacGregor et al. [32] a new cadre of low-level pharmacy workers has also been approved to address legal grey areas in terms of dispensing ART off-site for the community-based and home-based AC models.

Following the two two-monthly (four months) ART supply provided to ART patients gaining traction, and with evidence indicating that longer ART supply refill intervals over holiday periods does not have a negative impact on patient outcomes [30], some considerations have been made with regard to establishing clubs with three and four months medication supply to further reduce the number of club attendance. Nevertheless, the change from the original two months’ supply is not evident at policy level [32].

Although an estimated 30 patients are required per club [9], there is evidence that some clubs could harbour more than 40 members [15]. We found a dearth of information with regard to how the number of patients per club influences the roll out, organisation and logistics of clubs per health centre. At the initial stages of the rollout of ACs, the systematic criteria for the identification of ‘stable patients’ for placement into clubs as established by MSF was crucial. Nevertheless, as the scaling up and diffusion of the intervention progressed, the entry and number of members per club criteria were altered to enable rising recruitment targets [32]. According to MacGregor et al. [32], albeit there being systematised procedures for starting clubs, there had been less effort to formalise plans for addressing the organisational complexity and challenges that comes with a large increase in the number of clubs in a facility. Each healthcare facility seem to manage their own situation depending on the resources available to them. We propose that having clear policies statements and guidelines on how to deal with organisational complexities regarding the growing number of patients in clubs could be useful in the context of ‘test and treat’.

Query 10: There are still some typo's (eg names in references written in different ways), so a re-read is recommended.

Response 10: Thank you. We have addressed these.