Reviewer’s report

Title: Sustainability of the streamlined ART (START-ART) implementation intervention strategy among ART-eligible adult patients in HIV clinics in public health centers in Uganda: a mixed methods study

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Reviewer: Aaloke Mody

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Overall comments:

This is an important follow-up study to previous START-ART trial (in and of itself an important trial). The initial trial used a stepped-wedge design, and a very important question, particularly with stepped wedge designs that eventually role out the intervention to all facilities, is what happens after the study ends. Is the intervention sustained? The overall study design seems sound with a quantitative aspect (with what appears to be a reasonable sampling approach) and qualitative component that seeks to identify the mechanisms of sustainability (or lack of it). Considerations that need to be addressed are: 1) There is no discussion of how secular trends or how treatment practices changed over the course of their analysis time period. When did Uganda adopt universal treatment which would limit the importance of the PIMA machine? Was there ever a national push for more rapid ART initiation? These factors need to be discussed directly in the manuscript as they would significantly contribute to whether the intervention seemed to be sustained and are important for contextualizing what is happening over time. 2) I really enjoyed that they attempted to describe the heterogeneity across clinics but quantitative analyses that attempt to capture the factors (i.e., patient and clinic factors) associated with differences in sustainability would be a strength (not just analyzing factors associated with rapid start before and after the intervention). An analysis focused on successful sustainability (not just good outcomes during the sustainability period) gets more at the research question at hand. 3) A bit more discussion about what there is ultimately to learn from this experience and specifically what people need to be consider going forward. Overall, I think this is an important paper and that the authors have put careful consideration into their analytic choices. The paper’s clarity can be improved and some additional targeted analyses per above would really strengthen the paper, but I think it has a solid foundation to be an important contribution to the literature.

Specific comments:

Intro:
Though the importance of ART and some its research background is important to bring up, the research is question is more about what happens to intervention implementation after a study as ended, particularly one that was designed for its effects to persists. I think it is important to bring up this tension about how an intervention can remain in place after the resources from the research study are no longer there.
I think it is also important to bring up in the introduction the prevailing thoughts with regards to rapid ART initiation, the influence on universal treatment, as these all will influence how to interpret this study.

Methods
I believe the methods are probably relatively sound, but I had a difficult time following the methods section.
I think a very clear description of what the design for the analysis (intervention ran from xxx to xxx, we analyzed patients in periods before and after xxx at y number of clinics), a brief description of the study population for the quantitative and qualitative study, and a clear description of the initial intervention (mostly there) need to be up front. I had a very hard time following what was being referred to in each section.
I think it would also be good to describe how the intervention was handed over to MJAP for continuation. This process is important and should be described.
I do like how the different periods were defined and clearly described with the rationale behind choices.
How were the 15 clinics selected? Initially there were 20 in the study.
Part of the sampling discussion is also related to data collection (to get the information to inform the sampling). The mixing of different topics makes it hard to follow.
The data collection for START study and from routine care are a different. A description of how the databases are generated (and differences between them) is probably needed.
The quantitative analysis seems relatively simple compared to the sampling methods and doesn't fully answer the question at hand. First, secular trends are very important in understanding what is going. An interrupted time series like approach could help to understand how the end of the study influenced outcomes. Additionally, one could envision an analysis trying to examine factors associated with high levels of rapid ART initiation in the sustained period. Clinic level characteristics included how well they performed during the intervention period, maybe what wave they were in, could all potentially be potential covariates to help explain what is associated with rapid ART initiation in the sustainability period.
A discussion regarding the role of secular trends and changes in HIV treatment practices over time (was universal treatment rolled out) is needed.

RESULTS

Were the missings charts from the intervention period or sustainability period or both?

As stated above, I think the assessment of whether a clinic did better or worsens must incorporate secular trends. An analysis like an interrupted time series may be needed to better get at that. At a minimum, at least a figure displaying a graph of rapid ART initiation over time (time on the x axis). Its possible that improvements were very rapid initially during the intervention, but slowed down afterwards (but still went up). Also could incorporate other changes that may have happened to Ugandan treatment guidelines.

Rather than perform stratified analyses for each clinic and report the results, a forest plot or other figure may better help demonstrate the heterogeneity across clinics.
Also rather than reporting whether the p-value was significant for one clinic vs. the other (I could imagine this potentially be due to clinic size and I don’t find particularly helpful), rethinking the analysis to understand the differences between clinics that performed and those that performed poorly is important. A mixed effects regression and calculating an ICC for clinic is a start, but that only explains heterogeneity in rapid ART initiation across clinics, not heterogeneity in how improvements were sustained (which is more the topic of this paper). I like the use of COM-B model and categorizing findings from the qualitative study into that framework very much.

I wasn’t clear if the positive comments regarding sustainability only came from the clinics that did well and vice versa (negative comments came from clinics that didn’t sustain as well). Was this envisioned as a positive deviance like analysis? I could also imagine that HCWs across all clinics experienced different types of barriers and facilitators and that was my understanding from initially reading the results. If a very specific theme did emerge about why certain clinics did poorly or did well, I missed it and these should be more clearly specified. Overall, more figures would be a nice way to present some of the day.

Discussion

I think the discussion is reasonably sound. I would have like to see some more thought about what the findings ultimately mean? What needs to be done to ensure interventions remain sustainable? What aspects may not be feasible beyond a research study (e.g., PIMAs seemed important for the initial study but were also hard to maintain over the long term. Training also helped and its effects persisted, but some degree of mentoring still seemed to be needed)? What should researchers be considering when they initially conceptualize an intervention and research study to ensure that it remains sustainable. The authors should have a lot of insight into these important questions and it would be great to have more fleshed out discussion on them (including integrating findings and literature from other areas).

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