Reviewer’s report

Title: Infant HIV testing at birth using point-of-care and conventional HIV DNA PCR: an implementation feasibility pilot study in Kenya

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Reviewer: Victoria Simms

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This is an important and useful pilot study. It’s not a cluster-randomised trial. The random allocation of two different techniques for the POC test is a minor tweak of the study design and unrelated to the main research question or primary outcomes. This needs to be fixed, because presenting it as a trial causes quite a bit of confusion.

Figure 1 and the description show the study to be a two-arm cluster-randomised trial, with one arm getting Xpert and the other arm getting Alere. However, the focus of the study is not in comparing those two, which means they can't be trial arms. The key comparison is between a POC test and standard of care(SOC). Each participant acts as their own control because each participant gets both the intervention and SOC. Confounding is prevented via self-matching, not randomisation. This is a self-controlled case series implementation study. There's a bit of work looking at the sensitivity and specificity of Xpert versus Alere, but you could do that just as effectively (if not better) by putting both machines in one hospital and running them on the same samples.

Since this is not a trial, that frees you up from some trial requirements which don't make sense here. For example, the clinicaltrials.gov registration shows you are enrolling 1440 participants, while the power calculation requires 36. If it was a trial you would need to justify the need for all those extra people. It would be better to explain why you actually decided to enrol 1440 participants.

You will need to use pair-matched analysis. Rather than comparing two groups of children you are comparing each child with itself. Any non-time-varying characteristics (distance to clinic etc) will be cancelled out and don't need to be adjusted for. The primary outcome is time to event, so rate methods may be better. Consult a statistician.

You have clinical outcomes, assay performance outcomes and implementation outcomes. They're all useful to report but I'm not sure it is helpful to call them all outcomes, which implies they are affected by some intervention. The assay performance outcomes are compared between Xpert and Alere. They are really process data, not outcomes. HIV prevalence at birth and 6 weeks is more of a participant characteristic, unless you think the POC tests might be more sensitive than the PCR.

The introduction has a sensible and clear argument for why at-birth testing hasn't been done up to now and why it might now be worth doing.
The discussion is only 2 paragraphs long. It's an opportunity to be more specific about how the results of this study will be useful and why you chose to do things in this way.

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