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

Version: 0 Date: 11 Oct 2018

Reviewer: Bindiya Meggi

Reviewer's report:

1. Trial Design: On the title of the protocol is mentioned that this study is small cluster randomized trial. But in Methods its not clearly stated if it is cluster or individual (justification is also needed why cluster). In a CRT there is one group of clusters who receives the intervention and other who are Control group. And the analysis should be done comparing the outcomes on this two groups. It is not clear what is the intervention and what is control. Both groups have POC and SOC in each. So how the comparasation will be done. Ideally the intervention arm would be POC tesing and the Control would be SOC. None of the primary outcomes compares two tyes of POC that consists in the two interventions.

2. Do clearly define the cluster in the protocol;

3. Define the eligibility criteria for the selected clusters that will be later randomised.

4. Sample Size: For a Cluster Trial the sample size should include the number of clusters, cluster size(s) (and whether equal or unequal cluster sizes are assumed), a coefficient of intracluster correlation (ICC or k), and an indication of its uncertainty. This is not stated in the protocol.

5. POC testing at birth: it is stated tat the birth testing is considered to be within 2 weeks of age. But then is stated that the mother will be informed of the POC result before the discharge within 24 hours. Could the authors clarify what they mean with discharged. Is it common for a 1 week baby to be in hospital? Or its before they leave the clinic (outpatient).

6. Quantitative analysis should reflect the cluster randomise trial analysis.

7. Over all: Protocol could be revised according to the Consort Checklist for the Cluster RT (although its for reporting of results, its will help the authors to report).

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