Reviewer's report

Title: HIV Surveillance in a Large, Community-Based Study: Results from the Pilot Study of Project Accept (HIV Prevention Trials Network 043)

Version: 2 Date: 8 July 2011

Reviewer: Kevin Delaney

Reviewer's report:

This manuscript describes the performance of in-country rapid HIV testing algorithms used as part of Project Accept. The authors compared the results of in-country HIV testing to testing performed on samples shipped to the Project Accept reference laboratory, and found that 99.5% of study participants were correctly classified by the in-country testing algorithm. The study methods are well-described and consistent with international standards for laboratory testing and the report of evaluations of laboratory tests. The results are clearly and concisely presented, and the discussion and conclusions are relevant to these data and balanced. Overall the manuscript is well-written and clear.

Major Compulsory Revisions: None

Minor Essential Revisions:

1) In the first sentence of Methods in the abstract, suggest you revise to: “Two HIV rapid tests were performed in parallel by local laboratories.”

2) Last sentence of abstract, suggest that for clarity and consistency the authors report the adjusted HIV prevalence in the last sentence i.e. (range: 0.6 to 24.4%).

3) Under the section Laboratory testing at the HPTN Network Laboratory, the authors mention Amplicor testing. I assume no Amplicor results are presented because there were no discrepancies between the Architect assay and Western blot, but I think they can delete reference to the Amplicor from the methods since results are not included...

4) Results, page 9 second paragraph line 6, suggest “(five samples were non-reactive with the Vitros EIA assay and the APTIMA HIV-1 RNA test,”

5) Results, page 10, first paragraph. It would be useful to add the sites for the 2 specimens identified as discordant that had a reactive 3rd test in-country, and were eventually classified as false-positive. I would guess that the two false-positives came from Tanzania or possibly Thailand as you would expect this to happen with more frequency in a low-prevalence setting, but maybe not. If these did occur in the low-prevalence settings the authors should also make this point in the discussion on page 12. If not, the current sentence stating that the authors can’t differentiate between possible explanations for the incorrect in-country results is probably sufficient.

6) List of abbreviations: unless I missed it OD-n does not appear anywhere in the manuscript but s/co does and should be included here… Also, CMIA is used in
Table 1 but is not defined here or as a footnote to the table…

7) Table 1: The labeling of the Bioline test is inconsistent between Thailand and Tanzania; I think it should be the Bioline HIV-1/2 Rapid Test or simply Bioline HIV-1/2. Also, it would be cleaner to move the HIV 1/2 below Determine for Tanzania to be consistent with the rest of the row…

8) Footnotes to table 1, not sure if the journal requires this, but several of the names listed here have either trademarks ™ or registered trademarks ® that could be added to their names…

9) Table 2: in the title, I believe ‘samples’ should be plural and to avoid using collect twice the second could be “included”

10) Footnotes for Table 2: Again, OD-n is listed but not used…

Discretionary Revisions:

1) Methods: Do the authors have information on self-reported HIV status of participants prior to testing? I presume that they do not have information on the HIV status of those that did not participate, but it is interesting that participation was lowest in Soweto and much higher in Vulindlela, if participation was differential by HIV status this would bias the prevalence estimates? Would the authors be able to discuss this issue?

2) As stated under the minor essential revisions #5, if it proves true that the 2 specimens that tested false-positive based on the in-country algorithm were from Tanzania I would suggest that the authors add a sentence to the discussion paragraph on page 12 pointing out that the true prevalence can play a role in the probability that a third test will be false-positive.

3) Also on page 12, the authors include a sentence that states “In the Project Accept pilot study, participants were provided with information about how to access their test results and were provided with pre and post-test counseling; however, most participants did not seek their results.” I presume that this refers to their in-country testing results, rather than the reference laboratory results, but this should be clarified. If this does refer to the in-country results and most participants did not seek their results, then most did not get post-test counseling and the sentence should be revised so that this is clear. I think leaving receipt of results up to participants is reasonable for the purpose of surveillance (particularly since the authors are simultaneously offering other places to test as part of their intervention), but assuming the other points I have made here are correct, I think I would make one additional change. If the authors move the revised sentence up to the end of the preceding paragraph, where they discuss the acceptability of phlebotomy, they can also discuss the fact that fingerstick testing would allow same-day receipt of results. This can be a very important improvement over current surveillance programs, because, as the authors state, when we draw blood and schedule (actively or passively) participants to come back for results many or most do not return to get their results. Again, this is “ok” when we conduct surveillance, but if we could simultaneously conduct surveillance and provide the prevention benefits of an HIV test result and
post-test counseling I think this would be better model for public health.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests.