Reviewer's report

Title: Evaluation of Simple Rapid HIV Assays and Development of National Rapid HIV Test Algorithms in Dar es Salaam, Tanzania

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Reviewer: John N Nkengasong

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Manuscript Title: Evaluation of simple rapid HIV assays and development of national rapid HIV testing algorithms in Dar es Salaam, Tanzania

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Reviewer: John Nkengasong

Date: October 24, 2008

General comment: HIV rapid testing is a cornerstone for scaling-up care and treatment in limited resource setting. The outcome of this evaluation will be of great interest for guiding on testing strategies in hard to reach communities in Tanzania where HIV testing is needed for enrolment in care and treatment and prevention strategies.

Major Compulsory Revisions

1- It does not appear clearly what gold standard was used to determine the performances of each of the rapid test. The authors confirmed all positive samples by Inno-Lia, however there is not mentioned of confirming the negative samples. Because the panel of samples used for this evaluation is not a panel of well characterized samples, not confirming all the specimens but only 10% non-reactive samples randomly and all positive (by any or all rapid test) may not be sufficient to determine the performance (sensitivities and specificities) of tests evaluated.

The previous testing algorithm could have been used as reference to compare the performances of the rapid tests evaluated against.

2- The author did not clearly explain the testing strategy (serial or parallel) used for both the previous and proposed testing combinations.

3- What's the rationale for using whole blood collected onto tube for this evaluation instead of serum, plasma or DBS. If the main purpose of this study is to evaluate rapid tests that can be used in hard to reach communities and been able to provide same day results, maybe a phase II/III evaluation will be more appropriate using whole blood from finger prick.

Minor essential revisions
1) It does not appear, from the description of the method, if the HIV sero-status of specimens used for this evaluation is known prior the evaluation.

2) Pg 7: suggest replacing the word “indeterminate results” by either “undetermined discrepant, discordant or inconclusive results” and elsewhere in text. Indeterminate usually refers to western blot results. Thus, using it for inconclusive RT results may be confusing.

3) Pg 8, 2nd sentence beginning by “every testing laboratory .....to perform repeat testing” needs some editing for clarity. Maybe should be rephrased.

4) Pg 8, sentence 5 “Data of all assay...... were also obtained” needs some editing for clarity.

5) Pg 8, sentence 4 “All samples that were.... (Immunogenetics). Suggest rephrasing as follows “10% of non-reactive samples randomly selected were tested....”

6) Pg 8: Test performances (sensitivity and specificity) should not be the only inclusion criteria for a national algorithm. Should also consider the PPV for a specific HIV prevalence rate. If whole blood will be obtained from clients/patients using finger prick, we recommend including the availability of sample collection devices as another criteria to be considered.

Results

7) Pg 9: Not clear why the samples collected on the 1st two days were decided as pilot samples. Is the decision based on a certain proportion compared to overall sample size. Need to provide more information.

8) Pg 9: suggest moving up, in 1st paragraph, the following sentences “ A total of 1649 samples.... excluded from the analysis”. to the end of the paragraph beginning by “ A total of 1649 whole blood samples were collected between June and September 2006...” on pg 7 and restructure accordingly for more clarity.

Result paragraph will then begin as follows “ Of a total of 1433 samples that were tested....”

9) Pg 9, 2nd paragraph & sentence 2: Suggest rephrasing as follows “Of the five assays evaluated, HIV-1/2 Stat Pack Dipstick had comparatively lowest sensitivity and specificity on the initial screening.”

10) Pg 9, 2nd paragraph & sentence 6: the authors refer to “... using different types of samples from....”. Not clear if other types of specimens than whole blood were collected for the purpose of this evaluation. Need for clarification.

11) Pg 9, 2nd paragraph & sentence 7: description of each study site should be moved up to the method section on page 6 under collection of blood sample paragraph.

12) Pg 10: The cost of the combinations should be based on more recent test prices.
13) Pg 11: last sentence of results paragraph needs some editing for more clarity.

14) It will be useful to see a table summarizing samples for which a tie breaker was used.

Discussion

15) Pg 11: In the discussion, 2nd paragraph can be moved to the introduction. However, would suggest deleting it.

16) Pg 13 1st paragraph: the last sentence is incomplete. Suggest rephrasing along the line as follows: “However, in the present study, .... of antiretroviral drugs, making it difficult to explain the lowest performance of some of the RTs evaluated.

17) Discussion: It will be useful if the present study findings are discussed and compared against published data if any. (Exple: in pg 15, the last sentence of the discussion paragraph needs some reference).

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

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