Author's response to reviews

Title: Determine TB-LAM lateral flow urine antigen assay for HIV-associated tuberculosis: recommendations on the design and reporting of clinical studies

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Author's response to reviews: see over
28th August 2013

Philippa Harris
Executive Editor,
BMC Infectious Diseases

Re: Commentary Article
Determine TB-LAM lateral flow urine antigen assay for HIV-associated tuberculosis: recommendations on the design and reporting of clinical studies

Dear Philippa,

Many thanks for your e-mail of the 22\textsuperscript{nd} August and for forwarding the reviewers’ comments. I am pleased that the paper was found to be of interest and that you have invited a revised version. I have now revised the manuscript and below I have provided a point-by-point response to each of the comments.

Reviewer: Frank van Leth

The manuscript by Lawn et al. describes the potential role as a point-of-care test of the lateral flow test of LAM in urine in the context of diagnosing tuberculosis. It summarizes current knowledge and critically identifies areas of uncertainty. From these observation the authors identify priority research areas. The manuscript will appeal to the TB research community at large, since diagnosis of TB at the point-of-care in the HIV-positive population is a crucial component of TB-control strategies.

Response: Thank you.

The manuscript does not present new data, except from some “preview findings” presented at conferences.

Response: This is a commentary article and not an original research article.
Minor Essential Revisions

1. Make it more clear that the current findings are almost exclusively from the South Africa in studies performed by the authors or their colleagues.

Response: *This has been acknowledged at the end of the Introduction and under Point 5 of the main text in the revised manuscript.*

2. Page 9: “reproducible cut-off when using grade 2 cut-off. Should this not be “reproducible test result”. If so, then the sentence needs to be slightly Reformulated

Response: *This has been amended.*

3. The reference list is heavy on self citations. To some extent this is understandable given the nice the authors work in. But even in the more broader topic (Xpert and C-reactive protein), there are additional possibilities

Response: *We agree, but the authorship of this article has purposely drawn together the key researchers in this specific area of TB diagnostic research who have conducted much of the work. Two additional references on CRP and Xpert have been included.*

Reviewer: Patrick Moonan

Minor Essential Revisions:

The authors should consider including a section discussing the implications of reporting results for surveillance purposes. In a similar way, the widescale implementation of Xpert and it's subsequent results have challenged the public health surveillance system with regards to reporting these data. Based upon the Xpert experience, the author’s should also consider operational research that describes this reporting process and how these data inform the initiation of treatment.

Response: *We agree that implementation should accompanied by appropriate reporting and surveillance systems. This has been included.*

Yours sincerely,
Dr. Stephen D. Lawn BMedSci MB BS FRCP MD DTM&H Dip HIV Med