Evaluating the incremental value of using the TB LAM test in Intensified Case Finding for TB in People Living with HIV in Swaziland

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The Swaziland HIV and TB Programmes have a joint goal of improving tuberculosis (TB) case detection in People Living with HIV (PLHIV). Urine TB lipoarabinomannan (LAM) test, which detects the LAM antigen, has potential of rapidly detecting TB and/or add value to the TB screening process. This point-of-care test has a potential of scaling up intensified case finding (ICF) including extra-pulmonary TB cases in PLHIV. We conducted a study to evaluate the value of adding urine TB LAM test to the national TB screening algorithm. The diagnostic accuracy of TB LAM was compared to that of Xpert MTB/RIF relative to TB culture stratified by the CD4 cell count.

## Background

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## Methods

- PLHIV aged ≥18, not on TB treatment, screening positive for TB regardless of ART status were consecutively recruited at three hospitals from April to September 2015.
- Sputum (including induction if not spontaneously produced), urine and blood samples were collected for Xpert MTB/RIF and culture, Alere determine LAM, and FACS Calibur CD4 count respectively (Figure 1).
- All the samples were processed and tested at the national reference laboratory.
- Demographic, clinical and laboratory data were entered into Epi data 3.1 software and exported to STATA 12.1 where all data cleaning and analysis were conducted.
- Sensitivity, specificity, positive (PPV) and negative (NPV) predictive values of TB LAM and Xpert MTB/RIF were stratified by CD4 cell count.
- Logistic regression was conducted to identify significant determinants of true positive TB LAM (in terms of age, sex, ART status and CD4 cell count category).

## Results

- A total of 417 participants where enrolled with characteristics shown in Figure 2. The results of each step of the study are shown in Figure 3.
- Three hundred and sixty-seven (88%) had conclusive sputum culture results.

## Conclusions

- Use of TB LAM is feasible and may aid TB diagnosis but the benefit is largely confined to those with a CD4 cell count of <100 regardless of ART status.
- The added value of TB LAM in patients unable to produce sputum spontaneously was limited although a more targeted sample for patients with CD4 cell count <100 may yield more informative and precise results. The small sample size for CD4 cell count<100 limited the precision of the results.
- The low sensitivity of Xpert MTB/RIF among those who had CD4 count ≥100 reiterate the need to perform culture testing on negative Xpert MTB results if the ultimate control of TB in the country is to be realized.