Diagnosing tuberculosis in a high HIV prevalence setting

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Background
Diagnosis of tuberculosis (TB) remains a challenge in resource-limited countries. XpertMTB/RIF assay (Xpert) and Determine urine TB-LAM test (LAM), are currently available. We evaluated the incremental diagnostic yield of including Xpert and/or LAM test into the clinical-radiological algorithm to diagnose pulmonary TB (PTB) in a HIV prevalent setting.

Methods
Prospective observational study conducted in Homa Bay District Hospital, Kenya. The algorithm with Xpert was evaluated in smear-negative ambulatory patients with symptoms of PTB who received clinical exam, Xpert and chest X-ray. The algorithm with LAM test was evaluated in HIV-positive patients whether hospitalized, with CD4<200cell/µl, BMI<17Kg/m2 or severely ill. LAM test done prior to Xpert. The primary end point was TB treatment initiation and the reference standard was MTB culture (confirmed TB).

Results
In total, 487 smear-negative and 474 HIV-positive patients were included in the evaluation of the Xpert and LAM+Xpert algorithms respectively. Median age was 37 and 35 years, 59.3% and 51.5% were women. Among 487 smear-negative, 67.1% (320/477) were HIV-positive. Xpert was positive in 11.8% (57/485), culture in 14.7% (69/467). Using the Xpert algorithm, 87.0% (95%CI:76.7-93.9) of confirmed TB patients were started on treatment, as compared to 55.0% (95%CI:41.6-67.9) with the clinical-radiological algorithm alone.

The proportion of culture-negative patients started on TB treatment did not change by adding Xpert (69.4% vs 71.3%,p=0.792).
Among 474 HIV-positive, LAM test was positive in 39.0% (185/474), Xpert in 31.5% (115/365), culture in 32.9% (105/319). Using the LAM algorithm, 80.0% (95%CI:71.1-87.2) of confirmed TB patients were started on treatment as compared to 55.2% (95%CI:45.2-65.0) with the clinical-radiological algorithm alone. Adding Xpert to LAM increased the proportion of confirmed TB cases started on treatment to 92%.

Conclusions
Including Xpert and LAM as initial tests was very useful to start adequately on TB treatment a large majority of patients with confirmed TB smear-negative and HIV-positive patients respectively. Urine LAM test was able to achieve high proportion of advanced HIV infected with confirmed TB started on treatment on the day of admission.

Xpert allows appropriate TB treatment in 90% of smear-negative patients. Urine LAM is useful in HIV-positive patients whether hospitalized, severely ill, with BMI<17 or CD4<200.