

Low cost, 25 min TB-test could help reduce tuberculosis death rate among patients with HIV in sub-Saharan Africa

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A low cost, easy to use, urine test to diagnose tuberculosis (TB) among patients with HIV could help reduce the TB death rate of HIV-positive patients in hospital, according to a new study published in *The Lancet* today.

In Africa, nearly 40% of all adult deaths related to HIV or AIDS are due to [tuberculosis](#), but almost half of the TB cases remain undiagnosed and untreated before death. The authors of the study, which was conducted in 10 hospitals in sub-Saharan Africa, say that if implemented more widely, this low-cost intervention could save thousands of lives per year.

"This is the first trial of any diagnostic test for tuberculosis to show a reduction in the number of deaths. The reduction in mortality is likely to be because urine-testing, in conjunction with routine testing, resulted in a greater proportion of [patients](#) starting tuberculosis treatment early," explains senior author and project supervisor Professor Keertan Dheda from the University of Cape Town in South Africa.

He adds: "When used in conjunction with routine testing, urine-testing for tuberculosis reduced the TB death rate of HIV patients in hospital. Importantly, we found that the test was particularly effective in identifying tuberculosis among patients with advanced HIV infection who are most vulnerable to advanced TB disease. The absolute reduction in mortality was small at 4%, but with 300000 patients with HIV dying

from tuberculosis in Africa every year, implementing this low cost, rapid, bedside test could potentially save thousands of lives annually."

Tuberculosis is the leading cause of death in people with HIV in low and middle income countries and hospitals are often overwhelmed with HIV-positive individuals who have suspected TB. Diagnosis of TB usually includes taking a chest X-ray and microbiological examination of sputum (mucus that has been coughed-up). However, for severely ill patients with TB and HIV, it can be hard to produce sputum and alternative approaches (sputum induction or alternative invasive sampling) are often unavailable. The LAM [urine-test](#) detects a glycolipid molecule (lipoarabinomannan), which is linked to TB. It provides a result in 25 minutes and each test costs about US\$2.66.

Professor Keertan Dheda says: "Since November 2015, a test measuring urine LAM has been recommended by WHO. However, the recommendation was conditional, meaning it is up to the doctor or health system to decide whether or not to use the test. These data make use of the test more compelling and suggest that scale up and roll out of the test is now required."

In this study, the research team randomly allocated 2528 patients with HIV from ten hospitals in four countries in sub-Saharan Africa (four in South Africa, two in Tanzania, two in Zambia, and two in Zimbabwe) to receive either routine testing (smear, Xpert MTP/RIF and culture) as well as the LAM urine-test (LAM group, 1257 patients) or routine testing alone (no-LAM group, 1271 patients).

Eight weeks after being discharged from [hospital](#), 21% (261) of patients in the LAM group had died compared to 25% (317) of patients in the non-LAM group - an absolute reduction of 4%. A greater proportion of patients in the LAM group (648; 52%) were treated for TB than in the no-LAM group (598; 47%). And, of those who started TB treatment, a

higher proportion of patients were treated in the first 3 days in the LAM group (513/648; 79%) compared to the non-LAM group (413/598; 69%).

The effect of LAM testing on mortality varied by country but the highest sensitivity was found in people with the lowest CD4 cell count (a measure of how badly the immune system is damaged in patients with HIV) who are the hardest to diagnose with TB using routine testing. The authors found that the LAM urine-test had a sensitivity of 46% (the proportion of people with TB correctly diagnosed) and specificity of 90% (the proportion of healthy people who are correctly identified as healthy).

However, as Dr Andrew Kerkhoff, University of California San Francisco School of Medicine, San Francisco, USA, writes in a linked Comment: "Peter and colleagues report on the diagnostic accuracy of urine LAM testing even though the study was not primarily designed a priori to rigorously assess this. If their finding that urine LAM specificity was less than 90% is taken at face value, these data would raise serious concerns about the potential of the assay to generate large numbers of false-positive diagnoses... The reference standard for tuberculosis diagnosis against which the diagnostic accuracy of the LAM-test was assessed was often only one sputum culture or Xpert test, both of which represent insufficiently robust reference standards. In a similar inpatient study population in Cape Town, South Africa, our results showed that the specificity of the same urine-LAM lateral flow assay exceeded 99% when compared with a rigorous microbiological reference standard that incorporated sampling of sputum, blood, and urine, for which we did a mean of 5.6 reference standard tests per patient."

He concludes: "In summary, Peters and colleagues report findings from their landmark trial that provide key evidence showing that urine-LAM

testing is an effective means of rapid, low-cost, ante-mortem diagnosis for the large burden of HIV-associated tuberculosis. This burden for the past 25 years has only been brought to light by a long series of post-mortem studies. With the recent backing of WHO recommendations, we strongly advocate that the Determine TB-LAM point-of-care assay should be implemented by national tuberculosis programmes in sub-Saharan Africa to reduce AIDS-related inpatient deaths."

More information: *The Lancet*, [www.thelancet.com/journals/lan ...](http://www.thelancet.com/journals/lan...)
 [\(15\)01092-2/abstract](http://www.thelancet.com/journals/lan...)

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