









14 April 2021

A blood test to find those at high risk of tuberculosis in people living with HIV

A new study has reported findings of a host blood test that can find those at high risk of tuberculosis (TB) in people living with HIV. The blood mRNA biomarker differentiated between people living with HIV who had active TB from those without TB and predicted which individuals would develop TB within 15 months.

Researchers from the <u>South African Tuberculosis Vaccine Initiative (SATVI)</u> at the <u>University of Cape Town (UCT)</u>, the <u>Aurum Institute</u>, the <u>Centre for the AIDS Programme of Research in South Africa (CAPRISA)</u>, <u>Stellenbosch University</u>, the <u>London School of Hygiene and Tropical Medicine and the Fred Hutchinson Cancer Research Center</u> have published the results from a study of a blood-based RNA biomarker which tested diagnostic and prognostic performance for TB in people living with HIV in <u>The Lancet Global Health</u> journal.

Almost a quarter of the world's population is estimated to be infected with the bacterium (*M. tuberculosis*) responsible for TB disease. Importantly, only 5-10% of people with the infection are at risk of progression to TB disease and would benefit from antibiotic treatment. Existing tests for *M. tuberculosis* infection (the tuberculin skin test or interferon gamma release assay would result in considerable over-treatment with preventive therapy.

Traditional TB symptom screening would miss the majority of undiagnosed TB in people living with HIV in community settings, as the majority of early TB is asymptomatic. The repercussions of a missed TB diagnosis in people living with HIV are potentially catastrophic: severe illness, hospitalisation, long-term lung damage, and death. A delayed diagnosis could also potentially allow onward transmission of TB to family members and close contacts.

UCT's Professor Mark Hatherill, principal investigator of the study said: "These results bring us one step closer to a TB blood test for use at point of care to guide curative and preventive TB therapy for people living with HIV".

"The ability to identify people living with HIV that are at high risk of developing active TB disease that may benefit from TB preventive treatment is a major scientific advance," added Professor Gavin Churchyard, Group CEO, the Aurum Institute.

This publication advances the development of a point-of care blood test with which health practitioners could accurately identify people at risk of TB disease, who would then require confirmatory diagnostic testing and treatment, or others who are likely to progress from *M. tuberculosis* infection to active TB disease and make it possible to apply available TB preventive antibiotic regimens selectively to those who are most likely to benefit in communities.

The research team set out to test the diagnostic and prognostic performance of a blood-based RNA biomarker of TB risk (RISK11) in people living with HIV. The study was

conducted between 2017 and 2019 across five distinct geographic communities across South Africa.

"These promising results are similar to those seen in a trial of the RISK11 biomarker in HIV-uninfected persons. They highlight the importance of finding people with undiagnosed, subclinical TB," shared Professor Tom Scriba, laboratory director of SATVI, where the test was developed.

While Professor Kogie Naidoo, study co-investigator at the CAPRISA site, said: "TB remains the leading cause of death among people living with HIV/AIDS. These results bring hope for more efficient diagnosis of current active TB, and for detection of those at heightened risk of progression to active TB disease, thereby enabling effective patient triage to TB treatment or prevention."

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Read the full study.

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