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A single swab is sufficient: Study paves the way for simplified tuberculosis diagnosis

Led by researchers from Heidelberg Faculty of Medicine at Heidelberg University and the University of California, San Francisco (USA), an international research team has evaluated a novel approach for the diagnosis of pulmonary tuberculosis. The method enables detection of Mycobacterium tuberculosis without laboratory infrastructure, within a markedly shorter time frame than conventional diagnostics, and using a simple swab. The test was evaluated in patients across seven countries with a high tuberculosis burden and demonstrated high diagnostic accuracy as well as feasibility for use by minimally trained personnel. The results, published in the New England Journal of Medicine, made a significant contribution to the World Health Organization's decision to already recommend the global use of the diagnostic method.

Using the new method, tuberculosis bacteria can be detected directly at the site of sample collection via a tongue or sputum swab, with results available in under 35 minutes. Diagnostics rely on two portable devices: one device lyses bacterial cells in the swab sample to release genetic material, while the second device performs molecular detection and indicates the result through visual signal lights as either positive (presence of bacterial DNA) or negative (absence of bacterial DNA).

The diagnostic accuracy of the test and the usability of each procedural step in the hands of non-specialist users were evaluated by Professor Claudia Denkinger, Chair of Infectious and Tropical Medicine at Heidelberg Faculty of Medicine at Heidelberg University and Medical Director of the Department of Infectious and Tropical Medicine at Heidelberg University Hospital, together with Dr. Seda Yerlikaya, group leader in Infectious and Tropical Medicine, and international collaborators.

Study design and key findings

The multicentre study enrolled 1,380 individuals with suspected pulmonary tuberculosis at outpatient facilities in India, Nigeria, South Africa, Uganda, Vietnam, Zambia, and the Philippines. Participants provided both respiratory specimens (sputum) and tongue swab samples. Diagnostic performance was assessed for each specimen type by determining sensitivity (the proportion of correctly identified tuberculosis cases) and specificity (the proportion of correctly identified non cases).

Tuberculosis detection based on tongue swabs correctly identified approximately four out of five individuals with confirmed disease (sensitivity 80%) and resulted in false positive findings in only 0.5% of participants (specificity 99.5%). Comparable diagnostic accuracy was observed when the new method was applied to sputum samples. Overall, the performance of the test was similar to that of established laboratory based molecular diagnostics currently considered the gold standard for tuberculosis detection. In an additional comparative analysis, the researchers showed that the diagnostic yield of the new test using tongue swabs – i.e., the number of patients identified with tuberculosis – was comparable to that of existing sputum-based tuberculosis diagnostics.

"Our study demonstrates that this test meets the World Health Organization's target product profile criteria for near point of care tuberculosis diagnostics," says first author Dr. Yerlikaya. "These findings provide robust evidence to support consideration of the test for use in adolescents and adults presenting with symptoms suggestive of tuberculosis." The study also confirmed high usability of the test under simulated routine use conditions, with most procedural steps performed correctly by test naïve users following only the manufacturer's instructions for use.

According to Professor Denkinger, reliance on tongue swabs substantially simplifies sample collection and broadens access to tuberculosis testing. Not all individuals with suspected tuberculosis are able to produce sputum – particularly children, severely ill patients, and people living with HIV, who are at increased risk of tuberculosis and often present with paucibacillary disease. Additional advantages of the new diagnostic system include its compact size, battery powered operation, rapid turnaround time, and ease of use with minimal training. Battery operability is particularly critical in settings where access to reliable electricity is limited. Moreover, the costs of the point of care test are considerably lower than those of conventional molecular tuberculosis assays.

Development, policy relevance, and next steps

Professor Denkinger and her team contributed to the development of the diagnostic method, providing technical expertise and conducting accompanying evaluation studies. The project received financial support from the U.S. National Institutes of Health (National Institute of Allergy and Infectious Diseases), the Gates Foundation, the U.S. Department of State (formerly USAID), and the European Union through the European and Developing Countries Clinical Trials Partnership (EDCTP).

Based on the accumulating evidence, the World Health Organization recommended the test as the first near point of care molecular diagnostic for tuberculosis. Preparations for pilot implementation in countries with high tuberculosis burden are underway, supported by international funding partners including the Global Fund to Fight AIDS, Tuberculosis and Malaria and the Children's Investment Fund Foundation. "For successful implementation, procurement alone is not sufficient," explains Professor Denkinger. "Implementation requires defining target populations and testing sites, training users, engaging stakeholders, and adapting deployment strategies to country specific contexts." Building trust in the new testing approach among healthcare workers and patients alike will be essential to its impact.

Background: tuberculosis and diagnostic challenges

Tuberculosis remains one of the leading causes of death from infectious disease worldwide, accounting for more than one million deaths each year and over ten million new cases annually (2024). The disease primarily affects the lungs but can involve other organs. Although effective antibiotic treatment is available, timely diagnosis remains a major challenge. Existing diagnostic methods are often costly, technically demanding, or insufficiently accessible in high burden, resource limited settings. Diagnostics are frequently not available at the point of care, leading to delayed results, postponed treatment initiation, and loss of patients to follow up. "Against this background," Professor Denkinger concludes, "tongue swab-based tuberculosis detection represents a significant step forward in making high quality diagnostics accessible where they are most urgently needed."

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