United States of America

SMART4TB Consortium

ADAPT for Kids Study

Assessing Diagnostics At Point-of-care for Tuberculosis in Kids

BACKGROUND

The U.S. government invests in and promotes American health innovation globally, with TB pediatric research a vital component of these efforts. Tuberculosis is one of the top 10 causes of death among children under five, leading to nearly 174,000 deaths in 2024 according to the Global TB Report 2025. Once started on treatment, children generally have excellent outcomes, but diagnosing them can be especially difficult. Current tests for TB are sputum-based, which is hard to collect in children and the tests don't work well because they tend to have lower amounts of TB bacteria in their sputum. A simple, inexpensive, easy to use test that doesn't involve collecting sputum would be a game changer for pediatric TB and help young people go on to lead healthy, productive lives.

STUDY GOAL

To rigorously assess promising, point-of-care TB diagnostic tests in children in high TB burden settings to inform global guidelines and national policymaking.

STUDY LEADERS

Devan Jaganath at the University of California, San Francisco, **Nilesh Bhatt** at the Elizabeth Glaser Pediatric AIDS Foundation in partnership with Johns Hopkins University, **Eric Wobudeya** at MU-JHU in Uganda and **Celso Khosa** at at Instituto Nacional de Saúde in Mozambique.

STUDY POPULATION

Children under 15 years who have signs and symptoms of pulmonary TB.

STUDY LOCATIONS

Mozambique
Uganda

STUDY DESIGN

ClinicalTrials.gov NCT05989802

ADAPT for Kids is a study platform study enrolling 400-500 children annually that will evaluate the accuracy of various novel TB tests for kids on a rolling basis. ADAPT for Kids will also assess health workers at each clinical site's perceptions of the usability of each test. The study will support SMILE-TB in Mozambique and Uganda, potentially helping identify participants for that trial.

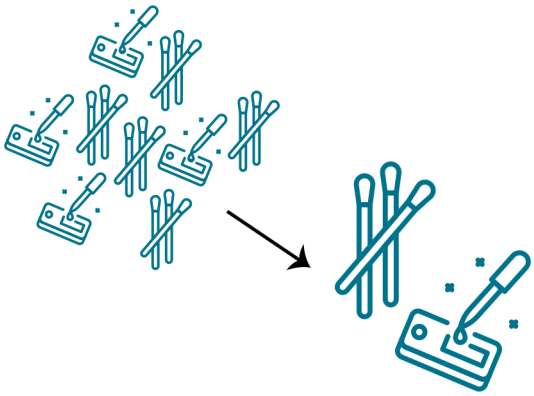
The types of tests to be evaluated include tongue swab molecular tests, urine lipoarabinomannan (LAM) tests, and artificial intelligence algorithms to predict TB from chest X-ray. Each of these tests are expected to be easier on kids, their caregivers, and health workers. Primary outcomes are sensitivity and specificity as compared to a microbiological reference standard.

ADAPT for Kids initially focused on detecting TB using molecular tongue swabs. These are polymerase chain reaction (PCR) tests, already globally endorsed and in use in many countries for detecting TB (and some forms of drug resistance) via sputum. This has the potential to provide a non-invasive approach to testing TB in children. As novel diagnostics come through the development pathway, and are design-locked and ready for evaluation, ADAPT for Kids will add them into its standardized protocol for evaluation.

Microbiological Reference Standard is defined by a positive culture or a molecular test for TB on sputum samples.

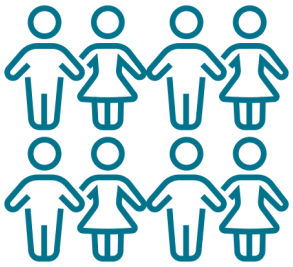
Polymerase Chain Reaction tests is a type of test that copies DNA to look for diseases, in this case to identify TB bacteria.

HOW ADAPT FOR KIDS WORKS



Selecting promising novel diagnostic tests for evaluation

Evaluating most promising diagnostic tests for accuracy in children



Evaluating diagnostic tests for ease of use in healthcare setting

If you have any questions, please contact smart4tbcomms@jh.edu

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