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Supporting, Mobilizing, and Accelerating Research for Tuberculosis Elimination

SMART4TB Consortium

ADAPT for Kids Study

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

BACKGROUND

Tuberculosis is one of the top 10 causes of death among children under five, leading to nearly 150,000 deaths annually. 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.

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

ADAPT For Kids is led by **Nilesh Bhatt** at the Elizabeth Glaser Pediatric AIDS Foundation, **Devan Jaganath** at the University of California, San Francisco, and **Adithya Cattamanchi** at the University of California, Irvine in partnership with Johns Hopkins University, KNCV Tuberculosis Foundation, Treatment Action Group, and local community and research partners.

STUDY POPULATION

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

STUDY LOCATIONS

Mozambique and Uganda

STUDY DESIGN (ClinicalTrials.gov NCT05989802)

ADAPT for Kids is a platform study, enrolling 400-500 children annually, that will evaluate the accuracy of various novel TB tests for kids on a rolling basis, as SMART4TB and partners identify new tests ready for field evaluation. ADAPT for Kids will also assess health workers at each clinical site's perceptions of the usability of each test.

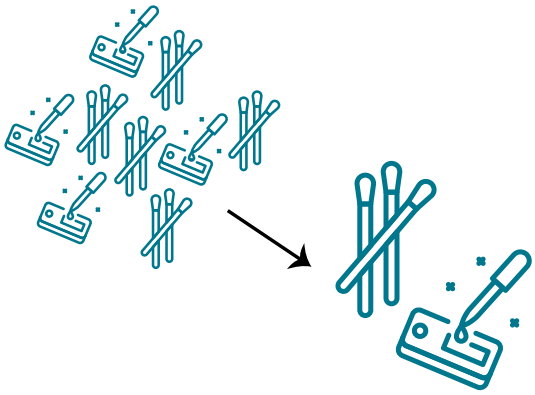
The types of tests to be evaluated include tongue swab molecular tests, and artificial intelligence algorithms to predict TB from chest X-ray. Each of these tests are expected to be easier on kids, their caregivers, and health workers. Primary outcomes are sensitivity and specificity as compared to a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

ADAPT for Kids is currently evaluating Xpert MTB/RIF Ultra (Cepheid, USA) and Truenat MTB Ultima (Molbio Diagnostics, India) on tongue swab samples. Both 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 for TB on sputum samples.

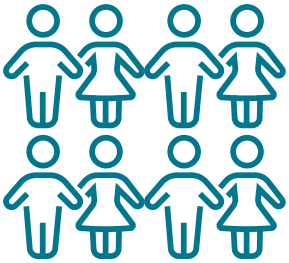
Polymerase Chain Reaction tests is a type of test that copies DNA to look for diseases, in this case to identify TB bacteria.

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

ABOUT SMART4TB

The SMART4TB Consortium brings together experts in TB tools development, implementation science, capacity strengthening, civil society engagement and policy translation. Led by Johns Hopkins University, consortium members include the University of California, San Francisco; the Elizabeth Glaser Pediatric AIDS Foundation; KNCV Tuberculosis Foundation; Treatment Action Group; and local community and research partners.

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If you have any questions, please contact us at: smart4tbinfo@jh.edu