USE OF TREATMENT DECISION ALGORITHMS FOR TB DIAGNOSIS IN CHILDREN

THE DECIDE TB PROJECT

DecideTB

decide-tb.com

TUBERCULOSIS IN CHILDREN

Tuberculosis (TB) is an infectious disease affecting mostly the lungs. It is transmitted through airborne droplets expectorated when a person with TB coughs. TB symptoms include persistent cough, fever, and weight loss. TB is treatable with antibiotics taken for 4-6 months.



WHO GLOBAL ESTIMATES IN 2024

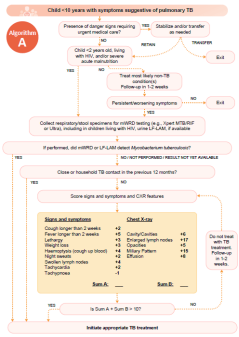
- **1.25 million** TB in children
- **613 000** children with TB notified to WHO
- **214 000** TB deaths in children
- **95%** of children who died were not diagnosed[1]

CHILDHOOD TB DIAGNOSTIC CHALLENGES

- Low yield of microbiological tests (paucibacillary disease) and challenging microbiological sample collection (difficulty to self-expectorate) requiring alternative methods
- Clinical diagnosis challenged by poorly specific symptoms and limited access to good quality radiography and interpretation
- Poor access to childhood TB diagnosis services at low levels of health care

WHAT ARE TREATMENT DECISION ALGORITHMS (TDAs)?

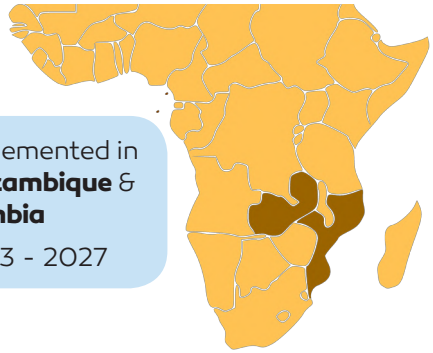
- TDAs can contribute to rapid and uniform diagnosis and treatment-decision making
- TDAs attribute points to clinical data, radiographic data, and results from bacteriological tests
- TDAs compute scores informing on whether a child needs to start TB treatment or not after a certain threshold



WHO TDA A

DECIDE TB PROJECT AIMS

- Implement and generate scientific evidence on a comprehensive Treatment Decision Algorithm (TDA)-based approach for screening, diagnosis and management of TB in children
- Facilitate integration of this evidence within practices and policies



Implemented in **Mozambique** & **Zambia**
2023 - 2027

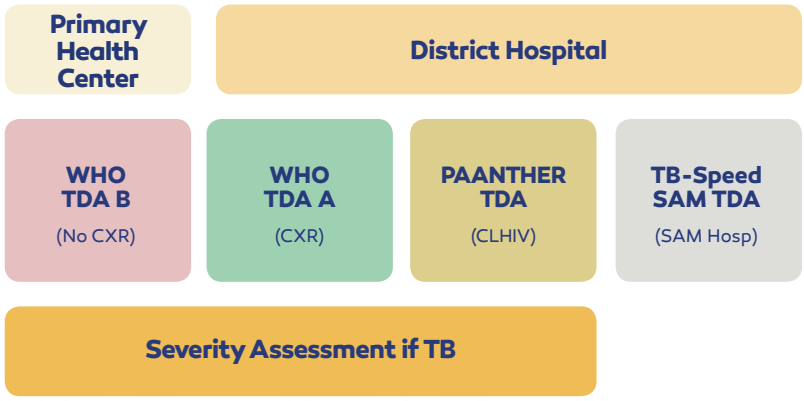
DECIDE TB COMPONENTS

1. A programmatic pilot implemented with a pragmatic cluster randomized trial with a stepped-wedge design
2. An Individual-patient data (IPD) meta-analysis

DECIDE TB COMPREHENSIVE TDA-BASED APPROACH

The Decide TB comprehensive TDA-based approach adopted by Mozambican and Zambian NTPs for project implementation and evaluation includes:

- The World Health Organization (WHO)-suggested TDAs A & B for use in settings with (WHO-TDA A) and without (WHO-TDA B) Chest X-Ray (CXR). Both have been adapted and adopted for use at country level in Mozambique and Zambia
- TDAs developed for vulnerable children: PAANTHER TDA for children living with HIV [CLHIV] and TB-Speed SAM TDA for children with severe acute malnutrition [SAM])
- WHO-suggested TB severity assessment for shorter (4 months) TB treatment regimen in children with non-severe TB



DECIDE TB TRIAL

Design & Methods

- Programmatic pilot of TDAs by National TB Programs in Mozambique & Zambia
- Pragmatic cluster randomized trial with a stepped-wedge design (NCT06593080)[2]
- Interdisciplinary research (clinical, epidemiology, socio-behavioural, modelling, health economy, policy)

Clusters

- 5 districts/country (4 districts in SW-CRT, 1 observational district per country)
- 1 District Hospital (DH) + 6 Primary Health Centers (PHC) in each district

Participants

- All children < 15 years attending care (screening) and all those with presumptive TB
- Parents/caregivers, health care workers, implementers & decision-makers


TDAs Mentorship, Zambia


Scientific workshop, Consortium, France


TDAs Training Southern Zambia


Supervision, Mozambique

DECIDE TB INDIVIDUAL

Design & Methods

- Individual Patient Data meta-analysis using data from previous childhood TB studies (Rapaed, TB Speed HIV and Decentralization, Umoya)
- Assessment of the performance of WHO TDAs (sensitivity, specificity) for TB diagnosis in all children and in vulnerable groups
- Assessment of the performance of WHO-suggested severity assessment for classifying radiological disease severity for shorter TB regimen selection

Participants

- Children with presumptive TB from the former TB pediatric studies (Rapaed, TB-Speed HIV and Decentralization, Umoya)

KEY RESEARCH COMPONENTS AND FINDINGS

EFFECTIVENESS OF TDAS

We assessed whether implementing the comprehensive TDAs based approach in routine healthcare settings could improve the detection, diagnosis and treatment of childhood tuberculosis. Using a pragmatic stepped-wedge trial, we compared standard-of-care practices with the comprehensive TDA-based approach to determine its impact on TB case detection and patient management under real-world conditions.

Main results

Implementing a comprehensive TDA-based intervention was associated with a significant twofold increase in childhood TB treatment initiation overall in both countries. In Mozambique, the increase was about 2.2; in Zambia it was about 1.6.

Introducing TDAs at PHC level, was associated with a 2.5-fold increase in the number of children treated for tuberculosis among those attending care. There was no effect of the intervention shown at DH level.

The proportion of children among all TB cases nearly doubled from 6.4 to 11.9%.

COST & COST-EFFECTIVENESS OF TDAS

Beyond their clinical benefits, the adoption of TDAs by NTP will be conditional to how cost-effective they are. We assessed the costs and the cost-effectiveness of implementing the TDA-based approach from the perspective of the healthcare provider, compared to the standard-of-care phase in Mozambique and Zambia.

Main results

Major cost contributors to the TDA-based intervention were drugs, personnel, medical supplies, laboratory and radiology equipment. Per child screened, assessed and treated for tuberculosis, about 75-90% of total costs were externally funded. Compared to the standard-of-care, incremental cost per child treated for TB using the TDA-based approach was US$520 in district hospitals and $460 in primary healthcare centers in Mozambique, and about $230 across healthcare levels in Zambia. Relatively low cost per extra child starting tuberculosis treatment suggests that TDA are cost-effective, however the diagnostic accuracy is unknown. Financial planning for TDA scale-up in these countries should account for externally funded inputs.



Meetings at Primary Health Centers



Radio talks

Community Mobilization Activities



School outreach activities

ACCEPTABILITY AND FEASIBILITY FINDINGS

TDAs will be successfully integrated into routine childhood TB care if they are both acceptable for healthcare workers, and feasible within existing health services. We explored healthcare workers' experiences of using the TDA-based approach, as well as the perspectives of children and caregivers, while identifying factors that may facilitate or hinder its use in routine practice.

Main results

The perceived feasibility and acceptability of childhood diagnosis practices at decentralized levels in Zambia and Mozambique were high both during standard of care and at intervention periods, and did not decrease when using TDAs. Among healthcare workers using TDAs, acceptability was driven by increased awareness of childhood TB as well as faster and more confident clinical decisions, thanks to the scoring system. Barriers to TDA use over time are the turn-over of trained staff, lack of continuous training opportunities and TB drug shortages.

TDA IMPLEMENTATION AND DIGITAL TOOLS

Translating TDAs into routine practice requires more than introducing new clinical algorithms: healthcare workers also need appropriate training, supervision, tools and health-system support. We investigated how the TDA-based approach was implemented in health facilities, the perspectives and experiences from Health Care Workers and Key implementers, the barriers and facilitators influencing its delivery, and the usability of digital tools — including the Clinical Decision Support System (CDSS) and DHIS2 — designed to support clinical decision-making and patient data management.

Main results

In Mozambique and Zambia, 5 and 22 district-level managers and 99 and 145 HCWs, respectively were trained on TDAs. Cascade training and orientation of other facility healthcare workers was supported by job aids, EMR and CDSS user-guides, and tablet-based training curricula. Electronical Medical Record (EMR) training based on bedside practicum was appreciated. CDSS and the EMR usability were above average; navigation challenges and sub-optimal clinical knowledge were the main barriers to proper use of the tools.

DIAGNOSTIC ACCURACY OF TDAs – INDIVIDUAL PATIENT DATABASE (IPD) META-ANALYSIS FINDINGS

Using individual patient data (IPD) from former TB pediatric studies (Rapaed-TB, TB Speed, Umoya), we assessed how accurately WHO TDAs identify childhood TB and examined their diagnostic performance across different populations and clinical settings. These findings help inform the selection and use of TDAs for childhood TB diagnosis.

Main results

In a pooled IPD of 1,886 children from four cohorts, both WHO TDAs showed high sensitivity - 84.3% for TDA A (with Chest X-Ray) and 90.6% for TDA B (without Chest X-Ray) – but sub-optimal specificity (50.6% and 30.8%, respectively). This is consistent with the original discovery meta-analyses and confirms robust performance in similar study settings, including in high-risk groups such as children living with HIV and those with severe acute malnutrition. These accuracy estimates might differ in Primary Health Centers settings, which is something Decide TB will answer through the prospective trial.

CONCLUSION

The Decide TB trial and IPD results contribute to evidence required by the WHO for external validation of TDAs. There results suggest that TDAs could be an effective, acceptable and feasible, and cost-effective strategy to address the childhood TB diagnosis gap.

The Decide TB project also provides TDA implementation tools that can be used by NTPs, such as training kits, supervision and mentoring checklists, and a CDSS and/or EMR to support HCWs in using TDAs.

Overall, the Decide TB evidence shows that, by contributing to increased case detection, TDAs would contribute to reducing the risk of children with TB not being diagnosed and treated, thus to reducing the risk of mortality associated with TB in this population.

References

[1] *Dodd PJ, Yuen CM, Sismanidis C, Seddon JA, Jenkins HE. The global burden of tuberculosis mortality in children: a mathematical modelling study. The Lancet Global Health. 2017;5(9):e898-e906*

[2] *Orne-Gliemann J, Roucher C, Khosa C, et al. Validation of treatment decision algorithms for childhood tuberculosis at district healthcare levels in Mozambique and Zambia: the Decide TB cluster-randomised pragmatic trial - a study protocol. BMJ Open 2026; 16(5): e114005*

KEY DATES

April 1st — Sept 30



----Preparation ----

Protocols
Data systems
Processes and Standard operating procedures
Pre-intervention

---------- Implementation ----------

Implementation of TDAs at low level of Health Care
Stepped wedge trial
Implementation, socio-behaviour & policy research
Cost collection

--- Translating results into policy ---

Analysis including cost-effectiveness analysis
Results dissemination
Meetings with WHO
Paediatric working group
National policies updated

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