

Implementation of WHO-endorsed technologies for TB diagnosis in Africa: opportunities, strengths and challenges

Submission date 10/08/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/08/2022	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/01/2025	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

TB is caused by Mycobacterium tuberculosis which affects the lungs. In 2020, out of 10 million people who fell ill, a total of 1.5 million died. TB incidence is falling at about 2% per year and between 2015 and 2020 and the cumulative reduction was 11%, over halfway to the 20% milestone. TB control in the Africa Region has evolved since the disease was declared a global emergency by WHO in 1993. The launch of the Stop TB Strategy, the End TB Strategy and the UN political declaration to meet the MDG and SDG followed respectively. In parallel, several ministerial mandates and recommendations have been made with regard to strengthening laboratory services in the African region. Besides all, the benchmark set in the MDG (Stop TB Strategy) and the targets set in the SDG (End TB Strategy) was not achieved in Africa. Many countries are still relying on smear microscopy to diagnose TB, with little progress in strengthening the access to rapid diagnostics as initial tests and universal Drug Susceptibility Testing (DST) to early detect TB and drug-resistant TB including the quality of laboratory services. The study will look at the implementation status of the WHO-endorsed rapid diagnostic technologies for TB in Sub-Saharan Africa, identify predisposing, enabling and need factors associated with the uptake at the country level and suggest solutions and easy-to-approach practices to mitigate the delay in rolling out and scaling up a technology after WHO endorsement.

Who can participate?

Adults aged 18 years and above who occupy the position of managers of the National TB Programme, National TB Reference Laboratories and Partners in 47 African countries.

What does the study involve?

Predisposing, enabling and need factors influencing rapid uptake of WHO-endorsed TB diagnostic technologies will be collected through a survey questionnaire sent to the Heads of the National Tuberculosis Programme, National TB Reference Laboratory Managers and partners. Participants will be required to consent and respond to different questions.

What are the possible benefits and risks of participating?

None

Where is the study run from?

Makerere University (Uganda)

When is the study starting and how long is it expected to run for?

July 2022 to June 2026

Who is funding the study?

Makerere University (Uganda)

Who is the main contact?

Jean de Dieu Iragena, iragena.jddi@gmail.com

Contact information

Type(s)

Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Roll-out and scale-up of WHO-endorsed technologies for TB diagnosis in Africa: opportunities, strengths and challenges

Acronym

RSWTBD

Study objectives

Research questions

1. How are WHO-endorsed TB diagnostic policies adopted, accepted, and translated into practice at the country level?
2. What are the strengths, challenges and opportunities for rapid uptake of WHO-recommended diagnostics?
3. What are the predisposing, enabling and need factors influencing the uptake?
4. What can be the easy-to-implement tool to assist countries in optimising the existing TB diagnostic services and technologies to strengthen laboratory system

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/07/2022, Makerere University, College of Health Sciences, School of Biomedical Sciences Research Ethics Committee (SBSREC, P.O. Box 7072 Kampala, Uganda; +256 779340363; uncstresearch@uncst.go.ug), ref: 1.0, 2022-07-19

Study design

Observational study (cross-sectional study)

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Tuberculosis

Interventions

There will be a focus on the uptake, utilization, roll-out, implementation, adoption and the operationalization of WHO-TB diagnostic technologies upon endorsement by the World Health Organization followed by the implementation at country levels, between 2007 and 2017 (up to 2021). Predisposing, enabling and need factors influencing rapid uptake of WHO-endorsed TB diagnostic technologies will be collected through a survey questionnaire sent to the Heads of the National Tuberculosis Programme, National TB Reference Laboratory Managers and partners in 47 countries in Africa. Participants will be required to consent and respond to different questions. Systematic reviews and meta-analysis of studies published between 2007 and 2017 at country level in Africa will inform how stakeholder awareness, predisposing and need factors are related to uptake, access and utilization. An "easy to use tool" will be developed and disseminated by email to selected countries (slow implementers, where the uptake has been identified as poor) as a guide for a better implementation.

Intervention Type

Other

Primary outcome(s)

We will analyze responses by classifying countries into categories (scoring from 0 to 5). Rapid implementers will have a score of 5 if the specified technology shows its implementation occurred within 1 to 3 years after WHO endorsement, moderate implementers will be from 3 to 5 years and slow implementers will be countries that show implementation after 5 years onward following the WHO endorsement. Gaps on diagnostic part per countries will be highlighted as an impediment to notification of TB cases and enabling factors (funding, leadership,...) will be developed to better guide countries in improving their uptake. We will document threats and opportunities (from field experience) including good practices from TB laboratory services contribution to support recent emergency disease outbreaks in Africa and identify areas where integration of TB diagnostic platforms can serve other disease programmes.

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

30/06/2026

Eligibility**Key inclusion criteria**

Adults aged 18 years and above who occupy the position of managers of the National TB Programme, National TB Reference Laboratories and Partners

Participant type(s)

Health professional

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Participants who do not consent to respond to the survey questionnaire
2. Those who are in position for less than a year

Date of first enrolment

20/07/2022

Date of final enrolment

19/06/2024

Locations

Countries of recruitment

Algeria

Angola

Anguilla

Burkina Faso

Burundi

Cameroon

Uganda

Zambia

Zimbabwe

Study participating centre

Makerere University

Dpt of Immunology & Mol biology Makerere University College of Health Sciences

Kampala

Uganda

7072

Sponsor information

Organisation

Makerere University

ROR

<https://ror.org/03dmz0111>

Funder(s)

Funder type

University/education

Funder Name
Makere University

Results and Publications

Individual participant data (IPD) sharing plan

All data will be collected anonymized. Informed consent will be sought from all participants for data collection from online interviews. The questionnaire will be sent to participants by email in a blind carbon copy and their names will not be disclosed to better protect their privacy and confidentiality. Responses will be stored on a secured computer with password protection. Only authorized persons will allowed to access this data.

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. The ethical approval will be sought from the Makerere University School of Biomedical Sciences Research Ethics committee (SBS-REC). All data will be collected anonymized.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results		04/03/2024	03/05/2024	No	No