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

Submission date
10/08/2022

Recruitment status
No longer recruiting

Registration date
23/08/2022

Overall study status
Ongoing

Last Edited
20/01/2025

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 though 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cross sectional study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
No participant information sheet available

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 though 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 measure
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.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
20/07/2022

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

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
188 participants (respondents)

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

Sponsor details
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+256 783422722
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Sponsor type
University/education

Website
http://mak.ac.ug/

ROR
https://ror.org/03dmz0111

Funder(s)

Funder type
University/education

Funder Name
Makere University

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/06/2026

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?
Preprint results		04/03/2024	03/05/2024	No	No