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Predisposing, enabling, and need factors influencing rapid uptake of the world health organization-endorsed TB diagnostic technologies in Africa

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Abstract

Background Rapid tuberculosis (TB) diagnostics are essential for TB control. Factors influencing the uptake of these technologies in Africa are not well-documented for all technologies and are completely undocumented for some countries. We conducted a survey to collect the status and document Predisposing, Enabling, and Need (PEN) factors influencing uptake so that we understand the associated barriers and inform interventions to improve the uptake.

Methods We designed, piloted, and distributed a survey questionnaire in January 2023 to the National TB Programme (NTP) and National TB Reference Laboratory (NTRL) managers as well as key partners of the Ministry of Health in the 47 Member States of the World Health Organization African Region (WHO/AFR). Responses were accepted until July 2023. We performed quantitative data analysis using STATA version 14.0.

Results From the 47 eligible countries, 22 responses (47%) were received from the NTRL managers, 17 (36%) from Technical Assistants (TAs) for NTRL and NTP, and 8 (17%) from the NTP managers. Our findings showed that it took between two to nine years from the endorsement of a new technology to its full implementation, with the duration increasing with the complexity of the test. Laboratory preparedness, staff competence, and policy reform were the main predisposing factors; availability of funds was the primary enabling factor, whereas the emergence of MDR-TB was the key need factor. Good governance and political commitment aligned with the existence of the Directorate of Laboratory Services and the NTRL, were crucial facilitators driving the adoption, adaptation, and implementation.

Conclusion Our findings demonstrated that the uptake of TB diagnostics in Africa is slow. Considering the laboratory preparedness, staff competence, policy reform, availability of funds, and the emergence of MDR-TB as the main PEN factors identified could help speed up the uptake and rapid implementation of any new technology.

Keywords Predisposing factors, Enabling factors, Need factors, Rapid uptake, Endorsed TB diagnostics

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Introduction

The WHO's End Tuberculosis (TB) Strategy calls for the early diagnosis of TB including universal drug-susceptibility testing (DST) and a quality-assured laboratory network [1].

In 2022, an estimated 10.6 and 2.5 million people fell ill with TB globally and in Africa respectively, with almost 1.7 million (68%) of the new and relapse TB cases being diagnosed and notified leaving a gap of 32% undiagnosed and unnotified [2]. Since 2007, WHO has endorsed different diagnostic technologies, each with advantages and limitations [3]. In 2007, a highly sensitive MGIT liquid culture system was endorsed as a first-line culture method instead of the Lowenstein–Jensen (LJ) solid medium culture [4]. Subsequently, WHO endorsed the molecular GenoType®MTBDR*plus* and GenoType®MTBDR*sl* (Hain Lifescience, Nehren, Germany) for the rapid detection of RIF and INH resistance [5], and second-line fluoroquinolone (SL-FQ) and injectable agents (IAs), respectively [6]. However, their use has not yet solved the diagnostic dilemma of low uptake, largely due to the need for expensive laboratory infrastructure with proper design, extensive biosafety precautions to avoid cross-contamination, and specialized staff [7].

In 2010, WHO endorsed the use of Light-emitting diodes (LED) microscopy [8], which is 10% more sensitive than conventional light microscopy (LM) using Ziehl-Neelsen (ZN) staining, with a positive impact on the HIV population [9]. Then another Policy on rapid Non-commercial culture and DST methods for screening patients at risk for MDR-TB was endorsed [10], but the use of these techniques has been limited due to technical complexity and the need for sophisticated laboratory infrastructure [11].

Late in 2010, The Xpert®MTB/RIF assay (Xpert) (Cepheid, Sunnyvale, CA, USA) was endorsed as a breakthrough, rapid, and more sensitive technology, initially limited to MDR or HIV-associated TB [12]. In 2013, a new policy expanded its use on all people suspected of TB [13]. The test was upgraded in 2017 to a better version with improved performance in detecting TB and RIF resistance, the Xpert®MTB/RIF Ultra assay (Ultra) [14]. Recently in 2019, a new class of Xpert®MTB/XDR cartridge was recommended to detect susceptibility to INH, ethionamide, FQs, and IAs (amikacin, kanamycin, and capreomycin) [15]. Unlike the Xpert MTB/RIF and Ultra, this test can only run on a 10-color machine, necessitating a swap from the 6-color machine by the manufacturer [16]. The running cost, infrastructure, equipment maintenance, and skilled personnel are among the noted limitations for the optimal utilization of Xpert in general.

In 2015, WHO issued a policy on Lateral Flow Lipoarabinomannan (LF-LAM), a rapid diagnostic test (Alere Determine™TB LAM Ag, Alere Inc, Waltham, MA, USA) as a point-of-care test for diagnosing and screening active TB in the urine of people living with HIV (PLHIV) [17]. In 2019, its use in diagnosing active tuberculosis in PLHIV was further endorsed [18]. Despite not requiring laboratory infrastructure and skilled personnel, the adoption and uptake of the test have been slow [19]. New evidence has emerged with the Fujifilm SILVAMP TB LAM, Tokyo, Japan (FujiLAM), a novel rapid lateral flow assay that is twice as sensitive as LF-LAM in detecting TB in PLHIV [20]. However, lot-to-lot variability affecting sensitivity and specificity estimates has limited utilization [21].

In 2016, TB LAMP [the Loopamp™ *Mycobacterium tuberculosis* complex (MTBC) detection kit, Eiken Chemical Company] was endorsed as a rapid alternative to sputum-smear microscopy [22]. The test is rapid, robust, and requires the same biosafety level as microscopy; however, it does not provide a resistance profile, limiting its use. In 2020, a new molecular TB diagnostic tool named Truenat (MTB, MTB Plus, and MTB-RIF) was developed by Molbio Diagnostics, Bangalore, India for detecting TB and RIF-resistance from sputum samples within an hour. Truenat MTB identified more positives among culture-confirmed samples than Xpert and had higher sensitivity [23].

Despite these technologies being in place for several years, their reported uptake in high TB-burden countries remains low and the factors hindering their uptake are varied and poorly documented by countries [24]. Our study aimed to document the uptake status and PEN factors influencing the uptake of WHO-endorsed TB diagnostic technologies in the 47 member states of WHO/AFR, considering TB diagnostic technologies endorsed by WHO between 2007 and 2021. The identified factors will help inform rapid TB diagnostic uptake and roll-out of the already endorsed technologies and those in the pipeline.

Methods

Study design

This cross-sectional study utilized a survey questionnaire, available in French and English, to gather information on the uptake and PEN factors influencing the adoption of WHO-endorsed TB diagnostic technologies. PEN factors were defined as follows: Predisposing factors (political security, policy reform, laboratory network assessment, staff competence, laboratory preparedness, and infrastructure upgrade), enabling factors (availability of funding, political commitment, in-country partners, winning grant, SRL support) and need factors (increase in TB incidence and mortality, HIV prevalence, and emergence of multi/extra drug-resistant TB, SRL supervisory). This study was approved by the Research and

Ethics Committee (REC) of the School of Biomedical Sciences (SBS-2022-154) at Makerere University, Kampala, Uganda, and the Uganda National Council for Science and Technology (HS2393ES).

Study setting, and study population

The study population consisted of adults aged 18 years and above who held positions as managers of the National TB Programme (NTP), National TB Reference Laboratories (NTRLs), or international consultants supporting either NTP or NTRL in 47 African countries.

Survey questionnaire

An online survey questionnaire, approved by REC was piloted using Google Forms (https://docs.google.com/forms/u/0/). It was distributed in January 2023 to NTP Managers, NTRL Managers, key partners, and officials from the Ministry of Health (MoH) in all 47 countries of the WHO/AFR (Fig. S1). Follow-ups by phone and/or email were conducted as reminders. The survey consisted of multiple-choice and open-ended questions, with an informed consent section on the cover page (see Supplementary file 1).

Sample size and techniques, data management, and analysis

We expected almost 100 responses (at least 2 responses per country). Survey responses were downloaded from Google and summarized into variables for analysis. Multiple responses from 47 countries were managed to retain one response per country by eliminating duplicates according to the specific criteria. (1) Responses from NTRL Managers were prioritized as they were considered more representative of laboratory diagnostics. (2) Where NTP and NTRL Managers provided complete responses, we reviewed their responses, clarified discrepancies, and selected the most knowledgeable. (3) We considered the survey's completeness and the responder's experience in position, merging responses between respondents per country. (4) Where responses were discordant and/or missing, we verified the right response to retain. Responses were accepted until July 2023. Quantitative analysis of summarized variables was performed using STATA version 14.0, focusing on frequency, percentage, and 95% Confidence Intervals. Our data analysis was classified as follows: (1) Number and category of respondents, (2) Characteristics of respondent countries, (3) Years of policy endorsement and implementation status, (4) Map of the countries and their status of implementation, and (5) PEN factors influencing the rapid uptake of TB diagnostic technologies. We mapped responses by categorizing countries as rapid or moderate/slow implementers using color-coded categories. Rapid implementers were assigned a green color, and moderate/slow implementers an orange color if the specified technology was implemented within 1 to 3 years and 3 to 5 years onward, respectively. WHO endorses new technology every 1–2 years; we focused on 2 categories (rapid and moderate/slow combined) instead of 3 to get a clear picture of the implementers.

We classified PEN factors as follows: highly influencing the uptake if the rate of respondents was 80% or more, moderate for the rate between 70% and 80%, low influencing for rates between 50% and 70%, and not influencing the uptake when the rate was below 50%. This analysis considered enabling environment such as (1) Laboratory Governance and structure within the MoH including influencers of the uptake and funders, (2) Policy adoption and their implementations with different phases of laboratory preparedness, technology transfer, and the onset of routine testing.

Results

A total of 68 responses were received from all 47 countries, with 40 responses from both NTP and NTRL Managers, and 28 from Technical Assistants (TAs) for both NTRL and NTP. After removing duplicates, less experienced respondents, and incomplete responses, 22 (47%) were from NTRL Managers, 8 (17%) were from the NTP Managers, and 17 (36%) were from TAs to both NTRL and NTP. In total 47 responses were considered (Fig. 1).

Characteristic of respondent countries: laboratory governance

Of the 47 country respondents, n (%, 95%CI), 25 (53, 38–68) experienced national security issues between 2007 and 2021 that affected in-country health services. A total of 34 (72, 57–84) had national laboratory policy in place, and 32 (68, 53–81) had a Department of Laboratory Services (DLS) within the Ministry of Health (MoH), of which 18 (56, 38–74) were established between 2006 and 2021. A total of 31 (66, 51–79) had National TB Laboratory Strategic Plans (LSP), of which 18 (58, 39–75) were integrated into the National TB strategic plans. Only 14 (45, 27–64) LSPs have a comprehensive annual budget line. A total of 44 (94, 82–99) had National TB Reference Laboratories (NTRLs) formally recognized by the MoH, of which 27 (57, 42–72) were classified as TB-containment Laboratories (high-risk TB Laboratories or Biosafety Level 3). Of the 47 respondents, 32 (68, 53–81) identified Political Commitment as the most influential factor in the uptake of TB diagnostic technologies at the country level. This was followed by recommendations from in-country technical assistance mission reports, which were highly ranked by 24 (51, 36–66) respondents (Table 1).

The MoH, combined with DLS and the National TB Program (NTP), was ranked the highest as the funders

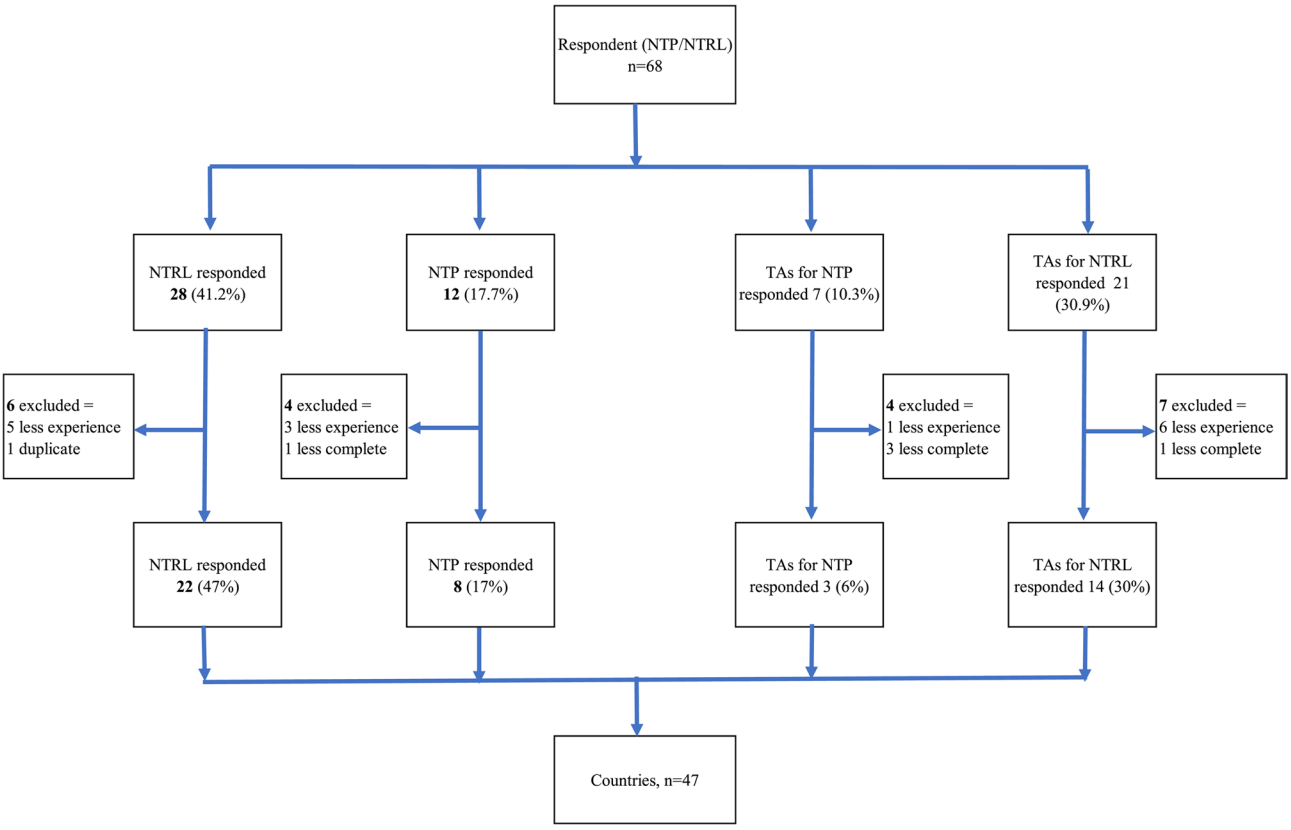

Fig. 1 Number and category of responders. Key: NTRL managers, National TB Reference Laboratory managers; NTP managers, National TB Programme managers and TAs, Technical Assistants for NTRL and NTP

of NTRL operationalization and drivers of the adoption, adaptation, and implementation of new TB diagnostic technologies, with 18 (36, 23–51) and 27 (53, 38–68) respondents respectively (Fig. S2. a and b).

Considering and combining the MoH, DLS, and NTP as domestic (national) and Partners with WHO (HQ, AFRO, and Country Offices) as international, on average, 35% of respondents stated the source of funds for NTRL was domestic. As the driver of the whole implementation, the combination showed that 52% of respondents ranked domestic (national = MoH, DLS, NTP, and NTRL) as the highest driving source.

Policy endorsement and implementation status for TB diagnostics

Table 2 shows the years of policy endorsement and the implementation status of TB diagnostic technologies. The implementation has been influenced by many factors based on the laboratory preparedness, technology transfer, and routine testing phases.

By 2016, of the 47 countries, 30 (64, 49–77), 34 (72, 57–84), and 31 (66, 51–79) were in the routine testing phase for MGIT, LPA, and phenotypic DST respectively. Similarly, by 2017, almost 37 (79, 64–89) for LED microscopy, 5 (11, 4–23) for non-commercial culture and DST methods, and 43 (91, 80–98) for Xpert MTB/RIF were in the routine testing phase.

Reviewing the status of the uptake of LF-LAM and TB-LAMP, at the time of the survey, 23 (49, 34–64) respondents confirmed adopting LF-LAM and 13 (28, 34–64) TB-LAMP respectively as TB diagnostic test in their countries. As of 2021, almost 22 (47, 32–62) for LF- LAM and 10 (21, 11–36) for TB LAMP were in the routine testing phase.

Considering the Xpert ULTRA, TrueNat MTB/RIF and Xpert MTB/XDR, as of 2021, 34 (72, 57–84) for Xpert ULTRA, 7 (15, 6–28) for TrueNat MTB/RIF, and 20 (43, 28–58) for Xpert MTB/XDR were in the routine testing phase following their endorsement (Table 2).

Figure 2 shows a map of countries in the WHO/AFR according to their category of implementation with color coded such as green color for countries that are rapid implementers and orange color for those that are moderate/slow implementers (Fig. 2).

PEN factors influencing the uptake across technologies

Table 3 summarizes PEN factors. Predisposing factors, including lab preparedness and staff competence, were ranked as key factors highly influencing the uptake. The availability of funds was the highest-ranked enabling

Table 1 The characteristics of respondent countries: laboratory governance

Parameter	*n* (%, 95%CI)
Countries that experienced national security issues between 2007 and 2021	25 (53, 38–68)
Countries that have a national laboratory policy	34 (72, 57–84)
Countries that have a Directorate of Laboratory Services (DLS)	32 (68, 53–81)
Established before 2005	14 (44, 26–62)
Established between 2006–2021	18 (56, 38–74)
Countries that have a National TB Laboratory Strategic Plan (LSP)	31 (66, 51–79)
Standalone specific to TB Laboratory	10 (32, 17–51)
Integrated into National Public Health LSP	7 (23, 10–41)
Integrated into TB NSP	18 (58, 39–75)
Integrated into other health strategic plans	7 (23, 10–41)
Has a comprehensive annual budget	14 (45, 27–64)
Countries that have NTRL formally recognized by the Ministry of Health	44 (94, 82–99)
Standalone and specific to TB	35 (74, 60–86)
Integrated into NPHL	18 (38, 25–54)
Has a formal collaboration agreement with WHO-SRL	40 (85, 72–94)
Receives TA from the WHO-SRL	42 (89, 77–96)
Upgraded at level 3 of the biosafety (BSL-3)	27 (57, 42–72)
Upgraded at BSL-3 between 2016–2021	15 (56, 35–75)
The NTRL Manager formally reports to the NTP Manager	31 (66, 51–79)
Highly ranked influencers in the uptake of TB diagnostic technologies	
WHO policy support	23 (49, 34–64)
Funders	21 (45, 30–60)
Political Commitment	32 (68, 53–81)
Lab reports (programme reviews, GLC)	24 (51, 36–66)

DLS Directorate of Laboratory Services, *LSP* Laboratory Strategic Plan, *NSP* National Strategic Plan, *NTRL* National TB Reference Laboratory, *NPHL* National Public Health Laboratory, *WHO-SRL* WHO TB Supranational Reference Laboratory, *BSL-3* Biosafety Level-3, *GLC* Green Light Committee

factor, while the emergence of MDR-TB was the highest-ranked need factor.

Impediments and barriers to rapid implementation

All 47 countries reported impediments and barriers to implementing WHO-endorsed diagnostic technologies. A total of 33 (70, 55–83) ranked insufficient finance to procure the test as the highest impediment, followed by the procurement issues with 26 (55, 40–70) respondents (Fig. S3).

Discussion

Our study showed that multiple factors influence the uptake of TB diagnostic technologies in the WHO/AFR. These factors range from laboratory preparedness and availability of funds to the emergence of MDR-TB, which are significant predisposing, enabling, and need factors, respectively. Despite the availability of WHO guidelines, our study reveals that it takes several years from the time a technology is endorsed to when it reaches the routine testing phase, allowing countries to report its impact. Through different phases of laboratory preparedness, technology transfer, and routine testing, our study showed that the impact of a technology can be measured between two and nine years after endorsement. For instance, the uptake of MGIT and LPA took over eight and nine years, respectively to reach the routine testing phase after their endorsement. The laboratory preparedness phase, during which the infrastructure and other requirements must be established before the technology transfer, significantly influenced this delay. However, countries with strong governance structures (DLS, NTRL) and the availability of funds showed higher uptake. This finding is similar to what has been reported by Maningi et al. [7] and confirms data from a recent study in the WHO European Region, where two-thirds of the NTRLs were able to perform DST for Bedaquilin (BDQ) over nine years after its endorsement by WHO [25]. Technologies like MGIT, LPA, and Xpert MTB/RIF saw quicker adoption in countries with better laboratory preparedness and policy reforms. Almost seven years after the endorsement of LED Fluorescence Microscopy (LED FM), only 37 (79, 64–89) countries were routinely using it. LED FM has been found to offer a legitimate alternative to conventional ZN techniques due to its higher sensitivity, time-saving nature, and minimal effort required [26]. The LED FM did not resolve the issue in HIV-positive patients, as its sensitivity, even better than ZN, was reduced in this group. Indeed, its lower specificity compared to ZN made it hesitant in its use.

Similarly, almost 43 (91, 80–98) countries were at the routine testing phase for Xpert MTB/RIF seven years after its first and second endorsement in 2010 and 2013 respectively with 32 (68, 53–81) countries in the laboratory preparedness phase. This shows that its acceptance was quicker than LPA. However, Xpert faced unexpected health system challenges that hindered TB case notification in high-burden countries such as Nigeria, DRC, and South Africa as demonstrated by Williams et al. [27].

Awareness of Xpert as a platform contributed positively at the time of the survey, with 44 (94, 82–99) countries confirming the start of Ultra implementation only three years after its recommendation. The transition was rapid partly because Cepheid stopped manufacturing the Xpert MTB/RIF cartridges. The uptake of Xpert XDR was quicker, occurring two years after its recommendation, likely because it required minimal training for technicians already experienced with Xpert Ultra. Our findings align with those reported recently by Katamba et al. [16].

For LF-LAM and TB LAMP, almost 22 (47, 32–62) and 10 (21, 11–36) countries respectively were at the routine testing phase five years after their endorsement. The uptake of LF-LAM was influenced by a combination of

Table 2 Policy endorsement and implementation status for TB diagnostics.

Parameter	*n* (%, 95%CI)
MGIT (Liquid culture & speciation), 2007	
Laboratory preparedness (2007–2011)	22 (47, 32–62)
Technology transfer (2012–2015)	21 (45, 30–60)
Routine testing (> = 2016)	30 (64, 49–77)
LPA (first and second-line), 2008	
Laboratory preparedness (2008–2011)	19 (40, 26–56)
Technology transfer (2012–2015)	25 (53, 38–68)
Routine testing (> = 2016)	34 (72,57–84)
DST (second-line phenotypic), 2008	
Laboratory preparedness (2008–2011)	15 (32, 19–47)
Technology transfer (2012–2015)	21 (45, 30–60)
Routine testing (> = 2016)	31 (66, 51–79)
LED Microscopy, 2010	
Laboratory preparedness (2010–2013)	26 (55, 42–72)
Technology transfer (2014–2017)	35 (74, 60–86)
Routine testing (> = 2017)	37 (79, 64 – 9)
Non-Commercial Culture and DST, 2010	
Implemented	5 (11, 4–23)
CRI (Colorimetric Redox Indicator) method in use for Culture and DST	4 (9, 2–20)
NRA (Nitrate Reductase Assay)method in use for Culture and DST	2 (4, 1–15)
MODS (Microscopic Observation Drug Susceptibility Assay) method in use for Culture and DST	3 (6, 1–18)
Laboratory preparedness (2010–2013)	4 (9, 2–20)
Technology transfer (2014–2017)	5 (11, 4–23)
Routine testing (> = 2017)	5 (11, 4–23)
Xpert MTB/RIF, 2010	
All adult and children suspected of TB	39 (83, 69–92)
Laboratory preparedness (2010–2013)	32 (68, 53–81)
Technology transfer (2014–2017)	40 (85, 72–94)
Routine testing (> = 2017)	43 (91, 80–98)
LF-LAM, 2015	
Implemented	23 (49, 34–64)
Used to test TB in PLHIV seriously ill only	19 (40, 26–56)
Test used for all adults and children	19 (40, 26–56)
Used in limited number of hospitals	7 (15, 6–28)
Laboratory preparedness (2015–2018)	13 (28, 16–43)
Technology transfer (2018–2020)	15 (32, 19–47)
Routine testing (> = 2021)	22 (47, 32–62)
TB LAMP, 2016	
Implemented	13 (28, 16–43)
Laboratory preparedness (2015–2018)	4 (9, 2–20)
Technology transfer (2019–2020)	9 (19, 9–33)
Routine testing (> = 2021)	10 (21, 11–36)
Xpert ULTRA, 2017	
Implemented (transition from Xpert MTB/RIF to Xpert ULTRA)	44 (94, 82–99)
Laboratory preparedness (2017–2020)	28 (60, 44–74)
Technology transfer (2019–2020)	42 (89, 77–96)
Routine testing (> = 2021)	34 (72, 57–84)
TrueNat TB/RIF, 2019	
Implemented	12 (26, 14–40)
Laboratory preparedness (2019–2020)	4 (9, 2–20)
Technology transfer (> = 2021)	9 (19, 9–33)
Routine testing (> = 2021)	7 (15, 6–28)
Xpert MTB/XDR, 2019	

Table 2 (continued)

Parameter	*n* (%, 95%CI)
Laboratory preparedness (2019–2020)	5 (11, 4–23)
Technology transfer (> = 2021)	27 (57, 42–72)
Routine testing (> = 2021)	20 (43, 28–58)

MGIT Mycobacterium Growth Indicator Tube, *LPA* Line Probe Assay, *DST* Drug Susceptibility Testing, *LED* Light-Emitting Diodes, *CRI* Colorimetric Redox Indicator, *NRA* Nitrate Reductase Assay, *MODS* Microscopic Observation Drug Susceptibility, *Xpert MTB/RIF* Xpert Mycobacterium tuberculosis/Rifampicin, *LF-LAM* Lateral Flow Lipoarabinomannan, *TB LAMP* TB Loop-Mediated Isothermal Amplification, *Xpert ULTRA* Xpert MTB/RIF ULTRA, *Xpert MTB/XDR* Xpert Mycobacterium tuberculosis/Extensively drug-resistant TB

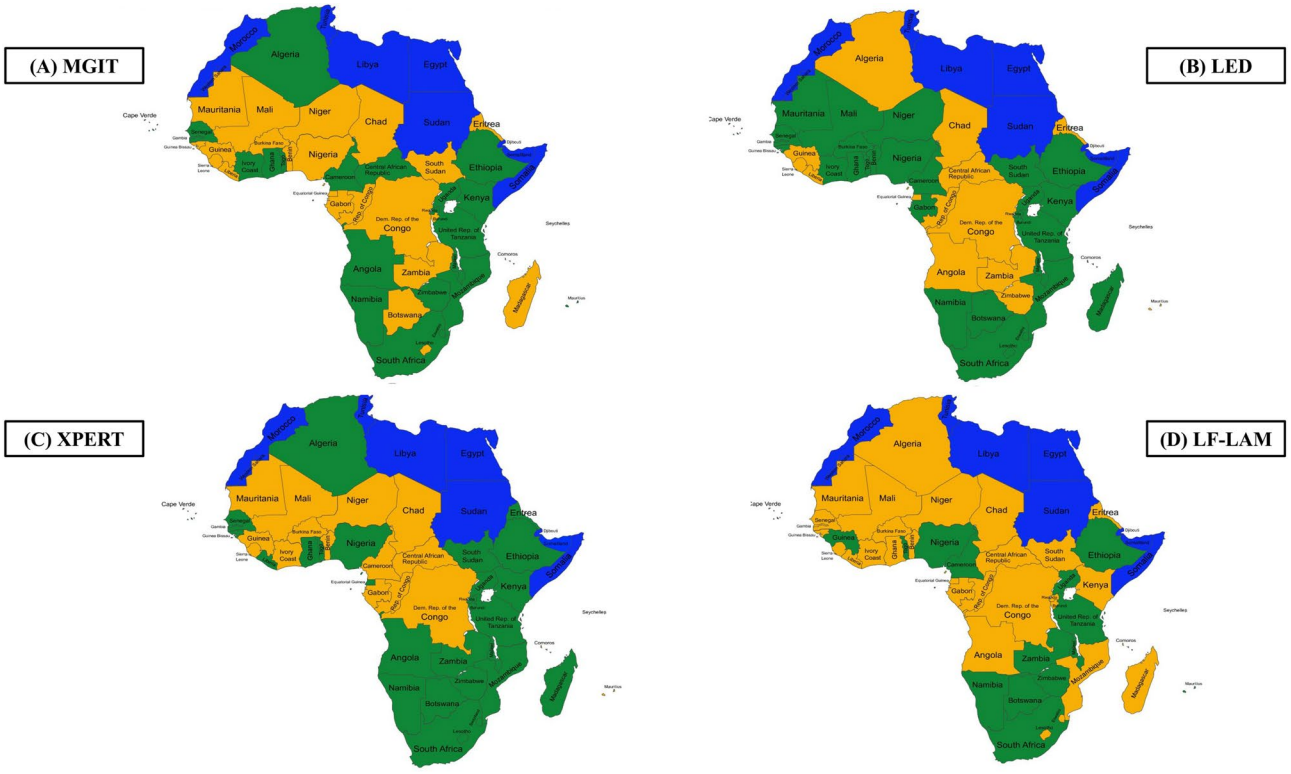

Fig. 2 Rapid, moderate, and slow implementers of (**A**) MGIT, (**B**) LED, (**C**) XPERT, and (**D**) LF-LAM in WHO/AFR. Key: MGIT,MycobacteriumGrowth Indicator Tube; LED, Light Emitting Diodes Fluorescence microscopy; LF-LAM, Lateral Flow Lipoarabinomannan assay. Blue color: countries outside of WHO/AFR; Orange color, countries that are moderate/slow implementers (within 3 to 5 years/5 years onward after endorsement); green color, countries that are rapid implementers (within 1-3 years).

political commitment, and the need to address MDR-TB and high HIV prevalence. Our results are like those found by Singhroy et al. in high HIV-burden countries, where 46% of countries implement LF-LAM [28].

However, the TB LAMP assay does not provide a resistance profile, and countries were reluctant to adopt it. This reluctance was compounded by the rapid uptake of the better alternative, GeneXpert, which was available at the same time. Additionally, having 22 out of 47 high HIV/TB burden countries in Africa may have limited its use, where Xpert is better recommended [29]. TB LAMP uptake may have been influenced by supportive policies, political commitment, availability of funds, and the need to address TB at the lowest level of the health system.

For TrueNat MTB/RIF, the country's willingness to include it in their algorithm is progressing. However, its quick implementation was limited by the fact that it was endorsed at a time when countries had already finalized their plans and budgets and applied to the Global Fund for funding requests.

Our study shows that East and Southern African (ESA) countries are among the rapid implementers across all diagnostic technologies, due to funding allocation, health infrastructure, and governance frameworks, while many countries in Central and West Africa are still lagging and slower, due to security issues, lack of funding, and weaker governance structures. Extra effort is needed to better document factors associated with delays in the uptake of technologies in this part of Africa. This aligns with the high burden of TB, TB/HIV, and MDR-TB in ESA, which drew the attention of the member states [30]. Uptake requires in-country ownership with a well-established

Table 3 Predisposing, Enabling, and need factors influencing the rapid uptake of TB diagnostic technologies

	MGIT	LPA (1st and 2nd line)	DST (2nd line phenotypic)	LF-LAM	TB-LAMP	ULTRA
	n/N (%); *N* = 9	n/N (%); *N* = 11	n/N (%); *N* = 7	n/N (%); *N* = 5	n/N (%); *N* = 1	n/N (%); *N* = 16
Predisposing factors						
Political security	2 (22.2)	4 (36.4)	3 (42.9)	2 (40)	0 (0)	12 (75)
Policy reform	7 (77.8)	9 (81.8)	7 (100)	4 (80)	0 (0)	15 (93.7)
Lab network assessment	5 (55. 6)	8 (72.7)	6 (85.7)	4 (80)	1 (100)	16 (100)
Staff competence	7 (77.8)	10 (90.91)	7 (100)	4 (80)	1 (100)	16 (100)
Lab preparedness	8 (88.9)	10 (90.9)	7 (100)	4 (80)	1 (100)	16 (100)
Infrastructure upgrade	7 (77.8)	8 (72.7)	7 (100)	4 (80)	1 (100)	16 (100)
Enabling factors						
Availability of fund	7 (77.8)	9 (81.8)	6 (85.7)	3 (60)	1 (100)	14 (87.5)
Political commitment	4 (44.4)	8 (72.7)	5 (71.4)	3 (60)	1 (100)	12 (75)
In country partners	7 (77.8)	7 (63.6)	4 (57.1)	3 (60)	1 (100)	11 (68.7)
Winning a grant	3 (33.3)	8 (72.7)	5 (71.4)	3 (60)	1 (100)	10 (62.5)
Lab SRL support	5 (55.6)	8 (72.)	6 (85.7)	3 (60)	1 (100)	8 (50)
Need factors						
Increase in TB incidence and mortality	4 (44.4)	5 (45.4)	3 (42.9)	2 (40)	1 (100)	10 (62.5)
Emergence of MDR-TB	6 (66.7)	8 (72.7)	4 (57.1)	2 (40)	0 (0)	13 (81.2)
Emergence of XDR-TB	3 (33.3)	5 (45.4)	4 (57.1)	1 (20)	0 (0)	6 (37.5)
Increase in HIV Prevalence	4 (44.4)	3 (27.3)	3 (42.9)	2 (40)	0 (0)	9 (56.2)
SRL supervisory requirements	4 (44.4)	7 (63.7)	3 (42.9)	2 (40)	0 (0)	8 (50)

MGIT Mycobacterium Growth Indicator Tube, *LPA* Line Probe Assay, *DST* Drug Susceptibility Testing, *LED* Light-Emitting Diodes, *CRI* Colorimetric Redox Indicator, *NRA* Nitrate Reductase Assay, *MODS* Microscopic Observation Drug Susceptibility, *Xpert MTB/RIF* Xpert Mycobacterium tuberculosis/Rifampicin, *LF-LAM* Lateral Flow Lipoarabinomannan, *TB LAMP* TB Loop-Mediated Isothermal Amplification, *Xpert ULTRA* Xpert MTB/RIF ULTRA

structure at the Ministry of Health level to drive the laboratory system and address TB diagnostic needs as confirmed by 32 (68, 53–81) respondents. Our findings agree with the Lancet Commission on diagnostics by Fleming et al. [31], and also complements the findings from Pai et al., stating that the availability of new tools does not guarantee their adoption, correct use, scale-up, or public health impact [32]. Comparison with previous studies shows progress in countries having national laboratory policies and strategic plans specific to TB, with more than twice the increase from the 28.6% we previously reported in 2017 [33]. This progress aligns with the 2008 Maputo declaration and the 2008 WHO/AFR Regional Committee Resolution [34], which called on member states to establish national laboratory strategies and policies to strengthen laboratory systems as an integral part of disease control [35].

The establishment of the NTRLs formally recognized by the MoH, their collaboration agreement in place with the WHO-SRL, and the increase in ISO 15189:2012 accredited NTRLs demonstrate the importance of regional support and mentoring processes for a quick uptake [36].

Looking at predisposing actors, laboratory preparedness and staff competence were highly ranked and varied across all technologies. Our findings are comparable to previous studies [31], stating that technological innovation goes hand in hand with workforce empowerment and capacity building.

On the laboratory preparedness side, our data show that the preparedness phase after any technology endorsement varies by country and is based on the laboratory requirement per technology. This phase was given three years. Our findings confirm that most countries started their laboratory preparatory phases once those technologies were endorsed. However, they were delayed in reaching the routine testing phase due to requirements such as training, in-country validation of the technology, quality assurance, and procurement process, which needed to be addressed before the technologies could be transferred. For instance, once the policy on the use of Xpert was issued in 2010, WHO developed a manual on the "know-how to" implement to assist countries in preparing before adopting this technology [37].

On the other hand, looking at enabling factors, the availability of funds was ranked as the highest enabling factor for all the technologies, followed by political commitment, including the in-country partners, and the TB Supranational Reference Laboratory support for some others. Technical assistance was crucial for knowledge transfer, where partners and SRL played an important role in implementation.

While considering the need factors for diagnostic uptake, the emergence of MDR-TB ranked highest. The

emergence of MDR/XDR-TB and increased HIV prevalence have led to the use of LPA, Xpert and MGIT for rapid detection of resistance to rifampicin and isoniazid, to manage rising TB incidence, mortality and coinfection. The adoption of these technologies has been facilitated by the supervision of Supranational Reference Laboratories (SRLs) and much emphasized in the technical assistance missions to most of the high TB burden countries.

Country respondents on PEN varied according to the complexity of each technology compared with the country's economic status. The number was high with ULTRA as a near-point-of-care molecular test, moderate with MGIT and LPA, and low for LF-LAM and TB LAMP, which are endorsed as conditional methods.

As limitations, the uptake of diagnostic technologies has been driven by donor funding and disease burden priorities. Most donors do not fund all 47 countries that implement technologies equally. Consequently, some countries with low TB, TB/HIV, and MDR-TB burdens experienced delays in uptake, faced barriers, and lacked DLS, formal NTRL, and no LSP to address TB laboratory requirements. Additionally, there was a delay in receiving feedback from respondents due to poor response rates on surveys. The lack of experience of some respondents also affected the quality and completeness of the survey.

As strengths of the study, nearly 77% of respondents were NTRL Managers and technical assistants for the NTRL. Their responses were consistent in addressing laboratory data concerns, as being at the frontline for uptake and well-positioned for implementing WHO-TB diagnostic technologies as they become available. Having the NTP Manager's response to complete any missing information from other respondents was also a strength. All 47 countries in WHO/AFR responded, and our analysis covered all of them.

As a recommendation on the required efforts for speeding up the uptake, the implementation guide or tools should be available for each diagnostic technology upon its endorsement. Our findings show high relevance to future policy and new diagnostics implementation planning. Furthermore, we systematically map the PEN factors across various diagnostic technologies, countries, and implementation timeframes, providing a structured and coherent analytical approach. Our study provides action-oriented insights, identifying key implementation barriers such as funding constraints and policy delays, while proposing concrete solutions like earlier release of implementation guidance and provision of long-term technical assistance.

Conclusion

Besides the availability of diagnostic technologies and the existence of the WHO Guidelines for their implementations, multiple factors influence their uptake to improve access at the country level. It can take from two to nine years for a new TB diagnostic test to reach the routine testing phase after endorsement. Key factors include governance and political commitment to address the human resources for laboratories (workforce empowerment for laboratory preparedness), the establishment of a Directorate of Laboratory Services with formal recognition of the National TB Reference Laboratory within the Ministry of Health, and the existence of budgeted laboratory strategic plans are key. In-country partnerships to map the technical assistance and support from the TB Supranational Reference Laboratory network should be considered as factors influencing the uptake of TB diagnostic technologies for the TB control programme. Every diagnostic technology, upon endorsement by WHO, should be accompanied by the "know-how to" implement guidance and funding for its rapid uptake and roll out. It is recommended to advocate for more resources to strengthen TB laboratory capacity in Central and West African countries (where uptake shows a delay) while maintaining gains in the East and Southern African Regions, where the burden of TB, TB/HIV, and MDR-TB is still high. Extensive technical assistance (mid-to long-term technical assistance in the laboratory) is recommended to boost the uptake of TB Diagnostic technologies in countries classified as moderate/slow implementers. Beyond the identified factors influencing uptake from our study, it is important to study other cultural and socio-economic factors that may potentially contribute to the uptake.

Abbreviations

TB	Tuberculosis
WHO	World Health Organization
PEN	Predisposing, Enabling, and Need
NTP	National TB Programme
NTRL	National TB Reference Laboratory
WHO/AFR	World Health Organization African Region
MDR-TB	Multi-Drug Resistant Tuberculosis
DST	Drug Susceptibility Testing
MGIT	Mycobacterium Growth Indicator Tube
LJ	Lowenstein–Jensen (solid medium culture)
RIF	Rifampicin
INH	Isoniazid
SL-FQ	Second-Line Fluoroquinolone
IAs	Injectable Agents
LED	Light-Emitting Diodes
LM	- Light Microscopy
ZN	Ziehl-Neelsen (staining)
Xpert	Xpert®MTB/RIF assay
Ultra	Xpert®MTB/RIF Ultra assay
XDR	Extensively Drug-Resistant
LF-LAM	Lateral Flow Lipoarabinomannan
PLHIV	People Living with HIV
FujiLAM	Fujifilm SILVAMP TB LAM
TB LAMP	TB Loop-Mediated Isothermal Amplification
MTBC	Mycobacterium tuberculosis complex
Truenat	Truenat MTB, MTB Plus, and MTB-RIF
MoH	Ministry of Health
DLS	Directorate of Laboratory Services
LSP	Laboratory Strategic Plan
NSP	National Strategic Plan

NPHL	National Public Health Laboratory
WHO-SRL	WHO TB Supranational Reference Laboratory
BSL-3	Biosafety Level-3
GLC	Green Light Committee
CRI	Colorimetric Redox Indicator
NRA	Nitrate Reductase Assay
MODS	Microscopic Observation Drug Susceptibility
BDQ	Bedaquilin

Supplementary Information

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Supplementary Material 1.

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Authors' contributions
JI led the design of the study, data analysis, and manuscript writing. AK and AM critically reviewed the manuscript. MJ advised on the study design, and interpretation of results, and reviewed the manuscript. WS critically advised on the design, data collection, and analysis and reviewed the manuscript. All authors have approved the final manuscript and agreed to be personally accountable for the author's contributions.

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Data availability
All relevant data are within the paper and its supporting information file1.

Declarations

Ethics approval and consent to participate
The ethical approval was obtained from the Research and Ethics Committee of the School of Biomedical Sciences (SBS-2022-154) at the College of Health Sciences, Makerere University, Kampala, Uganda, and from the Uganda National Council for Science and Technology (HS2393ES). In addition, participants were requested to consent by agreeing to participate in the data collection from the online survey.

Consent for publication
The first author works for the World Health Organization (WHO). The contents of this article are the author's opinion.

Competing interests
The authors declare no competing interests.

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