From Evidence to Action: Community-led Monitoring for Access to TB Screening and Diagnostic Testing



May 4, 2022



Webinar Instructions

- During presentations, participants are in "listen-only" mode
- To share questions during the presentations, use the questions feature



Webinar Agenda

- Welcoming remarks, background, and agenda -- Solange Baptiste (ITPC)
- Presentations:
 - WHO recommendations for TB screening and diagnostic testing: a benchmark for monitoring access -- David Branigan (TAG)
 - Community-led monitoring for access to TB screening and diagnostic testing -- Harry Madukani (COWLHA)
 - Impact of rapid molecular testing at the point of care: XPEL-TB trial results -- Dr. Achilles Katamba (Makerere University)
- Facilitated discussion -- Moderator: Solange Baptiste (ITPC)
- **Closing remarks** -- Solange Baptiste (ITPC)

COMMUNITY-LED MONITORING FOR Access to tuberculosis screening And diagnostic testing

APRIL 2022



https://www.treatmentactiongroup.org/publicati on/community-led-monitoring-for-access-totuberculosis-screening-and-diagnostic-testing/

"The qualitative and quantitative data collected through CLM helps to identify gaps and barriers in *health service delivery faced by* affected communities, and it helps to inform advocacy at the health facility, district, and national levels to improve the accessibility and quality of TB services. If done well, CLM can increase access to TB screening and diagnostic tests used according to the WHOrecommended standard of care."

WHO recommendations for TB screening and diagnostic testing: a benchmark for monitoring access

Presented by: David Branigan, TB Project Officer Treatment Action Group



The right to quality TB screening and diagnostic testing



People at risk of TB have a right to TB screening and diagnostic testing in accordance with the World Health Organization (WHO) recommended standard of care.

Adapted from: Paran Sarimita Winari's Journey Fighting Drug-Resistant Tuberculosis

Yet, many countries with high burdens of TB have limited uptake of WHO-recommended tools, such as rapid molecular tests and urine-LAM tests for people living with HIV.

WHO recommendations

WHO's evidence-based recommendations on the use of TB screening and diagnostic tools represent the global standard of care and can be used as a benchmark against which access (or lack-thereof) can be monitored and measured.





WHO recommendations





- WHO recommends systematic screening for TB among high-risk / high-prevalence populations, including:
 - Rapid molecular tests and C-reactive protein to screen for TB among for people living with HIV
 - Use of chest X-ray and computer-aided detection
 - (Not just symptom screening...)
- WHO recommends rapid or high-throughput molecular tests as the initial TB diagnostic test to replace smear microscopy
- WHO recommends urine LAM tests for TB among eligible people living with HIV
- WHO recommends universal drug susceptibility testing, including:
 - Rapid or high-throughput molecular tests
 - Line probe assays (LPAs)
 - Mycobacterial culture

Figure 1. TB screening and diagnostic tools that should be available at different levels of the health system

PERIPHERAL HEALTH CENTER



Tools that should* be available:

- WHO four-symptom screen
- Rapid molecular tests
- Lateral-flow LAM tests for people living with HIV
- C-reactive protein (CRP) for people living with HIV
- Sample referral for complex drug-susceptibility testing (DST)

Tools that may** be available:

 Chest X-ray + computer-aided detection (CAD)





Tools that should be available:

- WHO four-symptom screen
- Rapid molecular tests
- Lateral-flow LAM tests for people living with HIV
- CRP for people living with HIV
- Chest X-ray +/- CAD
- Sample referral for complex DST

Tools that may be available:

- High-throughput molecular tests
- Line probe assays for DST
- Mycobacterial culture DST

CENTRAL HOSPITAL



Tools that should be available:

- WHO four-symptom screen
- Rapid molecular tests
- Lateral-flow LAM tests for people living with HIV
- CRP for people living with HIV
- Chest X-ray +/- CAD
- High-throughput molecular tests
- Line probe assays for DST
- Mycobacterial culture DST

- * "Should" indicates that the tools are expected to be available at this level, in accordance with WHO recommendations.
- ** "May" indicates that the tools are not expected to be available but are technically able to be implemented at this level.

Note: Smear microscopy is not included in this figure because it is not currently recommended by the WHO as an initial TB diagnostic test, though it does still play a role in TB treatment monitoring.

Closing the TB diagnostic gap



 "A WHO-recommended rapid molecular test was used as the initial diagnostic test for only 1.9 million (33%) of the 5.8 million people newly diagnosed with TB in 2020." Just 19% of the estimated 10 million people who developed active TB in 2020...



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 According to the the MSF and Stop TB Partnership Step Up for TB 2020 report, just 38% of high-TB-burden countries surveyed (14/37) indicated policies for routine use of lifesaving urine LAM testing among people living with HIV.

WORCHS WS FROMTIGRES

From evidence to action

Community-led Monitoring for Access to TB Screening and Diagnostic Testing is designed as a simple and accessible tool to assist communities and civil society to generate evidence and translate this into an agenda for advocacy at the health facility, district, and national levels.

Because the framework uses WHO recommendations as the benchmark for monitoring access, it can be adapted to different countries and settings.









Community-led Monitoring for Access to TB Screening and Diagnostic Testing

Presented by:

Harry Madukani, Coalition of Women Living with HIV and AIDS (COWLHA), Malawi

4th May, 2022



Introduction



- Community-led monitoring (CLM) for access to tuberculosis (TB) screening and diagnostic testing enables communities—recipients of care in particular—to monitor the availability, accessibility, acceptability, and quality of TB screening and diagnostic services.
- CLM comes against a backdrop that diagnosis is the weakest link in the TB cascade of care and many countries with high burdens of TB have limited uptake of WHO-recommended tools.
- Qualitative and quantitative data collected through CLM helps to identify gaps and barriers in health service delivery and helps inform advocacy at various levels to improve accessibility and quality of TB services.
- If implemented optimally, CLM can increase access to TB screening and diagnostic tests according to WHO recommended standard of care.



Methodology



- The Coalition of Women Living with HIV and AIDS (COWLHA) developed this CLM framework with the intention for it to be adapted and used in different countries and contexts.
- The framework uses WHO guidelines as a benchmark for the standard of TB screening and diagnostic testing that countries are expected to provide.
- Through the tool, communities can identify gaps in the availability of tools, services, and care delivered.
- COWLHA conducted a literature review and desk research to develop the framework and piloted it at three health facilities in Malawi—a peripheral health center, a district hospital, and a central hospital.



Methodology continued....



- The tool has quantitative and qualitative indicators according to four thematic areas namely: (1) TB screening, (2) TB diagnostic testing, (3) LAM testing, and (4) drug-susceptibility testing.
- The tool was piloted using structured questionnaires in google forms, key informant interviews and focus group discussions.
- Respondents involved when the tool was being piloted were health facility staff and recipients of care.
- After data collection, COWLHA then analyzed the data, identified access gaps, and translated these into an advocacy agenda.

Methodology continued....

INDICATOR FRAMEWORK			
Indicators (AAAQ)	Source for data collection	Method of data collection	Questions for data collection
Availability: WHO-recommended tools available at the health facility			
Quantitative	Health facility	Questionnaire or interview	Which tools are available and implemented at the health facility?
Qualitative	Recipient of care	Interview or focus group	Were the tools the recipient of care preferred to receive available at the health facility?
Accessibility: Distance to point of care			
Quantitative	Recipient of care	Interview or focus group	How far did the recipient of care have to travel to access health services?
Qualitative	Recipient of care	Interview or focus group	How did this distance impact the ability of the recipient of care to access services?
Acceptability: Turna	around time to results		
Quantitative	Health facility	Questionnaire or interview	What is the average turnaround time from sample to results delivery? What factors contribute to this?
Qualitative	Recipient of care	Interview or focus group	What is the recipient of care experience of the time it took to receive results?
Quality: Loss to follow-up			
Quantitative	Health facility	Questionnaire or interview	How many recipients of care are lost to follow-up and why?
Qualitative	Recipient of care	Interview or focus group	Was the recipient of care able to access follow-up services? Why or why not?



Tools required to implement TB screening and diagnostic testing according to the WHO recommended standard of care



- **TB Screening**: Chest X-ray +/- computer-aided detection (CAD), Creactive protein (CRP) for people living with HIV and rapid molecular tests for people living with HIV;
- **TB Diagnostic Testing:** Rapid molecular tests and high-throughput molecular tests;
- LAM Testing: Lateral-flow LAM tests for people living with HIV;
- **Drug-susceptibility Testing:** Rapid molecular tests, high-throughput molecular tests, line probe assays (LPAs) and mycobacterial culture.



General Findings



- Generally, TB and drug-resistant TB (DR-TB) remain a major public health concern in Malawi, where high HIV prevalence and high HIV/TB coinfection further exacerbate this situation;
- In Malawi, about 30 percent of TB diagnoses are bacteriologically confirmed using molecular tests, and the remainder are bacteriologically confirmed using smear microscopy, a century-old technique that is insufficiently accurate;
- Malawi is in the process of expanding diagnostic coverage in the country despite numerous challenges such as limited laboratory coverage at peripheral health facilities and shortage of human resources for health just to mention a few.



Findings According to the 4 Thematic Areas



i. TB Screening

- TB screening is usually conducted using the WHO four-symptom screen (current cough, fever, weight loss, and night sweats) at peripheral and district health facilities;
- Rapid molecular tests are available primarily at the district and central hospitals to screen people living with HIV for TB;
- Chest X-ray is available only at the district and central hospitals;
- Simultaneous screening for both TB and COVID-19 is taking place in some cases but not all, indicating that there is a need to intensify the campaign for simultaneous TB and COVID-19 screening.



Findings continued....



• ii. TB Diagnostic Testing

- Sputum smear microscopy is usually performed as the initial TB diagnostic test at peripheral health centers with very few peripheral facilities equipped with rapid molecular testing. This poses a big challenge to recipients of care with difficulty in producing sputum;
- Confirmatory rapid molecular testing for TB and resistance to rifampicin is available through referral or sample transport to district or central hospitals.
- Health worker respondents from the district and central hospitals reported using rapid molecular tests as the initial test, but the overall numbers of people tested for TB appear to be low, indicating that there are other barriers to diagnostic testing.
- Molecular testing is generally done within one to two days, but the challenges lies on turnaround time related to sample transport.



Findings continued....



• iii. LAM Testing

- TB LAM testing is sufficiently available to eligible people living with HIV seeking care and is performed according to WHO recommendations on the initial visit to the health facility (though this is based on limited data from laboratory technicians);
- Confirmatory molecular testing is also sufficiently available; however, it is sometimes not conducted in parallel with TB LAM testing;
- When someone tests positive with TB LAM, treatment is initiated, but confirmatory rapid molecular testing is not always performed.



Findings continued....



• iv. Drug-susceptibility Testing

- Recipients of care who are diagnosed with TB in peripheral health centers are referred for drug-susceptibility testing using GeneXpert to test for resistance to rifampicin;
- Those seeking care at district or central hospitals generally receive rapid molecular testing for TB and resistance to rifampicin as the initial test;
- More advanced drug-susceptibility tests such as line probe assays (LPAs) and mycobacterial culture are done in central hospital laboratories;
- Laboratories are usually sufficient, but the challenge remains with turnaround time;
- Recipients of care do not pay for the tests.



Discussion



This CLM data collection and analysis process identified several gaps such as:

• Use of smear microscopy as the initial TB diagnostic test at peripheral facilities, which is not in line with WHO recommendations to use rapid molecular tests as the initial TB test. Smear microscopy is insufficiently accurate for detecting TB thereby leaving some recipients of care to battle with TB without care.

"I felt tired all the time and decided to go for TB screening at the community health center. I was not found to have TB but was not satisfied with the results, so I went to the district hospital for another test, where I was diagnosed with TB after using the GeneXpert machine and the results came out the same day." – Excerpt from interview with recipient of care



Discussion continued...



- Accessibility of diagnostic testing is hampered by transportation issues;
- Lack of awareness and inadequate information given to recipients of care is also affecting access to TB screening and diagnostic testing;
- Malawi does not have Truenat tests for TB and resistance to rifampicin.
- The gaps identified through this CLM process show that the availability, accessibility, acceptability, and quality of TB screening and diagnostic testing in Malawi do not fully meet the standard of care recommended by the WHO.



Recommendations and Conclusion



- There is a need to expand rapid molecular testing to all peripheral health centers;
- There is a need for intensified TB awareness campaigns in communities;
- There is an advocacy agenda to push the government of Malawi to raise its standards for TB screening and diagnostic testing in line with WHO guidance.

The study has shown importance of CLM in identifying gaps in accessing TB services, which informs an advocacy agenda. CLM empowers communities to monitor their own TB services and advocate for improvement.



Adapting the CLM Framework to your country and setting

Treatment Action Group

To implement the CLM framework, an organization should develop data collection tools, capacitate staff to do data collection, cleaning, and analysis, conduct entry meetings with institutions where the data will be collected such as health centers and with recipients of care, and finally conduct the data collection.

- There is a full indicator framework which can be downloaded as a google spreadsheet (link in the publication). Thereafter, others can adapt the indicators and implement the CLM framework in their countries by collecting data in a particular context and using the WHO recommendations as a yardstick.
- The data collected locally can then be compared with the WHO recommended standard of care thereby establishing gaps and using those gaps to develop an advocacy plan/agenda at health facility, district, and country level. The advocacy, however, has to take into consideration the resource limited context.

--End---

Impact of rapid molecular testing at the point of care: XPEL-TB trial results Dr Achilles Katamba Multicomponent strategy with decentralized molecular testing for tuberculosis: XPEL TB trial results

TB case detection remains a critical challenge



Subaramman R et al, PLoS Med 2016

Xpert MTB/RIF - a game changer?

- First molecular TB test to be endorsed by WHO (2010)
 - Semi-automated
 - Detects TB and RIF resistance in 2 hours
 - Sensitivity 85%, Specificity 98%
- Significant donor and country investment → rapid scale-up in high burden countries



As of 31 December 2014, a total of 3,763 GeneXpert instruments (comprising 17,883 modules) and 10,013,600 Xpert MTB/RIF cartridges had been procured in the public sector in 116 of the 145 countries eligible for concessional pricing

Uganda Context – Key successes

- Rapid scale-up of Xpert testing coverage
 - >200 GeneXpert devices (hub-and-spoke model)
 - >400,000 Xpert MTB/RIF cartridges
- Nearly 4-fold increase in confirmed MDR TB patients (2009 → 2015)
- ? increase in total TB cases notified annually
 - 40-42000 → 44-45000 cases (pre-2010 → 2015)
- ? increase in proportion of bacteriologicallyconfirmed TB cases
 - 60-65% → >70% (pre-2010 → 2015)



Unresolved questions

- How well are Xpert referral networks (*i.e.*, **hub-and-spoke model**) functioning?
- What is the quality of TB diagnostic care within Xpert referral networks?
- What policy changes and co-interventions can further enhance implementation of Xpert (and future molecular tests)?

<u>Xpert Performance Evaluation to facilitate Linkage to TB</u> care (XPEL TB)

AIMS

- To quantify gaps in TB diagnosis at health centers linked to Xpert testing sites
- To identify modifiable barriers to high-quality TB diagnostic services
 - Provider-level
 - Patient-level
 - Health system-level
- To develop and evaluate a theory-driven intervention to improve the quality of TB diagnostic services

Study setting

- 24 health centers (spokes) linked to 16 Xpert testing sites (hubs)
- Selected based on 2015 Uganda TB case notification data and proximity to Kampala (within 6 hours)



Pragmatic collection of TB evaluation outcome data

- Data collection from routine data sources
 - Data sources: Presumptive TB register, TB laboratory register, Xpert requisition forms, TB treatment register



• GxAlert server and machine data used to ensure complete capture of Xpert results

Aim 1: Quality of TB diagnostic evaluation

6744 adults undergoing pulmonary TB evaluation (Jan – Dec 2017)	%	Range
Indicator 1: Proportion referred for sputum-based TB testing	79%	59 – 92%
Indicator 2: Proportion completing recommended TB testing (if referred)	56%	21 – 81%
Indicator 3: Proportion treated within 14 days (if smear- or Xpert-positive)	75%	14 – 100%
Indicator 4: Proportion receiving ISTC-recommended care	42%	16 – 64%

Davis JL, Katamba A et al. AJRCCM. 2011 Farr K, Nalugwa T et al. JC TUBE 2019

Utilization of Xpert testing

- 20% (1316/6744) of patients referred for Xpert testing
 - 33% (1075/3229) of HIV-positive adults
 - 7% (241/3515) of HIV-negative adults
- 6% (81/1316) of patients referred for Xpert as first-line test
- 52% (63/119) of Xpert-positive patients initiated treatment within 14 days
 High coverage of Xpert testing services ≠ High quality care

Farr K, Nalugwa T et al. JC TUBE 2019

Aim 2: "Understand quality gap"

• Conceptual Model: Theory of Planned Behavior



Aim 2 Summary: Barriers to high-quality TB evaluation

PRECEDE framework	Recurring themes	
Predisposing factors (Knowledge, attitudes,	 Time and resource constraints (<i>i.e.</i>, high workload) → low self-efficacy Belief that TB evaluation is not urgent 	
beliefs, intention)		
Enabling Factors	 Failure of patients to return after initial visit (due to time and costs) 	
(Factors that if addressed make it easier to initiate the desired behavior)	 Inconsistent/delayed specimen transport to Xpert testing sites Inability to track and follow-up patients When they have a cough for more than 2 weeks they are sent to the lab. But the problem is they get the first sample and sometimes, actually most times they don't bring the second sample." 	
Reinforcing Factors	Lack of communication and coordination among staff	
(Factors that if addressed make it easier to continue the desired behavior)	• Insufficient oversight from NTP "Actually at times we have met but we don't meet [regularly], only when we realize there is a problem that's when we communicate and say why is this happening, then we try to rectify."	

1. Shete P, Haguma P et al. IJTLD 2015; 2. Nalugwa T, Shete PB et al. BMC Health Serv Res 2020; 3. Cattamanchi A et al. BMC Health Serv Res. 2015

Aim 3: "Improve quality gap"

Intervention design process:

- Evidence review
- Stakeholder consultation \succ 2. Select interventions
- Feasibility

- 1. Prioritize barriers
- - 3. Specify how interventions delivered

XPEL TB Intervention Strategy

- 1. Onsite Xpert testing at health clinic
 - Reduce workload, increase speed and accuracy of testing
- 2. Structured clinic process redesign to facilitate same day testing and treatment of TB
 - Address lack of urgency and failure of patients to return
- 3. Regular feedback of quality metrics to health facility staff
 - Improve communication, coordination and oversight







XPEL TB trial design and population

- **Objective**: To evaluate the effectiveness, implementation and costs/cost-effectiveness of the XPEL TB strategy at community health centers.
- **Design**: Cluster-randomized, hybrid effectiveness implementation (Type 2) trial at 20 community health centers in Uganda



- Population: All adults evaluated for pulmonary TB from Oct 2018 to Mar 2020
 - Patients with RIF resistance excluded from analysis

Reza T, Nalugwa T et al. Implement Sci 2020 Cattamanchi A et al. NEJM 2021

XPEL TB trial procedures

Public randomization ceremony



- restricted + stratified randomization using 2017 TB data
- "Ultra-pragmatic features"
 - Waiver of informed consent
 - No trial-specific changes to usual care (e.g., no CXR, culture, additional patient contact)
 - Outcomes assessed using routine data sources (*i.e.*, TB registers)
 - Minimal contact with health centers
 - initial training visit + quarterly site visits to resolve data queries and conduct nested sub-studies

Reza T, Nalugwa T et al. Implement Sci 2020 Reza T, Nalugwa T et al Contemporary Clinical Trials communication

XPEL TB trial effectiveness outcomes

Primary outcome:

Number of patients treated for microbiologicallyconfirmed TB within 14 days

Secondary outcomes:

Care Cascade	Outcome
Testing	Number completing TB testing per national guidelines
Diagnosis	Number diagnosed with confirmed TB*
Treatment	Number treated for confirmed TB*
Treatment	Number treated for TB*

*Assessed within 1-day (same-day) and 14 days



Trial flow chart

- 20 of 84 eligible health centers selected and randomized
- >10,000 in target population (adults evaluated for pulmonary TB)
 - <2% excluded
- Harmonic mean number of patients higher in intervention arm (456 vs. 366)

Patient-level characteristics

Characteristic	Intervention (n=5,546)	Control (n=5,093)
Female – no. (%)	3289 (59.3)	3112 (61.0)
Age in years – median (IQR)	40 (30-52)	38 (27-50)-
HIV status* – no. (%)		
Positive	2,285/5273 (43.3)	1,905/4290 (44.4)
Negative	2,988/5273 (56.7)	2,385/4290 (55.6)

Primary outcome

• Cluster-level analysis using negative binomial regression models



* Adjusted for: Randomization strata, number of patients treated for confirmed TB within 14 days in 12-month pre-trial period

Subgroup analyses of primary outcome

 Table 2. Subgroup Analysis of Treatment for Confirmed Tuberculosis within 14 Days after Presentation (Primary Outcome).*

Subgroup	Intervention	Control	Unadjusted Rate Ratio (95% CI)†	Adjusted Rate Ratio (95% CI);
	number of p	patients		
All patients	342	220	1.55 (1.16-2.08)	1.56 (1.21-2.01)
Sex				
Male	234	147	1.59 (1.17–2.17)	1.59 (1.21–2.09)
Female	108	73	1.48 (1.02-2.15)	1.46 (1.03-2.07)
HIV infection status§				
Positive	134	75	1.79 (1.13-2.83)	1.78 (1.15-2.77)
Negative	206	144	1.43 (0.94-2.18)	1.46 (0.98-2.18)

* Adjusted for: Randomization strata, number of patients treated for confirmed TB within 14 days in 12month pre-trial period

Secondary outcomes

A Count-based Outcomes		
Subgroup	Adjusted Rate Ratio (95% CI)	
Tested according to national guidelines	·	1.85 (1.21-2.82)
Same-day outcomes		
Received diagnosis of confirmed tuberculosis	· · · · · · · · · · · · · · · · · · ·	1.89 (1.39-2.56)
Treated for confirmed tuberculosis	• • • • • • • • • • • • • • • • • • • •	2.38 (1.57-3.61)
Treated for tuberculosis	·	1.90 (1.21-2.98)
14-Day outcomes		
Received diagnosis of confirmed tuberculosis	• • • • • •	1.28 (0.99-1.66)
Treated for confirmed tuberculosis	· · · · · · · · · · · · · · · · · · ·	1.56 (1.21-2.01)
Treated for tuberculosis	• • • • • • • • • • • • • • • • • • • •	1.48 (1.04-2.12)
0	1 2 3	4

High implementation fidelity and improved quality across the cascade of care

Key limitations

- Potential imbalance in the underlying prevalence of TB and other factors by trial arm given relatively small number of clusters
- Multi-faceted intervention effect of decentralized molecular testing alone unknown
- Generalizability uptake and impact of intervention strategy in other high burden countries uncertain

Conclusions

- Scale-up of novel diagnostics alone is unlikely to significantly increase case detection or improve patient outcomes
- The XPEL TB strategy (onsite Xpert testing + implementation supports)
 - increased 14-day TB diagnosis and treatment by 56%
 - improved quality metrics at each step along the TB diagnostic evaluation cascade of care
- National TB programs should consider decentralized molecular testing to close
 the case detection gap and improve quality of care
- Implementation science-based methods are useful for designing and evaluating health system interventions to improve quality of care

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#### COMMUNITY-LED MONITORING FOR Access to tuberculosis screening And diagnostic testing

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"CLM empowers community members to monitor their own TB services and advocate for *improvement in areas such as* availability, accessibility, acceptability, and quality. Because this CLM framework uses WHO recommendations as the benchmark for the TB standard of care, it can be easily adapted to different countries and settings and may be adapted to different diseases."

# **THANK YOU!**

Please be in touch with any questions about *Community-led Monitoring for Access to TB Screening and Diagnostic Testing,* including how to adapt and apply this framework.



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