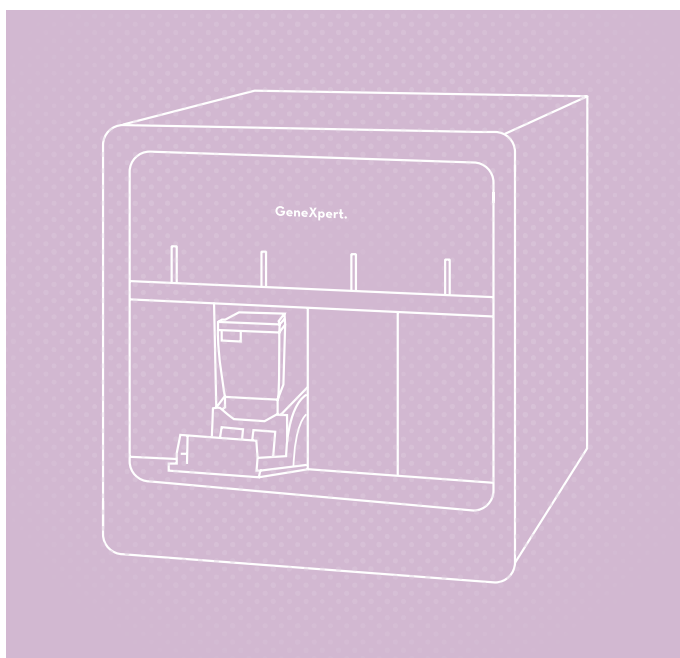
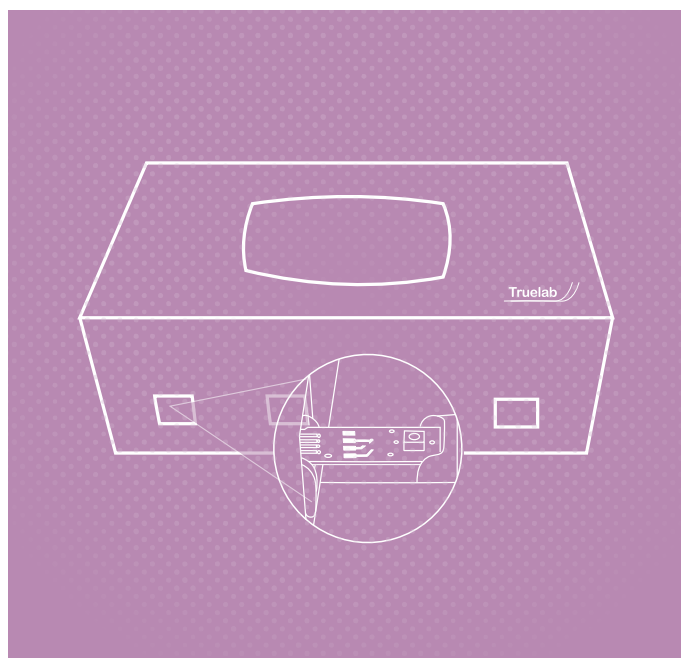


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# COMMUNITY-LED MONITORING FOR ACCESS TO TUBERCULOSIS SCREENING AND DIAGNOSTIC TESTING

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APRIL 2022





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**April 2022**

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## 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. Diagnosis is the weakest link in the TB cascade of care. In 2020, for the first time since 2005, deaths from TB increased, and only 5.8 million of the estimated 10 million people who developed active TB were officially diagnosed. That was a decrease of 18 percent compared with 2019, following the onset of the COVID-19 pandemic.<sup>1</sup> People at risk of TB have a right to TB screening and diagnostic testing, according to the World Health Organization (WHO) recommended standard of care (see Table 1). 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. 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 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, thereby enabling communities to 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. COWLHA developed quantitative and qualitative indicators according to four thematic areas: (1) TB screening, (2) TB diagnostic testing, (3) LAM testing, and (4) drug-susceptibility testing. COWLHA developed and piloted data collection tools with health facility staff and recipients of care, including structured questionnaires in Google forms, key informant interviews, and focus group discussions. While a national ethics review of the CLM data collection protocol was not required, COWLHA still ensured that no personal identifiers were used in the collection of data to protect the identity of the participants, who underwent an informed consent process clarifying the confidentiality of the data and intended use of the results before participation. COWLHA then analyzed the data, identified access gaps, and translated these into an advocacy agenda.

**Table 1. Tools required to implement TB screening and diagnostic testing according to the World Health Organization-recommended standard of care**

THEME	WHO-RECOMMENDED TOOLS*	WHO RECOMMENDATIONS
<b>TB screening</b>	<ul style="list-style-type: none"> <li>• WHO four-symptom screen</li> <li>• Chest X-ray +/- computer-aided detection (CAD)</li> <li>• C-reactive protein (CRP) for people living with HIV</li> <li>• Rapid molecular tests for people living with HIV</li> </ul>	<b>WHO consolidated guidelines: Systematic screening for tuberculosis disease</b>
<b>TB diagnostic testing</b>	<ul style="list-style-type: none"> <li>• Rapid molecular tests</li> <li>• High-throughput molecular tests</li> </ul>	<b>WHO consolidated guidelines: Rapid diagnostics for tuberculosis detection</b>
<b>LAM testing</b>	<ul style="list-style-type: none"> <li>• Lateral-flow LAM tests for people living with HIV</li> </ul>	<b>WHO consolidated guidelines: Rapid diagnostics for tuberculosis detection</b>
<b>Drug-susceptibility testing</b>	<ul style="list-style-type: none"> <li>• Rapid molecular tests</li> <li>• High-throughput molecular tests</li> <li>• Line probe assays (LPAs)</li> <li>• Mycobacterial culture</li> </ul>	<b>WHO consolidated guidelines: Rapid diagnostics for tuberculosis detection</b>

\* As of April 2022

## FINDINGS

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.<sup>2</sup> Malawi is in the process of expanding diagnostic coverage in the country despite numerous challenges, including limited laboratory coverage at peripheral health facilities, shortage of human resources for health, health system inefficiencies, and infrastructure-related issues such as inadequate space for TB laboratories and unreliable electricity.

**TB screening:** At peripheral and district health facilities, TB screening is usually conducted using the WHO four-symptom screen (current cough, fever, weight loss, and night sweats). 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.

**TB diagnostic testing:** Sputum smear microscopy is usually performed as the initial TB diagnostic test at peripheral health centers. Confirmatory rapid molecular testing for TB and resistance to rifampicin is available through referral or sample transport to district or central hospitals. A few peripheral health centers in Malawi are equipped with rapid molecular testing because of project-specific funding and support. 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 performed by laboratories within one to two days, but challenges related to transporting samples and delivering results delay the turnaround time. The central and district hospitals are equipped to collect a variety of sample types for molecular testing, but peripheral health centers are equipped to collect only sputum. This is a problem because some recipients of care, such as children and people living with HIV, may have difficulty producing sputum. There is therefore a need to advocate for non-sputum sample collection and access to rapid molecular testing at all health facility levels.

**LAM testing:** From the experience of the laboratory technicians, 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. The technicians reported that 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.

**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. While laboratories performing drug-susceptibility testing are relatively efficient, the turnaround time for results is often delayed by logistical challenges related to weak systems for transporting samples and delivering results. Similar to the foregoing thematic areas, recipients of care do not pay for drug-susceptibility testing, but in the case of referrals, they do pay transportation costs.

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

#### PERIPHERAL HEALTH CENTER



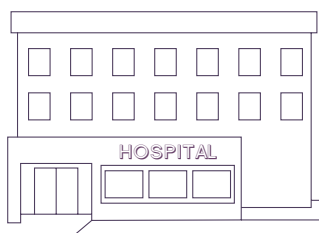
##### Tools that should\* be available:

- 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)

#### DISTRICT 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
- 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.

## DISCUSSION

This CLM data collection and analysis process identified several gaps, the foremost being that peripheral health centers continue to use smear microscopy as the initial TB diagnostic test, 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 people who are undiagnosed to battle TB without care or requiring them to travel long distances to access rapid molecular testing for TB at district hospitals. This is supported by the qualitative interview with one recipient of care who said, “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.”

Lack of awareness and inadequate information given to recipients of care is also affecting access to TB screening and diagnostic testing. From the focus group discussion, recipients of care reported that health workers often visit people with TB signs and symptoms in their homes (door to door), and often the recipient of care is not aware that the signs and symptoms that they are experiencing are related to TB. If not reached out to in their communities, such people often seek care when TB disease has reached an advanced stage. There is a need for intensified TB awareness campaigns in communities, in addition to bringing services closer to people in communities.

Malawi does not have Truenat tests for TB and resistance to rifampicin. There is a need to advocate for more financial resources to procure Truenat for selected facilities in Malawi because of the test's comparative advantage. Truenat was designed to replace smear microscopy in peripheral health centers—closer to communities than GeneXpert, which is placed at the district level and relies on sample transport or referral from peripheral health centers. Truenat tests are rapid and can provide results for TB and drug resistance within hours at the point of care.

While peripheral and district health facilities in Malawi generally implement LAM testing in line with the WHO-recommended indication (people living with HIV with signs and symptoms of TB, severe illness, or advanced HIV disease [CD4 <200 cells/mm<sup>3</sup> for inpatients and <100 cells/mm<sup>3</sup> for outpatients]), confirmatory rapid molecular testing is sometimes not conducted after LAM-positive results, contrary to WHO guidance.

Drug-susceptibility testing is initially done at the district and central hospitals using Xpert MTB/RIF. More advanced drug-susceptibility testing using LPAs and culture is done in the central laboratories. Malawi has only three central laboratories equipped to conduct complex testing such as LPA and culture, and these labs serve a large population. This leads to a high volume of tests to be conducted at these sites, which, combined with challenges of logistics such as transportation, often delays the turnaround time for results. There is a need to advocate for more advanced drug-susceptibility testing at health facilities closer to the point of care.

From the data analyzed in the foregoing sections, it is clear that referral systems often lead to loss to follow-up because recipients of care must self-support for further management. This leaves some recipients of care who do not have the capacity to support themselves unable to access further diagnosis and treatment. Effective coordination between health facilities to follow up with recipients of care is also lacking. Loss to follow-up is very common in referrals from peripheral health centers to district or central hospitals and is even more common when peripheral health centers without laboratories refer samples to other peripheral health centers with laboratories.

Infrastructure remains a huge challenge. Almost half of all peripheral health centers do not have laboratories, and those that do are often not sufficiently equipped for TB diagnostic testing (i.e., lacking rapid molecular testing). Also, necessities such as running water are not available in some peripheral health center laboratories. Human resources are also a big challenge because of regularly shifting roles and the placement of health workers with little experience and minimal training in some health facility laboratories.

The gaps identified through this CLM effort inform four key areas of future advocacy:

1. In Malawi, most peripheral health centers continue to use smear microscopy as the initial TB test, though a few peripheral health centers do offer rapid molecular testing as the initial test through project-specific funding and support. There is a need to expand rapid molecular testing to all peripheral health centers and mobilize the necessary additional financial resources to support this from agencies such as the Global Fund to Fight AIDS, Tuberculosis and Malaria; United States Agency for International Development (USAID); Unitaid; U.S. President's Emergency Plan for AIDS Relief (PEPFAR), and others.
2. Accessibility of diagnostic testing is hampered by transportation issues as described above. From the focus group discussions, it is clear that some recipients of care were lost to follow-up when they were referred for further TB care simply because of the long distance to the referral facility or because they were obligated to continue working to support their families. Bringing TB services closer to the people in communities should be a priority.
3. Limited awareness and inadequate information given to recipients of care also affects access to TB screening and diagnostic testing. When people in communities are not aware of the signs and symptoms of TB or how to access TB screening and diagnostic services, they may not seek care until they have reached an advanced stage of TB disease. This leads to increased risk of morbidity and mortality from TB, as well as increased risk of onward TB transmission. There is a need for intensified TB awareness campaigns in communities.
4. 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. This informs an advocacy agenda to push the government of Malawi to raise its standards for TB screening and diagnostic testing in line with WHO guidance, and to push for increased funding and support from health and development partners to realize this.

## CONCLUSION

The findings of this pilot demonstrate the benefits of community-led monitoring for identifying gaps in access to TB services and translating this into evidence-based advocacy at the health facility, district, or national levels. 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.



## ANNEX 1: COMMUNITY-LED MONITORING DATA COLLECTION TOOL

**How to use this tool to collect data:** This community-led monitoring framework is designed to be adaptable to different settings and purposes. It is organized by four themes of TB screening, TB diagnostic testing, LAM testing, and drug-susceptibility testing, and it uses the WHO recommendations and recommended tools as a benchmark for the standard of care that should be implemented in all countries with high burdens of TB. The indicators were developed to assess the availability, accessibility, acceptability, and quality (AAAQ) of TB screening and diagnostic testing and to identify gaps in care. The indicator framework details sources of quantitative and qualitative data and suggested methods and questions to assist with data collection. Please note that the indicators and questions can be adapted as needed. The entire indicator framework can be applied to each of the four themes and can form the basis for the data collection process.

A template of the CLM data collection tool can be downloaded [here](#).

INDICATOR FRAMEWORK			
Indicators (AAAQ)	Source for data collection	Method of data collection	Questions for data collection
<b>Availability: WHO-recommended tools available at the health facility</b>			
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?
<b>Availability: Challenges related to the availability of tools</b>			
Quantitative	Health facility	Questionnaire or interview	Which tools aren't available that should be?
Qualitative	Health facility	Questionnaire or interview	What are the challenges faced in making WHO-recommended tools available?
<b>Accessibility: Cost to person seeking care</b>			
Quantitative	Recipient of care	Interview or focus group	How much money was paid to access care (including transportation)?
Qualitative	Recipient of care	Interview or focus group	What impact does this payment have on the recipient of care and their family?
<b>Accessibility: Distance to point of care</b>			
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?
<b>Acceptability: Stigma and discrimination</b>			
Quantitative	Health facility	Questionnaire or interview	What policies are in place to prevent stigma and discrimination and are they implemented?
Qualitative	Recipient of care	Interview or focus group	Did the recipient of care experience stigma or discrimination when receiving care?
<b>Acceptability: Experience of care and follow-up</b>			
Quantitative	Health facility	Questionnaire or interview	What complaints if any did the health facility receive from recipients of care?
Qualitative	Recipient of care	Interview or focus group	What was the recipient of care experience regarding information provided, sample collection, and follow-up?

INDICATOR FRAMEWORK			
Indicators (AAQ)	Source for data collection	Method of data collection	Questions for data collection
<b>Acceptability: Turnaround time to results</b>			
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?
<b>Quality: Implementation of tests in line with WHO recommendations</b>			
Quantitative	Health facility	Questionnaire or interview	Are the policies for implementing tests in line with WHO recommendations?
Qualitative	Recipient of care	Interview or focus group	What is the recipient of care perspective on the standard of care they received?
<b>Quality: Loss to follow-up</b>			
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?

## ADDITIONAL RESOURCES

- World Health Organization's **WHO TB Knowledge Sharing Platform**
- Treatment Action Group's **An Activist's Guide to Tuberculosis Diagnostic Tools**
- International Treatment Preparedness Coalition and Stop TB Partnership's **OneImpact Community-Led Monitoring Framework**

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