DEVELOPMENT OF STRATEGIES TO STRENGTHEN TUBERCULOSIS DIAGNOSTIC SYSTEM IN OROMIA REGION, ETHIOPIA

by

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Declaration

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Abstract

Development of strategies to strengthen Tuberculosis Diagnostic system in Oromia region, Ethiopia

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Background: Tuberculosis (TB) remains a significant public health challenge in Ethiopia, particularly in the Oromia Region, where diagnostic system gaps contribute to missed cases and delayed treatment. The diagnostic policy emphasizes prompt identification, yet implementation barriers persist.

Objective: This study aimed to evaluate physical access to TB diagnostics, assess utilisation patterns and determinants, examine diagnostic information use for decision-making, and develop evidence-based strategies to strengthen the TB diagnostic system in Oromia Region, Ethiopia.

Methods: A quantitative, cross-sectional descriptive design was employed across the Oromia Region of Ethiopia, encompassing a study population of 171 health facilities and 222 professionals. Using stratified random sampling, a total of 112 health facilities (comprising 31 hospitals, 42 health centres, and 39 public-private mix facilities) alongside 59 managing health organisations were selected. Data collection took place from December 2023 to August 2024, utilizing 2 instruments: (1) structured checklists for retrospective review of tuberculosis diagnostic records (2018–2023); (2) questionnaires administered to 222 health professionals (78% male, 22% female), including laboratory technicians, TB focal persons, and program managers; and geospatial analysis based on the Global Moran's I statistic to evaluate physical accessibility within radii of <5 km, 5–10 km, and >10 km. Data were analyzed using SPSS version 29 (descriptive statistics and multivariate logistic regression) and Microsoft Excel. To validate and refine strategic priorities, a modified three-round Delphi technique was conducted with 11 national and regional TB experts (radiologists, Histopathologists, national TB program officers, and reference laboratory managers), with a consensus threshold of >70% for item inclusion.

Results: Basic laboratory amenities averaged only 58% availability. Only 18.5% of health professionals demonstrated knowledge of national TB guidelines. Conventional microscopy was available in 84% of facilities, but WHO-recommended rapid

diagnostics (GeneXpert) reached only 24.1%, with significant urban-rural disparities. Geospatial analysis revealed that 41-50% of populations lacked access within 10km of AFB microscopy, Xpert MTB, and X-ray services. Test utilisation remained below 11% among symptomatic patients, associated with supply shortages (71% of respondents), equipment failures (68%), and inadequate screening practices (OR=0.358, p=0.216). Pulmonary TB case detection averaged 64%, and 27.6% of facilities lacked diagnostic service plans. The Delphi process yielded consensus on five strategic objectives with 30 specific strategies, including: establishing district-level molecular diagnostic centres (90.9% consensus), implementing multi-tiered buffer stock systems (100% consensus), mandating healthcare worker competency training (100% consensus), developing unified diagnostic M&E frameworks with digital dashboards (90.9% consensus), and establishing dedicated coordination bodies from ministry to district level (81.8-100% consensus).

Conclusion: The TB diagnostic system in Oromia Region faces critical gaps in infrastructure, health worker knowledge, diagnostic utilisation, and monitoring systems. The developed 30-strategy framework provides an evidence-based, expert-validated roadmap to strengthen confirmatory and supportive TB diagnostics through tiered service delivery, supply chain resilience, workforce capacity building, and data-driven governance.

Key terms: -Tuberculosis Diagnostics; Diagnostic strategies; diagnostic system in Oromia region Ethiopia; TB diagnostic Access; TB diagnostic utilisation; Diagnostic information use; confirmatory diagnostics; supportive diagnostics; Diagnostic equipment’s, associated factors for diagnostic utilisation.

Dedication

I dedicate this thesis to my late father, Alemu Fetenesa Dadi. You sent me to school with a dream in your heart that you never had the chance to fulfil yourself. You taught me the value of education without ever reading a book. This degree is the fulfilment of your greatest hope and is a testament to your love and sacrifice.

My eternal gratitude to my Glory God, my source of light and perseverance.

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List of Acronyms

ACF - Active Case Finding
AFB - Acid Fast Bacilli
CEO - Chief Executive Officer
CHWs - Community Health Workers
CT - Computed Tomography
CXR - Chest X-ray
DMC - Direct Microscopy
DRTB - Drug Resistant TB
DST - Drug Susceptibility Testing
EPHI - Ethiopian Public Health Institute
HIV - Human Immunodeficiency Virus
ISTC - International Standards for Tuberculosis Care
LAMP - Loop Mediated Isothermal Amplification
LF-LAM - Lateral Flow Lipoarabinomannan Assay
LPA - Line Probe Assay
LTBI - Latent TB Infection
M&E - Monitoring and Evaluation
MOHE - Ministry of Health Ethiopia
MRI - Magnetic Resonance Imaging
MTB - Mycobacterium Tuberculosis
mWRDs - Molecular WHO-Recommended Rapid Diagnostics
MDR TB - Multi Drug Resistant TB
NAAT - Nucleic Acid Amplification Test
NTM - Non-Tuberculosis Mycobacterium
PCR - Polymerase Chain Reaction
POC - Point-of-Care
PTB - Pulmonary TB
QA - Quality Assurance
QC - Quality Control
RHB - Regional Health Bureau
RIF - Rifampicin
RR TB - Rifampicin Resistant TB

SDG - Sustainable Development Goal

SLMTA - Strengthening Laboratory Management Toward Accreditation

TB - Tuberculosis

TBLLD - TB, Leprosy, and other Lung Diseases

WHO - World Health Organization

WoHO - Woreda Health Office

XDR - Extensively Drug Resistant

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CHAPTER 1

ORIENTATION TO THE STUDY

1.1 Introduction

Tuberculosis (TB) continues to pose a significant global health challenge, marked by its high prevalence and substantial rates of morbidity and mortality. According to the World Health Organization (WHO, 2025), an estimated 10.7 million new TB cases and approximately 1.25 million TB-related deaths occur annually, with the burden disproportionately affecting low and middle-income countries. The disease is caused by Mycobacterium tuberculosis, an infectious bacterium that primarily targets the pulmonary system but can also manifest in extra pulmonary forms, thereby contributing to its widespread impact (Green, 2025; WHO, 2025).

The burden of TB is disproportionately high in the African region. Sub-Saharan Africa (SSA) bears a particularly heavy share of this epidemic, with the WHO African Region achieving a 28% reduction in TB incidence rates and a 46% reduction in TB deaths between 2015 and 2024 (WHO, 2025). Despite these gains, the region continues to face significant challenges in diagnostic access. Over a decade since the WHO recommended replacing smear microscopy with rapid molecular diagnostics, only half of people with TB in Africa have access to these tools (WHO, 2024). These persistent gaps in diagnostic availability contribute to ongoing transmission and mortality in the region.

Ethiopia, situated within this high-burden region, is classified as one of the 30 high TB and MDR-TB burden countries globally (WHO, 2024). The country ranks third in Africa and eighth in the world in terms of TB prevalence. According to the WHO Global TB Report 2024, there are an estimated 188,000 incident TB cases in Ethiopia, with an estimated incidence rate of 146 per 100,000 populations (WHO, 2024). A comprehensive systematic review and meta-analysis further confirmed the widespread nature of TB in the country, reporting a pooled prevalence of 11.7% among key and vulnerable populations residing in hotspot settings (Reta et al., 2024). The review also observed an increase in TB incidence, underscoring the critical need for

enhanced infection prevention, monitoring systems, and collaborative efforts at local, national, and international levels (Reta et al., 2024).

Ethiopia has made concerted efforts to align with global strategies to combat TB. In 2014 and 2015, all WHO Member States and the UN committed to ending the TB epidemic through the adoption of the WHO's End TB Strategy and the UN Sustainable Development Goals (SDGs) (WHO, 2025). SDG Target 3.3 specifically aims to "end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases" by 2030 (WHO, 2025). The WHO End TB Strategy further operationalizes this target, with milestones to reduce TB incidence by 20% by 2020, 50% by 2025, and 90% by 2030 (relative to 2015 levels) (WHO, 2025). Notably, Ethiopia is among seven high-burden countries that have already achieved the 2020 End TB Strategy milestone (WHO, 2024). The country's TB priorities for the National Strategic Plan (NSP) 2021–2026 include quality-assured TB diagnostics access, community-based TB care and prevention, health facility-based TB care, and integrated TB/HIV service delivery (Ministry of Health Ethiopia, 2023).

1.2 Ethiopian Health System and Diagnostic Governance

In Ethiopia, public health service provision is collaboratively overseen by the Ministry of Health (MoH) and regional health bureaus (RHBs). This governance structure mirrors the country's political organization and extends down to the district (woreda) level (Ministry of Health Ethiopia, 2023). The MoH is responsible for developing national policies, strategies, standards, and strategic plans. However, at the MoH level, there is no dedicated unit that adequately follows up, coordinates, or manages the diagnostic system as a whole (Ministry of Health Ethiopia, 2023). While the MoH serves as the primary policy-maker for TB diagnostic strategy, the absence of a specific governance body for diagnostics means that oversight remains fragmented and reactive rather than systematic.

Key technical agencies, such as the Ethiopian Public Health Institute (EPHI), play important but limited roles. EPHI functions primarily as a referral laboratory service unit, focusing on laboratory capacity building, quality monitoring, public health emergency management, research, and technical operations for TB laboratory

services (Ministry of Health Ethiopia, 2023). However, EPHI's mandate does not extend to governing the broader diagnostic system, nor does it include the coordination of supportive diagnostic services such as imaging (chest X-ray), ultrasonography or histopathology. The national TB, Leprosy, and Other Lung Diseases (TBLLD) desk, situated within the MoH's Disease Prevention and Control department, has its structure mirrored at RHB and district levels (Ministry of Health Ethiopia, 2023). This desk focuses specifically on TB, leprosy and lung diseases, but it does not have a mandate to oversee the full spectrum of diagnostic services – including bacteriology, molecular diagnostics, radiology and pathology – as an integrated system. Moreover, there is no specific body responsible for supportive diagnostics such as imaging and histopathology, despite their critical role in TB diagnosis, particularly for extra pulmonary and smear-negative cases.

Consequently, the entire diagnostic system is not properly managed. Responsibilities are distributed across multiple entities (MoH policy unit, EPHI laboratory unit, TBLLD desk, regional bureaus, and individual health facility heads) without a clear, unified governance framework. Diagnostic functions are embedded within health facilities and administered by hospital CEOs and facility heads, none of whom are formally accountable for system-wide diagnostic performance (Ministry of Health Ethiopia, 2023). This fragmented governance structure results in inconsistent implementation, poor coordination between different diagnostic modalities, and a lack of strategic direction.

1.3 Tuberculosis Diagnostic Modalities and Implementation in Ethiopia

1.3.1 Biology and Transmission of Mycobacterium tuberculosis

Tuberculosis is caused by a bacterium called Mycobacterium tuberculosis complex, a rod-shaped acid-fast bacillus. The Mycobacterium complex is composed of M. tuberculosis (MTB) and other closely related mycobacterial species (M. bovis, M. africanum, M. microti, M. caprae, and M. canetti) that are known to cause TB disease in humans (Federal Democratic Republic of Ethiopia Ministry of Health, 2021:7). Most TB cases are caused by M. tuberculosis organisms, also called tubercle bacilli. TB is spread to the air when people who are ill with TB release bacteria into the atmosphere by coughing or sneezing while in contact with those who do not have TB (WHO,

2021:1). M. tuberculosis is carried in 1–5-micron airborne particles called droplet nuclei. When people with pulmonary or laryngeal tuberculosis cough, sneeze, shout, or sing, infectious droplet nuclei are produced. These tiny particles can remain suspended in the air for several hours. Transmission occurs when a person inhales M. tuberculosis-containing droplet nuclei, which travel through the nasal passages and reach the alveoli (Federal Democratic Republic of Ethiopia Ministry of Health, 2021; MOHE, 2021:18). The bacteria usually attack the lungs (pulmonary tuberculosis), but can attack any part of the body. Two conditions exist: TB disease and latent TB infection (LTBI) (MOHE, 2021:18).

1.3.2 Diagnostic Modalities in Ethiopia

In Ethiopia, TB diagnostics are achieved through bacteriologic confirmatory techniques such as microscopic examination, rapid molecular diagnostic tests (e.g., Xpert MTB/RIF assays), and culture. Furthermore, when bacilli are not detected by bacteriologic techniques, additional supportive investigations (imaging techniques, histopathology) are used to assist clinicians in diagnosing TB (MOHE, 2021:21-22). The national TB strategic plan and guidelines include smear microscopy, TB culture, drug susceptibility testing (DST), Xpert MTB/RIF/Ultra assay, line probe assay, Truant MTB plus, MTB diagnosis test Xpert MTB DR assay, lateral flow lipoarabinomannan (LF-LAM), loop-mediated isothermal amplification (TB LAMP), as well as supportive methods such as histopathological examination, radiological examination, ultrasonography, CT, and MRI (MOHE, 2020:21-30).

1.3.3 Global and National Diagnostics

Globally, TB is the leading cause of death from an infectious disease. In 2021, an estimated 10 million people fell ill from TB and 1.519 million people died due to TB (WHO, 2021:1-3). The outbreak of drug-resistant tuberculosis (DR-TB) brings a major challenge to ending the TB epidemic. In 2021, an estimated 3-4% of new and 18-21% of previously treated people with TB had rifampicin-resistant/multi-drug-resistant TB (RR-/MDR-TB). Worldwide, DR-TB is a threat to global health security and is the leading cause of death from antimicrobial resistance (WHO, 2020:23). Ethiopia is one of the 30 countries with a high TB and TB/HIV burden, with an estimated yearly TB incidence of 132 per 100,000 people and reported TB deaths of 21,500 (15 per

100,000 people) (WHO, 2020:10-15). About one-third of TB cases are missed every year in Ethiopia. Despite recent investments in TB diagnostics, 108,193 TB cases are reported, and an estimated 42,807 TB cases are missed (WHO, 2020:5-10).

Universal drug susceptibility testing is a component of the WHO End TB Strategy, introduced for early detection of TB. A prerequisite for any national TB programme to achieve this goal is a quality-assured diagnostic network equipped with rapid diagnostics (WHO end TB). TB programmes cannot function without diagnostics, yet diagnostics receive far less attention than vaccines and drugs (Pai, Dewan & Swaminathan, 2023). Despite recent investments, the potential for diagnostics to generate value for patients and health systems has not been realised in all settings, particularly in low- and middle-income countries like Ethiopia, where the TB burden is high and TB diagnosis remains a significant gap in care cascades (Pai et al. 2023)

Rapid and accurate diagnosis is crucial for timely initiation of anti-tuberculosis treatment, but many people with TB (or TB symptoms) do not have access to adequate initial diagnosis. In many countries, TB diagnosis still relies on sputum microscopy, a test with low sensitivity. Moreover, the prevention, diagnosis and treatment of TB have grown increasingly challenging as a result of MDR-TB, whilst still being problematic and difficult to access. Many people die from TB because their diagnosis is delayed, and the epidemic continues to endure because we are unable to significantly reduce transmission with current diagnosis (Gobena Gemechu, Gezahegn & Jihad, 2024)

1.3.4 Tuberculosis(TB) Diagnostic Implementation in Ethiopia

Ethiopia began TB control and prevention in the 1960s at TB control centres and hospitals in just three urban areas; the national TB control programme began operating in 1976 (FMOHE, 2017:9). Ethiopia began to accept the international commitment from STOP TB to the present WHO End TB announcement and strategies in 1992, when well-organised TB control and prevention started. Ethiopia is one of the countries that have openly embraced the End TB Strategy and have seen positive results (MOHE, 2021:10). However, despite this commitment, major implementation gaps persist.

Only 80% of health facilities offer TB microscopy services, and the coverage of conventional sputum microscopy testing is suboptimal. The available molecular WHO-recommended rapid diagnostics (mWRDs), such as GeneXpert, are not adequate: out of 3,848 health facilities, GeneXpert is installed at only 285 health facilities, and the installed ones are not fully utilised (MOHE, 2020:18-20). In the Oromia Region, one of the most populous regional states with an estimated population of 40,001,625 – there are 112 hospitals, 1,417 health centres, 7,090 community health posts, and referral laboratories. According to the regional annual TB performance report from 2019, only 72% of health centres are AFB-performing health centres, and the region has only 89 GeneXpert sites. Additionally, the diagnostic service utilisation and service delivery monitoring system, as well as the laboratory referral and managerial network, are not well established.

Similar challenges exist in other high-burden countries. A study in south India found that, due to a shortage of laboratory workers and insufficient training, 9% of presumptive pulmonary TB patients enrolled for evaluation had not had any TB diagnostic testing done (Imaad, Akshaya, Poonam, Badarudeen & Srinath, 2020:326). In Lesotho, although GeneXpert systems are physically accessible, test performance is underutilised because of networking and instrument placement flaws (Heidi, Ryan, Ying, Kekeletso, Mathabo, Zachary, Bridget & Tsietso, 2020:1-15). Chest X-ray (CXR) is a highly sensitive test: a recent prevalence survey in Kenya found TB sensitivity of 100% in HIV-negative individuals and 92% in HIV-positive individuals. CXR is very useful for smear-negative TB diagnosis (paediatric TB or HIV-positive TB cases), screening high-risk populations, and screening general populations in prevalence surveys. CXR should be used at the beginning or early stages of decision algorithms. Regrettably, CXR is only available in limited health facilities (García-Basteiro, 2018:77). In West India, patients had to travel 28 kilometres to receive a microscopy smear test, indicating restricted access (Tripathy, 2013:1). and also the study in Ethiopia, geographic variation exists in access to TB diagnostic services, including AFB smear microscopy, with rural settings presenting particular difficulties. Research conducted in the East Gojjam Zone revealed that the average distance to the nearest health facility offering TB services was roughly 8 km, and some populations had to travel up to 16 km (Tadesse et al., 2020).

The national guidelines advocate for the use of rapid diagnostic technologies, yet implementation and financial burdens present ongoing challenges (MOHE, 2023). Despite the existence of a national TB strategic plan, the absence of a dedicated diagnostic unit at the MoH, the lack of a body responsible for supportive diagnostics, and the fragmented governance of laboratory services collectively mean that no competent, fully articulated diagnostic strategy exists to adequately address TB diagnostic needs across all levels of the health system.

1.4 Problem Statement

Diagnostic services receive significantly less attention and investment compared to medications and vaccines, despite their essential role in healthcare decision-making (Schroeder, 2016). Ethiopia has publicly embraced the End TB Strategy, which encourages early TB diagnosis with universal drug susceptibility testing. The national TB strategic plan includes a wide range of WHO-recommended diagnostic modalities (smear microscopy, culture, DST, Xpert MTB/RIF, line probe assay, TB LAMP, LF-LAM, as well as supportive diagnostics such as histopathology, radiology, ultrasonography, CT and MRI) (MOHE, 2020:21-30). However, a large number of people with TB (or TB symptoms) do not have access to first-line WHO-recommended TB diagnostics and sufficiently sensitive TB screening. The main technique for diagnosing TB in Ethiopia is still conventional sputum microscopy, which is less sensitive. Neither public nor private laboratories that are part of the TB diagnostic network have established and implemented tier-specific minimal testing packages. Sputum microscopy is sometimes difficult to access, as only 80% of health facilities are equipped and most rural communities lack direct access (MOHE, 2020:18-20).

The few currently accessible mWRDs (e.g., GeneXpert) are not used to their full potential, and the extent of utilisation is unknown. MDR-TB has made TB prevention, diagnosis and treatment more challenging. Second-line drug susceptibility testing is inadequate, and national referral labs are not equipped to provide adequate treatment follow-up requiring culture and sensitivity. Delays in diagnosis cause many TB deaths, and the epidemic persists because the country is unable to significantly reduce transmission at the current stage of diagnosis (MOHE, 2020:18-20). The most recent mWRD TB diagnostic modalities are lacking; only 285 facilities have been supplied

with Xpert MTB/RIF, and sensitive TB screening and rapid recommended TB diagnostic drug susceptibility testing tools are not widely available. Only 72% of health centres are AFB-performing health centres (MOHE, 2020:18-20).

The significance of rapid and accurate diagnostic expansion is well addressed in the literature. Each mWRD's and supportive diagnostic's suitability, sensitivity and specificity have been thoroughly investigated. The most recent TB screening methods, including new rapid molecular tests recommended by the WHO, are well addressed. A national strategic plan for the TB programme is available. However, the benchmark for coverage and accessibility of confirmatory and supportive TB tests both traditional and current is not well addressed, and there is no strategy for TB diagnostics or policy document available for strengthening the TB diagnostics system in Ethiopia's Oromia Region. The WHO End TB Strategy correctly argues that TB diagnosis is the key to achieving the End TB goal by 2035. The necessity of rapid and accurate diagnostic expansion is widely explored, but the difficulties in TB case detection and treatment follow-up are not solved by simply expanding diagnostic equipment. Issues of coverage, utilisation, accessibility, and the factors leading to slow implementation remain unaddressed.

Therefore, this study aims to assess the level of confirmatory and supportive TB diagnostics using both traditional and contemporary WHO-recommended techniques examining availability, physical accessibility (proximity), coverage, utilisation and determinants in order to develop a TB diagnostics strategy for Ethiopia. Without such a strategy, the persistent gaps in availability, quality and utilisation of TB diagnostics will remain unaddressed, and the country will continue to fall short of the End TB targets.

1.5 Theoretical/conceptual framework

A theory is a set of propositions that set out the inter dependencies among a set of variables and thus present a systematic view of the phenomena described by the variables (Varpio *et al* 2020:4). Theory explains phenomena by specifying which variables are related to which variables and how they are related, allowing the researcher to predict from certain variables to certain other variables. Theory must be logical, coherent, and include clear terms, definitions and variables. It has a domain

where it applies (Varpio *et al* 2020:4). Theory has concepts, themes, principles, and constructs, and it must be based on empirical data. Its assertions or predictions must be different and better than those in existing theories, and it must be general enough to be applicable to and in a variety of contexts, and if applied as predicted, will result in the predicted outcome (Varpio *et al* 2020:4).

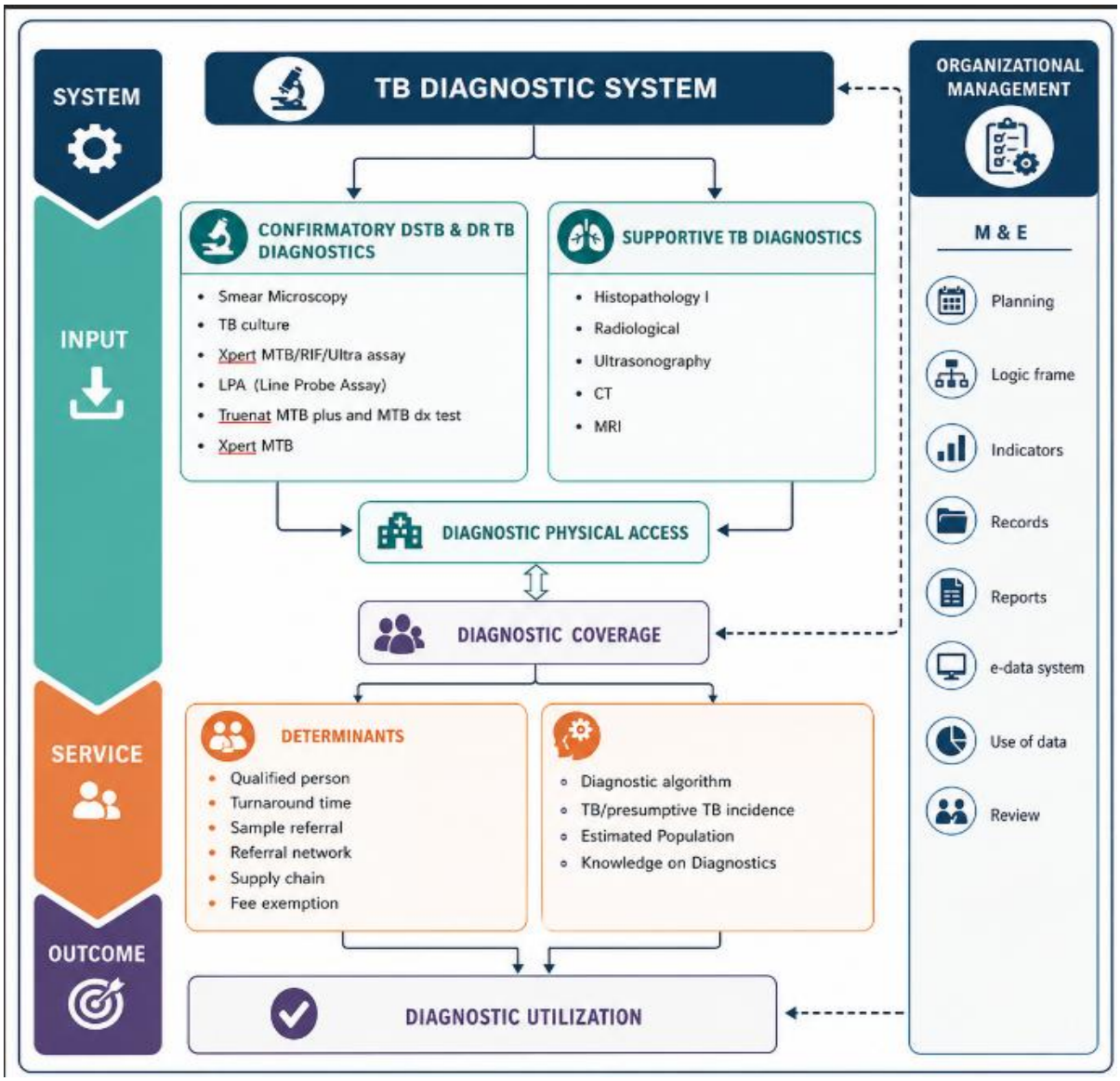

Figure 1. 1 Conceptual framework for TB diagnostic system strengthening (Lassi et al 2014: 2).

The conceptual framework model that revolves around objectives inputs processes, outputs, outcomes and impacts was used in this study. The framework is developed to describe the basic components of TB diagnostics, performance assessment system, and serves as the foundation of TB diagnostic strategy. It is intended to guide what should be measured to inform and drive efforts to improve TB diagnostic system

focused on physical access to recommended TB diagnostics, universal access to drug susceptibility testing, TB diagnostic utilisation, and the use of information for decision making by management and/or organisations. It demonstrated the relationship between the delivery of the intervention targeting TB diagnostics through various implementation platforms and its ensuing impacts on optimal TB diagnostic that result in best-performed TB case detection and treatment outcome (Lassi et al 2014:1).

1.6 Definition of Key concepts

Key concepts are “building blocks of key elements” (Glanz, Rimer & Viswantath 2008:28). Concept definitions are meant to prevent ambiguity and vagueness so that the reader and writer can understand one another. The following are the conceptual definitions used in this study:

The term "TB diagnostics" was used frequently in the research study. In this study, "**TB diagnostics**" refers to any form of supporting diagnostic and confirmatory testing performed to identify whether a patient has active tuberculosis (TB) or not, (Federal Democratic Republic of Ethiopia Ministry of Health 2021) (World Health Organization 2020).

Tuberculosis case refers to a patient in whom TB has been bacteriological confirmed or diagnosed by a clinician through supportive investigation (MOHE 2020:21).
TB diagnostic system refers to approaches used in diagnosing tuberculosis diseases (MOHE 2020:18-30).
Strategy Development - Strategy is defined as leadership style in which, individuals at the top levels of an organization perform functions with strategic implications for the firm (making strategic decisions, engaging stakeholders, human resource management, overseeing operations and administration, and so on) (Samimi et al., 2022). In this study, strategy development is defined as developing TB Diagnostic strategy or leadership style by assessing performance functions in TB diagnostic related to diagnostic availability, accesses, and utilisation.
Access to TB diagnostics - In this study, access to TB diagnostics was defined as being accessible in terms of TB diagnostics availability and the distance or proximity

to the closest healthcare facility for WRD TB diagnostics service for all suspected TB cases as the initial test (Kuupiel, Bawontuo & Thompson 2017:3).

Access to TB universal DST - In this study, access to TB Universal DST entails providing second-line injectable drugs such as Amikacin, Kanamycin, and capreomycin (that meet the criteria of XDR TB), as the current WHO update of new drugs redefined the XDR TB by replacing injections with Bedaquiline and linezolid and fluroquinolones as well as DST for at least rifampicin for all patients with bacteriologically confirmed TB.

TB Diagnostic utilisation - In this study, TB diagnostic utilisation meant investigation into the characteristics and trends of TB screening tests as well as TB laboratory diagnostic testing in healthcare facilities. Laboratory tests in relation to TB disease include smear microscopy, culture, drug susceptibility testing (DST), Nucleic Acid Amplification Test (NAAT) for the fast identification of non-tuberculosis mycobacterium (NTM), serologic detection of latent TB, and X-RAY testing for TB screening (Kim, Choi & Park 2014:6-9).

Monitoring is the regular tracking of program aims utilizing data gathered on an ongoing, regular basis to determine whether or not planned tasks are completed on time. In this context, monitoring means the constant processes of tracking the major components of TB laboratory diagnostics implementation performances implanted by the Ethiopian laboratory network system (WHO 2004:1-2).

Evaluation is a methodological process for gathering, analyzing and using evidence based results to answer the question related to completed or ongoing project or work objectives (Perrin 2012:2-5). Evaluation in this study is the procedure that aims to determine and inform as methodologically as feasible, and to influence the strategic decisions made about the expansion and utilisation of the TB diagnostics program.

1.7 Purpose of the study

The research purpose statement clarifies the intent of the study and explicitly addresses the scientific knowledge gap identified in the problem statement (Wisler, 2009:112-115). Existing literature has documented the global and national burden of tuberculosis (TB), the range of WHO-recommended diagnostic modalities, and the fragmented governance of diagnostic services in Ethiopia (WHO, 2024, 2025; Reta et al., 2024; Ministry of Health Ethiopia, 2023). However, no previous study has systematically assessed, within a single framework, the four interconnected dimensions that determine diagnostic system performance in the Oromia Region: physical access to confirmatory and supportive TB diagnostics, actual utilisation of these tests, determinants of utilisation, and the functioning of the monitoring and evaluation (M&E) system. Furthermore, there is no existing strategy or policy document specifically designed to strengthen the TB diagnostic system in the Oromia Region. Therefore, the purpose of this study was to generate new, integrated evidence by evaluating these four dimensions and, based on the empirical findings, to develop evidence-based strategies to strengthen the TB diagnostic system, thereby improving access to and utilisation of TB diagnostic services in the Oromia Region, Ethiopia.

1.8 Research objectives and questions

1.8.1 Research objectives

The objectives of this study were to:

- Evaluate the magnitude of physical access to tuberculosis diagnostics in Ethiopia's Oromia Region.
- Assess the extent of TB diagnostic utilisation from diagnostic health facilities records of Ethiopia’s Oromia Region.
- Assess Factors Associated with TB Diagnostic utilisation in health facilities of Ethiopia’s Oromia Region.
- Assess the TB diagnostic monitoring and evaluation system used to make decisions in Ethiopia’s Oromia Region.
- Develop strategies to strengthen tuberculosis diagnostic system in Oromia region, Ethiopia.

Table 1.1 Alignment Table: Objectives, Research Questions, Data Sources,

Methods & Results Chapters

Objective	Research Question	Data Source	Analytical Method	Results Chapter(s)
1. Evaluate the magnitude of physical access to tuberculosis diagnostics in Oromia Region, Ethiopia	What is the magnitude of TB diagnostic physical access for drug-susceptible and universal DST coverage in Oromia, Ethiopia?	Facility checklist (N=112 facilities) • GPS coordinates of health facilities • Catchment population data	Descriptive statistics (frequencies, percentages) • Geospatial analysis (Euclidean distance, 5/10/25 km buffers) • Global Moran's I (spatial autocorrelation)	Chapter 4 (sections 4.4.1 – 4.4.9)
2. Assess the extent of TB diagnostic utilisation from diagnostic health facilities records in Oromia Region, Ethiopia	What is the status of TB diagnostic utilisation in health facilities of Oromia Region, Ethiopia?	Retrospective facility records (2018–2023) from 112 health facilities: • Test volumes (AFB, Xpert, LF-LAM, CXR) • OPD attendance • Presumptive TB estimates	Descriptive trend analysis (2018–2023) • Ratio analysis (tests performed / expected presumptive cases) • Positivity rate calculation (by method and year)	Chapter 4 (sections 4.5.1 – 4.5.6)
3. Assess factors associated with TB diagnostic utilisation in health facilities of Oromia Region, Ethiopia	What determines optimum TB diagnostic test utilisation in health facilities of Oromia Region, Ethiopia?	Health professional questionnaire (N=222) • Facility checklist (N=112) • Knowledge assessment section	Multivariate logistic regression (odds ratios, 95% CI, p-values) • Pearson correlation (facility-level) • Multiple linear regression (TB case detection)	Chapter 4 (sections 4.6.1 – 4.6.3)
4. Assess the TB diagnostic monitoring and evaluation system used to make decisions in Oromia Region, Ethiopia	What is the status of the TB diagnostic monitoring and evaluation system available in Ethiopia, and how does it work?	Health professional questionnaire (N=222) • Facility checklist (N=112) • Review of M&E plans and indicator use	Descriptive statistics (frequencies, percentages) • Cross-tabulation of planning vs. review practices	Chapter 4 (sections 4.7.1 – 4.7.3)
5. Develop strategies to strengthen the tuberculosis diagnostic system in Oromia Region, Ethiopia	What strategies strengthen the tuberculosis diagnostic system in Oromia Region, Ethiopia?	Empirical findings from Objectives 1–4 • Modified Delphi technique (3 rounds, 11 national/regional experts)	Thematic analysis (Round 1 open-ended responses) • Consensus scoring (≥70% agreement for retention) • Prioritisation ranking (impact + feasibility)	Chapter 6 (Delphi results) Chapter 7 (final strategies) Chapter 8 (performance indicators, risks, management)

1.8.2 Research Questions

- What are the magnitudes of TB Diagnostic physical access for drug susceptible and Universal DST coverage in Oromia of Ethiopia?

- What is the status of TB diagnostic utilisation in health facilities of Ethiopia's Oromia Region?
- What determines optimum TB diagnostic test utilisations in health facilities of Ethiopia's Oromia region?
- What is the status of TB diagnostic monitoring and evaluation system available in Ethiopia and how does it work?
- What strategies strengthen tuberculosis diagnostic system in Oromia region, Ethiopia?

1.9 Justification of the study

The practical and scientific importance of this study arises from persistent, well-documented gaps in TB diagnostic access and system performance in Ethiopia, particularly in the Oromia Region. Despite Ethiopia's commitment to the WHO End TB Strategy and the presence of a National Strategic Plan (NSP) 2021–2026 (Ministry of Health Ethiopia, 2023), major implementation shortfalls remain. Nationally, only 80% of health facilities offer TB microscopy, and WHO-recommended rapid diagnostics (mWRDs) such as GeneXpert are installed in only 285 of 3,848 health facilities, with suboptimal utilisation (Ministry of Health Ethiopia, 2020:18-20). In the Oromia Region specifically home to over 40 million people only 72% of health centres perform acid-fast bacilli (AFB) microscopy, and the region has just 89 GeneXpert sites. The diagnostic service utilisation, service delivery monitoring system, and laboratory referral network are not well established (Ministry of Health Ethiopia, 2020). Moreover, there is no dedicated diagnostic unit at the Ministry of Health, no governing body responsible for supportive diagnostics (e.g., radiology, histopathology), and no coherent diagnostic strategy to guide implementation (Ministry of Health Ethiopia, 2023). Consequently, many people with TB symptoms lack access to first-line WHO-recommended diagnostics, leading to diagnostic delays, ongoing transmission, and avoidable mortality.

This study is justified because it moves beyond isolated descriptions of barriers to provide an integrated, empirical basis for strategy development. While previous research has examined individual aspects of TB diagnosis such as the accuracy of specific tests or national policy frameworks limited study has simultaneously

quantified physical access (proximity, coverage), measured actual utilisation, identified determinants of underutilisation, and evaluated the diagnostic M&E system within the Oromia Region. Without such integrated evidence, interventions risk being fragmented and ineffective. By generating this evidence and then using it to develop context-specific strategies, this study will directly inform the Oromia Regional Health Bureau, the National TB Program, and other stakeholders. Ultimately, the findings aim to reduce diagnostic delays, improve case detection, and contribute to Ethiopia's progress toward the End TB targets of a 90% reduction in TB incidence by 2030 (WHO, 2025). No similar study has been conducted in the Oromia Region, making this research both original and necessary.

1.10 Research paradigm

A paradigm is a way of viewing the world; a set of ideas used to understand or explain something, often related to a specific subject (Kelly, Dowling and Millar,2018: 9). Furthermore, it is a way of framing what we know, what we can know, and how we can know it. Research paradigm is a conceptual lens through which the researcher evaluates the methodological aspects of the research system to understand the research methods employed and the data that will be evaluated, as well as the basic set of beliefs or worldview that guides research activity and inquiry. Research paradigm determines what should be studied, how it should be studied, and how the study's results should be interpreted by researchers in a given area (Kivunja and Kuyini 2017:26). This study is grounded in the positivist research paradigm, which assumes that reality is objective, measurable, and independent of human perception. Consistent with this worldview, the current state of TB diagnostic access, utilisation, and system performance in Oromia Region is treated as an observable reality that can be quantified and empirically analysed. The study therefore adopts a quantitative approach to collect value-neutral data, test relationships among variables, and generate evidence to inform strategy development. A detailed discussion of the ontological, epistemological, methodological, and axiological assumptions underpinning this paradigm is presented in Chapter 3 (section 3.3).

1.11 Study Approach

This study adopted a quantitative approach comprising two components: a retrospective analysis of prior TB diagnostic evaluations using checklist reviews, and a cross-sectional survey examining determinants and information use practices. A research study approach describes methods for organising studies, gathering data, and conducting systematic analysis (Polit & Beck 2024:731).

1.12 Study Design

The study employed a descriptive cross-sectional design for the survey component and a retrospective record review design for the checklist component. Study design is a framework of techniques and procedures used to gather and analyse data on specified variables (Taherdoost, 2022). Quantitative approaches gather numerical, empirical data (Creswell & Creswell, 2023).

1.12.1 Cross sectional survey

Descriptive survey examining determinants of TB diagnostic use, information use practices for decision-making, and strategy planning. Cross-sectional surveys measure health status, plan services, and establish preliminary evidence (Wang & Cheng, 2020; Wang & Cheng, 2021).

1.12.2 Retrospective review: -

Analysis of previous year's TB diagnostic records using a structured checklist to assess utilisation, access, and DST coverage. No new primary data collection.

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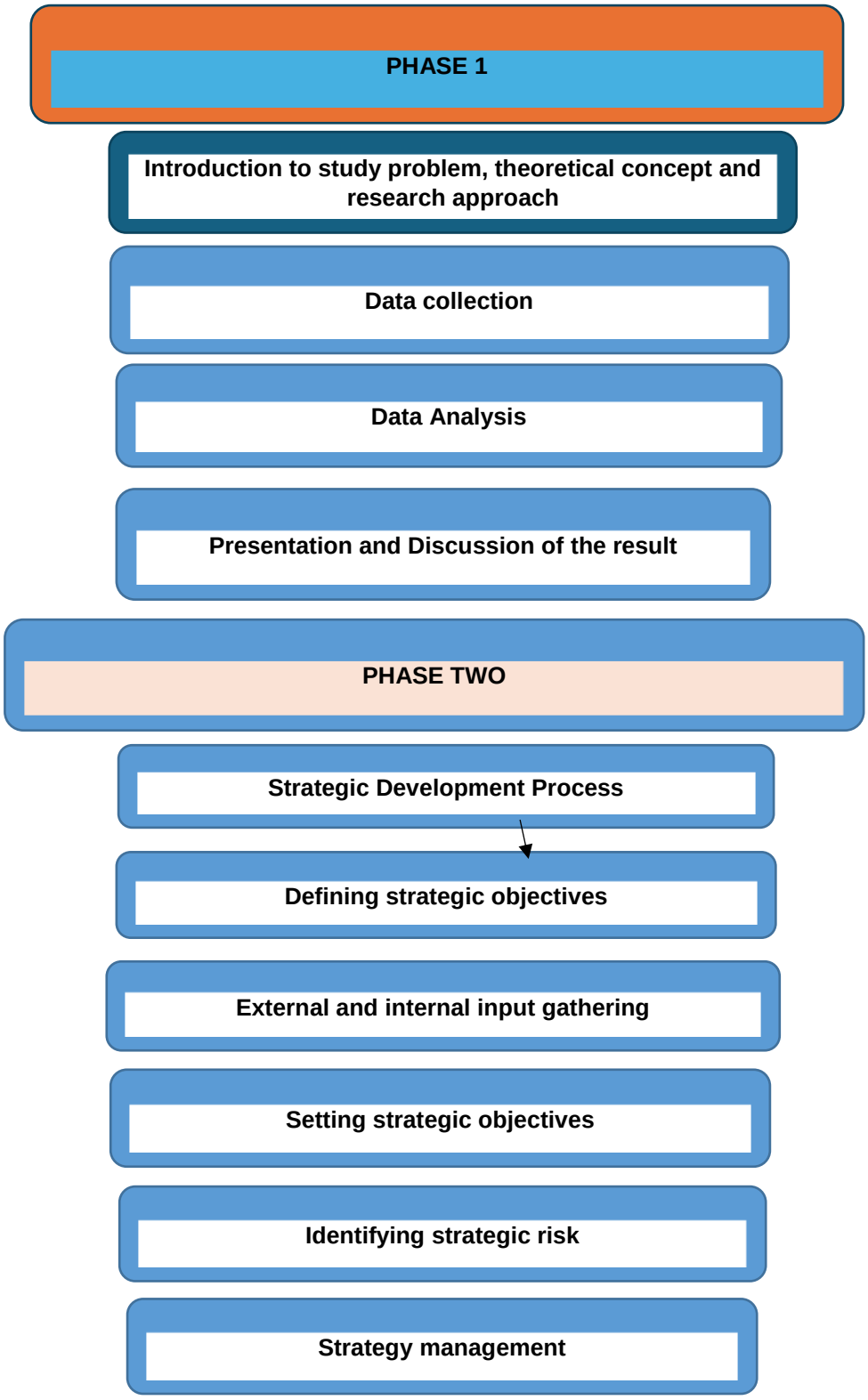

Figure 1. 2 Summary flow of study phase

1.13. Summary of study phases

The study phases consisted of introduction of study theoretical concepts, study approach, data collection, analysis and discussion of the results. Phase two consisted of defining the strategic objectives, input gathering, setting strategic objectives, identifying strategic risk, and strategic management and conclusion. The detailed information is presented in chapter 3.

1.13.2 Phase one

Phase one is a foundational analysis, focused on establishing a comprehensive understanding of the research problem. This involved a systematic process of data acquisition, rigorous analysis, and insightful interpretation to create a robust evidence base for subsequent strategic development.

1.13.3 Data collection

Data collection methods included a review of existing literature, policies, and frameworks, alongside primary data collection utilizing quantitative methods such as checklists for retrospective diagnostic test data and questionnaires administered to diagnostic experts and health officials.

1.13.4. Data analysis

The collected data underwent quantitative analysis employing statistical techniques (descriptive statistics, inferential analysis and trend identification) and software tools (SPSS Version 29, Excel). The findings were summarized using visual aids and descriptive statistics to characterize the sample and evaluate access to TB diagnostics, including spatial accessibility assessed via Global Moran's I statistic.

1.13.5. Presentation and Discussion of the result

The discussion of results highlighted key trends, challenges, and opportunities, contextualizing these findings within existing literature to identify consistencies, gaps, and novel contributions, ultimately informing the strategic direction for phase two.

1.13.6. Phase Two

Phase two constitutes a foundational stage dedicated to strategic development. This phase involves defining strategic objectives, gathering internal and external inputs, and establishing a vision statement. It further focuses on creating performance measures, while also identifying strategic risks and corresponding management protocols

1.13.7. Strategy development process

Strategic framework development was built upon the empirical findings of the initial phase to formulate an evidence-based strategy aimed at addressing identified challenges and enhancing TB diagnostic outcomes.

1.13.8. Defining strategy objectives

This phase employed a structured approach involving the definition of clear and measurable strategic objectives aligned with policy and stakeholder needs.

1.13.9. External internal input gathering

External and internal input was gathered through questionnaires distributed to a panel of experts using the Delphi technique.

1.13.10. Setting vision statement

The strategy development process encompassed formulating a vision statement and developing a detailed action plan with interventions and timelines.

1.13.11. Creating strategic objectives

Establishing specific strategic objectives (improving access, enhancing accuracy and speed, strengthening the network, building capacity, improving infrastructure and coordination, exploring new approaches).

1.13.12. Setting strategic performance measure

Setting strategic performance measures with clear metrics, identifying potential strategic initiatives and priorities.

1.13.13. Identifying strategic risks

Analysing internal and external strategic risks.

1.13.14. Setting strategy Management

Establishing a framework for strategy management with defined roles, responsibilities, and a communication plan. Detailed information on strategy development has been presented in chapter 3 of this study.

1.13.15. Conclusion

The study effectively progressed from an initial exploratory analysis in Phase One to the development of a practical and evidence-driven strategic framework in Phase Two. This sequential design ensured that the strategic recommendations for improving TB diagnostics services were grounded in a thorough understanding of the existing landscape, thereby enhancing the potential for effective implementation and improved beneficiary outcomes.

1.14 Structure of the thesis

The content of thesis is organized into nine interrelated chapters. These chapters are described below.

Chapter 1: Introduction and orientation to the study.
Chapter 2: Literature review.
Chapter 3: Research design and methods.
Chapter 4: Analysis, presentation and description of findings.
Chapter 5: Discussion of the research findings.
Chapter 6: Development of strategies.
Chapter 7: Final strategies.
Chapter 8: Strategic Management, Measuring Performance and Mitigating Risk.
Chapter 9: Conclusion and recommendations.

1.15 Conclusion

Chapter 1 delineated the contextual framework within which the investigation was undertaken. The background section provided a comprehensive overview of Tuberculosis (TB) and the TB diagnostic framework in Ethiopia, with a specific focus on the Oromia region. Furthermore, the research problem, objectives, and the significance of the study, along with the research design and methodologies employed, were elucidated. A compilation of terms that are pivotal for the understanding of subsequent chapters was also presented. The following chapter is devoted to a literature review, wherein an extensive examination of the pertinent literature regarding TB diagnostics is articulated.

CHAPTER 2

2. LITERATURE REVIEW

2.1 Introduction

This chapter provides a review of the literature on the accessibility, use, and determinants of tuberculosis utilisation of confirmatory and supportive diagnostics, as well as the use of tuberculosis diagnostic monitoring and evaluation for decision-making in Ethiopia. In this chapter, the concept and detailed description of TB diagnostics are discussed, as are the current and existing TB diagnostic availability, accessibility, utilisation, and determinants of the use of monitoring and evaluation in the TB diagnostics system for decision-making. For this purpose, the review was based on books, research journals, policies, and guidelines from electronic searches such as Sabinet, Academic Premier, PubMed, Unisa, libraries, and World Health Organization recommendations. The literature review will also help contextualize the problem as stated in this study.

2.2 Literature review

A literature review is a form of research that uses remaining literature to generate new knowledge on a specific topic. It involves analysing and summarizing related literature to identify key themes, trends, and gaps in knowledge. Literature reviews can serve various purposes, including providing an outline of existing research, identifying research questions, and informing decision-making processes. They can be conducted using different methods, such as integrative literature reviews, which use existing literature to create new knowledge (Torraco 2016:62). Integrative literature reviews aim to provide unity and coherence to the review by aligning the methods with their purpose (Konno 2020:256)

2.3 Introduction to Tuberculosis

Mycobacterium tuberculosis complex, a rod-shaped acid-fast bacillus, is the bacterium that causes tuberculosis (TB). The Mycobacterium complex is made up of M. tuberculosis (MTB) and other mycobacterial species that are known to cause TB disease in people and are closely related to them (M. bovis, M. africanum, M. microti, M. caprae, and M. canetti) (Federal Democratic Republic of Ethiopia Ministry of Health 2021:7).

Tuberculosis (TB) is an infectious disease caused by *Mycobacterium tuberculosis*, primarily affecting the lungs but capable of spreading to other organs (WHO, 2023). *M.tuberculosis* is carried in 1–5-micron airborne particles called droplet nuclei in circumferences when people with pulmonary or laryngeal tuberculosis cough, sneeze, shout, sing, infectious droplet nuclei are produced. These tiny particles can remain suspended in the air for several hours based on the environment. M. tuberculosis is spread through the air, and transmission occurs when a person inhales M. tuberculosis-containing droplet nuclei, which travel through the nasal passages and reach the papillae (Federal Democratic Republic of Ethiopia Ministry of Health 2021; (*MOHE 2021:18).*

The bacteria usually attack the lungs (pulmonary tuberculosis), but TB bacteria can attack any part of the body. Not every person who contracts the TB bacteria gets ill. As a result, there are two ailments connected to TB, TB illness and latent TB infection (LTBI), (MOHE 2021:18). TB can be classified as either latent or active; latent TB occurs when the bacteria remains dormant without causing symptoms, whereas active TB manifests with clinical signs such as persistent cough, weight loss, fever, and night sweats (Dheda et al., 2017).

Despite being preventable and curable, TB remains a leading cause of mortality worldwide, particularly in regions with high HIV prevalence, as co-infection exacerbates disease progression (WHO,2023). Effective TB control measures include

early diagnosis, adherence to treatment regimens, and vaccination with the Bacillus Calmette-Guérin (BCG) vaccine (Pai, Schito, & Migliori, 2016).

2.3.1 Overview of Tuberculosis as a Global Health Issue

Tuberculosis (TB) continues as a critical global health challenge, characterized by extensive prevalence and significant morbidity and mortality. World Health Organization (WHO) data from 2024 indicated that there are approximately 10.7 million new cases and 1.25 million deaths annually, disproportionately affecting low- and middle-income countries (WHO, 2025). The infectious nature of Mycobacterium tuberculosis, primarily impacting the lungs but with the potential for extrapulmonary manifestation, contributes to its global burden (WHO, 2025). The ongoing public health crisis of multidrug-resistant TB (MDR-TB), with limited treatment access, further exacerbates the challenge (WHO, 2025). Socioeconomic determinants, including poverty and limited healthcare access, are significant factors in the transmission and impact of TB (Yang et al., 2024), with stigma and misconceptions also hindering timely diagnosis and treatment adherence (WHO, 2023).

Despite substantial global efforts that have saved an estimated 79 million lives since 2000 (WHO, 2025), achieving the Sustainable Development Goal (SDG) target of ending the TB epidemic by 2030 necessitates sustained and enhanced public health interventions requiring an estimated annual investment of US$ 22 billion (WHO, 2025). To overcome diagnostic and treatment complexities, including drug resistance, and to improve global health outcomes, a thorough and cooperative approach that integrates ethical considerations and addresses the disease's multifaceted nature is still necessary (Dhawan, de Almeida, Adchitre, Salve and Mahajan, 2024).

2.3.2 Epidemiology and Impact of Tuberculosis

Tuberculosis (TB), caused by *the Mycobacterium tuberculosis*, remains a significant global health challenge with a widespread epidemiological impact. In 2023, approximately 10.8 million individuals worldwide were projected to have contracted TB, affecting all demographic segments and nations globally (WHO, 2023; WHO 2025). This included 6.0 million males, 3.6 million females, and 1.3 million children, resulting in 1.25 million deaths, with 161,000 of these fatalities occurring among individuals co-infected with HIV (WHO, 2023; WHO 2025). It is estimated that around

one-quarter of the global population harbours a latent TB infection (WHO, 2023). While TB is curable and preventable, it persists as a leading cause of mortality from a single infectious agent (WHO 2025). The emergence and persistence of multidrug-resistant TB (MDR-TB) poses a critical public health dilemma and a substantial threat to health security, with limited treatment access for affected individuals (WHO, 2023; WHO 2025).

The impact of TB is particularly profound in low- and middle-income countries, where factors such as poverty, malnutrition, and limited access to healthcare exacerbate its spread and consequences (Yang, Li and Wang, 2024). The socioeconomic ramifications are significant, affecting individuals' capacity to work and sustain their families, thereby contributing to cycles of poverty (Yang et al., 2024). Furthermore, TB can lead to severe long-term health consequences, including permanent lung damage and other organ complications (Chauhan, 2024). The development of extensive drug-resistant TB (XDR-TB) presents additional complexities in treatment (Chauhan, 2024). The COVID-19 pandemic has further strained TB control efforts, underscoring the necessity for sustained and intensified public health interventions (Yang et al., 2024). Achieving the United Nations Sustainable Development Goal (SDG) target of ending the TB epidemic by 2030 necessitates substantial financial investment, estimated at US$ 22 billion annually, dedicated to TB prevention, diagnosis, treatment, and care (WHO 2025). In summation, TB remains a critical global health issue characterized by its extensive prevalence, high mortality rate, and the persistent challenges posed by drug-resistant strains, demanding continued global efforts and significant financial commitment to achieve elimination goals.

2.4 Historical and Evolving Approaches to Tuberculosis Diagnosis

The diagnosis of tuberculosis (TB) has undergone a significant evolution, moving from ancient clinical observations to modern molecular techniques, reflecting the disease’s persistent global health challenge. Early diagnosis relied heavily on clinical signs and skeletal modifications, particularly in paleopathology, where Pott’s disease was identified through skeletal analysis (Papa, Smith, Jones and van Zyl, 2023). In historical contexts, retrospective diagnostic approaches using well-structured scoring

systems have demonstrated reliability, enhancing accuracy in diagnosing historical cases (Krüger, 2024).

As laboratory methods advanced, smear microscopy and culture became cornerstones of TB diagnosis. While effective, these traditional techniques were time-consuming and often lacked sensitivity (Zaporojan, Schmidt, Nkosi and Tanaka, 2024; Mugenyi, Nakiwala, Ssemambo and Tumwesigye, 2023). The introduction of liquid culture systems improved both speed and sensitivity compared to solid media (Zaporojan et al., 2024).

A pivotal shift occurred with the advent of molecular diagnostics, such as Xpert MTB/RIF and line probe assays (LPA), enabling rapid identification of Mycobacterium tuberculosis and detection of drug-resistant strains, thus facilitating timely treatment decisions (Moorthy, Bansal, Rajesh and Kumar, 2022; Mugenyi et al., 2024). Advances in nucleic acid extraction techniques have further enhanced the reliability of these molecular tests (Goyani and Mukhopadhyaya, 2023).

In paleopathology, ancient DNA analysis and lipid biomarkers have emerged as valuable tools for diagnosing TB in historical contexts, underscoring the disease's long-standing impact on human health (Papa et al., 2023). Overall, the integration of diverse methodologies from skeletal analysis and clinical scoring to culture, molecular assays, and ancient biomarkers highlights the complexity and ongoing evolution of TB diagnostics, which is crucial for improving TB detection and management globally (Zaporojan et al., 2024; Mugenyi et al., 2024).

2.5 Current Challenges in Tuberculosis Diagnosis

Timely and accurate TB diagnosis is hindered by several persistent challenges. First, latent tuberculosis infection (LTBI) is asymptomatic, and existing tests (tuberculin skin test, interferon-gamma release assays) have limitations including false positives in BCG-vaccinated populations and false negatives in immunocompromised individuals (Chin et al., 2023). Second, multidrug-resistant TB (MDR-TB) complicates diagnosis because conventional methods often fail to identify resistance patterns beyond rifampicin and isoniazid (Kadiri et al., 2024). Third, paediatric TB remains difficult to diagnose due to pauci bacillary samples and challenges obtaining respiratory

specimens (Khurana & Dhingra, 2023). Fourth, while advanced molecular techniques improve accuracy, their accessibility and affordability in low-resource settings remain major barriers (Huang et al., 2022). These challenges collectively underscore the need for innovative, cost-effective, and context-appropriate diagnostic solutions.

2.6 Key Milestones in Tuberculosis Diagnostic System Development

The development of tuberculosis (TB) diagnostic systems has seen significant milestones aimed at improving accuracy, speed, and accessibility. The introduction of the Xpert MTB/RIF assay marked a pivotal advancement as the first rapid molecular test, yet challenges remain, particularly in detecting drug-resistant strains and diagnosing extra pulmonary TB (Walzl et al., 2018) (Denkinger & Pai, 2017). Recent innovations include an integrated microfluidic system capable of detecting live Mycobacterium tuberculosis within 90 minutes, enhancing point-of-care diagnostics (Lee & Dou, 2022). Additionally, novel diagnostic methods utilizing molecular beacons for simultaneous detection of genetic fragments and drug resistance mutations have emerged, demonstrating high sensitivity and specificity (Huang et al., 2017). Despite these advancements, the need for further investment in biomarker discovery and the development of non-sputum-based tests, especially for vulnerable populations, remains critical to achieving comprehensive TB control (Walzl et al., 2018; Denkinger & Pai, 2017).

2.7 Existing Tuberculosis Diagnostic Technologies

Existing tuberculosis (TB) diagnostic technologies encompass a range of innovative methods aimed at improving detection, particularly for multidrug-resistant strains. Current approaches include classical microbiological techniques, such as microscopy and culture methods, alongside advanced molecular genetic tests like GeneXpert and multiplex PCR, which enhance diagnostic accuracy and speed (Zhurilo, Smirnova, Petrov & Ivanov, 2022). Emerging technologies, particularly those utilizing omics approaches, are being explored for their potential to identify biomarkers and improve understanding of TB pathogenesis (Bespyatykh & Basmanov, 2022). Additionally, non-invasive, point-of-care tests are under development, focusing on populations that struggle with sputum production, such as those with HIV (Abdulgader, Maphanga, Moolla & Kaba, 2022). However, many of these new technologies face challenges in achieving the World Health Organization's target product profile, highlighting the need

for further research and optimization (Abdulgader et al., 2022; Halliday et al., 2021). Overall, while advancements are promising, the integration of these technologies into clinical practice remains a critical hurdle (Patil & Vijaykumar, 2024; Halliday et al., 2021).

2.8 Overview of Current TB Diagnostic Tools

Accurate and timely diagnosis is paramount for effective tuberculosis (TB) treatment and control, necessitating the utilisation of a range of diagnostic tools, each with specific advantages and limitations. Traditional methods include:

1 Sputum smear microscopy, a widely employed but less sensitive technique (49.8% for infiltrative TB) for detecting acid-fast bacilli, and sputum culture, considered the gold standard due to its higher sensitivity and ability to detect drug resistance, albeit with a longer turnaround time (Lapteva et al., 2023; Pai et al., 2023).

2 The Tuberculin Skin Test (TST), or Mantoux test, assesses the immune response to tuberculin purified protein derivative (PPD) but can yield false positives in BCG-vaccinated individuals (CDC, 2024).

3. Interferon-Gamma Release Assays (IGRAs) offer greater specificity by measuring interferon-gamma release in response to TB antigens and are unaffected by BCG vaccination (CDC, 2024).
4. Advanced molecular techniques, particularly Nucleic Acid Amplification Tests (NAATs) such as the Xpert MTB/RIF assay, have significantly improved diagnostic capabilities by detecting TB DNA and identifying rifampicin resistance within hours, exhibiting high sensitivity (up to 94.7%) and specificity (93.9%) (Lapteva et al., 2023; Lugmania & Asimbaya-Alvarado, 2024; Pai et al., 2023).
5. Urine Lipoarabinomannan (LAM) tests offer a rapid point-of-care diagnostic, particularly useful for HIV-positive individuals with low CD4 counts, although with lower sensitivity compared to other methods (Pai et al., 2023). Saliva has also emerged as a potential non-invasive diagnostic medium, demonstrating promising positivity rates in culture, which could simplify sample collection (Lodhi, Khan, Abbas and Ahmed, 2023). Furthermore, emerging CRISPR-based diagnostics hold the potential to further enhance TB detection through increased sensitivity and reduced turnaround times (Qi, Wang, Zhao and Wang, 2022).

6. Chest X-rays serve as a supplementary imaging technique to identify lung abnormalities suggestive of TB (CDC, 2024). Despite the availability of these diverse tools, challenges persist in ensuring accessible, affordable, and effective TB diagnosis, particularly in resource-limited settings, highlighting the ongoing need for innovative diagnostic solutions (Pai et al., 2023).

2.9 Strengths and Limitations of Current Diagnostic Techniques

Current tuberculosis (TB) diagnostic techniques exhibit both strengths and limitations. Conventional methods, such as sputum smear microscopy and tuberculin skin tests, often suffer from low sensitivity and specificity, particularly in immunocompromised populations like those with HIV, leading to delayed diagnoses (Sun, Li, Zhang and Chen, 2023) ("Tuberculosis Diagnosis: Updates and Challenges", 2022). Molecular techniques, including GeneXpert and loop-mediated isothermal amplification (LAMP), enhance rapid detection and can identify drug resistance, yet they remain costly and may not be widely accessible (Abdulgader et al., 2022). Emerging technologies, such as Nano diagnostics and CRISPR-based assays, promise improved accuracy and point-of-care applications, but their implementation is hindered by resource constraints and the need for further validation (Perveen & Sharma, 2023) (Abdulgader et al., 2022). Additionally, challenges persist in diagnosing extra pulmonary TB and differentiating active infections from latent ones, underscoring the necessity for a multi-faceted diagnostic approach that combines various methodologies to optimize patient outcomes (Huang et al., 2022).

2.10 Molecular and Emerging Diagnostic Technologies for Tuberculosis

The past decade has witnessed transformative advances in TB diagnostics, moving from microscopy and culture toward molecular and digital technologies. Among these, the Xpert MTB/RIF and Xpert MTB/RIF Ultra assays (Cepheid, Sunnyvale, CA) represent the most widely implemented molecular point-of-care tests. Xpert Ultra demonstrates sensitivity of 94.7% for smear-positive and 70-80% for smear-negative pulmonary TB, with specificity exceeding 98% (Yadav et al., 2024). However, critical appraisal reveals important limitations: cartridge costs remain $9.98-15.00 per test, instrument maintenance is challenging in peripheral Ethiopian laboratories, and a 2022

multi-country study found that 14% of Xpert machines in high-burden countries were non-functional at any given time (WHO, 2023).

Polymerase chain reaction (PCR) -based assays, including line probe assays (LPA), target genetic sequences such as IS6110 and mtp40 for both detection and drug resistance identification. While PCR offers faster turnaround than culture (2-5 days vs. 4-8 weeks), studies report variable sensitivity (71-89%) depending on sample type and bacillary load (Hemeg et al., 2023). Next-generation sequencing (NGS) provides comprehensive mutation profiling for drug resistance but requires substantial infrastructure and bioinformatics expertise, limiting its current utility to reference laboratories (Liang & Tang, 2023).

Emerging optical and electrochemical devices offer potential for true point-of-care testing. Photonic micro-ring sensors and microfluidic platforms have demonstrated sensitivity down to 10 CFU/mL in sputum samples under laboratory conditions (Chauke et al., 2023). An amperometric urine biosensor using aptamer-antibody capture has been developed for use without professional assistance, though clinical validation studies remain limited (Delgrange et al., 2023). The diagnostic gap evident in this literature is the scarcity of prospective field evaluations in peripheral health facilities—most studies report analytical sensitivity rather than real-world clinical utility.

CRISPR-based diagnostics (e.g., SHERLOCK, DETECTR) represent a newer frontier, achieving attomolar sensitivity in proof-of-concept studies (Qi et al., 2022). However, no CRISPR-based TB test has yet received WHO prequalification, and cost-effectiveness analyses for low-resource settings are absent.

While the technical performance of these emerging technologies is well-documented, the literature suffers from three biases: (1) publication bias favoring positive results, (2) a near-exclusive focus on pulmonary over extrapulmonary TB, and (3) neglect of health system factors (workforce training, supply chains, quality assurance) that determine actual diagnostic utilisation. This study addresses the third gap by examining determinants of utilisation in Ethiopia**.**

*2.11 Point-of-Care Testing for Tuberculosis

Point-of-care (PoC) testing for tuberculosis (TB) has gained significant attention due to its potential to enhance diagnostic accessibility, particularly in resource-limited settings. Various innovative approaches have emerged, focusing on rapid and accurate detection methods that can be deployed outside traditional laboratory environments (WHO,2020).

2.12 Serum Protein-Based Diagnostics

Recent studies have identified specific serum proteins as promising biomarkers for active TB diagnosis. For instance, proteins like SULT4A1 and WASPF3 demonstrated over 70% diagnostic performance in distinguishing active TB from community-acquired pneumonia. The combination of multiple proteins further improved diagnostic accuracy, achieving up to 81% performance in cross-validation tests (Essone, Mbazoa, Loemba & Dagnra, 2024).

2.13 Optical and Electrochemical Devices

Optical-based devices, including photonic sensors and microfluidic platforms, have shown high sensitivity and specificity for TB detection in sputum samples (Chauke, Mthiyane, Bester and Dlamini, 2023). Additionally, an amperometric urine biosensor utilizing aptamer-antibody assays has been developed, allowing for sensitive TB detection in urine without professional assistance, making it suitable for use in underdeveloped regions (Delgrange, Kruger, Fernández and Santos, 2023).

2.14 Multiplexed Testing Technologies

Innovative multiplex diagnostic technologies have also been created to detect both TB and HIV co-infections simultaneously. These colorimetric assays have demonstrated high specificity and sensitivity, indicating their potential for PoC applications (Malatji, Mboweni, Serero & Moloi, 2023). Furthermore, a smartphone-based microfluidic

device employing loop-mediated isothermal amplification (LAMP) offers a low-cost solution for multiplexed gene detection of M.tb (Tavakoli, 2023).

While these advancements in PoC testing for TB are promising, challenges remain in ensuring widespread implementation and accessibility, particularly in the most affected regions. Continued research and development are essential to address these barriers and improve global TB management.

2.15 Emerging technologies in tuberculosis

Emerging technologies in tuberculosis (TB) diagnosis are revolutionizing the field by enhancing accuracy, speed, and accessibility. Traditional methods, while effective, often face challenges such as variability in sensitivity and lengthy turnaround times. Recent advancements, particularly in artificial intelligence (AI) and molecular diagnostics, are addressing these issues and paving the way for improved TB management. AI technologies, including machine learning and deep learning, automate the analysis of chest X-rays and genomic data, significantly improving diagnostic accuracy (Yadav et al., 2024). These systems can expedite treatment initiation and personalize medicine approaches, although challenges related to data quality and ethical considerations remain (Yadav et al., 2024).

2.16 Molecular Diagnostic Techniques

The Xpert MTB/RIF Ultra system represents a significant advancement, offering rapid and accurate identification of Mycobacterium tuberculosis and rifampicin resistance (Yadav et al., 2024). Molecular tests like LPA and Xpert MTB/RIF enhance sensitivity and specificity, crucial for diagnosing multidrug-resistant TB (Zaporojan et al., 2024) (Zaporojan et al., 2023).

2.17 Challenges in Tuberculosis Diagnosis

The diagnosis of tuberculosis (TB) faces numerous challenges that hinder timely detection and treatment, significantly impacting public health. Key issues include the accessibility of diagnostic tools, the emergence of drug-resistant strains, and the complexities involved in diagnosing latent TB. These challenges necessitate innovative solutions and improved strategies for effective TB management (Kadiri et al., 2024).

2.17.1 Accessibility and Affordability

Many individuals with TB remain undiagnosed due to socioeconomic barriers, including lack of access to healthcare facilities and financial constraints (Kadiri et al., 2024). Diagnostic methods, such as solid- and liquid-based cultures, are often limited in resource-poor settings, delaying treatment initiation (Naidoo, Pillay, Govender and Reddy, 2023).

2.17.2 Drug Resistance

The rise of multidrug-resistant TB (MDR-TB) complicates diagnosis and treatment, as existing tests may not effectively identify resistance patterns (Chin et al., 2023). Rapid diagnostic tests are available but often lack comprehensive coverage for newer drugs, necessitating a return to traditional culture methods (Naidoo et al., 2023).

2.17.3 Paediatric Challenges

Diagnosing TB in children is particularly difficult due to the paucibacillary nature of the disease and challenges in obtaining suitable samples (Khurana & Dhingra, 2023). Current screening tests, such as the tuberculin skin test, have limitations, including false positives and negatives, complicating accurate diagnosis (Chin et al., 2023). Despite these challenges, advancements in optical-based diagnostic devices and point-of-care testing offer promising avenues for improving TB detection and management (Chauke et al., 2023). However, the ongoing issues of drug resistance and accessibility remain critical hurdles that require sustained attention and innovative solutions.

2.17.4 Delayed or Missed Diagnosis

The delayed or missed diagnosis of tuberculosis (TB) is a critical public health issue that exacerbates the spread of the disease and complicates treatment outcomes. Various studies highlight significant factors contributing to diagnostic delays, including patient awareness, health system inefficiencies, and socio-economic barriers. Understanding these factors is essential for developing effective interventions to enhance TB diagnosis and treatment (limo&Onyango,2024).

2.17.5 Key Factors Contributing to Delayed Diagnosis

Patient Awareness and Education: Low awareness of TB symptoms leads to prolonged patient delays. For instance, a study in Mombasa found that patients with extra pulmonary TB experienced an average diagnostic delay of 81 days due to insufficient knowledge (Limo & Onyango, 2024).

2.17.6 Health System Inefficiencies

Long turnaround times for laboratory results and multiple healthcare visits significantly contribute to delays. In Tharaka Nithi County, 70.86% of patients reported delays, with factors like cash payment and far diagnostic centres being significant barriers (Kithinji, Kinyua & Mbabu, 2024). Demographic Influences: Age and gender also play roles; older patients and those in peri-urban areas face longer delays (Longo et al., 2023; Vigneswaran et al., 2023).

2.17.7 Implications of Delayed Diagnosis

Delayed TB diagnosis not only increases morbidity but also heightens transmission risks within communities. The median total delay reported in various studies ranges from 40 to 90 days, underscoring the urgent need for improved awareness and health system responsiveness (Regmi et al., 2023; Vigneswaran et al., 2023).

2.18 Quality Assurance in Tuberculosis Diagnostics

Quality assurance in tuberculosis (TB) diagnostics is critical for accurate detection and treatment, with various methods and practices currently in use. In Ethiopia, a study revealed that while 79.4% of Xpert® MTB/RIF testing laboratories participated in external quality assessment proficiency testing, significant gaps existed in internal quality control practices, such as lot-to-lot verification and method validation (Abebaw, Moges, Tarekegn and Gebreyes, 2022). Additionally, the development of a heterogeneous quality control library for the Xpert MTB/RIF assay has emerged as a promising solution to enhance biosafety and efficiency in quality control processes (Guan, Li, Wang and Zhao, 2023). Furthermore, the implementation of structured quality management systems, like the TB SLMTA program, has shown potential in improving laboratory practices and achieving accreditation, thereby enhancing diagnostic reliability (Albert, Nathavitharana, Isaacs, Pai & Denkinger, 2017). Despite advancements, challenges remain, particularly in differentiating active TB from latent infections and ensuring the sensitivity and specificity of diagnostic methods (Huang et al., 2022). Overall, ongoing efforts to refine quality assurance practices are essential for improving TB diagnostic outcomes globally (Anuradha et al., 2013).

2.18.1 Importance of Quality Control and Quality Assurance Measures

Quality control (QC) and quality assurance (QA) measures are critical in tuberculosis (TB) diagnostics to ensure accurate and reliable test results, which are essential for effective patient management and public health interventions. The implementation of robust QA systems, such as proficiency testing and internal quality controls, helps identify and rectify laboratory errors that could lead to missed diagnoses, thereby reducing morbidity and mortality associated with TB (Dhawan, 2023; Estran, 2023). For instance, studies have shown that many laboratories lack adequate QC practices, such as lot-to-lot verification and method validation, which are vital for maintaining the integrity of diagnostic results (Abebaw et al., 2022; Nakitare & Mutharia, 2022).

Furthermore, innovative approaches, like the development of a heterogeneous quality control library for the Xpert MTB/RIF assay, have been proposed to mitigate biosafety risks while enhancing the monitoring of diagnostic accuracy (Guan et al., 2023).

Overall, effective QA and QC measures not only improve diagnostic capacity but also support the broader goal of TB control and elimination efforts globally (Dhawan, 2023; Estran, 2023).

2.18.2 International Standards of quality control system for Tuberculosis Diagnostic Testing

The International Standards for Tuberculosis Care (ISTC) establish a framework for high-quality tuberculosis (TB) diagnostic testing and management, emphasizing the need for uniformity in care across various healthcare settings. Initially published in 2006 and updated subsequently, the ISTC aims to engage all healthcare providers, particularly in low- and middle-income countries, to ensure effective TB diagnosis and treatment (WHO, 2021; Pai et al., 2023) The standards encompass 21 key areas, including rapid molecular diagnostics, which significantly enhance the speed and accuracy of TB detection, particularly for drug-resistant strains (WHO, 2021; Pai et al., 2023). In India, the adaptation of these standards has led to the formulation of specific guidelines that incorporate social inclusion and public health strategies, addressing the diverse needs of TB patients (Pai et al., 2023). However, adherence to these standards remains a challenge, especially in the private sector, where deviations from recommended practices are common (pai et al., 2023). Overall, the ISTC serves as a vital resource for improving TB care globally, promoting collaboration among healthcare providers to achieve universal access to quality diagnostics and treatment (Pai et al., 2023).

2.18.3 Role of artificial intelligence and machine learning in TB diagnosis.

The integration of Artificial Intelligence (AI) and Machine Learning (ML) in tuberculosis (TB) diagnosis is revolutionizing the field by enhancing accuracy, efficiency, and accessibility. These technologies address traditional diagnostic challenges, such as variability in sensitivity and lengthy turnaround times, by automating the analysis of various diagnostic data. The following sections outline the key roles AI and ML play in TB diagnosis (Chen & Yuan, 2024; Ito-Fujita & Katz, 2023).

2.18.4 Applications of AI in Tuberculosis Diagnosis

AI algorithms improve the interpretation of chest X-rays, enabling early detection of TB lesions with higher accuracy (Arora, Joshi, Mehta and Singh, 2024). Automated microscopy systems, like TB-Scan, have shown a 95% accuracy rate in identifying acid-fast bacilli (AFB), significantly outperforming manual methods (Chen & Yuan, 2024). AI facilitates the automation of screening processes, allowing for rapid and efficient TB program management (Arora et al., 2024).

The use of AI in image analysis and classification techniques reduces the labour-intensive nature of traditional diagnostic methods (Ito-Fujita & Katz, 2023). While AI and ML present significant advancements in TB diagnosis, challenges such as data quality, integration into existing healthcare systems, and ethical considerations remain critical for successful implementation.

2.18.5 Impact of Machine Learning Algorithms on TB Diagnostic Accuracy

The integration of machine learning (ML) algorithms into tuberculosis (TB) diagnostics has significantly enhanced diagnostic accuracy, addressing traditional challenges such as sensitivity variability and lengthy turnaround times. These advancements leverage various data types, including imaging and biomarker profiles, to improve early detection and treatment outcomes (Parreira, Santos, Silva and Costa, 2024).

Machine learning models, such as Random Forest and ResNet-50, have demonstrated high sensitivity (up to 99.4%) and specificity (up to 99.7%) in detecting TB from chest X-rays (Parreira et al., 2024). A study identified a nine-biomarker signature using ML that achieved an area under the receiver operating characteristic curve (AUROC) of 0.89 to 0.99, indicating robust diagnostic capabilities (Yao et al., 2024). The XmarTB tool exemplifies this automation, providing rapid and accurate TB detection, which is crucial for timely intervention (Parreira et al., 2024).

2.19 Community Engagement And Tuberculosis Diagnosis

Community engagement plays a crucial role in enhancing tuberculosis (TB) diagnosis and treatment, particularly in low- and middle-income countries. By involving community health workers (CHWs), private pharmacies, and local advisory groups, health systems can improve access to TB services, increase case detection, and foster supportive environments for patients. The following sections outline key aspects of community engagement in TB diagnosis (Semakula, Nalugwa, Nantongo and Jobba, 2024).

Community health workers significantly contribute to TB case notification, with studies showing varied timeframes for treatment initiation based on the referral source (Semakula et al., 2024). Engaging these local resources can reduce the time from symptom recognition to treatment, thereby limiting community transmission (Semakula et al., 2024).

2.19.1 Importance of Community Involvement in Tuberculosis Detection

Community involvement plays a crucial role in enhancing tuberculosis (TB) detection and management. Engaging local stakeholders not only facilitates early identification of cases but also strengthens health systems and fosters a supportive environment for affected individuals. The following sections outline the key aspects of community involvement in TB detection (Ahmed & Dadlani, 2023).

2.19.2 Strategies for Engaging Communities in Tuberculosis Diagnosis

Active Case Finding (ACF): ACF strategies, such as door-to-door screening, have proven effective in identifying TB cases, particularly in low-resource settings (Taylor, Miller, Johnson and van Rensburg, 2024). Household Contact Screening: Studies show that screening household contacts significantly increases case detection rates, with a notable prevalence of drug-susceptible TB identified through community engagement (Ahmed & Dadlani, 2023).

2.20 Policy and Regulatory Considerations

The policy and regulatory considerations in tuberculosis (TB) diagnosis are critical for ensuring effective implementation of diagnostic tools and safeguarding public health. These considerations encompass the need for robust regulatory frameworks, adherence to safety standards, and the facilitation of timely access to innovative diagnostic technologies. The following sections outline key aspects of this consideration (Toktonalieva & Toktonaliev, 2023).

2.20.1 Global Initiatives and Policies Affecting Tuberculosis Diagnosis

The global initiatives and policies affecting tuberculosis (TB) diagnosis are multifaceted, focusing on improving accessibility, affordability, and the implementation of effective diagnostic tools. These efforts are crucial in addressing the ongoing TB crisis, particularly in low- and middle-income countries where the burden is highest. The following sections outline key aspects of these initiatives. The World Health Organization (WHO) has set ambitious targets to "END TB" by 2030, emphasizing early diagnosis and innovative treatments (Kadiri et al., 2024).

Many countries lag in adopting WHO recommendations, with only about half implementing rapid diagnostic tests like Xpert MTB/RIF (Saran, Balaji, Kumar and Sharma, 2019). Advances in molecular diagnostics and artificial intelligence are being

explored to enhance TB detection and management (Dhawan et al., 2024). New drugs and treatment regimens are in development, but their adoption remains inconsistent across high-burden countries (Saran et al., 2019). Collaborative efforts, partnerships and resources are vital for improving TB diagnostics, particularly in paediatric care (Kasznia-Brown, 2023). A unified approach among governments, NGOs, and international bodies is essential for effective policy implementation and resource sharing (Dhawan et al., 2024).

2.20.2 Regulatory Framework for Tuberculosis Diagnostic Tools

A strong regulatory framework is essential for the circulation of high-quality anti-tuberculosis drugs and diagnostic tools, ensuring that patients receive effective treatments (Toktonalieva & Toktonaliev, 2023). In developing countries, regulatory oversight is often weak, allowing substandard products to enter the market, which can hinder TB control efforts (WHO, 2021). Policymakers must utilize data-driven models to assess the impact of new diagnostic tools, particularly in resource-limited settings, to make informed decisions about their deployment efforts (pai et al., 2024). The WHO has established guidelines for systematic TB screening, emphasizing the need for targeted approaches to reach high-risk populations (WHO, 2022).

2.21 TB diagnostic Services

Tuberculosis (TB) diagnostics have historically suffered from neglect in stagnant case detection and increasing drug resistance. However, significant progress has been made in the development of new diagnostic tools over the last decade, driven by concerns about drug resistance (WHO,2020). Modern molecular technologies have surpassed conventional microbiological methods for TB diagnosis and resistance detection (WHO,2021). A multi-view stereo approach utilizing calibrated cameras and image analysis has been proposed for creating an inventory of objects in lab automation for healthcare diagnostics (Albert et al., 2023). Additionally, a method using the Gaussian Mixture Model (GMM) algorithm and Markov Random Field (MRF) parameters has been suggested to support physicians in analysing TB sputum preparations based on digital microscopic images (WHO,2021). The challenge of TB diagnostics in India was addressed in a conference, emphasizing the necessity for coordination among stakeholders and innovations in delivery systems, partnerships, funding, regulatory mechanisms, and communication (Sharma & Rai, 2021)

Improved diagnostic techniques are urgently required for the detection of tuberculosis (TB) in Africa (WHO,2023). Although there have been advancements in TB diagnostics, many hospitals in Tanzania continue to rely on traditional diagnostic methods such as TB score charts, screening questions, acid-fast bacilli, and chest x-rays (WHO,2021). However, molecular tests such as Xpert MTB/RIF, loop-mediated isothermal amplification, and molecular line-probe assays have demonstrated notable progress (WHO,2023). Sonography has also been found to be an effective diagnostic tool for detecting Extra pulmonary TB (WHO 2021).

The FAST Plaque TB test, which is based on bacteriophage, has shown promise in detecting smear-negative TB cases (WHO,2023). Although the Xpert MTB/RIF assay holds great potential as a point-of-care test, the implementation of this test in resource-limited settings necessitates changes in budgets, staffing, and infrastructure. In high-burden settings, fine needle aspirate cytology has been found to be a practical tool that can improve the diagnosis of lymph node TB (WHO 2023).

2.22 Future directions in Tuberculosis diagnostics.

Future directions in tuberculosis (TB) diagnostics focus on enhancing accuracy, speed, and accessibility through innovative technologies and methodologies. The integration of molecular assays, advanced imaging techniques, and antigen-specific approaches is pivotal in addressing the challenges posed by drug-resistant strains and delayed diagnoses (Yadav et al., 2024).

2.23 Confirmatory TB Diagnostics

Confirmatory TB diagnostics and DST recommended by the World Health Organization (WHO) include nucleic acid amplification tests (NATs) and culture-based methods such as microscopic observation of drug susceptibility (MODS), thin-layer agar (TLA), and colorimetric redox-indicator (CRI) assays. These novel diagnostics have shown high sensitivity and specificity for detecting drug resistance, particularly for rifampicin and isoniazid, and have been useful in accurately detecting multidrug-resistant TB (MDR-TB) in various settings (Seki Kim, Hayakawa & Mitarai, 2018). However, the sensitivity of these tests for other drugs varies across reports, and more evidence is needed for the utility of TLA assays (WHO 2021). The WHO-endorsed assays, including Xpert® MTB/RIF and MTB/RIF Ultra assays, are recommended for

high-burden countries, but their scale-up is hindered by limited resources and infrastructure (WHO 2021). Regular proficiency testing has been shown to improve the quality of DST, and performance goals have been proposed for the Supranational Reference Laboratories Network (WHO 2021).

2.24 Xpert MTB/RIF Ultra Technology

The Xpert MTB/RIF Ultra system offers rapid identification of Mycobacterium tuberculosis and rifampicin resistance, enhancing patient outcomes (Yadav et al., 2024). It has shown high sensitivity and specificity, making it a critical tool in both pulmonary and extra pulmonary TB diagnosis (Yadav et al., 2024).

2.25 Optical-Based Devices

Emerging optical-based devices, such as photonic micro-ring sensors and microfluidics, provide rapid and portable TB detection with high sensitivity (Chauke, Mthiyane, Bester and Dlamini, 2023). These devices can detect low concentrations of target molecules, making them suitable for point-of-care applications (Chauke et al., 2023).

2.26 Serological Platforms

Research into recombinant proteins from Mycobacterium tuberculosis has led to the development of a novel ELISA platform, which shows promise for early TB detection (Ramalingam, Sharma, Chen & Li, 2023) Combination of specific antigens demonstrated a high reactivity rate in TB-positive samples, indicating potential for improved diagnostic sensitivity (Ramalingam et al., 2023). While these technologies present significant advancements, challenges such as cost, infrastructure, and the need for further validation in clinical settings persist. Addressing these issues is essential for the successful implementation of these innovative diagnostic tools in global TB control efforts.

2.27 Supportive TB Diagnostics

CXR, ultrasound, CT, and histopathology can all be used in the diagnosis of tuberculosis (TB) (Burrill, Williams & Bainbridge, 2022). Chest X-rays (CXR) are commonly used for initial evaluation, but their sensitivity is limited (WHO,2021). Ultrasound can be helpful in detecting biliary tract involvement and ductal dilatations (Heller et al., 2020). CT is more sensitive than CXR in detecting cavitation, lymphadenopathy, endo bronchial spread, and complications of TB (Heller et al., 2020) Computer-aided diagnosis (CADx) systems based on image processing, such as those using CXR, can assist doctors and radiologists in the early detection of TB. However, histopathologic diagnosis may still be required, especially in areas where TB is not endemic (WHO,2021).

2.27.1 Artificial Intelligence in Diagnosis

AI technologies, including machine learning and deep learning, automate the analysis of chest X-rays and genomic data, significantly improving diagnostic accuracy (Yadav et al., 2024). These systems can expedite treatment initiation and personalize medicine approaches, although challenges in data quality and ethical considerations remain (Yadav et al., 2024).

TB diagnostics in Ethiopia face several challenges. Non-adherence to national diagnostic guidelines is a major problem, leading to low detection of smear-positive cases and over-diagnosis of smear-negative cases (Mulugeta et al. 2025). The available diagnostic tests for extra pulmonary TB (EPTB) include histopathology, fine needle aspirate cytology (FNAC), and culture. Histopathology has high sensitivity and specificity, while FNAC has lower sensitivity but higher specificity (Kumbi et al. 2024). However, naked eye examination of FNAC has limited sensitivity and specificity (Biadglegne et al., 2021). The use of direct smear microscopy as the primary diagnostic method is common, but it is insensitive and can result in misdiagnosis (Datiko et al., 2020). Other diagnostic methods used include chest X-ray, tuberculin skin test (TST), and Quantiferon-TBGoldIn-Tube test (QFTGIT) (Gashu et al., 2023). There is a need for more affordable, sensitive, and specific diagnostic tools for TB in

resource-poor settings like Ethiopia. Overall, the diagnostic challenge of EPTB in Ethiopia highlights the need for improved TB control strategies (WHO,2023).

2.28 TB Diagnostic's physical accessibility

The availability and accessibility of TB diagnostics have improved in recent years with the development of new technologies and the endorsement of these technologies by WHO. The Xpert MTB/RIF test, in particular, has been widely adopted and used in many countries (Pai et al.,2023). However, there is still a need for more accurate and affordable diagnostics, especially in high-burden countries (Pai, Nicol, and Boehme 2016).

The current diagnostic methods, including molecular tests, have limitations and have not been able to meet the demand in endemic countries. Efforts are being made to develop new tools, particularly molecular diagnostics, and there are over 50 companies actively engaged in product development (Elizabeth, Talbot & Pai 2019). In addition to improving diagnostics, there is a need to improve the efficiency of healthcare delivery systems and ensure better uptake of new technologies. Increased investments are also necessary to support biomarker discovery and validation for TB diagnostics. Overall, while progress has been made, there is still work to be done to ensure that TB diagnostics are widely available and accessible (Elizabeth etal 2019).

TB diagnostic availability and accessibility in Africa vary across different diseases. In terms of tuberculosis (TB), the availability of diagnostic tests is limited in many African countries. Sputum smear microscopy is available at 87% of facilities, representing 97% of patients (WHO,2023). However, other diagnostic tests such as chest X-ray, tuberculin skin tests, and acid-fast bacillus culture have lower availability, ranging from 26% to 53% of facilities (Klinkenberg et al,2020)

The distance to health facilities for tuberculosis (TB) diagnostics varies across different studies. In one study conducted in Punjab, India, it was found that more than 50% of presumptive TB cases had to travel more than 7 km to reach the designated microscopy centres (DMCs) for sputum examination (Karan et al., 2021). Another study in KwaZulu-Natal, South Africa, reported that participants had to travel a mean

distance of 2.9 km to the nearest clinic and 17.6 km to the nearest hospital for XDR-TB diagnosis (Kapwata and Morris, 2017). The distance to health facilities can be a barrier to timely diagnosis and treatment of TB, potentially contributing to ongoing transmission (Velen & Shingde 2021). Tuberculosis (TB) diagnostic coverage in Ethiopia varies based on geographic distance. In East Gojjam zone, the overall TB health service coverage (THSC) was 23%, with a mean distance of 8 km from the nearest health facility (Asemahagn & Alene 2020:16).

2.29 TB diagnostic utilisation

In low- and middle-income countries, reliance on direct sputum smear microscopy for diagnosis hinders case detection. Improved microscopy services integrated with rapid methods for identifying multidrug-resistant cases can have a significant impact on case finding (WHO,2021). In India, barriers to utilisation of TB services include health provider-related factors, lack of information about TB, and dissatisfaction with the DOTS provider (Kwan et al.,2019). Existing TB diagnostic tools are poorly adapted for resource-limited settings and show poor performance in diagnosing TB in specific populations, such as children, people living with HIV/AIDS, and those with extra pulmonary forms of the disease (WHO,2022). These limitations result in either fair access to poor diagnostics or poor access to fair diagnostics for TB patient. The magnitude of TB diagnostic utilisation varies across different countries and healthcare settings. In the 22 high TB burden countries (HTBBC), which harbour 80% of global TB, sputum smear microscopy with its low detection rate remains the most commonly used diagnostic test for pulmonary TB (WHO, 2018). In high TB burden countries, like Ethiopia, there is underutilisation of diagnostic tools like Xpert MTB/RIF due to insufficient knowledge among health professionals (Mulualem, Assefa & Feven 2018:48).

In the year 2021, the percentage of individuals who were reported with tuberculosis and had received a WRD as their primary diagnostic test differed significantly among countries like Kazakhstan (99%), Vietnam (96%), and Zambia (100%). Furthermore, country of Asia such as China (57%), Indonesia (50%), and Pakistan (55%), had a moderate proportion. Many nations with a high tuberculosis burden had a low proportion of individuals who received a WRD as their initial diagnostic test, including Bangladesh (24%), India (22%) Democratic Republic of Congo (9%), Ethiopia (<1%) (WHO, 2022). It is crucial to identify drug resistance early to ensure that the most

effective therapy is started as soon as feasible and that the spread of drug-resistant strains is minimized (WHO, 2022.)

The utilisation of chest X-rays for TB diagnosis varies across different studies. In China, it was found that 99.9% of suspected TB patients underwent X-ray checks, with 33.8% being identified as pulmonary TB (PTB) (Wei et al.,2021). Another study conducted in Melbourne, Australia, focused on asymptomatic children with TB infection and found that a small but noteworthy number of children with radiological abnormalities suggestive of TB were identified through chest X-rays (Graham et al.,2022) However, the specific magnitude of X-ray and other supportive diagnostic utilisation for TB diagnosis was not explicitly mentioned.

Low levels of drug resistance testing are another worry. Only 70% of all bacteriologically verified cases were tested for rifampicin (RIF) resistance, and less than 50% of all RIF-resistant (RR) TB patients were tested for fluoroquinolone (FQ) resistance. Despite its growing importance, testing for resistance to other group A drugs such as bedaquiline and linezolid remains quite limited (WHO,2023).

2.30 TB Diagnostic information use for Decision-making

The use of decision-making tools, such as feasibility, viability, key performance indicators, and time evaluation, can aid in making timely and informed choices in complex socio-technological systems. Additionally, research on ecological rationality and adaptive heuristics suggests that simple decision processes, or heuristics, can enable fast and effective decision making by ignoring unnecessary information (Gigerenzer, Hertwig, Hoffrage, Garcia-Retamero & ABC Research Group, 2017).

Monitoring and evaluation play a pivotal role in assessing the efficacy of laboratory tests, thereby enabling experts to gauge the effectiveness of these diagnostic procedures in detecting and managing tuberculosis. Furthermore, this monitoring and evaluation process is also instrumental in monitoring the progress made in combatting this debilitating disease. By diligently keeping track of the advancements made, policymakers and stakeholders are equipped with accurate and up-to-date information, which in turn empowers them to make more well-informed decisions. This

wealth of timely and validated data serves as a catalyst in expediting efforts aimed at ultimately eradicating tuberculosis from our society (WHO 2019).

Monitoring the diagnostic procedures for tuberculosis (TB) is utilized to assess the capacity of TB laboratories for testing. According to the global target indicator set by the World Health Organization (WHO) as part of the END TB framework, the capacity of TB diagnostics is measured by the number of diagnostic equipment per 100,000 individuals (WHO, 2015). Recently, the WHO has provided specific recommendations for setting targets that take into account the epidemiology of TB and issues related to patient access, including the distinction between urban and rural populations and the establishment of specimen referral systems. To calculate country-specific targets for the quantities of tests and facilities required for each of the main diagnostic technologies, such as microscopy, WRDs (including the Xpert® MTB/RIF assay by Cepheid, Sunnyvale, CA, United States), culture, and DST, a recommended methodology has been proposed by the WHO (WHO, 2016). As part of the WHO's end TB strategy for the years 2015 to 2026, 12 core diagnostic indicators are globally monitored to track the progress of countries in achieving the set targets (2026). The national TB program in Ethiopia monitors certain confirmatory methods of TB diagnostic indicators through the district health information system 2 (DHIS2). However, the country does not monitor the supportive diagnostic system, as indicated by the Ministry of Health (MOH, 2021).

2.31 TB Diagnostic strategy

Strategy is a complex concept that involves making decisions, setting objectives, and developing plans to achieve those objectives. It also involves understanding external forces such as competition, economics, and technology. Strategy is crucial for organisations to formulate informed recommendations and make valuable contributions to shareholders, employees, customers, and communities (Lenox, Snell & Harris, 2011). Diagnostic policy refers to the development and implementation of strategies to improve the use of diagnostic tests in healthcare settings. It aims to provide timely and reliable diagnostics for patients, leading to better patient management and reduced inappropriate use of medicines (Josie, Frédérique, Michael, Andrew, Jorge, Stathis & Martin, 2021:104).

Several countries have developed TB laboratory strategy documents. The European Union (EU) and European Economic Area (EEA) member states have adopted global strategies for TB control, including the development of consensus-based documents within the Wolfheze initiative (Migliori, Tiberi, Zumla, Petersen, Chakaya, Wejse, Muñoz-Torrico & Duarte, 2020). In addition, the European Reference Laboratory Network for TB (ERLN-TB) was established in 2009 to provide technical support and harmonization of methods for TB diagnosis (ECDC, 2022).

Diagnostic imaging, policy formulation and implementation is a complex process due to the high costs and poorly defined benefits of imaging technologies (OECD, 2021). In order to make informed policy decisions, it is necessary to synthesize imperfect data from various perspectives and supplement it with effective dissemination and feedback of information (WHO,2022 & International Telecommunication Union, 2022) (Suzanne, Brendan & Rick, 2015). The current strategic landscape for imaging informatics is characterized by contrasts and paradoxes, with advances in technology and the inclusion of diagnostic image-sharing pushing the field forward (Pesapane, Rotili & Penco, 2023).

Diagnostic policy in Ethiopia has been a topic of concern. The country has recognized the importance of health technology assessment (HTA) and the need to establish a national HTA system (Jonathan & Font, 2017). However, the historic overview of HTA in the context of health policy documents of Ethiopia is not clearly reported (Desalegn, 2022). Ethiopia has consented to adopt all forms of molecular diagnostic techniques suggested by the World Health Organization for global health. Additionally, the country has embraced the national TB strategic plan and guidelines, which encompass various TB diagnostic methods (MOHE, 2020:21-30).

Ethiopia has additionally formulated a comprehensive plan for tuberculosis laboratory testing, aiming to enhance confirmatory tests and scale up the utilisation of the molecular WHO recommended diagnostic (GeneXpert machine) from 276 to 526 between 2021 and 2026. Although the country has already attained this target, the challenge lies in ensuring accessibility and effective utilisation (MOH, 2021).

2.32 Conclusion

The chapter's literature extensively explores the diagnostic system and strategy for tuberculosis. In 2020, Ethiopia developed and implemented its own comprehensive national TB strategic plan, meticulously designed guidelines, and a highly effective national tuberculosis and leprosy laboratory strategy. However, despite these concerted efforts, it is disheartening to note that the implementation of this framework has not reached its full potential, resulting in an alarmingly low rate of diagnostic accessibility and utilisation amongst the population. Furthermore, it is unfortunate that the realm of supportive diagnostic systems, such as imaging and histopathology, lacks the presence of comprehensive diagnostic strategy documents. The current strategy document available to healthcare practitioners and policymakers alike was not crafted based on evidence-driven approaches, as it fails to take into account the fact that certain objectives stated in the document have already been successfully achieved. Regrettably, even amidst these circumstances, the issue of diagnostic accessibility and utilisation continues to persist as an unresolved problem.

In summary, prior research on TB diagnostics in Ethiopia has not sufficiently addressed four interrelated gaps for Oromia Region: (1) detailed physical access barriers, (2) actual utilisation patterns of confirmatory and supportive tests, (3) how M&E data inform diagnostic decisions at sub-national level, and (4) the status of region-specific diagnostic strategy development. This study addresses these gaps by focusing on Oromia.

CHAPTER 3

RESEARCH DESIGN AND METHODOLOGY

3.1 Introduction

The previous chapters focused on providing an overview, explanation, and comprehensive background on the critical issue of accessibility, utilisation, and information utilisation for decision-making in the context of tuberculosis diagnostics. A quantitative approach using cross-sectional descriptive study design was utilized to evaluate the extent of physical access, utilisation patterns, and information usage for decision-making in the field of tuberculosis diagnostics. Furthermore, the systematic process was undertaken to develop a national TB diagnostic strategy, grounded in strategic planning principles and informed by expert consensus.

3.2 Study Setting

The term "study setting" within the realm of health service research denotes the environment or context wherein the research is executed, thereby impacting the design, methodology, and results of the study (Kanwal, Smith, Jones and Lee, 2022).

3.2.1 National Context: Ethiopia

Ethiopia, the second-most populous country in Africa, is situated in the Horn of Africa. It shares borders with the Republic of the Sudan and South Sudan to the west, Djibouti to the east, Eritrea to the north, Kenya to the south, and Somalia to the southeast. The country covers an area of 1.1 million square kilometres, with altitudes ranging from as low as 110 metres below sea level to high mountain peaks. The governance and leadership framework is characterized as a Federal Parliamentary Republic, overseen by a Prime Minister. The structure of the federal government comprises 12 regional states and two city administrations (MOHNTP, 2024).

3.2.2 The Oromia Regional State

This study was conducted in the Oromia Regional State of Ethiopia. Oromia is situated centrally within Ethiopia, sharing borders with all other regional states except for the Tigray region. It is the largest region in the country, covering an area of 364,219 km², with an estimated population of 40 million individuals (Oromia, 2024). Although the population of Oromia shares a common ethnicity, the region exhibits considerable diversity in terms of living conditions and topography. Topographical features include rugged mountain ranges, elevated plateaus, and prominent peaks, with the Afro-Arabian plateau being the predominant geographical feature. Altitudes vary from below 500 metres above sea level to towering summits such as Mount Batu (4,607 metres). In varying areas, the inhabitants of Oromia engage in agricultural practices, while others adopt pastoralist lifestyles (Oromia, 2024).

3.2.3 Health System Structure in Oromia

The public sector serves as the main provider of health services within the nation. Private entities, encompassing both non-profit and for-profit organisations, oversee the remaining 27% of healthcare facilities. The public health service delivery framework is structured into three hierarchical levels: primary, secondary, and tertiary. The Primary Health Care Unit (PHCU) consists of five satellite health posts, a health centre, and a primary hospital in rural locales, as well as a health centre located in urban environments. Diagnostic services are available within the confines of health facilities and are administered by the Chief Executive Officer of the hospital or the head of the primary health care unit. The governance of the health system is a collaborative endeavour between the Ministry of Health and the regional health bureau, adhering to the established political framework. The Ministry of Health is tasked with the formulation of national policies and strategies, delegating specific responsibilities to self-governing agencies. The Ethiopian Public Health Institute is charged with overseeing diagnostic laboratory activities in accordance with relevant legislation (MOHNTP, 2024).

3.2.4 TB Diagnostic Facilities in Oromia

The Oromia region is administratively organized into 23 towns and 21 zonal health departments. Each zonal health department oversees between 50 and 100 health centres and 10 to 20 districts. Within health facilities, each hospital and health centre has a laboratory compound overseen by the hospital or health centre head (OHB, 2022).

According to the Oromia Health Bureau (OHB, 2022), the region has a total of 1,417 health centres, 112 hospitals, 273 public-private mix (PPM) health facilities, and 3 regional referral laboratories that are expected to provide TB diagnostic services. From this total, a sample was drawn for the study, as described in section 3.9. The study sample included 31 hospitals, 38 health centres, 38 PPM health facilities, 3 referral laboratories, 21 zonal health departments, and 38 district (woreda) health offices. Data collection took place from December 15, 2023, to August 6, 2024.

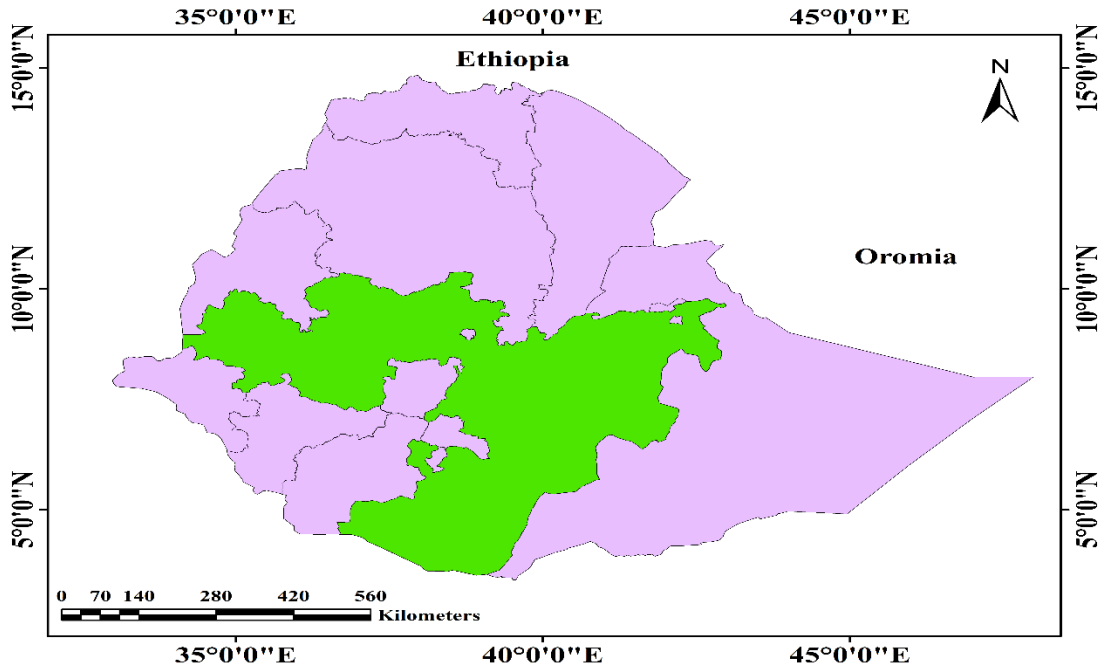

Figure 3. 1: Map of Ethiopia and Oromia region (Source: Author's own work, generated from study coordinate data using [ArcGIS 10.8])

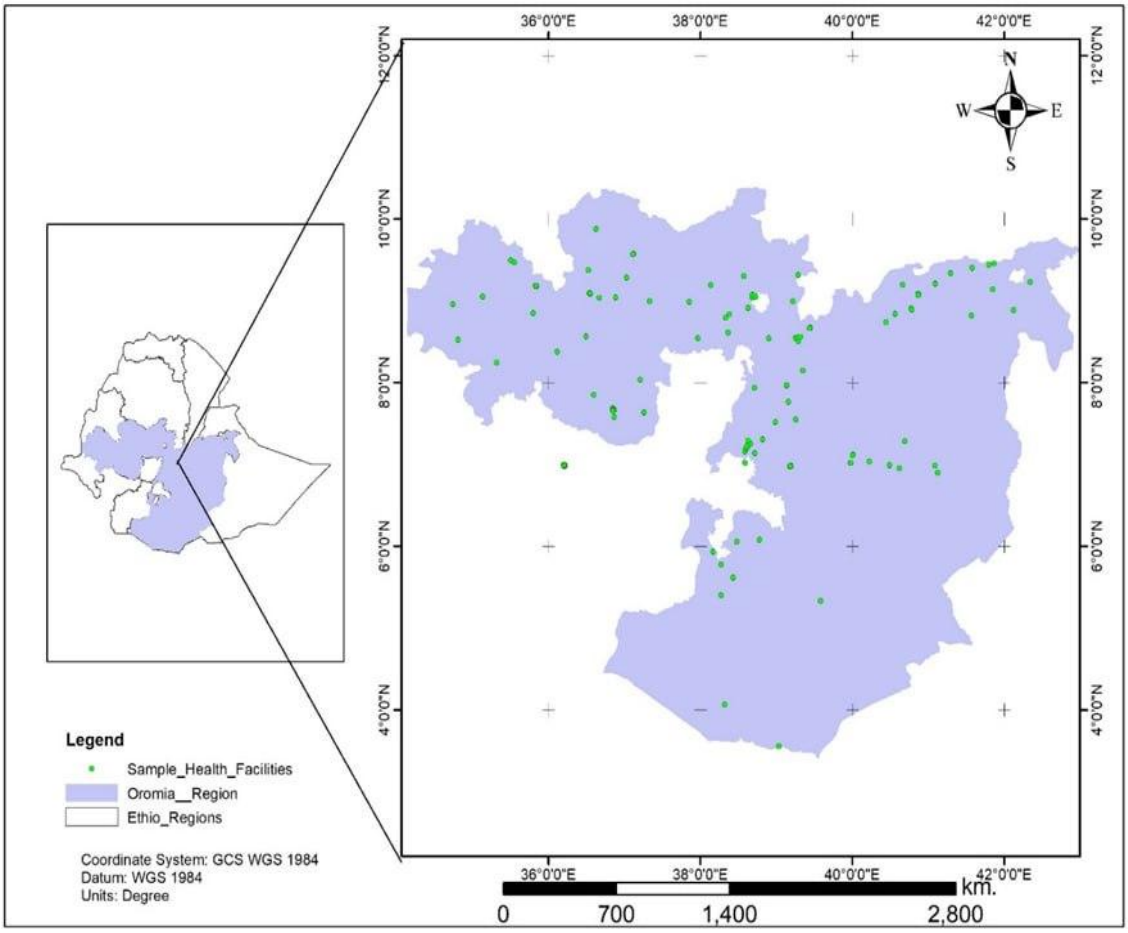

Figure 3. 2 : Map of Oromia region indicating the specific study districts and Health facilities (Source: Author's own work, generated from study coordinate data using [ArcGIS 10.8])

3.3 Research Paradigm

A paradigm is a conceptual lens through which the researcher evaluates the methodological aspects of the research system (Kivunja & Kuyini, 2017). This study is situated within a positivist research paradigm. Positivism assumes an objective reality that can be observed and measured through empirical observation and logical analysis (James, 2016). In line with this paradigm, the study assumes that the current state of TB diagnostic access, utilisation, and monitoring in Oromia is an objective reality that can be quantified and analyzed. The research is further underpinned by the following assumptions:

Ontological: An objective reality exists regarding TB diagnostic service availability, infrastructure, and performance.

Epistemological: Knowledge about this reality is best acquired through objective, value-neutral measurement and statistical analysis, independent of the researcher's own beliefs.

Methodological: A structured, quantitative approach using surveys, checklists, and record reviews is the most appropriate method of inquiry.

Axiological: The research process is value-free, with the researcher maintaining objectivity and avoiding bias in data collection and interpretation.

A paradigm is a way of viewing the world; a set of ideas used to understand or explain something, often related to a specific subject (Morgan, 2017). It is a way of framing what we know, what we can know, and how we can know it.

Research paradigm is a conceptual lens through which the researcher evaluates the methodological aspects of the research system to understand the research methods employed and the data that will be evaluated, as well as the basic set of beliefs or worldview that guides research activity and inquiry. Research paradigm determines what should be studied, how it should be studied, and how the study's results should be interpreted by researchers in a given area (Kivunja and Kuyini 2017:26). The study used the positivism paradigm.

3.3.1 Positivism

This research is situated in a positivist research paradigm, which is consistent with the tradition in natural science to explore cause-and-effect relationships among phenomena that can be observed. Positivism believes in empirical observation and logical analysis in seeking the reality, which is considered as being objective. From this perspective, researchers aim to "find the truth" by controlling for variables, collecting value-neutral data, and predicting mechanistic results (James, 2016:106). Therefore, the evidence collection about the evolution of Ethiopia's TB diagnosis system is the main emphasis of this research. The aim is to increase the availability and use of supporting and confirmatory TB diagnostics. The research is further underpinned by ontological, epistemological, methodological and axiological assumptions.

3.3.2. Ontological assumptions

Ontologically, the study assumes the existence of an objective reality, namely, the current state of TB diagnostic access and utilisation, as well as the structural and systemic factors influencing it. Ontology, in this context, pertains to the nature of what exists and the essential characteristics of that reality (Fletcher, 2017).

3.3.3. Epistemological assumptions

Epistemologically, the study is concerned with understanding the nature and scope of knowledge about TB diagnostics and how such knowledge is acquired, validated, and applied. This includes considerations of validity, parameters of inquiry, and the methods through which knowledge about TB diagnostic systems is generated (Creswell and Poth, 2018).

3.3.4. Methodological assumptions

Methodologically, the study adopts a structured approach to inquiry, employing specific strategies and processes that align with the research objectives. The selection and application of methodologies are guided by methodological assumptions, which guarantee that the intended results and the study design are coherent (Polit and Beck, 2022).

In line with these assumptions, the study employed a triangulation approach to comprehensively assess the magnitude of physical access to TB diagnostics, the extent of universal drug susceptibility testing (DST) coverage, the utilisation and determinants of TB diagnostic services, and the existing practices of monitoring and evaluation.

3.3.5. Axiological assumptions

Axiology deals with the role of values in research what is considered important, ethical, and valuable. It explores whether research should be value-free (as in positivism) or value-laden (as in interpretivism or critical theory). Axiological assumptions influence the researcher's stance, ethical considerations, and the purpose of the inquiry (Ugwu

et al., 2021). This multi-faceted approach enabled the development of a strategic framework aimed at optimizing the TB diagnostic system within the Ethiopian TB laboratory network.

3.4 Research Approach

A research approach is the overall plan directing the study from philosophical assumptions to data interpretation. It includes the reasoning and framework for conducting a research, including the kind of data gathered, the analysis done, and the findings reached (Creswell 2023). According to Creswell (2023), a research approach integrates the philosophical worldview of the researcher, the chosen research design, and the specific methods used for data collection and analysis.

It serves as a guide that ensures coherence and rigor throughout the study by matching the research objectives with suitable procedures. According to Saunders et al. (2023), a research strategy reflects the researcher's theoretical orientation and comprehension of reality rather than being only a technical decision. It encompasses mixed-methods, qualitative, and quantitative paradigms, each with its own set of presumptions on the creation of knowledge and the interpretation of evidence.

3.4.1 Quantitative approach

A quantitative approach is systematic and focuses on collecting and analyzing numerical data to quantify relationships, test objective theories by examining relationships among variables, and identify patterns (Creswell & Creswell, 2018). This approach was chosen because the primary study objectives measuring diagnostic access, calculating utilisation rates, assessing universal DST coverage, and evaluating monitoring practices required the collection and statistical analysis of numerical data from a large number of health facilities, health workers, and records.

3.5 Study Design

A research design is the overall strategy or blueprint that outlines how a research study is to be conducted. It provides a structured framework for collecting, measuring, and analysing data in a way that ensures the research question is effectively

addressed (Hazari, 2023) Research design refers to the framework of methods and techniques chosen by a researcher to conduct a study, aiming to collect relevant evidence and provide accurate and unbiased insights (Hazari, 2023).
According to Creswell and Creswell (2022), research design is the plan or proposal to conduct research, involving the intersection of philosophy, strategies of inquiry, and specific methods. It serves as a guide that connects the research problem with the appropriate data collection and analysis techniques, ensuring coherence and methodological rigor.

Saunders et al. (2023) describe research design as a logical plan that links the research questions to the data and the conclusions drawn from that data. For this study, the design decisions were: a descriptive study type (to characterize TB diagnostic access and utilisation), a quantitative research approach (to collect and analyze numerical data), and a cross-sectional time horizon (to capture data at a single point in time from December 2023 to August 2024).

3.5.1 Cross-Sectional Study Design

A cross-sectional study design was employed in this research to assess health-related practices and conditions at a specific point in time. Cross-sectional research design is an observational study in which data from a population or representative subgroup are collected at a single time. It softened to assess the prevalence of the results, describe the characteristics of the population, and explore the relationship between variables without manipulating them. This design provides a sample of the population and helps identify patterns and establish hypotheses for further research (Setia, 2016).

Cross-sectional studies are valuable in public health because they measure exposure and disease prevalence at the same time, allowing comparisons across groups without following participants over time (Simkus, 2023). This design directly supports the objectives of the present study. Specifically, it enabled the assessment of TB diagnostic utilisation, its determinants, access to diagnostics, universal DST coverage, and the use of information for monitoring and evaluation. By collecting data from a wide range of health facilities across Ethiopia at a single time point, the cross-sectional approach revealed patterns and disparities in TB diagnostic service delivery.

3.5.2 Descriptive Study design

In addition to being cross-sectional, the study adopted a descriptive research design to provide a detailed and contextual understanding of the TB diagnostic landscape. Descriptive studies are designed to offer a comprehensive examination of a phenomenon, including its characteristics, distribution, and the relationships among its components (Hu & Chang, 2017).

In the social sciences and health research, descriptive research is fundamental because it offers crucial baseline data that can guide the creation of policies, programs, and additional analytical studies. This design is particularly effective in answering foundational questions such as what the phenomenon is, where it occurs, how it manifests, and when it typically arises (Creswell et al., 2023). In the context of this study, the descriptive component focused on exploring the accessibility and utilisation of TB diagnostic services, as well as the use of diagnostic information for decision-making within health facilities. Given the persistent challenges in TB diagnosis and management in Ethiopia, this design was essential for capturing the complexity and variability of diagnostic practices across different settings (Fu, Li, Wang, Zhao & Zhang, 2023).

3.6 Study population

A study population is a critical component of research design, encompassing all individuals eligible to participate in a study (Shah, 2023).

3.6.1 Target Population

This study had two distinct target populations, each corresponding to a different data collection method.

3.6.1 Target Population 1; - the first target population consisted of all organizational units involved in TB diagnostic service delivery in Oromia. This included public hospitals, health centres, and public–private mix (PPM) health facilities providing TB diagnostic services, as well as all regional referral laboratories and the relevant administrative bodies responsible for management, including zonal health

departments and district (woreda) health offices. A sample was drawn from this population of organisations for the facility-based assessment using checklists and record reviews.

3.6.2 Target Population 2: Health Workers

The second target population comprised individual health workers and managers with sufficient knowledge of TB diagnostics. This included laboratory technicians, TB focal persons, health centre managers, district health managers, zonal TB focal persons, regional laboratory officers, referral laboratory department heads, and health informatics technicians. A sample was drawn from these health facilities and individuals were respondents for the structured questionnaire.

3.6.3 Data Source

In addition to the two target populations above, data were extracted from existing TB diagnostic records. These records are data sources, not a study population, because they are documents, not living subjects. The records were reviewed using a standardized checklist to obtain retrospective data on diagnostic test volumes, results, and turnaround times. Sources included laboratory registers, patient records, and quarterly reports from health centres, hospitals, referral laboratories, and PPM facilities for the preceding year.

3.7 Inclusion and Exclusion Criteria

3.7.1 Inclusion Criteria

Administrative offices (Regional Health Bureau, zonal, and district/TB focal persons) responsible for overseeing TB diagnostics. Hospitals, health centres, and private health facilities established for more than six years.

Outpatient department physicians, laboratory workers, and laboratory professionals working in referral labs. Health workers who provided voluntary informed consent.

3.7.2 Exclusion Criteria

Districts or health facilities located within zones of active conflict at the time of data collection. Health facilities that were non-operational due to security instability or extensive physical damage at the time of data collection, as this would prevent reliable data collection and do not represent the routine system interventions (e.g., facilities that had been robbed or damaged to the point of non-function). Government or private health facilities not participating in the PPM for TB diagnosis and treatment.

3.8 Sampling Method and Sample Size

3.8.1 Sampling Strategy Overview

A multi-stage stratified random sampling method was used to select health facilities and administrative offices. Purposive sampling was then used to select individual health worker respondents within each selected facility. This combination ensured representativeness of facilities while targeting knowledgeable informants.

3.8.2 Stratification

The Oromia region was divided into six geographic strata based on administrative zones: Western Oromia, Southwest Oromia, Central Oromia, Eastern Oromia, Southeast Oromia, and Southern Oromia. Stratification ensured that the sample reflected the geographic and population diversity of the region.

3.8.3 Facility Selection

Zone selection: From each of the six strata, zonal health departments were randomly selected. A total of 21 zones were selected.
District selection: From each randomly selected zone, districts (woredas) were randomly selected. A total of 38 districts were selected.
Facility selection: From each randomly selected zones, 2 health centres under each zone not in the same districts are randomly selected,
From 273 PPM health facilities present in the region,38 PPM health facilities were randomly selected.
Hospital selection: from All hospitals within the region the hospitals were randomly selected (31 hospitals).

Referral laboratories: All three regional referral laboratories were included.
Managing offices: All zonal health departments (21) and district health offices (38) in the selected zones and districts were included.

3.8.4 Individual Health Worker Selection (Purposive Sampling)

Within each selected facility and administrative office, individual respondents were purposively selected based on their knowledge and role in TB diagnostics. The following individuals were targeted: At health facilities (hospitals, health centres, PPM facilities): One head of facility, one radiographer, one laboratory technologist, and one TB focal person.
At managing offices (zonal, district, regional): TB focal persons and program officers.
At referral laboratories: Laboratory heads and TB diagnostic specialists.
Purposive sampling was chosen because TB diagnostic knowledge is concentrated among specific roles, and random sampling of all health workers would include many without relevant expertise.

3.8.5 Sample Size Determination

The sample size for health facilities (n=176) was estimated using the WHO Service Availability and Readiness Assessment (SARA) tool and the rule of thumb for large country design effects (Creswell & Plano Clark, 2018). The sample size was calculated based on the desired confidence level and known population characteristics, using the formula for subnational estimates that accounts for the large country design effect. In this formula, (n) is the desired sample size, (N) the total population size, (p) the proportion of the population with a given characteristic, (e) the margin of error, and (z) the z-score for the desired confidence level (1.96 for 95% confidence). The following statistical parameters were applied at the regional level: Z = 1.96, P = 0.5, q = 0.5, and ME = 0.15. These parameters were used to compute the total primary sample size. Subsequently, the final sample size for each facility type was determined using stratified proportional allocation, based on the total number of facilities within each stratum

Table 3.1: Total Target Population of Health Facilities and Managing Administrative Offices in Oromia Region (Sampling Frame)

SN	Managing authority and facility type	Type	Total number managing organization and facility
1	Oromia regional Bureau	Managing	1
2	Referral laboratory	Managing and lab service provider	5
2	Zonal Health office	Managing	40
3	Woreda Health office	Managing	337
4	Hospitals	Facility	112
5	Health center	Facility	1417
6	Private Health facilities	Facility	273
	Total		2185

$$n = \frac{N\frac{z^2p(1-p)}{e^2}}{\frac{z^2p(1-p)}{e^2} + N - 1}$$

Table 3. 2 Sample Size Calculation and Final Sample Distribution by Facility Type

Facility name	All facilities	Districts	Region	Zone	Z	P	q	ME	primary size	Total sample size
Oromia region	1		1		**1.96**	**0.5**	**0.5**	**0.15**		1
Zonal Health office	40			40						21
Referral laboratory	5									5
Woreda Health office	337	337								38
Hospitals	112									31
Health Center	1417									42
Private Health facilities	273									38
Total	2185	337	1	40						176

3.8.6 Final Sample Achieved

Of the 176 health facilities and administrative offices targeted for visitation, 171 were successfully contacted. A total of 222 health professionals from 171 organisations completed the questionnaires.

Checklists were used to collect TB diagnostic records from 112 health facilities. Specifically, 60 individuals from managing health offices (district, zonal, and regional levels) responded to the questionnaires, while 10 individuals at referral laboratories responded to both questionnaires and checklists. Respondents from health centres, hospitals, and PPM facilities also contributed to both the questionnaires and the checklists.

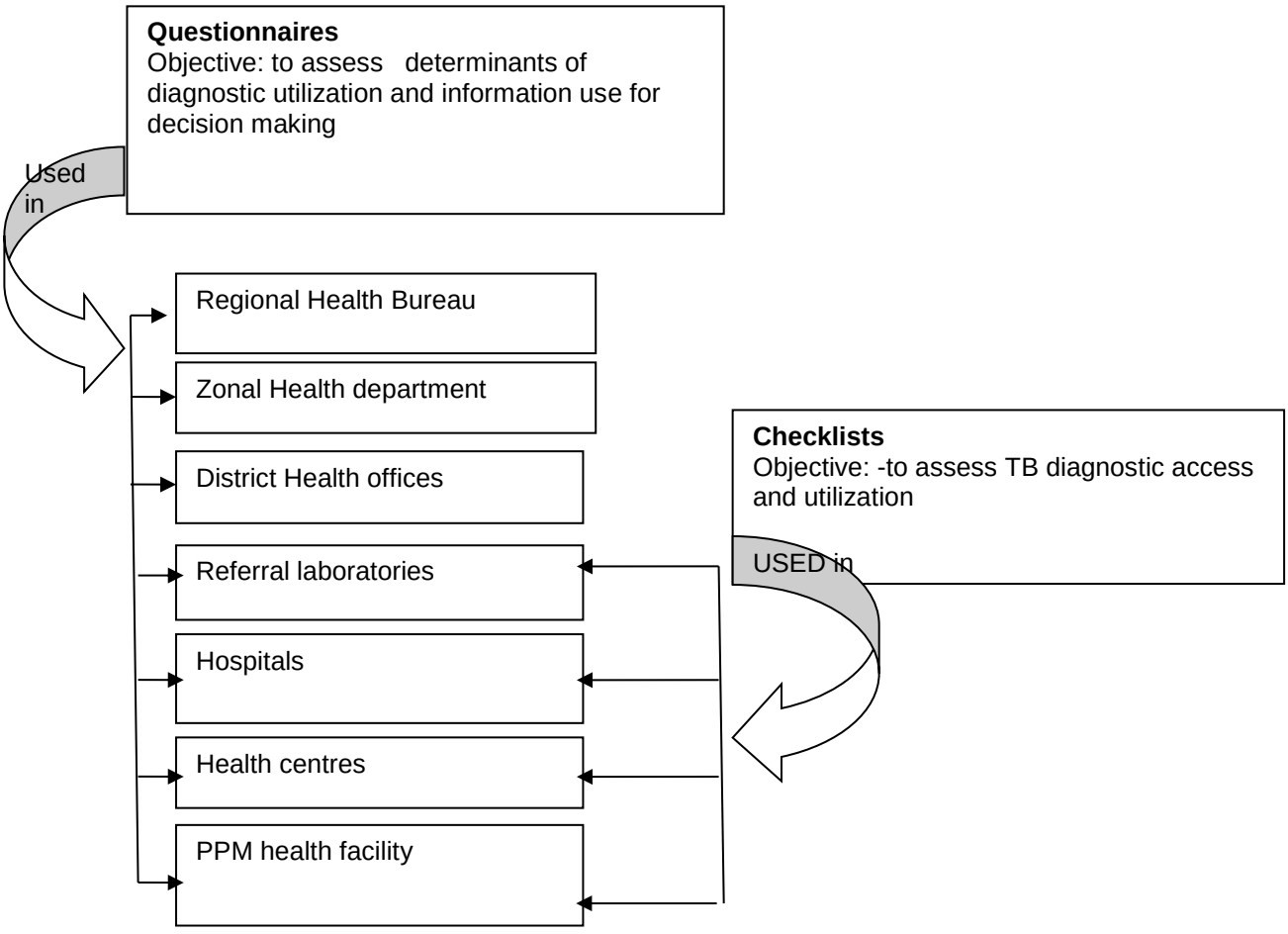

Figure 3. 3 Sampling flow diagram (Source: Author's own work)

3.9 Data Collection

Data collection is a critical process in research, encompassing various strategies and methods tailored to specific objectives. It involves gathering and measuring information on targeted variables, which is essential for answering research questions and evaluating outcomes (Boyle, 2022). Quantitative data collection refers to the systematic process of gathering numerical data that can be statistically analysed to test hypotheses, identify patterns, and draw generalizable conclusions. This approach is rooted in the positivist paradigm, which assumes that reality can be objectively measured and quantified.

According to Creswell and Creswell (2023), quantitative data collection involves the use of designed instruments such as surveys, questionnaires, and checklists to gather data from large samples. These tools are designed to ensure consistency, reliability, and replicability across different contexts.

Hoy and Adams (2023) emphasize that the strength of quantitative data collection lies in its ability to produce measurable and comparable results. They advocate for the use of standardized procedures to minimize bias and enhance the validity of findings, especially in educational and social sciences research**.**

3.9.1 Data Collection Tools

Two primary tools, adapted from the WHO Service Availability and Readiness Assessment (SARA) guidelines (WHO, 2021), were used:

Structured questionnaire: Used to interview health workers and managers. It assessed TB diagnostic access, utilisation determinants, and monitoring practices.

Systematic checklist: Used to retrospectively collect data from facility records and reports on TB laboratory tests, imaging, DST, and monitoring indicators.

Both tools were digitized using Kobo Collect software for mobile-based data entry.

3.9.2 Pre-Testing of Data Collection Instruments

A pre-test of the instruments was conducted in four health facilities (two health centres and two hospitals) not included in the main study. This pre-test identified ambiguities, unclear questions. Questions that lacked clarity were rephrased, and modifications were made to the questionnaires and checklists. The results of the pre-test were excluded from the final study findings.

3.9.3 Data Collection Process

The data collection process was carefully planned and executed to ensure the reliability and validity of the information gathered. A total of 12 data collectors and 4 field supervisors were recruited based on their prior experience in health-related surveys and familiarity with digital data collection tools. Prior to field deployment, all team members underwent a comprehensive training program. The training covered the objectives of the study, ethical considerations, the content and structure of the data collection instruments, and the practical use of Kobo Collect software, into which the tools had been digitized.

Following the training, the data collectors were deployed to various health facilities, managing health offices, and regional referral laboratories across the study regions. Each data collector was equipped with a mobile device preloaded with the Kobo Collect application and the finalized data collection forms. The use of digital tools facilitated real-time data entry, minimized errors, and ensured secure data transmission to a central server.

During fieldwork, data collectors conducted structured interviews, reviewed facility records, and observed diagnostic practices as per the study protocol. Supervisors played a critical role in overseeing the data collection process, providing on-site support, and conducting random spot checks to ensure adherence to data quality standards. They also reviewed submitted data daily to identify inconsistencies or missing information, which were promptly addressed through follow-up with the respective data collectors.

The data collection process was conducted from Dec 15, 2023 to Aug 6, 2024 period, ensuring that all targeted facilities and stakeholders were reached. Ethical protocols, including informed consent and confidentiality, were strictly observed throughout the process. Permission letters were obtained from the district and zonal health departments within the Oromia regional state. Each data collection tool was coded, and agreements were signed with the data collectors to ensure adherence to confidentiality protocols. Following the resolution of all ethical concerns, the data gathering process involved reviewing documents using checklists and interviewing the data collector in-person using a standardised questionnaire. The Kobo collect tool was created by the system of self-validation to check for the missing data solution.

3.10 Ethical Considerations

3.10.1 Institutional Approval

Ethical approval for this study was obtained from the College of Human Sciences Research Ethics Committee at the University of South Africa (UNISA), with approval reference number 17677041_CREC_ChS_2023, valid from 13 October 2023 to 13 October 2024 (see Annex A). In addition, gatekeeper permission was granted by the Health Research Ethical Review Committee of the Oromia Health Bureau (Ethiopia) following review and approval of the research proposal (see Annex B)**.**

3.10.2 Informed Consent

All eligible participants were provided with a participant information sheet explaining the study's purpose, procedures, risks, and benefits. Written informed consent was obtained from each participant before any data collection. Participants were explicitly informed that their participation was voluntary, that they could withdraw at any time and that their decision would not affect their employment or services.

3.10.3 Principle of respect for persons

Individuals are referred to as autonomous beings. Every individual possesses the right to self-determination, and researchers are obligated to respect this fundamental right (Brink et al., 2018:29). The right to self-determination was respected. No coercion was used. Individuals who declined participation faced no prejudice or penalties.

3.10.4 Beneficence and Non-maleficence

Non-maleficence, as defined by Fouché, Strydom and Roestenburg (2021), means avoiding intentional or unintentional harm, misery, or suffering. The study was designed to cause no harm. Questions focused on workplace processes, policies, and records, not on personal or sensitive matters.

3.10.5 Privacy, Confidentiality, and Anonymity

Privacy is the area where data collection will take place; it must be designed to make participants feel at ease and ensure that any information they supply will remain private (Fouche et al., 2021:124). The researcher guaranteed participants that their information would remain confidential. The researcher conducted interviews using a prepared questionnaire and checklists inside a participant's office during their break time.

Anonymity is when the source of the information is not known to others even when they are not asked to identify themselves (Fouche et al 2021:124). In this project, participant identities were not used to label data collected from participants.

Confidentiality is ensuring that the participant's identity is never connected to the data that will be collected, stored, and analysed (Fouche et al., 2021:124) The researcher stored hard copies of participant answers for at least five years. These hard copies were kept in a locked cupboard/filing cabinet within a secured office for potential future research or academic use. Electronic information resided on a password-protected computer. Eventually, all hard copies were shredded, and electronic copies were permanently deleted using appropriate software. Future use of this data will require further Research Ethics Review and approval, if necessary.

3.10.6 Scientific Integrity

Scientific integrity refers to the adherence to ethical standards in conducting and reporting research. It is essential for preserving the credibility of scientific findings and fostering public trust in research outcomes (McIntosh & Hudson Vitale, 2023) The researcher adhered to the highest standards of scientific integrity by avoiding data fabrication or falsification, accurately reporting all methods and results, and acknowledging all sources to prevent plagiarism.

3.11 Validity And Reliability

Ensuring the validity and reliability of data collection instruments is essential for the credibility and accuracy of research findings. In this study, multiple strategies were employed to uphold both validity and reliability, in alignment with established research standards

3.11.1 Validity

Validity refers to the extent to which a research instrument accurately measures what it is intended to measure (Krabbe, 2017). To ensure the validity of the data collection tools used in this study, the researcher applied three key forms of validity: content validity, construct validity, and face validity**.**

Content validity: Content validity assesses the degree to which an instrument comprehensively captures all relevant aspects of the construct under investigation (Krabbe, 2017). The questionnaire was developed based on an extensive literature review and reviewed by TB program specialists and statisticians to ensure all critical dimensions of TB diagnostic access, utilisation, and monitoring were covered.

Construct validity: Construct validity refers to the extent to which a measurement tool accurately reflects the theoretical construct it is intended to measure (Brink et al., 2018). The survey instrument was piloted in four health facilities (two health centres, two hospitals) to assess whether it effectively captured the intended attributes.

Face validity: Face validity involves a subjective assessment of whether an instrument appears to measure what it is supposed to measure (Brink et al., 2018:152). The researcher and a statistician reviewed the questionnaire to ensure each item was clearly worded, relevant, and appropriate for the study objectives.

3.11.2 Reliability

Reliability refers to the consistency and stability of a measurement instrument over time and across different contexts. In this study, reliability was ensured through careful training, pretesting, and verification procedures.

Reliability of Data Collection Instruments

To ensure consistent data collection, a qualified health professional with expertise in TB diagnostics and program implementation was recruited as a data collector. All data collectors received comprehensive training on the use of the Kobo Collect tool, ethical considerations, and the specific procedures for administering the instruments. This training aimed to standardize data collection practices and minimize variability across data collectors.

Reliability of the Questionnaire

The reliability of the questionnaire was assessed by examining the consistency of responses obtained from health facility staff and managerial-level respondents (Heryyanoor et al., 2024). Prior to the main data collection, the instrument was pretested in local health centres and district health offices not included in the study sample. This pretesting phase helped identify ambiguities and inconsistencies, which were addressed to improve the tool's reliability**.**

Reliability of Checklists

To assess the reliability of the checklists used for facility record reviews, the researcher conducted pre-tests in nearby health facilities at two different time points using the same group of data collectors. The correlation between the two sets of results was calculated under the guidance of a statistician, confirming the internal consistency of the checklist items. Following the main data collection, the researcher also conducted random verification visits to selected health facilities to cross-check the accuracy and consistency of the collected data.

3.12 Data Analysis Method

Data analysis is characterized as the systematic evaluation and quantitative interpretation of non-numerical data through the application of various methodologies and theoretical frameworks (Creswell and Poth, 2018). It can be articulated as a systematic endeavour to integrate data, to render the imperceptible perceptible, to establish connections and assign ramifications to prior events, as well as a cyclical process of hypothesis formulation and validation, rectification and adaptation, proposition and justification. Through the transformation and interpretation of data, the researcher is tasked with structuring the information, imbuing it with significance, and arranging it coherently (Polit and Beck, 2022).

Data collected via Kobo Collect were exported to Microsoft Excel 2022 with the assistance of a statistician and then transferred to IBM SPSS (version 29) for statistical analysis. All study variables were complete for facilities providing the respective services. However, chest X-ray utilization data were available only from 11 of the 31 hospitals, as the remaining facilities did not offer chest X-ray services. Therefore, this variable was analyzed only for applicable facilities and was not treated as missing data Based on the study’s objectives, three forms of analysis were used: descriptive, inferential, and geospatial.

3.12.1 Descriptive Analysis

Descriptive statistics (frequencies, percentages, means, modes, ranges, standard deviations) were calculated to summarise the data. The following indicators were assessed:

Access to TB diagnostics: Availability of initial TB tests, supportive diagnostic techniques, TB screening methods, and WHO-recommended molecular rapid diagnostic tests. Mean availability of TB diagnostic tools was computed.

The percentage of health facilities following the national TB diagnostic algorithm for initial diagnostics was calculated, Health facilities with TB diagnosis and follow-up policies allowing free TB diagnostics. New and relapse cases with bacteriological confirmation. Testing sites using a WHO-recommended rapid diagnostic (WRD) with a data connectivity system that transmits results electronically to clinicians and information management systems., Notified new and relapse cases tested with WRD as the initial diagnostic.

Physical accessibility: Means, modes, ranges, and standard deviations were used to determine how close a facility was to the community.

Universal DST coverage: The following three WHO TB drug susceptibility indicators were calculated: Percentage of notified bacteriologically confirmed TB cases with DST results for at least rifampicin. Percentage of second-line DST (rifampicin-resistant TB cases with DST results for fluoroquinolones, and phenotypic DST for Group A DRTB treatment). Percentage of health facilities with a national policy for universal DST.

Monitoring and evaluation practices: The following were determined:

Percentage of health facilities with M&E plans, Percentage of management-level health facilities that monitor TB diagnostic and staff performance. Percentage of health facilities and managerial levels that meet TB diagnostic performance targets and where corrective action was implemented.

Key denominators used in analysis: For facility-level indicators: total number of health facilities surveyed, For DST coverage: total number of notified bacteriologically confirmed TB cases, for test utilisation: total number of estimated presumptive TB cases in the catchment population., For imaging: total number of chest X-rays performed for TB diagnosis.

3.12.2 Inferential Analysis

To assess the performance of TB diagnostic utilisation, laboratory test results were compared to estimated presumptive TB cases, including tests requested and eligibility for first- and second-line DST, trends of test performance, and imaging performed for TB diagnosis in the catchment population.

Chi-square tests were used to assess associations between categorical variables (e.g., facility type and availability of GeneXpert), Multivariate logistic regression was performed to identify factors contributing to under-utilisation of TB diagnostics.

3.12.3 Geospatial Analysis

To evaluate physical accessibility to TB diagnostic services for each type of initial TB test method, supportive diagnostic technique, TB screening method, and WHO molecular rapid diagnostic, geographic coordinates of facilities were collected using GPS. Analysis was performed using ArcGIS software (WHO, 2015).

Distance calculation: Straight-line (Euclidean) distances from population centroids (town/village centres) to the nearest TB diagnostic facility were calculated.
Access threshold: An access threshold of 10 kilometres was defined, consistent with WHO guidelines for an acceptable walking distance to primary health services in rural settings.
Spatial autocorrelation: The Global Moran's I tool was used to assess whether high-access or low-access areas were clustered spatially or randomly distributed.

3.13 Strategy Development and Description

This section outlines the systematic process undertaken to develop a national TB diagnostic strategy, grounded in strategic planning principles and informed by expert consensus. The strategy aims to strengthen TB diagnostic access, utilisation, and quality across Ethiopia's health system.

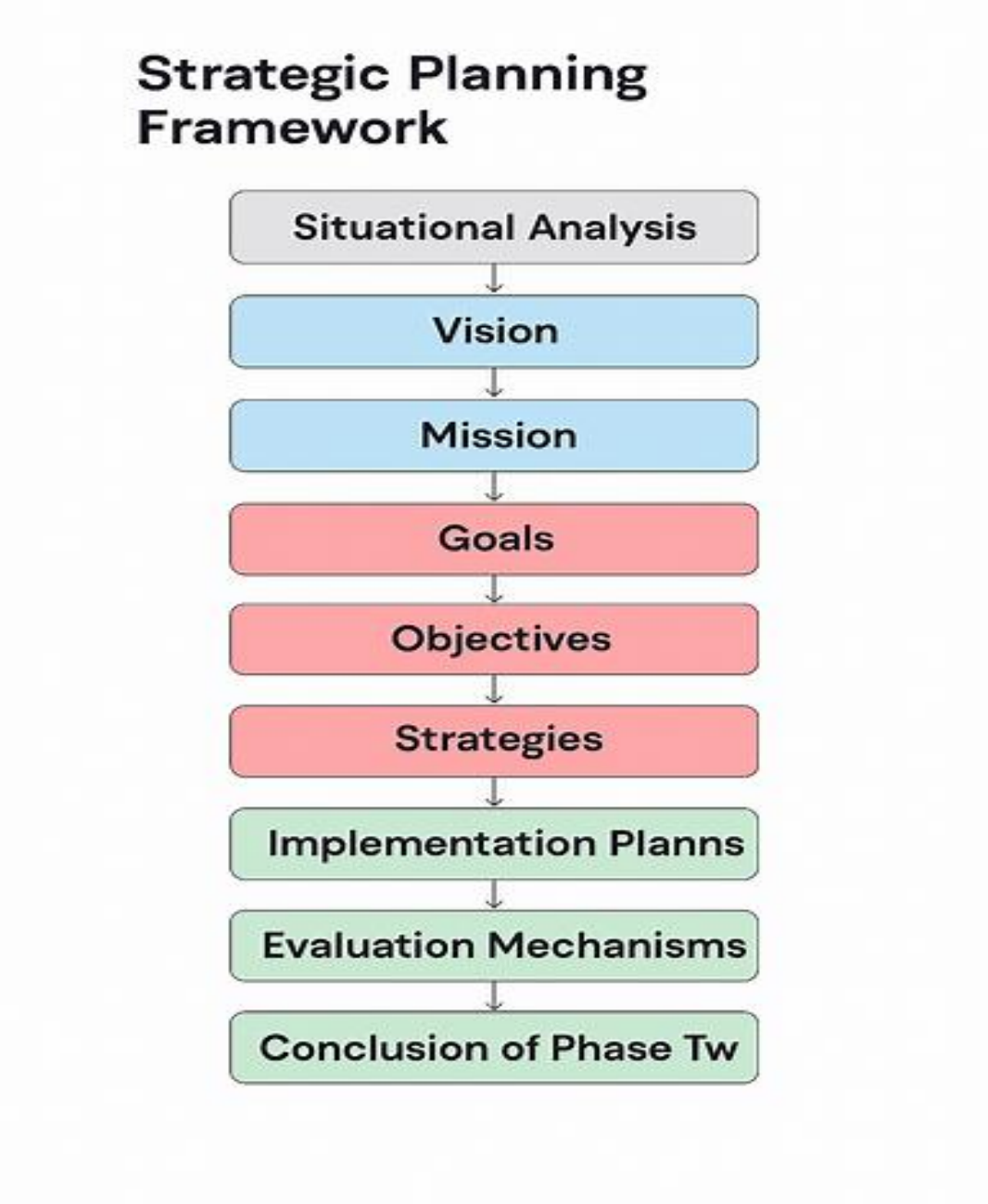

Figure 3. 4 Strategic Planning Framework (UNDP,2025)

3.13.1 Eight Strategic Planning Elements Defined by the United Nations

The strategy was developed using the eight strategic planning elements defined by the United Nations: vision, mission, goals, objectives, strategies, performance indicators, implementation plans, and evaluation mechanisms. These elements provide a structured framework to ensure that the strategy is both comprehensive and actionable.

The following descriptions are based on the United Nations Strategic Planning Guide for Managers (United Nations, 2006) and the United Nations Development Group guidance documents (UNDG, 2017).

This research study adopted the United Nations (2006) model for strategic development, which emphasizes a vision-driven, values-based, and forward-looking approach to planning and implementation. The model was used as a conceptual framework to guide the development of strategies aimed at strengthening the TB diagnostic system, with a focus on improving access and utilisation. The UN model advocates for strategies that are aspirational, inclusive, and aligned with sustainable development goals (SDGs) particularly SDG 3, which seeks to ensure healthy lives and promote well-being for all. In applying this model, the research began by articulating a clear vision for an equitable and efficient TB diagnostic system that is accessible to all, especially underserved populations. This vision informed the identification of strategic pillars, including infrastructure enhancement, human resource development, community engagement, policy alignment, and digital integration. Each strategy was developed to reflect the UN's emphasis on equity, participation, sustainability, and accountability.

Furthermore, the model's focus on intersectoral collaboration and evidence-based planning was integrated into the research design by engaging stakeholders from health, community, and policy sectors, and by grounding strategy formulation in both empirical data and global best practices. The strategies also incorporate monitoring and evaluation mechanisms, in line with the UN's results-based management approach, to ensure continuous learning and improvement.

By using the UN model, the research ensured that the proposed strategies are not only contextually relevant but also globally informed, ethically grounded, and aligned with long-term public health goals.

3.13.1.1 Vision

The vision articulates the desired long-term future state of the organization or initiative. It serves as a guiding star, providing inspiration and direction. A strong vision statement is aspirational, forward-looking, and reflects the values and ambitions of the organization (United Nations, 2006). The researcher complied vision that guides the direction and ambition, motivating every strategic decision.

3.13.1.2 Mission

The mission defines the core purpose of the organization, why it exists and what it seeks to achieve. It is more immediate and action-oriented than the vision and should clearly state the organization's role and primary activities (United Nations, 2006). The goal of the TB diagnosis strategy, according to my research, was to address the organisational role and take prompt, long-lasting action.

3.13.1.3 Goals

Goals are broad, long-term aims that support the mission and move the organization toward its vision. They are general statements of desired outcomes and provide a framework for setting more specific objectives (UNDG, 2017). In this study, the goal of the TB diagnostic strategy addressed specific objectives that which generate better diagnostic outcome.

3.13.1.4 Objectives

Objectives are specific, measurable steps that help achieve the broader goals. They are time-bound and clearly define what success looks like (UNDG, 2017). In this study, specific measurable that help to achieve the broader goals that clearly define what success TB diagnostic strategy for Oromia region were addressed.

3.13.1.5 Strategies

Strategies outline the approaches or methods the organization will use to achieve its objectives. They provide the 'how' and often include partnerships, resource allocation, and programmatic focus (United Nations, 2006). Every stage in which the use of TB diagnostics addressed the stated objectives was covered in this study.

3.13.1.6 Performance Indicators

Performance indicators are quantitative or qualitative metrics used to assess progress towards objectives. Indicators help track effectiveness, efficiency, and impact (UNDG, 2017). In this study, the best measurable TB diagnostic indicators which can help to track effectiveness, efficiency, and impact of the TB diagnostic, were addressed.

3.13.1.7 Implementation Plans

Implementation plans detail the activities, timelines, responsibilities, and resources required to execute the strategies. They ensure that the strategy is actionable and grounded in operational reality (United Nations, 2006). In this study, the ways in which this TB diagnostic strategy can be implemented were addressed.

3.13.1.8 Evaluation Mechanisms

Evaluation mechanisms are systems and processes for monitoring, reviewing, and learning from the implementation of the strategy. They help ensure accountability and continuous improvement (UNDG, 2017). The planning process began with a situational analysis of the current TB diagnostic landscape, identifying gaps in access, service delivery, and monitoring. This analysis informed the formulation of a clear vision and mission for the TB diagnostic system. The goals were aligned with national TB control priorities and global targets, such as those outlined in the WHO End TB Strategy. Each element was designed to build upon the previous one, ensuring logical coherence and alignment with the broader health system strengthening agenda.

3.13.2 Strategy Mapping and Objective Setting

To operationalize the strategic framework, strategy maps were developed to visually represent the alignment between the vision, mission, and strategic objectives. These maps served as a tool to communicate the strategy's logic model and to ensure that all stakeholders had a shared understanding of the intended outcomes. Strategic objectives were defined across five key domains:

- Client and Community Engagement: Enhancing awareness, demand, and trust in TB diagnostic services.
- TB Diagnostic Service Delivery: Expanding access to confirmatory and supportive diagnostics, including universal drug susceptibility testing (DST).
- Internal Operational Processes: Improving logistics, sample referral systems, and turnaround times.
- Human Resource and Knowledge Management: Strengthening the capacity of laboratory personnel and program managers through training and mentorship.
- Financial and Resource Mobilization: Ensuring sustainable funding and efficient resource allocation for diagnostic services.

Each objective was linked to specific initiatives and performance indicators to facilitate monitoring and evaluation.

3.13.3 Expert Consultation Using the Modified Delphi Technique

To ensure the strategy was evidence-informed and contextually appropriate, a modified Delphi technique was employed to gather expert input and build consensus. This method, as described by Nasa, Jain and Juneja (2021) is particularly effective for addressing complex public health challenges. A panel of experts was purposively selected based on their experience in TB diagnostics and program implementation. Participants included national TB program officers, TB diagnostic advisors, laboratory

managers from national and regional reference laboratories, and representatives from regional health bureaus.

The Delphi process was conducted in three iterative rounds via email:

- Round 1: Experts responded to 13 different open-ended questions designed to elicit ideas and priorities for the TB diagnostic strategy which is mainly divided into 3 sections: diagnostic barriers and gaps; system improvement, monitoring and evaluation, and human resource and system strengthening. Furthermore, their responses were analysed thematically.
- Round 2: Based on the results of the first round, 50 unique strategic structured questionnaires were created under five theme-proposed strategic components. Experts were asked to assess and prioritise the viability and impact of the suggested strategic components using a 5-point Likert scale. To lessen bias, responses were anonymized.
- Criteria for retaining/modifying/rejecting strategies: Items with ≥ 75% agreement (i.e., proportion of respondents rating the item as 4 or 5) were retained for the final strategy; items with 50–74% agreement were modified and presented again in Round 3; items with <50% agreement were rejected.
- Round 3: The summarized feedback from the second round was analyzed and five main strategic objectives with 30 specific strategic objectives was shared with the panel, allowing participants to revise their judgments and move towards consensus and validate the strategy.

This iterative process ensured that the final strategy reflected a broad range of expert perspectives and was grounded in practical realities.

3.13.4 Risk Identification and Mitigation

A critical component of the strategy development process was the identification of potential risks and barriers to implementation. These included:

- Infrastructure limitations, such as inadequate diagnostic equipment and unreliable electricity supply.

- Human resource constraints, including shortages of trained laboratory personnel.
- Data quality and reporting challenges, which affect monitoring and decision-making.
- Financial sustainability, particularly in maintaining diagnostic supplies and equipment.

For each identified risk, mitigation strategies were proposed. These included capacity-building initiatives, investment in infrastructure, integration of digital health tools, and advocacy for increased domestic and donor funding. Risk mitigation was embedded within the implementation and evaluation plans to ensure the strategy's resilience and adaptability.

3.13.5 Visual Representation of Strategic Elements

The eight elements of the strategic plan are visually summarized in Figure 3.2 below. This diagram illustrates the logical flow from vision to evaluation, providing a clear overview of the strategic planning process.

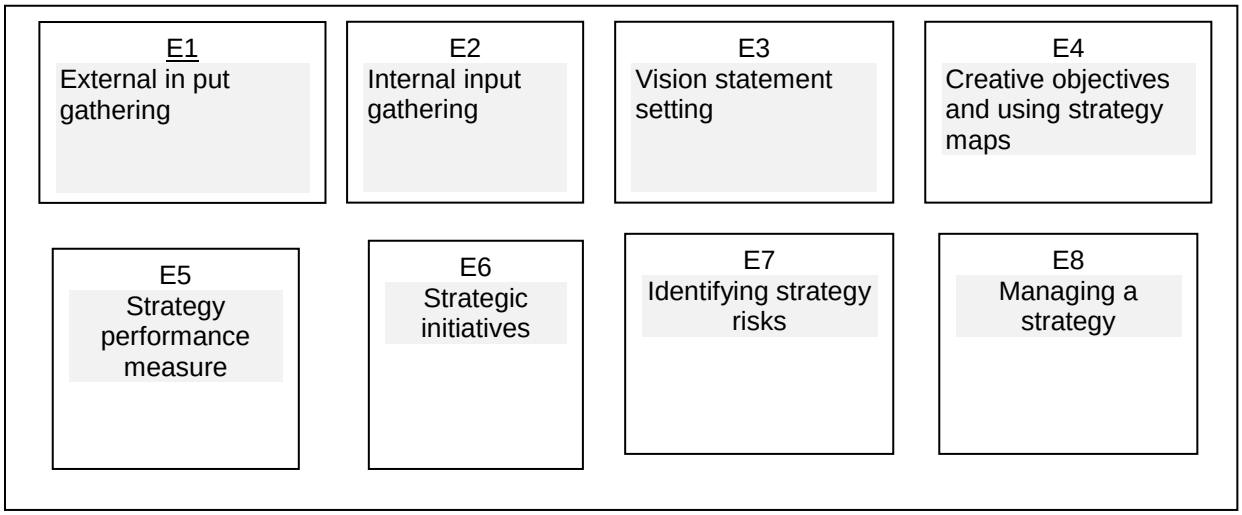

Figure 3.5 Elements to build strategy plan.

3.14 Conclusion

The current chapter has described the research design and methodology used to fulfil the purposes of this study. The study setting was health institutions and their mother organisations in the Oromia region. The study was based on a positivist perspective, characterized by certain ontological and epistemological positions that justified the use of a quantitative methodology. A cross-sectional study design was used and healthcare workers and health facilities were included in the study population. A sample size of 176 health facilities and 222 health workers were included into the study. A structured checklist was used to collect data to review the TB diagnostic records and a structured questionnaire to interview health workers. The field work was conducted according to the ethical guidelines of the research. The statistical analysis started with descriptive statistics to describe the data. The feedback from this analysis was finally incorporated in synthesized fashion to provide a straight tactical plan, based on the model of United Nations in strategic planning. The next chapter 4 discusses data analysis and data presentation.

CHAPTER 4

4. ANALYSIS AND PRESENTATION OF THE RESEARCH FINDINGS

4.1 Introduction

The preceding chapter 3 delineated the research design along with the methodologies employed for the execution of the study. This chapter presents findings from 171 health organisations (112 service delivery facilities and 59 managing offices) and 222 health professionals in Oromia Region, Ethiopia. The chapter emphasizes the data management, presentation, and interpretation of research findings pertaining to tuberculosis diagnostics, including physical accessibility, utilisation rates, determinants influencing the use of tuberculosis diagnostic tools, and the implementation of a tuberculosis diagnostic monitoring and evaluation system. The chapter is organized according to the 4 research objectives listed below, with each finding explicitly linked to its corresponding objective. The strategic developments associated with the fifth objective are discussed comprehensively in Chapters 6, 7, and 8. Results are presented in tabular and graphical formats utilizing descriptive statistics, multivariate regression, and geospatial analysis. Every table reports the sample size (N), and statistical results are accompanied by p-values, confidence intervals, and practical interpretations. All figures and tables are cited explicitly in the text before they appear.

4.2 Data Management And Analysis

The objectives of this study were to:

- Evaluate the magnitude of physical access to tuberculosis diagnostics in Ethiopia's Oromia Region.
- Assess the extent of TB diagnostic utilisation from diagnostic health facilities records of Ethiopia’s Oromia Region.
- Assess Factors Associated with TB Diagnostic utilisation in health facilities of Ethiopia’s Oromia Region.
- Assess the TB diagnostic monitoring and evaluation system used to make decisions in Ethiopia’s Oromia Region.

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Data collection was done by questionnaires (annexure E) and checklists (Annexure D) . These tools make data collection through mobile applications easier and are integrated into the Kobo Collect software. Data validation protocols are implemented in the software and GPS coordinates are recorded during the data collection process. Using strict security measures, such as password-protected accounts, all of the collected data has been sent to a researcher account that has been expressly created. After collecting data, a thorough data cleaning process was conducted in which the questionnaires and checklists were assessed for completeness and all potential discrepancies corrected. All data collected were entered into Microsoft Excel 2016 and analysed using IBM SPSS version 29. Descriptive statistical techniques were used, focusing on frequencies and percentages. Unstructured data were analysed using quantitative content data analysis methods.

4.3 Study Participants And Facility Characteristics

4.3.1 Sample Size Derivation and Participant Flow

The total sampling frame consisted of 2,185 health facilities and managing administrative offices in Oromia Region . Using the formula for subnational estimates with Z=1.96, P=0.5, q=0.5, and ME=0.15, the target sample size was calculated as 176 organisations .Final sample achieved: Of the 176 targeted organisations, 171 (97.2%) were successfully visited and participated. These comprised: 112 service delivery health facilities: 31 hospitals, 42 health centress, and 39 public-private mix (PPM) facilities.59 managing health organisations: 21 zonal health departments, 38 district (woreda) health offices (plus regional bureau and referral laboratories as detailed in Chapter 3).

Health professional respondents: A total of 222 health professionals completed the structured questionnaire. These were purposively selected based on their roles (facility heads, laboratory technicians, TB focal persons, district/zonal/regional TB officers). The response rate was 100% among those approached because the purposive sampling targeted individuals who were present and willing.

Facility record review (checklists): Checklists were completed for 112 service delivery health facilities (the same 112 facilities listed above) to extract TB diagnostic records from 2018–2023. Table 4.1 below summarize the sample composition of Hospitals, Health centress, PPM facilities, Zonal health departments, District Health offices, Total)

Table 4.1 Sample composition of health facilities and managing organisations N=171

Facility/organization type	Target sample	Achieved sample
Hospitals	31	31
Health centress	42	42
PPM facilities	39	39
Zonal health departments	21	21
District (woreda) health offices	38	38
Total	**171**	**171**

4.3.1 Sociodemographic Characteristics of Respondents and Facilities

Among the 222 health professional respondents: Gender: 173 (78%) male, 49 (22%) female indicating a gender imbalance in the TB diagnostic workforce. Educational qualification: Diploma 59 (26.5%), Bachelor's degree (BSc) 142 (63.9%), Master's degree (MSc) 17 (7.6%), specialized certificate 4 (1.8%) showing a predominantly qualified workforce.

Professional role: Outpatient care (OPD) specialists 65 (29.2%), diagnostics professionals 99 (44.6%), district TB focal persons 38 (17.2%), regional TB focal persons 20 (9.0%).

Among the 112 service delivery health facilities: Geographic location: Urban 79 (70.5%), rural 33 (29.5%). Community context: Agrarian populations 98 (87.5%), pastoralist communities 13 (11.6%) important for understanding access barriers for mobile populations. Below figure 4.1 presents these sociodemographic characteristics.

Figure 4.1 Sociodemographic characteristics of study participants and health facilities (Author's own work)

4.4 Objective 1: Availability and Spatial Accessibility of TB Diagnostic Services

4.4.1 Availability of Basic Amenities for TB Diagnostic Services

Findings related to Objective 1 indicate that essential basic amenities required for tuberculosis (TB) diagnostic operations were evaluated across 112 health facilities, with an overall mean availability of 58.8% (approximately 58%). Below Table 4.2 shows the percentage of facilities with each amenity.

Table 4.2 Availability of basic amenities in TB diagnostic facilities (N=112)

Basic amenity	Number of facilities with amenity	Percentage (%)
Power (grid or functional generator)	106	94.6%
Improved water source within facility	99	88.4%
Computer	69	61.6%
Ambulance	55	49.1%
Email/Internet	37	33.0%
Communication equipment (phone/radio)	29	25.9%
Mean (average)	**65.8**	**58.8%**

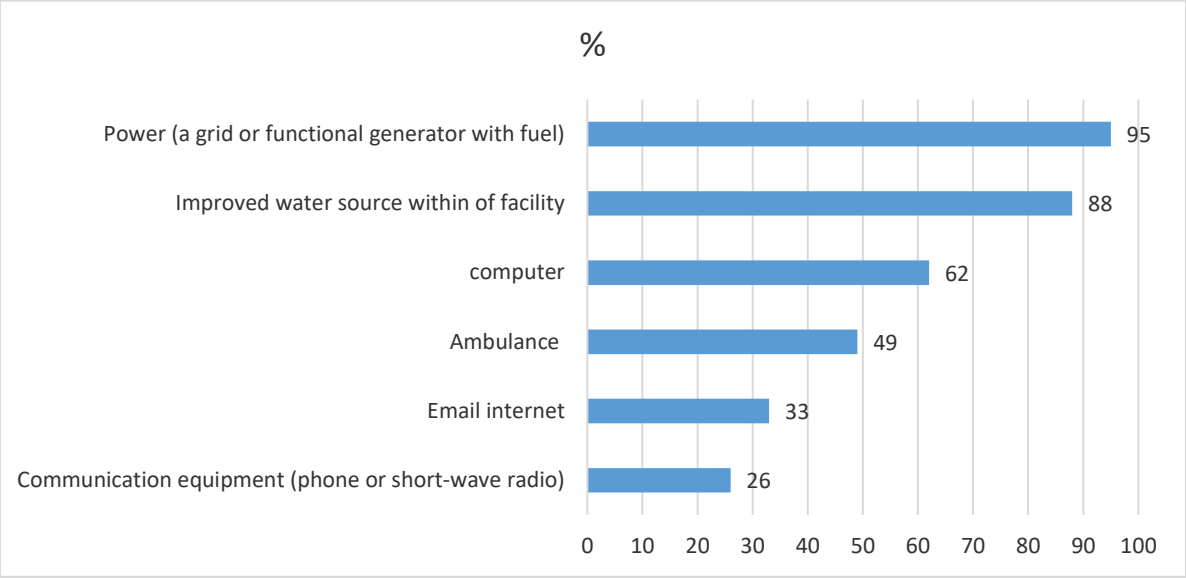


Figure 4.2 Availability of TB diagnostics basic amenities (Author's own work)

4.4.2 Basic TB Diagnostic Equipment

The availability of basic diagnostic equipment is fundamental for effective tuberculosis (TB) diagnosis and management. While advanced molecular technologies are critical for definitive confirmation, basic clinical tools play an essential role in the initial screening and clinical assessment of presumptive TB cases. A stethoscope is indispensable for chest auscultation to detect abnormal breath sounds, such as crackles or wheezing, which may suggest pulmonary involvement (Meepolprapai & Tantracheewathorn, 2020). Monitoring vital signs, including body temperature and respiratory rate, provides crucial clinical clues; persistent fever or tachypnoea can heighten suspicion of active TB disease (Long et al., 2020; Luies & du Preez, 2020). Furthermore, regular weight monitoring using adult and child weighing scales is vital, as unintentional weight loss is a common symptom of active TB, and poor weight gain is a key indicator for suspicion in children (Meepolprapai et al., 2023; Koegelenberg et al., 2023). A blood pressure apparatus, while not a direct diagnostic tool for TB, is a standard component of a comprehensive physical examination, which is necessary to assess a patient's overall clinical status and rule out other conditions. In the study area, the average availability of such vital sign equipment was 86%, as illustrated in Figure 4.3. This relatively high availability is a positive finding, ensuring that healthcare workers can conduct basic clinical assessments to identify individuals who require further laboratory investigation.

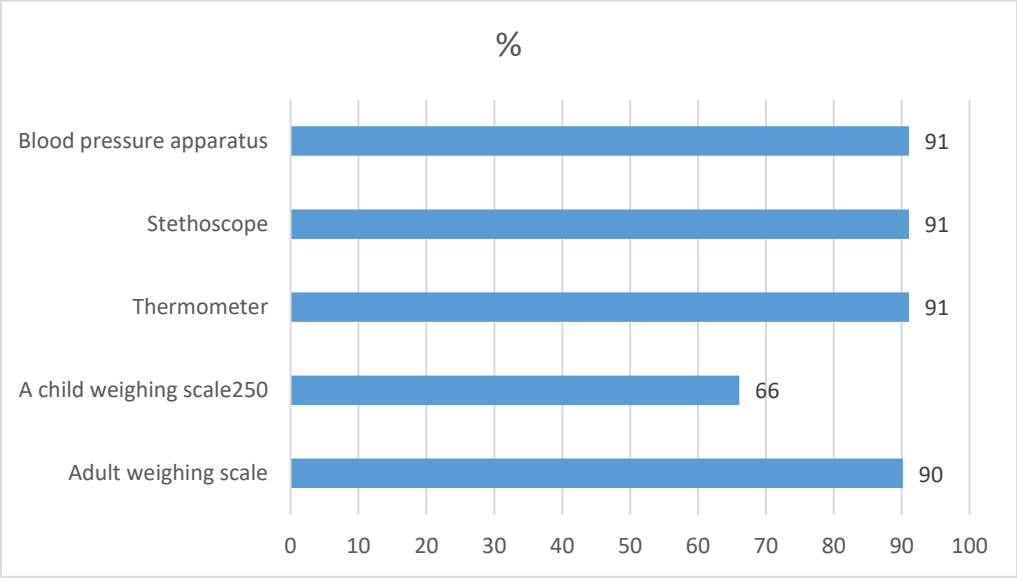


Figure 4.3 Availability of vital sign equipment's

4.4.3 Availability of Confirmatory TB Diagnostics

Finding related to Objective 1: Availability of WHO-recommended rapid diagnostics (WRDs) was critically low only 24.1% of health facilities have GeneXpert, the primary WHO-recommended initial diagnostic test for TB. Table 4.3 presents availability across 112 health facilities:

Table 4.3 Availability of TB diagnostic tests and equipment (N=112 facilities)

Diagnostic type	Available and functional (n)	Coverage (%)
Conventional TB diagnostics		
Light microscope	95	84.8%
Fluorescent microscope (FM)	17	15.2%
WHO-recommended rapid diagnostics (WRD)		
GeneXpert MTB/RIF	27	24.1%
LF-LAM	19	16.9%
Truenat	6	5.4%
Xpert XDR	9	8.0%
Second-line DST		
Line probe assay (LPA)	2	1.8%
TB culture	2	1.8%
Latent TB infection testing		
IGRA / Skin test	0	0%

4.4.4 Second line DST availability

It is recommended that phenotypic DST be available in reference laboratories; in our study, two reference laboratories are included and phenotypic DST is available in both. Drug sensitivity tests in the study area are low, 24 percent for the first line of anti-TB drugs and 8 percent for the second line of anti-TB drugs.

4.4.5 Latent TB infection testing availability

Latent TB infection testing was not available in all health facilities enrolled in the study.

4.4.6 Reagent Availability for Conventional and WRD Diagnostics

Finding linked to Objective 1: Reagent availability varied widely, with critical shortages for fluorescent microscopy and WRD supplies. While Ziehl-Neelsen reagents are relatively available (85-88%), fluorescent AFB reagents are severely lacking (acid alcohol only 10.7%, potassium permanganate 8.0%). WRD reagent supply is critically low, especially for Truenat (2.7%) and Xpert XDR (7.1%), directly limiting the functionality of existing diagnostic platforms. Table below shows the availability status of reagents at 112 health facilities.

Table 4.4 Reagent availability for TB diagnostics (N=112 facilities)

Reagent type	Available (n)	Coverage (%)
Ziehl-Neelsen stain reagents		
Forested slide	95	84.8%
Methylene blue	98	87.5%
Carbol fuchsine	96	85.7%
Fluorescent AFB reagents		
Auramine O	98	87.5%
Acid alcohol	12	10.7%
Potassium permanganate	9	8.0%
WRD reagents/supplies		
Xpert MTB cartridge	28	25.0%
LF-LAM	19	17.0%
Truenat (supply and reagent)	3	2.7%
Xpert XDR	8	7.1%

4.4.7 Supportive Diagnostics Availability and Population Ratios

Finding linked to Objective 1: Supportive diagnostics play an important role in TB diagnosis. According to the National TB Report, 60% of active TB cases are identified through supportive diagnosis. In Oromia, 51% of TB cases are bacteriologically confirmed, while 49% are clinically diagnosed (24% extra pulmonary, 25% clinically diagnosed pulmonary negative). Chest X-ray is available in only 27.7% of all health facilities (though 100% of hospitals), resulting in a ratio of one X-ray machine per 841,090 people far below WHO recommendations. AI-CAD, CT, and MRI are completely absent. Histopathology is extremely limited (one per 8.7 million people), severely constraining extra-pulmonary TB diagnosis. table 4.4 shows that Availability of supportive diagnostics in health facilities and ratio per population (N=112 facilities, catchment population 26,073,775**)**

Table 4.5 Availability of supportive diagnostics in health facilities and ratio per population (N=112 facilities, catchment population 26,073,775)

Supportive diagnostic	Available (n)	% at hospitals (N=31)	% of total HF (N=112)	Population per device
CRP	9	29.0%	8.0%	2,897,086
X-ray (any)	31	100%	27.7%	841,090
Digital X-ray	25	80.6%	22.3%	1,042,951
AI-CAD	0	0%	0%	NA
Ultrasound	44	100%	39.3%	592,586
CT scan	0	0%	0%	NA
MRI	0	0%	0%	NA
Histopathology	3	9.7%	2.7%	8,691,258
Mean	**13.75**	**39.9%**	**12.3%**	NA

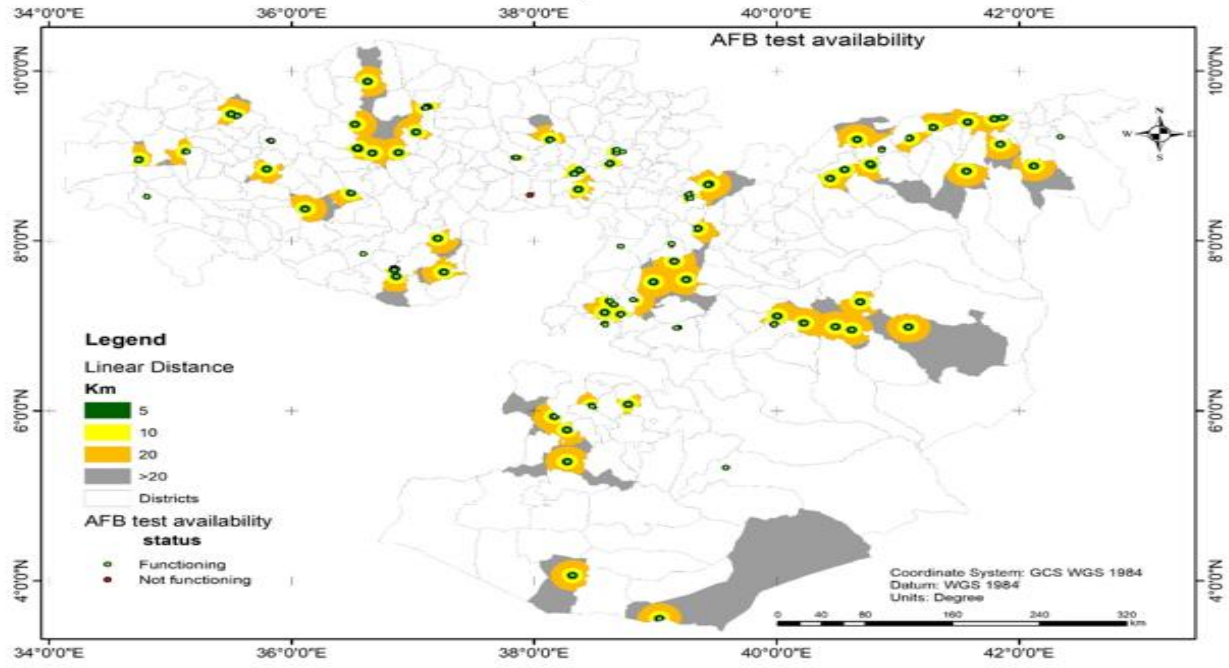
4.4.8 Spatial Accessibility of TB Diagnostic Services

Finding linked to Objective 1: Geospatial analysis was conducted for the population served by the 112 study health facilities. Distance thresholds: <5 km = adequate access, 5–10 km = moderate access, >10 km = poor access (WHO 2023). The result shows more than 40% of the population lives more than 10 km from AFB microscopy and X-ray services, and nearly 44% from GeneXpert. This exceeds the WHO acceptable walking distance and represents a major barrier to timely TB diagnosis.

Table 4.6 Level of confirmatory diagnostic access among catchment population

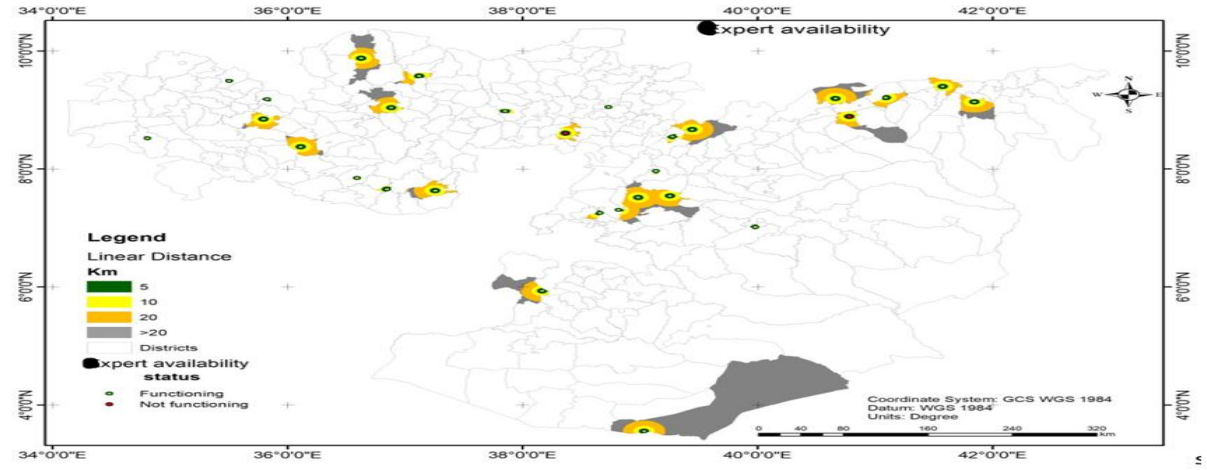
Service	Population with adequate access (<5 km)	Population with moderate access (5-10 km)	Population with poor access (>10 km)	Total population analyzed
AFB microscopy	4,098,371 (35.8%)	2,644,141 (23.1%)	4,705,419 (41.1%)	11,447,931
GeneXpert	1,953,761 (35.8%)	1,120,476 (20.5%)	2,387,275 (43.7%)	5,461,512
Chest X-ray	1,991,053 (36.4%)	767,153 (14.0%)	2,704,823 (49.5%)	5,463,030

A geospatial analysis reveals significant gaps in access to essential tuberculosis (TB) diagnostic services, including (AFB) microscopy, Xpert MTB and X-ray services in several Ethiopian districts. The results indicate that a significant proportion of the population, with numbering in the millions, lives in areas with low access to these critical health resources, potentially preventing timely diagnosis and treatment of tuberculosis. The analysis, which used the distance to functioning health facilities as an indicator of access, classified the population according to World Health Organization (WHO) benchmarks. According to these standards, a distance of less than 5 kms is considered adequate access, 5 to 10 kms is considered moderate access, and more than 10 kms is considered as limited or poor access.



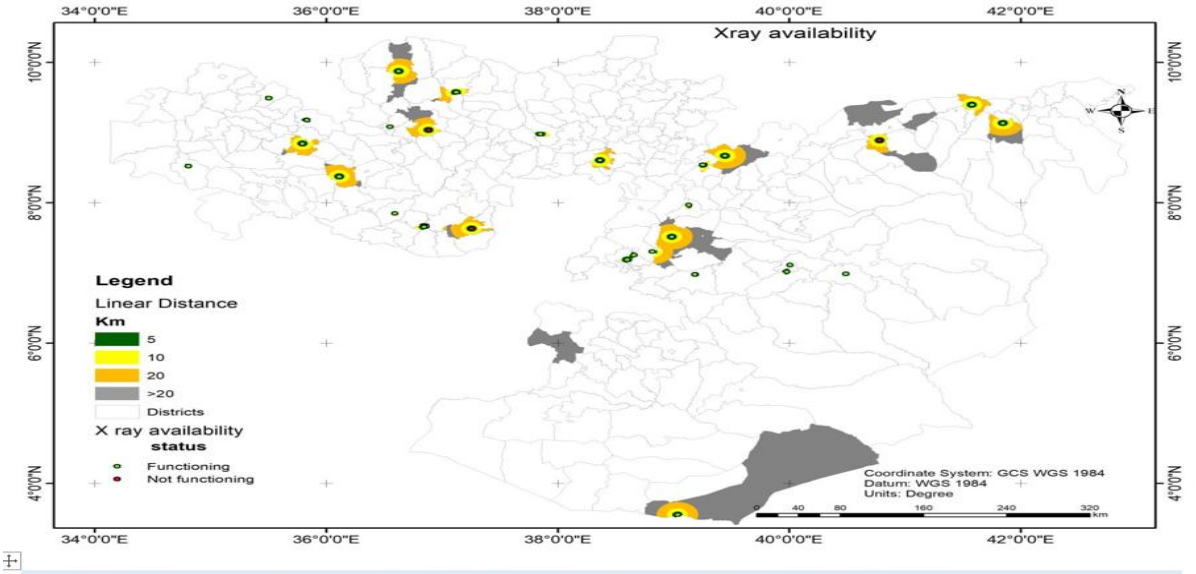
Row Labels	Sum of distance	Sum of pop sum
5	360	4,098,371.013
10	790	2,644,141.147
20	2060	3,064,092.797
300	17700	1,641,325.934
Grand Total	20910	11447930.89

Figure 4.4 The spatial distribution of AFB test Proximity



Row Labels	Sum of distance	Sum of pop sum
5	140	1953761.053
10	340	1120475.672
20	820	1383176.817
30	9900	1004098.183
Grand Total	11200	5461511.725

Figure 4.5 : the spatial distribution of Genexpert Test proximity



Row Labels	Sum of distance	Sum of pop sum
5	120	1,991,053.264
10	360	767,153.4574
20	620	1,043,905.204
30	8100	1,660,917.86
(blank)		
Grand Total	**9200**	**5463029.785**

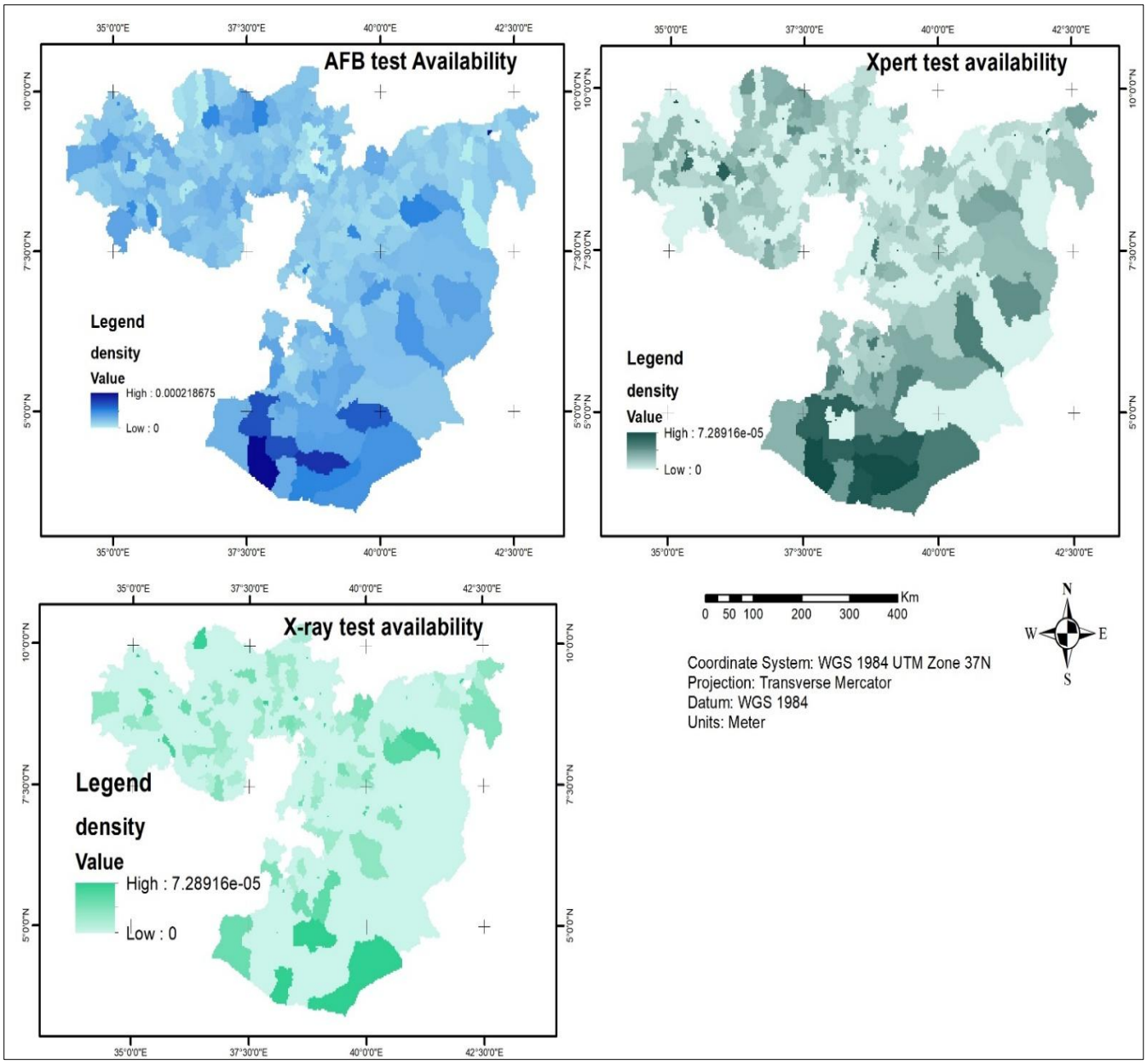
Figure 4.6 the spatial distribution of X-ray test proximity

4.4.9 Spatial Autocorrelation Analysis (Global Moran's I)

Finding linked to Objective 1: Spatial autocorrelation was assessed to determine whether TB diagnostic facilities are clustered, dispersed, or randomly distributed based the analysis result for GeneXpert: The z-score of -3.28 indicates a less than 1% probability that this dispersed pattern is due to random chance. GeneXpert facilities are deliberately spread out, yet 43.7% of the population still has poor access. Figure 4.4, 4.5,4.6 and table 4.7 shows Global Moran's I results for TB diagnostic distribution

Table 4.7 Global Moran's I results for TB diagnostic distribution

Diagnostic service	Moran's Index	z-score	p-value	Interpretation
AFB microscopy	-0.134865	-1.600132	0.109569	Not significantly different from random
GeneXpert	-0.277777	-3.281729	**0.001032**	Significantly dispersed ($p<0.01$)
Chest X-ray	-0.200008	-2.330366	**0.019787**	Significantly dispersed ($p<0.05$)



Note: Distance Threshold= 20000.0000 Meters

Figure 4.7 shows the spatial autocorrelation of TB diagnostic maps.

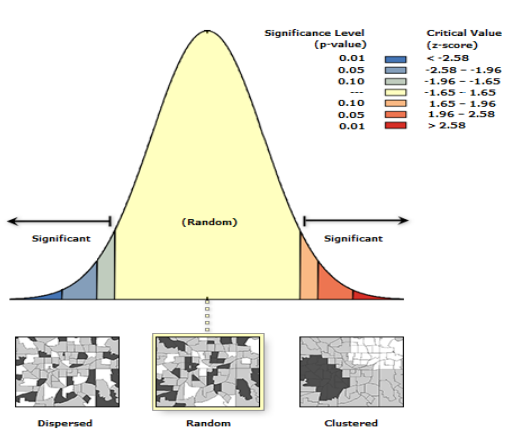


Figure 4.8 AFB test distribution

Statistic	Value
Moran's Index	-0.134865
Expected Index	-0.002976
Variance	0.006794
z-score	-1.600132
p-value	0.109569

Table 4.8 Global Moran's result

Given the z-score of **-1.600132**, the pattern does not appear to be significantly different than random.

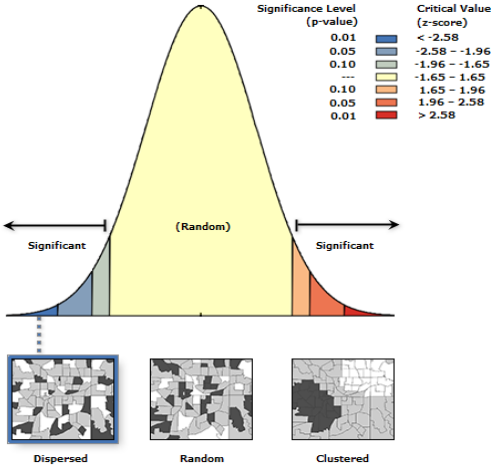


Figure 4.9 Xpert test distribution

Statistic	Value
Moran's Index	-0.277777
Expected Index	-0.002976
Variance	0.007012
z-score	-3.281729
p-value	0.001032

Table 4.9 : Xpert test distribution

Given the z-score of **-3.281729**, there is a less than 1% likelihood that this dispersed pattern is the result of random chance.

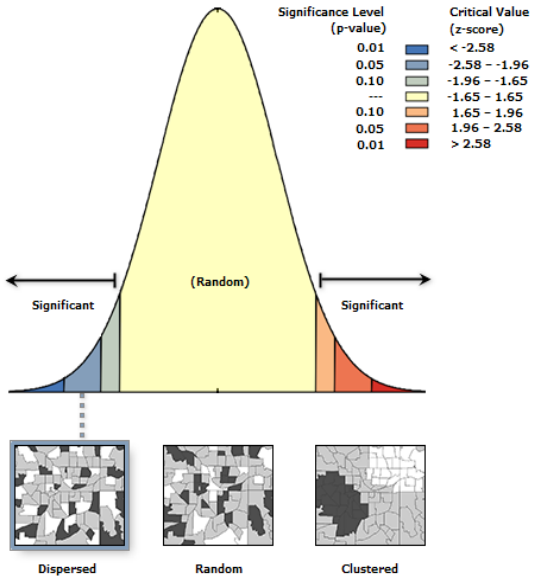


Figure 4.10 Global Moran's results

Statistic	Value
Moran's Index	-0.200008
Expected Index	-0.002976
Variance	0.007149
z-score	-2.330366
p-value	0.019787

Table 4.10 Global Moran's results X-ray distribution

Given the z-score of **-2.330366**, there is a less than 5% likelihood that this dispersed pattern is the result of random chance.

4.5 Objective 2: Level Of Tuberculosis Diagnostic Test Utilisation

4.5.1 Trends in Confirmatory Test Utilisation (2018–2023)

Finding linked to Objective 2: Among 112 health facilities, total confirmatory tests increased from 35,038 (2018) to 48,935 (2023), but utilisation rates remained low relative to expected presumptive TB cases. The assumption used a community presumptive TB prevalence = 2.7% of the given population (Arega et al., 2019). OPD presumptive TB prevalence = 10% of a given OPD attendants (Mohammed et al., 2022). based on the finding, the average test utilisation rate from the community level is only 6.2% over six years. Even among OPD attendees, only 12.3% on average are tested for TB, indicating major missed opportunities within health facilities. Table 4.11 show TB diagnostic test utilisation among eligible communities and OPD attendants.

Table 4.11 TB diagnostic test utilisation among eligible communities and OPD attendants of (N=112 facilities, 2018–2023)

Year	Total population	OPD attendants	Expected presumptive cases (community)*	Expected presumptive cases (OPD)**	Confirmatory tests done	Utilization rate (community)	Utilization rate (OPD)
2018	21,405,073	2,329,131	577,937	232,913	35,038	6.1%	15.0%
2019	23,065,197	2,133,608	622,760	213,361	34,850	5.6%	16.3%
2020	22,248,189	2,475,825	600,701	247,583	28,353	4.7%	11.5%
2021	23,690,907	3,544,919	639,654	354,492	38,644	6.0%	10.9%
2022	23,288,029	3,774,231	628,777	377,423	47,894	7.6%	12.7%
2023	26,286,985	6,568,308	709,749	656,831	48,935	6.9%	7.5%

Researchers visited 112 health facilities; between 2018 and 2023, the facilities served a Total of 21,405,073 to 26,286,985 catchment population rise. From 2,329,131 to 6,568,308 outpatient attendees were handled by the visited health institutions; the total number of TB confirmatory tests recorded increased from 35,038 to 48,935 confirming tests.

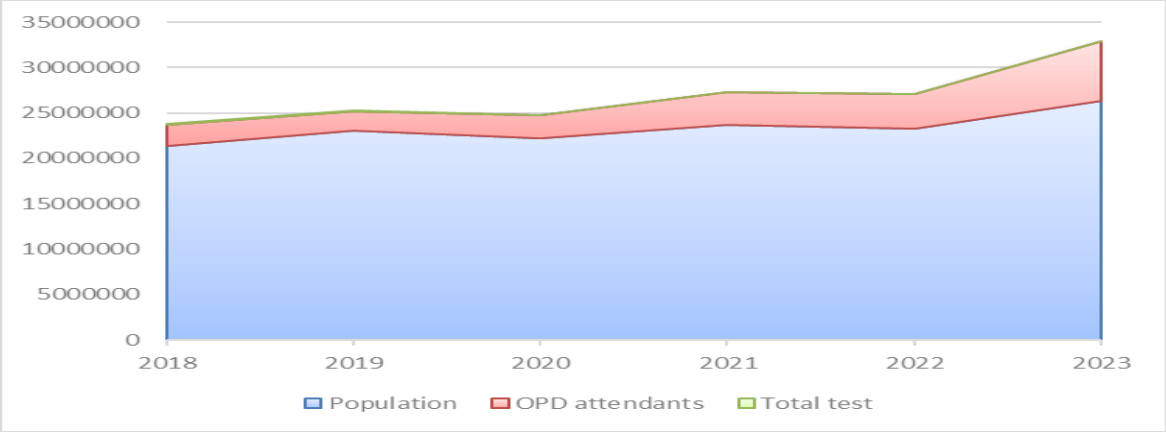


Figure 4.11 Trends of population served by the study health facilities with OPD attendants and who are tested by confirmatory laboratory tests.

The prevalence of presumptive TB in Ethiopia varies across different populations and settings. WHO 2023 reported a prevalence of 146 cases of tuberculosis per 100,000 people, and the well-known estimate for 10 presumptive tuberculosis cases is

estimated to be 1 active TB case. In refugee camps, it was found that bacteriologically confirmed TB accounted for 13.3% of the presumed cases (Meaza et al., 2023). In addition, a multi-center study indicated a prevalence of presumptive TB cases is 16.7% among people seeking healthcare who have been screened for cough (Mohammed et al., 2022). A systematic review showed a pooled prevalence rate of presumed tuberculosis of 2.7% in various community studies (Arega et al., 2019).

In outpatient setting, the probability of TB is expected to be higher in Ethiopian studies, with the prevalence of TB in the health seeker ranging from 1.6% to16.7%, and the likely hood of TB in the hospital seeker being pooled to 10%.

Therefore, the expected utilisation of diagnostic tests within health facilities can be inferred from the potential presumptive cases that have accessed these healthcare settings. The rate of utilisation for tuberculosis testing is derived from the expected population figures and outpatient department (OPD) attendees so that expected presumptive TB cases at catchment area population and expected presumptive TB among OPD attendants are a denominator for Diagnostic test utilisation. The number of OPD attendees has exhibited a marginal annual increase, and the utilisation of confirmatory tests also experienced a slight rise, yet a significant proportion of presumptive tuberculosis cases remain unaddressed within the community and consequently are not subjected to testing for tuberculosis. The average rate of test utilisation derived from expected presumptive tuberculosis cases is 6.2 % at the community level; conversely, the anticipated test utilisation among individuals seeking healthcare at health facilities is considerably lower than 12.3%.

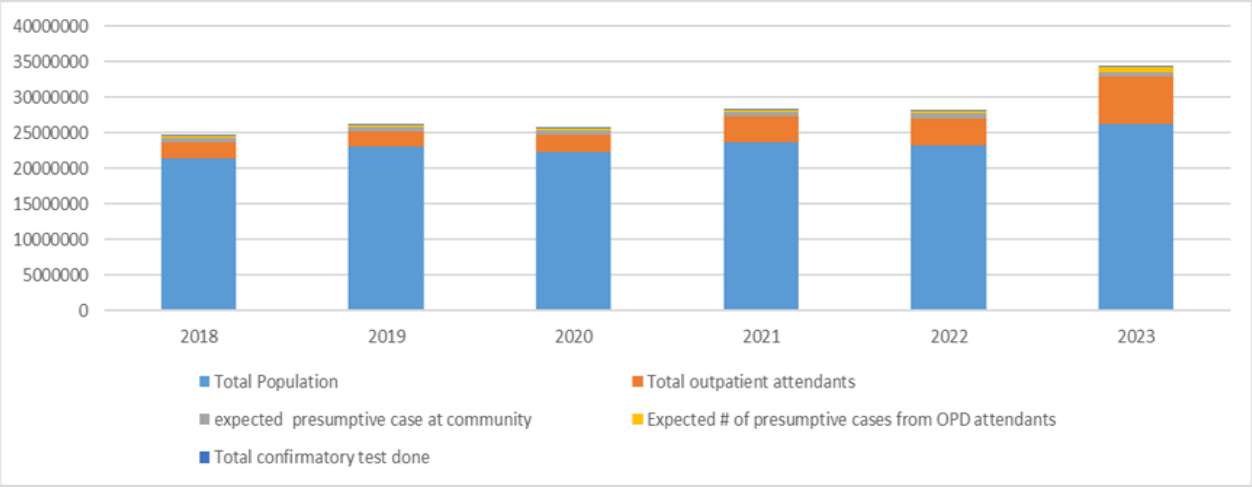


Figure 4.12 Trends of population, OPD attendant and test utilisation by number

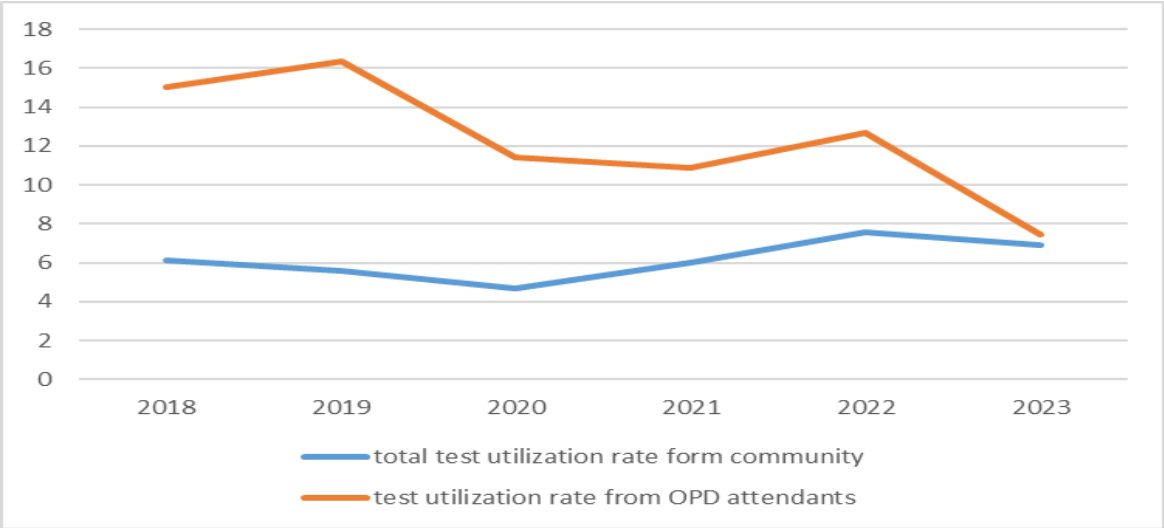


Figure 4.13 Trends of utilzation rate by community and OPD attendants

4.5.2 Urine LF-LAM Utilisation

Urine LF-LAM testing was introduced at the visited health facilities in 2021 (WHO 2019). Prior to this, from 2018 to 2020, no LF-LAM tests were performed. The primary denominator for LF-LAM utilisation is HIV-positive patients on antiretroviral therapy (ART); however, the clinically recommended target population per WHO guidelines is HIV-positive patients with a CD4 count below 200 cells/µL (WHO 2019, 2024). Utilisation increased from 171 tests in 2021 to 567 tests in 2023.

Despite this increase, uptake remains very low relative to the eligible population. By 2023, only 21.5% of HIV-positive patients with CD4 < 200 received LF-LAM testing, leaving nearly 80% of this high-risk group untested (Table 4.12). This represents a significant missed opportunity for early TB diagnosis among people living with HIV.

Table 4.12 Urine LF-LAM utilisation over years (N=112 facilities)

Year	Patients on ART	CD4 <200	LF-LAM tests	LF-LAM positive	Positivity rate	Utilization rate among CD4<200	Utilization rate among ART patients
2018	18,057	2,383	0	0	–	0%	0%
2019	19,204	2,936	0	0	–	0%	0%
2020	19,591	2,368	0	0	–	0%	0%
2021	19,986	2,855	171	44	25.7%	6.0%	0.9%
2022	20,453	2,483	386	8	2.1%	15.5%	1.9%
2023	20,791	2,633	567	94	16.6%	21.5%	2.7%

4.5.3 Test Positivity Rates by Method (2018–2023)

Among the 112 health facilities, total confirmatory tests increased from 35,038 in 2018 to 48,935 in 2023. For each testing method, the positivity rate was calculated as the number of positive results divided by the total number of tests performed for that method. For GeneXpert MTB/RIF, the denominator was the total Xpert tests performed each year (ranging from 16,646 in 2020 to 33,145 in 2022), and the numerator was the number of MTB-positive results (ranging from 1,691 to 3,174). The Xpert positivity rate remained stable, ranging from 9.54% to 10.51% over the six years. For AFB microscopy using Ziehl-Neelsen (ZN) staining, the denominator was the total ZN tests performed (12,815 to 15,908), with positivity ranging from 619 to 897; the ZN positivity rate declined from 6.55% in 2019 to 3.89% in 2023. For urine LF-LAM, the denominator was the total LF-LAM tests performed (zero from 2018–2019, then 69 in 2020, 171 in 2021, 386 in 2022, and 567 in 2023), and the numerator was LF-LAM positive results (23 to 94). The LF-LAM positivity rate was highest in 2020 (33.33%) and gradually decreased to 16.58% in 2023. The overall positivity rate across all methods (total positive / total tests) ranged from 7.79% to 8.90%, with a six-year average of 8.7%. These positivity rates reflect the proportion of presumptive TB cases among those tested and are directly linked to diagnostic utilisation (Objective 2): higher test volumes do not necessarily indicate appropriate targeting, as evidenced by the

declining AFB positivity rate despite stable test numbers. below table 4.13 show test volumes and positivity rates by methods.

Table 4.13 Test volumes and positivity rates by method, 2018–2023 (N=112 facilities)

Year	Xpert tests (n)	Xpert positive (n)	Xpert positivity (%)	AFB ZN tests (n)	AFB ZN positive (n)	AFB ZN positivity (%)	LF-LAM tests (n)	LF-LAM positive (n)	LF-LAM positivity (%)	Total tests (n)	Total positive (n)	Overall positivity (%)
2018	22,223	2,335	10.51	12,815	718	5.60	0	0	–	35,038	3,053	8.71
2019	21,160	2,206	10.43	13,690	897	6.55	0	0	–	34,850	3,103	8.90
2020	16,646	1,691	10.16	11,638	676	5.81	69	23	33.33	28,353	2,390	8.43
2021	25,534	2,557	10.01	12,939	784	6.06	171	44	25.73	38,644	3,385	8.76
2022	33,145	3,174	9.58	14,363	817	5.69	386	82	21.24	47,894	4,073	8.50
2023	32,460	3,098	9.54	15,908	619	3.89	567	94	16.58	48,935	3,811	7.79

4.5.4 TB Case Detection and Drug Susceptibility Testing (DST) Coverage

The ultimate outcomes of TB diagnostic test utilisation are case detection and drug susceptibility testing (DST) coverage. Among the 112 health facilities, the mean proportion of pulmonary TB cases detected (i.e., pulmonary cases as a percentage of all forms of TB) was 64% over the six-year period. The proportion of bacteriologically confirmed TB among all notified TB cases averaged 40.6%, meaning that 59.4% of TB cases were diagnosed clinically (without bacteriological confirmation). This high proportion of clinical diagnosis underscores the limited access to and underutilisation of confirmatory tests

DST coverage was calculated as follows:

First-line DST (rifampicin): Denominator = all bacteriologically confirmed TB cases (numerator = cases with DST result for rifampicin). Coverage increased from 37.0% in 2018 to 80.7% in 2023.

Second-line DST (fluoroquinolones, FQ): Denominator = notified bacteriologically confirmed rifampicin-resistant (RR/MDR) pulmonary TB cases (numerator = RR cases with DST result for FQ). Coverage increased from 0% in 2018 to 37.1% in 2023.

Group A drugs (bedaquiline and linezolid): Denominator = notified RR-resistant pulmonary TB cases (numerator = those with DST result for Bedaquiline/linezolid). Coverage was 5.0% in 2021 and 4.2% in 2022, with zero coverage in other years.
The WHO recommends that DST for rifampicin should be mandatory for all cases, and DST for fluoroquinolones should be mandatory in cases of demonstrated rifampicin resistance (TB Knowledge Sharing Platform 2024). Furthermore, DST for the drugs used in the newly recommended regimens (including bedaquiline and linezolid) is now increasingly critical (TB Knowledge Sharing Platform 2024).

Table 4.14 Trends in TB case detection and DST coverage among confirmed pulmonary cases (N=112 facilities, 2018–2023)

	Year					
	2018	2019	2020	2021	2022	2023
All forms TB cases diagnosed	4089	3832	3704	4310	4778	5799
Bacteriological confirmed pulmonary positive diagnosed TB c	1553	1500	1402	1806	2121	2456
EPTB	1030	1057	1028	1065	1334	1021
pulmonary negative TB cases	922	846	861	936	1305	1398
pulmonary TB cases	2475	2346	2263	2742	3426	3854
Number of bacterioligical confirmed tb case with DST result at least for rifampicin	574	718	867	1021	1581	1981
trends of % of Bact	38.0	39.1	37.9	41.9	44.4	42.4
% trends of pulmonary TB cases diagnosed	**60.5**	**61.2**	**61.1**	**63.6**	**71.7**	**66.5**
% of DST coverage for at least for rifampicin(1st line DST)	**37.0**	**47.9**	**61.8**	**56.5**	**74.5**	**80.7**
# of patients notified with bacteriologically confirmed RR pulmonary TB	38.0	19.0	35.0	40.0	48.0	97.0
#Number of patients notified with bacteriologically confirmed RR pulmonary TB and DST results for FQ	0.0	8.0	11.0	1.0	3.0	36.0
# of patients notified with bacteriologically confirmed RR /FQ-resistant pulmonary TB with DST results for bedaquiline and linozolid	0.0	0.0	0.0	2.0	2.0	0.0
DST covrage for FQ %	**0.0**	**42.1**	**31.4**	**2.5**	**6.3**	**37.1**
DST covrage for for group A drugs (Bdq and Ll)%	**0.0**	**0.0**	**0.0**	**5.0**	**4.2**	**0.0**

4.5.6 Result of Supportive Diagnostic Utilisation

Among the 31 hospitals equipped with functional chest X-ray (CXR) facilities (N=31 hospitals), only 11 (35.5%) had documented and accessible CXR utilisation records. In these 11 facilities, CXR utilisation increased consistently from 2,755 examinations in 2018 to 5,251 in 2023. The proportion of outpatient department (OPD) attendees who received a CXR ranged from 6.13% to 12.79% across the study period. The prevalence of radiographic abnormalities among those examined varied from 4.97% to 15.56%, peaking in 2019 (15.56%) and 2020 (14.99%). the Reasons for missing records included: lack of routine data compilation from facility report (n=11), destruction of records (n=5), and staff unable to locate records during data collection (n=3). The 11 hospitals with available data did not differ significantly from the 20 without data in terms of bed capacity or geographic location ($p>0.05$), suggesting the findings may be generalizable to CXR-equipped hospitals in the region For other supportive diagnostic modalities (ultrasound, histopathology), no routine utilisation data were documented at any of the health facilities, indicating that these tests are either not performed or their use is not systematically recorded. The low documentation rate (only 35.5% of CXR-equipped hospitals maintained usable records) and the absence of data for other supportive diagnostics represent a major gap in monitoring diagnostic utilisation, directly affecting the ability to assess the contribution of supportive diagnostics to TB case detection.

Table 4.15; CXR utilisation among 11 health facilities provided with x-ray N=11

CXR utilization @ n=11	Year					
	2018	2019	2020	2021	2022	2023
# of Catchment population	576139	554268	582496	655360	822278	109889
# of OPD attendants	31780	36723	36723	41066	43546	46659
# of Radiological Examination CXR test done	2755	2250	4157	4326	5571	5251
of radiological Examination with abnormal CXR findings	137	350	623	275	423	269
proportion CXR with abnormal x ray findings	4.97	15.56	14.99	6.36	7.59	5.12
proportion of patient utilized among OPD attendants	8.67	6.13	11.32	10.53	12.79	11.25
proportion of patient utilized CXR among community/Population	0.478	0.406	0.714	0.660	0.678	4.778

4.6 Objective 3: Factors Associated With TB Diagnostic Utilisation

4.6.1 knowledge of Health workers on available Diagnostic tools

Finding linked to Objective 3 (factors associated with low utilisation): Adequate utilisation of TB diagnostic tests depends on health professionals' knowledge of national guidelines, available test methods, and diagnostic algorithms. Among 222 surveyed health professionals by questionnaires , only 41 (18.5%) were familiar with Ethiopia's national TB guidelines, while 161 (72.5%) expressed uncertainty and 20 (9%) were completely unaware of WHO recommendations for rapid diagnostic tests. This widespread lack of guideline familiarity directly contributes to suboptimal test selection and underutilisation of WHO-endorsed rapid diagnostics (Xpert, Truenat, LF-LAM, TB-LAMP).

When asked to name confirmatory TB tests, 121 respondents (54.5%) mentioned only AFB microscopy, omitting molecular and culture methods. Only 36 (16.2%) correctly identified both AFB and GeneXpert, and 65 (29.3%) listed AFB, Xpert, culture and LF-LAM. Furthermore, 173 (77.9%) were unaware of WHO-endorsed molecular rapid TB tests. Among the 49 who claimed awareness, only 3 (6.8%) could correctly list all recommended rapid tests, while 40 (81.4%) could not name any. Although 150 (68%) reported receiving a TB diagnostic algorithm from higher authorities, 72 (32%) had no access to such an algorithm. These knowledge gaps mean that even when diagnostic tools are physically available, health professionals may not use them appropriately,

leading to missed opportunities for bacteriological confirmation and delayed treatment initiation. Table 3 shows the severe knowledge deficit, only 18.5% familiar with national guidelines and 22.1% aware of molecular rapid tests – is a major health system factor limiting diagnostic utilisation. Without adequate knowledge, health professionals cannot effectively implement the diagnostic algorithm, order appropriate tests, or interpret results correctly. Addressing this requires continuous training, supervision, and access to updated guidelines.

Table 4.16 Knowledge of TB diagnostic methods and national guidelines (N=222)

Survey Item	Response	Percentage / Count
Familiarity with national TB guidelines	Yes	18.5% (n=41)
	No (unaware)	9% (n=20)
	Uncertain	72.5% (n=161)
TB confirmatory diagnostics mentioned	AFB only	54.5% (n=121)
	AFB and GeneXpert	16.2% (n=36)
	AFB, Xpert, culture, LF-LAM	29.3% (n=65)
Awareness of WHO-endorsed molecular rapid TB tests	Yes	22.1% (n=49)
	No	77.9% (n=173)
Correctly listed WHO-recommended rapid diagnostics (among aware, n=49)	All tests listed	6.8% (n=3)
	Partial listing	11.8% (n=6)
	None listed	81.4% (n=40)
Availability of TB diagnostic algorithm	Yes	68% (n=150)

4.6.2 Factors Associated with TB Diagnostic Utilisation: Multivariate Analysis

To determine the factors associated with TB diagnostic test utilisation, a multivariate logistic regression analysis was conducted using data from 222 health professionals across different administrative levels. Respondents included health facility heads (28.4%, n=63), diagnostic technicians (38.2%, n=85), zonal TB focal persons (5.4%, n=12), district focal persons (23.8%, n=53), planning officers (1.8%, n=4), and regional/national TB experts (2.4%, n=5). Among all respondents, 75.2% (95% CI: 69.5%–80.9%) perceived TB diagnostic utilisation as inadequate, indicating systemic gaps in access, supply chain reliability, and service delivery efficiency hence on the

other hand all health workers asked what do you think the reason for low diagnostic utilisation.

Table 4.17 : Proportion of TB experts responding on reasons for low diagnostic utilisation (N=222, multiple responses allowed)

Perceived reason	% agreeing (yes)
Low health seeking / low patient flow	59.3%
Low TB screening practice	67.0%
Inadequate supply / reagent shortage	71.0%
Diagnostic equipment failure	67.9%
Inadequate manpower (general)	39.4%
Lack of trained manpower	56.6%
No information about sample referral system	51.6%
Absence of laboratory professionals	45.7%
Postal system for sample referral	50.2%
Alternative sample referral by health professional	22.7%

The multivariate model examined ten predictor variables potentially associated with low diagnostic test utilisation: low health seeking/low patient flow, low TB screening practice, inadequate supply/reagent shortage, diagnostic equipment failure, inadequate manpower (general), lack of trained manpower, no information about the sample referral system, existence of a postal system for sample transport, the alternative sample transportation system established by the Ministry of Health, and absence of laboratory professionals.

Significant predictors. Three variables emerged as statistically significant predictors of low diagnostic utilisation. Low health seeking/low patient flow showed a strong negative association (OR = 0.018, 95% CI: 0.001–0.218, p = 0.002), meaning that facilities reporting reduced patient flow had 98% lower odds of adequate diagnostic test utilisation. Inadequate supply or reagent shortage was also significantly associated (OR = 0.023, 95% CI: 0.002–0.299, p = 0.004), indicating that supply shortages drastically reduced the likelihood of optimal test utilisation. The strongest

predictor was no information about the sample referral system (OR = 0.006, 95% CI: 0.000–0.112, p < 0.001), suggesting that lack of knowledge about how to refer samples virtually eliminated the chance of adequate diagnostic utilisation.

Borderline and non-significant factors. Diagnostic equipment failure demonstrated a borderline association (OR = 0.114, 95% CI: 0.010–1.328, p = 0.083), suggesting a possible but not statistically significant reduction in utilisation. Low TB screening practice (OR = 0.358, p = 0.216), existence of a postal system for sample transport (OR = 0.296, p = 0.228), inadequate manpower (OR = 0.590, p = 0.558), and absence of laboratory professionals (OR = 1.507, p = 0.706) were not significantly associated. Lack of trained manpower yielded an OR of 1.731 (p = 0.580), and the Ministry of Health alternative sample transportation system produced an OR of 4.33 (95% CI: 0.482–38.918, p = 0.191); neither reached statistical significance. The constant term was 153.06 (p = 0.004).

Table 4.18 result of factors associated with low diagnostic test utilisation (N=222, multiple responses allowed)

Variable	Odds Ratio (Exp(B))	95% C.I. for Exp(B)	Significance (Sig.)
Low health seeking/low patient flow	0.018	0.001 - 0.218	0.002
Low TB screening	0.358	0.070 - 1.821	0.216
Inadequate supply	0.023	0.002 - 0.299	0.004
Equipment failure	0.114	0.010 - 1.328	0.083
Inadequate manpower	0.59	0.101 - 3.443	0.558
Trained manpower	1.731	0.247 - 12.110	0.58
No information about sample referral system	0.006	0.000 - 0.112	< .001
Postal office	0.296	0.041 - 2.139	0.228
Alternative Ministry of Health	4.33	0.482 - 38.918	0.191
Laboratory professionals	1.507	0.179 - 12.685	0.706
Constant	153.06		0.004

These multivariate findings confirm that both demand-side (low health seeking) and supply-side (reagent shortages, lack of referral system information) factors are the most critical drivers of inadequate TB diagnostic utilisation. Notably, while descriptive results showed high proportions of respondents citing equipment failure (67.9%) and low screening practice (67.0%), the multivariate analysis indicates that after adjusting for other variables, supply chain integrity and knowledge of sample referral pathways exert the strongest independent effects. Therefore, interventions to improve TB diagnostic utilisation should prioritize: (1) ensuring consistent availability of reagents and supplies, (2) establishing and disseminating clear sample referral protocols, and (3) community-level strategies to increase health-seeking behavior. Addressing manpower issues alone, without fixing supply and referral systems, is unlikely to substantially improve diagnostic utilisation.

4.6.3 Facility-level factors associated with diagnostic utilisation (checklist data, N=112 facilities)

To complement the health professional survey, facility-level data were extracted from checklists completed for all 112 service delivery health facilities. The analysis aimed to identify health system factors associated with two dependent variables: (1) total diagnostic test utilisation (sum of AFB microscopy, GeneXpert, and urine LF-LAM tests performed annually, averaged over 2018–2023), and (2) total all-forms TB cases detected (annual average). Independent variables included catchment population total health professionals, number of BSc laboratory technicians, number of generalist doctors, number of X-ray tests performed, and total OPD visits. The following bivariate correlations were observed (Table 4.10)

Table 4.19: Pearson correlations between facility characteristics and TB test utilisation (N = 112 facilities)

Variable pair	Pearson r	p-value	Interpretation
Catchment population ↔ Total test utilisation	0.822	<0.001	Strong, positive, statistically significant
Total health professionals ↔ Total test utilisation	0.451	<0.001	Moderate, positive, statistically significant

Variable pair	Pearson r	p-value	Interpretation
BSc lab technicians ↔ Total test utilisation	0.166	0.040	Weak, positive, statistically significant
Total health professionals ↔ Generalist doctors	0.822	<0.001	Strong, positive (expected collinearity)
Catchment population ↔ BSc lab technicians	-0.021	0.412	Weak, negative, not significant

Interpretation: Facilities serving larger populations performed more TB tests (r=0.822), which is expected. However, the very weak and non-significant correlation between catchment population and number of BSc lab technicians (r=-0.021, p=0.412) indicates that staffing of qualified laboratory personnel is not aligned with population need which is a critical system bottleneck.

Multiple linear regression analysis

A multiple linear regression model was fitted with total all-forms TB cases detected as the dependent variable. The model revealed two statistically significant predictors:

Table 4.20 : Multiple linear regression results for TB case detection (N = 112 facilities)

Predictor	Coefficient (β)	t-value	p-value	95% CI
Number of X-ray tests	0.940	4.254	0.002	[0.36, 1.52]
OPD visits	0.557	2.310	0.044	[0.02, 1.09]

interpretation: X-ray tests (β=0.940, p=0.002): Each additional X-ray examination was associated with a near-equivalent increase in TB cases detected. This reflects the critical role of chest X-ray in clinically diagnosing pulmonary TB, especially where bacteriological confirmation is limited.

OPD visits (β=0.557, p=0.044): Facilities with higher patient volumes detect more TB cases, but this also highlights missed opportunities – as shown in Section 4.5.1, only

12.3% of OPD attendees with presumptive TB were actually tested. Catchment population, total health professionals, and number of BSc lab technicians were not statistically significant in the multivariate model ($p>0.05$), likely due to collinearity with OPD visits and X-ray availability. Improving access to X-ray services and increasing systematic TB screening among OPD attendees would have the greatest impact on TB case detection. This means increasing population or staff numbers without addressing diagnostic equipment and screening protocols is unlikely to improve outcomes.

4.7 Use Of Diagnostic Data For Information Use (Tuberculosis Diagnostic Monitoring And Evaluation)

4.7.1 Diagnostic Monitoring in Tuberculosis Service Planning

The study investigated the diagnostic monitoring practices of participants working in organisations offering TB diagnostic services and at the management level. The conclusions reveal a significant gap in formal planning. Furthermore, among 222 health professionals surveyed from 171 organisations, 139 respondents (62.6%) reported that their organization had a diagnostic service plan, 61 (27.5%) reported no plan, and 22 (9.9%) did not know their planning status. For those who did not have a plan, 63% cited lack of diagnostic planning knowledge as the main reason, 25% perceived planning is unnecessary for TB diagnostics, and 12% said it was due to a lack of planning direction from the planning unit.

In order to achieve the goals of the plan, 58% of organisations with plans indicated that they provided a plan for achieving the planed goals. However, 42% of respondents reported that their plans did not specify the procedures for collecting and analyzing tuberculosis diagnostic data for project evaluation.

4.7.2 Use of Diagnostic Indicators for Decision-making

This analysis further examined the use of diagnostic indicators in decision making. Among the 222 professionals surveyed, 24 (10.8%) did not use indicators to monitor the TB diagnostic performance of tuberculosis. Furthermore, 41 (18.5%) used only two indicators,113 (51%) used four indicators, and 19 (1.6%) used five indicators. This indicates a variable level of use of TB diagnostic indicators for informed decision-making in the context of TB diagnostic services monitoring.

Table 4.21: professional Response to the use of Diagnostic the tuberculosis Diagnostic indicators for decision

Sn	Diagnostic indicators	Used by participants	N	%
1	WRD as the initial diagnostic test (coverage)	109	222	49.1
2	Percentage of notified new and relapse TB cases with bacteriological confirmed	136	222	61.3
3	Number of data connectivity system has been established	41	222	18.5
4	Number of TB diagnostic and follow-up tests provided through the national TB programme are free of charge	71	222	32.0
5	TB cases with DST results for rifampicin	119	222	53.6
6	Percentage of notified rifampicin-resistant TB cases with DST results for fluoroquinolones	50	222	22.5
7	Percentage of notified, rifampicin-resistant TB cases with DST results for Bedaquiline	31	222	14.0
8	Performance indicators are enrolled in an EQA system for all diagnostic methods performed	98	222	44.1
9	EQA panel testing for all DST methods performed	74	222	33.3
10	Percentage HF quality management system is being implemented / laboratory accreditation	30	222	13.5
11	Test utilisation (AFB, Xpert/urine lam/culture)	152	222	68.5
12	Imaging (X-ray, ultrasound, MRI, CT) Utilisation	24	222	10.8
13	Histopathology Utilisation	15	222	6.8

4.7.3 Diagnostic review and staff performance result

Asked about the frequency of periodic TB diagnostic review and staff performance assessments, 43.9% said they regularly conducted. However, 28.5% indicated that the examinations were conducted inconsistencies. In particular, 27.6% of organisations did not conduct program performance reviews.

Table 4.22 Frequency of Periodic Tuberculosis review and staff performance assessment (N=222 Health Professionals)

Response	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	97	43.9%	43.9%	43.9%
No	62	27.9%	27.9%	71.8%
Sometimes	63	28.4%	28.4%	100.0%
Total	**222**	**100.0%**	**100.0%**	

4.8 Conclusion

Chapter 4 analyzed TB diagnostic services in Oromia Region using data from 112 health facilities and 222 health professionals. Key findings: (1) Access was poor – only 24.1% of facilities had GeneXpert, over 40% of the population lived >10 km from diagnostic services, and basic amenities averaged 59%. (2) Test utilisation was very low – only 6.2% of expected community presumptive TB cases and 12.3% of OPD attendees were tested. (3) Major associated factors included supply shortages (OR=0.023), lack of referral system knowledge (OR=0.006), and low health-seeking behavior (OR=0.018); only 18.5% of staff knew national guidelines. (4) M&E systems were weak – 37% lacked diagnostic plans, and 56% had inconsistent program reviews. The chapter concludes that severe systemic gaps collectively drive underutilisation of TB diagnostics.

CHAPTER 5

DISCUSSION OF THE RESEARCH FINDINGS

5.1 Introduction

Discussion of research findings is writing that interprets and contextualizes the results while addressing the questions of research raised. Discussions interpret the results and provide insights into their meaning and relevance within the broader context of existing research (Marten et al., 2024). This chapter interprets and contextualizes the findings presented in Chapter 4, linking them to existing literature and theoretical frameworks. It addresses each of the four research objectives, explains the meaning and relevance of the results, and draws actionable implications for policy, practice, and future research. The chapter also acknowledges study limitations and concludes with an integrative synthesis.

5.1.1 Summary of Key Findings from chapter 4

Objective 1 (Availability & Accessibility): Only 24.1% of health facilities had GeneXpert; basic amenities averaged 58.8%; over 40% of the population lived >10 km from AFB microscopy and X-ray services; supportive diagnostics were severely limited (X-ray in 27.7% of facilities; AI-CAD, CT, MRI: 0%).

Objective 2 (Utilisation): Total confirmatory tests increased from 35,038 (2018) to 48,935 (2023). However, utilisation from expected community presumptive TB cases averaged only 6.2%; among OPD attendees, only 12.3% were tested. Urine LF-LAM reached only 21.5% of eligible HIV patients by 2023.

Objective 3 (Associated Factors): Multivariate analysis identified inadequate supply/reagent shortages (OR=0.023, p=0.004), lack of sample referral system information (OR=0.006, p<0.001), and low health-seeking behavior (OR=0.018, p=0.002) as strongest predictors. Only 18.5% of health professionals were familiar with national TB guidelines.

Objective 4 (Monitoring & Evaluation): Only 62.6% of organisations had a diagnostic service plan; 42% of those lacked data collection/analysis procedures; 56.1% had inconsistent or no periodic programme reviews.

5.1.2 Theoretical Framework

This discussion is guided by the WHO Health System Strengthening (HSS) Framework (WHO, 2007), which conceptualizes health systems across six building blocks: service delivery, health workforce, health information systems, access to essential medicines and technologies, financing, and leadership/governance. Applying this framework reveals how deficiencies across multiple blocks interact to produce low TB diagnostic utilisation. Each section below identifies which building blocks are implicated and how they reinforce one another

5.2 TB Laboratory Service Availability Basic Amenities

Access to basic services is the foundation for effective TB diagnosis in resource-limited settings implicated to HSS building blocks which Service delivery, technologies, infrastructure. The WHO stresses that robust diagnostic systems require not only advanced tools but also supporting infrastructure (WHO, 2022). In this study, although electricity (94.6%) and water (88.4%) were relatively available, digital and logistical infrastructure remained underdeveloped: only 33% of facilities had internet/email, and only 26% had communication equipment.

These infrastructure deficits directly undermine digital diagnostic tools. GeneXpert machines, for instance, depend on internet connectivity for real-time data transmission, monitoring cartridge stocks, and integrating with national health information systems. Although progress in internet-based diagnostic frameworks including those employing artificial intelligence promises shorter waiting times and greater diagnostic accuracy, persistent connectivity problems and delays remain critical obstacles that must be resolved to improve overall healthcare delivery (Wang et al., 2023). Our findings are consistent with a recent multi-country African study (2025), which found that in 2023 only 58% of people with TB received a WHO-recommended rapid diagnostic (WRD) test, with the main barriers being supply

chain breakdowns, insufficient funding, and weak specimen transport systems (Mupfumi et al., 2025)

Transport arrangements are another key gap. Only 49% of facilities had access to an ambulance, which considerably delays patient referral, especially in remote areas. A scoping review confirmed that in South Africa, transportation barriers are a critical structural factor leading to delays in TB diagnosis and treatment, significantly increasing mortality risk (Meneni, Kigozi & van Rensburg, 2023). Communication tools (telephones) are essential for coordinating specimen transport and patient follow-up; their absence has been linked to operational inefficiency and lost samples in rural Uganda (Brendish et al., 2020).

Interpretation: These findings show substantial misalignment between diagnostic capability and system readiness. While electricity and water support basic instrument operation, lack of digital connectivity and transport infrastructure severely weakens the potential of WHO-endorsed technologies. The WHO End TB Strategy laboratory strengthening framework (2016) explicitly identifies a quality-assured laboratory network equipped with rapid diagnostics as a prerequisite for universal DST access. Oromia remains far from that goal.

5.3 Knowledge Of tuberculosis Diagnostic Methods

Implicated HSS building block: Health workforce.

Ethiopia's National Guidelines on Tuberculosis recommend WHO-approved rapid diagnostic tests as the primary screening mechanism for symptomatic individuals. However, only 18.5% of the 222 surveyed health professionals showed familiarity with these guidelines; 72.5% expressed uncertainty, and 9% were completely unaware of WHO recommendations for rapid diagnostics.

When asked to name confirmatory TB tests, 54.5% mentioned only AFB microscopy, omitting molecular and culture methods. Only 16.2% correctly identified both AFB and GeneXpert, and 29.3% listed AFB, Xpert, culture and LF-LAM. Furthermore, 77.9% were unaware of WHO-endorsed molecular rapid TB tests. Among the 49 who claimed awareness, only 6.8% could correctly list all recommended rapid tests.

These knowledge gaps are not unique to Ethiopia. A study in Gujarat, India, found significant gaps in TB management knowledge among healthcare providers, with 26% failing competency tests (Shah, Kadu & Sharma, 2024). In Ethiopia, the National Comprehensive TB, Leprosy and TB/HIV Training Manual for Health Care Workers (FMOH, 6th edition) exists, but its existence does not guarantee knowledge transfer. The 7th edition of Ethiopia's national TB guidelines (2024) provides updated guidance, yet frontline workers remain unaware,indicating a failure in continuing education and supervision systems rather than absence of materials.

Interpretation: The severe knowledge deficit means that even when diagnostic tools are physically available, health professionals may not use them appropriately. This directly contributes to suboptimal test selection, under utilisation of WHO-endorsed rapid diagnostics, and missed opportunities for bacteriological confirmation. Addressing this requires structured, continuous competency-based training, regular supervision, and accessible job aids.

5.4 Availability Of Confirmatory Tuberculosis Diagnostics

Implicated HSS building blocks: Essential medicines/technologies, service delivery. The study highlights significant differences in the availability of diagnostic reagents and equipment for tuberculosis (TB) in health facilities. Conventional microscopy reagents, such as Methylene blue (87.50%) and fuchsine carbon (85.71%), have relatively high coverage, but key fluorescent AFB reagents, such as acid alcohol (10.71%) and potassium permanganate (8.04%), are severely limited, potentially compromising the accuracy of acid-fast bacilli diagnostics. Similarly, molecular diagnostic tools such as Gene Xpert MTB (24.1%) and advanced tool such as LPA (1.8%) and tuberculosis culture (1.8%) are scarce, reflecting a reliance on outdated methods and gaps in infrastructure.

The lack of latent TB diagnosis (IGRA and skin tests) demonstrates the constraints of system resources. These conclusions are consistent with the global challenges of tuberculosis diagnosis in a resource-limited setting that often struggle to adopt new technologies (World Health Organization, 2021). To address these gaps, it is

necessary to invest in the supply chain of reagents and molecular diagnostic capacity to improve the detection and management of tuberculosis.

Interpretation: The reliance on outdated microscopy (84% coverage) alongside critically low molecular diagnostic availability perpetuates diagnostic delay, especially for smear-negative and extra-pulmonary TB. The absence of latent TB testing is particularly concerning given that an estimated 30% of Ethiopia's population has latent infection (WHO, 2018), a precursor to active disease. Without systematic LTBI screening, high-risk groups (HIV-positive individuals, household contacts) remain undiagnosed, perpetuating transmission.

5.5 Availability Of Supportive Diagnostics

Supportive diagnostics play an essential role in TB diagnosis. In Ethiopia, 60% of active TB cases are identified through supportive methods (chest X-ray, ultrasound, histopathology). In Oromia, 51% of TB cases are bacteriologically confirmed, while 49% are clinically diagnosed 24% extra-pulmonary and 25% clinically diagnosed pulmonary negative.

Our study found that chest X-ray was available in only 27.7% of all health facilities (though 100% of hospitals), yielding a ratio of one X-ray machine per 841,090 people far below WHO recommendations. Digital X-ray was available in 22.3% of facilities; AI-CAD, CT, and MRI were completely absent. Histopathology was available in only 2.7% of facilities (one per 8.7 million people), severely constraining extra-pulmonary TB diagnosis.

Interpretation: The concentration of supportive diagnostics at hospital level creates a two-tier system: patients in rural areas without hospital access rely solely on clinical examination or basic microscopy, leading to under diagnosis of smear-negative and extra-pulmonary TB. Decentralizing X-ray services to health centress and introducing AI-CAD could bridge this gap.

5.6 Availability Of Latent Tuberculosis Testing

In our study area, the availability of tuberculosis latent testing in hospitals remains very limited, and the data indicates that no facility offers systematic screening of tuberculosis latent infection. This gap is concerning given the high burden of TB in Ethiopia where an estimated 30% of the population is thought to have latent TB, a pre cursor to active disease (WHO, 2018).). Access to interferon-gamma release tests (IGRAs) or tuberculosis skin tests (TSTs) is limited due to lack of trained personnel and funding (Mesfin et al., 2019). Without an active LTBI screening, high-risk groups such as HIV-positive people and active tuberculosis patients' families were not diagnosed, perpetuating the transmission cycle, while latent tuberculosis treatments were administered without excluding latent tuberculosis infections. Strengthening LTBI services in accordance with World Health Organization (WHO) guidelines, which recommend systematic testing in high-impact environments, is essential to curb TB incidence (WHO, 2018). To address this gap, targeted investments in diagnostics, health worker training and integrated strong TB diagnostic policies are required.

Interpretation: The absence of LTBI testing represents a missed opportunity for preventive therapy. Strengthening LTBI services requires targeted investment in diagnostics, health worker training, and integration into routine HIV and TB services.

5.7 Availability Of Drug Susceptibility Testing

Implicated HSS building blocks: Technologies, service delivery, laboratory network.

The study found critically low DST availability: 24% for first-line anti-TB drugs and only 8% for second-line drugs. Phenotypic DST (the gold standard) was available at both referral laboratories included in the study, but its centralized nature contributes to low accessibility. This reflects a common bottleneck: diagnostic services concentrated at higher-level facilities create barriers for peripheral patients due to travel costs, delays, and inadequate specimen referral systems (Meneni et al., 2023). The WHO

recommends decentralizing DST to improve access (WHO, 2020), yet implementation remains inconsistent.

A multi-regional survey WHO (2025) found DST access for children with HIV ranged from 30% to 82% across low- and middle-income countries, showing wide variation. The 8% second-line DST availability in our study mirrors findings from Maningi, Daum & Boyle (2017), who highlighted that second-line DST remains inaccessible in many high-TB-burden regions, perpetuating empirical treatment and amplifying drug resistance risks.

Interpretation: The low DST coverage means that many rifampicin-resistant (RR) TB patients do not receive fluoroquinolone or bedaquiline DST, risking ineffective regimens and further resistance. The WHO End TB Strategy calls for universal DST with 12 core indicators for laboratory strengthening; Oromia falls far short.

5.8 Tuberculosis Diagnostics Physical Proximity

Implicated HSS building blocks: Service delivery, financing, governance.

Geospatial analysis revealed that more than 40% of the population lives >10 km from AFB microscopy and X-ray services, and nearly 44% from GeneXpert exceeding WHO acceptable walking distance. Spatial autocorrelation showed significant dispersion for GeneXpert (Moran's I $z = -3.28$, $p = 0.001$), indicating that while facilities are deliberately spread, coverage remains inequitable.

These findings align with broader Ethiopian research. A study in East Gojjam zone found that 32% of administrative areas had poor geographic access to TB services (>10 km) (Asemahagn, Alene & Yimer, 2020). Our analysis suggests an even more severe situation for advanced diagnostics. Qualitative evidence from Ethiopia confirms that patients with chronic cough often do not access TB services due to travel distances to district-level facilities; rural populations with high poverty, particularly women, are at disproportionately high risk of undiagnosed TB (Tulloch et al., 2015).

Furthermore, a recent Ethiopian study (Deribew et al., 2024) found that the proportion of households facing TB-related catastrophic costs reduced from 64.7% to 43.8% after

interventions including installing GeneXpert machines and establishing specimen referral systems. However, costs remain unacceptably high, and distance remains a key driver.

Interpretation: Our analysis relies on linear distance, which does not account for terrain, road networks, or transport availability meaning actual travel time and difficulty are likely greater. Achieving universal access requires strategic placement of new facilities, scaling up advanced diagnostics at peripheral health centress, and implementing community-based screening and sputum collection programmes.

5.9 Tuberculosis Diagnostics Test Utilisation

To analyze tuberculosis (TB) diagnostic test utilisation, it is essential to define the appropriate denominator and numerator for the analysis. The denominator typically represents the total population at risk or the total number of individuals who could potentially undergo TB testing. TB diagnostic test utilisation can be conducted using only presumptive pulmonary TB cases, as the study focused on individuals reporting TB symptoms or having abnormal chest X-ray findings, highlighting the importance of targeted screening in high-risk populations (Owusu-Edusei, Marks and Baker, 2017).

TB diagnosis test utilisation depends on prevalence of TB and presumptive in the community and attendance of outpatient department attendance at health facilities (Ohene, Bonsu and Akweongo, 2017). The prevalence of presumptive tuberculosis (TB) in Ethiopia varies across different populations and settings. WHO (2023) reported a prevalence of 147 TB cases per 100,000 populations, and the well-known presumptive estimate for 1 TB case per 10 presumptive TB cases are estimated.

In refugee camps, the prevalence of bacteriologically confirmed pulmonary TB among presumptive cases was found to be 13.3% (Meaza et al., 2023). Additionally, a multicenter study indicated a prevalence of 16.7% among health care-seeking individuals screened for cough (Mohammed, Aman and Aseffa, 2022). A systematic review highlighted a pooled prevalence rate of presumptive TB at 2.7% across various community studies (Arega, Mersha and Minda, 2019). It is anticipated that there will be more TB presumptive cases in outpatient settings. According to a study conducted in Ethiopia, the prevalence of presumptive TB among patients varies between 1.6%

and 16.7%. Ten percent is the combined prevalence among facility health care seekers. Therefore, the anticipated utilisation of diagnostic tests within health facilities can be inferred from the potential presumptive cases that have accessed these healthcare settings.

The rate of utilisation for tuberculosis testing is derived from the expected population figures and outpatient department (OPD) attendees. The number of OPD attendees has exhibited a marginal annual increase, with the exception of the year 2019, which corresponded with the COVID-19 pandemic; during this period, the utilisation of confirmatory tests also experienced a slight rise, yet a significant proportion of presumptive tuberculosis cases remain unaddressed within the community and consequently are not subjected to testing for tuberculosis. The average rate of test utilisation derived from expected presumptive tuberculosis cases is below 8% at the community level; conversely, the anticipated test utilisation among individuals seeking healthcare at health facilities is considerably lower than 12.3 %.

Confirmatory TB diagnostic test utilisation in our study area remains suboptimal, as evidenced by data from 112 health facilities (2018–2023). Despite an increase in outpatient department (OPD) attendees from 2.3 million to 6.6 million, confirmatory TB tests rose only marginally (35,038 to 48,935), reflecting low test utilisation rates relative to presumptive cases. The study's denominator analysis, focusing on presumptive pulmonary TB cases (symptomatic individuals or those with abnormal chest X-rays), underscores systemic gaps in targeted screening (Owusu-Edusei et al., 2017). For instance, community-level test utilisation averaged <8%, while facility-based rates remained below 12.3%, far below the expected demand given the pooled prevalence of presumptive TB (10%) among healthcare seekers (Arega et al., 2019; Mohammed et al., 2022). The COVID-19 pandemic in 2019 further disrupted testing, with OPD attendance declining but test numbers showing a slight rise, suggesting inconsistent prioritization of TB diagnostics during health emergencies. Additionally, urine LF-LAM utilisation for HIV-positive patients (CD4 <200) remained low until 2023 (21.5% utilisation rate), despite its potential to improve TB detection in immunocompromised populations (Meaza et al., 2023). These findings highlight persistent under utilisation of confirmatory tests, even in high-risk groups, and emphasize the need for intensified case-finding strategies.

The disparities in diagnostic utilisation reflect structural and operational challenges. While Xpert MTB/RIF and LF-LAM tests are critical for early TB diagnosis, their inconsistent adoption evidenced by LF-LAM's delayed scale-up (0% utilisation until 2021) suggests gaps in policy implementation or resource allocation (Banti et al., 2022). The higher LF-LAM positivity rate (25.7% in 2021) compared to later years (16.6% in 2023) may indicate initial targeting of high-risk subgroups, though utilisation rates among eligible ART patients remained suboptimal (≤2.7%). Similarly, the low community-level test utilisation (<8%) underscores missed opportunities for passive case detection, particularly in regions like Oromia.

Strengthening diagnostic capacity requires integrating TB screening into routine OPD services, expanding access to rapid tests in rural settings, and addressing stigma or logistical barriers that deter testing. Future efforts must align with WHO recommendations to prioritize high-yield populations, such as refugees (13.3% TB prevalence) and immunocompromised individuals, to optimize diagnostic efficiency and reduce Ethiopia's TB burden (Meaza et al., 2023; Arega et al., 2019).

Interpretation: The very low utilisation rates indicate that passive case finding is failing. Missed opportunities occur both at community level (people with symptoms not seeking care) and at facility level (symptomatic patients not being tested). Strengthening diagnostic capacity requires integrating TB screening into routine OPD services, expanding rapid test access in rural settings, and addressing stigma and logistical barriers.

5.10 Factors Associated With Tuberculosis Diagnostic Utilisation

Implicated HSS building blocks: All six (systemic interaction).
Multivariate logistic regression identified three statistically significant predictors of low diagnostic test utilisation: Low health seeking / low patient flow (OR = 0.018, p = 0.002) facilities with reduced patient flow had 98% lower odds of adequate utilisation.
Inadequate supply / reagent shortage (OR = 0.023, p = 0.004) supply shortages drastically reduced utilisation. No information about sample referral system (OR = 0.006, p < 0.001) lack of knowledge about sample referral virtually eliminated adequate utilisation.

Notably, while 67.9% of respondents cited equipment failure as a reason for low utilisation, this was not statistically significant in the adjusted model (p = 0.083). Similarly, inadequate manpower and lack of trained manpower were associated but not significant. This suggests that supply chain integrity and knowledge of referral pathways exert stronger independent effects than equipment or staffing alone.

These findings are corroborated by studies from Ethiopia and Uganda, which confirm that interruptions in diagnostic commodity supply and persistent equipment failures are critical bottlenecks (Abayneh et al., 2020; Tumuhairwe et al., 2023). A PhD thesis on TB diagnostic scale-up in Africa (Iragena, 2025) identified laboratory preparedness, staff competence, policy reform, funding availability, and political commitment as key factors influencing uptake, noting that despite WHO endorsement, roll-out and scale-up in Africa have been delayed by systemic and contextual barriers.

Interpretation: Interventions to improve TB diagnostic utilisation should prioritise: (1) ensuring consistent reagent and cartridge availability, (2) establishing and disseminating clear sample referral protocols, and (3) community-level strategies to increase health-seeking behavior. Addressing manpower issues alone, without fixing supply and referral systems, is unlikely to substantially improve utilisations.

5.11 Use Of Diagnostic Data For Information Use (Tuberculosis Diagnostic Monitoring And Evaluation)

Implicated HSS building blocks: Information, leadership/governance.

The study found significant gaps in formal diagnostic planning and M&E. Only 62.6% of organisations reported having a diagnostic service plan; 27.5% had no plan, and 10% did not know. Among those without a plan, 63% cited lack of diagnostic planning knowledge, 25% perceived planning as unnecessary, and 12% cited lack of direction from the planning unit.

Of organisations with plans, 58% indicated that the plan outlined how to achieve objectives. However, 42% reported that their plan did not specify procedures for collecting and analyzing TB diagnostic data for project evaluation. Regarding periodic TB diagnostic reviews and staff performance assessments, only 43.9% conducted

regular reviews; 28.5% conducted them inconsistently, and 27.6% conducted no reviews.

Interpretation: The finding that 42% of plans lacked data collection procedures indicates that the information building block is severely underdeveloped. Without functional M&E, performance cannot be managed, resource allocation remains untargeted, and accountability is absent

5.11.1 Use of Diagnostic Indicators for Decision-making

The World Health Organization (WHO) has established a comprehensive set of diagnostic standards and indicators for tuberculosis (TB) control programs, which are essential for monitoring and evaluating efforts globally. These standards are designed to facilitate effective program management and improve patient outcomes. Key diagnostic tests emphasized by WHO include Sputum Smear Microscopy, Rapid Molecular Tests like Xpert MTB/RIF, Culture, Chest Radiography, and Drug-Susceptibility Testing (DST) (World Health Organization, 2020a). The proper utilisation of these diagnostics is vital for ensuring timely diagnosis and treatment initiation, which are critical in controlling TB transmission. While these standards are widely recognized, the WHO also highlights the ongoing need for programmatic data to address implementation challenges, particularly in resource-limited settings where access to and the quality of advanced testing may be constrained (World Health Organization, 2021). despite the global standardization of TB diagnostic indicators, an ongoing discourse advocates for the development of supplementary metrics to better address persistent system-level bottlenecks and evolving evidentiary needs, particularly in resource-limited settings where structural barriers impede effective implementation (World Health Organization, 2021; McNerney et al., 2022).

The result of the study, concerning 11.3% of the 222 professionals surveyed reported using no indicators for monitoring TB diagnostic performance. While 18.5% utilized only two indicators, the average number of indicators used was four. This implies that there is not a consistent level of indicator use for well-informed decision-making in the context of TB diagnostic services.

Interpretation: The finding show’s Strengthening diagnostic data use requires mandatory periodic data reviews at facility and district levels, standardised indicator reporting, and training in data utilisation for decision-making.

5.12 Conclusion: Synthesis And Implications

Returning to the four objectives of this study, the findings collectively demonstrate that low TB diagnostic utilisation in Oromia Region is not a problem of isolated resource shortages but a multidimensional systemic failure involving geographic access, workforce capacity, supply chain integrity, and governance deficiencies that span all six building blocks of the WHO Health System Strengthening framework.

Interpretation of Objective 1 (Access): The finding that over 40% of the population lives >10 km from essential diagnostics confirms that Oromia remains far from the WHO End TB Strategy target of universal access to rapid molecular testing (⩾90% by 2025). The spatial dispersion pattern (GeneXpert: Moran's I z = –3.28, p = 0.001) indicates that while facilities are deliberately spread, this has been insufficient to achieve equitable coverage. This echoes broader African trends where only 7 of 24 countries are on track to meet 2027 targets.

Interpretation of Objective 2 (Utilisation): The very low test utilisation (6.2% at community level, 12.3% among OPD attendees) reveals that passive case finding – Ethiopia's current strategy is failing. The gap between available diagnostics and their actual use points to demand-side barriers distance, low health-seeking behaviour) and supply-side failures (reagent shortages, lack of referral system knowledge). The 21.5% LF-LAM utilisation among eligible HIV patients represents a missed opportunity for early diagnosis in the highest-risk population.

Interpretation of Objective 3 (Associated factors): The multivariate analysis identified inadequate supply (OR = 0.023), lack of referral system information (OR = 0.006), and low health-seeking behaviour (OR = 0.018) as the strongest predictors. Notably, while 67.9% of respondents cited equipment failure as a reason for low utilisation, this was not significant in the adjusted model suggesting that supply chain integrity and knowledge of referral pathways exert stronger independent effects. The finding that only 18.5% of health professionals were familiar with national guidelines indicates that technology introduction without accompanying capacity building is insufficient.

Interpretation of Objective 4 (Monitoring & Evaluation): The finding that 42% of organisations with diagnostic plans lacked data collection procedures, and 56.1% had inconsistent programme reviews, indicates that the information and governance building blocks are severely underdeveloped. Without functional M&E, performance cannot be managed, and resource allocation remains untargeted.

Implications for Policy and Practice

Achieving universal TB diagnostic access in Oromia requires: Decentralising Xpert placement with mobile sample transport for remote areas, Continuous competency-based training on national guidelines, establishing real-time reagent supply monitoring Mandatory diagnostic data review at facility and district levels Community-based screening to bridge demand-side gaps

Bridge to Strategy Development (Chapters 6-8) The systemic gaps identified in this chapter particularly the interplay between access barriers, utilisation failures, and M&E deficiencies provided the empirical foundation for the Delphi process described in Chapter 6. The strategies presented in Chapters 6-8 were developed specifically to address each of the four objectives and their underlying HSS building block deficiencies.

Implications for Theory

The findings validate the HSS framework's premise that health system building blocks are interdependent. Supply chain improvements alone (technologies block) cannot increase utilisation without corresponding investments in workforce training (health workforce) and referral systems (service delivery).

Implications for Future Research

Implementation science studies are needed to evaluate the effectiveness of targeted interventions such as community-based screening, sample transport systems, and digital decision support tools. Cost-effectiveness analyses of different diagnostic placement strategies would also inform resource allocation.

Implications for policy and practice: Achieving universal TB diagnostic access in Oromia requires: (1) decentralising Xpert placement with mobile sample transport for

remote areas; (2) continuous competency-based training on national guidelines; (3) establishing real-time reagent supply monitoring; (4) mandatory diagnostic data review at facility and district levels; and (5) community-based screening to bridge demand-side gaps.

Implications for theory: The findings validate the HSS framework's premise that health system building blocks are interdependent. Supply chain improvements alone (technologies block) cannot increase utilisation without corresponding investments in workforce training (health workforce) and referral systems (service delivery). The strong effect of "lack of referral system information" highlights the governance and information blocks as critical enablers.

Implications for future research: Implementation science studies are needed to evaluate the effectiveness of targeted interventions such as community-based screening, sample transport systems, and digital decision support tools. Cost-effectiveness analyses of different diagnostic placement strategies would also inform resource allocation.

Final conclusion: This study moves beyond documenting low TB diagnostic utilisation to explaining its systemic drivers. Addressing these interconnected barriers requires a coordinated health system strengthening approach rather than isolated investments in diagnostic technology. Without such integration and without urgently bridging the gap between Ethiopia's national TB guidelines (7th edition, 2024) and frontline health worker practice the goal of ending TB by 2030 will remain unattainable for the 26 million people of Oromia Region.

CHAPTER 6

DEVELOPMENT OF STRATEGIES

6.1 Introduction

This chapter synthesizes the incorporation of results alongside the proposed implementation of tuberculosis diagnostic strategies for the Oromia Region. This chapter elucidates the validation of the findings of this study from both a tuberculosis diagnostic and tuberculosis program expertise perspective. The overarching aim of this chapter is to formulate and present a tuberculosis diagnostic strategy that will enhance physical access to TB diagnostics, promote their utilisation, and facilitate the application of TB diagnostic information for informed decision-making.

Bridge from Chapter 5: As established in Chapter 5, the Oromia Region faces systemic deficiencies in TB diagnostic access, utilisation, and monitoring. This chapter synthesizes those findings with expert input to develop implementable strategies.

6.1.1 The Rationale for a Comprehensive Diagnostic Strategy

The absence of a comprehensive, dedicated national strategy for TB confirmatory and supportive diagnostics (histopathology, imaging, ultrasound, MRI, CT) represents a critical gap in Ethiopia's TB response. Developing such a strategy is vitally important for addressing the complex TB epidemic. Extrapulmonary TB (EPTB) accounts for a significant proportion (30%) of TB cases, often requiring supportive diagnostics for accurate diagnosis where smear microscopy and GeneXpert frequently fail. Furthermore, many pulmonary cases are smear-negative, especially in children and people living with HIV (PLHIV), needing advanced tools for confirmation. In addition, complex drug-resistant TB (DR-TB) cases, treatment monitoring, and complication assessment heavily rely on imaging and histopathology (World Health Organization, 2023).

Beyond fundamental instruments, although confirmatory testing is crucial, it is not sufficient for the evaluation of treatment response and differential diagnosis in EPTB and complicated pulmonary patients. For the diagnosis of several types of EPTB (such as lymph node, pleural, peritoneal, and CNS), histopathology remains the gold standard. Imaging is crucial for detecting disease in bones/joints, abdomen, and CNS, and assessing complications (e.g., cavities, effusions, miliary TB). Supportive diagnostics are essential to rule out other conditions mimicking TB (e.g., malignancies, fungal infections, sarcoidosis), preventing misdiagnosis and inappropriate treatment (Sharma & Rai 2021, World Health Organization, 2021).

Advanced diagnostic technologies such as CT scans, MRI, and specialized histopathology are predominantly concentrated in urban centres, creating significant access barriers for rural and underserved populations. To address this disparity, a comprehensive diagnostic strategy must prioritize equitable geographic distribution of diagnostic services. This includes mapping existing diagnostic infrastructure, identifying service gaps, and establishing efficient referral pathways to ensure timely access to advanced diagnostics for all populations, regardless of location.

6.1.2 Strategic Priorities for Strengthening Diagnostic Services

A critical component of the strategy is ensuring the consistent functionality of diagnostic infrastructure across all levels of the health system. This includes:

Establishing reliable systems for the maintenance and calibration of diagnostic equipment Ensuring uninterrupted access to essential utilities such as electricity and clean water Securing a stable supply chain for reagents and consumables necessary for diagnostic testing These foundational elements are essential for sustaining high-quality diagnostic services (Tadesse et al., 2021; Abebe et al., 2020).

The strategy promotes a clearly defined, tiered approach to diagnostic service delivery, assigning specific roles and responsibilities to each level of the health system:

Primary hospitals: Provision of basic diagnostic tools such as X-ray and ultrasound

General hospitals: Availability of intermediate diagnostics, including basic X-ray services

Tertiary and specialized centres: Advanced imaging modalities such as CT and MRI

This model is supported by efficient patient and specimen referral systems to ensure timely diagnosis and continuity of care (Abebe et al., 2020).

Robust Monitoring and Evaluation (M&E): Current M&E frameworks often focus narrowly on basic bacteriological diagnostics. This strategy calls for a more comprehensive M&E system that includes regular tracking of the availability and operational status of diagnostic equipment, monitoring the volume and types of diagnostic tests performed at each facility level, evaluating the proportion of EPTB and smear-negative cases diagnosed using advanced diagnostic tools

These metrics will guide continuous quality improvement and strategic resource allocation. This includes implementing mandatory quality assurance programs in imaging and histopathology, and assessing how enhanced access to supportive diagnostics influences key outcomes, such as time to diagnosis, rates of confirmed versus empirically treated cases, treatment success rates (particularly for EPTB and DR-TB), and the reduction of diagnostic errors. Furthermore, M&E data should be leveraged to identify systemic bottlenecks, direct investments, refine training curricula, and substantiate the value of these diagnostic tools for policymakers and funders. Currently, this comprehensive approach remains unaddressed in the Oromia Region of Ethiopia.

The challenges and solutions for supportive diagnostics (infrastructure, workforce, utilisation patterns, M&E needs) are distinct from those of basic bacteriology or molecular testing. A dedicated strategy elevates the importance of these tools within the national TB response, ensuring they receive the necessary policy attention, planning, and resources. Furthermore, it provides a clear framework for coordinating the efforts of the TB program, radiology and pathology societies, hospital administrations, and supply chains in addition to confirmatory diagnostic strategy, helping to establish clear targets and responsibilities for improving access, quality, and utilisation.

The lack of a focused national strategy for TB confirmatory and supportive diagnostics in Ethiopia hinders accurate diagnosis, particularly for complex and EPTB, perpetuating diagnostic delays, inappropriate treatment, and preventable mortality. A comprehensive strategy is essential to guarantee equitable physical access to life-saving diagnostics and systematically drive uptake and correct utilisation by healthcare providers. Moreover, it is used to establish rigorous M&E to measure impact and guide continuous improvement and ultimately achieve TB control goals by ensuring every TB case, regardless of type or location, has access to accurate and timely diagnosis. This strategy must be integrated within the broader TB National Strategic Plan but given dedicated focus due to its unique complexities and critical importance.

6.2 Strategy Input Gathering And Processes Of Development

The development of the tuberculosis diagnostic strategy was facilitated by the integration of: Evidence Synthesis based on the study findings presented in Chapter 4 (physical accessibility, utilisation patterns, associated factors, and M&E gaps)

Delphi Consensus involving national TB programs, regional TB programs, and referral and regional diagnostics experts The Delphi method was employed through three iterative rounds conducted via email. This approach was chosen because it allows for anonymous input, reduces dominance by vocal participants, and enables convergence toward consensus on complex strategic priorities.

6.3 Research Results And Discussion Of Findings Of Delphi Technique

A panel of 11 participants, comprising TB program providers, TB diagnostic advisers, and implementers (diagnostic specialists, pathologists, and radiologists) participated in the 1, 2, and 3 rounds. The participants were chosen based on their expertise in the TB program at the Ministry of Health of Ethiopia, the national TB program at the National TB Institute of Ethiopia and the regional TB program.

6.3.1 Sample Characteristics

The researcher selected expert participants based on four key variables aligned with the study objectives: (1) confirmatory diagnostics professionals working in managerial and reference laboratory roles; (2) supportive diagnostic professionals, specifically hospital-based radiologists and Histo-pathologists; (3) TB program monitoring and evaluation experts; and (4) professionals working at the national level. This Delphi phase recruited 11 participants using the Kobo Collect database via email. The response rate for each survey round is detailed in the corresponding section.

6.3.2 Participant profile

A cohort of specialists from various organisations were assembled, comprising of 11 individuals, two of whom are engaged in supportive diagnostics as a radiologist and a histopathology expert. Five participants are actively involved in tuberculosis (TB) programs at both national and regional levels. All participants hold advanced degrees, specifically MD, MSc, and PhD, and are aged over 35 years, possessing considerable expertise in TB programs. Four female participants contributed to the Delphi expert review process**.**

Table 6. 1: characteristics ” Participant status involved on Delphi Technique

SN	Type of profession	Places of work	Level of education	Sex	Age range	#
1	Radiologist	Hospital	MD, Radiology specialist	Male	35-40	1
2	Histopathology ??	Hospital	MD/ Histopathology	Female	35-40	1
3	National TB program TB expert	National TB program	MD,MPH	Male	35-55	3
4	Medical laboratory technologist	National reference laboratory	Laboratory , MSC	Male	35-45	3
5	TB program monitoring and evaluation Advisers	National and regional TB program	BSC/MPH	Female	35-45	3

6.4.1 Delphi technique Round one

Professionals engaged in national tuberculosis programs, referral laboratories, and regional tuberculosis initiatives were invited to address 13 distinct open-ended questions designed to elicit insights and priorities relevant to the tuberculosis diagnostic framework. Following this, a coding process was undertaken. The concluding phase involved the formulation of five overarching themes that encapsulated a compilation of thirty-five tuberculosis diagnostic strategies.

6.4.2 Round one Delphi result

A semi-structured questionnaire consisting of 13 open-ended questions and an aggregate of the replies from all 11 individuals was presented to the participants.

Table 6. 2: 1st Round Delphi Questionnaire and Response rate of the participants

Sn	Delphi open ended questions	Response	Response rate
1	What are the highest-priority barriers to accessing confirmatory TB diagnostics (conventional and molecular and drug susceptibility testing) and supportive diagnostics (e.g., imaging, histopathology, ultrasonography strategies for TB prevention which best fit their religion	• Accessibility, • Resource, • Constraints, and • Centralized services. • Long turnaround times • Sample transport	72%
2	The reason why healthcare workers under-utilize available diagnostic tools (both confirmatory and supportive) despite their availability and the key factors (behavioural, training-related, systemic, or logistical).	• Clinician knowledge gaps an • Logistical/supply shortages • Weak systemic support	83%
3	What critical gaps exist in DST (Drug Susceptibility Testing) coverage within your local or national context.	• Limited availability of DST tests • Centralized testing. • Underutilisation due to poor sample referral.	83%
4	What are most significant weaknesses in the current monitoring and evaluation (M&E) practices for TB diagnostics and barriers related to data collection, analysis, or use for decision-making.	• Poor data quality and • No data analysis at local levels. • Inadequate feedback loops • Resource limitations.	91%
5	suggest the low-cost, high-impact interventions that could rapidly improve TB diagnostic access or utilisation. By Consider feasibility in resource-constrained environments.	• Strengthen sample transport a • Digitalize results. • Expand point-of-care testing • Ensure supply chains	91%
6	What types of community incentives, financial, social, or operational—would most effectively increase demand for TB diagnostic testing.	• Financial support • Operational aids • Transport • Awareness campaigns • Survivor engagement.	91

7	. List 5–7 core indicators to track TB diagnostic system performance at the facility or district level.	• Testing volumes, • Turnaround time, • EQA participation. • Utilisation rates of rapid diagnostics • DST coverage.	91%
8	What role do digital health tools (e.g., AI, EMRs, telemedicine) currently play or could play in improving TB diagnostics in your setting?	• Critical for reducing delays • Improving screening (e.g., AI). • Enable remote data reporting • Early detection	72%
9	What emerging diagnostic technologies or models should be prioritized for testing or scale-up in resource limited	• Prioritize POCT • GeneXpert for affordability/sensitivity. • AI-assisted tools to minimize expertise dependency	83%
10	How well the TB diagnostic services integrated into broader health platforms (e.g., maternal care, HIV services, primary healthcare)	• Weak integration • High potential in broader platforms (e.g., HIV/maternal care). • Referral systems • Screening linkages are critical.	91%
11	Which population groups are most underdiagnosed or excluded from TB diagnostic services? - What targeted actions could address this inequity	• Children, • Rural/pastoralist, • Immunocompromised populations. • Mobile clinics and multi-sectoral outreach needed.	91%
12	What training approaches (e.g., mentorship, simulation, e-learning) are most effective in improving provider competency in TB diagnostics?	• Mentorship emphasized as most effective. • Simulation and on-job training also valued.	91%
13	What motivational or performance-based approaches could enhance provider use of existing tools?	• Incentives (financial/career advancement) • recognition. • Capacity building • Supportive supervision.	72%

Summarized key findings indicate that primary barriers to TB diagnostic access in resource-limited settings include inadequate infrastructure (centralized services, sample transport delays), resource constraints (equipment/supply shortages), and workforce limitations (skills gaps, high workload). Underutilisation stems from insufficient training, logistical failures, and weak data utilisation for decision-making. The participants also proposed strategies with high-impact solutions, prioritized point-of-care molecular testing, digital result systems, and strengthened sample referral. Critical gaps persist in drug susceptibility testing coverage and equity for rural, pediatric, and mobile populations. Respondents emphasized mentorship-based training and digital/AI tools to enhance system resilience, alongside integrated service

delivery and community engagement to boost demand. The results of first round after thorough analysis were sent to experts again for further interrogation and further scrutiny.

6.4.3 Delphi Technique Round two

The questionnaire for this round was compiled from integration of outlines strategies from round one. The participants of this round were experts who participated in round one. A structured questionnaire was formulated based on the outcomes of the initial round. Experts were requested to rank and prioritize the suggested strategic and feasibility elements. In order to reduce bias, the replies were anonymized before being evaluated. If more than 75% of the comments were scored, strategic objectives with activities were taken into consideration.

6.4.4 Delphi round two and result

The questionnaire for round one was compiled from integration of the research findings and strategies from round one. The participants of this round were experts who participated in round one. A structured five main strategic objectives with activities were formulated based on the expert response and researcher input from the study result to assess impacts and feasibility.

Access to improved TB diagnostic geographic and equipment coverage, improvement of diagnostic utilisation using current tools, expansion of drug susceptibility testing, enabling data-driven decision through monitoring and evaluation strengthening, increased patient uptake and demand generation for test utilisation, creating enabling environments through policy action, and any additional strategic objectives not addressed were requested as a narrative.

Experts were asked to prioritize and rank the suggested strategic and feasibility factors. Participants were asked to score from 1 to 5, with 5 representing strong impact and feasibility. In order to reduce bias, the replies were anonymized. They were then scored, and as can be seen in the table below, strategic objectives with activity that were ranked higher than 70% were selected.

Table 6. 3: Strategic Objectives Proposed and Rank Given by Delphi participants

SN	Strategic objectives and activities	Feasibility (cost, simplicity and local adaptability score%	Impact potential to improve TB case detection and treatment outcome) score%	Average score%
1	**I. ACCESS IMPROVEMENT (Objective: Expand geographic/equipment coverage)**			
2	A1. Establish at least one TB molecular testing lab per district (woreda	86	86	86%
3	A2. Establish at least one TB molecular testing lab per 30,000 population and within 10 km radius (hence woreda population and land mass coverage are different	66	86	76%
4	A3. Establish at least one (x-ray and ultrasound center) district level considering population and travel distance at including primary (hospital as well health center level)	65	80	72.5%
5	A4. Establish histopathology and biopsy preparation centre at least at Hospital level	66	85	75.5%
6	A5. Establish CT and MRI centre at least at zonal level	72	72	72%
7	A6 .Avail latent TB testing at all TB treatment centre	58	78	68%
8	A7 Engage private sector for specimen transport (e.g., motorbike networks)	84	88	86%
9	A8. Deploy mobile testing units to remote areas	72	82	77%
10	A9. Establish health facility networking to cascade patient referral for chest x-ray , and other supportive TB diagnostics	78	76	77%
11	A10. Any additional objectives or comments for TB access improvements			
12	**II UTILISATION ENHANCEMENT (Objective: Optimize use of existing tools)**			
13	U1. Mandatory HCW training on test eligibility/algorithms	90	96	93%
14	U2. Solar power and other backups for labs to reduce downtime	82	90	86%
15	U3. 24/7 TB testing services at high-burden sites	88	90	89%
16	U4. Design and implement quality improvement project for low performed TB screening at health facilities and communities.	80	84	82%
17	U5. Establish coordinating bodies to oversee the placement, implementation, and utilisation of supportive diagnostic technologies(imaging, ultrasonography and histopathology etc) ,	78	76	77%

18	U6. Decentralize Equipment maintenance through capacity building to reduce equipment down time	82	90	86%
19	U7. Any additional objectives for utilisation enhancement and any comments	0	0	0
20	**III.** DST COVERAGE EXPANSION (Objective: Scale up drug-susceptibility testing)			
21	D1. Buffer stocks of critical reagents	82	90	86%
22	D2. Decentralize DST Services (including all phenotypic DST) to mid-level lab and lower level health facilities	66	82	74%
23	D3. Enhance Clinical Awareness & Protocols to health facility clinicians (mandate universal DST, train providers to systematically request TB DST	80	88	84%
24	D4. Leverage Data-Driven Approaches (use electronic TB register to flag patient needing DST, Dashboards tracking DST coverage gaps)	80	88	84%
25	D5. Advocate for national TB budget line for DST	78	78	78%
26	D6. Use AI-assisted X-rays to prioritize DST candidates	68	72	70%
27	D7 Any additional objectives to scale up DST testing and utilisation	0	0	0
28	IV. M&E SYSTEM STRENGTHENING (Objective: Enable data-driven decisions)			
29	M1 Develop an integrated TB diagnostic framework that includes structures for confirmatory and supportive diagnostics monitoring, and evaluation, and implement a well-organized diagnostic reporting system covering both confirmatory and supportive diagnostics	82	86	84%
30	M2 Avail comprehensive tool to track key Dx (confirmatory and supportive diagnostics) performances.	88	92	90%
31	M3. Unified digital dashboard (other MOH/EPHI-led, DHIS2-integrated)	76	80	78%
32	M4. Monthly and Quarterly facility-level Diagnostic test data audits (analysis and visualization)	80	92	86%
33	M5. Automated SMS/telegram (both confirmatory and supportive diagnostic alerts for overdue results	86	92	89%
34	M6 any additional objectives TB M&E system strengthening			
35	V. DEMAND GENERATION (Objective: Increase patient uptake and test utilisation)			
36	DG1. Training/ awareness for OPD physicians	82	92	87%
37	DG2. Transport vouchers for patients during supportive diagnostics referral.	60	88	74%
38	DG3. HEP-led sputum collection at household level	66	78	72%

39	DG4. "TB Ambassador/champions " community mobilization that the patient seek care for TB freely	84	82	83%
40	DG5. any additional comments on demand generation to increase patient uptake and test utilisation	0	0	0
41	VI. POLICY ACTIONS (Objective: Create enabling environment)			
42	P1. Establish Diagnostics coordinating body at MOH level and cascading to regional, zonal and woreda level	88	84	86%
43	P2. National policy for point-of-care testing	88	88	88%
44	P3. Private Accreditation labs for maintenance/services	82	82	82%
45	P4 National Policy for local availability of expertise on the technical management of the diagnostics technology	80	82	81%
46	P5. Any comments and additional objective to create enabling environment for TB diagnostics accesses utilisation and information use decision making	None		
47	**VII FINAL QUESTIONS STRATEGY OBJECTIVE PRIORITIZATION**			
48	1. Which 3 options across all categories deserve urgent piloting? Why?	Solar power and other back up for laboratory equipment maintenance		
49	2. What critical gaps remain unaddressed in this prioritization?	Create environment for Turnaround time reduction		
50	3. would you Suggest refining top-scoring options for local context?			

The Delphi Round Two results highlighted several critical gaps that contribute to delays in this process, which can negatively impact TB case detection and treatment outcomes. One major gap is the lack of reliable infrastructure in many health facilities, particularly in rural areas. Frequent power outages and the absence of backup systems such as solar power lead to laboratory downtime, delaying the processing of specimens. This issue was addressed in the Delphi strategy underutilisation enhancement, where solar power and other backup systems were identified as a high-priority intervention.

Another significant gap is the inefficiency in specimen transport. In many regions, there is no structured or timely system to move specimens from collection points to testing laboratories. This results in delays, especially in remote areas. The strategy to engage the private sector for specimen transport such as motorbike courier networks was highly rated for its feasibility and impact, indicating its potential to address this logistical challenge.

Human resource constraints also contribute to extended turnaround times. Many facilities lack adequately trained personnel to operate diagnostic equipment or interpret results promptly. This leads to backlogs and slower reporting. The Delphi results emphasized the importance of mandatory training for healthcare workers on test eligibility and diagnostic algorithms to improve efficiency.

Digital system limitations further exacerbate TAT issues. Many facilities rely on manual processes for tracking and reporting test results, which are prone to delays and errors. The Delphi panel recommended automated alerts for overdue results and unified digital dashboards to streamline communication and ensure timely follow-up.

Lastly, patient-level barriers such as long travel distances, lack of transport, and poor follow-up mechanisms mean that even when results are ready, patients may not receive them promptly. Strategies like transport vouchers and community mobilization through TB ambassadors were proposed to improve patient access and engagement.

In summary, the gaps in turnaround time are multifaceted, involving infrastructure, logistics, human resources, digital systems, and patient-level challenges. Addressing these gaps through targeted interventions many of which were prioritized in the Delphi process can significantly enhance TB case detection and treatment outcomes.

6.4.5 Delphi Technique Round three

The panel received consolidated feedback from the second round, which allowed participants to modify their assessments and move closer to a consensus on a TB diagnostic strategy for the same groups by selecting "yes" or "no." The results were downloaded to Excel, analysed, and five primary strategic objectives and thirty strategic objectives were approved following evaluation.

6.4.6 Delphi Round three and result

The panel was given consolidated feedback from the second round, which allowed participants to modify their assessments and move closer to reaching a consensus on a TB diagnostic strategy with the same experts by selecting "yes" or "no." The results were downloaded to Excel and examined; five major strategic objectives and thirty strategic objectives were approved because they scored higher than 70%.

Table 6. 4:Delphi Round 3 Strategy Validation

SN	Strategic activity	Validation (yes %)	
		1 yes	2. No
SO1	**SO 1: Access to Advanced Diagnostic Infrastructure for TB Control in Oromia**		
1	1.1 Implement one WHO-endorsed molecular diagnostic centre in each district (serving approximately 60,000 individuals within a 10 km radius) to facilitate prompt and confirmatory tuberculosis testing.	90.91%	
2	1.2. Create strong referral networks linking all health facilities within a district to the central molecular hub.	90.91%	
3	1.3 Equip each district with at least one digital X-ray unit and one ultrasound machine.	72.73%	
4	1.4 Establish Facility Networking for Imaging Access: Develop clear referral pathways within districts for patients requiring chest X-ray or other supportive diagnostics not available at their initial point of contact	81.82%	
5	1.5 Establish biopsy preparation and histopathology reading capabilities at all hospitals, including primary hospitals	82.81%	
6	1.6 Establish CT and MRI services within General/Specialty Hospitals at the zonal level (serving ~1 million people within a 100 km radius.	90.91%	
7	1.7 Implement a structured, public-private partnership (PPP) model for reliable sample transportation and patient referral logistics	90.91%	
8	1.8 Deploy mobile units equipped with rapid molecular diagnostics and portable, AI-assisted digital X-ray systems to reach remote and underserved populations.	72.73%	
SO2	**SO 2: Maximize Utilisation of Existing TB Diagnostic Capacity (Confirmatory & Supportive)**		
9	2.1 Train and certify all relevant healthcare workers on current national TB diagnostic algorithms, eligibility criteria, and result interpretation.	100%	
10	2.2 Avail reliable power solutions (solar + battery backup, generators) specifically for diagnostic equipment at all levels.	90.91%	
11	2.3 Implement 24/7 or extended-hour testing services specifically for TB diagnostics at strategically identified high-burden facilities/labs	90.91%	
12	2.4 Design and implement facility/community-specific QI projects to identify and address root causes of low TB screening rates	81.82%	
13	2.5 Establish dedicated coordination bodies (at Ministry of health, Regional and district/zonal level) with clear mandates to monitor placement, functionality, and utilisation rates of confirmatory and supportive diagnostics and ensure optimal integration into diagnostic pathways.	100%	
14	2.6 Build local technical capacity through training and equipping regional/zonal biomedical engineers and technicians to perform routine maintenance and basic repairs on key diagnostic equipment (GeneXpert, microscopes, X-ray, ultrasound).	81.82%	
SO3	**SO 3: DST COVERAGE EXPANSION**		
15	3.1. Implement multi-tiered buffer stock systems (national/regional), establish vendor-managed inventory agreements for key items, utilize forecasting tools based on testing volumes and pipeline visibility	100%	
16	3.2 Decentralize DST Services (including core phenotypic DST)	90.91%	
17	3.3 prepare DST results guide treatment decisions and Integrate DST request prompts into electronic medical records (EMR) or standardized	90.91%	

	paper forms, develop simplified job aids/flowcharts for clinicians, incorporate DST modules into routine clinical mentorship and continuous professional development programs.	
18	3.4 Avail electronic TB registers (ETR) or surveillance systems are interoperable with lab information systems (LIS) for automated flagging, design user-friendly dashboards accessible to district/provincial managers, train data managers and program staff on interpreting and acting upon DST coverage gap data	90.91%
19	3.5 Develop and compelling investment cases demonstrating DST's cost-effectiveness (e.g., averting costly DR-TB treatment), utilize domestic resource mobilization strategies, advocate for inclusion in national health insurance schemes, present phased costing plans to Ministries of Health and Finance.	90.91%
20	3.6 Avail adequate digital infrastructure (connectivity, X-ray digitization) at screening points, train radiographers/technicians on AI tool use and interpretation within the DST workflow, establish clear referral pathways from AI triage	81.82%
	SO 4: DIAGNOSTIC M&E SYSTEM STRENGTHENING	
21	4.1 Develop and implement a unified framework defining structures, indicators, and processes for monitoring and evaluating both confirmatory (e.g., molecular, culture) and supportive (e.g., X-ray, CT MRI Histopathology) TB diagnostics. Implement a standardized, well-organized diagnostic reporting system across all levels	90.91%
22	4.2 Make available a user-friendly tool (digital preferred) specifically designed to track, analyse, and visualize key performance indicators (KPIs) for all TB diagnostics (confirmatory & supportive) at facility, sub-national, and national levels	90.91%
23	4.3 Design the tool with tiered complexity (simple dashboards for clinics, advanced analytics for national level) and ensure integration with the national health information system (e.g., DHIS2).	90.91%
24	4.4 Develop and operationalize a Ministry of Health/EPHI-led digital dashboard, integrated with DHIS2, providing real-time visualization of key TB diagnostic metrics for all levels	90.91%
25	4.5 Conduct monthly and quarterly facility-level audits of diagnostic test data (volume, turn-around-time, positivity rates, concordance) involving analysis and visualization to identify errors and improvement opportunities.	81.82%
26	4.6 Avail automated SMS/Telegram alerts for clinicians and coordinators for overdue confirmatory and supportive diagnostic results requiring urgent action.	81.82%
	SO 5: Diagnostics Policy and Expertise	
27	5.1 Establishing dedicated bodies at all administrative levels from ministry of health to the woreda level to oversee planning, resource allocation, and problem-solving across the diagnostic network	100%
28	5.2 Avail a national policy to promote rapid Point-of-Care Testing (POCT) closer to patients, reducing delays and loss to follow-up.	100%
29	5.3 Endorse private laboratories to supplement public services, increasing overall testing capacity and geographic coverage while ensuring quality standards are met.	100%
30	5.3 Mandate the development of national and regional, and zonal technical expertise to maintain and repair TB diagnostic equipment	100%

In the third round of the Delphi process for TB strategy validation, a total of 30 strategic activities were evaluated. Out of these, 6 strategies received full consensus with a validation score of 100%, indicating strong agreement among stakeholders. These top-rated strategies include: (1) training and certifying healthcare workers on TB

diagnostic protocols; (2) establishing dedicated coordination bodies at various administrative levels to oversee diagnostic implementation and utilisation; (3) implementing multi-tiered buffer stock systems and vendor-managed inventory agreements for critical diagnostic supplies; (4) developing a national policy to promote point-of-care testing (POCT) closer to patients; (5) endorsing private laboratories to supplement public diagnostic services; and (6) mandating the development of national and regional technical expertise for the maintenance and repair of TB diagnostic equipment.

These results reflect a strong consensus on the need for capacity building, infrastructure reliability, and policy-level support to improve TB diagnostic access, efficiency, and sustainability. The high validation scores suggest that these strategies are not only feasible but also seen as essential for strengthening TB control efforts, particularly in resource-limited and high-burden settings like Oromia.

6.5 Conclusion

District-level molecular hubs, strong referral networks, zonal CT/MRI, dependable power, 24/7 testing at key sites, organised public-private partnerships, logistics, multi-tiered buffer stocks, thorough workforce training, dedicated diagnostic coordination bodies, DST decentralisation and integration, rapid Point of care testing policy, private lab endorsement, and unified M&E frameworks with digital dashboards. Furthermore, there are strategic activities that offer the most effective pathway to strengthen TB diagnosis in Oromia, according to the high expert consensus (≥90.91%) attained through the Delphi rounds. Critical diagnostic gaps will be most successfully filled by focussing resources on implementing these high-validation activities across infrastructure, systems, workforce, governance, drug susceptibility testing, and monitoring. To greatly enhance TB diagnostic capability and patient outcomes throughout the region, coordinated execution is crucial.

CHAPTER 7

7. FINAL STRATEGIES

7.1 Introduction

The strategy was developed using the eight strategic planning components outlined by the United Nations: vision, mission, goals, objectives, strategies, performance indicators, implementation plans, and evaluation mechanisms. These components offered a systematic framework to guarantee that the strategy was both exhaustive and practicable. The planning process commenced with a situational analysis of the existing TB diagnostic environment, pinpointing deficiencies in access, service delivery, and monitoring. This analysis guided the development of a definitive vision and mission for the TB diagnostic framework. The goals were synchronized with national TB control priorities and international objectives, such as those described in the WHO End TB Strategy.

7.2 Strategies To Strengthen Tuberculosis Diagnostic System In Oromia Region, Ethiopia

Strategy in health services refers to a comprehensive approach that guides organisations in achieving their goals through effective planning and leadership. It encompasses long-term planning, resource allocation, and the adaptation to changing environments to enhance service quality and operational efficiency. The following sections elaborate on key aspects of strategy in health services (Child, 2013).

7.3 The Objective Of The Strategy

To provide a comprehensive Regional framework for systematically addressing the critical gaps in access, utilisation, quality, and monitoring of TB confirmatory (AFB, TB culture, molecular and DST, latent TB testing) and supportive diagnostics (histopathology, imaging, ultrasound, MRI, CT scan) in Ethiopia, thereby enabling accurate, timely, and equitable diagnosis of all forms of tuberculosis.

7.4 Vision

To see a nation where prompt, reliable, and easily available diagnostics, strengthen public health resilience, improve patient outcomes, and empower health decisions.

7.5 Mission

To transform confirmatory and supporting TB diagnostic services by means of solid M&E systems integrated at all levels of the health system, equitable access, optimal use, and evidence-based decision-making**.**

7.6 Goals

1. Access: Expand physical/geographic access to diagnostics by 50% in underserved areas within 2026 to 2030 years.
2. Utilisation: Increase diagnostic utilisation rates (supportive and confirmatory) by 40% by year 2028.
3. Monitoring and evaluation: Establish a Regional Diagnostic M&E framework by 2026 year
4. Data Use: Ensure 90% of health facilities and health facility managing organization use diagnostic data for decision-making by year 2026.

7.7 Strategy Objectives

1. **Access Improvement:** Expand advanced diagnostic infrastructure for TB control in Oromia to increase geographic coverage by 50% in underserved areas between 2026 and 2030.

2. **Enhance TB Diagnostic Utilisation**: Maximise use of existing confirmatory and supportive TB diagnostic capacity to increase overall diagnostic utilisation rates by 40% by the year 2028.

3. **DST Coverage Expansion**: Expand drug susceptibility testing (DST) coverage to 100% of all bacteriologically confirmed TB cases in Oromia by 2028.

4. **Diagnostic M&E System Strengthening**: Implement a comprehensive diagnostic monitoring and evaluation (M&E) framework for TB by 2026, and ensure that by the same year, 90% of health facilities in Oromia use diagnostic data for routine decision-making.

5. **Diagnostics Policy and Expertise:** Adopt a national TB diagnostics policy by 2026 that promotes the establishment of dedicated bodies from MoH to woreda level for planning, resource allocation, and network oversight, ensuring 100% of districts have functional diagnostic governance by 2028**.**

7.8 Strategies For Tuberculosis Diagnostic System Strengthening In Oromia Region Of Ethiopia

The successful execution of the following strategies requires a coordinated, multi-sectoral approach. Responsible leadership rests primarily with the Oromia Regional Health Bureau, which will oversee implementation in close collaboration with the Ministry of health of Ethiopia, regional hospitals, zonal health departments, district health offices, and implementing partners A phased Timeline is proposed: Year 1 (2026) for foundational activities (policy approval, coordination bodies, training curricula, M&E frameworks, and resource mobilization); Years 2-3 (2027-2028) for core implementation (equipment deployment, network establishment, capacity building, and DST scale-up); and Year 4 (2029) for sustainability, maintenance, and impact evaluation. Crucial Resources will be mobilized from a blend of domestic government budget and donor funding (Global Fund, World Bank, bilateral partners

for capital investments, advanced diagnostics, and technical assistance). This framework ensures accountability and feasibility

7.8.1 Enhance Access to Advanced Diagnostic Infrastructure for TB Control in Oromia

The severely inadequate availability of crucial diagnostic apparatus (encompassing both confirmatory and adjunct tools) throughout Oromia profoundly obstructs the identification of tuberculosis cases and results in diminished treatment coverage. To address this challenge, the strategic implementation of a hierarchical framework of diagnostic technologies, utilizing collaborative networks and innovative service delivery paradigms to enhance population coverage and accessibility, represents a viable and effective intervention.

7.8.1.1 Establish District-Level Molecular Diagnostic Centres

Implement one WHO-endorsed molecular diagnostic centre (e.g., GeneXpert, Truenat) in each district of primary health care unit in Ethiopian context primary Hospital and primary health care unit health centre (serving approximately 60,000 individuals within a 10 km radius) to facilitate prompt and confirmatory tuberculosis testing.

Expected Outcome: Accelerates time to diagnosis, enables immediate treatment initiation, and reduces TB transmission through timely and accurate case detection at the district level.

7.8.1.2 Establish Integrated Diagnostic Network

Create robust referral networks linking all health facilities within a district to the central molecular hub. Ethiopian districts have an average of 4-6 health centres and putting on molecular diagnostics ensures samples from peripheral sites reach confirmatory testing swiftly and reliably, maximizing hub utilisation.

Expected Outcome: Enhances diagnostic efficiency and coverage by ensuring timely sample transport and result dissemination across all health facilities in a district.

7.8.1.3 Establish District-Level Essential Imaging

Equip each district with at least one digital X-ray unit and one ultrasound machine at primary hospital and grade A health centres enables diagnosis of smear-negative pulmonary TB and complex extra-pulmonary TB cases, significantly improving case detection rates.

Expected Outcome: Improves detection of smear-negative and extra-pulmonary TB cases, contributing to comprehensive TB diagnosis and better patient outcomes.

7.8.1.4 Establish Facility Networking for Imaging Access

Develop clear referral pathways within districts for patients requiring chest X-ray or other supportive diagnostics not available at their initial point of contact.

Expected Outcome: Streamlines patient referrals and reduces delays in accessing essential imaging services, thereby improving diagnostic timelines and treatment initiation.

7.8.1.5 Establish Hospital-Based Histopathology

Establish biopsy preparation and histopathology reading capabilities at all hospitals, including primary hospitals. Essential for definitive diagnosis of challenging extra-pulmonary TB (e.g., lymph node, bone), crucial in high-HIV burden settings.

Expected Outcome: Enables accurate diagnosis of complex TB cases, especially in HIV co-infected patients, enhancing diagnostic precision and clinical decision-making.

7.8.1.6 Zonal Advanced Imaging Centres

Establish CT and MRI services within General/Specialty Hospitals at the zonal level (serving ~1 million people within a 100 km radius).

Expected Outcome: Provides advanced diagnostic capabilities for complex TB cases and differential diagnoses, improving overall diagnostic accuracy and patient management.

7.8.1.7 Establish Efficient Sample & Patient Transport

Implement a structured, public-private partnership (PPP) model for reliable sample transportation and patient referral logistics.

Expected Outcome: Ensures timely delivery of samples and patient movement, overcoming geographical barriers and reducing diagnostic delays and dropouts.

7.8.1.8 Mobile Diagnostic Outreach

Deploy mobile units equipped with rapid molecular diagnostics and portable, AI-assisted digital X-ray systems to reach remote and underserved populations.

Expected Outcome: Expands diagnostic reach to marginalized communities, promotes equity in TB care, and supports active case finding in high-burden areas.

7.8.2 Maximize Utilisation of Existing TB Diagnostic Capacity (Confirmatory & Supportive)

The interventions are designed to dramatically increase the use of already available TB diagnostic technologies (both confirmatory like molecular tests and supportive like imaging) by addressing critical operational bottlenecks. Their high impact stems from optimizing existing tools and systems. The interventions directly address the human, operational, and systemic barriers (knowledge gaps, power, hours, screening quality, coordination, downtime) that prevent existing diagnostics from being used to their full potential. By screening feeds, more patients into labs with dependable power, longer hours, and well-maintained equipment—all under the direction of skilled personnel and coordinated oversight these interventions are more effective when combined.

7.8.2.1 Mandatory health care worker Competency on Testing Criteria & Algorithms

Systematically train and certify all relevant healthcare workers on current national TB diagnostic algorithms, eligibility criteria, and result interpretation.
Expected Outcome: Increases appropriate test ordering by ensuring HCWs know when and which test to use, reducing missed opportunities and under-utilisation of available capacity.

7.8.2.2 Ensure Uninterrupted Power for Diagnostic Labs

Implement reliable power solutions (solar + battery backup, generators) specifically for diagnostic equipment at all levels.
Expected Outcome: Eliminates downtime due to power outages, maximizing operational hours and throughput of molecular machines, microscopes, and digital imaging systems, directly increasing the number of tests performed daily/weekly.

7.8.2.3 Extend TB Diagnostics Operating Hours at High-Burden Sites

Implement 24/7 or extended-hour testing services specifically for TB diagnostics at strategically identified high-burden facilities/labs.

Expected Outcome: Dramatically increases accessibility and throughput, allowing for faster sample processing, same-day results (especially for molecular tests), and accommodating patients outside standard hours, leading to a higher volume of tests conducted.

7.8.2.4 Launch Targeted Quality Improvement for TB Screening

Design and implement facility/community-specific QI projects to identify and address root causes of low TB screening rates (e.g., poor symptom inquiry, lack of sputum collection cups, weak referral links).

Expected Outcome: Boosts the pipeline of presumptive TB cases reaching diagnostic services. More effective screening directly translates to more patients eligible and referred for confirmatory/supportive testing, driving up demand and utilisation of diagnostic equipment.

7.8.2.5 Establish Diagnostic Technology Coordination & Oversight

Establish dedicated coordination bodies (at Ministry of Health, Regional and district/zonal level) with clear mandates to monitor placement, functionality, and utilisation rates of confirmatory and supportive diagnostics and ensure optimal integration into diagnostic pathways.

Expected Outcome: Optimizes the use of existing confirmatory and supportive diagnostic resources by preventing underuse. Coordination ensures timely patient referrals, rational scheduling, identification of underperforming sites for interventions, and promotes shared resources where feasible.

7.8.2.6 Decentralize and Strengthen Equipment Maintenance Capacity

Build local technical capacity through training and equipping regional/zonal biomedical engineers and technicians to perform routine maintenance and basic repairs on key diagnostic equipment (GeneXpert, microscopes, X-ray, ultrasound).

Expected Outcome: Minimizes equipment downtime. Faster local response to malfunctions ensures diagnostic machines are operational more consistently, directly increasing the available testing hours and overall test volume output.

7.8.3 DST Coverage Expansion Strategies for TB Diagnostic System Strengthening in Oromia Region of Ethiopia

This strategy aims to significantly expand DST coverage by ensuring reliable access to testing and driving its systematic use. It focuses on securing critical reagent supplies to prevent stock outs and strategically decentralizing core DST services to lower-level facilities to reduce turnaround times and improve geographic equity. Clinicians will be empowered through enhanced awareness, standardized protocols, and integrated tools to universally request DST for eligible patients. Data-driven systems, including electronic registers and dashboards, will proactively identify testing gaps and track progress. Dedicated national budget advocacy ensures sustainable funding, while validated AI-assisted chest X-ray triage optimizes resource use by prioritizing high-risk patients for DST. The integrated approach targets timely, appropriate treatment initiation and combats drug resistance.

7.8.3.1 Secure Robust Buffer Stocks of Critical Reagents

Implement multi-tiered buffer stock systems (national/regional), establish vendor-managed inventory agreements for key items, utilize forecasting tools based on testing volumes and pipeline visibility.

Expected Outcome: Prevent catastrophic testing interruptions, ensure continuous DST availability, reduce patient treatment delays and development of drug resistance.

7.8.3.2 Strategically Decentralize DST Services (including core phenotypic DST)

Implement tiered decentralization based on facility capacity, provide intensive hands-on training and sustained mentorship for mid/lower-level lab staff, ensure robust specimen referral networks for complex tests.

Expected Outcome: Drastically reduce turnaround times for DST results, increase access for geographically isolated populations, and enable faster initiation of appropriate treatment regimens.

7.8.3.3 Enhance Clinical Awareness & Standardize DST Protocols

Integrate DST request prompts into electronic medical records (EMR) or standardized paper forms, develop simplified job aids/flowcharts for clinicians, incorporate DST modules into routine clinical mentorship and continuous professional development programs.
Expected Outcome: Systematically identify all patients eligible for DST, reduce clinician hesitancy/oversight, ensure DST results guide treatment decisions.

7.8.3.4 Leverage Data-Driven Approaches for Proactive DST Identification & Monitoring

Ensure electronic TB registers (ETR) or surveillance systems are interoperable with lab information systems (LIS) for automated flagging, design user-friendly dashboards accessible to district/provincial managers, train data managers and program staff on interpreting and acting upon DST coverage gap data.

Expected Outcome: Enable real-time identification of missed DST opportunities, target interventions to specific facilities/populations with low coverage, improve accountability and program performance.

7.8.3.5 Advocate for Dedicated & Sustainable National and regional TB Budget Allocation for DST

Develop compelling investment cases demonstrating DST's cost-effectiveness, utilize domestic resource mobilization strategies, advocate for inclusion in national health insurance schemes, and present phased costing plans to Oromia Health Bureau and Finance.

Expected Outcome: Ensure predictable long-term funding for reagents, equipment maintenance, training, quality assurance, and reducing dependency on unstable external funding sources.

7.8.3.6 Utilize Validated AI-Assisted Chest X-ray Triage to Prioritize Patients for DST

Deploying AI tools pre-validated for the specific context and population, ensure adequate digital infrastructure at screening points, train radiographers/technicians on AI tool use and interpretation within the DST workflow, establish clear referral pathways from AI triage to DST collection.

Expected Outcome: Increase efficiency by rapidly identifying high-risk individuals among presumptive TB cases for prioritized DST, optimizing resource use.

7.8.4 Diagnostic M&E System Strengthening

This M&E strategy aims to transform fragmented diagnostics data into actionable intelligence. By establishing a standardized framework and a dedicated performance tracking tool, it ensures consistent capture of all relevant diagnostic data. This data feeds a unified national dashboard for real-time visibility. Regular audits validate data quality and pinpoint local issues, while automated alerts trigger immediate follow-up on critical delays. Together, these components create a closed-loop system: reliable data flows upward for strategic oversight while insights and alerts flow downward to drive rapid operational responses enabling program managers to optimize testing

networks, allocate resources effectively, address bottlenecks promptly, and ultimately improve patient outcomes through timely, appropriate diagnosis.

7.8.4.1 Establish Integrated Diagnostics Framework & Reporting

Develop and implement a unified framework defining structures, indicators, and processes for monitoring and evaluating both confirmatory and supportive TB diagnostics. Pilot the framework and reporting templates in high-volume facilities first, leveraging existing TB/HIV M&E structures.

Expected Outcome: Creates a consistent national standard, ensures critical supportive diagnostic data isn't ignored and facilitates data aggregation and comparability.

7.8.4.2 Deploy Comprehensive Diagnostics Performance Tracking Tool

Make available a user-friendly tool (digital preferred) specifically designed to track, analyse, and visualize key Diagnostic performance indicators (KDPIs) for all TB diagnostics at facility, sub-national, and national levels.

Expected Outcome: Provides a single source of truth for diagnostic performance, enabling rapid identification of bottlenecks for specific tests.

7.8.4.3 Implement Unified Regional Diagnostics Dashboard

Develop and operationalize Oromia health bureau-led digital dashboard, integrated with DHIS2, providing real-time visualization of key TB diagnostic metrics for all levels.

Expected Outcome: Improves strategic oversight and facilitates timely decision-making across the diagnostic network.

7.8.4.4 Conduct Regular Diagnostic Data Audits

Institute mandatory monthly and quarterly facility-level audits of diagnostic test data involving analysis and visualization to identify errors and improvement opportunities.

Expected Outcome: Improves data quality, identifies local issues, and supports continuous improvement in diagnostic services.

7.8.4.5 Automate Critical Diagnostic Alerts

Implement automated SMS/Telegram alerts for clinicians and coordinators for overdue confirmatory and supportive diagnostic results requiring urgent action.
Expected Outcome: Enables rapid follow-up and reduces delays in diagnosis and treatment initiation.

7.8.5 Diagnostics Policy and Expertise

This strategy aims to create a robust, sustainable national system for TB diagnostics by focusing on foundational governance, access, quality assurance, and human resources. This strategy moves beyond simply deploying machines. It builds the essential governance, policy frameworks, partnerships, and human resource capabilities needed to ensure TB diagnostic services are widely accessible, reliable, high-quality, and sustainable over the long term, directly contributing to improved case detection and treatment outcomes.

7.8.5.1 Structured Coordination

Establishing dedicated bodies at all administrative levels from Ministry of Health to the district level to oversee planning, resource allocation, and problem-solving across the diagnostic network.

Expected Outcome: Improves governance and oversight of diagnostic services, ensuring coordinated and effective implementation.

7.8.5.2 Decentralized Testing

Implementing a national policy to promote rapid Point-of-Care Testing (POCT) closer to patients, reducing delays and loss to follow-up.

Expected Outcome: Enhances access to diagnostics and reduces diagnostic delays, especially in remote areas.

7.8.5.3 Expanded Quality Capacity

Accrediting private laboratories to supplement public services, increasing overall testing capacity and geographic coverage while ensuring quality standards are met.

Expected Outcome: Expands diagnostic reach and ensures consistent quality across public and private sectors.

7.8.5.4 Local Technical Sustainability

Mandating the development of national and regional, and zonal, and hospital level technical expertise to maintain and repair TB diagnostic equipment.

Expected Outcome: Minimizes equipment downtime and ensures long-term functionality of diagnostic infrastructure.

7.9 Conclusion

The chapter presented strategies developed according to the objectives of this study which has vision, mission, Goals and which as five strategy objectives Access Improvement: - Expand Geographic equipment coverage, Enhance TB diagnostic utilisation by optimizing existing diagnostic tools and Scale up DST coverage testing using DST coverage expansion and Enable Data driven decision through Diagnostic monitoring and evaluation strengthen. Furthermore, these strategies were validated based on specific key indicators and the results have been presented in chapter 8 of this study.

CHAPTER 8

8.STRATEGIC MANAGEMENT, MEASURING PERFORMANCE AND MITIGATING RISK

8.1 Introduction

Strategic Performance Measures (SPMs) represent quantifiable metrics employed to evaluate diagnostic performance that is intrinsically associated with strategic objectives and critical success factors. The strategic performance measures facilitate the monitoring of advancements towards long-term objectives, elucidate diagnostic strategic alignment, and furnish insights for decision-making extending beyond mere operational efficiency. The strategic performance measures predominantly utilized were categorized within a standardized framework that encompasses input metrics for assessing mobilization, process metrics for optimizing diagnostic workflows, output indicators for quantifying diagnostic program activity volume, and outcome indicators to evaluate diagnostic effectiveness and impact, thereby assessing long-term influences of enhancements in tuberculosis diagnostics**.**

8.2 Strategic Performance Indicators

Strategic Performance Indicators (SPIs), often used interchangeably with Key Performance Indicators (KPIs) in a strategic context, are a select set of metrics designed to measure an organisation's progress towards achieving its most critical strategic objectives. Unlike operational metrics that track day-to-day activities, SPIs are explicitly linked to the high-level goals and vision of the organisation, providing a clear view of its overall health and long-term viability (Parmenter, 2015).

Table 8. 1: Strategic Performance Indicators With Strategic Objectives and Activities

SN	Strategic activity	Validation score %	Performance indicators
SO1	**SO** 1. Access to Advanced Diagnostic Infrastructure for TB Control in Oromia		
1	1.1 Implement one WHO-endorsed molecular diagnostic centres in each district (serving approximately 60,000 individuals within a 10 km radius) to facilitate prompt and confirmatory tuberculosis testing.	90.91%	1. proportion of districts with operational WHO –endorsed molecular centres 2.% diagnostic coverage per Population coverage and within 10 km radius (%) 3. Proportion of presumptive TB cases with initial access WHO indorsed molecular diagnostic centres 4.. Monthly volume of TB tests performed per diagnostic centres 5. percentage of reduction in turnaround time for confirmatory testing 6. proportion bacteriologically confirmed TB cases identified 7. TB treatment coverage rate
2	1.2. Create strong referral networks linking all health facilities within a district to the central molecular hub.	90.91%	8. proportion of districts that provide molecular testing with vehicles/motorbikes for sample transportation 9. Number of Samples transported/week to hubs (avg) 10 Proportion reduction in loss to follow-up pre-diagnosis
3	1.3 Implement a structured, public-private partnership (PPP) model for reliable sample transportation and patient referral logistics.	90.91%	11. Proportion of Public private partnership contracts signed for sample transportation and patient referral logistics 12. Volume Samples transported via PPP per month 13. percentage samples reaching labs and with viable results within 24 timelines
4	1.4 Establish Facility Networking for Imaging Access: Develop clear referral pathways within districts for patients requiring chest X-ray or other supportive diagnostics not available at their initial point of contact.	90.91	14. proportion of Health facilities using standardized referral protocol documents 15. Volume of patients referred for imaging 16. % Patients referred for imaging diagnosed with TB /extra pulmonary TB and clinically diagnosed pulmonary negative TB
6	1.5 Establish CT and MRI services within General/Specialty Hospitals at the zonal level (serving ~1 million people within a 100 km radius.	90.91	16. Proportion of CT/MRI machines installed per zone 17. Number of Staff trained in TB-specific imaging protocols 18. Volume of Monthly CT/MRI scans for TB 19. Proportion complex TB cases (e.g., CNS/spinal) diagnosed
7	1.6 Establish biopsy preparation and histopathology reading capabilities at all hospitals, including primary hospitals.	81.82	20. proportion of hospitals with functional Biopsy and histopathology processing equipment 21. % hospitals with trained histo-pathologists 22. Volume of Monthly histopathology tests performed. 23. proportion of histopathology tests with confirmed all forms of TB / clinically diagnosed pulmonary negative TB and extra pulmonary TB. 24. proportion of extra pulmonary TB diagnosed

	1.7 Equip each district with at least one digital X-ray unit and one ultrasound machine.	72.73%	25. Proportion of districts with functional Digital X-ray/ultrasound equipment. 26. monthly volume Chest X-rays/ultrasound test performed 27. Proportion presumptive TB cases screened by chest –ray 28. Ratio of X-ray screenings to molecular confirmations
8	1.8 Deploy mobile units equipped with rapid molecular diagnostics and portable, AI-assisted digital X-ray systems to reach remote and underserved populations.	72.73%	29. number of existed mobile units equipped with rapid molecular diagnostics and AI-assisted digital x-ray 30. Number of remote communities visited per quarter 31. Number of remote clients screened for TB 32 proportion of mobile screened TB positive confirmed
SO2	**2. Maximize Utilisation of Existing TB Diagnostic Capacity (Confirmatory & Supportive)**		
9	2.1 Train and certify all relevant healthcare workers on current national TB diagnostic algorithms, eligibility criteria, and result interpretation.	100%	34. percentage of HCWs certified in TB diagnostics 35.% Health facilities equipped with TB diagnostic algorithms
10	2.2 Establish dedicated coordination bodies (at Ministry of health, Regional and district/zonal level) with clear mandates to monitor placement, functionality, and utilisation rates of confirmatory and supportive diagnostics and ensure optimal integration into diagnostic pathways.	100%	36. Establishment of TB Diagnostic Directorate formed at ministry of health, Regional Bureau, and Diagnostic focal person and zonal and district office level. 37. percentage of non-functional equipment reactivated 38.Diagnostic test utilisation rate per equipment
11	2.3 Avail reliable power solutions (solar + battery backup, generators) specifically for diagnostic equipment at all levels.	90.91%	39. Number of diagnostic centre with backup generators/solar installed 40.percentage of facilities with backup power maintenance plans 41. percentage of reduction in test interruptions tests/lab/month (avg.)
12	2.4 Implement 24/7 or extended-hour testing services specifically for TB diagnostics at strategically identified high-burden facilities/labs	90.91	42. Number of High-burden facilities identified 43.percentage of facilities offering extended hours 44. percentage of patients starting treatment ⩽24h post-diagnosis
13	2.5 Design and implement facility/community-specific QI projects to identify and address root causes of low TB screening rates	81.82	45. Number of Diagnostic Health facilities implemented QI projects 46. proportion of Diagnostic health facilities Root causes addressed. 47 proportion of Facilities with improved screening rates 48. percentage of presumptive TB case identified 49. TB screening yield (%)
14	2.6 Build local technical capacity through training and equipping regional/zonal biomedical engineers and technicians to perform routine maintenance and basic repairs on key diagnostic equipment	81.82%	50. number of Biomedical engineers trained 51. proportion of equipment with Preventive maintenance sessions per month 52. frequency Equipment downtime per week 53. percent of repairs completed locally 54 Equipment lifespan (years)

	(GeneXpert, microscopes, X-ray, ultrasound).		
SO3	**3 DST COVERAGE EXPANSION**		
15	3.1. Implement multi-tiered buffer stock systems (national/regional), establish vendor-managed inventory agreements for key items, utilize forecasting tools based on testing volumes and pipeline visibility	100%	55. Number of Stock audits conducted per quarter 56. DST commodity stockout rate (%) 57. proportion Eligible TB cases with DST test result (DST coverage) (1st line anti TB drug DST coverage, second line anti TB DST coverage, phenotypic DST coverage) 58. proportion RR/MDR. Pre-XDR and XDR cases identified
16	3.2 Decentralize DST Services (including core phenotypic DST)	90.91	59. Proportion health Facilities equipped with DST. 60. DST TAT (days)
17	3.3 Prepare DST results guide treatment decisions and Integrate DST request prompts into electronic medical records (EMR) or standardized paper forms, develop simplified job aids/flowcharts for clinicians, incorporate DST modules into routine clinical mentorship and continuous professional development programs.	90.91	61 proportion of Diagnostic centre with EMR systems upgraded 62. proportion of health facilities using DST-guided treatment decisions
18	3.4 Avail electronic TB registers (ETR) or surveillance systems are interoperable with lab information systems (LIS) for automated flagging, design user-friendly dashboards accessible to district/provincial managers, train data managers and program staff on interpreting and acting upon DST coverage gap data	90.91	63. proportion of Diagnostic health facilities with automated DST coverage reports generated 64. proportion of facilities with real-time DST dashboards
19	3.5 Develop and compelling investment cases demonstrating DST's cost-effectiveness (e.g., averting costly DR-TB treatment), utilize domestic resource mobilization strategies, advocate for inclusion in national health insurance schemes, present phased costing plans to Ministries of Health and Finance.	90.91%	65. Number of advocacy meetings with MoH/Finance 66. Amount of Domestic funding allocated
20	3.6 Avail adequate digital infrastructure (connectivity, X-ray digitization) at screening points, train radiographers/technicians on AI tool use and interpretation within the DST workflow, establish clear referral pathways from AI triage	81.82%	67. Proportion of Health facilities with AI-compatible x-ray 68 proportion of Radiographers trained in AI interpretation 69 proportion of X-rays analyzed by AI/CAD per month
So	4 DIAGNOSTIC M&E SYSTEM STRENGTHENING		
21	4.1 Develop and implement a unified framework defining structures,	90.91%	70. Existence of M&E framework developed

	indicators, and processes for monitoring and evaluating both confirmatory (e.g., molecular, culture) and supportive (e.g., X-ray, CT MRI Histopathology) TB diagnostics. Implement a standardized, well-organized diagnostic reporting system across all levels		71 Number of indicators developed to monitor TB diagnostic performances
22	4.2 Make available a user-friendly tool (digital preferred) specifically designed to track, analyse, and visualize key performance indicators (KPIs) for all TB diagnostics (confirmatory & supportive) at facility, sub-national, and national levels	90.91%	71. availability of Digital tool developed and deployed 72. Diagnostic Data entries, and completeness
23	4.3 Design the tool with tiered complexity (simple dashboards for clinics, advanced analytics for national level) and ensure integration with the national health information system (e.g., DHIS2).	90.91%	73. Number of diagnostic data displayed on national and regional DHIS2 integration dashboard
24	4.4 Develop and operationalize a Ministry of Health/EPHI-led digital dashboard, integrated with DHIS2, providing real-time visualization of key TB diagnostic metrics for all levels	90.91%	74 .number of diagnostic Key metrics accessible at all levels
25	4.5 Conduct monthly and quarterly facility-level audits of diagnostic test data (volume, turn-around-time, positivity rates, concordance) involving analysis and visualization to identify errors and improvement opportunities.	81.82%	75. number LQAS Audit reports with corrective actions
26	4.6 Avail automated SMS/Telegram alerts for clinicians and coordinators for overdue confirmatory and supportive diagnostic results requiring urgent action.	81.82%	76. Number of Alerts data generated per month
SO	**5 Diagnostics Policy and Expertise**		
27	5.1 Avail a national policy to promote rapid Point-of-Care Testing (POCT) closer to patients, reducing delays and loss to follow-up.	100%	79. Availability of TB diagnostic point of care testing policy approved
28	5.2 Endorse private laboratories to supplement public services, increasing overall testing capacity and geographic coverage while ensuring quality standards are met.	100%	80. Proportion of Private labs accredited for TB for TB diagnostic 81. proportion private health participated in EQA
29	5.3 Mandate the development of national and regional, and zonal technical expertise to maintain and repair TB diagnostic equipment	100%	82. Number of Technicians certified on equipment maintenance
30	5.4 Establishing dedicated bodies at all administrative levels from ministry of health to the woreda level to oversee planning, resource	81.82%	77.Availability of Diagnostic Coordinated Bodies established at all 78. presence of Resource allocation plans

	allocation, and problem-solving across the diagnostic network		

8.2.1 Indicator Definition on main strategic objective

1. Proportion of districts with operational WHO-endorsed molecular centres: - Number of districts with at least one functional GeneXpert or equivalent molecular diagnostic centre divided by total number of districts in Oromia × 100
2. Percentage diagnostic coverage per population within 10 km radius; - Proportion of district population residing within 10 km travel distance of a functional molecular diagnostic centre
3. Proportion of presumptive TB cases with initial access to WHO-endorsed molecular diagnostic centres: - Number of presumptive TB cases who first sought care at a facility with molecular testing ÷ Total presumptive TB cases × 100
4. Monthly volume of TB tests performed per diagnostic center; - Total number of molecular diagnostic tests (e.g., GeneXpert) conducted at each centre per month
5. Proportion of districts with vehicles/motorbikes for sample transportation; - Number of districts with at least one functional vehicle/motorbike dedicated to sample transport ÷ Total districts × 100

8.3 Tuberculosis Diagnostic Strategy Risks Identification

The strategic risks associated with TB diagnostics encompass various factors that hinder the effective strengthening of the TB diagnostic system. These include:

- Implementation Challenges: New diagnostic tools must be evaluated for compatibility with Ethiopian health infrastructure. Many require uninterrupted electric supply and backup, complicating the selection of effective combinations based on sensitivity, specificity, and operational feasibility.
- Resource Limitations: High demand for training and low operational capacity can lead to improper usage of new diagnostic tools.
- Costly Diagnostic Infrastructure: Expensive equipment may be underutilized, leading to wasted resources, persistent misdiagnosis, poor patient outcomes, and failure to achieve return on investment.

8.4 Strategic Management

Effective management of strategies aimed at enhancing tuberculosis diagnostics requires a comprehensive and anticipatory methodology. The strategy implementation will pursue four principal objectives:

- Broadening the array of diagnostic tests available.
- Augmenting the utilisation of these tests by clinicians.
- Expanding the coverage of Drug Susceptibility Testing (DST).
- Improving the application of information for informed decision-making.

8.5 Strategic Interventions And Expected Outcomes

8.5.1 Diversification of Procurement Channels:

Expected Outcome: Mitigates supply chain instability and ensures consistent availability of diagnostic reagents and tools.
Ongoing Capacity Enhancement via Training: Expected
Outcome: Increases diagnostic test utilisation and reduces operational errors.
Resource Allocation for Accelerated Molecular Technologies.
Expected Outcome: Addresses DST backlogs and improves timely diagnosis.
Integration of Health Information Systems.
Expected Outcome: Eliminates data silos and enhances evidence-based decision-making.

8.6 Monitoring And Evaluation

Diagnostic performance will be systematically monitored using Key Diagnostic Performance Indicators (KDPIs), including test turnaround times and utilisation rates.

This enables:

- Regular diagnostic-specific evaluations.
- Collaborative diagnostic mentorship and supportive supervision.

- Adaptive modifications to ensure strategic investments yield tangible improvements in TB patient outcomes.
- Support for evidence-based public health policies.

8.7 Conclusion

In conclusion, this integrated strategy decisively addresses Oromia's critical TB diagnostic gaps by establishing a tiered network of accessible molecular, imaging, and advanced diagnostic services from zonal to district levels, coupled with robust sample transport and mobile outreach to ensure equity. It simultaneously maximizes the utilisation of existing capacity through operational improvements like extended hours, reliable power, optimized screening through capacity building, strengthened maintenance, and enhanced healthcare worker competency. Furthermore, the strategy systematically expands Drug Susceptibility Testing (DST) coverage, fortifies diagnostic monitoring and evaluation with real-time data and alerts, and establishes essential policy frameworks and coordination bodies from ministry to district level to ensure sustainable, high-quality diagnostic services. Collectively, these interventions are designed to dramatically accelerate case detection, enable timely and appropriate treatment initiation, disrupt transmission chains, and ultimately achieve significant progress in TB control across the region.

CHAPTER 9

9.CONCLUSIONS AND RECOMMENDATIONS

9.1 Introduction

This final chapter summarizes the main conclusions drawn from current research and gives concrete recommendations directly addressing the objectives of the research. The report outlines the research in a concise manner, presents and interprets the main findings, examines the limitations of the research to contextualize the results, and proposes practical application and recommendations.

9.1.1 Summary of Key Findings

The aim of the study was to evaluate the level of physical access, utilisation, and application of information use for decision-making regarding tuberculosis diagnostics in Ethiopia's Oromia region. The study formulated strategy development to strengthen tuberculosis diagnostic in the Oromia region of Ethiopia. The researcher conducted a comprehensive literature review to gain insight into the access, use and application of tuberculosis diagnostic information to decision-making in health facilities throughout Oromia, as well as at the national and international level of health system management, along with strategies for improving tuberculosis diagnostic strategies.

9.1.2 The objectives of the study were to:

1. Evaluate the magnitude of physical access to tuberculosis diagnostics in Ethiopia's Oromia Region.
2. Assess the extent of TB diagnostic utilisation from diagnostic health facilities records of Ethiopia’s Oromia Region.
3. Assess Factors Associated with TB Diagnostic utilisation in health facilities of Ethiopia’s Oromia Region.
4. Assess the TB diagnostic monitoring and evaluation system used to make decisions in Ethiopia’s Oromia Region., Ethiopia.
5. Develop strategies to strengthen tuberculosis diagnostic system in Oromia region, Ethiopia

Data was electronically captured with Kobo Collect data collection instruments. Each data collector was equipped with a mobile device preloaded with the Kobo Collect application and the finalized data collection forms and the tools aided real-time data entry, reduced errors, and warranted secure data transmission to a central server. Data cleaning was done prior to analysis to determine missing values and the distribution (normality) of the variables. Descriptive analysis was conducted to summarize frequency distribution, measuring central tendency using mean, graphical presentation, cross tabulation assess association between categorical variables using chi-square, logistic regression, stratified analysis using each group Content analysis was also applied on unstructured data to develop strategies for TB diagnostic system strengthens.

9.1.3 Findings

The findings are discussed according to the five objectives of the study.

9.1.3.1. Evaluate the magnitude of physical access to tuberculosis diagnostics in Ethiopia's Oromia Region

The evaluation revealed severe deficits across three dimensions:

Availability: Conventional light microscopy was available in 84% of health facilities, but fluorescent microscopy in only 15%. (WRDs) were critically low: GeneXpert in 24.1% of facilities, first-line DST in 24%, second-line DST in only 8%. Supportive diagnostics were very limited: chest X-ray in 27.7% of facilities (though 100% of hospitals), ultrasound in 39%, and histopathology in only 2.7%. CT, MRI, and AI-CAD were absent entirely. Latent TB infection testing was unavailable in all facilities.

Geographic access: among the catchment population, adequate access (within 5 km) to AFB microscopy was only 35.8%, while 41.1% had poor access (>10 km). For GeneXpert, 43.7% had poor access. For chest X-ray, 49.5% had poor access. Spatial autocorrelation analysis showed significant dispersion for GeneXpert (Moran's I $z = -3.28$, $p = 0.001$) and X-ray ($z = -2.33$, $p = 0.02$).

Functional capacity: Reagent availability for fluorescent microscopy was only 35% where machines existed, and Xpert reagent availability was 66%, meaning many advanced machines were non-functional due to supply chain failures.

9.1.3.2. Assess the extent of TB diagnostic utilisation from diagnostic health facilities records of Ethiopia's Oromia Region.

Among 112 health facilities over six years (2018-2023), the total confirmatory tests increased from 35,038 to 48,935. However, utilisation rate relative to expected presumptive TB cases was very low: the average test utilisation rate from the community level was only 6.2% over six years. Even among outpatient department (OPD) attendees, only 12.3% on average were tested for TB, indicating major missed opportunities within health facilities. The overall positivity rate across all methods was 8.7% over six years, with Xpert MTB/RIF maintaining a consistent positivity rate of approximately 10%. Urine LF-LAM utilisation reached only 21.5% of eligible HIV-positive patients (CD4 <200) by 2023. Rifampicin DST coverage increased from 37.0% (2018) to 80.7% (2023), but second-line DST for fluoroquinolones reached only 37.1% by 2023, DST for Bedaquiline/linezolid remained below 5%.

9.1.3.3 Assess associated factor of low TB diagnostic utilisation in health facilities of Ethiopia's Oromia Region

Multivariate logistic regression identified three statistically significant predictors of low diagnostic test utilisation: (1) low health seeking/low patient flow (OR = 0.018, 95% CI: 0.001-0.218, p = 0.002); (2) inadequate supply/reagent shortage (OR = 0.023, 95% CI: 0.002-0.299, p = 0.004); and (3) no information about the sample referral system (OR = 0.006, 95% CI: 0.000-0.112, p < 0.001). Only 18.5% of health professionals were familiar with Ethiopia's national TB guidelines, and 77.9% were unaware of WHO-endorsed molecular rapid TB tests. Facility-level analysis showed a strong positive correlation between catchment population and test utilisation (r = 0.822, p < 0.001), but no significant correlation between catchment population and number of BSc laboratory technicians (r = -0.021, p = 0.412), indicating staffing is not aligned with population need. Multiple linear regression revealed that number of X-ray tests (β = 0.940, p = 0.002) and OPD visits (β = 0.557, p = 0.044) were significant predictors of TB case detection.

9.1.3.4 Assess the TB diagnostic monitoring and evaluation system used to make decisions in Ethiopia's Oromia Region

Among 222 health professionals from 171 organisations, 62.6% reported having a diagnostic service plan, but 27.5% had no plan, and 9.9% did not know. Of those with plans, 42% reported that their plan did not specify procedures for collecting and analyzing TB diagnostic data for project evaluation. Regarding use of diagnostic indicators, 10.8% of professionals used no indicators to monitor TB diagnostic performance, while the average number of indicators used was only four. Regular periodic TB diagnostic reviews were conducted by only 43.9% of organisations; 28.5% conducted them inconsistently, and 27.6% conducted no reviews. Notably, supportive diagnostic indicators (imaging, histopathology utilisation) were used by only 10.8% and 6.8% of professionals respectively.

9.1.3.5 Develop strategies to strengthen tuberculosis diagnostic system in Oromia region, Ethiopia

Using a modified three-round Delphi technique with 11 national and regional TB experts (radiologists, Histopathologists, national TB program officers, reference laboratory managers), consensus was achieved on five strategic objectives with 30 specific strategies. The validated strategies include: establishing district-level molecular diagnostic centres (90.91% consensus), implementing multi-tiered buffer stock systems (100% consensus), mandating healthcare worker competency training on national guidelines (100% consensus), developing unified diagnostic M&E frameworks with digital dashboards (90.91% consensus), establishing dedicated coordination bodies from ministry to district level (81.82-100% consensus), decentralizing DST services (90.91% consensus), and endorsing private laboratories to supplement public services (100% consensus). The full strategy framework is presented in Chapter 7.

9.2 Conclusions

This study concludes that the TB diagnostic system in Oromia Region, Ethiopia, faces a multidimensional systemic challenge rather than isolated resource shortages. The following specific conclusions are drawn:

1. Physical access is critically insufficient. Over 40% of the population lives more than 10 km from AFB microscopy and X-ray services, and nearly 44% from GeneXpert, exceeding WHO acceptable walking distances. Even where equipment exists, reagent stock-outs render advanced diagnostics non-functional for significant periods.

2. Diagnostic utilisation is dangerously low. Only 6.2% of expected community presumptive TB cases and 12.3% of OPD attendees with presumptive TB are tested. This means the vast majority of people with TB symptoms are not being diagnosed, perpetuating transmission and avoidable mortality.

3. Health workforce knowledge is a critical bottleneck. With only 18.5% of health professionals familiar with national TB guidelines, technology introduction without accompanying competency-based training is insufficient to improve outcomes.

4. Supply chain and referral system failures are the strongest predictors of low utilisation. Multivariate analysis identified reagent shortages (OR=0.023) and lack of referral system knowledge (OR=0.006) as the most powerful independent predictors, outweighing equipment failure or manpower shortages.

5. **The M&E system is non-functional** for supportive diagnostics. While confirmatory tests are partially monitored, there is no systematic tracking of imaging, histopathology, or ultrasound utilisation for TB diagnosis. Over 56% of organisations have inconsistent or no program reviews, making data-driven management impossible.

6**. Expert consensus validated a 30-strategy framework**. The Delphi process achieved strong consensus (>90% for most strategies) on a comprehensive roadmap addressing infrastructure, workforce, supply chain, DST expansion, M&E, and governance**...**

9.3 Recommendations

9.3.1 Policy Recommendations for the Ministry of Health of Ethiopia

1. Establish a dedicated Diagnostic Coordination Body at the Ministry of Health level, cascading to regional, zonal, and district levels, with a clear mandate to oversee planning, resource allocation, and problem-solving across the TB diagnostic network (Delphi consensus: 100%).
2. Adopt a national policy for point-of-care testing (POCT) to decentralize rapid molecular testing closer to patients, reducing delays and loss to follow-up (Delphi consensus: 100%).
3. Mandate the development of national, regional, and zonal technical expertise for the maintenance and repair of TB diagnostic equipment to minimize downtime (Delphi consensus: 100%).
4. Accredit private laboratories to supplement public services, increasing overall testing capacity and geographic coverage while ensuring quality standards are met (Delphi consensus: 100%).
5. Allocate a dedicated national TB budget line for DST reagents, equipment maintenance, training, and quality assurance to reduce dependency on unstable external funding (Delphi consensus: 90.91%).

9.3.2 Practice Recommendations for Regional Health Bureaus and Health Facilities

The practical recommendations are as follows:

- Establish district-level molecular diagnostic centres serving approximately 60,000 individuals within a 10 km radius (Delphi consensus: 90.91%).
- Implement mandatory competency-based training and certification for all healthcare workers on national TB diagnostic algorithms, eligibility criteria, and result interpretation (Delphi consensus: 100%).
- Implement multi-tiered buffer stock systems (national/regional) for critical reagents, utilizing forecasting tools based on testing volumes (Delphi consensus: 100%).
- Decentralize DST services (including core phenotypic DST) to mid-level laboratories to reduce turnaround times (Delphi consensus: 90.91%).

- Deploy mobile diagnostic units equipped with rapid molecular diagnostics and portable AI-assisted digital X-ray systems to reach remote and underserved populations (Delphi consensus: 72.73%).
- Implement 24/7 or extended-hour testing services at strategically identified high-burden facilities (Delphi consensus: 90.91%).
- Ensure reliable power solutions (solar + battery backup, generators) specifically for diagnostic equipment at all levels (Delphi consensus: 90.91%)

9.3.3 Recommendations for Monitoring and Evaluation

- Develop and implement a unified diagnostic M&E framework defining structures, indicators, and processes for both confirmatory and supportive TB diagnostics (Delphi consensus: 90.91%).
- Deploy a user-friendly digital tool to track, analyze, and visualize key diagnostic performance indicators at facility, sub-national, and national levels (Delphi consensus: 90.91%).
- Conduct monthly and quarterly facility-level audits of diagnostic test data (volume, turnaround time, positivity rates) to identify errors and improvement opportunities (Delphi consensus: 81.82%).
- Implement automated SMS/Telegram alerts for clinicians and coordinators for overdue diagnostic results requiring urgent action (Delphi consensus: 81.82%)

9.3.4 Recommendations for Future Research

- Conduct implementation science studies to evaluate the effectiveness of targeted interventions such as community-based screening, sample transport systems, and digital decision support tools.
- Perform cost-effectiveness analyses of different diagnostic placement strategies (district hubs vs. mobile units vs. facility-based) to inform resource allocation.
- Conduct qualitative studies to understand patient-level barriers to health-seeking behavior, including stigma, transportation costs, and cultural factors.

- Evaluate the impact of the proposed strategies through a longitudinal study design with baseline and follow-up measurements after 3-5 years of implementation.

9.4 Strategic Implications

The findings from Oromia reveal critical gaps in TB diagnostic access, utilisation, and system performance that directly hinder both the WHO End TB Strategy and Ethiopia's national TB control objectives. The low availability of advanced diagnostics (e.g., only 24% of facilities have Xpert), poor geographic access (over 40% of the population must travel >10km for testing), and severe supply chain failures impede early detection and universal DST coverage key pillars of the End TB Strategy. These deficiencies exacerbate diagnostic delays, increase catastrophic costs for households, and undermine Ethiopia's goal of achieving $\geqslant$ 80% bacteriological confirmation and universal DST by 2030, spreading high TB incidence and mortality.

Strategically, the proposed interventions, such as establishing district-level molecular hubs, decentralizing DST, strengthening supply chains, and implementing diagnostic M&E systems align closely with the End TB Strategy's pillars. By enhancing physical access, optimizing utilisation, and building resilient diagnostic networks, these measures support Ethiopia's national targets for expanded screening, rapid diagnosis, and universal DST. This integrated approach not only addresses immediate systemic barriers but also fosters sustainable, equity-oriented TB control essential for achieving the 2035 End TB targets and advancing universal health coverage in line with global and national priorities.

9.5 Limitations of The Study

Comprehensive assessment of population-level access to tuberculosis (TB) diagnostics necessitates demonstrating that services are available, geographically accessible, affordable, acceptable, and of high quality, thereby ensuring their utilisation by the target population. A limitation of the present study is that it did not evaluate the dimensions of affordability and acceptability. Furthermore, precise metrics of geographical accessibility, such as travel time and walking distance to health centres, were not collected from health facility attendees**.**

9.6 Reflections on The Research Process

A significant methodological reflection pertains to the deliberate exclusion of the patient perspective from our data collection. We recognized that while patients are the ultimate end-users of diagnostic services, their knowledge of specific diagnostic modalities such as which health facilities host GeneXpert machines or what constitutes the recommended diagnostic algorithm for TB is often limited. This reality would have made interviewing patients on technical aspects of service availability uninformative for our specific research objectives. Consequently, we focused on measuring objectively verifiable metrics like geographic proximity through geospatial analysis as a proxy for physical access. This trade-off, while necessary, highlights a limitation in our study: we captured the system's capability but not the patient's complete journey, which is also shaped by knowledge, perception, and stigma.

The research process was also significantly shaped by unforeseen contextual challenges. Most notably, the data collection phase was suspended for over six months due to serious security issues within the study region. This prolonged delay was a substantial logistical and operational hurdle, impacting our timeline and necessitating a flexible and adaptive research management approach. It served as a stark reminder that public health research in complex settings is often at the mercy of external political and social factors beyond the researcher's control.

On a personal and professional level, navigating these obstacles became a profound learning experience. To conduct this comprehensive systems evaluation, I acquired and applied new technical skills in GIS and geospatial analysis, which were indispensable for quantifying geographic barriers. Furthermore, I engaged with expert methodologies like the Delphi technique to build consensus around strategic priorities and immersed myself in the literature on various frameworks for public health strategy development. This process, tested by real-world adversity, not only equipped me with valuable analytical tools but also fundamentally shifted my perspective from a narrow, technical view of healthcare delivery to a more holistic, systems-thinking approach. I now more deeply appreciate that a diagnostic system is a complex interplay of technology, logistics, human resources, policy, and the overarching security

environment, and that sustainable solutions must be resilient and adaptable to these realities.

9.7 Final Remarks

This study provides a critical, systems-level evaluation of the tuberculosis (TB) diagnostic landscape in the Oromia Region of Ethiopia, moving beyond mere facility-level inventories to a multidimensional analysis of access, utilisation, and system performance. Its significance is: -

9.7.1 Bridging a Critical Knowledge Gap

It generates empirical evidence on the profound disparities in access to essential and advanced TB diagnostics, quantifying the specific technological and geographical barriers that prevent equitable service delivery.

9.7.2 Uncovering Systemic Bottlenecks

The research reveals that the core challenge is not solely a lack of TB diagnostic equipment but a failure of systems. The critical findings on reagent stock-outs, which render machines like Xpert MTB/RIF and fluorescent microscopes non-functional, and the weak diagnostic monitoring and evaluation frameworks and absence of diagnostic coordinating bodies highlight operational deficiencies that are often overlooked in top-down planning.

9.7.3 Informing Evidence-Based Resource Allocation

The strong correlation identified between diagnostic utilisation and factors like catchment population size, health workforce availability, and the existence of sample referral systems offers a data-driven blueprint for policymakers. It shifts the focus from simply placing equipment to strengthening the underlying health system components that enable its use.

9.7.4 Aligning with National and Global Agendas

The study's framework and findings are directly pertinent to Ethiopia's goal of achieving universal drug susceptibility testing (DST) and the World Health Organization's (WHO) End TB Strategy targets.

9.7.5 Potential Impact on TB Diagnostics and Public Health Policy

The insights from this study have the potential to catalyse significant improvements in TB control through direct impacts on policy and practice:

- **Immediate Health System Strengthening**: The findings can immediately inform the operational plans of Ethiopia's Ministry of Health and regional health bureaus. The proposed strategies such as establishing district-level molecular hubs, decentralizing DST, implementing robust sample referral networks, and fortifying supply chains provide a concrete, evidence-based roadmap for optimizing existing investments and guiding future procurement and infrastructure development.
- **Shifting Policy Priorities:** The study compellingly argues for a policy shift from a focus on availability to a focus on functional access. This could influence national health policy to mandate budget lines for recurrent costs (reagents, maintenance), prioritize the development of human resources for laboratory medicine, and formally integrate the monitoring of diagnostic functionality and equity into national TB program performance indicators.
- **Catalyzing Strategic Investment:** By quantifying the gaps and modeling the impact of proposed solutions, this study serves as a powerful investment case for domestic and international donors. It demonstrates that strategic funding for operational components like logistics, training, and quality assurance is as crucial as funding for the diagnostics themselves to achieve a return on investment in terms of lives saved.
- **Contributing to Global TB Control Efforts:** The methodology and lessons learned from the Oromia Region are transferable to other high-burden, resource-limited settings facing similar challenges. This study contributes to the global knowledge base on implementing complex health technologies in decentralized health systems, offering a replicable model for achieving

equitable access to TB diagnostics and accelerating progress towards the global End TB targets.

9.5 Conclusion

In conclusion, this study transcends a regional assessment to offer a scalable model for transforming TB diagnostic services. Its primary impact lies in its ability to translate data into actionable intelligence, guiding policies and investments that are not only technically sound but also equitable and sustainable, thereby directly contributing to the reduction of TB morbidity and mortality.

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ANNEXURE

ANNEXURE A: Ethics Approval from the University of South Africa

UNISA university of south africa

COLLEGE OF HUMAN SCIENCES RESEARCH ETHICS REVIEW COMMITTEE

13 October 2023

NHREC Registration # :
Rec-240816-052
CREC Reference # :
17677041_CREC_CHS_2023

Dear Mr Bizuneh Alemu Fetenesa

Decision:
Ethics Approval from 13 October 2023 to 13 October 2024

Researcher(s): Name: Mr B. A. Fetenesa
Contact details: 17677041@mylife.unisa.ac.za
Supervisor(s): Name: Prof P. R. Risenga
Contact details: risenpr@unisa.ac.za

Title: Development of strategies to strengthen Tuberculosis Diagnostic system in Oromia region, Ethiopia
Degree Purpose: PhD

Thank you for the application for research ethics clearance by the Unisa College of Human Science Ethics Committee. Ethics approval is granted for one year.

The *low-risk application was reviewed by* College of Human Sciences Research Ethics Committee, in compliance with the Unisa Policy on Research Ethics and the Standard Operating Procedure on Research Ethics Risk Assessment.

The proposed research may now commence with the provisions that:

1. The researcher(s) will ensure that the research project adheres to the values and principles expressed in the UNISA Policy on Research Ethics.
2. Any adverse circumstance arising in the undertaking of the research project that is relevant to the ethicality of the study should be communicated in writing to the College Ethics Review Committee.
3. The researcher(s) will conduct the study according to the methods and procedures set out in the approved application.
4. Any changes that can affect the study-related risks for the research participants, particularly in terms of assurances made with regards to the protection of participants' privacy and the

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confidentiality of the data, should be reported to the Committee in writing, accompanied by a progress report.

5. The researcher will ensure that the research project adheres to any applicable national legislation, professional codes of conduct, institutional guidelines and scientific standards relevant to the specific field of study. Adherence to the following South African legislation is important, if applicable: Protection of Personal Information Act, no 4 of 2013; Children's act no 38 of 2005 and the National Health Act, no 61 of 2003.
6. Only de-identified research data may be used for secondary research purposes in future on condition that the research objectives are similar to those of the original research. Secondary use of identifiable human research data require additional ethics clearance.
7. No fieldwork activities may continue after the expiry date **(13 October 2024).** Submission of a completed research ethics progress report will constitute an application for renewal of Ethics Research Committee approval.

Note:

*The reference number **17677041_CREC_CHS_2023** should be clearly indicated on all forms of communication with the intended research participants, as well as with the Committee.*

Yours sincerely,

Signature: 

Prof. KB Khan
CHS Research Ethics Committee Chairperson
Email: khankb@unisa.ac.za
Tel: (012) 429 8210

Signature: PP

Prof ZZ Nkosi
Exécutive Dean: CHS
E-mail: nkosizz@unisa.ac.za
Tel: 012 429 6758

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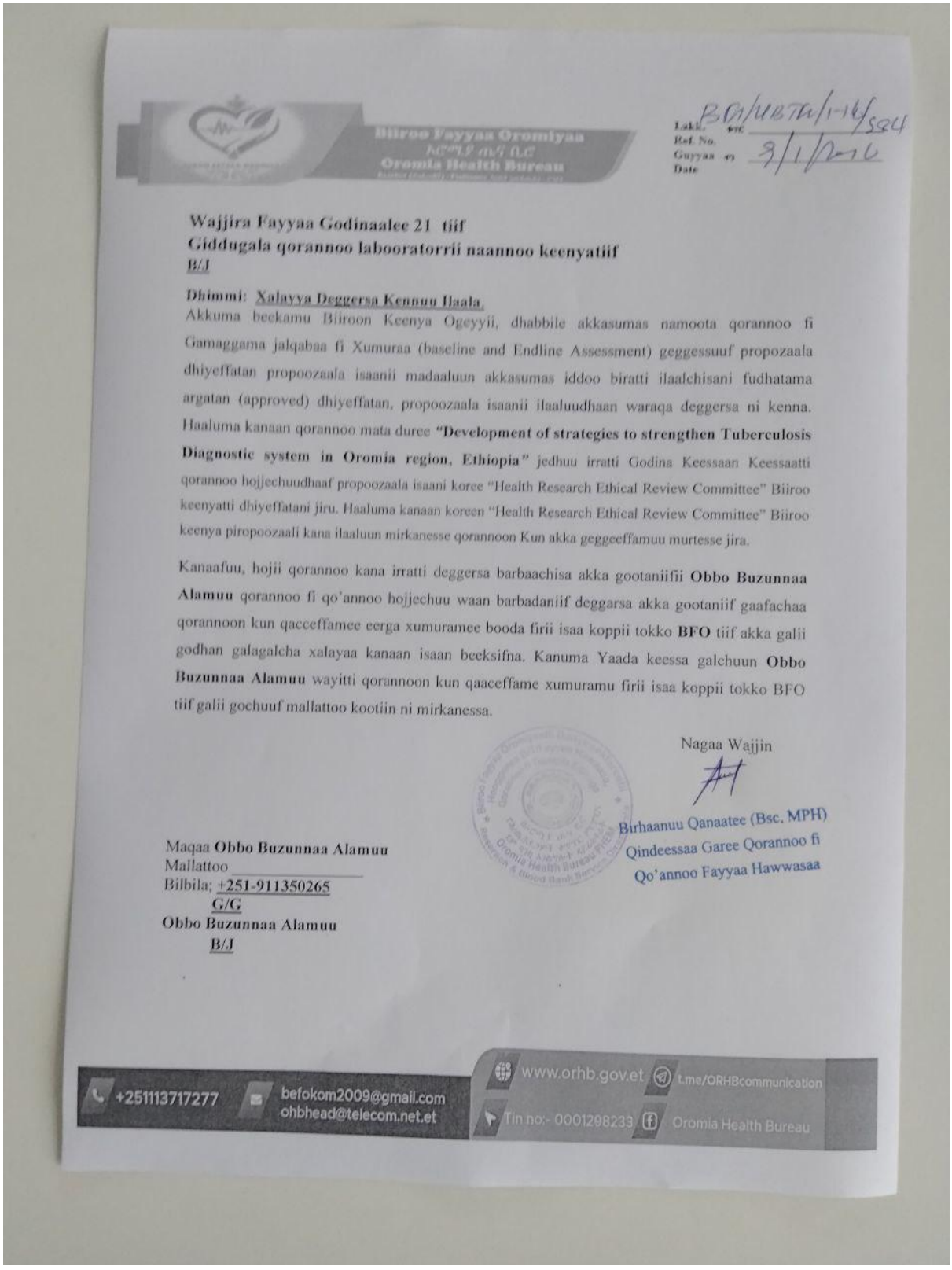
ANNEXURE B: letter of permission from Oromia health bureau



Biiroo Fayyaa Oromiyaa
ኦሮሚያ ጤና ቢሮ
Oromia Health Bureau

Lakk. Ref. No. BO/HBTa/1-14/5844
Guyyaa Date 3/1/2016

Wajjira Fayyaa Godinaalee 21 tiif
Giddugala qorannoo labooratorrii naannoo keenyatiif
B/J

Dhimmi: Xalayya Deggersa Kennuu Ilaala.

Akkuma beekamu Biiroon Keenya Ogeyyii, dhabbile akkasumas namoota qorannoo fi Gamaggama jalqabaa fi Xumuraa (baseline and Endline Assessment) geggessuuf propozaala dhiyeffatan propoozaala isaanii madaaluun akkasumas iddoo biratti ilaalchisani fudhatama argatan (approved) dhiyeffatan, propoozaala isaanii ilaaluudhaan waraqa deggersa ni kenna. Haaluma kanaan qorannoo mata duree **"Development of strategies to strengthen Tuberculosis Diagnostic system in Oromia region, Ethiopia"** jedhuu irratti Godina Keessaan Keessaatti qorannoo hojjechuudhaaf propoozaala isaani koree "Health Research Ethical Review Committee" Biiroo keenyatti dhiyeffatani jiru. Haaluma kanaan koreen "Health Research Ethical Review Committee" Biiroo keenya piropoozaali kana ilaaluun mirkanesse qorannoon Kun akka geggeeffamuu murtesse jira.

Kanaafuu, hojii qorannoo kana irratti deggersa barbaachisa akka gootaniifii **Obbo Buzunnaa Alamuu** qorannoo fi qo'annoo hojjechuu waan barbadaniif deggarsa akka gootaniif gaafachaa qorannoon kun qacceffamee eerga xumuramee booda firii isaa koppii tokko **BFO** tiif akka galii godhan galagalcha xalayaa kanaan isaan beeksifna. Kanuma Yaada keessa galchuun **Obbo Buzunnaa Alamuu** wayitti qorannoon kun qaaceffame xumuramu firii isaa koppii tokko BFO tiif galii gochuuf mallattoo kootiin ni mirkanessa.

Nagaa Wajjin

Birhaanuu Qanaatee (Bsc. MPH)
Qindeessaa Garee Qorannoo fi
Qo'annoo Fayyaa Hawwasaa

Maqaa **Obbo Buzunnaa Alamuu**
Mallattoo
Bilbila; +251-911350265
G/G
Obbo Buzunnaa Alamuu
B/J

+251113717277 befokom2009@gmail.com ohbhead@telecom.net.et
www.orhb.gov.et t.me/ORHBcommunication
Tin no:- 0001298233 Oromia Health Bureau

BIIROO FAYYAA OROMIYAA
ኦሮሚያ ጤና ቢሮ
OROMIA HEALTH BUREAU

Guyyaa Date ቀን _____
Lakk Ref.no ቁጥር _____

Ethical Review Form

Tele: +251118337275 P.O. Box.24341 Addis Ababa, Ethiopia

Criteria/Item	Rating
1. consent form ✓ Does the consent contain all the necessary information that subject should be aware of?	X Yes _____ Requires revision _____ No _____ Not applicable _____ Not attached
2. Are the objectives of the study clearly stated	X Yes _____ No
3. Are provisions to overcome risks well described and accepted? ✓ Justice ✓ Beneficence ✓ Respect for a person	X Yes _____ Not well described _____ No _____ Not applicable
4. Are the safety procedures in the use of vaccines, drugs, and other biological products acceptable?	_____ Yes _____ No X Not applicable
5. Are the procedures to keep confidentiality well described?	X Yes _____ No _____ Not applicable
6. Are the proposed researchers competent to carry out the study in a scientifically sound way?	X Yes _____ No _____ Not applicable _____ Unable to assess
7. Does it have material transfer agreement?	_____ Yes _____ No X Not applicable
Recommendation	X Approved _____ Approved on condition _____ Not approved

Ethical Clearance Committee Members

Signature of secretory

1. Name: **Abate Zewude**
2. Signature _____

Biiroo Fayyaa Oromiyaatti Daayireektoreetii Hooggansa B/T/Fayyaa Hawaasa, Qorannoo fi Tajaajila B/Dhiiga
Oromia Health Bureau Research & Blood Bank Service Directorate

Signature of Chair Person

1. Name: **Birhanu Kenate**
2. Signature: _____

Birhaanuu Qanaatee (Bsc. MPH)
Qindeessaa Garee Qorannoo fi Qo'annoo Fayyaa Hawwaasaa

6955
befokom2009@gmail.com
info@orhb.gov.et
www.orhb.gov.et
Oromia health bureau
t.me/ORHBCommunication
saarbet (calclii) finfinnee

ANNEXURE C: Cconsent form

UNISA university of south africa

APPENDIX

CONCENT TO PARTICIPATE IN THE STUDY

Ethics clearance reference number: REC-240816-052

Research permission reference number = BFO/KBTKU/H6/584

Title: - Development of strategies to strengthen Tuberculosis Diagnostic system in Oromia region, Ethiopia

Dear Prospective Participant

My name is Bizuneh Alemu, Alemu I am conducting research for a PhD in Public Health at the University of South Africa with Professor Patron Rebeca Risenga, a senior lecturer in the Department of Health Studies your health facilities are selected to be a part of study entitled **"Development of strategies to strengthen Tuberculosis" Diagnostic system in Oromia region Ethiopia**

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this research study is to develop strategies to strengthen TB diagnostic system which will improve TB diagnostic access and utilization

WHY AM I BEING INVITED TO PARTICIPATE?

Your participation in this study will help us gain new ideas, suggestions and perceptions on TB diagnostic access, utilisation and information use for decision making to develop TB diagnostic strategy.

participants include laboratory technicians, imaging technician , radiographers, pathologist, TB focal persons, health centre managers, district health managers, district TB focal persons, zonal TB focal persons regional laboratory officers, referral laboratory departmental heads and health informatics technician who are involved in data recording, compiling, reporting and utilization of TB diagnostics are chosen to participate in this particular research. It is highly believed that these target groups have better understanding and knowledge on the utilisation of TB diagnostics in your health care facilities.

The lists of the study participants will be obtained from Human Resource units of each Health facilities and district health offices by adhering to the Protection of Personal Information Act, nr 4 of 2013. The purpose of the Act is to protect personal information,

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to strike a balance between the right to privacy and the need for the free flow of, and access to information, and to regulate how personal information is processed. You are one among 252 survey participants who will take in the study.

Confidentiality: All information obtained from you will be kept strictly confidential and your name will not be written in this form. The information you tell us will never be exposed to other parties that means it will be used only in connection with this study

WHAT IS THE NATURE OF PARTICIPATION IN THIS STUDY?

The study involves survey questionnaires, where you will take part in the survey questionnaires assisted by data collectors (research assistants) assigned to this study and Your health facility diagnostic records data, TB diagnostic availability functionality, reporting system, will be collected assisted by checklist.'

The study involves data collection procedure and face to face interview sessions that will take approximately 60 minutes.

You are expected to sign a consent form that will only be applicable on this study and the information will only be used for this specific study.

CAN I WITHDRAW FROM THIS STUDY EVEN AFTER HAVING AGREED TO PARTICIPATE?

Free participation and withdrawal: Your participation is voluntarily and you are not obliged to answer any questions you don't want to respond. You may also withdraw from the study at any time and you would not be penalized for your decision to withdraw.

Participating in this study is voluntary and you are under no obligation to consent to participation. If you decide to take part, you will be given this information sheet to keep and be asked to sign a written consent form. You are free to withdraw at any time and without giving a reason.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THIS STUDY?

There is no direct financial or other in kind benefit for participation in this study but your participation helps us to improve the service. If you have questions you can ask any time using the following address.

ARE THEIR ANY NEGATIVE CONSEQUENCES FOR ME IF I PARTICIPATE IN THE RESEARCH PROJECT?

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This study will pose a "low risk" to the study participants. That means the probability and magnitude of harm or discomfort anticipated in this research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

WILL THE INFORMATION THAT I CONVEY TO THE RESEARCHER AND MY IDENTITY BE KEPT CONFIDENTIAL?

You have the right to insist that your name will not be recorded anywhere and that no one, apart from the researcher and identified members of the research team, will know about your involvement in this research OR your name will not be recorded anywhere and no one will be able to connect you to the answers you give Your answers will be given a code number or a pseudonym and you will be referred to in this way in the data, any publications, or other research reporting methods such as conference proceedings

Your answers may be reviewed by people responsible for making sure that research is done properly, including the transcribers, external coder, and members of the College Research and Ethics Committee (CREC). Otherwise, records that identify you will be available only to people working on the study, unless you give permission for other people to see the records.

Every effort will be made by the researcher to ensure that you will not be connected to the information that you share during the survey.

HOW WILL THE RESEARCHER(S) PROTECT THE SECURITY OF DATA?

Hard copies of your answers will be stored by the researcher for a minimum period of five years in a locked cupboard/filing cabinet in a secured office for future research or academic purposes; electronic information will be stored on a password protected computer. Future use of the stored data will be subject to further Research Ethics Review and approval if applicable. Lastly, all the hard copies and soft copies will be destroyed , hard copies will be shredded and/or electronic copies will be permanently deleted from the hard drive of the computer through the use of a relevant software programme.

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WILL I RECEIVE PAYMENT OR ANY INCENTIVES FOR PARTICIPATING IN THIS STUDY?

In this particular study, no any payment or reward will be offered in any form. Prior to the study the participants will be informed that no financial provision will be made to the participants.

HAS THE STUDY RECEIVED ETHICS APPROVAL

This study has received written approval from the College Research and Ethics Committee (CREC), Dr J Moodley moodljk@unisa.ac.za +27 (0) 12 429 8069 if you have any ethical concerns, you can contact them by using the email and phone number. A copy of the approval letter can be obtained from the researcher if you so wish.

HOW WILL I BE INFORMED OF THE FINDINGS/RESULTS OF THE RESEARCH?

The feedback of the research findings will be obtained in professional network, such as a meeting or conference and copy of the finding will be provided to you and to your institution. If you would like to be informed of the final research findings, please contact (Full Name) _____ on +251-_____ or email address: _____
The findings are accessible for anytime. Please do not use home telephone numbers. Departmental and/or mobile phone numbers are acceptable.
Should you require any further information or want to contact the researcher about any aspect of this study, please contact ___full name_____ at +251-_____ and email address: _____

Should you have concerns about the way in which the research has been conducted, you may contact my Professor _____, Email: _____ Tel: +27 (0)1_____.

Contact the research ethics chairperson of the College Research and Ethics Committee (CREC), Dr J Moodley moodljk@unisa.ac.za +27 (0) _____ if you have any ethical concerns.

Thank you for taking time to read this information sheet. If you are willing to participate in this study, kindly complete the consent form below.

Kind regards

Bizuneh Alemu Fetenesa

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Appendix 6: CONSENT TO PARTICIPATE IN THIS STUDY

I, _____ (participant name), confirm that the person asking my consent to take part in this research has told me about the nature, procedure, potential benefits and anticipated inconvenience of participation.

I have read (or had explained to me) and understood the study as explained in the information sheet.I have had sufficient opportunity to ask questions and am prepared to participate in the study.

I understand that my participation is voluntary and that I am free to withdraw at any time without penalty (if applicable).

I am aware that the findings of this study will be processed into a research report, journal publications and/or conference proceedings, but that my participation will be kept confidential unless otherwise specified.

I agree to the recording of the interview sessions.

I have received a signed copy of the informed consent agreement.

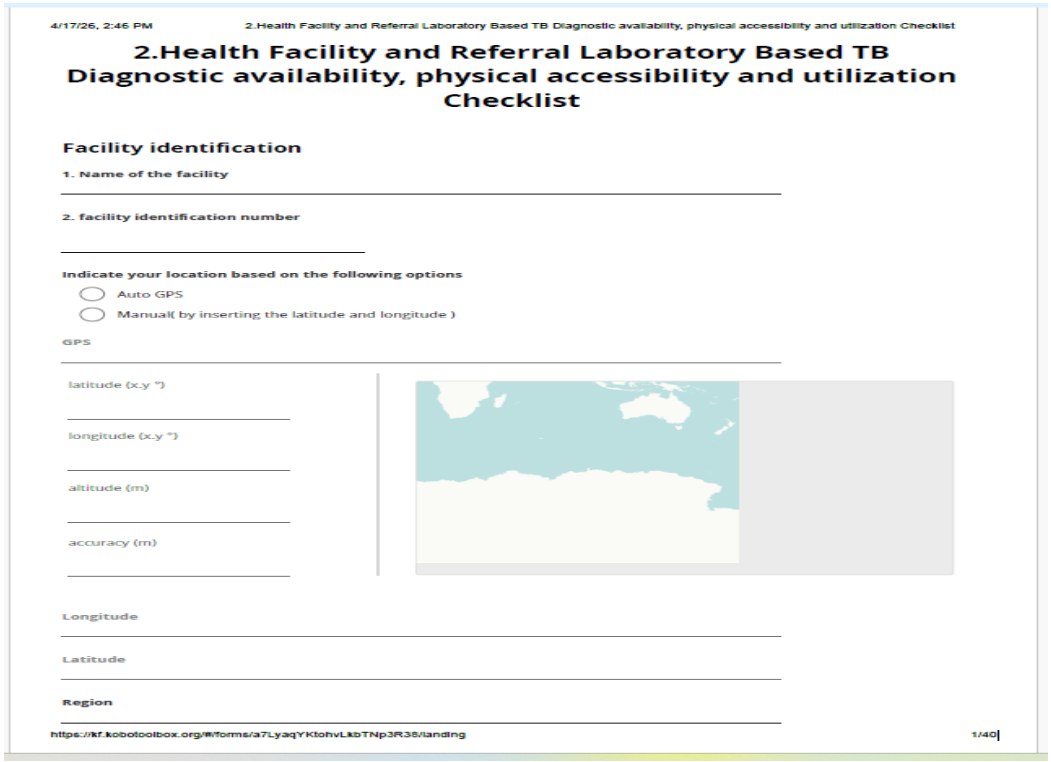
Participant Name & Surname.....(please print)

Participant Signature……Date……

Researcher's Name & Surname: Bizuneh Alemu Researcher's signature

Date……

ANNEXURE D: Data collection Checklist used developed in kobo collect



4/17/26, 2:46 PM 2.Health Facility and Referral Laboratory Based TB Diagnostic availability, physical accessibility and utilization Checklist

2.Health Facility and Referral Laboratory Based TB Diagnostic availability, physical accessibility and utilization Checklist

Facility identification

1. Name of the facility

2. facility identification number

Indicate your location based on the following options

- ◯ Auto GPS
- ◯ Manual(by inserting the latitude and longitude)

GPS

latitude (x.y °)

longitude (x.y °)

altitude (m)

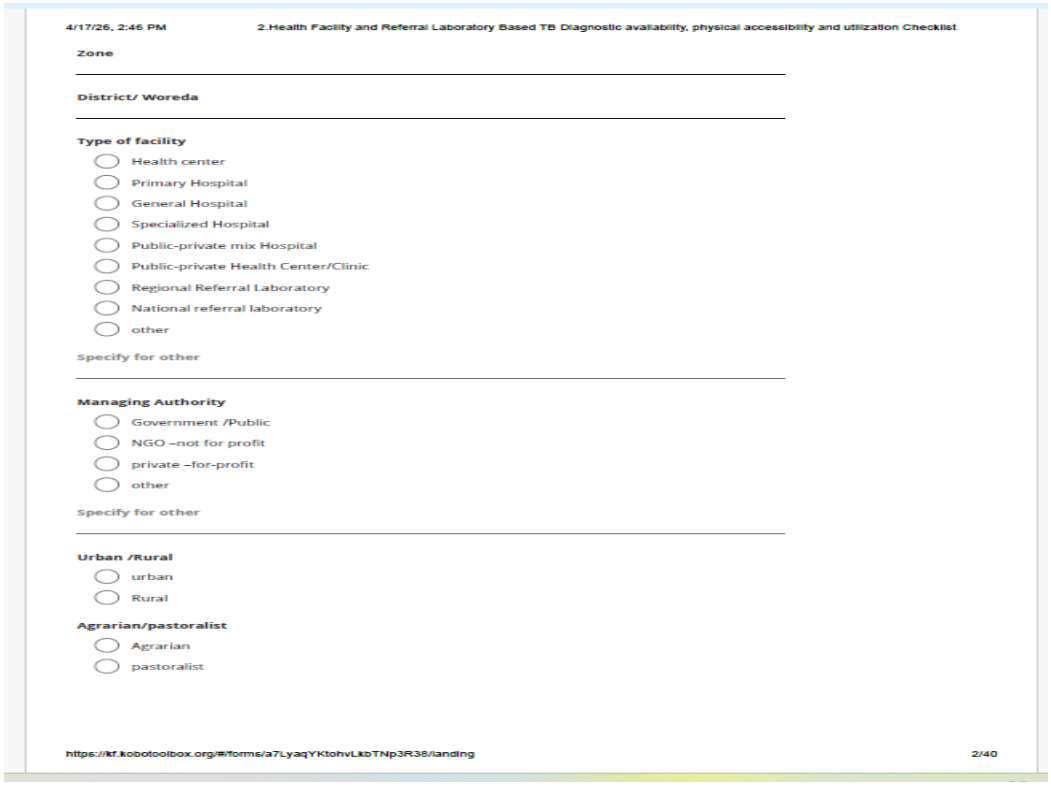
accuracy (m)

Longitude

Latitude

Region

https://kf.kobotoolbox.org/#/forms/a7LyaqYKtohvLkbTNp3R38/landing 1/40



4/17/26, 2:46 PM 2.Health Facility and Referral Laboratory Based TB Diagnostic availability, physical accessibility and utilization Checklist

Zone

District/ Woreda

Type of facility

- ◯ Health center
- ◯ Primary Hospital
- ◯ General Hospital
- ◯ Specialized Hospital
- ◯ Public-private mix Hospital
- ◯ Public-private Health Center/Clinic
- ◯ Regional Referral Laboratory
- ◯ National referral laboratory
- ◯ other

Specify for other

Managing Authority

- ◯ Government /Public
- ◯ NGO –not for profit
- ◯ private –for-profit
- ◯ other

Specify for other

Urban /Rural

- ◯ urban
- ◯ Rural

Agrarian/pastoralist

- ◯ Agrarian
- ◯ pastoralist

https://kf.kobotoolbox.org/#/forms/a7LyaqYKtohvLkbTNp3R38/landing 2/40

1, staffing, I have a few questions about staffing for this facility. Please tell me how many staff with each of the following qualifications are currently assigned to, employed by, or seconded to this facility. Please count each staff member only once, on the basis of the highest technical or professional qualification. For doctors, I would also like to know, of the total number, how many are part-time in this facility

Total Number of Health professionals

_____

Is Health worker assigned/ employed by part-time

- ◯ yes
- ◯ No

number of per- timer assigned

_____

1.total number of Generalist (non-specialist) medical doctors

_____

02. total number Specialist medical doctors

_____

03. Health officers

_____

04. Clinical nurse

_____

05. Pharmacist

_____

06. Laboratory Technician Diploma

_____

07. Laboratory technician BSC

_____

08. Microbiologist MSC

_____

09. Radiographer

_____

10. Radiologist

_____

11. Pathologist

_____

LABORATORY INFRASTRUCTURE

Does this facility/laboratory have a functioning landline telephone that is available to call outside at all times client services are offered

- ◯ yes
- ◯ No

Does this facility laboratory have a functioning computer?

- ◯ yes
- ◯ no

Is the lab access to email or internet within the facility today?

- ◯ Yes
- ◯ No

Does this facility have access to an ambulance or other vehicle for laboratory sample transport to another facility in near proximity?

- ◯ YES
- ◯ NO

POWER SUPPLY

Does your facility have electricity from any source (e.g. electricity grid, generator, solar, or other) including for stand-alone devices

- ◯ YES
- ◯ NO

What is the electricity used for in the facility?

- ◯ Only stand-alone electric medical devices/appliances (e.g. epi cold room, refrigerator, suction apparatus,
- ◯ Electric lighting (excluding flashlights) and communications
- ◯ Electric lighting, communications, and 1 to 2 electric medical devices/ appliances..
- ◯ All electrical needs of facility .....

What is the facility's main source of electricity?

- ◯ Central supply of electricity (e.g. national or community grid)
- ◯ Generator (fuel or battery operated generator)
- ◯ Solar system
- ◯ Other

specify for other

_____

Other than the main or primary source, does the facility have a secondary or backup source of electricity?

- ◯ yes
- ◯ No

What is the secondary source of electricity

- ◯ central supply of electricity (e.g. national or community grid)
- ◯ Generator (fuel or battery operated generator)
- ◯ solar system
- ◯ other

specify for other

_____

During the past 7 days, was electricity available at all times from the main or any backup source when the facility was open for services?

- ◯ always available (no interruptions
- ◯ available (interruptions of less than 2 hours per day
- ◯ sometimes available (frequent or prolonged interruptions of more than 2 hours per day)

Is the generator functional?

- ◯ yes
- ◯ No
- ◯ don't know

Is there fuel or a charged battery available today?

- ◯ yes
- ◯ No
- ◯ don't know

Is the solar system functional?

- ◯ yes, functioning.
- ◯ partially, battery needs servicing/replacement.
- ◯ Not functional
- ◯ don't know

water supply

what is the most commonly used source of water for the facility at this time? observe that water is available from the source or in the facility on the day of the visit. e.g. check that the pipe is functioning.

- ◯ piped into facility
- ◯ piped onto facility grounds
- ◯ public tap/standpipe
- ◯ tubewell/borehole
- ◯ protected dug well
- ◯ unprotected dug well
- ◯ protected spring
- ◯ unprotected spring
- ◯ rainwater collection
- ◯ bottled water
- ◯ cart w/small tank/drum
- ◯ tanker truck
- ◯ surface water
- ◯ no water source
- ◯ don't know.....
- ◯ other

specify others

_____

Is water available from this source on facility premises?

- ◯ yes, inside the facility
- ◯ yes, within the ground of the facility
- ◯ no, outside the facility grounds

BASIC TB DIGNOSTIC EQUIPMENT(Please tell me if the following TB diagnostic equipment and supplies used in the provision of TB Diagnostic services are available and functional in this facility today. ASK TO SEE THE ITEMS

Adult weighing scale

- ◯ available and functioning
- ◯ Available but not functioning
- ◯ Not avilable

A child weighing scale250-gramam gradation

- ◯ available and functioning
- ◯ available but not functioning
- ◯ Not available

Thermometer

- ◯ available and functioning
- ◯ available but not functioning
- ◯ Not available

Stethoscope

- ◯ available and functioning
- ◯ available but not functioning
- ◯ not avilable

Blood pressure apparatus (may be digital or manual sphygmomanometer with a stethoscope)

- ◯ available and functioning
- ◯ available but not functioning
- ◯ not avilable

Does this facility have an accredited/certified microscopist?

- ◯ yes
- ◯ No

Light Microscope

- ◯ available and functioning
- ◯ available but not functioning
- ◯ not available

FM Microscope

- ◯ available and functioning
- ◯ available but not functioning
- ◯ not available

Forested slide

- ◯ available
- ◯ not Available

AFB methylene blue

- ◯ available
- ◯ Not Available

3% Acid Alcohol

- ◯ available
- ◯ Not available

Carbon fusion

- ◯ available
- ◯ Not Available

Auramine O

- ◯ available
- ◯ Not available

Acid alcohol

- ◯ available
- ◯ Not available

Potassium permanganate

- ◯ available
- ◯ Not available

Xpert MTB/RIF/ultra diagnostic testing for TB onsite
- ◯ available and functioning
- ◯ available but not functioning
- ◯ not available

Xpert MTB/RIF rapid test Cartridge
- ◯ Available
- ◯ Not available
- ◯ expired

LF Lam testing
- ◯ available
- ◯ not available
- ◯ expired

TB LAMP
- ◯ Available
- ◯ not available

Xpert XDR /High or moderate complexity
- ◯ available
- ◯ not available

Truenat® MTB or MTB Plus for TB detectionreflectinggb to Truenat MTB-RIF-Dx for DR-TB detection
- ◯ available and functioning
- ◯ available but not functioning
- ◯ not available

1st line LPA
- ◯ available and functioning
- ◯ available but not functioning
- ◯ not available

2nd line LPA
- ◯ available and functioning
- ◯ available but not functioning
- ◯ not available

Solid TB culture
- ◯ available and functioning
- ◯ available but not functioning
- ◯ not available

Liquid TB culture
- ◯ available and functioning
- ◯ available but not functioning
- ◯ not available

XDR Genexpert
- ◯ available and functioning
- ◯ available but not functioning
- ◯ not available

Xpert XDR cartridge
- ◯ available
- ◯ not available
- ◯ expired

Interferon-gamma release assay
- ◯ available
- ◯ not available
- ◯ expired

Tuberculin skin test
- ◯ available
- ◯ not available
- ◯ Expired

CRP
- ◯ available
- ◯ not available
- ◯ expired

Imaging equipment

X-ray

- ◯ available and functioning
- ◯ available but not functioning
- ◯ not available

Digital x-ray

- ◯ available and functioning
- ◯ available but not functioning
- ◯ not available

AI CAD

- ◯ available
- ◯ Not available

Ultrasound

- ◯ available and functioning
- ◯ available but not functioning
- ◯ not available

CT scan

- ◯ available and functioning
- ◯ available but not functioning
- ◯ not available

MRI

- ◯ available and functioning
- ◯ available but not functioning
- ◯ not available

Histo-Pathological Examination

- ◯ available
- ◯ not Available

other TB diagnostics

_____

Basic Background Data

101.1 Total estimated population in which the health facility gives service in 2018

_____

101.2 Total estimated population in which the health facility gives service in 2019

_____

101.3 Total estimated population in which the health facility gives service in 2020

_____

101.4 Total estimated population in which the health facility gives service in 2021

_____

101.5 Total estimated population in which the health facility gives service in 2022

_____

101.6 Total estimated population in which the health facility gives service in 2023

_____

102.1 Total estimated TB incidence cases in 2018

_____

102.2 Total estimated TB incidence cases in 2019

_____

102.3 Total estimated TB incidence cases in 2020

_____

102.4 Total estimated TB incidence cases in 2021

_____

102.5 Total estimated TB incidence cases in 2022

_____

102.6 Total estimated TB incidence cases in 2023

_____

103.1 Total number all forms TB case enrolled In first line Anti TB treatment in 2018

_____

103.2 Total number all forms TB case enrolled In first line Anti TB treatment in 2019

_____

103.3 Total number all forms TB case enrolled In first line Anti TB treatment in 2020

_____

103.4 Total number all forms TB case enrolled In first line Anti TB treatment in 2021

_____

103.5 Total number all forms TB case enrolled In first line Anti TB treatment in 2022

_____

103.6 Total number all forms TB case enrolled In first line Anti TB treatment in 2023

_____

104.1 Total number Bacteriological TB case enrolled in first line anti TB treatment in 2018

_____

104.2 Total number Bacteriological TB case enrolled in first line anti TB treatment in 2019

_____

104.3 Total number Bacteriological TB case enrolled in first line anti TB treatment in 2020

_____

104.4 Total number Bacteriological TB case enrolled in first line anti TB treatment in 2021

_____

104.5 Total number Bacteriological TB case enrolled in first line anti TB treatment in 2022

_____

104.6 Total number Bacteriological TB case enrolled in first line anti TB treatment in 2023

_____

105.1 Total number of EPTB Case enrolled in first line anti TB in 2018

_____

105.2 Total number of EPTB Case enrolled in first line anti TB in 2019

_____

105.3 Total number of EPTB Case enrolled in first line anti TB in 2020

_____

105.4 Total number of EPTB Case enrolled in first line anti TB in 2021

_____

105.5 Total number of EPTB Case enrolled in first line anti TB in 2022

_____

105.6 Total number of EPTB Case enrolled in first line anti TB in 2023

_____

106.1 Total number clinically diagnosed Pneg TB in 2018

_____

106.2 Total number clinically diagnosed Pneg TB in 2019

_____

106.3 Total number clinically diagnosed Pneg TB in 2020

_____

106.4 Total number clinically diagnosed Pneg TB in 2021

_____

106.5 Total number clinically diagnosed Pneg TB in 2022

_____

106.6 Total number clinically diagnosed Pneg TB in 2023

_____

Is your Health facility is DRTB treatment initiative center

- ◯ yes
- ◯ NO

107.1 Total number of DRTB case enrolled on second line TB treatment in 2018

_____

107.2 Total number of DRTB case enrolled on second line TB treatment in 2019

_____

107.3 Total number of DRTB case enrolled on second line TB treatment in 2020

_____

107.4 Total number of DRTB case enrolled on second line TB treatment in 2021

_____

107.5 Total number of DRTB case enrolled on second line TB treatment in 2022

_____

107.6 Total number of DRTB case enrolled on second line TB treatment in 2023

_____

108.1 Total number of OPD attendants in 2018

_____

108.2 Total number of OPD attendants in 2019

_____

108.3 Total number of OPD attendants in 2020

_____

108.4 Total number of OPD attendants in 2021

_____

108.5 Total number of OPD attendants in 2022

_____

108.6 Total number of OPD attendants in 2023

_____

109.1 Total number of impatient in 2018

_____

109.2 Total number of impatient in 2019

_____

109.3 Total number of impatient in 2020

_____

109.4 Total number of impatient in 2021

_____

109.5 Total number of impatient in 2022

_____

109.6 Total number of impatient in 2023

_____

IS your Health facility is ART center

- ◯ yes
- ◯ NO

110.1 Total number of patients on ART in 2018

_____

110.2 Total number of patients on ART in 2019

_____

110.3 Total number of patients on ART in 2020

_____

110.4 Total number of patients on ART in 2021

_____

110.5 Total number of patients on ART in 2022

_____

110.6 Total number of patients on ART in 2023

_____

111.1 Total number HIV patients with with < 200 CD4 clients in 2018

_____

111.2 Total number HIV patients with with < 200 CD4 clients in 2019

_____

111.3 Total number HIV patients with with < 200 CD4 clients in 2020

_____

111.4 Total number HIV patients with with < 200 CD4 clients in 2021

_____

111.5 Total number HIV patients with with < 200 CD4 clients in 2022

_____

111.6 Total number HIV patients with with < 200 CD4 clients in 2023

_____

Diagnostic Test Utilization

201.1a Total # of test done by direct AFB smear (fuschin staining) in 2018

_____

201.1b Total # of test done by direct AFB smear (fuschin staining) and # of AFB positive in 2018

_____

201.2a Total # of test done by direct AFB smear (fuschin staining) in 2019

_____

201.2b Total # of test done by direct AFB smear (fuschin staining) and # of AFB positive in 2019

_____

201.3a Total # of test done by direct AFB smear (fuschin staining) in 2020

_____

201.3b Total # of test done by direct AFB smear (fuschin staining) and # of AFB positive in 2020

_____

201.4a Total # of test done by direct AFB smear (fuschin staining) in 2021

_____

201.4b Total # of test done by direct AFB smear (fuschin staining) and # of AFB positive in 2021

_____

201.5a Total # of test done by direct AFB smear (fuschin staining) in 2022

_____

201.5b Total # of test done by direct AFB smear (fuschin staining) and # of AFB positive in 2022

_____

201.6a Total # of test done by direct AFB smear (fuschin staining) in 2023

_____

201.6b Total # of test done by direct AFB smear (fuschin staining) and # of AFB positive in 2023

_____

is your laboratory FM site

- ◯ YES
- ◯ No

202.1a Total # of test done by direct AFB smear (fluorochrome staining) in 2018

_____

202.1b Total # of test done by direct AFB smear (fluorochrome staining) and # of AFB positive in 2018

_____

202.2a Total # of test done by direct AFB smear (fluorochrome staining) in 2019

_____

202.2b Total #of test done by direct AFB smear (fluorochrome staining) and # of AFB positive in 2019

_____

202.3a Total # of test done by direct AFB smear (fluorochrome staining) in 2020

_____

202.3b Total # of test done by direct AFB smear (fluorochrome staining) and # of AFB positive in 2020

_____

202.4a Total # of test done by direct AFB smear (fluorochrome staining) in 2021

_____

202.4b Total # of test done by direct AFB smear (fluorochrome staining) and # of AFB positive in 2021

_____

202.5a Total # of test done by direct AFB smear (fluorochrome staining) in 2022

_____

202.5b Total # of test done by direct AFB smear (fluorochrome staining) and # of AFB positive in 2022

_____

202.6a Total # of test done by direct AFB smear (fluorochrome staining) in 2023

_____

202.6b Total # of test done by direct AFB smear (fluorochrome staining) and # of AFB positive in 2023

_____

203.1a Total # of Xpert MTB Rif/ultra assay test done in 2018

_____

203.1b Total # of xpert MTB Rif/ultra assay test done and MTB detected in 2018

_____

203.2a Total # of Xpert MTB Rif/ultra assay test done in 2019

_____

203.2b Total # of xpert MTB Rif/ultra assay test done and MTB detected in 2019

_____

203.3a Total # of Xpert MTB Rif/ultra assay test done in 2020

_____

203.3b Total # of xpert MTB Rif/ultra assay test done and MTB detected in 2020

_____

203.4a Total # of Xpert MTB Rif/ultra assay test done in 2021

_____

203.4b Total # of xpert MTB Rif/ultra assay test done and MTB detected in 2021

_____

203.5a Total # of Xpert MTB Rif/ultra assay test done in 2022

_____

203.5b Total # of xpert MTB Rif/ultra assay test done and MTB detected in 2022

203.6a Total # of Xpert MTB Rif/ultra assay test done in 2023

203.6b Total # of xpert MTB Rif/ultra assay test done and MTB detected in 2023

Moderate Complexity

205.1a Total # of Moderate complexity automated nucleic acid amplification tests (NAATs) test done in 2018

205.1b Total # of Moderate complexity automated nucleic acid amplification tests (NAATs) (one of INH&RR) detected in 2018

205.2a Total # of Moderate complexity automated nucleic acid amplification tests (NAATs) test done in 2019

205.2b Total # of Moderate complexity automated nucleic acid amplification tests (NAATs) (one of INH&RR) detected in 2019

205.3a Total # of Moderate complexity automated nucleic acid amplification tests (NAATs) test done in 2020

205.3b Total # of Moderate complexity automated nucleic acid amplification tests (NAATs) (one of INH&RR) detected in 2020

205.4a Total # of Moderate complexity automated nucleic acid amplification tests (NAATs) test done in 2021

205.4b Total # of Moderate complexity automated nucleic acid amplification tests (NAATs) (one of INH&RR) detected in 2021

205.5a Total # of Moderate complexity automated nucleic acid amplification tests (NAATs) test done in 2022

205.5b Total # of Moderate complexity automated nucleic acid amplification tests (NAATs) (one of INH&RR) detected in 2022

205.6a Total # of Moderate complexity automated nucleic acid amplification tests (NAATs) test done in 2023

205.6b Total # of Moderate complexity automated nucleic acid amplification tests (NAATs) (one of INH&RR) detected in 2023

High Complexity

206.1a Total # of High complexity reverse hybridization NA test done in 2018

206.1b Total # of High complexity reverse hybridization NA test done in 2018 with any TB/DR-TB resistance detection

206.2a Total # of High complexity reverse hybridization NA test done in 2019

206.2b Total # of High complexity reverse hybridization NA test done in 2019 with any TB/DR-TB resistance detection

206.3a Total # of High complexity reverse hybridization NA test done in 2020

206.3b Total # of High complexity reverse hybridization NA test done in 2020 with any TB/DR-TB resistance detection

206.4a Total # of High complexity reverse hybridization NA test done in 2021

206.4b Total # of High complexity reverse hybridization NA test done in 2021 with any TB/DR-TB resistance detection

206.5a Total # of High complexity reverse hybridization NA test done in 2022

206.5b Total # of High complexity reverse hybridization NA test done in 2022 with any TB/DR-TB resistance detection

206.6a Total # of High complexity reverse hybridization NA test done in 2023

206.6b Total # of High complexity reverse hybridization NA test done in 2023 with any TB/DR-TB resistance detection

Truenat MTB

207.1a Total number of Truenat MTB/MTB plus in 2018

207.1b Total number of Truenat MTB/MTB pus test done and detected for MTB or RIF resistance in 2018

207.2a Total number of Truenat MTB/MTB plus in 2019

207.2b Total number of Truenat MTB/MTB pus test done and detected for MTB or RIF resistance in 2019

207.3a Total number of Truenat MTB/MTB plus in 2020

207.3b Total number of Truenat MTB/MTB pus test done and detected for MTB or RIF resistance in 2020

207.4a Total number of Truenat MTB/MTB plus in 2021

207.4b Total number of Truenat MTB/MTB pus test done and detected for MTB or RIF resistance in 2021

207.5a Total number of Truenat MTB/MTB plus in 2022

207.5b Total number of Truenat MTB/MTB pus test done and detected for MTB or RIF resistance in 2022

207.6a Total number of Truenat MTB/MTB plus in 2023

207.6b Total number of Truenat MTB/MTB pus test done and detected for MTB or RIF resistance in 2023

TB LAMP ASSAY

208.1a Total # of TB-LAMP ASSAY tested in 2018

208.1b Total # of TB-lamp ASSAY Tested positive in 2018

208.2a Total # of TB-LAMP ASSAY tested in 2019

208.2b Total # of TB-lamp ASSAY Tested positive in 2019

_____

208.3a Total # of TB-LAMP ASSAY tested in 2020

_____

208.3b Total # of TB-lamp ASSAY Tested positive in 2020

_____

208.4a Total # of TB-LAMP ASSAY tested in 2021

_____

208.4b Total # of TB-lamp ASSAY Tested positive in 2021

_____

208.5a Total # of TB-LAMP ASSAY tested in 2022

_____

208.5b Total # of TB-lamp ASSAY Tested positive in 2022

_____

208.6a Total # of TB-LAMP ASSAY tested in 2023

_____

208.6b Total # of TB-lamp ASSAY Tested positive in 2023

_____

LPAS

209.1a Total number LPAS(1st and second assay) test done in 2018

_____

209.1b Total number of LPAS(1ST and 2nd line assay) test detected for any resistance in 2018

_____

209.2a Total number LPAS(1st and second assay) test done in 2019

_____

209.2b Total number of LPAS(1ST and 2nd line assay) test detected for any resistance in 2019

_____

209.3a Total number LPAS(1st and second assay) test done in 2020

_____

209.3b Total number of LPAS(1ST and 2nd line assay) test detected for any resistance in 2020

_____

209.4a Total number LPAS(1st and second assay) test done in 2021

_____

209.4b Total number of LPAS(1ST and 2nd line assay) test detected for any resistance in 2021

_____

209.5a Total number LPAS(1st and second assay) test done in 2022

_____

209.5b Total number of LPAS(1ST and 2nd line assay) test detected for any resistance in 2022

_____

209.6a Total number LPAS(1st and second assay) test done in 2023

_____

209.6b Total number of LPAS(1ST and 2nd line assay) test detected for any resistance in 2023

_____

is your HF is ART site

- ◯ Yes
- ◯ NO

LF-LAM

210.1a Total # of Urine LAM assay test done in 2018

210.1b Total number of urine LAM assay test done and positive in 2018

210.2a Total # of Urine LAM assay test done in 2019

210.2b Total number of urine LAM assay test done and positive in 2019

210.3a Total # of Urine LAM assay test done in 2020

210.3b Total number of urine LAM assay test done and positive in 2020

210.4a Total # of Urine LAM assay test done in 2021

210.4b Total number of urine LAM assay test done and positive in 2021

210.5a Total # of Urine LAM assay test done in 2022

210.5b Total number of urine LAM assay test done and positive in 2022

210.6a Total # of Urine LAM assay test done in 2023

210.6b Total number of urine LAM assay test done and positive in 2023

Culture with DST

211.1a Total # of Culture with DST (solid media /liquid Media test done in 2018)

211.1b Total # of Culture with DST (solid media /liquid Media test done and positive test result in 2018)

211.2a Total # of Culture with DST (solid media /liquid Media test done in 2019)

211.2b Total # of Culture with DST (solid media /liquid Media test done and positive test result in 2019)

211.3a Total # of Culture with DST (solid media /liquid Media test done in 2020)

211.3b Total # Culture with DST (solid media /liquid Media test done and positive test result in 2020)

211.4a Total # Culture with DST (solid media /liquid Media test done in 2021)

211.4b Total # Culture with DST (solid media /liquid Media test done and positive test result in 2021)

211.5a Total # Culture with DST (solid media /liquid Media test done in 2022)

211.5b Total # Culture with DST (solid media /liquid Media test done and positive test result in 2022)

211.6a Total # Culture with DST (solid media /liquid Media test done in 2023)

211.6b Total # Culture with DST (solid media /liquid Media test done and positive test result in 2023)

Genotypic DST

212.1a Number of patients notified with bacteriologically confirmed pulmonary TB with DST results for RIF in 2018

212.1b Number of patients notified with bacteriologically confirmed pulmonary TB in 2018

212.2a Number of patients notified with bacteriologically confirmed pulmonary TB with DST results for RIF in 2019

212.2b Number of patients notified with bacteriologically confirmed pulmonary TB in 2019

212.3a Number of patients notified with bacteriologically confirmed pulmonary TB with DST results for RIF in 2020

212.3b Number of patients notified with bacteriologically confirmed pulmonary TB in 2020

212.4a Number of patients notified with bacteriologically confirmed pulmonary TB with DST results for RIF in 2021

212.4b Number of patients notified with bacteriologically confirmed pulmonary TB in 2021

212.5a Number of patients notified with bacteriologically confirmed pulmonary TB with DST results for RIF in 2022

212.5b Number of patients notified with bacteriologically confirmed pulmonary TB in 2022

212.6a Number of patients notified with bacteriologically confirmed pulmonary TB with DST results for RIF in 2023

212.6b Number of patients notified with bacteriologically confirmed pulmonary TB in 2023

213.1a Number of patients notified with bacteriologically confirmed RR pulmonary TB and DST results for FQ 218

213.1b Number of patients notified with bacteriologically confirmed RR pulmonary TB in 2018

213.2a Number of patients notified with bacteriologically confirmed RR pulmonary TB and DST results for FQ in 2019

213.2b Number of patients notified with bacteriologically confirmed RR pulmonary TBin 2019

213.3a Number of patients notified with bacteriologically confirmed RR pulmonary TB and DST results for FQ in 2020

213.3b Number of patients notified with bacteriologically confirmed RR pulmonary TB in 2020

213.4a Number of patients notified with bacteriologically confirmed RR pulmonary TB and DST results for FQ in 20 21

213.4b Number of patients notified with bacteriologically confirmed RR pulmonary TB in 2021

213.5a Number of patients notified with bacteriologically confirmed RR pulmonary TB and DST results for FQ 2022

213.5b Number of patients notified with bacteriologically confirmed RR pulmonary TB 2021

213.6a Number of patients notified with bacteriologically confirmed RR pulmonary TB and DST results for FQ 2023

213.6b Number of patients notified with bacteriologically confirmed RR pulmonary TB 2023

is your HF is TIC site

- ◯ Yes
- ◯ NO

214.1a Number of patients notified with bacteriologically confirmed RR and FQ-resistant pulmonary TB with DST results for bedaquiline in 2018

214.1b Number of notified patients with bacteriologically confirmed RR and FQ-resistant pulmonary TB in 2018

214.2a Number of patients notified with bacteriologically confirmed RR and FQ-resistant pulmonary TB with DST results for bedaquiline in 2019

214.2b Number of notified patients with bacteriologically confirmed RR and FQ-resistant pulmonary TB in 2019

214.3a Number of patients notified with bacteriologically confirmed RR and FQ-resistant pulmonary TB with DST results for bedaquiline in 2020

214.3b Number of notified patients with bacteriologically confirmed RR and FQ-resistant pulmonary TB in 2020

214.4a Number of patients notified with bacteriologically confirmed RR and FQ-resistant pulmonary TB with DST results for bedaquiline in 2021

214.4b Number of notified patients with bacteriologically confirmed RR and FQ-resistant pulmonary TB in 2021

214.5a Number of patients notified with bacteriologically confirmed RR and FQ-resistant pulmonary TB with DST results for bedaquiline in 2022

214.5b Number of notified patients with bacteriologically confirmed RR and FQ-resistant pulmonary TB in 2022

214.6a Number of patients notified with bacteriologically confirmed RR and FQ-resistant pulmonary TB with DST results for bedaquiline in 2023

214.6b Number of notified patients with bacteriologically confirmed RR and FQ-resistant pulmonary TB in 2023

215.1a Number of patients notified with bacteriologically confirmed RR and FQ-resistant pulmonary TB with DST results for linezolid in 2018

215.1b Number of notified patients with bacteriologically confirmed RR and FQ-resistant pulmonary TB in 2018

215.2a Number of patients notified with bacteriologically confirmed RR and FQ-resistant pulmonary TB with DST results for linezolid in 2019

215.2b Number of notified patients with bacteriologically confirmed RR and FQ-resistant pulmonary TB in 2019

215.3a Number of patients notified with bacteriologically confirmed RR and FQ-resistant pulmonary TB with DST results for linezolid in 2020

215.3b Number of notified patients with bacteriologically confirmed RR and FQ-resistant pulmonary TB in 2020

215.4a Number of patients notified with bacteriologically confirmed RR and FQ-resistant pulmonary TB with DST results for linezolid in 2021

215.4b Number of notified patients with bacteriologically confirmed RR and FQ-resistant pulmonary TB in 2021

215.5a Number of patients notified with bacteriologically confirmed RR and FQ-resistant pulmonary TB with DST results for linezolid in 2022

215.5b Number of notified patients with bacteriologically confirmed RR and FQ-resistant pulmonary TB in 2022

215.6a Number of patients notified with bacteriologically confirmed RR and FQ-resistant pulmonary TB with DST results for linezolid in 2023

215.6b Number of notified patients with bacteriologically confirmed RR and FQ-resistant pulmonary TB in 2023

LTBI Test

216.1a # of Interferon-gamma release assay test done in 2018

216.1b # of interferon –gamma release assay test done and test positive in 2018

216.2a # of Interferon-gamma release assay test done in 2019

216.2b # of interferon –gamma release assay test done and test positive in 2019

216.3a # of Interferon-gamma release assay test done in 2020

216.3b # of interferon –gamma release assay test done and test positive in 2020

216.4a # of Interferon-gamma release assay test done in 2021

216.4b # of interferon –gamma release assay test done and test positive in 2021

216.5a # of Interferon-gamma release assay test done in 2022

216.5b # of interferon –gamma release assay test done and test positive in 2022

216.6a # of Interferon-gamma release assay test done in 2023

216.6b # of interferon –gamma release assay test done and test positive in 2023

217.1a # of Tuberculin skin test done in 2018

217.1b # of tuberculin skin test positive in 2018

217.2a # of Tuberculin skin test done in 2019

217.2b # of tuberculin skin test positive in 2019

_____

217.3a # of Tuberculin skin test done in 2020

_____

217.3b # of tuberculin skin test positive in 2020

_____

217.4a # of Tuberculin skin test done in 2021

_____

217.4b # of tuberculin skin test positive in 2021

_____

217.5a # of Tuberculin skin test done in 2022

_____

217.5b # of tuberculin skin test positive in 2022

_____

217.6a # of Tuberculin skin test done in 2023

_____

217.6b # of tuberculin skin test positive in 2023

_____

218.1a # of CRP test done in 2018

_____

218.1b # of CRP test done and tested positive in 2018

_____

218.2a # of CRP test done in 2019

_____

218.2b # of CRP test done and tested positive in 2019

_____

218.3a # of CRP test done in 2020

_____

218.3b # of CRP test done and tested positive in 2020

_____

218.4a # of CRP test done in 2021

_____

218.4b # of CRP test done and tested positive in 2021

_____

218.5a # of CRP test done in 2022

_____

218.5b # of CRP test done and tested positive in 2022

_____

218.6a # of CRP test done in 2023

_____

218.6b # of CRP test done and tested positive in 2023

_____

Supportive TB Diagnostic

219.1a Total # of Histo-Pathological Examination test done in 2018

_____

219.1b Total # of Histo-pathological examination with suggestive of TB in 2018

_____

219.2a Total # of Histo-Pathological Examination test done in 2019

219.2b Total # of Histo-pathological examination with suggestive of TB in 2019

219.3a Total # of Histo-Pathological Examination test done in 2020

219.3b Total # of Histo-pathological examination with suggestive of TB in 2020

219.4a Total # of Histo-Pathological Examination test done in 2021

219.4b Total # of Histo-pathological examination with suggestive of TB in 2021

219.5a Total # of Histo-Pathological Examination test done in 2022

219.5b Total # of Histo-pathological examination with suggestive of TB in 2022

219.6a Total # of Histo-Pathological Examination test done in 2022

219.6b Total # of Histo-pathological examination with suggestive of TB in 2023

220.1a # of Radiological Examination CXR test done in 2018

220.1b # of Radiological Examination CXR test with abnormal CXR suggestive of TB 2018

220.2a # of Radiological Examination CXR test done in 2019

220.2b # of Radiological Examination CXR test with abnormal CXR suggestive of TB in 2019

220.3a # of Radiological Examination CXR test done in 2020

220.3b # of Radiological Examination CXR test with abnormal CXR suggestive of TB in 2020

220.4a # of Radiological Examination CXR test done in 2021

220.4b # of Radiological Examination CXR test with abnormal CXR suggestive of TB in 2021

220.5a # of Radiological Examination CXR test done in 2022

220.5b # of Radiological Examination CXR test with abnormal CXR suggestive of TB in 2022

220.6a # of Radiological Examination CXR test done in 2023

220.6b # of Radiological Examination CXR test with abnormal CXR suggestive of TB in 2023

221.1 # of examination done by Digital x-ray assisted with CAD in 2018

221.2 # of examination done by Digital x-ray assisted with CAD in 2019

221.3 # of examination done by Digital x-ray assisted with CAD in 2020

221.4 # of examination done by Digital x-ray assisted with CAD in 2021

221.5 # of examination done by Digital x-ray assisted with CAD in 2022

221.6 # of examination done by Digital x-ray assisted with CAD in 2023

Ultrasonography

222.1 # of TB examination done by Ultrasonography in 2018

222.2 # of TB examination done by Ultrasonography in 2019

222.3 # of TB examination done by Ultrasonography in 2020

222.4 # of TB examination done by Ultrasonography in 2021

222.5 # of TB examination done by Ultrasonography in 2022

222.6 # of TB examination done by Ultrasonography in 2023

IMRI

223.1 # of TB examination done by IMRI in 2018

223.2 # of TB examination done by IMRI in 2019

223.3 # of TB examination done by IMRI in 2020

223.4 # of TB examination done by IMRI in 2021

223.5 # of TB examination done by IMRI in 2022

223.6 # of TB examination done by IMRI in 2023

CT

224.1 # of TB examination done by CT in 2018

224.2 # of TB examination done by CT in 2019

224.3 # of TB examination done by CT in 2020

224.4 # of TB examination done by CT in 2021

224.5 # of TB examination done by CT in 2022

224.6 # of TB examination done by CT in 2023

ANNXURE E: Data collection Questionnaires developed in kobo collect

TB Diagnostics Questionnaire for Health Facilities, Regional, Zonal, Woreda and Referral Laboratories

Health Facility Identification

1.2.Facility identification number

_____

2.Facility Type

gov or None Gov

_____

3.Name of the facility

_____

5.Region

_____

6.Zone

_____

7.District /Woreda

_____

8.Organization Type

- ◯ Health Center
- ◯ Primary Hospital
- ◯ General Hospital
- ◯ Specialized Hospital
- ◯ Public-private mix Hospital
- ◯ Public-private Health Center/Clinic
- ◯ Regional Referral Laboratory
- ◯ National referral laboratory
- ◯ Woreda Health Office
- ◯ Zonal Health Office
- ◯ Regional Health Bureau

Location of the Facility

Fill out your locations based on the following options

- ◯ By automatically selecting your GPS
- ◯ By entering your own Latitude and Longitude

Auto GPS

latitude (x.y °)

longitude (x.y °)

altitude (m)

accuracy (m)

Longitude

Latitude

Demographic Information

9.Contact person code

10.Sex

- ◯ Male
- ◯ Female

11.Age

12.Highest qualification

- ◯ Certificate course
- ◯ Diploma
- ◯ Basic degree
- ◯ Honors degree
- ◯ Masters Degree
- ◯ PhD
- ◯ Other

13.Specify for others

Organization Information

14.How long has the organization been undertaking TB diagnosis (any method)

- ◯ 0 to 5 years
- ◯ 6 to 10 years
- ◯ 11 to 15 years
- ◯ 16 to 20 years
- ◯ above 20 years

15.What position do you hold in the organization HC /Hospital/Woreda/Zone/RHB/Regional lab?

- ◯ Laboratory technician
- ◯ Laboratory Head
- ◯ Health center/Hospital Head
- ◯ Planning officer
- ◯ Woreda TBFP
- ◯ Zonal TBFP
- ◯ Regional laboratory Head/TBFP
- ◯ National laboratory Head/TBFP
- ◯ Regional TB Coordinator

16.How long have you been employed within the Health sector (include if you are worked in other similar health facilities)

in years

17.Organization Hierarchy

- ◯ Health Facility
- ◯ Woreda/District
- ◯ Zonal Department
- ◯ Regional laboratory
- ◯ Regional Health Bureau
- ◯ National Laboratory Ministry of Health
- ◯ PPM
- ◯ PRISION
- ◯ OTHER

Involvement on an Organization

18.Are you involved in any implementation of TB diagnostic services project/ program in the organization

- ◯ Yes
- ◯ No
- ◯ Sometimes

19.Please select the type of tasks/profession in which you are involved in your organization

- ☐ OPD physician
- ☐ AFB /FM/ZN Diagnostic
- ☐ Genexpert/MTB rif
- ☐ TB/culture and sensitivities
- ☐ Imaging
- ☐ TB laboratory coordinated body
- ☐ Referral laboratory
- ☐ Woreda Health office
- ☐ Zonal Health office
- ☐ Regional Health Bureau

20.if you are working in Health facility what is your profession

- ◯ OPD clinician
- ◯ Diagnostic technician
- ◯ TB FP

21.Does the national diagnostic algorithm indicate a WRDa is the initial diagnostic test for all people with signs and symptoms of TB?

- ◯ Yes
- ◯ No
- ◯ Don't know

22.Does testing sites using data connectivity system has been established that electronically to clinicians and to an information management system?

- ◯ Yes
- ◯ No
- ◯ Don't know

23.Does national policy indicate that TB diagnostic and follow-up tests provided through the national TB programme are free of charge or that fees can be fully reimbursed through health insurance, or both, for all people with signs and symptoms of TB?

- ◯ Yes
- ◯ No
- ◯ Don't know

24.What confirmatory TB diagnostics' do you know?

- ☐ AFB
- ☐ Genexpert tastes
- ☐ Trunat
- ☐ LF/LAM/
- ☐ TB Culture
- ☐ LPA

25.Which confirmatory TB diagnostic method do you think is available in your health facility?

_____

26.Have you been informed about molecular world Health organization recommended TB diagnostics?

- ◯ Yes
- ◯ No

27.List world health organization recommended TB diagnostics diagnosis

_____

28.Does your health facility provide with TB diagnostic algorithm

- ◯ Yes
- ◯ No

29.Number of HF networked to your Health facility for TB diagnosis

_____

30.Number of health facilities sent samples to your health facility for TB diagnosis per year

- 1-10 Health facilities
- 11-20 Health facilities
- 21- and more Health facilities
- None

31.What are the available sample transportation method system/couriers you aware

- Postal Office
- Alternative sample by MOH
- Laboratory Profession
- other

32.Specify for other

_____

33.How frequent you have been visited by courier's within a week

_____

34.Which TB diagnostic method is free of charge

- AFB
- Imaging
- Genexpert
- LF-LAM
- other

35.specify other

_____

3 .Do you think your Health facility Diagnostic utilization is Adequate?

- Yes
- No

why do you think your Diagnostic utilization is not adequate or low ?

any Diagnostic xpert , AFB Xray only for available diagnostic at your cathement

- low Health seeking from patient /low patient flow
- low TB case load at the catchment
- low TB screening at Health facility and low presumptive identification
- inadequate supply of reagents cartridge
- inadequate health professional
- frequent equipment interruption
- other

other

_____

Diagonostic M&E

36.Does the organization have a formal M&E Plan on TB diagnostic service?

- Yes
- No
- Don't know

37.Why?

_____

38.Does the Laboratory M & E plan describe how project objectives will be achieved?

- Yes
- No

39.Does the monitoring and evaluation plan explain procedure in which the TB diagnostics data will be collected and analyzed for project evaluation?

- Yes
- No

40.How many Diagnostic indicators is used by your organization?

_____

41.Which of the following Diagnostic indicators is used by your organization for decision making
Check performance for each selected

- [ ] WRD as the initial diagnostic test(coverage)
- [ ] Percentage of notified new and relapse TB cases with bacteriological confirmed
- [ ] number of data connectivity system has been established
- [ ] number of Hf TB diagnostic and follow-up tests provided through the national TB programme are free of charge or that fees can be fully reimbursed through health insurance
- [ ] percentage of notified, bacteriologically confirmed TB cases with DST results for rifampicin
- [ ] Percentage of notified, rifampicin-resistant TB cases with DST results for fluoroquinolones
- [ ] Percentage of notified, rifampicin-resistant TB cases with DST results for Bedquline
- [ ] Percentage of diagnostic testing sites that monitor performance indicators and are enrolled in an EQA system for all diagnostic methods performed
- [ ] Percentage of DST sites that have demonstrated proficiency by EQA panel testing for all DST methods performed
- [ ] Percentage Hf quality management system is being implemented of laboratory accreditation
- [ ] AFB test utilization /xpert/urine lam/culture
- [ ] Imaging(cxr, ultrasound, MRI,CT) Utilization
- [ ] Histopathology Utilization

42.Does the organization Review TB diagnostic and staff performance periodically?

- ◯ Yes
- ◯ No
- ◯ Sometimes

43.Does the organization implement corrective actions in situations where targets have not been met?

- ◯ Yes
- ◯ No

44.Does the TB diagnostics system addressed in Monitoring and Evaluation system

- ◯ Yes
- ◯ No
- ◯ Sometimes

45.Is there Performance management in the organization

- ◯ Yes
- ◯ No

46.Is TB diagnostics indicator included in PMT

- ◯ Yes
- ◯ No

47.How often does TB Diagnostic Performance management meeting take Place?
per year

_____

48.Does the organization compare the TB diagnostic target against performance output?

- ◯ Yes
- ◯ No

49.Does The organization evaluate TB diagnostic periodically

- ◯ Yes
- ◯ No
- ◯ Sometimes

50.Does the organization monitor staff performance on TB diagnostic

- ◯ Yes
- ◯ No
- ◯ Sometimes

51.How would you rate the organizations on TB diagnostics performance management system?

- ◯ Outstanding
- ◯ Good
- ◯ Adequate
- ◯ Needs Improvment
- ◯ Poor
- ◯ Not known

Data Quality Managment

52.What data management tool does the organization employ for TB diagnostic data collection, verification and documentation

- [ ] Electronic spread sheet
- [ ] Hard copy form (Paper form)
- [ ] Electronic verification of data
- [ ] Human verification
- [ ] None of them

53.How often does the TB diagnostic staff conduct data review meeting?

- ◯ Monthly
- ◯ Quarterly
- ◯ Bi-Annually
- ◯ Annually
- ◯ Not at all

54.Which TB indicators are addressed in supportive TB Diagnostic monitoring and evaluation

- [ ] X-ray test utilization
- [ ] Ultrasound test utilization
- [ ] Histopathology test utilization
- [ ] MRI/CT test utilization
- [ ] None

55.Which supportive diagnostic indicators are monitor?

- [ ] Proportion of health facilities using Diagital x-ray as intial screening of TB
- [ ] Utilization of Imaging
- [ ] Proportion of Hf pathological examination
- [ ] other

56.specify other

_____

57.Are test TB diagnostic request forms standardized for all kind of TB diagnostics testing and being used in your HF ?

- ◯ Yes
- ◯ No

58.Is TB quality control of data entry performed?

- ◯ Yes
- ◯ No

59.Are the data on the request forms collected by the laboratory required fields completed; or are all TB lab tests being ordered according to the national algorithm?

- ◯ Yes
- ◯ No

60.Are standardized forms used for collecting and reporting data on the performance of the diagnostic network (e.g., test statistics or key performance indicators

- ◯ Yes
- ◯ No

61.Are reporting forms for all TB tests standardized and according to best practice, and include information on interpretation of results

- ◯ Yes
- ◯ No

62.Is there an electronic system (e.g., LIMS) that enables reporting of laboratory test data (e.g., test statistics or key performance indicators) to local and national programs Do local and national programs give feedback to reporting laboratories?

- ◯ Yes
- ◯ No

63.Do local and national programs analyze and use data routinely for decision-making and program improvement, including network management and equipment maintenance, supply chain, quality assurance?

- ◯ Yes
- ◯ No

64.Have data connectivity solutions been implemented in the TB diagnostic in your organization

- ◯ Yes
- ◯ No

65.Is there a fully functional laboratory data unit with adequate numbers of trained personnel, hardware and software that receives laboratory data if your organization to, analyzes the data and generates reports?

- ◯ Yes
- ◯ No

66.Does higher levels collects and analyzes TB laboratory data at your organization ?

- ◯ Yes
- ◯ No

67.Are TB diagnostic data reported, analyzed, used for decision making purposes and shared within to higher and other government agencies in your organization?

- ◯ Yes
- ◯ No

68.Are laboratory-based surveillance procedures in place and implemented for TB and DR-TB? Are TB and DR-TB surveillance data reported to the epidemiology unit and used as per procedure?

- ◯ Yes
- ◯ No

69.Is the implementation of TB diagnostic monitoring and evaluation activities are time consuming?

- ◯ Yes
- ◯ No

70.Does monitoring and evaluation important to the TB diagnostic activity in the organization?

- ◯ Yes
- ◯ No

ANNXURE F: Delphi questionnaires

Delphi round 1 questionnaires

Delphi Questionnaire: Strengthening TB Diagnostic Systems in Resource-Limited Settings

Your consent

ARE YOU WILLING TO PARTICIPATE IN OUR STUDY'S DELPHI CONTRIBUTION?

- ◯ 1.yes
- ◯ 2.No

Section 1: Diagnostic Barriers and Gaps

1. IN YOUR OPINION, WHAT ARE THE HIGHEST-PRIORITY BARRIERS TO ACCESSING CONFIRMATORY TB DIAGNOSTICS (CONVENTIONAL, MOLECULAR, AND DRUG SUSCEPTIBILITY TESTING) AND SUPPORTIVE DIAGNOSTICS (E.G., IMAGING, HISTOPATHOLOGY, ULTRASONOGRAPHY)?

2. WHY DO HEALTHCARE WORKERS UNDER-UTILIZE AVAILABLE DIAGNOSTIC TOOLS (BOTH CONFIRMATORY AND SUPPORTIVE) DESPITE THEIR AVAILABILITY? - PLEASE IDENTIFY 3–5 KEY FACTORS (BEHAVIOURAL, TRAINING-RELATED, SYSTEMIC, OR LOGISTICAL).

3. WHAT CRITICAL GAPS EXIST IN DST (DRUG SUSCEPTIBILITY TESTING) COVERAGE WITHIN YOUR LOCAL OR NATIONAL CONTEXT?

Section 2: Monitoring, Evaluation, and System Improvement

4. WHAT ARE THE MOST SIGNIFICANT WEAKNESSES IN THE CURRENT MONITORING AND EVALUATION (M&E) PRACTICES FOR TB DIAGNOSTICS? - DESCRIBE BARRIERS RELATED TO DATA COLLECTION, ANALYSIS, OR USE FOR DECISION-MAKING.

5. PLEASE SUGGEST 3 LOW-COST, HIGH-IMPACT INTERVENTIONS THAT COULD RAPIDLY IMPROVE TB DIAGNOSTIC ACCESS OR UTILIZATION. - CONSIDER FEASIBILITY IN RESOURCE-CONSTRAINED ENVIRONMENTS.

6. WHAT TYPES OF COMMUNITY INCENTIVES—FINANCIAL, SOCIAL, OR OPERATIONAL—WOULD MOST EFFECTIVELY INCREASE DEMAND FOR TB DIAGNOSTIC TESTING? - PLEASE SHARE ANY EXAMPLES OF INTERVENTIONS THAT HAVE WORKED IN YOUR SETTING.

7. LIST 5–7 CORE INDICATORS TO TRACK TB DIAGNOSTIC SYSTEM PERFORMANCE AT THE FACILITY OR DISTRICT LEVEL. - FOCUS ON ACTIONABLE METRICS RELATED TO ACCESS, QUALITY, OR UTILIZATION.

Section 3: Innovation, Integration, and Equity

8. WHAT ROLE DO DIGITAL HEALTH TOOLS (E.G., AI, EMRS, TELEMEDICINE) CURRENTLY PLAY—OR COULD PLAY—IN IMPROVING TB DIAGNOSTICS IN YOUR SETTING?

9. WHAT EMERGING DIAGNOSTIC TECHNOLOGIES OR MODELS SHOULD BE PRIORITIZED FOR TESTING OR SCALE-UP IN RESOURCE-LIMITED SETTINGS—AND WHY?

10. HOW WELL ARE TB DIAGNOSTIC SERVICES INTEGRATED INTO BROADER HEALTH PLATFORMS (E.G., MATERNAL CARE, HIV SERVICES, PRIMARY HEALTHCARE)?

11. WHICH POPULATION GROUPS ARE MOST UNDERDIAGNOSED OR EXCLUDED FROM TB DIAGNOSTIC SERVICES? - WHAT TARGETED ACTIONS COULD ADDRESS THIS INEQUITY?

Section 4: Human Resources and Systems Strengthening

12. WHAT TRAINING APPROACHES (E.G., MENTORSHIP, SIMULATION, E-LEARNING) ARE MOST EFFECTIVE IN IMPROVING PROVIDER COMPETENCY IN TB DIAGNOSTICS?

13. WHAT MOTIVATIONAL OR PERFORMANCE-BASED APPROACHES COULD ENHANCE PROVIDER USE OF EXISTING TOOLS?

14. ARE THERE REGULATORY, PROCUREMENT, OR QUALITY ASSURANCE ISSUES THAT CONSTRAIN DIAGNOSTIC CAPACITY OR TIMELY ACCESS?

15. WHAT LESSONS FROM HEALTH EMERGENCIES (E.G., COVID-19) CAN INFORM MORE RESILIENT AND ADAPTIVE DIAGNOSTIC SYSTEMS?

Delphi Round 2 questionnaire

ROUND 2 DELPHI QUESTIONNAIRE: TB DIAGNOSTIC STRATEGY PRIORITIZATION

I. ACCESS IMPROVEMENT ((Objective: Expand geographic/equipment coverage)

	1 very low	2 low	3 medium	4 high	5 very high
A1. Establish at least one TB molecular testing lab per district (woreda					
Feasibility(cost ,simplicity and local adaptability	◯	◯	◯	◯	◯
impact potential to improve TB case detection	◯	◯	◯	◯	◯
A2. Establish at least one TB molecular testing lab per 30,000 population and within 10 km radius (hence woreda population and land mass coverage are different	1	2	3	4	5
Feasibility (cost ,simplicity and local adaptability	◯	◯	◯	◯	◯
impact (potential to improve TB case detection	◯	◯	◯	◯	◯
A3. Establish at least one (x-ray and ultrasound center) district level considering population and travel distance at including primary (hospital as well health center level)	1	2	3	4	5
Feasibility	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯
A4. Establish histopathology and biopsy preparation centers at least at Hospital level	1	2	3	4	5
Feasiblity	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯
A5. Establish CT and MRI centers at least at zonal level	1	2	3	4	5
Feasibility	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯
A6 .Avail latent TB testing at all TB treatment centers	1	2	3	4	5
Feasibility	◯	◯	◯	◯	◯
impact	◯	◯	◯	◯	◯
A7 Engage private sector for specimen transport (e.g., motorbike networks)	1	2	3	4	5

feasiblity	◯	◯	◯	◯	◯
impact	◯	◯	◯	◯	◯
A8. Deploy mobile testing units to remote areas	1	2	3	4	5
feasibility	◯	◯	◯	◯	◯
impact	◯	◯	◯	◯	◯
A9. Establish health facility networking to cascade patient referral for chest x-ray , and other supportive TB diagnostics	1	2	3	4	5
feasibility	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯

A10,Any additional objectives or comments for TB access improvements

_____

II UTILIZATION ENHANCEMENT (Objective: Optimize use of existing tools)

U1. Mandatory HCW training on test eligibility/algorithms	1	2	3	4	5
Feasibility	◯	◯	◯	◯	◯
impact	◯	◯	◯	◯	◯
U2. Solar power and other backups for labs to reduce downtime	1	2	3	4	5
feasibility	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯
U3. 24/7TB testing services at high-burden sites	1	2	3	4	5
Feasibility	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯
U4. Design and implement quality improvement project for low performed TB screening at health facilities and communities.	1	2	3	4	5
feasibility	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯
U5.Establish coordinating bodies to oversee the placement, implementation, and utilization of supportive diagnostic technologies(imaging ,ultrasonography and histopathology etc) ,	1	2	3	4	5

feasibility	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯
U6. Decentralize Equipment maintenance through capacity building to reduce equipment down time	1	2	3	4	5
Feasibility	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯

U7. any additional objectives for utilization enhancement and any comments

_____

III. DST COVERAGE EXPANSION (Objective: Scale up drug-susceptibility testing)

D1. Buffer stocks of critical reagents	1	2	3	4	5
feasibility	◯	◯	◯	◯	◯
impact	◯	◯	◯	◯	◯
D2. Decentralize DST Services (including all phenotypic DST) to mid-level lab and lower level health facilities	1	2	3	4	5
feasibility	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯
D3. Enhance Clinical Awareness & Protocols to health facility clinicians (mandate universal DST, train providers to systematically request TB DST	1	2	3	4	5
feasibility	◯	◯	◯	◯	◯
impact	◯	◯	◯	◯	◯
D4. Leverage Data-Driven Approaches (use electronic TB register to flag patient needing DST, Dashboards tracking DST coverage gaps)	1	2	3	4	5
feasiblity	◯	◯	◯	◯	◯
impact	◯	◯	◯	◯	◯
D5. Advocate for national TB budget line for DST	1	2	3	4	5
feasibility	◯	◯	◯	◯	◯
impact	◯	◯	◯	◯	◯
D6. Use AI-assisted X-rays to prioritize DST candidates	1	2	3	4	5
feasibility	◯	◯	◯	◯	◯

impact	◯	◯	◯	◯	◯

D7 any additional objectives to scale up DST testing and utilization

_____

IIV. M&E SYSTEM STRENGTHENING (Objective: Enable data-driven decisions)

M1 Develop an integrated TB diagnostic framework that includes structures for confirmatory and supportive diagnostics monitoring, and evaluation, and implement a well-organized diagnostic reporting system covering both confirmatory and supportive diagnostics	1	2	3	4	5
feasibility	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯
M2 Avail comprehensive tool to track key Dx (confirmatory and supportive diagnostics) performances.	1	2	3	4	5
feasibility	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯
M3. Unified digital dashboard (other MOH/EPHI-led, DHIS2-integrated)	1	2	3	4	5
Feasibility	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯
M4. Monthly and Quarterly facility-level Diagnostic test data audits (analysis and visualization)	1	2	3	4	5
Feasibility	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯
M5. Automated SMS/telegram (both confirmatory and supportive diagnostic alerts for overdue results	1	2	3	4	5
Feasiblity	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯

M6 any additional objectives TB M&E system strengthening

_____

V. DEMAND GENERATION (Objective: Increase patient uptake and test utilization)

DG1. Training/ awareness for OPD physicians	1	2	3	4	5

feasibility	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯
DG2. Transport vouchers for patients during supportive diagnostics referral.	1	2	3	4	5
feasibility	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯
DG3. HEP-led sputum collection at household level	1	2	3	4	5
feasibility	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯
DG4. "TB Ambassador/champions " community mobilization that the patient seek care for TB freely	1	2	3	4	5
feasibility	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯

DG5. any additional comments on demand generation to increase patient uptake and test utilization

_____

VI. POLICY ACTIONS (Objective: Create enabling environment)

P1. Establish Diagnostics coordinating body at MOH level and cascading to regional ,zonal and woreda level	1	2	3	4	5
feasibility	◯	◯	◯	◯	◯
impact	◯	◯	◯	◯	◯
P2. National policy for point-of-care testing	1	2	3	4	5
feasibility	◯	◯	◯	◯	◯
impact	◯	◯	◯	◯	◯
P3. Accreditation private labs for maintenance/services	1	2	3	4	5
feasibility	◯	◯	◯	◯	◯
impact	◯	◯	◯	◯	◯
P4 National Policy for local availability of expertise on the technical management of the diagnostics technology	1	2	3	4	5
feasibility	◯	◯	◯	◯	◯
Impact	◯	◯	◯	◯	◯

P5 .Any comments and additional objective to create enabling environment for TB diagnostics accesses utilization and information use decision making

_____

VII FINAL QUESTIONS STRATEGY OBJECTIVE PRIORITIZATION

1. Which 3 options across all categories deserve urgent piloting? Why?

_____

2. What critical gaps remain unaddressed in this prioritization?

_____

3. would you Suggest to refine top-scoring options for local context?

_____

Delphi Round 3 Questionnaires

Delphi Round 3 strategy validation

SO 1. Access to Advanced Diagnostic Infrastructure for TB Control in Oromia

1.1 Implement one WHO-endorsed molecular diagnostic center in each district (serving approximately 60,000 individuals within a 10 km radius) to facilitate prompt and confirmatory tuberculosis testing.

- ◯ yes
- ◯ No

1.2. Create strong referral networks linking all health facilities within a district to the central molecular hub.

- ◯ yes
- ◯ No

1.3 Equip each district with at least one digital X-ray unit and one ultrasound machine.

- ◯ Yes
- ◯ No

1.4 Establish Facility Networking for Imaging Access: Develop clear referral pathways within districts for patients requiring chest X-ray or other supportive diagnostics not available at their initial point of contact

- ◯ Yes
- ◯ No

1.5 Establish biopsy preparation and histopathology reading capabilities at all hospitals, including primary hospitals

- ◯ yes
- ◯ No

1.6 Establish CT and MRI services within General/Specialty Hospitals at the zonal level (serving ~1 million people within a 100 km radius.

- ◯ yes
- ◯ No

1.7 Implement a structured, public-private partnership (PPP) model for reliable sample transportation and patient referral logistics

- ◯ yes
- ◯ No

1.8 Deploy mobile units equipped with rapid molecular diagnostics and portable, AI-assisted digital X-ray systems to reach remote and underserved populations.

- ◯ yes
- ◯ no

SO 2. Maximize Utilization of Existing TB Diagnostic Capacity (Confirmatory & Supportive)

2.1 Train and certify all relevant healthcare workers on current national TB diagnostic algorithms, eligibility criteria, and result interpretation.

- ◯ Yes
- ◯ No

2.2 Avail reliable power solutions (solar + battery backup, generators) specifically for diagnostic equipment at all levels.

- ◯ Yes
- ◯ No

2.3 Implement 24/7 or extended-hour testing services specifically for TB diagnostics at strategically identified high-burden facilities/labs

- ◯ Yes
- ◯ No

2.4 Design and implement facility/community-specific QI projects to identify and address root causes of low TB screening rates

- ◯ Yes
- ◯ No

2.5 Establish dedicated coordination bodies (at Ministry of health, Regional and district/zonal level) with clear mandates to monitor placement, functionality, and utilization rates of confirmatory and supportive diagnostics and ensure optimal integration into diagnostic pathways.

- ◯ Yes
- ◯ No

2.6 Build local technical capacity through training and equipping regional/zonal biomedical engineers and technicians to perform routine maintenance and basic repairs on key diagnostic equipment (GeneXpert, microscopes, X-ray, ultrasound).

- ◯ Yes
- ◯ No

SO 3. DST COVERAGE EXPANSION

3.1. Implement multi-tiered buffer stock systems (national/regional), establish vendor-managed inventory agreements for key items, utilize forecasting tools based on testing volumes and pipeline visibility

- ◯ Yes
- ◯ No

3.2 Decentralize DST Services (including core phenotypic DST)

- ◯ Yes
- ◯ No

3.3 prepare DST results guide treatment decisions and Integrate DST request prompts into electronic medical records (EMR) or standardized paper forms, develop simplified job aids/flowcharts for clinicians, incorporate DST modules into routine clinical mentorship and continuous professional development programs.

- ◯ Yes
- ◯ No

3.4 Avail electronic TB registers (ETR) or surveillance systems are interoperable with lab information systems (LIS) for automated flagging, design user-friendly dashboards accessible to district/provincial managers, train data managers and program staff on interpreting and acting upon DST coverage gap data

- ◯ Yes
- ◯ No

3.5 Develop and compelling investment cases demonstrating DST's cost-effectiveness (e.g., averting costly DR-TB treatment), utilize domestic resource mobilization strategies, advocate for inclusion in national health insurance schemes, present phased costing plans to Ministries of Health and Finance.

- ◯ Yes
- ◯ No

3.6 Avail adequate digital infrastructure (connectivity, X-ray digitization) at screening points, train radiographers/technicians on AI tool use and interpretation within the DST workflow, establish clear referral pathways from AI triage

- ◯ Yes
- ◯ No

SO 4. DIAGNOSTIC M&E SYSTEM STRENGTHENING

4.1 Develop and implement a unified framework defining structures, indicators, and processes for monitoring and evaluating both confirmatory (e.g., molecular, culture) and supportive (e.g., X-ray, CT MRI Histopathology) TB diagnostics. Implement a standardized, well-organized diagnostic reporting system across all levels

- ◯ Yes
- ◯ No

4.2 Make available a user-friendly tool (digital preferred) specifically designed to track, analyse, and visualize key performance indicators (KPIs) for all TB diagnostics (confirmatory & supportive) at facility, sub-national, and national levels

- ◯ Yes
- ◯ No

4.3 Design the tool with tiered complexity (simple dashboards for clinics, advanced analytics for national level) and ensure integration with the national health information system (e.g., DHIS2).

- ◯ Yes
- ◯ No

4.4 Develop and operationalize a Ministry of Health/EPHI-led digital dashboard, integrated with DHIS2, providing real-time visualization of key TB diagnostic metrics for all levels

- ◯ Yes
- ◯ No

4.5 Conduct monthly and quarterly facility-level audits of diagnostic test data (volume, turn-around-time, positivity rates, concordance) involving analysis and visualization to identify errors and improvement opportunities.

- ◯ Yes
- ◯ No

4.6 Avail automated SMS/Telegram alerts for clinicians and coordinators for overdue confirmatory and supportive diagnostic results requiring urgent action.

- ◯ Yes
- ◯ No

SO 5. Diagnostics Policy and Expertise

5.1 Establishing dedicated bodies at all administrative levels from ministry of health to the woreda level to oversee planning, resource allocation, and problem-solving across the diagnostic network

- ◯ Yes
- ◯ No

5.2 Avail a national policy to promote rapid Point-of-Care Testing (POCT) closer to patients, reducing delays and loss to follow-up.

- ◯ Yes
- ◯ No

5.3 Endorse private laboratories to supplement public services, increasing overall testing capacity and geographic coverage while ensuring quality standards are met.

- ◯ Yes
- ◯ No

5.4 Mandate the development of national and regional, and zonal technical expertise to maintain and repair TB diagnostic equipment

- ◯ Yes
- ◯ No

Annexure G:- Turnitin report

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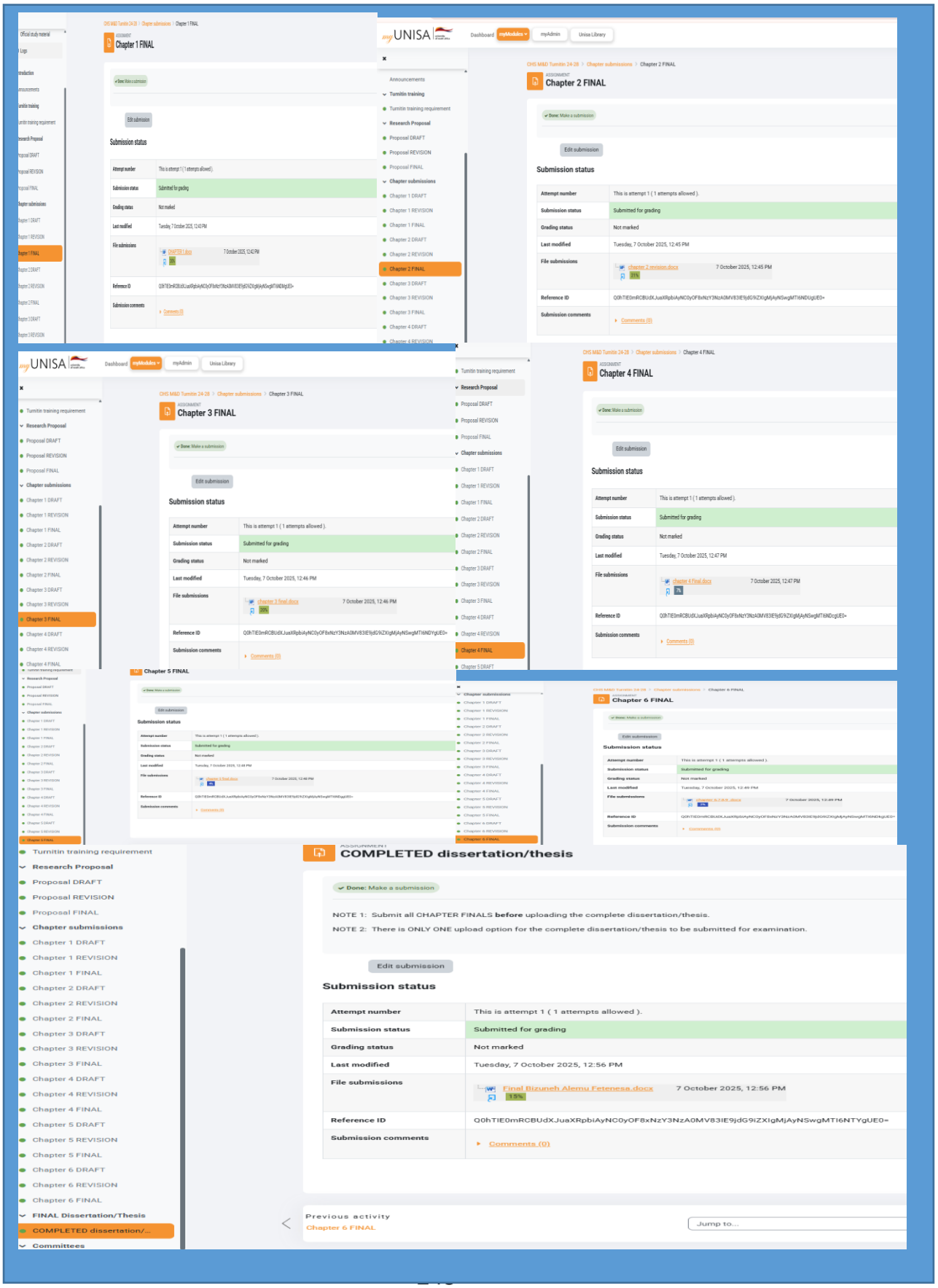
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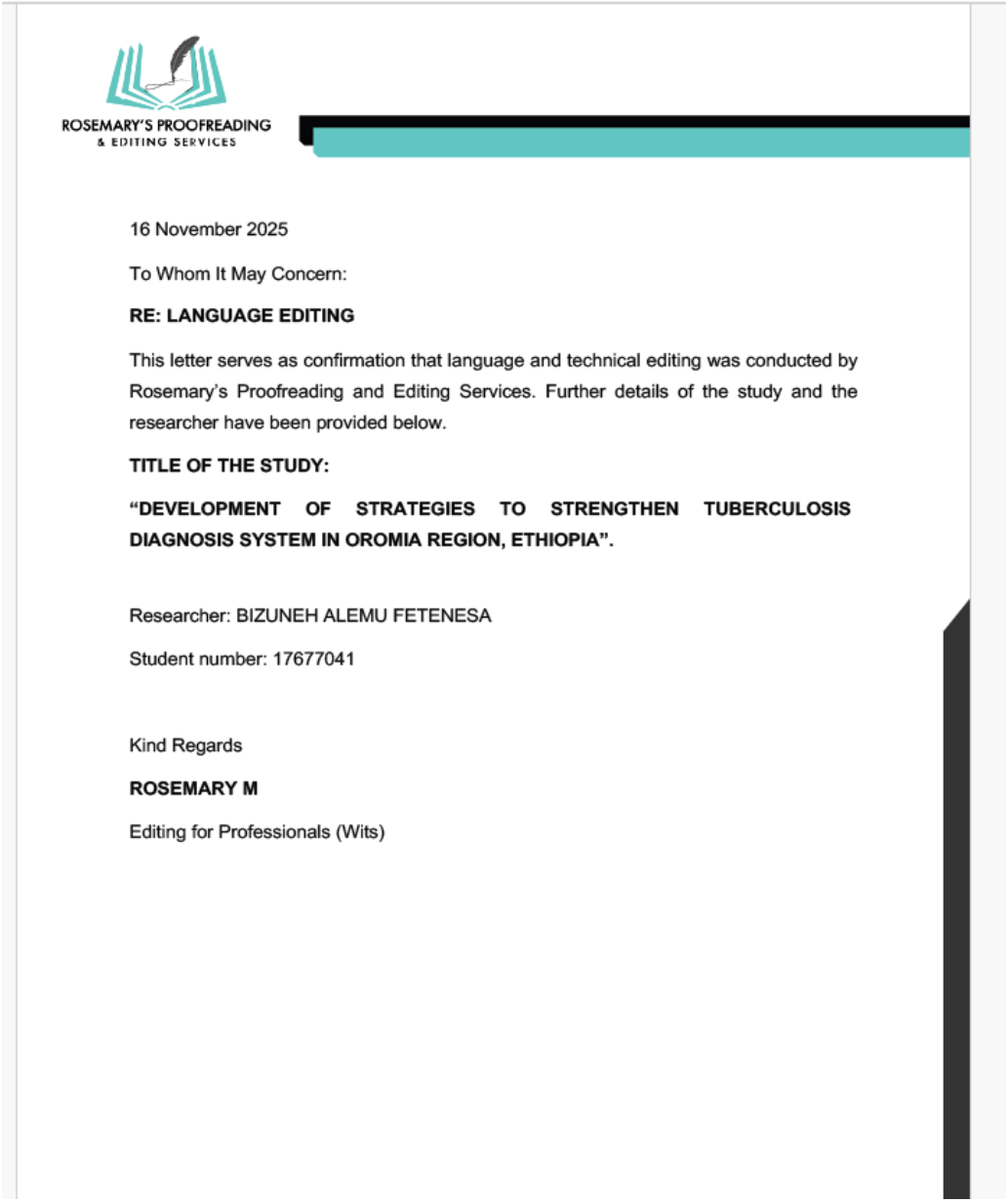

ROSEMARY'S PROOFREADING
& EDITING SERVICES

16 November 2025

To Whom It May Concern:

RE: LANGUAGE EDITING

This letter serves as confirmation that language and technical editing was conducted by Rosemary's Proofreading and Editing Services. Further details of the study and the researcher have been provided below.

TITLE OF THE STUDY:

"DEVELOPMENT OF STRATEGIES TO STRENGTHEN TUBERCULOSIS DIAGNOSIS SYSTEM IN OROMIA REGION, ETHIOPIA".

Researcher: BIZUNEH ALEMU FETENESA

Student number: 17677041

Kind Regards

ROSEMARY M

Editing for Professionals (Wits)