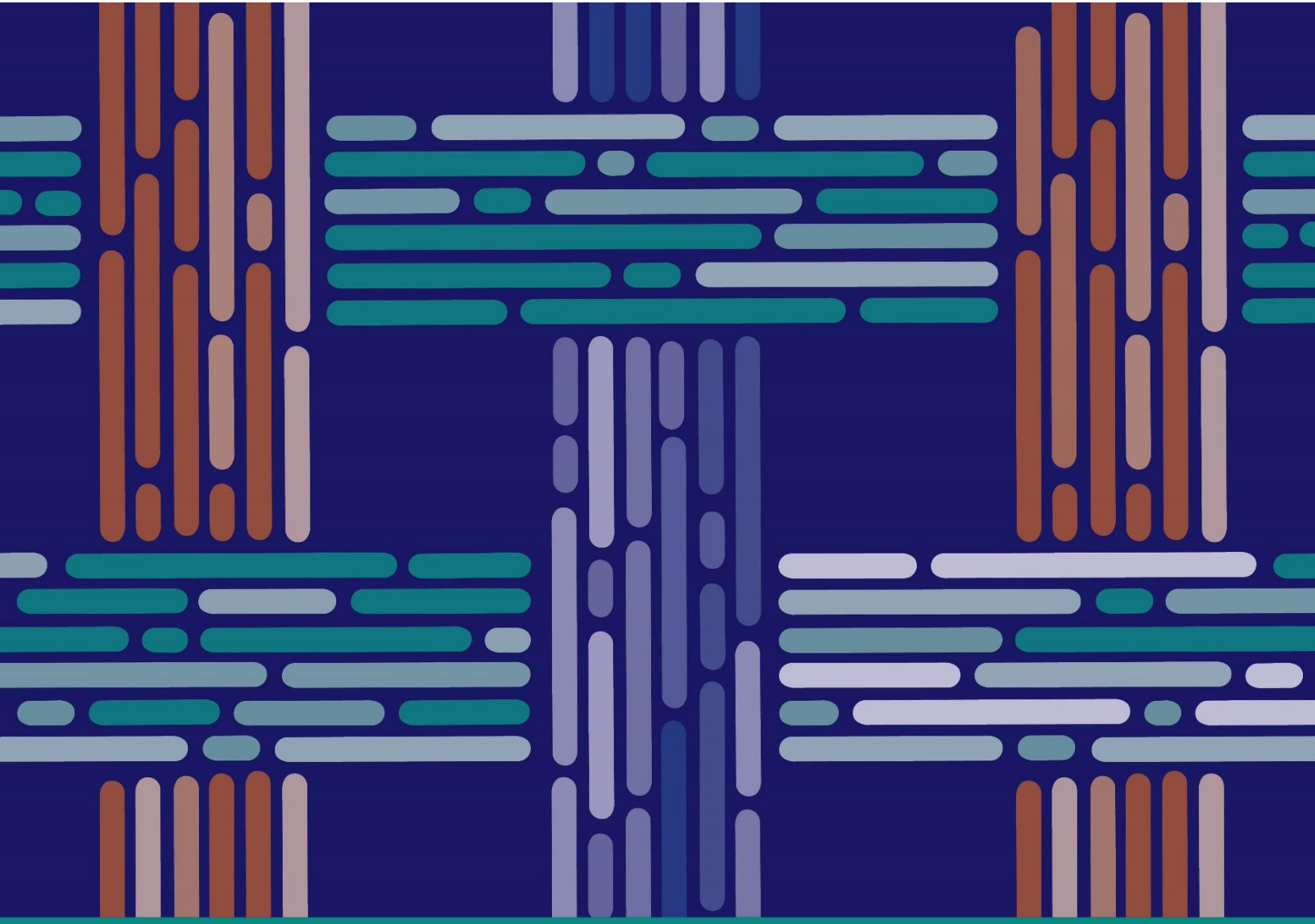

Quality of Tuberculosis Services Assessment

Global Implementation Guide

July 2021

USAID
FROM THE AMERICAN PEOPLE

MEASURE Evaluation

TB DIAH
Tuberculosis Data, Impact Assessment and Communications Hub

Quality of Tuberculosis Services Assessment

Global Implementation Guide

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MEASURE Evaluation

TB DIAH
Tuberculosis Data, Impact Assessment and Communications Hub

In Memoriam

Suzanne Cloutier, 1957–2021

This Guide is dedicated to Suzanne Cloutier, who was instrumental in the conceptualization and development of the Quality of Tuberculosis Services Assessment (QTSA) method and was involved in implementing the survey in Nigeria, the Philippines, Uganda, Ethiopia, and Afghanistan. Suzanne leveraged her expertise in TB surveillance, survey design, and information technology to streamline data collection and analysis, which resulted in efficiencies in survey processes and enhanced data quality. She is remembered fondly for her dedication to improving TB information systems and services, commitment to public health, the diligence with which she did her work, and enthusiasm for life.

Acknowledgments

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We would like to acknowledge the USAID/Washington TB Team for its support and leadership in advancing the state of the art in measuring TB quality of care. Particular thanks go to our advisors, Charlotte Colvin and Kenneth Castro, at USAID/Washington.

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Contents

Figures

Tables

Abbreviations

DR-TB	drug-resistant tuberculosis
DS-TB	drug-susceptible tuberculosis
HMIS	health management information system
IOM	Institute of Medicine
IRB	institutional review board
ISTC	International Standards for Tuberculosis Care
LRO	local research organization
MDR-TB	multidrug-resistant tuberculosis
MFL	master facility list
MOH	Ministry of Health
MTB	*Mycobacterium tuberculosis*
NTP	national tuberculosis program
PCA	person-centered approach
QTSA	Quality of Tuberculosis Services Assessment
RIF	resistance to rifampicin
TB	tuberculosis
TB DIAH	TB Data, Impact Assessment and Communications Hub
USAID	United States Agency for International Development
WHO	World Health Organization

Introduction

The Quality of Tuberculosis Services Assessment (QTSA) Global Toolkit consists of this Implementation Guide and the QTSA Global Tools. These materials are designed to be adapted to a specific country context for use by national tuberculosis programs (NTPs), donors, and other key stakeholders to assess the quality of tuberculosis (TB) diagnosis, treatment, and care services. The QTSA is a health facility assessment. It employs several data collection methods, including facility audits, extraction of TB data from facility-based registers and records, interviews with TB service providers and interviews with TB patients. The findings can assist policy makers, program managers, and service providers to develop action plans to improve and strengthen the quality of TB services.

The QTSA Implementation Guide is organized into four modules.

The tools and information about QTSAs conducted in different countries are available at https://www.tbdiah.org/assessments/quality-of-tuberculosis-services-assessments/

Module 1. Rationale, Framework, and Overview of the QTSA

Module 1 describes the rationale for assessing the quality of TB services and provides a framework for conducting the assessment, including the core components that are examined and an illustrative list of indicators generated by the assessment.

Background

Despite significant progress toward eliminating TB as a global public health challenge, it remains the leading cause of morbidity and mortality from a single infectious agent (ranking above HIV/AIDS). In 2019, about 10 million people developed TB and 1.4 million died globally (World Health Organization [WHO], 2020). Although *Mycobacterium tuberculosis* (MTB) can infect anyone anywhere, TB is a disease of poverty, predominantly afflicting the world's poor. Thirty high-burden TB countries account for almost 90 percent of those who fall sick with TB each year (WHO, 2020).

TB is curable and preventable. About 85 percent of people who develop TB disease can be successfully treated with a six-month drug regimen; treatment has the additional benefit of curtailing onward transmission of infection. Since 2000, TB treatment has averted more than 60 million deaths, although access still falls short of universal health coverage (WHO, 2020).

The Global Stop TB Partnership estimates that 3.6 million individuals are "missed" each year by health systems and do not get the TB care they need and deserve (Centers for Disease Control and Prevention, n.d.). More than 75 percent of missed cases are concentrated in just 13 countries (Centers for Disease Control and Prevention, n.d.). Moreover, the emergence and rapid spread of multidrug resistant tuberculosis (MDR-TB) is threatening the reversal of two decades of progress in mitigating the impact of TB.

Early and accurate detection and appropriate treatment of patients are pivotal strategies employed by NTPs in most high-burden TB countries. In addition to expanding access, TB programs are increasing their efforts to improve the quality of diagnosis, care, and treatment services, recognizing the importance of quality of care in ameliorating case detection and treatment success rates. Improving the basic standard of TB care aims to ensure that patients receive the care they deserve, and by doing so, encourage more patients to seek services in a timely manner. Hence, improving screening, diagnosis, and treatment services ultimately contributes to reducing the burden of TB disease.

The International Standards for Tuberculosis Care (ISTC) describe a broadly accepted level of care that all healthcare providers—public and private—should strive to adhere to when treating and managing patients who have, are suspected of having, or are at an increased risk of developing TB (TB CARE I, 2014). These standards are intended to promote the engagement of all providers in delivering high-quality care to patients of all ages, and to empower patients to evaluate the quality of care they receive from healthcare providers. The standards offer a reference point to assess healthcare provider or system performance and quality of care, and they help identify current and expected levels of quality in healthcare delivery. Failure of providers or systems to adhere to the defined standards of diagnosis, care, and treatment of TB compromises the quality of services provided to the patients.

The ISTC exist to guide service providers to offer quality TB services that are aligned with global standards of care. However, there is a dearth of guidelines or tools that NTPs and other stakeholders can use—either routinely or periodically—to assess and monitor the quality of TB services at a programmatic level. The QTSA was designed to fill this information gap. It offers stakeholders a facility-based measurement approach and standardized tools that can be used to generate a set of indicators to assess and monitor the quality of TB services.

Importance of Quality of Care

There is mounting evidence that improved access to healthcare alone is insufficient to impact health outcomes in a positive way and that the quality of care provided by the health system is an important link to achieve better patient health outcomes. An article by Kruk, et al. for the Lancet Global Health Commission on High Quality Health Systems in the Sustainable Development Goals Era estimated that 60 percent of deaths from conditions amenable to healthcare are due to poor-quality care, whereas the remaining 40 percent resulted from the non-use of the health system (Kruk, et al., 2018). Such data demonstrate that what happens after patients have accessed the health system, and whether they are provided the services they need in a competent and caring manner, are equally important, if not more important than access to the services (Kruk, et al., 2018); Arsenault, et al, 2019) .

Such findings have led the global TB community to promote a person-centered approach (PCA) to TB care as a way to ensure high-quality diagnosis and treatment services (WHO, 2019). The National Academy of Medicine defines PCA as "providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions" (Institute of Medicine [IOM], 2001). Pillar One of the End TB Strategy, which puts "patients at the heart of service delivery," explicitly endorses a PCA, which recognizes that the direct beneficiary of TB care is the individual who is sick, and that strategies must be designed with this individual's rights and welfare in mind (WHO, n.d.). The objective of a PCA is therefore to provide high-quality TB diagnosis, treatment, and care to all patients without their having to incur catastrophic costs.

Measuring the quality of care is critical for advancing a PCA to care for three main reasons. First, improved quality of care is of utmost importance to patients, who are the first to benefit from better quality services. High-quality healthcare may also encourage patients to continue and complete treatment for their current condition, and to seek care for future health challenges. Second, measuring and assessing quality of care demonstrate to healthcare providers that quality is an important component of the program, and thus sets the bar for improving staff performance. Third, when an intervention to improve quality of care is complemented with the routine measurement of quality, the multiple data points generated can help determine the effectiveness of the intervention and inform future program strategies.

The QTSA is a facility-based survey, like the Service Provision Assessment,[1] but is specifically designed to assess the quality of TB services. The QTSA consists of a set of standardized tools that employ several data collection methods, including the review of facility-based TB registers, interviews with healthcare providers, and patient interviews, to collect quantitative[2] information to assess and monitor the quality of TB services provided by the NTP.

Seminal Frameworks

In light of the importance of quality of care and the benefits of its assessment, it is helpful to have a framework that describes the components that are examined to monitor the quality of TB care.

Avedis Donabedian, among others, is often credited with the seminal systematic examination of healthcare quality. Donabedian proposed a framework for assessing quality of care that describes quality in terms of three key components or dimensions: structure (i.e., the resources available at a health facility), process (i.e., the interaction between healthcare providers and patients), and outcomes (i.e., the consequences of care) (Donabedian, 1966 and 2005). He postulated that services can be deficient in any one, or more, of these three

[1] The Service Provision Assessment survey is a health facility assessment that provides a comprehensive overview of a country's health service delivery. For more information on the Service Provision Assessment, visit https://dhsprogram.com/methodology/Survey-Types/SPA.cfm

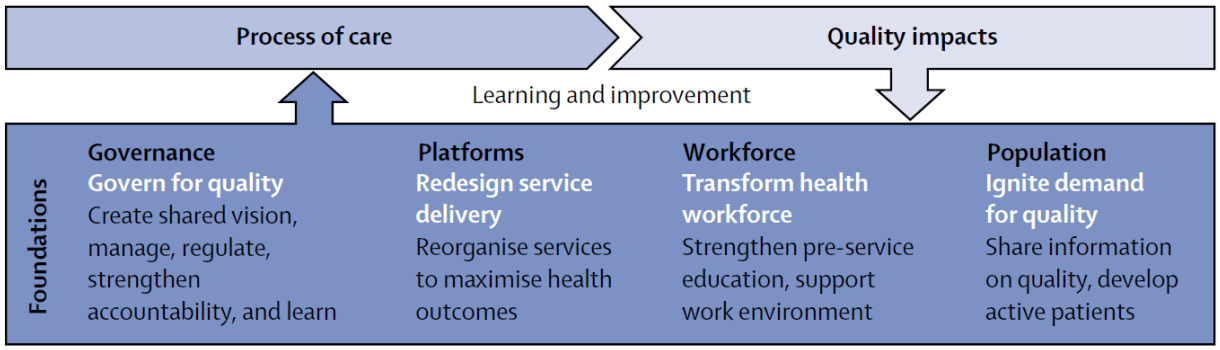
[2] Although the QTSA primarily collects quantitative data, qualitative data are also collected and can be emphasized in a country's customization of the assessment.

components, and that any such deficiency(ies) can lead to poor quality of care. Subsequent studies by others, such as Berwick (1989), and Murray and Frenk (2000), supported Donabedian's framework and demonstrated that deficiencies in quality of care were indeed related to gaps in several areas, including provider knowledge, inappropriate use of available technology, and the inability of health institutions to respond to changes in a patient's health.

In 2001, the United States-based IOM (now called the National Academy of Medicine), defined quality of care as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (IOM, 2001). The IOM noted that health systems in the 21st century should seek to improve performance on six dimensions of quality of care: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity (IOM, 2001). This definition of quality of care, and its dimensions, have since been adopted and used by international organizations, such as the WHO, and many low- and middle-income countries.

In 2018, charged with defining and developing a framework for high-quality health systems, the Lancet Global Health Commission proposed a definition that closely aligns with the IOM's definition of quality of care. The Commission stated that a high-quality health system is "one that optimizes healthcare in a given context by consistently delivering care that improves or maintains health outcomes, by being valued and trusted by all people, and by responding to changing population needs" (Kruk, et al., 2018). The IOM and the Lancet Global Health Commission's definitions emphasize the fundamental linkage between quality of care and health outcomes. The Commission's definition goes a step further to highlight the linkages among the value, trust, and confidence people put in the care they receive, and the responsiveness of the healthcare system to the changing needs of the population, with "optimized" or high-quality healthcare. The Commission's definition for high-quality health systems was accompanied by a conceptual framework, which was informed by Donabedian's seminal framework. Its conceptual framework has three key domains: foundations, processes of care, and quality impacts (Figure 1).[3]

Figure 1. High-quality health systems framework



Source: Kruk, et al, 2018.

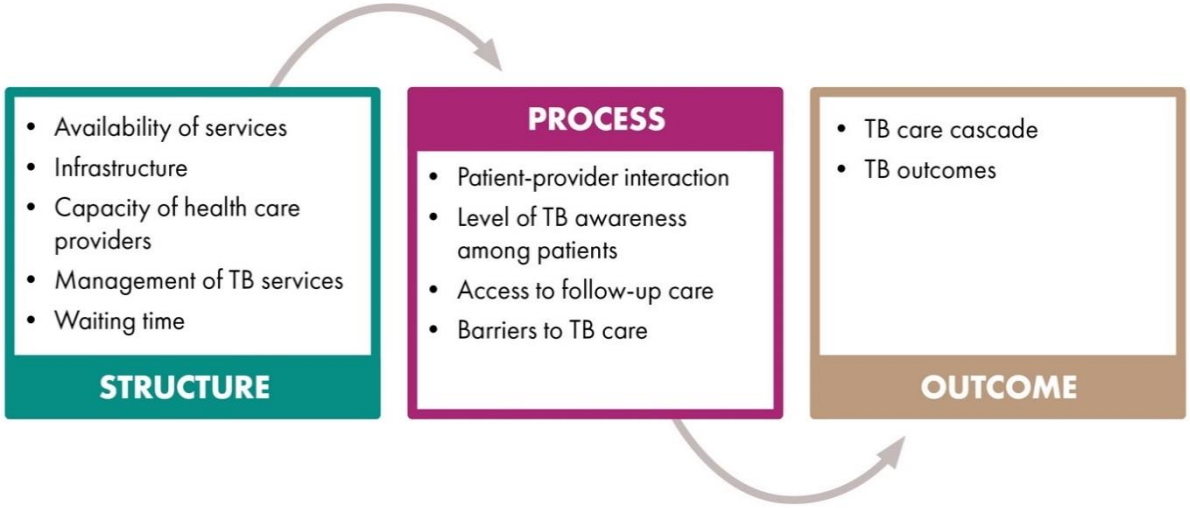
An examination of the Commission's high-quality health systems framework offers more insight for understanding quality of care. Instead of what Donabedian referred to as "structure," this framework has the domain of "foundations," a term that encapsulates the criticality and extensiveness of this component. Unlike structure, which brings to mind a solid physical presence, foundations include a range of five diverse elements that are essential for healthcare: (1) population – health needs and expectations; (2) governance – policy, insurance, and non-health sectors; (3) platforms – accessibility and organization of care; (4) workforce – numbers, skills, and support; and (5) tools – equipment, medicines, and data (Kruk, et al., 2018). Moreover,

[3] The Commission's framework sets out to define health system quality. Its content is more comprehensive than Donabedian's framework for quality of care. Nevertheless, the two frameworks are closely aligned.

the placement of "foundations" at the base of the framework helps illustrate the hierarchical relationship of this component with the others. If the foundations of care are not present, there is no point talking about quality of care. The framework illustrates that as critical as foundations are to the provision of high-quality care, its presence alone does not guarantee that good healthcare is provided to people or that people have good health outcomes.

Building on Donabedian's seminal framework for quality healthcare, and informed by more recent thinking in this area, including the Commission's framework for quality health systems, Figure 2 presents the framework used by the QTSA to define the quality of TB care.

Figure 2. Components of the TB Quality of Care Framework



Source: MEASURE Evaluation.

TB Quality of Care Framework

The TB Quality of Care Framework illustrates a logical pathway that links the key components of high-quality TB care, which must be present and properly functioning to achieve desired TB health outcomes. The framework can be used to define and measure the key elements of each component, which generate information that TB program managers and policymakers can use to inform their thinking and decision making to improve the quality of TB services. The key components and elements of TB quality of care are described below.

Structure

Structure refers to the foundational elements and the environmental factors that facilitate (or hinder) health facilities and service providers from providing high-quality TB services and care. This includes the physical infrastructure of the health facility; the availability and organization of specific TB services, as determined by the type and level of the health facility; the availability of and adherence to national TB standards and guidelines; appropriate human resources to provide services offered; staff training and competencies; the availability of drugs, medical equipment, and other supplies; adequate management and supervision structures and systems; and resources and funding for social support, such as payment schemes and incentives, and transportation reimbursement, to facilitate the delivery and receipt of TB services.

Process

Process refers to the interaction between TB service providers and patients during the delivery of services, in other words, during the caregiving process. In conjunction with the structural factors, which are associated with the health facility and more generally with the healthcare system, process—or the way in which care is provided—influences the subsequent health-related behavior of patients and, ultimately, their TB outcomes.

Process quantifies "what is done" by asking about the various types of TB screening, diagnosis, treatment, monitoring, and follow-up services and procedures delivered by healthcare providers that are received by patients during the caregiving process, and "how it is done." Services assessed in the QTSA include TB screening and case detection at all service entry points and for key populations; the conduct of appropriate diagnostic tests; interpretation and provision of test results in a timely and sensitive fashion; prescription and provision of appropriate treatment according to national standards of care; and identification and testing for TB drug resistance according to NTP algorithms. Delivery of these services, and the interactions with patients, should take place in a way that avoids stigmatizing TB patients and with a focus on addressing their needs. From the patient's point of view, access to TB care and treatment services should be easy; the interaction with providers should be respectful and comfortable; and patients should have a good understanding of their disease and its management.

Outcome

Outcome refers to the consequences of care. Outcomes are measured in terms of TB and related health outcomes and patient satisfaction. Depending on data needs, cases detected and notifications can be disaggregated by multiple factors, including TB type (new, retreatment), site of disease (pulmonary, extra-pulmonary), drug resistance status, HIV status, and sex and age group, to gain a better understanding of the types of patients accessing (and not accessing) TB services. Treatment outcomes, including treatment completion, cure, failure, loss-to-follow-up, and deaths while on TB treatment, provide insights on the NTP's ability to provide successful treatment services. Assessing patients' satisfaction or their reaction and responsiveness to the care provided by the healthcare system is a key aspect of assessing quality of care because it provides further insights on their subsequent health and care-seeking behavior.

Quality of TB Services Indicators

The assessment and measurement of the quality of TB services requires a well-defined framework, like the one presented in the previous section. This section reviews a selection of illustrative indicators (Table 1) that are mapped to the three components of the TB Quality of Care Framework (Figure 2). Depending on the type of indicator, some are disaggregated by level of facility, location (e.g., rural or urban), and facility management authority (e.g., public or private). Indicators pertaining to survey participants (e.g., TB service providers and patients) are disaggregated by sex, age, and education level, among other things. Note that this list is meant to be illustrative and does not represent the comprehensive list of QTSA indicators, nor does it account for country-specific priorities and areas of interest.

Table 1. Quality of TB Care Framework and illustrative indicators

Factors	Category	Indicators
Structure		
Availability of services	TB screening and diagnosis	Percentage of facilities providing screening and diagnosis according to NTP guidelines Percentage of facilities diagnosing TB (by diagnosis method) in the past 12 months Percentage of facilities providing first-line drug susceptibility testing Percentage of facilities providing second-line drug susceptibility testing
	TB treatment	Percentage of facilities providing care and treatment for TB according to NTP guidelines Percentage of facilities providing care and treatment for TB in the past 12 months Percentage of facilities providing care and treatment for TB-HIV coinfection according to NTP guidelines Percentage of facilities providing care and treatment for drug-resistant TB (DR-TB) according to NTP guidelines Percentage of facilities providing pediatric TB care and treatment
Infrastructure	Infection control	Percentage of facilities implementing standards for infection prevention and control
	Laboratory networks	Percentage of facilities following guidelines for specimen transportation Percentage of specimens returned to facility within specified period according to NTP guidelines Percentage of facility laboratories practicing quality control according to NTP guidelines
	Medical equipment and supplies	Percentage of facilities with basic items and equipment required for the diagnosis of TB
	TB drug supply	Percentage of facilities with all (approved) drugs and medicines available on the day of the assessment Percentage of facilities with a buffer stock according to NTP guidelines Percentage of facilities reporting a stockout of any TB drug in the past month Percentage of patients reporting that drugs were always available Percentage of facilities storing drugs and medicines according to NTP standards
	Linkages with other services and community	Percentage of facilities linked to community-based TB services Types of TB services that community-based workers provide to the community Percentage of facilities providing contact investigation and management (by type of contact) according to NTP guidelines
	Management of TB-HIV patients	Number/percentage of TB patients having an HIV test result/status recorded in the TB register Percentage of TB patients having an HIV test result/status recorded on their patient card Percentage of HIV-positive TB patients starting antiretroviral therapy
	Implementation of TB preventive therapy	Percentage of HIV-positive TB patients on cotrimoxazole preventive therapy recorded in the TB register

Factors	Category	Indicators
		Number/percentage of eligible patients (e.g., people living with HIV/AIDS, child contacts) receiving TB preventive therapy
	Management of DR-TB patients	Percentage of confirmed DR-TB patients starting second-line treatment in the past year Number/percentage of successfully treated DR-TB patients (cured or completed treatment) Number/percentage of patients receiving drug resistance testing per NTP guidelines
Capacity of TB providers	Trained TB care provider	Percentage of facilities with at least one provider trained in the past 24 months to deliver TB services Percentage of providers who received training or refresher training in the past 24 months to deliver TB services
	Patient counseling about TB	Percentage of providers reporting good counseling skills Percentage of providers reporting good counseling skills for screening of TB/initial patient assessment (i.e., addressed all topics) Percentage of providers reporting good counseling skills for screening, diagnosis, and treatment of TB (i.e., providers' competencies)
	Adherence	Percentage of providers reporting the discussion of adherence to treatment and the importance of treatment completion Percentage of patients reporting being counseled on adherence to treatment and the importance of treatment completion
Management of TB services	TB policies and guidelines	Percentage of facilities with up-to-date TB policies, protocols, and guidelines present on the day of the survey
	Privacy	Percentage of facilities offering a private space for counseling and diagnosis Percentage of patients reporting that they had privacy during counseling and diagnosis services Percentage of patients reporting that they worry other patients can hear their conversation with their health provider
	Waiting times	Percentage of patients reporting acceptable waiting times Percentage of facilities with a mechanism for TB patients that supports rapid access to care without waiting for extended periods (e.g., triage/fast track of symptomatic patients)
	Supervision and monitoring and evaluation	Percentage of providers receiving a supervisory visit according to NTP guidelines Percentage of facilities receiving a supervisory visit according to NTP guidelines

Factors	Category	Indicators
Process		
Level of TB awareness among patients	Level of awareness of TB disease	Percentage of patients interviewed demonstrating a "high" level of awareness of TB and its treatment Percentage of patients correctly identifying symptoms an individual would experience if s/he has TB disease Percentage of patients correctly identifying what causes TB Percentage of patients correctly identifying how TB spreads Percentage of patients correctly identifying risk factors for getting TB Percentage of patients knowing that TB can be cured
	Knowledge of treatment and disease management	Percentage of patients knowing how long TB treatment takes Percentage of patients interviewed demonstrating a "high" level of knowledge of side effects of TB treatment Percentage of patients counseled on infection control Percentage of patients informed of methods for preventing transmission to other family members and the community in general
Patient-provider interaction and communication	Patients' access to support; consultations with their TB care provider when required	Percentage of providers reporting counseling or discussing methods with patients for preventing transmission to family members and the community in general Percentage of providers discussing with family members and/or those living with a TB patient basic information and skills to protect household members and contacts from infection Percentage of patients reporting that a health provider at the facility talked with members of their family/household on how to prevent the spread of TB from one person to another Percentage of patients reporting that a health provider at the facility usually explained things in a way they could understand Percentage of patients reporting that a health provider at the facility listens to their opinions and ideas on the best way to follow treatment Percentage of patients reporting that a health provider at the facility discusses their status or progress with them at every scheduled appointment Percentage of patients reporting that a health provider at the facility gives them a chance to ask questions about anything of concern Percentage of patients reporting that a health provider at the facility tells them how TB can affect their everyday life Percentage of patients reporting that a health provider at the facility takes their worries about TB seriously during facility visits Percentage of patients reporting that a health provider at the facility explains how to cope with their problems Percentage of patients reporting that a health provider at the facility carefully listens to them Percentage of patients reporting that they usually have enough time to discuss their health needs with the health providers

Factors	Category	Indicators
Barriers to TB care	Problems encountered in getting care	Percentage of patients reporting barriers to TB care Percentage of patients reporting experiencing stigma at TB facilities
Access to follow-up care	Availability and access to community-based or follow-up care	Percentage of patients reporting taking their TB drugs per national protocol Percentage of patients reporting having been monitored for side effects Percentage of patients receiving smear conversion tests
Outcomes		
Screening and diagnosis	Testing and notification	Percentage of presumptive TB patients receiving a diagnostic test Percentage of presumptive TB patients receiving bacteriological results, including smear microscopy, culture, or GeneXpert (Xpert MTB/RIF®) Percentage of patients with TB who are bacteriologically confirmed Percentage of patients with TB who are clinically diagnosed Percentage of smear microscopy test results received within a specified turnaround time (per NTP guidelines)
TB treatment	Treatment outcomes	Percentage cured (per NTP definition for cure) Percentage completing treatment without evidence of cure per NTP guidelines Percentage with treatment failure Percentage who died while on TB treatment Percentage lost to follow-up Percentage not evaluated for treatment outcome
Patient satisfaction	Patient satisfaction	Percentage of patients indicating that they were satisfied or very satisfied with the TB services they received at the facility

Overview of Method and the Standard QTSA Tools

Study Objectives

The purpose of the QTSA is to assess the quality of TB services at randomly selected TB diagnosis and treatment facilities to identify strengths and weaknesses in the quality of TB services provided by the NTP. The assessment results provide the NTP and other TB stakeholders in the country with information they can use to develop interventions to improve the quality of TB services.

The QTSA objectives depend on the data needs of the specific country implementing the assessment, but typically include the following:

- Assess the current condition of TB diagnosis, treatment, and care services in terms of the availability of skilled providers, equipment, and organizational structures.
- Determine the quality of TB services provided by health facilities and existing gaps to address to improve service quality.
- Assess TB service providers' knowledge and skills.

- Assess TB patients' perception of TB services and patient satisfaction.
- Evaluate the clinical outcomes of TB patients who have received diagnosis and treatment services.

Study Population

The QTSA study population includes patients and providers from a representative sample of health facilities that are providing TB and TB-related services, such as diagnosis, care, and treatment, in a specific country. The study draws a sample of current TB diagnostic and treatment facilities using the Ministry of Health's (MOH) master facility list (MFL) or health management information system (HMIS) as the basis for sampling. The study focuses on the quality of TB services; therefore, the sampling frame is restricted to the health facilities providing TB and TB-related services, as defined by the country's MFL, and other facilities known by stakeholders to provide TB services but which are not included in the MOH's MFL. Health facility staff and TB patients are asked to participate in the study to answer questions about the quality of TB services and TB outcomes. The patients typically include confirmed drug-susceptible TB (DS-TB) and DR-TB patients, ages 15 years and older, visiting the health facilities on the day of data collection.

Study Design

The QTSA is a cross-sectional study conducted at a sample of diagnostic and treatment facilities selected using a multistage random sampling procedure, the exact nature of which is determined by the specific needs of the country implementing the QTSA. In addition to the randomly selected facilities, the NTP may decide to purposely sample and include specific facilities, such as higher-level facilities (tertiary facilities, regional or provincial and general references hospitals) and facilities that provide specialized services. If this is the case, weights can be used during the analysis stage as a correction factor for the oversampling of any one specific type of facility.

Standard QTSA Tools

The QTSA uses several data collection tools and methods, including an assessment of TB-related facility services, physical infrastructure, drugs and supplies, including observation of essential laboratory and TB unit resources and equipment (Facility Audit); key informant interviews of TB service providers (Provider Interview) and TB patients (Patient Interview); and a review of data recorded in TB registers to determine TB-related outcomes, including treatment outcomes (Register Review). Each of these four standard tools are described below.

Facility Audit: The Facility Audit is administered to the health facility in-charge, TB focal person, and other service providers who are engaged in the provision of TB services at the facility to determine the availability and functionality of the facility infrastructure, TB services offered, and equipment and resources available to serve TB patients with quality TB care. One Facility Audit is conducted at each health facility sampled.

Provider Interview: The Provider Interview is administered to service providers who are actively engaged in the provision of TB services, such as the TB focal person and/or other staff in charge of specific TB-related services, to understand the clinical processes and protocols applied during TB counseling, screening and diagnosis, and treatment and follow-up. This tool evaluates the technical competence, knowledge, and practices of the service providers in the provision of clinical care and management of TB services. One or more Provider Interview(s) is conducted at each sampled health facility depending on the facility size, typically ranging from one to five.

Patient Interview: The Patient Interview is administered to TB patients receiving diagnosis and treatment at the facility to collect information about the client's experience as the recipient of care. It provides data on the patient's perspective of the quality of TB-related services offered by the facility. One or more Patient

Interview(s) is conducted at each sampled health facility depending on the facility size and patient load, typically ranging from one to five.

Register Review: The Register Review involves the review and extraction of relevant TB data from the appropriate registers (i.e., laboratory registers, TB treatment registers, DR-TB treatment register, TB contact register) for a specific period of time to assess the services provided to TB patients and TB-related outcomes of patients. One Register Review is conducted at each health facility sampled.

Other tools or modules to tools can be added to supplement these standard tools, based on the data needs of each country.

Methodological and Ethical Issues

The QTSA uses multiple methods to assess the quality of TB care and services. Therefore, it is critical to consider the following methodological issues when reviewing the results.

Recall Bias

Patient interviews solicit information on their experiences with TB services. However, patients may not remember the sequence and content of counseling and clinical evaluation sessions in the course of diagnosis and treatment, especially given the long time needed to complete TB treatment. For this reason, the patient interview includes a limited number of questions focused on each patient's satisfaction and perception of the care they receive.

Courtesy Bias

It is likely that the patient interviews will convey an image of quality that is better than reality. Patients may feel inclined to say positive things about the services they received because they may fear that negative feedback will threaten their continued receipt of services at the facility. To minimize this bias, interviewers should be trained to assure patients that they are free to express their opinions honestly, without fear of losing access to services at the facility. Investigators should also emphasize the importance of keeping patients' responses confidential to minimize the sharing of opinions and experiences beyond the interview.

Generalizability

Generalizability measures the degree to which experimental results from a sample can be extended to a population as a whole. The sampling design for this study requires that the sample be selected from populations in such a way that the sample matches the characteristics of the population as closely as possible. The results of the closely matched samples will be nationally representative and can be used to generate national estimates.

Ethical Considerations

Measuring quality of care entails collecting information from patients and healthcare providers about their interactions. The design and implementation of the assessment must take into account the rights of both patients and providers. It is essential that data collectors obtain informed consent from patients and providers before interviewing them. The informed consent may be administered verbally or in a written form, depending on the educational level of the respondent.

Participants in the assessment should be made aware of any likely risks and/or benefits of the assessment. They should also be informed that they do not have to participate in the study and that choosing not to participate will not affect their care at the facility in any way. In addition, patients should be assured that the information collected will be kept confidential.

Individual respondent (patient and provider) and individual facility-level data should be kept confidential, and the data should only be presented at an aggregate level so that no specific respondent or facility can be identified in the QTSA results. Therefore, facility managers, providers, and patients should not fear suffering negative consequences for any findings of low-quality services, poor patient outcomes, or for complaints or negative feedback expressed.

In addition to informed consent, protocols should be developed to determine how forms and data collected electronically are stored to preserve confidentiality. This assessment method uses code numbers, rather than names, to identify facilities, providers, and patients. The lists linking facility code numbers to the facility names should be stored separately from the questionnaires, and access to the list restricted to assessment personnel. In the case of the standard tools in this QTSA Global Toolkit, it is not necessary to collect providers' or patients' names. However, if names *are* collected, they should also be kept separately from any identifying codes and should not be released to non-study personnel. Researchers should take particular care to protect the confidentiality of patients and providers in small facilities, where the patients might be more easily identified. All assessment staff should be informed that they should not discuss the results of the interviews with anyone outside the QTSA team. This rule should be strictly enforced.

There are no major risks to participating in this study. Minimal non-physical risks include personal information about people (providers and patients at the health facilities) being shared with the study personnel, although little to no information of a confidential nature is collected and all information collected during the assessment should be treated as confidential.

The primary research burden for both health staff and patients participating in the study is the time spent providing information to the research team. No direct benefits accrue to respondents from participating in this survey, unless the NTP and investigators decide to reimburse patients for their transportation expenses.

During training, data collectors are instructed to report any perceived problems resulting from the study to the supervisor. The supervisors produce a written record of the reported problem to the local research organization (LRO), principal investigator, and co-investigators. The LRO and principal investigator are responsible for determining whether the report constitutes a problem and subsequently reporting to the ethics committee, to the NTP of the MOH, and/or other appropriate institutions. If during the survey, data collectors observe patients exposed to serious risk or low-quality services that may compromise the patients' well-being, they should immediately inform the NTP. A point of contact at the NTP is established specifically for this purpose and the NTP is responsible for follow-up.

At the national level, the benefits from this study are that the MOH and its partners receive feedback on the quality of care in the TB program, and the findings may help lead to policy and program improvements.

Module 2. Planning and Implementation

Implementation Overview and Timeframe

The QTSA is a type of facility-based survey conducted to generate data that help strengthen the quality of care offered by TB programs and improve TB and TB-related health outcomes.

The time needed to conduct a QTSA from start to finish depends on general variables, such as the scope of the assessment (i.e., if additional modules or tools are added to the standard tools), the sample size, and several country-dependent variables, such as country size and the accessibility of geographic areas included in the survey, average length of time to secure institutional review board (IRB) approval, etc. On average, the QTSA can take between 9 to 15 months to complete.

Table 2 provides an overview of the survey, organized into four main phases (planning and preparations, data collection fieldwork, data analysis and validation, and report writing and dissemination of results); the steps required under each phase; and the activities that are typically undertaken during each step. The steps and activities are suggested based on previous implementations of the QTSA; however, they should be adapted to reflect the available time, resources, and needs of each specific county.

Table 2. QTSA planning and implementation: phases, steps, and activities

Phases	Steps and activities		
Phase I: Planning and preparations (3–6 months)	**1**		**Step 1: Initial planning and coordination**
		1.1	Clarify survey scope (i.e., data needs, NTP priorities) with the NTP, USAID Mission, and other stakeholders
		1.2	Establish a steering committee with defined roles
		1.3	Develop the QTSA budget and timeline
	2		**Step 2: Develop the study protocol**
		2.1	Calculate the total sample size
		2.2	Obtain the master list of health facilities delivering TB-related services from the MOH/NTP and sample facilities
		2.3	Draft the protocol
	3		**Step 3: Recruit a LRO**
		3.1	Recruit a LRO or university entity with experience implementing large-scale facility surveys to conduct fieldwork and data collection activities
	4		**Step 4: Customize the survey tools**
		4.1	Customize/adapt the QTSA tools to meet country-specific needs and reflect NTP priorities and guidelines
		4.2	Develop additional modules or tools, if needed
		4.3	Translate the tools, if necessary

Phases	Steps and activities		
	5		**Step 5: IRB approval**
		5.1	Submit the protocol and tools to the IRB
		5.2	Secure IRB approval
	6		**Step 6: Finalize the survey tools**
		6.1	Plan and conduct a field test of the tools
		6.2	Revise and finalize the tools and consent forms (including electronic tools for tablet/phone-based data collection)
		6.3	Draft a data analysis plan
	7		**Step 7: Prepare for data collection**
		7.1	Recruit/identify data collectors and field supervisors
		7.2	Plan and conduct training for data collectors and field supervisors
		7.3	Prepare fieldwork guidelines, letter of introduction to present to health facilities, and other fieldwork job aids
		7.4	Secure all national and regional/provincial approval for data collection
		7.5	Arrange all logistics for data collection, including supplies and transport
Phase II: Data collection fieldwork (3–4 months)	**8**		**Step 8: Data collection fieldwork**
		8.1	Arrange for daily communication between the data collection teams and LRO data manager/assessment coordinator during the data collection period
		8.2	Organize the supervision of data collection teams by LRO staff, especially during the first weeks of data collection
		8.3	Team leader/supervisor conducts daily confirmation of appointments with health facilities
		8.4	Visit health facilities and collect data
		8.5	Enter data using a survey software (e.g., SurveyCTO)
		8.6	Daily transfer of completed data electronic files to the LRO data manager
		8.7	Daily review and data quality checks to resolve missing/unreliable information by the data collection team leader/supervisor before submission and by the LRO data manager after submission
		8.8	When data collection is complete, team leader/supervisor submits all survey forms (paper and/or electronic) to the LRO
		8.9	Clean the data set and conduct data quality checks for consistency and accuracy

Phases	Steps and activities		
Phase III: Data analysis and validation (1–2 months)	**9**		**Step 9: Analyze and validate data**
		9.1	Export the final data set for analysis (e.g., STATA)
		9.2	Conduct analyses according to the data analysis plan
		9.3	Conduct a data validation meeting with the steering committee to validate the data, interpret the results, and formulate recommendations
Phase IV: Report writing and dissemination of results (2–3 months)	**10**		**Step 10: Produce and disseminate the final report**
		10.1	Complete the data analysis and draft the report
		10.2	Share the draft report with the steering committee for input
		10.3	Finalize the report
		10.4	Disseminate the study findings
		10.5	Document and archive the survey using metadata standards

Stakeholder Roles and Responsibilities in QTSA Planning and Implementation

The purpose of conducting the QTSA is to generate information that can be used by the NTP to improve the quality of TB services and, ultimately, improve TB health outcomes. To generate information that is relevant and useful, and ensure that stakeholder data needs are met, it is imperative to conduct the QTSA in a collaborative manner.

In this section, the roles and responsibilities of various stakeholders who are typically involved in the process of planning and conducting a QTSA are described.

TB Data, Impact Assessment and Communications Hub (TB DIAH) (or another implementing partner or agency): TB DIAH is the lead implementer and is responsible for the planning and implementation of the QTSA. This includes developing the study and sampling design, protocol development, and tool customization. TB DIAH is also responsible for recruiting and managing a qualified LRO for implementation of field activities, and provides technical oversight during survey implementation. Once the data set has been finalized, TB DIAH leads the data analysis, interpretation of the findings, and drafting and finalization of the technical report. TB DIAH can also be involved in the dissemination and use of data, if requested and approved by the NTP and USAID Mission.

National TB Program: The NTP is a primary stakeholder and serves a critical advisory role in planning and implementing the QTSA. The NTP provides: input on protocol development and the adaptation and customization of the survey tools to the country context; information on the NTP's strategic priorities, intervention areas, and services; the TB MFL to the implementers for study design and sampling; feedback during data analysis and interpretation, including participating in the data validation meeting; and input on the final technical report. In collaboration with the USAID Mission and local implementing partners, the NTP is primarily responsible for the dissemination and use of data.

Local research organization: Working under the supervision of TB DIAH (or another implementing partner or agency), the LRO is responsible for the implementation of field activities for the survey, including field-testing the survey tools; recruiting qualified data collectors and field supervisors; training data collectors and field supervisors; managing, assisting, and supervising data collection teams during data collection; and data

cleaning and quality assurance. The LRO also contributes to data interpretation during analysis, and organizes and participates in the data validation meeting.

USAID Mission: The USAID Mission assists the implementer in coordinating local buy-in for the QTSA with key partners in the NTP and MOH; provides feedback during data analysis and interpretation; participates in the data validation meeting; and reviews and provides input on the final technical report.

USAID/Washington: The USAID/Washington TB Team provides funding for the study and has an active role in monitoring the technical direction of the survey. It also reviews and provides input on the final technical report.

Phase I: Planning and Preparations

Planning and preparations make up the first phase of a QTSA implementation. This can be the longest phase of the study and can take from **three to six months**, depending on the time it takes to carry out and complete the activities in each step of this phase. Table 3 presents the steps and sub-activities of this initial phase.

Table 3. Phase I steps and activities

1		**Step 1: Initial planning and coordination**
	1.1	Clarify survey scope (i.e., data needs, NTP priorities) with the NTP, USAID Mission, and other stakeholders
	1.2	Establish a steering committee with defined roles
	1.3	Develop the QTSA budget and timeline
2		**Step 2: Develop the study protocol**
	2.1	Calculate the total sample size
	2.2	Obtain the master list of health facilities delivering TB-related services from the MOH/NTP and sample facilities
	2.3	Draft the protocol
3		**Step 3: Recruit a LRO**
	3.1	Recruit a LRO or university entity with experience implementing large-scale facility surveys to conduct fieldwork and data collection activities
4		**Step 4: Customize the survey tools**
	4.1	Customize/adapt the QTSA tools to meet country-specific needs and reflect NTP priorities and guidelines
	4.2	Develop additional modules or tools, if needed
	4.3	Translate the tools, if necessary
5		**Step 5: IRB approval**
	5.1	Submit the protocol and tools to the IRB
	5.2	Secure IRB approval
6		**Step 6: Finalize the survey tools**

	6.1	Plan and conduct a field test of the tools
	6.2	Revise and finalize the tools and consent forms (including electronic tools for tablet/phone-based data collection)
	6.3	Draft a data analysis plan
7		**Step 7: Prepare for data collection**
	7.1	Recruit/identify data collectors and field supervisors
	7.2	Plan and conduct training for data collectors and field supervisors
	7.3	Prepare fieldwork guidelines, letter of introduction to present to health facilities, and other fieldwork job aids
	7.4	Secure all national and regional/provincial approval for data collection
	7.5	Arrange all logistics for data collection, including supplies and transport

Step 1: Initial planning and coordination

1.1 Clarify survey scope (i.e., data needs, NTP priorities) with the NTP, USAID Mission, and other relevant stakeholders

1.2 Establish a steering committee with defined roles

1.3 Develop the QTSA budget and timeline

To generate information that is relevant and useful, during each country implementation of the QTSA, the standard protocol and tools should be adapted and customized to meet the specific priorities and data needs of the country. During this initial step, it is important to identify and engage the main stakeholders who will advise on the technical direction and focus of the QTSA in-country and ultimately use the data generated by the survey. The main in-country stakeholders are typically the NTP and the USAID Mission, and may also include other divisions of the MOH, such as the Monitoring and Evaluation and Health Information System Directorate. The in-country stakeholders, along with the lead QTSA implementer, form the steering committee. The steering committee should discuss and agree on the study design, study objectives, and the scope of the QTSA, which will inform the development of the budget and timeline, and subsequently, the study protocol (under Step 2).

Step 2: Develop the study protocol

2.1 Calculate the total sample size

2.2 Obtain the master list of health facilities delivering TB-related services from the MOH/NTP and sample facilities

2.3 Draft the protocol

The QTSA is conducted at a sample of health facilities. Sample size calculation and sampling of health facilities are carried out in a systematic way, usually by the QTSA implementer, to ensure that the findings are representative of the country or region/province/state in which the assessment is being conducted. (See Module 3 for more in-depth guidance on sampling.) The national HMIS database (or MFL) is used to identify health

facilities offering TB services. As the implementer and steering committee work through the QTSA objectives, study design and method, and sampling, these pieces are used to inform the study protocol.

Step 3: Recruit a LRO

3.1 Recruit a LRO or university entity with experience implementing large-scale facility surveys to conduct fieldwork and data collection activities

The LRO is responsible for the implementation of all field activities for the QTSA, including field testing survey tools; recruiting qualified data collectors and field supervisors; training data collectors and field supervisors; managing, assisting, and supervising data collection teams during data collection; and data cleaning and quality assurance. The lead QTSA implementer identifies and contracts a qualified LRO using a fair and competitive recruitment process.

Step 4: Customize the survey tools

4.1 Customize/adapt the QTSA tools to meet country-specific needs and reflect NTP priorities and guidelines

4.2 Develop additional modules or tools, if needed

4.3 Translate the tools, if necessary

The standard QTSA tools should be adapted for country use to reflect the structure and operation of each country's healthcare system, and should be aligned with the national TB guidelines and protocols, TB algorithms for screening and diagnosis, and treatment regimens, especially for DR-TB treatment. This customization of tools is done with input from the steering committee, with specific attention paid to NTP needs and priorities. When adapting the tools, consideration should be given to how changes would affect data collection. Adjustments should be made to determine that definitions are specific enough to assure comparability across the country and within administrative sub-units (districts, zones, etc.).

It is important to remember that the QTSA is not intended to generate broad data on all aspects of health system functioning. Rather, it focuses on key elements and components of service delivery that are critical to quality of care for TB services. This should be kept in mind while adapting the tools and adding questions or modules.

The standard QTSA tools are available at the following link:
https://www.tbdiah.org/resources/publications/quality-of-tuberculosis-services-assessment-global-tools/

Table 4 highlights some key areas where the tools should be adapted to the country context. Further tips for customizing the tools are given in Appendix A.

Table 4. QTSA tool content areas for country customization

Area	Reference(s)	Comments
Health facility types	National classification of health structures	Facility classification should reflect the national health system, including both public and private facilities. It should conform to the service package offered by each facility type (based on the national basic package of essential services, if available).
Health facility managing authority	National classification of health structures	The managing authority types should reflect the national classification of authorities in charge of a facility.

Area	Reference(s)	Comments
Staffing categories	Official categorization of human resources for health	The proposed human resources list in the questionnaire should be mapped to the official classification of certified health personnel, and appropriate cadres should be added.
Educational levels of providers and patients	Ministry of Education on the level of formal schooling and issuance of certificates	Use country-specify ranking and nomenclature.
Country-specific medicines policy	National drug policy and other specific drug policies (essential medicines, TB, etc.)	Standard lists of tracer items for medicines are proposed in the questionnaire according to international standards. If there is a country-specific regimen for certain treatments, it should be edited accordingly (tracer items).
Trained staff	Official training cycle for health workers	A standard of a two-year interval in training cycle updates for staff is used in the questionnaire. If the timeframe for staff training updates is different according to official policy, it should be reflected in the questionnaire.
Supervision	Supportive supervision guidelines	Customized based on the supervision and monitoring guidelines for the TB program or the general health sector.
Methods for screening and diagnosis of TB	TB protocol and guidelines	This should be based on the most up-to-date NTP guidelines on the preferred screening and diagnosis algorithms and diagnosis procedures expected at all facility types. Given the evolving nature of international guidelines on screening and diagnosis, it is critical to ensure that the most recent protocols are included in the QTSA.
TB treatment modalities	NTP guidelines	Whether TB treatment is provided only at the facility, or at both the facility and in the community.
TB regimens	NTP guidelines	The specific TB regimens that are available and offered at the facility (e.g., which DR-TB treatment regimens are in use). Given the evolving nature of international guidelines for TB prevention and treatment, it is critical to ensure that the most recent protocols and regimens are included in the QTSA.

Step 5: IRB approval

5.1 Submit the protocol and tools to the IRB

5.2 Secure IRB approval

As with any other study, the QTSA should comply with a country's regulations governing ethical research procedures. The exact nature of these regulations varies across countries, institutions, and funding bodies. In some contexts, the QTSA may require IRB review and approval, whereas in other contexts it may qualify for exemption. The QTSA implementer should research and be informed about what is required. If IRB review and approval are required, this process can take several months in some countries, and may act as a rate-limiting step for the entire study. It is therefore advised that the QTSA implementer look into IRB options early in the preparation phase so that the necessary approvals are secured and the survey is in full compliance before data collection begins.

Step 6: Finalize the survey tools

6.1 Plan and conduct a field test of the tools

6.2 Revise and finalize the tools and consent forms (including electronic tools for tablet/phone-based data collection)

6.3 Draft a data analysis plan

After the tools have been customized to the country context and have passed ethical approval, they are field tested to ensure that the questions are interpreted and understood as intended. The LRO is responsible for planning the pretest, organizing the pretest team, and conducting the field test. The pretest team should include at least one clinician with experience managing TB, and who is familiar with NTP guidelines and protocols. Members of the broader steering committee may also choose to participate. The LRO should identify a small number of facilities (five to seven), that represent the types and levels of facilities included in the survey, but which are not a part of the sample. Typically, the pretest is carried out over the course of a week, and the tools are iteratively adapted at the end of each day based on the day's findings. During the field test, the LRO should keep detailed notes on how questions, question sequence, response choices, etc. need to be updated, share these findings with the QTSA implementer, and update the tools after the pretest.

Once the tools have been updated, the electronic tools can also be developed, piloted, and finalized. The use of an online survey platform or software that allows for data collection, transfer, and processing, such as SurveyCTO, CSPro, Qualtrics Research Core, Key Survey, etc., is highly recommended for reasons of practicality and feasibility in most settings, and for improved data quality assurance. Once developed, the electronic tools can be easily administered on a digital device (e.g., tablet, smartphone, computer). Usually, the survey software is a fully integrated tool and includes a powerful, offline-capable Android data collection application, a hosted server with user management and two-way data sync, and a desktop client for downloading and exporting data into multiple formats.

Once the tools are finalized, a data analysis plan, which serves as a roadmap for how to organize and analyze the data, is developed. This should be done in collaboration with key stakeholders to ensure that their data needs are fully captured and are part of the final report. More information on developing a data analysis plan is found in Module 4. A sample data analysis plan is provided in Appendix C.

Step 7: Prepare for data collection

7.1 Recruit/identify data collectors and field supervisors

7.2 Plan and conduct training for data collectors and field supervisors

7.3 Prepare fieldwork guidelines, letter of introduction to present to health facilities, and other fieldwork job aids

7.4 Secure all national and regional/provincial approval for data collection

7.5 Arrange all logistics for data collection, including supplies and transport

The LRO is responsible for recruiting and hiring qualified data collectors and team leaders/field supervisors. Ideally, data collectors and supervisors should have some medical background and have prior experience conducting health facility surveys.

The number and exact composition of the data collection teams depend on the study sample size (i.e., the number of facilities that need to be visited, and the expected number of interviews). Typically, each data collection team consists of two to four data collectors and a supervisor or team leader. The data collectors are responsible for administering the survey tools at each facility, and the team leader/supervisor is responsible for managing the team and data collection, reviewing data for quality assurance daily before submission, maintaining daily contact with the LRO data manager/study coordinator, and following up as advised by the

LRO team. In addition, in some contexts, it might be helpful to have a field coordinator assigned to manage data collection at the regional/provincial level. The field coordinators should work with the team leaders/supervisors on problem solving, verifying the quality of data collected when there are questions, and reviewing submitted data for data quality assurance.

The training of data collectors and team leader/field supervisors (and the field coordinator, where appropriate) should take place just before data collection. The training typically takes five to nine days, depending on needs and resource availability, and includes a detailed review of the survey method and tools, transfer of skills and knowledge on NTP protocols and services, and field practice using the tools. Table 5 provides a sample training agenda.

Table 5. Illustrative training agenda

Day	Training activities
1	Introductions Background on TB quality of care and the NTP Concepts and terminology for TB and the NTP Overview of data collection and methodological issues (including tablet-based data collection) Review of the QTSA Facility Audit tool and guidelines (part I)
2	Review of the QTSA Facility Audit tool and guidelines (part II) Tips for conducting a provider interview Review of the QTSA Provider Interview tool and guidelines Practice interview and role play
3	Tips for conducting a patient interview Review of the QTSA Patient Interview tool and guidelines Practice interview and role play Review of the national TB registers and data collection tools Review of the QTSA Register Review tool and guidelines (part I)
4	Review of the QTSA Register Review tool and guidelines (part II) Discussion about issues arising from tool reviews (e.g., items that must be updated or adapted to the local context) Discussion about ethical and safety issues relevant to QTSA data collection
5	Data collection field practice at health facilities
6	Debrief and discussion about the field practice experience, overall and by tool Discussion about any final adaptation needed to the survey tools
7	Discussion about roles and responsibilities of the data collection team members and LRO support team Discussion about the assessment logistics and organization Review and planning of fieldwork logistics by the data collection teams Wrap-up

Training is an extremely important component of the QTSA. The extra time and effort spent on this activity increases the validity and reliability of the results, and allows the teams to understand what is expected of them as the study is conducted.

The first part of training focuses on familiarizing participants with the objectives of the study, the study protocol, the data collection method, and a basic overview of TB disease and services offered by the TB program. This is followed by a detailed review of the survey instruments and guidelines, including screening and selection criteria for respondents; obtaining informed consent; reviewing the meaning and intent of each question; and selecting and recording responses. The training agenda should include adequate time for participants to practice using the tools, role-play, and eventually apply the tools at a health facility, to further increase their familiarity and comfort with the instruments.

The LRO should prepare comprehensive fieldwork guidelines for data collectors that summarize the key points to remember for administering the QTSA tools, and data collection schedules for the team leaders/supervisors to ensure efficient planning and timely completion of data collection.

Ensuring timely logistical arrangements for data collection are equally important. Before the start of data collection, the LRO should secure all administrative approvals and coordinate with the NTP manager (or another MOH official) to notify appropriate regional/provincial and district authorities of the QTSA in advance of the fieldwork. This may take the form of an official letter of introduction, with signed approval from the NTP/MOH (see example below) and introducing the QTSA and the data collection team, which team leaders/supervisors can present to subnational authorities and health facility heads.

To: The District Health Officer

Subject: Quality of Tuberculosis Services Assessment

The Ministry of Health and NTP, with support from the [NAME OF DONOR AGENCY] has collaborated with [NAME OF LOCAL RESEARCH ORGANIZATION] to undertake a Quality of Tuberculosis Services Assessment (QTSA) in [NAME OF COUNTRY]. The study will be conducted in [NUMBER] districts and [NUMBER] health facilities. Your district/health facility has been identified as one of the study districts/sites.

This letter is to inform you about this upcoming QTSA and ask for your full support in ensuring its successful implementation. We expect that the assessment will provide very important insights on the quality of TB services in the country and will ultimately help improve TB control.

In the coming weeks, a team will be visiting your district/health facility to undertake this assessment. You are kindly requested to give them all the necessary support.

Yours Sincerely,

[SIGNATURE*]

***Minister of Health, Director of the NTP, Director General of Health Services, or other.**

Team leaders/supervisors are responsible for contacting sampled facilities in advance of the scheduled visits. (See details in the next section.)

Team leaders/supervisors should also make sure that all equipment and supplies (i.e., QTSA tools, consent forms, training manuals, tablets, backup power supply and/or chargers, pens, clipboards) are available. (A checklist is included in Appendix B.) Transportation arrangements for the data collection teams (i.e., drivers, vehicles, gas, meals, and incidentals) should also be organized and confirmed by the LRO or delegated to the team leaders/supervisors, if appropriate. The LRO and/or team leader/supervisor should likewise confirm accommodation arrangements and budget for the data collection team, if overnight stays are required, before starting data collection.

Phase II: Data Collection Fieldwork

Data collection should immediately follow the training of data collectors and team leaders/supervisors. Table 6 lists the specific activities carried out during this phase. This phase usually lasts three to four months.

Key documents and checklists for the data collection phase can be found in Appendix B.

Table 6. Phase II steps and activities

8		**Step 8: Data collection fieldwork**
	8.1	Arrange for daily communication between the data collection teams and LRO data manager/assessment coordinator during the data collection period
	8.2	Organize the supervision of data collection teams by LRO staff, especially during the first weeks of data collection
	8.3	Team leader/supervisor conducts daily confirmation of appointments with health facilities
	8.4	Visit health facilities and collect data
	8.5	Enter data using a survey software (e.g., SurveyCTO)
	8.6	Daily transfer of completed data electronic files to the LRO data manager
	8.7	Daily review and data quality checks to resolve missing/unreliable information by the data collection team leader/supervisor before submission and by the LRO data manager after submission
	8.8	When data collection is complete, team leader/supervisor submits all survey forms (paper and/or electronic) to the LRO
	8.9	Clean the data set and conduct data quality checks for consistency and accuracy

Daily communication between the field-based data collection teams and the LRO during this phase, adequate supervision and monitoring, and regular data quality checks are key to ensuring that data collection challenges are addressed promptly and that high-quality data are collected.

During the first few weeks of data collection, the LRO coordinator, data manager, and other relevant staff (or field coordinators, if relevant) should accompany the data collection teams to health facilities and supervise/monitor data collection. The team leader/supervisor is responsible for preparing and keeping a facility visit schedule up-to-date covering all facilities in the team's catchment area. To minimize travel costs, the schedule should be designed to limit "doubling back," which will increase cost-effectiveness while decreasing the distances the team is required to travel. When developing the schedule, the team leader/supervisor should

consider the location of each facility and the areas where the team will likely be staying overnight. The team should generally arrive at a facility at or before the official opening time; therefore, the lodging that the team uses each night should be within an appropriate distance of the facility that will be visited the next day. It is the supervisor's responsibility to keep senior assessment staff updated on the team's schedule.

It may also be necessary to plan for courtesy meetings at the district or regional/provincial level to inform them about the survey. Courtesy visits to the subnational TB program office can be very helpful in securing facility staff cooperation and providing the data collection team with pertinent information (such as facility hours of operation, times when specific TB services are offered and when patients are likely to be visiting the facility, and the name and contact information of the in-charge). This information should still be asked in advance by contacting facilities because the subnational level may not have updates at a granular level, such as the days or hours of specific services.

The team leader/supervisor should confirm the appointment with the health facility before visiting it to ensure the availability of the TB provider(s) and patients on the day scheduled for data collection.

On arrival at each facility, the team should ask to see the facility in-charge. If the facility in-charge is not present on the day of the assessment, the QTSA team should request to see the acting in-charge.

The initial impression given to facility staff is important for gaining their willingness to cooperate with the assessment. The team should introduce the assessment and explain the purpose of the visit and the activities that the assessment entails. At this time, the introductory letters from the NTP/MOH and the letters explaining the purpose of the assessment and authorizing the team to visit the facility should also be given to the in-charge. The following is an example of an introduction on arrival:

Good day. My name is _____. My colleagues and I are conducting an assessment of the quality of TB services being provided at various facilities in [NAME OF COUNTRY AND DISTRICT]. We have received authorization from the Ministry of Health and the National TB Program to collect data from this facility on their behalf.

As a part of the assessment, we will interview TB service providers at this facility and TB patients who are at the facility today to assess their perception of the services they received.

We will ask questions about the types of TB services that are provided; medication, equipment, and supplies that are available; and staff training and competencies. We will also review TB registers to assess treatment and other outcomes.

The information collected from this facility will be aggregated with information collected from other facilities to give an overall picture of the quality of TB-related services in the country. In other words, information from any one specific facility, provider, or patient cannot be identified and will therefore remain confidential.

The purpose of this assessment is to provide general information to health planners and policymakers on the state of TB care and related services. The information will be used to develop the most appropriate quality improvement intervention for TB-related services in [NAME OF COUNTRY].

Do you have any questions? May we proceed? Thank you!

Facilities may be reluctant to participate if they fear that the assessment will result in negative findings, punitive measures, or if they believe that the assessment will interfere with service provision. Prior notification about the purpose of the assessment from the subnational level or the facility's managing authority helps pave the way for agreement to participate. Facilities may also be concerned about data confidentiality. It is therefore very important for the team leader/supervisor to explain that any reports or presentation of the findings of the QTSA contain only aggregate results (grouping facilities) so that the findings from any one facility (or responses from any one participant) remain confidential and will never be shared.

The data collection team members must treat facility staff with respect and politeness at all times.

If the facility in-charge refuses to allow the QTSA to proceed, the team leader/supervisor should contact the LRO and provide the name of the facility, its managing authority, and its location. Because the facilities included in the survey have been sampled using a statistically sound method, the LRO should make every effort to conduct the QTSA at the selected facilities and should contact appropriate people who can help understand and address the facility staff's concerns and reluctance to allow the data collection and interviews. However, if the facility still does not comply, the LRO should select a replacement facility using the replacement facility selection criteria.

It is a good idea to sample the replacement facilities at the same time that the study facilities are sampled. Pre-sampling the replacement facilities removes any bias in replacing facilities on the spot, respects the sampling protocol, and allows the data collection teams to be prepared to visit these facilities (i.e., have directions on to how to get to the replacement facility and a point of contact at the facility).

The team leader/supervisor is responsible for ensuring that data are collected from all the sampled facilities in the team's catchment area. If a facility is not accessible during the assessment period (e.g., the facility is closed, roads/bridges are closed or collapsed, facility is not found even after contacting multiple appropriate authorities/partners), or if it is unclear whether a facility is actually on the QTSA list, the team leader should contact the LRO to identify the appropriate replacement facility.

The team leader/supervisor should reassure the facility-in-charge that, other than some questions about the management of TB services, s/he can delegate responsibility for responding to the questionnaires to others at the facility who are specifically responsible for providing TB services.

After receiving permission to conduct the QTSA, the assessment team should discuss the following with the facility-in-charge to become familiar with the spatial organization of services and staff, and to plan efficient data collection:

- Where are TB and other TB-related service delivery areas (e.g., HIV) to be assessed in the QTSA located?
- Which appropriate staff member(s) can provide the needed information or data in a detailed manner?
- What is the typical flow of patients for the TB services at [time and day of the assessment]?
- Where are medications and supplies stored?
- Where is the laboratory located (if the facility has one)?
- Where are registers and records stored and where can the data managers be found?
- What are staff shifts and work patterns?

The team leader/supervisor should have informed the team members of their specific roles and responsibilities for that day at the start of the day. The team leader/supervisor can make adjustments to the plan, if required.

The typical organization of the data collection team is as follows:

- One data collector stays with the facility in-charge to complete the questions in the Facility Audit about the management of TB services and identifies the most appropriate staff person(s) to complete the rest of the questionnaire. This is usually the TB focal person but may include other staff responsible for the delivery of specific services (e.g., laboratory staff for lab-related questions), especially at larger facilities.
- A second data collector starts conducting the Provider Interview with any other TB service providers or starts the Patient Interview.
- Two data collectors work with the facility HMIS staff to complete the Register Review.

During data collection, the team leader/supervisor ensures accurate and smooth data collection, and performs spot checks to ensure the consistency, completeness, reliability, accuracy, and coherence of data. At the end of data collection, the team leader/supervisor checks the questionnaires for completeness, consistency of information among the tools, and resolves any missing/unreliable information before electronically submitting the forms to the LRO. Once the forms are submitted, the data undergo real-time automated checks for validity (e.g., checks to ensure that values are within the appropriate range, flagging of outliers). These alerts are sent directly to the LRO data manager, who can work with the team leader/supervisor to resolve any outstanding data issues.

Ideally, the preceding steps take place on the same day as data collection so that the team can resolve issues at the facility before leaving the area. In the event that a team submits forms with missing, incomplete, or inconsistent data, it will be required to return to the facility to complete data collection or rectify data issues.

In addition to the daily quality checks done during data collection, the LRO data manager reviews and cleans the data, as needed, after they are aggregated by the survey software. This process includes, for example, checking for outliers across all the survey tools, recoding missing data, or categorizing "other" or open-ended responses.

Phase III: Data Analysis and Validation

Data analysis generates quality of care indicators that policymakers, program managers, donors, and development partners can use to inform evidence-based decisions to improve the quality of TB services. Table 7 lists the key steps in data analysis and validation. This phase usually lasts one to two months.

Table 7. Phase III steps and activities

9		**Step 9: Analyze and validate data**
	9.1	Export the final data set for analysis (e.g., STATA)
	9.2	Conduct analyses according to the data analysis plan
	9.3	Conduct a data validation meeting with the steering committee to validate the data, interpret the results, and formulate recommendations

After the data set has been cleaned and finalized by the LRO, it is exported to an analysis package, such as STATA, SPSS, Microsoft Excel, or NVivo for analysis by the QTSA implementer. Module 4 and Appendix C provide more in-depth guidance on data analysis.

The data are analyzed following the analysis plan and with the study objectives and research questions in mind. The QTSA implementer conducts a complete analysis of the survey data to ensure that no important findings are overlooked.

The complete preliminary findings are presented to the NTP and the steering committee during a data validation meeting that is organized by the LRO. Results are presented using graphic formats, such as bar charts and pie charts, which can be easily viewed and understood. The meeting focuses on prioritizing and interpreting study findings, discussing key insights gleaned from the data, and the formulation of recommendations to include in the final technical report.

Phase IV: Report Writing and Dissemination of Results

The final phase of QTSA implementation consists of drafting and finalizing the QTSA report and the dissemination and use of survey results. This phase usually lasts two to three months.

Table 8 lists the key steps for finalizing the QTSA report and disseminating the results.

Table 8. Phase IV steps and activities

10		**Step 10: Produce and disseminate the final report**
	10.1	Complete the data analysis and draft the report
	10.2	Share the draft report with the steering committee for input
	10.3	Finalize the report
	10.4	Disseminate the study findings
	10.5	Document and archive the survey using metadata standards

Not all the analyses of assessment data should be included in the final report; rather, the report should focus on the results that are most important for supporting responsive interventions aimed at improving TB quality of care and patient health outcomes. A key objective of the data validation meeting in Phase III discussed above is to identify the key results for presentation in the final report. Moreover, the findings should be presented in a reader-friendly format that facilitates interpretation and supports decision making and action planning. Once drafted, the report is shared at least once with the NTP and the steering committee to get their input and insights.

Although the strategy for reporting the assessment results depends on the target audience, core information on many aspects of the assessment needs to be included in the report. A suggested report outline template is given in Module 4.

The clear communication of the findings is key to the successful implementation of actions needed to address gaps in service delivery identified by the QTSA. The assessment results are only useful if the findings are received in a timely manner by key stakeholders. Therefore, it is important to plan for dissemination activities from the initial stage of QTSA planning. Critical questions include identifying which stakeholders are responsible for the dissemination activities, the type of dissemination event best suited for different types of stakeholders, and how dissemination activities will be funded. One type of dissemination activity is a consultative meeting of key stakeholders involved in TB service delivery to present the main survey results and to discuss how the stakeholders can use them to inform their annual action plans to address gaps in the quality of TB care.

One of the last steps is to archive the survey data. The QTSA steering committee should be responsible for making decisions relevant to how assessment files should be archived. The practice that is recommended is to

use metadata[4] standards, which makes it easier to retrieve, use, and manage information such as the QTSA data set, with the following categories:

- Descriptive metadata—describes an information resource for identification and retrieval through such elements as title, author, and abstract.
- Structural metadata—documents relationships within and among objects through such elements as links to other components.
- Administrative metadata—helps manage information resources through such elements as version number, archiving date, and other technical information for the purposes of file management, rights management, and preservation.

[4] Metadata is a structured set of data that describes, summarizes, provides context, and gives basic information about other data. For example, information about the title, subject, author, typeface, enhancements, and size of the data file of a document constitutes metadata about that document. Metadata can also describe the conditions under which the data stored in a database were acquired; their accuracy; and the date, time, and method of compilation and processing.

Module 3. Guidelines for Sampling

Overview

An important aspect of the QTSA is the method used to select the sample of health facilities included in the survey, and the service providers and TB patients from whom data are collected. Unless sampling is done with some degree of scientific rigor, the QTSA findings could be misleading or not generalizable at the desired level.

Sampling

The primary objective of sampling is to obtain a representative subset of all health facilities providing TB-related services to ensure unbiased estimates of trends and patterns in the levels of service quality. If the sample is not representative, observed changes in quality of care indicators could be confounded by factors potentially related to differences in sampling procedures, if data collection is repeated in subsequent surveys. The QTSA uses a probability sampling method to guarantee that selected health facilities, providers, and patients are chosen randomly, ensuring that each eligible facility or participant has an equal chance of being included in the sample.

Facility Selection

The QTSA uses a dual-frame sampling method to select health facilities. This method consists of two samples: (1) a list frame of high-volume and other important TB facilities, such as those that provide specialized DR-TB services; and (2) an area (or geographic) frame for the remaining facilities not included in the list frame. The two frames produce a harmonized, comprehensive list of facilities for the QTSA, especially in countries where a MFL is not available.

It should be noted that dual-frame designs have several limitations. The first is the need for up-to-date information on the health facilities in the list frame. If a sizeable number of the facilities selected from the list have had a change in status that make them ineligible—for example, they are no longer providing TB services or a new facility providing TB services is not on the list—then the list frame is incomplete. A second disadvantage of using a list frame is that the facilities selected may be widely dispersed, increasing travel costs because of distances between facilities. Fortunately, facilities selected from the area (geographic) sampling frame will be clustered; thus, travel time and distance between facilities will be shorter.

The main steps of the selection procedure for the list frame and area frame follow.

List Frame Sample

- Compile a list of the high-volume and other important facilities in the system or program that provide TB services.
- Stratify the list by geographical location and information on patient volume (i.e., number of TB cases [all types] notified to the NTP the previous year) for each facility. This information is normally obtained from service statistics collected and reported by national surveillance systems.
- Select a sample from the list, either systematically or randomly, depending on the NTP's needs, and collect data from the selected facilities. Note that the NTP may be interested in including specific facilities providing specialized TB services, in addition to the sampled ones, in which case these facilities are considered to be purposively selected.
- In those facilities, further select a sample of patients and a sample of staff for interviews, either systematically or at random.

Area Frame Sample

- Compile a list of geographically defined areas that cover the entire system or program (e.g., census enumeration areas, regions, or provinces).
- Stratify the list by geographic location and information on patient volume (i.e., number of TB cases [all types] notified to the NTP the previous year) for each facility. This information is normally obtained from service statistics collected and reported by national surveillance systems.
- Select a systematic sample of these areas and conduct a quick inventory, or map facilities to identify service delivery points, excluding any that appear on the list frame.
- Conduct the survey at all facilities identified, except those that appear on the list frame.
- In the sample facilities, further select a sample of patients and a sample of staff for interviews.

Provider Selection

For the purposes of the QTSA, a TB provider delivering services on the day of data collection is interviewed from each selected facility. The staff member in charge of TB and TB-related services is also interviewed when there is more than one person delivering TB services. At small facilities, one or two staff members delivering TB-related services are asked to participate in the QTSA Provider Interview. At larger sites, four providers among those present on the day of data collection are randomly selected for participation in the provider interview. The selected provider(s) are excused or allowed to finish with or attend to any patients who may need their attention during the study.

Patient Selection

Interviews with TB patients are critical to obtain their perspectives on the quality of TB services. It is essential to collect information on the patients' perceptions of the care they received because quality of care is valued for its own sake and for its influence on subsequent service use and patient health-related behaviors, such as adherence to treatment. The interviewer or data collector selects a consecutive sample of two to five TB patients who are present at the facility on the day of data collection based on the inclusion and exclusion criteria that follow.

Inclusion Criteria

- Currently receiving TB treatment (regardless of whether they are in the intensive or continuation phase, whether they are receiving treatment for DS- or DR-TB, and whether this is their first episode of TB disease/treatment) and on treatment for at least two weeks and/or deemed not infectious. This includes patients who may have previously missed visits or had adherence problems as long as they are receiving TB treatment at the time of the assessment.
- Age 15 or older
- Pulmonary and extra-pulmonary TB patients
- MDR-TB patients should be interviewed when they have been on treatment for four weeks to eight months, or if they have a confirmed culture conversion.

Exclusion Criteria

- Having received less than two weeks of TB treatment
- Visiting the health facility for the first time
- Too weak, at the discretion of the data collector
- Refuse to be interviewed

- Younger than age 15
- Transferred-in TB cases

Calculating the Facility Sample Size

The following formula is commonly used to calculate the sample size:

$$n = \frac{Z^2 dq}{V^2 p}$$

n = sample size you wish to calculate

Z = critical value of 95% level of confidence in a normal distribution = 1.96

p = the expected proportion of facilities that meet the quality of care index threshold

q = 1-*p*

d = the design effect = 1.2

V = standard deviation of the sample proportion (*p*)

Margin of error = 5%

Confidence interval = $p \pm Vp$

As an example, here is how a sample of n=115 for a p=0.80 is derived and a standard deviation estimation V=10% by using the formula above.

$$n = \frac{1.96^2 \text{x } 1.2 \text{ x } 0.2}{0.1^2 \text{x } 0.8} = 115$$

Other sample size results were calculated considering a variety of p and standard deviation estimations V for a design effect d=1.2 (Table 9). Table 10 provides details about the elements of the formula.

Table 9. Sample size estimate based on the standard deviation of the sample proportion *p*

Value of item, *p*	V = standard deviation estimation		
	10%	15%	20%
	Sample size		
0.80	115	51	29
0.75	154	68	38
0.70	197	88	49
0.65	248	110	62
0.60	307	137	77
0.55	377	168	94
0.50	461	205	115

Table 10. Sampling variables definitions

Z	It is customary to use a 95% level of confidence in a normal distribution, for which the corresponding critical value of Z is 1.96. Thus Z^2=3.84.
Margin of error	The margin of error is the amount of random sampling error in a survey's results. For the QTSA, a margin of error of 5% is assumed and suggested to be used.
p	The QTSA estimates are mostly of the form "percent" (%) of *p* to select several facilities with attribute X. It is necessary to have some idea of the value of *p* to use the formula to calculate the sample size. The value of *p* used for the sample size calculation must be very accurate (otherwise there would be no need to conduct the survey), and it can be obtained from previous surveys conducted in the country, or from similar countries that conducted similar surveys.
d	The design effect is a value that reflects the ratio of sampling variances, where the numerator is the variance of the sample design being used for the specific facility survey, and the denominator is the variance that would result if a simple random sample of facilities with the identical sample size had been used. The design effect reflects the effects of stratification, stages of selection, and degree of clustering used in the facility survey. Generally, the clustering component—which is a measure of the degree to which two facilities in the same cluster have the same characteristic compared with two selected at random in the population of facilities—contributes the biggest effect. The interpretation of the design effect is that it shows how much more unreliable the sample is compared with a simple random sample of the same size. For example, if the design effect were 1.2, the facility sample would have sampling variance 20 percent greater than an alternative design using simple random sampling. If a different sampling strategy is used, then the design effect could be higher and can be adjusted accordingly. For example, a cluster sample is expected to have a higher value of design effect. If a country has information from a previous survey that suggests the value of the design effect, this value should also be used to calculate the sample size. For the blend of list frame and area frame sampling mentioned earlier, a value of d = 1.2 is recommended.

Calculating Sample Weights

Sample weights are applied in tabulations to adjust for differences in the probability of selection between units in a sample, resulting from either design or chance. The survey method implemented determines whether sample weights are needed and how to calculate them. If the allocation of the sample size is not proportional to the size of the subgroup, weights should be applied during analysis.

Because of the small number of higher-level health facilities in settings where the QTSA is likely to be implemented, such as large hospitals and referral or teaching hospitals, the sampling method for the survey may cover more high-level than lower-level facilities, resulting in an oversampling of high-level facilities. To correct for this effect and ensure a nationally and/or regionally representative sample, more lower-level facilities need to be sampled. The data should be weighted during analysis to account for oversampling and to ensure that the results reflect the actual distribution of facilities in the country.

Sample weights cannot be generated until after fieldwork is completed and the research team has the final list of facilities sampled. The following information is required to calculate the sample weights:

- Stratification variables used to partition the sampling frame (i.e., facilities stratified by region/province/state, facility type, patient volume, managing authority)
- Number of facilities in the sampling frame (i.e., total number of facilities in the country), by stratum
- Number of facilities in the selected sample, by stratum

To calculate the sample weights, begin by creating a table with columns, as shown in Table 11.

Table 11. Sample weight calculations: Table layout

A	B	C	D	E	F
Stratification Variable 1	Stratification Variable 2	Stratification Variable 3	Number of facilities in the sampling frame	Number of facilities in the sample	Weight

Use the information from the study protocol to complete columns A–E. For example, the sampling procedure of stratifying the study area by region/province, management (public, private, etc.), and facility type would be completed as follows: the regions/provinces are displayed in Column A, managing authority in column B, and facility types in Column C. The number of facilities in the sampling frame that correspond to the specified strata appear in Column D, and the number of facilities in the sample that correspond to the specified strata appear in Column E. Column F, the sampling weight, is the inverse of the probability of selection of the sample units by stratum, and is calculated as Column D/Column E or the number of facilities in the sampling frame divided by the number of facilities in the sample.

Table 12 provides sample data for a QTSA implemented in Country X. Facilities in the sampling frame are stratified by region and facility type. There are four regions in the country (coded 1–4), two managing authorities (coded 1–2), and three facility types (coded 1–3). If the sample design has only two stratifications, then Column C will be empty and can be deleted. If there are four or more stratification variables, additional columns after Column C would be required.

After the weights have been calculated, they are added to the final data set. The stratum that each facility belongs to is then determined and the appropriate weight is assigned. For example, using the weights calculated in Table 12, if a site is a primary health facility in the northwest region and is managed by the public sector, it would be assigned a weight of 3.71. A public sector secondary health facility in the southwest region would be assigned a weight of 17.26. To compare result analysis among the regions, the weight for the type of facility is applied, enabling the values of the indicators to reflect the share of the actual population. This step addresses the disproportionate sampling used in the selection by type of facility according to each region.

Table 12. Sample weight calculations: Sample data

A	B	C	D	E	F
Stratification Variable 1 (region)	Stratification Variable 2 (managing authority)	Stratification Variable 3 (type of facility)	Number of facilities in the sampling frame	Number of facilities in the sample	Weight (Column D/Column E)
Northeast	Public	Tertiary	2	2	1.00
		Secondary	34	8	4.25
		Primary	123	33	3.73
	Private	Tertiary	1	1	1.00
		Secondary	15	4	3.75
		Primary	45	13	3.46
Northwest	Public	Tertiary	4	2	2.00
		Secondary	54	18	3.00
		Primary	178	48	3.71
	Private	Tertiary	0	0	0
		Secondary	32	8	4.00
		Primary	89	21	4.24
Southeast	Public	Tertiary	6	4	1.5
		Secondary	415	57	7.28
		Primary	745	73	10.21
	Private	Tertiary	2	2	1.00
		Secondary	324	54	6.00
		Primary	405	56	7.23
Southwest	Public	Tertiary	14	4	3.5
		Secondary	1346	78	17.26
		Primary	1789	89	20.10
	Private	Tertiary	5	3	1.67
		Secondary	546	63	8.67
		Primary	345	54	6.39

Module 4. Data Analysis and Presentation of Results

Overview

The QTSA data analysis phase generates quality of care indicators that support evidence-based decisions to guide policymakers, donors, program managers, and development partners. The analysis focuses on key indicators for each component of the QTSA conceptual framework (i.e., structure, process, and outcome). These indicators are important for setting future goals and targets and enable a certain level of comparability between assessments from different countries and time periods. The indicators also place a focus on predetermined areas of the survey that are deemed most useful, relevant, and important to understanding current TB service delivery. Having a consistent indicator set also contributes to standardized analytical reporting.

This module provides guidance on presenting the QTSA results. The data analysis plan is directly linked to the list of QTSA indicators (Table 1) and is designed as a guide to presenting the results to various audiences.

QTSA Data Analysis Plan

The data analysis plan is a roadmap for organizing and analyzing data. The plan helps researchers think through the data collected, the types of analyses that are needed, and how the data will be used and presented. Preparing a data analysis plan is important for ensuring that all data analysis needs are addressed and to maximize the use of data for decision making.

The QTSA data analysis plan has the following elements:

- Summary information, including the name of the country, year(s), and duration of the assessment; type of study (i.e., cross-sectional); specific time period investigated in the QTSA Register Review; any other relevant contextual information about the country; and the names of the investigators and team members.
- The study overview/background, including a summary of what is already known about TB quality of care in the country context; study objectives and research questions; and the tools to be used during data collection. The standard QTSA tools are the Facility Audit, Provider Interview, Patient Interview, and Register Review.
- A detailed description of the sampling method/criteria applied for selecting facilities, providers, and patients. (The sampling method should follow the structure described in Module 3 of this guide.)
- A description of the study population, including the analysis per type of facility (public and private), facility location, TB care providers, and TB patients ages 15 years and older. (See the inclusion and exclusion criteria for sampling patients provided in Module 3 of this guide.)
- A description of the analytical strategy, including variables of interest, how to address missing data, analysis package(s), and types of analysis proposed.
- A list of ways in which the data will be presented, including "dummy" tables, charts, and graphs.
- A description of the dissemination strategy.
- An interpretation section detailing how the results will be interpreted in the context of the assessment objectives, and plausible assumptions or recommendations of what follow-up actions should be taken.

A QTSA data analysis outline/template is given in Appendix C showing how the QTSA analysis can be structured. A sample of dummy tables is provided in Appendix D. These tables can be used to present the data/results and for the QTSA technical report.

QTSA Technical Report

The survey findings are presented in an easy-to-understand format that facilitates interpretation and decision making. Not all analyses performed during the assessment should be included in the final report. Rather, the report should focus on the most important and relevant results that will support responsive interventions aimed at improving patient health outcomes, as defined by the NTP and other members of the steering committee during the data validation meeting. The survey results should be accessible and comprehensible to a range of different stakeholders and TB program implementers who can use the QTSA findings to improve the quality of care across all levels of TB services.

A recommended structure and core information for presentation in the QTSA technical report are provided in the outline below. (Bracketed phrases—[ ]—indicate additional notes on details needed in a given section.)

Report Outline Template

- Title
- Acknowledgments
- Contents
- Abbreviations
- Executive Summary
    - Introduction
    - Methods
    - Results
        - Structural Factors
        - Processes
        - TB Outcomes
    - Key Findings and Recommendations
- Introduction
    - Background of the Study
    - Rationale or Justification
    - Literature Review of Quality of Care with a Focus on TB [global, regional, and country levels]
    - Overview of TB Care and Prevention in [country name]
    - Study Objectives
    - Study Area
- Methods
    - Profile of the Country and Study Area
    - Study Design and Conceptual Framework
    - Sampling Procedures
        - Health Facilities
        - Service Providers
        - TB Patients

    - Data Collection and Instruments
        - Adaptation of the Standard Tools [approach and process of adaptation]
        - Recruitment of the Data Collectors and Research Assistants
        - Training
        - Fieldwork
        - Quality Assurance and Data Quality Check
    - Data Analysis [type of analysis—i.e., descriptive or analytical]
    - Ethical Review
- Results
    - Sample Characteristics [facility, provider, and patient]
    - Structural Indicators
        - Availability of TB Services
        - Infrastructure
        - Capacity of TB Providers
        - Management of TB Services
    - Process Indicators
        - TB Case Management
        - Patient's Knowledge about TB
        - Barriers to TB Care
        - Stigma and Discrimination
        - Patient Satisfaction
        - Patient-Provider Interaction
    - Outcome Indicators
        - TB Cascade of Care
        - TB Service Outcomes
- Discussion
    - Key Findings and Their Significance in the Context of What Is Known and Existing Literature
    - Study Challenges
    - Study Limitations
- Key Findings and Recommendations
    - Structure
    - Process
    - Outcomes
- Conclusion
- References
- Appendices

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Appendix A. Tips for Editing the QTSA Tools

Editing the Structure of the Questionnaire

The QTSA tools are available in an electronic format; therefore, any edits to the paper versions should be transferred to the electronic tool. When editing the tools, it is important to maintain the structure of the questionnaire. Edits should be made as follows:

- **Adding a question**: Country-specific questions about NTP guidelines on TB screening, diagnosis, treatment, and infection control measures can be added to the questionnaire. The best way to number a new question is to give it a unique number that appears in the right sequence. For example, if a new question is added between question 7.2.3 and 7.2.4, it could be numbered 7.2.3.1. This will allow assessors to easily locate the question in the tool if they need to return to it during data cleaning or analysis.
- **Deleting a question**: Certain questions may not be relevant or applicable to a country. In this case, a question can be deleted. For example, if a specific diagnosis method, such as lateral flow urine lipoarabinomannan assay, is not part of the NTP algorithm, questions on this topic can be deleted. Such items should be removed from the questionnaire and their question numbers deleted. The question number should not be reused or reassigned to a new question (to avoid issues during data analysis) unless the initially deleted question is reinserted. Deletion of questions should be kept to a minimum because the QTSA aims to measure quality based on a standard set of indicators for which data elements are included in the tools. Deleting too many questions will change the measurement's parameters.
- **Changing a question's text**: Question text should not be replaced by another question text. If needed, clarification can be added in parentheses to help the respondent understand the question. It is important to keep each question with its original numbering. Questions can be added or deleted, but the content of existing questions cannot be changed.
- **Skip patterns:** Any addition or deletion affecting a skip pattern in the questionnaire should be updated accordingly.

Important Tips

- **Do not change the numbering**: Retain the original numbering structure of the standard questionnaire. Changing the numbering will affect links to existing tools for processing data and producing results.
- The goal of the QTSA is to *measure quality of care based on key indicators* that measure standards and adherence to protocols or guidelines for TB screening, diagnosis, treatment, and follow-up that providers implement during service delivery. It is important **not to stray from the QTSA concept** by adding a long list of additional items. (The QTSA is not meant to be a census of all items that should be present in a facility.)
- It is also important to remember that **adding more to the tool will affect** training, data collection, and data analysis. Any question added should also be considered in terms of the analysis outputs. Before a question is added, it should first be added to the analysis plan so that it is clear how it will be used in the analysis.

Appendix B. QTSA Key Data Collection Phase Documents

Checklist of Items to Bring to the Facility

Each team should have the following supplies and equipment in its possession for every facility visit:

- ☐ Pencil and pen. A pencil is useful if you need to make any markings in any of the registers.
- ☐ Notepad or notebook. Especially important for tallying counts for the Register Review, and making any other notes and/or observations about the facility.
- ☐ Calculator. Crucial tool for the Register Review. Always double-check counts.
- ☐ The list of all facilities that a given QTSA team is charged with assessing. This list should include the names and phone numbers of the points of contact at each facility selected as part of the assessment, and the names and contact information of contact(s) at the district/regional/provincial office(s) to which the facilities belong. If assessing private facilities, each team should have the name and contact information of someone from the local managing authority office. This list should also contain any replacement facilities.
- ☐ The fieldwork schedule. This document should include a multi-week daily schedule for the QTSA team, specifying which facilities are visited each day, and where the team will be lodged. If hotel reservations are made in advance, the hotel address/location and phone number should be included in the schedule.
- ☐ The contact list. The list should include the name, role, and phone number of every person involved in the assessment (lead investigators and supervisors, team leaders, data collectors, drivers, etc.)
- ☐ Letter of introduction (on official letterhead and signed by the MOH, NTP, or another managing authority of the facility): see the example on page 33.
- ☐ Charged tablets. Bring a charger as well, just in case.
- ☐ Paper QTSA tools (in English and in local languages), just in case a tablet malfunctions or a respondent is uncomfortable with the use of a tablet. The QTSA standard tools are available at the following link: https://www.tbdiah.org/resources/publications/quality-of-tuberculosis-services-assessment-global-tools/
- ☐ Each different type of consent and assent form (in English and in local languages) in multiple copies. The QTSA standard consent and assent forms are available at the following link: https://www.tbdiah.org/resources/publications/quality-of-tuberculosis-services-assessment-global-tools/
- ☐ QTSA training manual and other training materials, to be used as reference documents, if the need arises.
- ☐ Cash in local currency. It will be used to compensate patients and/or providers (as agreed with the MOH/NTP, LRO, or local IRB) for their time, or to reimburse them for their transportation expenses. Make sure that you have enough change to give respondents the correct amount without needing to ask for change.

Appendix C. QTSA Analysis Plan Outline

- Study profile: country; investigators; year(s) of the study; who performed the analysis
- Study overview/background: include evidence of what is already known about TB quality of care
- Study objectives
- Number of cases/participants (estimated based on sampling design):
  - Number of facilities, providers, patients, and registers to review
  - Register review: 10 key indicators chosen from Table 1
- Duration of the study
- Study research questions
- Outcomes of interest: quality of care, patient satisfaction, provider's competencies
- Study type
- Description of the sampling
- Tools used: QTSA Facility Audit, QTSA Provider Interview, QTSA Patient Interview, and QTSA Register Review
- Analysis package
- Study population
- Variables, including outcome measures:
  - QTSA Facility Audit: facility attributes, infection control measures, service availability, training, diagnosis capacity, turnaround time, waiting time, etc.
  - QTSA Provider Interview: characteristics, competencies, etc.
  - QTSA Patient Interview: patient satisfaction, TB knowledge, etc.
  - QTSA Register Review: diagnosis and treatment outcomes of specified cohorts of patients who have completed treatment
- Addressing missing data
- Analytical strategy: descriptive and analytical
- Data presentation: a combination of tables, charts, and graphs used to present the results in a reader-friendly format
- Analysis dissemination strategy
- Interpretation

Appendix D. Sample of Dummy Tables

Profile of Facilities, Providers, and Patients

Table D1. Percent distribution of the sampled facilities according to the selected characteristics

Characteristics	Frequency	Percent
Overall number of facilities (N)		
Type of facility Type 1 Type 2 Type 3		
Managing authority Public Private		
Locality of facilities Urban Peri-urban Rural		
TB services Outpatient Both inpatient and outpatient		

Table D2. Percent distribution of the sampled providers according to the selected characteristics

Characteristics	Frequency	Percent
Health facility type		
Highest schooling reached to become practicing health worker		
Current occupational category at the facility		
Type of work performed at the facility (select all that apply)		
Performing TB-related services as part of current job schedule		

Table D3. Percent distribution of the sampled patients according to the selected characteristics

Patient characteristics	Frequency	Percent
Sex		
Female		
Male		
Age		
15–24 years		
25–34 years		
35–44 years		
45 years and above		
Highest level of education completed		
None		
Primary		
Secondary		
Postsecondary		
Place of residence		
Urban		
Peri-urban		
Rural		
Work status		
Working		
Not working		

Availability of Services

Table D4. Percentage of facilities in the sample providing TB diagnosis services, by facility type and managing authority

Type of TB diagnosis services	Total	Type of facility			Managing authority	
		Type 1	Type 2	Type 3	Public	Private
Providing screening and diagnosis services						
Providing screening and diagnosis for children (pediatrics)						
Providing care and treatment						
Providing care and treatment for children						
Onsite laboratory for TB diagnosis						

Table D5. Percentage of facilities offering TB diagnosis services or any treatment and/or treatment follow-up services, by type of facility and managing authority

TB services	Total	Type of facility			Managing authority	
		Type 1	Type 2	Type 3	Public	Private
Screening and referral for TB diagnosis*						
Any TB diagnosis services**						
Diagnosis of TB by clinical symptoms and signs						
Perform X-ray for TB diagnosis						
Diagnosis of TB by conventional X-ray						
Diagnosis of TB by computer-assisted digital X-ray (CAD4TB)						
Are patients charged a fee for diagnostic X-rays?						
Diagnosis of TB by smear microscopy						
Diagnosis of TB by culture						
Diagnosis of TB by GeneXpert						
Any TB treatment and/or treatment follow-up services						
Any TB diagnosis, treatment, and/or treatment follow-up services						

* Facility reports that it refers patients outside the facility for TB diagnosis, and there is documentation on the day of the assessment to support this assertion.

** Facility reports that providers in the facility make a diagnosis of TB by using any of the following methods: diagnosis of TB by clinical symptoms and signs; perform X-ray for TB diagnosis; diagnosis of TB by conventional X-ray; diagnosis of TB by computer-assisted digital X-ray (CAD4TB); diagnosis of TB by smear microscopy; diagnosis of TB by GeneXpert.

OR

The facility reports that it refers patients outside the facility for TB diagnosis, and a register was observed that indicates that patients were referred for TB diagnosis.

Availability of Guidelines and Protocols

Table D6. Availability of guidelines and protocols among facilities that offer any TB services and the percentage of facilities with TB guidelines, by facility type and managing authority

TB guidelines	Total	Type of facility			Managing authority	
		Type 1	Type 2	Type 3	Public	Private
Diagnosis and treatment of TB						
Diagnosis and treatment of MDR-TB						
Management of HIV/TB coinfection						
TB infection control						

TB Diagnosis Capacity

Table D7. Among facilities that offer any TB diagnosis, treatment, and/or treatment follow-up services, the percentage that have TB diagnosis capacity, by facility type and managing authority

Type of TB diagnosis service	Total	Type of facility			Managing authority	
		Type 1	Type 2	Type 3	Public	Private
TB smear microscopy*						
Culture medium**						
Xpert MTB/RIF (Gene Xpert)						
TB X-ray						

* Functioning microscope, slides, and all stains for Ziehl-Neelson test (carbol-fuchsin, sulfuric acid, and methylene blue) were available at the facility on the day of the assessment.

** Solid or liquid culture medium (e.g., MGIT 960).

Table D8. Availability of basic diagnosis equipment at facilities with capacity for carrying out TB diagnosis onsite

Items/equipment (observed)	Total	Type of facility					
		Type 1		Type 2		Type 3	
		Frequency	Percent	Frequency	Percent	Frequency	Percent

Table D9. Among facilities that offer any TB diagnosis, treatment, and/or treatment follow-up services, the percentage that have HIV diagnosis capacity, by facility type and managing authority

Type of TB diagnosis service	Total	Type of facility			Managing authority	
		Type 1	Type 2	Type 3	Public	Private

Availability of Medicines for TB Treatment

Table D10. Among facilities that offer any TB diagnosis, treatment, and/or treatment follow-up services, the percentage that have medicines for TB treatment available at the facility on the day of the assessment, by facility type and managing authority

Drugs/medications	Total	Type of facility			Managing authority	
		Type 1	Type 2	Type 3	Public	Private
Isoniazid 100 mg						
Isoniazid 300 mg						
Pyrazinamide						
Ethambutol 100 mg						
Ethambutol 400 mg						
Isoniazid + rifampicin (2FDC) 150/75 mg (adult formulation)						
Isoniazid + rifampicin (2FDC) 75/50 mg						
Isoniazid + rifampicin + pyrazinamide (RHZ) (3FDC) 75/50/150 mg						
Isoniazid + rifampicin + pyrazinamide + ethambutol (4FDC) 150/75/400/275 mg*						
3HP (rifapentine and INH)						

* Four-drug fixed-dose combination (4FDC) available, or isoniazid, pyrazinamide, rifampicin, and ethambutol are available, or a combination of these medicines, to provide first-line treatment.

Staff Training: Availability of Trained Staff for TB Services

Table D11. Among all facilities, the percentage with at least one staff member recently trained in TB services, by managing authority

Training	Managing authority			
	Public		Private	
	Frequency	Percent	Frequency	Percent
Screening algorithm for TB				
Screening or diagnosis of TB based on X-rays				
Diagnosis of TB based on clinical symptoms or examination (for adults)				
Diagnosis of TB based on sputum tests using smear microscopy				
Diagnosis of TB based on sputum tests using culture				
Diagnosis of TB using GeneXpert				
Prescription of drugs for TB treatment				
Management of DS-TB treatment				
Identification of presumptive DR-TB				
Management of DR-TB treatment				
Management of TB/HIV coinfection				
TB infection control				

Note: At least one interviewed provider reported receiving in-service training on any one of the following TB services during the 24 months preceding the survey: TB diagnosis and treatment, management of HIV and TB coinfection, MDR-TB treatment, identification of presumptive DR-TB, TB infection control, etc. The training should have had structured sessions, and does not include individual instruction that a provider may have received during routine supervision.

Linkages with Other Services and Community

Table D12. Linkages with other services and the community

TB services provided by community health workers	Frequency	Percent
Facility delivers TB services via community health workers		
Types of TB services community health workers provide	Frequency	Percent
Referral for screening and diagnosis		
Adherence counseling		
Trace or locate patients who miss follow-up visits		
Referral for treatment		
TB preventive education		
Phone calls to TB patients (e.g., appointment missed, to schedule a home visit)		
Emotional or social support		
HIV counseling and testing		
Directly observed treatment, short course (DOTS)		
SMS text reminders to support patients' adherence to medications and treatment		

Standard Precautions for Infection Control

Table D13. Percentage of facilities with sterilization equipment somewhere (especially in the examination area) in the facility, and other items for standard precautions available in the general outpatient area or TB unit of the facility on the day of the assessment, by facility type and managing authority

Items	Total	Type of facility			Managing authority	
		Type 1	Type 2	Type 3	Public	Private

Infection Prevention Control Measure for TB Care

Table D14. Implementation of managerial/administrative, environmental, and personal protection infection control measures at selected facilities, by facility type

Infection prevention and control practices	Type of facility					
	Type 1		Type 2		Type 3	
Administrative/managerial	Frequency	%	Frequency	%	Frequency	%
Environmental	Frequency	%	Frequency	%	Frequency	%
Personal protection	Frequency	%	Frequency	%	Frequency	%

Table D15. Implementation of managerial/administrative, environmental, and personal protection infection control measures, by managing authority

Infection prevention and control practices	Managing authority			
	Public		Private	
Administrative/managerial	Frequency	Percent	Frequency	Percent
Environmental	Frequency	Percent	Frequency	Percent
Personal protection	Frequency	Percent	Frequency	Percent

Table D16. Percentage of facilities with availability of equipment to support quality patient care on the day of the assessment, by managing authority

Basic equipment	Managing authority			
	Public		Private	
	Frequency	Percent	Frequency	Percent

Level of TB Awareness among Patients

Table D17. Level of TB awareness reported by patients, by managing authority

Level of TB awareness	Managing authority			
	Public		Private	
	Frequency	Percent	Frequency	Percent
Patients' knowledge and awareness of TB symptoms and signs	Frequency	Percent	Frequency	Percent
Patients' knowledge of causes and spread of TB from one person to another	Frequency	Percent	Frequency	Percent
Factors that put people at risk of getting TB	Frequency	Percent	Frequency	Percent

Patient-Provider Interaction/Communication

Table D18. Patient-provider interaction and communication on preventing TB transmission

Patient-provider interaction/communication	Provider		Patient	
Communication about TB transmission	Number	Percent	Number	Percent

Barriers to Care

Table D19. Patient-reported barriers and stigma experienced in accessing TB care

Barriers and stigma experienced in accessing TB care	Number	Percent
Patients reported the following barriers to accessing TB care		
Patients reported experiencing stigma in the following ways at TB facilities		

Supervision and Feedback Practices

Table D20. Activities conducted during supervisory visit, by facility type and managing authority

Activity type	Total	Type of facility			Managing authority	
		Type 1	Type 2	Type 3	Public	Private
Assess the pharmacy (e.g., drug stockouts, expirations, records)						
Assess TB data (e.g., completeness, quality, and/or timely reporting of registers, treatment cards, quarterly or monthly reports)						
Discuss the performance of the facility based on TB service data						
Complete the supervisory checklist						
Provide a record of written comments or suggestions from their visits						

Composite Measures of Knowledge, Practices, and Attitudes

Applying principal component analysis to derive composite measures (index grouped in three categories: low, medium, and high) for knowledge and practices of infection prevention and control and attitudes toward healthcare providers.

Table D21. Percent distribution of level of knowledge of infection prevention and control, by facility type and managing authority

	Level of knowledge		
	Low	Medium	High
Type of facility Type 1 Type 2 Type 3			
Managing authority Public Private			

Table D22. Percent distribution of level of practice of infection prevention and control, by facility type and managing authority

	Level of practice		
	Low	Medium	High
Type of facility Type 1 Type 2 Type 3			
Managing authority Public Private			

Table D23. Percent distribution of attitudes toward healthcare providers, by facility type and managing authority

	Attitude		
	Negative	Neutral	Positive
Type of facility Type 1 Type 2 Type 3			
Managing authority Public Private			

Table D24. Percent distribution of level of knowledge, by demographic factors

	Level of knowledge		
	Low	Medium	High
Sex Male Female			
Age category			
Education			
Health worker cadre			

Table D25. Percent distribution of level of practice, by demographic factors

	Level of practice		
	Low	Medium	High
Sex Male Female			
Age category			
Education			
Health worker cadre			

Table D26. Percent distribution of level of attitude toward healthcare providers, by demographic factors

	Level of attitude		
	Negative	Neutral	Positive
Sex Male Female			
Age category			
Education			
Health worker cadre			

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