Consolidated guidance on tuberculosis data generation and use
Module 1

Tuberculosis surveillance

World Health Organization

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Contents

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Abbreviations

ART	antiretroviral therapy
BCG	bacille Calmette–Guérin
CDC	centre for disease control
COVID-19	coronavirus disease 2019
CRVS	civil registration and vital statistics
DAK	digital adaptation kit
DHIS2	District Health Information System
DR-TB	drug-resistant tuberculosis
DST	drug susceptibility testing
DS-TB	drug-susceptible tuberculosis
HIV/AIDS	human immunodeficiency virus/acquired immunodeficiency syndrome
HIS	health information system
Hr-TB	isoniazid-resistant rifampicin-susceptible tuberculosis
ID	identification (number)
IT	information technology
MDR-TB	multidrug-resistant tuberculosis
NTP	national tuberculosis programme
Pre-XDR-TB	pre-extensively drug-resistant tuberculosis
RR-TB	rifampicin-resistant tuberculosis
SOP	standard operating procedure
TB	tuberculosis
TPT	tuberculosis preventive treatment
QA	quality assurance
UN	United Nations
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

Chapter 1
Introduction

In 1993, the World Health Organization (WHO) declared that tuberculosis (TB) was a global health emergency. TB was described as one of the most neglected health crises and "out of control" in many parts of the world. The following year, WHO provided recommendations for a new approach to TB control *(1)*. This was subsequently branded as the DOTS strategy and had five key components, one of which was the establishment and maintenance of a national monitoring system for standardized recording and regular reporting of data about people diagnosed with TB and their treatment outcomes.[1]

In 1995, WHO provided standardized case definitions for TB, standardized definitions of treatment outcomes for people diagnosed with TB, and standardized forms and registers for recording and reporting of individual-level and aggregated data, which were subsequently reviewed and updated in 2006 *(2)* and 2013 *(3)*.[2] In combination, these have ensured a standardized approach to national, regional and global surveillance of the number and key characteristics of people diagnosed and treated for TB, and their treatment outcomes, since 1995. At global level, WHO has collected data every year since 1997 and published them in an annual global TB report.[3]

Ten years on from the last comprehensive review and updating of WHO global guidance on TB surveillance, a new edition is required. The major reasons are:

- Previous guidance was developed in the context of the WHO Stop TB Strategy (2006–2015) *(4)*. This has been succeeded by the WHO End TB Strategy, which covers the period 2016–2035 *(5)*.
- There are updated WHO guidelines on TB diagnosis, treatment and prevention *(6–10)*.
- There has been considerable expansion in the use of case-based digital TB surveillance, replacing more traditional paper-based surveillance systems.[4]
- WHO case definitions for people with drug-resistant TB and definitions of treatment outcomes for people diagnosed with TB were updated in 2020 *(11)*.
- There is growing demand for more timely reporting of data, which intensified during the COVID-19 pandemic.
- More than 100 national TB epidemiological reviews that included assessments of TB surveillance have been implemented since 2013, providing a wealth of experience and lessons learned.

The goal of this new 2024 edition of guidance on TB surveillance is to ensure the continued worldwide standardization of TB surveillance, in the context of the WHO End TB Strategy and the latest WHO guidelines on TB diagnosis, treatment and prevention, while also promoting the use of digital case-based TB surveillance. The guidance is structured in six main chapters:

- **Purpose, principles and scope.** This describes the overall purpose of TB surveillance, defines the principles that underpin the guidance provided in subsequent chapters, and delineates the scope of the guidance (what is and is not covered).
- **Definitions**. All of the key terms used in the guidance are defined, separated into those terms that relate to the pathway of care for people with TB disease or infection and those that relate to the data generated by the system. For convenience, the main changes in terminology introduced in this guidance (relative to 2013) are summarized at the beginning.
- **Core indicators to report and use.** This defines and explains a core set of TB surveillance indicators to report and use, according to three frequencies: weekly/monthly, quarterly and annual. A minimum core set of indicators, which is applicable to both paper-based and case-based digital systems, is presented for all countries. Additional disaggregations and additional indicators that could be considered for reporting and use in countries with a case-based digital surveillance system are also listed.

[1] The other four components were: political commitment; diagnosis by quality-assured sputum smear microscopy; standardized short-course chemotherapy with direct observation of treatment (DOT); a regular and uninterrupted supply of high-quality anti-TB drugs. The recommended frequency for the reporting of data was "preferably quarterly".

[2] Minor revisions to the guidance issued in 2013 were published in 2014 and 2020.

[3] All reports published since 1997 are available here: https://www.who.int/teams/global-tuberculosis-programme/tb-reports.

[4] Previous WHO guidance consists primarily of a standard set of templates for paper-based forms and registers.

- **Core data items to collect.** This defines the variables for which data need to be collected so that the core indicators can be calculated. It includes a detailed specification of how each data item can be named, categorised and recorded in either a digital or paper-based system.
- **Digital surveillance.** This highlights the main advantages of case-based digital surveillance of TB and describes WHO products and tools that are available to support countries to establish, sustain and strengthen such systems.
- **Data quality assurance.** This describes a recommended set of routine quality assurance processes and procedures that should be implemented to ensure that surveillance data are of high quality. Case studies to illustrate good practices are provided.

The guidance is accompanied by six web annexes.

Web Annex A describes commonly observed problems in TB surveillance and associated solutions.

Web Annex B is the second edition of the WHO TB surveillance checklist of standards and benchmarks.[1]

Web Annex C provides guidance on how to conduct record-linkage studies, both to deduplicate notification data and to measure underreporting of people diagnosed with TB.

Web Annex D provides templates for quarterly and annual reporting of core data items, for countries that continue to rely on a paper-based system of aggregated reporting, along with formulae that can be used to calculate core indicators in both paper-based and digital systems.

Web Annex E provides illustrative scenarios related to the reporting of people diagnosed with TB, and their treatment initiation and treatment outcomes.

Web Annex F synthesizes findings from an evaluation of digital, case-based surveillance for TB using DHIS2 software in five countries.

This guidance is intended for everyone involved in the collection, management, reporting, analysis and use of TB surveillance data.

The methods used to develop the guidance are summarized in Box 1.

Box 1.1 Methods used for content development

The guidance was built on the foundation provided by the "Definitions and reporting framework" published by WHO in 2013 *(2)*. Updates, additions and other changes compared with this framework were based on:

- the WHO End TB Strategy *(5)*;
- the latest WHO clinical guidelines on TB diagnosis, treatment and prevention *(6–10)*;
- the latest WHO case definitions for people with drug-resistant TB and definitions of treatment outcomes for people diagnosed with TB *(11)*;
- a global synthesis of 100 national TB epidemiological reviews implemented between 2013 and 2021; and
- discussions and engagement with a wide network of national TB programmes, subject-matter experts and stakeholders.

The core team that developed and finalized the guidance comprised technical staff from the WHO Global Tuberculosis Programme and WHO regional offices. Consensus on the final content was achieved through a 2-year consultative and iterative review process.

[1] The first edition was published in 2014 *(12)*.

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Chapter 2
Purpose, principles and scope

This chapter provides the overall context for the rest of the guidance. It explains the purpose of TB surveillance, the principles that underpin the guidance provided in chapters 3–7, and the scope of the guidance (what is and is not included).

2.1 Purpose

TB surveillance can be described as the **systematic and continuous collection, analysis, reporting and use of data related to TB infection and disease in the population**. These data comprise demographic and diagnostic information about people screened and tested for TB disease or TB infection, as well as information about the management of those diagnosed with TB infection and disease, i.e. data on the treatment provided and treatment outcomes.

National TB surveillance systems of high quality are essential for:

- **reliable monitoring of TB epidemics** at global, regional, national and subnational levels in terms of the number of new cases (TB incidence)[1] in the population, and how this varies over time and according to characteristics such as age, sex and geographical location;
- **assessment of progress towards national, regional and global targets** for reductions in TB disease burden and provision of TB treatment, prevention and care services, including those set in national, regional and global TB strategies and political declarations adopted by all WHO or UN Member States;
- **assessment of the performance of TB services** (e.g. quality, coverage, effectiveness of interventions) along the full pathway of screening, diagnosis and treatment for TB infection and TB disease; and
- **informing the planning, budgeting, policy, programmatic and clinical actions** necessary to ensure high-quality and coverage of TB prevention and care services, including timely action in response to disease outbreaks.

[1] The prevalence of TB disease and infection is measured using cross-sectional population-based surveys.

2.2 Principles

The guidance in this document is underpinned by six principles.

1. **TB surveillance should be based on clear, comprehensive and standardized definitions**

Use of standardized definitions is necessary to ensure collection and reporting of consistent and comparable data both within and across countries, and over time.

Chapter 3 provides definitions related to TB cases, treatment (including preventive) and treatment outcomes, as well as definitions of terms relating to the surveillance system and the data it generates. The main changes in terminology compared with previous guidance issued in 2013 *(1)* are summarized at the beginning.

2. **TB surveillance should be limited to collection and reporting of data that will be used and that address specific predefined objectives**

It is important to only collect data that will be used. This is to avoid TB surveillance becoming overly complex, time consuming, resource intensive and resource wasting. Systematic and continuous collection of data for unnecessary variables also risks compromising the quality of data used for core indicators. To justify their collection, data should fulfil at least one of the purposes of surveillance described in Section 2.1.

Chapter 4 provides guidance on core indicators to be systematically reported and used in all countries. It also provides guidance on additional disaggregations of indicators as well as additional indicators that could be considered in countries with case-based digital surveillance systems.

Chapter 5 provides guidance on the core data items that need to be collected so that the core indicators can be calculated.

3. **Guidance on TB surveillance should be applicable to both case-based digital and more traditional paper-based systems, while promoting the transition to case-based digital surveillance**

Previous WHO guidance consisted largely of standardized templates for paper-based forms that could be

used (with country-specific adaptation) to record and report TB surveillance data *(1, 2)*.

This 2023 edition adopts a different approach. Chapter 4 identifies the core indicators for which data need to be reported and used, which are applicable to both digital and paper-based systems. Chapter 5 defines the core data items that need to be recorded and reported, which are the same irrespective of whether a digital or a paper-based system is used.[1]

A benefit of this approach is that it is better suited to the needs of those countries that have already adopted case-based digital systems for TB surveillance, while also facilitating the transition to case-based digital systems in countries that currently rely on paper-based systems.

The advantages of digital case-based surveillance systems and the products and tools that WHO has developed to support countries to transition to a fully digitized system for TB surveillance are presented in Chapter 6.

4. All collected data should be quality assured for completeness and accuracy

All surveillance systems should incorporate quality assurance processes and procedures to ensure the reliability and usefulness of reported data. Examples of data quality assurance processes, which should address data collection and reporting at all levels, include local data quality audits at regular intervals to ensure that the recorded information matches that in source documents (e.g. medical records, TB patient cards, laboratory results and registers); and regular batch checks of the completeness and internal and external consistency of reported values.[2]

Guidance on data quality assurance, which highlights the advantages of digital systems where certain checks and routines can be automated, is provided in Chapter 7.

5. The frequency with which data and indicators need to be reported and used varies according to their intended use and should be clearly specified

Some data items and indicators only need to be reported and used on an annual basis, while others are required more regularly (up to "real-time").

Chapter 4 provides guidance on the frequency with which data for key indicators should be reported, making a clear distinction between three frequencies: weekly/monthly,[3] quarterly and annual.

6. TB surveillance in individual countries should benefit from experience and lessons learned in other countries

Since 2013, more than 100 national TB epidemiological reviews that include assessments of TB surveillance have been implemented. These have provided a wealth of experience and lessons learned, which have informed all of the main chapters of this guidance (especially Chapters 4–7).

Web Annex A provides an overview of the main findings from these assessments. Web Annex B presents the second edition of the WHO TB surveillance checklist of standards and benchmarks that can be used for assessments of TB surveillance systems.

2.3 Scope

The scope of the guidance is based on the purpose and the principles.

2.3.1 What is included?

In terms of what is included, the scope of the guidance can be characterized in terms of who is covered, what indicators and associated data items are included, where data are collected and how data are collected.

Who is covered?

The guidance is for collection, reporting and use of data for people with presumptive TB, people diagnosed with TB disease (including drug-resistant TB) or TB infection, and people at risk of TB disease or infection.

Of note, the previous edition of this guidance *(1)* covered people with presumptive TB and people diagnosed with TB disease. In line with the latest WHO guidelines *(4)*, this edition has been expanded to include, for recommended subpopulations, the assessment of their eligibility for TB preventive treatment, and collection of data about initiation and completion of TB preventive treatment.

What is covered?

The guidance provides a core set of indicators related to people with presumptive TB, people diagnosed with TB disease or TB infection, and people at risk of TB disease or infection, along the pathway of TB prevention and care, and the data items that need to be collected

[1] For continuity with previous guidance, Web Annex D includes illustrative forms for reporting of data in a paper-based system.

[2] Further details are available in the WHO TB surveillance checklist *(3)*.

[3] Weekly is considered equivalent to "real-time" and is feasible if case-based digital TB surveillance is in place.

to calculate these indicators. The core indicators include a minimum set that is applicable to all countries, irrespective of the type of TB surveillance system in use (paper-based or digital case-based); and options for additional disaggregations of core indicators and additional indicators that could be considered in countries with case-based digital surveillance systems for TB.

Where - what locations are covered?
The guidance covers collection of data at health facilities, laboratories, within households and workplaces, and by mobile services in the community, within a given country.

Methods for data collection - how?
The guidance covers TB data that are routinely collected and reported on an ongoing basis as part of national health information systems, using either a case-based digital or paper-based aggregated surveillance system.

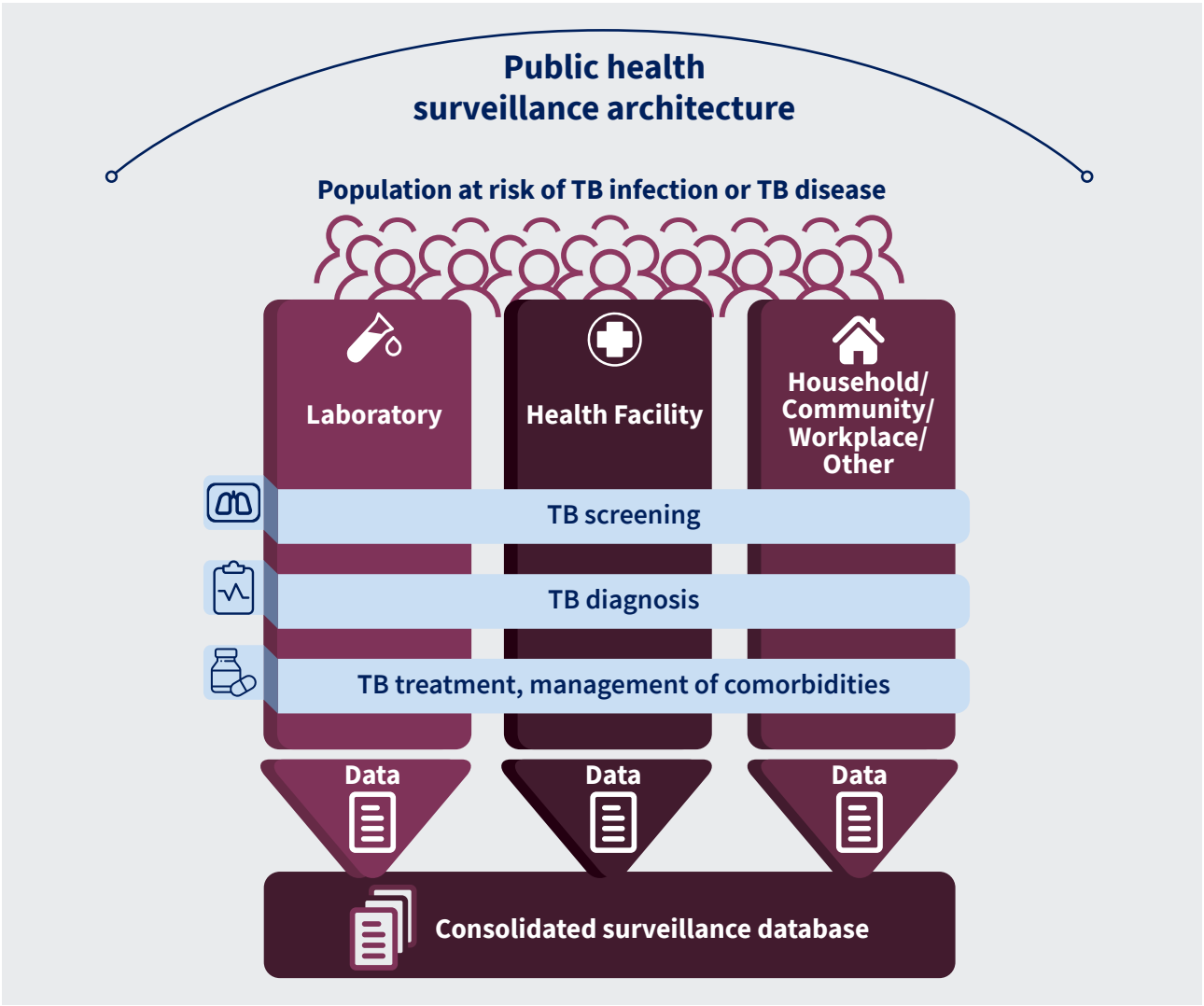
An illustration of the scope of the guidance, which also highlights that TB surveillance should be integrated or interoperable with the overall public health architecture (also see Section 6.2.3), as well as the flow and linkages of data, is provided in Fig. 2.1.

2.3.2 What is not included?

The guidance does not cover the collection and recording of additional data that are required for managing individual patient care: for example, the scheduling of appointments; request forms for laboratory tests; treatment cards; and medical records with details about clinical observations, the treatment provided, treatment adherence and adverse events.

The guidance does not cover the definition, collection, analysis and reporting of community-based monitoring of the TB response, for which guidance is available in other publications. However, meaningful engagement with civil society and affected communities in the development of resilient and sustainable systems for health is strongly encouraged *(5)*.

Fig. 2.1 An illustration of the scope of the 2024 edition of WHO guidance on TB



The guidance does not cover the collection, analysis and reporting of data through periodic population or health-facility based cross-sectional surveys (e.g. national TB prevalence surveys, national surveys of anti-TB drug resistance, national surveys of costs faced by TB patients and their households), for which WHO guidance is available in other publications *(6, 7, 8)*. These surveys are usually implemented once every few years. It also does not cover the routine collection, analysis and reporting of data related to TB mortality in national systems for civil registration and vital statistics; only recording and reporting of deaths as part of the monitoring of treatment outcomes is included. The guidance does not cover the collection, analysis and reporting of data for the management of NTPs and services such as planning, budgeting, financing, resource allocation and the procurement of anti-TB drugs, laboratory consumables and other commodities.

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Chapter 3
Definitions

The first principle of TB surveillance defined in Chapter 2 is that it should be based on clear, comprehensive and standardized definitions. This is necessary to ensure collection and reporting of consistent and comparable data within and across countries and over time.

This chapter provides such definitions, covering all of the terms used in the rest of the document (especially in Chapter 4 and Chapter 5). All definitions are aligned with the most recent WHO clinical guidelines for TB.[1] All terminology is based on guidance related to the suggested use of language in the context of TB *(1)*, and the principles that underpin the provision of people-centred, rights-based and gender-responsive TB care *(2, 3)*.

The terms have been divided into two main groups, and the chapter is structured accordingly. The first group comprises terms that relate to people with or at risk of TB disease or infection, and their contacts (Section 3.1). These are further subdivided according to the pathway of care: a) prevention of and screening for TB disease; b) diagnosis of TB disease; c) treatment for TB disease. The second group covers terms related to data and its flow through the health system (Section 3.2).

The terms and definitions include several notable changes compared with the previous edition of this guidance *(4)*. For ease of reference, these are summarized, along with their rationale, in Table 3.1.

There are some long-established terms that have been the subject of recent discussions, but for which no changes have been made in this guidance. There are three major examples.

- **Classification of intrathoracic lymph-node TB disease**. An expert group on childhood TB that was convened by WHO in 2021 proposed that for children aged under 10 years, this should be classified as pulmonary tuberculosis (PTB) rather than extrapulmonary tuberculosis (EPTB). However, it was recognized that such a change had to be considered in the context of other age groups as well. At the time this document was published, further consultations with a wider group of stakeholders, including national TB programmes (NTPs), as well as associated collection of data to inform these wider discussions, were still in process.
- **Classification of a TB episode based on anatomical site**. Use of the term "respiratory" TB (or TB of the respiratory system) was considered, to align with terminology used in the current edition of the International Classification of Diseases *(6)*. Of note, such terminology would allow both pulmonary TB and TB of intrathoracic lymph-nodes to be included under the same umbrella term of "respiratory TB", without having to classify intrathoracic lymph-node TB as "pulmonary". However, pulmonary TB and extrapulmonary TB are terms that have been widely used for decades. No change has been made in this guidance.
- **An alternative classification of a TB episode based on the method of diagnosis**. A proposal to use the terms "confirmed", "plausible" or "possible" TB, as alternatives to "bacteriologically confirmed" and "clinically diagnosed" TB, was discussed during the development of the 2013 edition of this guidance; the use of these terms was discussed again during the development of this guidance. The categorization agreed upon for the 2013 guidance has been retained.

It is also worth noting that there is growing use of the terms "sub-clinical" and "clinical" as subcategories of bacteriologically confirmed TB disease. However, these terms are not part of the core indicators to report and use that are set out in this document (Chapter 4), or the core data items that need to be collected to calculate the core indicators (Chapter 5). For this reason, they are not discussed further in this chapter.

[1] There are a few exceptions where this was not possible; an explanation is provided in these instances.

Table 3.1 Updates to TB terminology and definitions compared with WHO guidance published in 2013

New term or definition	Previous term or definition	Reason for update
Terms		
Recurrent case	Relapse case	It ensures alignment with case definitions for people with TB commonly used in TB clinical trials.
Re-registered for treatment	Retreatment	It is a more accurate descriptor for people who start a new TB treatment regimen (following either treatment failure or loss to follow-up) or for whom the outcome of a previous treatment is undocumented (see also Table 3.6).
New episode of TB	New or relapse case	It is a simplified descriptor of people newly diagnosed with TB.
Definitions		
Case outcomes	Not applicable	To allow assessment of outcomes for all those registered as a TB case, not only those who were started on treatment.
The same definitions are used for each category of treatment outcome, irrespective of a person's pattern of drug resistance and their treatment regimen.	The previous definitions used for some categories of treatment outcome (e.g. cured, treatment failed) were different for people treated for drug-susceptible TB and people treated for drug-resistant TB. The previous definitions for drug-resistant TB were relatively complex.	It allows for considerable simplification and streamlining of definitions, and is consistent with the outcomes of a WHO consultation convened in 2020 *(5)*.
A change of treatment regimen (e.g. from a standard first-line regimen for drug-susceptible TB to a regimen for drug-resistant TB) is recorded as a "treatment failure".	Patients initially treated for drug-susceptible TB whose treatment was changed (prior to completion of treatment) to a regimen for drug-resistant TB were previously recorded with the outcome "transferred". They were not included in the calculation of the treatment success rate for people treated for drug-susceptible TB.	It is important to identify the optimal treatment for people with TB disease at the start of treatment. The change also ensures more accurate assessment of treatment outcomes.

TB: tuberculosis; DS: drug-susceptible; DST: drug-susceptibility testing.

3.1 Definitions related to people with or at risk of TB disease or TB infection, and their contacts

This section defines terms related to people with or at risk of TB disease or infection, and their contacts. These are ordered and categorized according to the pathway of care: a) prevention of and screening for TB disease; b) diagnosis of TB disease; c) treatment for TB disease.

3.1.1 Prevention of and screening for TB disease

This subsection defines terms for the part of the clinical pathway of care involving investigations in specific populations to establish whether a person has TB disease (screening), or if the person does not have TB disease and they are eligible, whether they should be on treatment that prevents TB disease (prevention). The definitions (Table 3.2) are consistent with those in the latest WHO clinical guidelines for prevention and screening for TB disease *(7, 8)*.

3.1.2 Diagnosis of TB disease

This subsection defines terms related to the diagnosis of TB disease. Three general terms (TB disease, TB case and TB patient; see Table 3.3) are covered first, followed by definitions of more specific terms related to the method of diagnosis (Table 3.4), anatomical site of disease (Table 3.5), history of previous TB treatment (Table 3.6), susceptibility or resistance to TB drugs (Table 3.7), and HIV status (Table 3.8). All definitions are consistent with the latest WHO clinical guidelines for the diagnosis of TB disease *(9)*.

3.1.3 Treatment for TB disease

The terms in this subsection cover the period from initiation to completion of treatment for people diagnosed with TB disease.

Definitions related to treatment types and treatment initiation are shown in Table 3.9.

Table 3.2 Prevention and screening for TB disease

Term	Definition
Contact person	Any person who was exposed to a person with TB.
Close contact	A person who does not live in the same household as a person with TB but who has shared an enclosed space, such as a social gathering place, workplace or facility, with the index patient for extended periods during the day during the 3 months before the current disease episode commenced.[a]
Contact investigation (or evaluation)	A systematic process for identifying previously undiagnosed people with TB among the contacts of an index case. Contact investigation consists of identification, prioritization and clinical evaluation. It may also include testing for TB infection to identify candidates for TB preventive treatment. Recommendations on how to evaluate contacts can be found in WHO guidance on prevention and screening *(7, 8)*; however, approaches used to implement these methods vary according to country setting.
Household contact	A person who has shared the same enclosed living space as the index case for one or more nights or for frequent or extended daytime periods in the 3 months before TB disease was identified in the index case.
Index patient (index case) of TB	The initially identified person with TB disease in a specific household or other comparable setting in which others may have been exposed. An index patient is the person on whom a contact investigation is centred but who is not necessarily the original source of an outbreak of TB.
Patient-initiated care	A patient-initiated pathway to TB diagnosis involves: (1) a person with TB disease experiencing symptoms that they recognize as serious; (2) the person having access to and seeking care, and presenting spontaneously at an appropriate health facility; (3) a health worker correctly assessing that the person fulfils the criteria for presumptive TB; and (4) the successful use of a diagnostic algorithm with sufficient sensitivity and specificity to diagnose TB.
Person with presumptive TB	A person with symptoms or signs suggestive of TB disease.
Provider-initiated care	Screening and testing initiated by health care providers. This can be done in health facilities or communities by mobile teams, often using a mobile X-ray machine and rapid molecular tests.
Risk group	Any group of people at increased risk of TB infection, or progression from TB infection to TB disease, or TB-associated mortality, compared with the general population.
Screening	The systematic identification of people at risk for TB disease in a predetermined target group by clinical examination, assessing symptoms and using tests (sputum-smear microscopy, LF-LAM, C-reactive protein), or other procedures (e.g. chest radiography). For those who screen positive, diagnosis should be established by one or more diagnostic tests (e.g. mWRD, culture). This term is sometimes used interchangeably with "active tuberculosis case-finding". It should be distinguished from testing for TB infection (using a TB skin test or interferon-gamma release assay).
TB infection	A state of persistent immune response to stimulation by *M. tuberculosis* antigens with no evidence of the clinical manifestations of TB disease. This is also at times referred to as "latent TB infection". There is no gold standard test for direct identification of *M. tuberculosis* infection in humans. Most infected people have no signs or symptoms of TB but are at risk for progression to active TB disease.
TB preventive treatment (TPT)	Treatment offered to individuals who are considered at risk of progression from TB infection to TB disease. Also referred to as treatment of TB infection, treatment for latent TB infection or TB preventive therapy.

[a] Commencement of disease may be dated to the onset of first signs or symptoms.

Definitions related to treatment outcomes are based on a WHO expert consultation in 2020 *(5)*. In a marked departure from the 2013 edition of WHO guidance on TB surveillance *(4)*, the updated definitions for each category of treatment outcome in Table 3.10 apply to **all treatment regimens** – regardless of drug-resistance status, the type of drugs used or the duration of treatment.[1]

For the purposes of surveillance, a distinction is now made between **case outcomes**, which apply to all registered TB cases, and **treatment outcomes**, which apply only to people who started treatment.

3.2 Data, data flow and the health system

The terms in this section relate to the flow of TB data through the health system, to the data this system produces, and how these data are used to guide policy, planning and programmatic action (Table 3.11).

[1] Previously, the definitions of some categories of treatment outcome (e.g. cured, treatment failed) were different for patients treated for drug-susceptible and drug-resistant disease; see also Table 3.1.

Table 3.3 A person with TB disease

Term	Definition
TB disease	A person with disease caused by the *M. tuberculosis* complex. Note: The *M. tuberculosis* complex comprises nine distinct but closely-related organisms. The complex includes *M. africanum, M. bovis, M. canetti, M. caprae, M. microti, M. mungi, M. orygis, M. pinnipedii*, and *M. tuberculosis*.
TB case	The occurrence of TB disease in a person. *The term should be reserved for use in the context of registration or reporting of the clinical condition and not during the provision of care.* This definition also includes the identification of TB disease through post-mortem examination. All TB cases should be notified to public health authorities, regardless of whether TB treatment was started. People with TB who died or were lost to follow-up before TB treatment started should also be notified to public health authorities; this is because they are important from the perspective of both surveillance and public health (they may have contacts that require tracing and follow-up).
TB patient	A person who is receiving care for TB disease.

Table 3.4 Classification of a person with TB disease by method of diagnosis

Term	Definition
Bacteriologically confirmed	A person from whom a biological specimen is positive by a WHO-recommended rapid diagnostic test, culture, or smear microscopy.
WHO-recommended rapid diagnostic test (WRD)	A test approved by WHO that employs molecular (e.g. Xpert Ultra®) or biomarker-based techniques (e.g. urinary lipoarabinomannan assays (U-LAM)) for the diagnosis of TB. Throughout this publication, the term "WRD" refers to molecular WRDs unless otherwise specified.
Clinically diagnosed	A person who does not fulfil the criteria for bacteriological confirmation but has been diagnosed with TB disease by a medical practitioner who has decided to give the person a full course of TB treatment. This definition includes pulmonary cases diagnosed based on radiographic abnormalities and extrapulmonary cases diagnosed based on suggestive clinical presentation or histology. Clinically diagnosed cases subsequently found to be bacteriologically positive (before or after starting treatment) should be reclassified as bacteriologically confirmed.

Table 3.5 Classification of a person with TB disease by anatomical site

Term	Definition
Pulmonary TB	A person with TB disease involving the lung parenchyma or the tracheobronchial tree. Note: A case with both pulmonary and extrapulmonary TB should be recorded and counted as a pulmonary TB case for surveillance purposes. Miliary TB is classified as pulmonary TB.
Extrapulmonary TB	A person with TB disease involving organs other than the lung parenchyma or tracheobronchial tree (e.g. pleura, lymph nodes, digestive track, genitourinary tract, skin, joints and bones, meninges).

Table 3.6 Classification of a person with TB disease by history of previous treatment for TB

Term	Definition
New case	A person with TB disease who has never been treated for TB or has only ever taken TB drugs for less than 1 month.
Recurrent case	A person with TB disease who has previously been treated for TB, was declared *cured or treatment completed* at the end of their most recent course of TB treatment and is now diagnosed with a new episode of TB.
Re-registered case	A person with TB disease who has been notified previously as a TB case, who started treatment and took TB drugs for at least 1 month but who was not declared *cured* or *treatment completed*, and is now being started on a new course of TB treatment. Examples of re-registered cases include: • a person who was declared treatment *failed* during or at the end of their most recent course of TB treatment and who is starting a new course of TB treatment (normally using a different drug regimen); • a person who was declared *lost to follow-up* during or at the end of their most recent course of TB treatment and who has returned to start a new course of TB treatment; and • a person whose outcome after their most recent course of TB treatment is undocumented and who has returned to start a new course of TB treatment.

Table 3.6 Classification of a person with TB disease by history of previous treatment for TB (continued)

Term	Definition
Unknown previous treatment history	A person with TB disease who has no documented history of TB treatment.
New episode	A person with TB disease who is classified as a new case, a recurrent case or a case with unknown previous treatment history (i.e. any case apart from a re-registered case).
Previously treated case	A person with TB disease who is either a recurrent or a re-registered case.

Table 3.7 Classification of a person with TB disease by susceptibility or resistance to TB medicines (not mutually exclusive)

Term	Definition
Drug susceptibility testing (DST)	In vitro testing of a strain of *M. tuberculosis* complex using either: 1) molecular, genotypic techniques to detect resistance-conferring mutations; or 2) phenotypic methods to determine susceptibility to a medicine.
Drug-resistant TB (DR-TB)	A person with TB disease who is infected with a strain of *M. tuberculosis* complex that is resistant to any TB medicines tested. When available, DST results for individual drugs should be recorded.
Drug-susceptible TB (DS-TB)	A person with TB disease for whom there is no evidence of infection with a strain of *M. tuberculosis* complex that is resistant to rifampicin or isoniazid. This includes people for whom DST was not done or for whom DST shows a strain of *M. tuberculosis* complex that is susceptible to both rifampicin and isoniazid. This definition should only be used for the purposes of initiation of treatment for drug-susceptible TB and the recording of treatment outcomes. Wherever available, DST results for individual drugs should be recorded and used to define a person's drug susceptibility status. When DST results are not available for individual drugs, their absence should also be recorded. Chapter 5 provides examples of how to code DST results for different drugs.
Isoniazid-resistant, rifampicin-susceptible TB (Hr-TB)	A person with TB disease who is infected with a strain of *M. tuberculosis* complex that is resistant to isoniazid but susceptible to rifampicin.
Rifampicin-resistant TB (RR-TB)	A person with TB disease who is infected with a strain of *M. tuberculosis* complex that is resistant to rifampicin. Note: These strains may be either susceptible or resistant to isoniazid (i.e. MDR-TB) or resistant to other first-line or second-line TB medicines.
Multidrug-resistant TB (MDR-TB)	A person with TB disease who is infected with a strain of *M. tuberculosis* complex that is resistant to both rifampicin and isoniazid.
MDR/RR-TB	MDR-TB is a subset of RR-TB, and the two are often grouped together using the term MDR/RR-TB.
Pre-extensively drug-resistant TB (pre-XDR-TB)	A person with TB disease who is infected with a strain of *M. tuberculosis* complex that is resistant to rifampicin (and which may also be resistant to isoniazid), and which is also resistant to at least one fluoroquinolone (either levofloxacin or moxifloxacin).
Extensively drug-resistant TB (XDR-TB)	A person with TB disease who is infected with a strain of *M. tuberculosis* complex that is resistant to rifampicin (and which may also be resistant to isoniazid) as well as resistant to at least one fluoroquinolone (levofloxacin or moxifloxacin) and at least one other "Group A" drug (bedaquiline or linezolid) *(10)*.

Table 3.8 Classification of a person with TB disease by HIV status

Term	Definition
HIV-positive	A person with TB disease who has a documented positive result from HIV testing before, at the time of TB diagnosis or during the TB episode.
HIV-negative	A person with TB disease who has a negative result from HIV testing conducted at the time of TB diagnosis. Note: If the person is subsequently found to be HIV-positive during their TB treatment, they should be reclassified as an HIV-positive TB case.
HIV status unknown	A person with TB disease who has no result from HIV testing and no documented evidence of receiving treatment for HIV. Note: If the person's HIV status is subsequently determined, they should be reclassified as an HIV-positive TB case or an HIV-negative TB case, as appropriate.

Table 3.9 Treatment types and treatment initiation

Term	Definition
First-line TB medicine (or drug)	An agent used to treat a person with drug-susceptible TB disease.[a]
Second-line TB medicine (or drug)	An agent used to treat a person with drug-resistant TB disease.[b]
Treatment initiation	The initiation of an appropriate treatment regimen for a person with TB disease. Note: It is recommended to monitor this step in the pathway of care because diagnosis of TB disease does not necessarily mean that a person will be offered or accept to take treatment.

[a] First-line treatment regimens comprise combinations of the following drugs: isoniazid, rifampicin, ethambutol, pyrazinamide, rifabutin, rifapentine, moxifloxacin.
[b] Second-line treatment regimens comprise combinations of the following drugs: Group A: levofloxacin or moxifloxacin, bedaquiline, linezolid. Group B: clofazimine, cycloserine or terizidone. Group C (when Group A and Group B cannot be used): ethambutol, delamanid, pyrazinamide, imipenem-cilastatin or meropenem, amikacin, ethionamide or prothionamide, *p*-aminosalicylic acid.

Table 3.10 Case and treatment outcomes for both drug-susceptible and drug-resistant TB

Term	Definition
Cured	A pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment who completed treatment as recommended by the national policy with evidence of bacteriological response[a] and no evidence of failure.
Treatment completed	A person with TB disease who completed treatment as recommended by the national policy whose outcome does not meet the definition for cure or treatment failure.
Treatment successful	A person with TB disease who was either cured or who completed treatment as defined above.
Treatment failed	A person with TB disease whose treatment regimen needed to be terminated or permanently changed[b] to a new regimen option or treatment strategy.
Died	A person with TB disease who died for any reason before starting (for case outcomes), or during the course of, treatment (for both case and treatment outcomes).
Lost to follow-up	A person with TB disease who did not start treatment (for case outcomes) or whose treatment was interrupted for two consecutive months or more (for both case and treatment outcomes).
Not evaluated	A person with TB disease to whom no treatment outcome was assigned, excluding those lost to follow-up.

[a] In this context, a bacteriological response is defined as a bacteriological conversion with no reversion. A bacteriological conversion occurs when a patient with bacteriologically confirmed TB has at least two consecutive negative cultures (for DR-TB and DS-TB) or smears (for DS-TB only), taken on different occasions at least 7 days apart. Bacteriological reversion occurs when a patient with bacteriologically confirmed TB has at least two consecutive cultures (for DR-TB and DS-TB) or smears (for DS-TB only), taken on different occasions at least 7 days apart, which are positive either after a bacteriological conversion or in patients without bacteriological confirmation of TB.
[b] Reasons for regimen change may include no clinical response and/or no bacteriological response, an adverse drug reaction or evidence of additional drug resistance to medicines in the regimen.

Table 3.11 Data, data flow and the health system

Term	Definition
Aggregated data	Either data elements that are entered into a data system as a count of a grouping of individuals or services with shared characteristics (for example, the number of people with TB disease aged 25–34 years), or summary data calculated by combining information for multiple individuals.
Case-based data	Individual-level data that are structured so that multiple data elements can be linked to and analysed for a single person, for a single episode of TB disease and across different points of care.
Community care	Provision of health services outside a health facility, such as households of people with TB disease or a specific geographical location (e.g. village, census enumeration area).
Data element	The fundamental unit of information (data block) that has a unique meaning, often with categories of distinct values. Examples include gender (male, female, intersex, unknown/unspecified), age (age in years or age group) and a geographic location. The term is used synonymously with the term "data item".
Digital adaptation kit (DAK)	A package of standardised specifications that can be used to translate WHO clinical guidelines and associated derivative products (e.g. operational handbooks), as well as other WHO guidance (e.g. public health surveillance), into digital products that should facilitate their implementation and use. The specifications can be used by IT developers; the intended end-users of the digital products are primarily health care workers. Examples of digital products include: a) products that facilitate the provision of health care (e.g. tools to assist health care workers to follow WHO-recommended diagnostic and treatment algorithms and in turn make decisions about the clinical care to be provided to patients; electronic medical records to help with the management of individual patient care); and b) products that facilitate data generation, reporting and use (e.g. standard lists of indicators and associated data items, automated calculation of indicators, automated generation of reports).
Digital health information system	The computerized system used to store, manage and analyse routine surveillance data, including both aggregate and individual-level data. The term is used synonymously with the term "electronic health information system".
Programme evaluation	The process of measuring how well a programme's activities have met its expected objectives and whether the changes in the outcomes observed can be attributed to the programme. Evaluation entails the process of determining the value or significance of a programme or intervention.
Health care facility	A place where health care services are provided (prevention, screening, diagnosis, treatment, follow-up care).
Health facility level	Community (level 0), primary (level 1), secondary (level 2) or tertiary (level 3).
Health information system (HIS)	A system used to manage data to inform decisions on the design or management of health services. The system encompasses data collection, compilation, analysis, synthesis, reporting and use. In this guidance, the term "health management information system" is used synonymously with HIS.
Health sector	The sector consisting of organized public and private health services (including health promotion, disease prevention, diagnosis, treatment and care). This also includes the policies and activities of health departments and ministries, health-related nongovernmental organizations (NGOs), civil society and affected community groups, hospital and professional associations. *Public health sector:* all state-supported providers of health services, including parts of government such as ministries of health, internal affairs, correctional and labour services. *Private health sector:* all non-state supported providers of health services, including for-profit (both formal and informal) and not-for-profit (NGOs, faith-based organizations, community-based organizations) providers, domestic and international entities. The private health sector is heterogeneous and can include providers who are unqualified or underqualified.
Indicator	A measure to assess performance or reflect changes connected to an activity, project or programme. Indicators are constructed from data elements, should be SMART (specific, measurable, attainable, relevant and time-bound), associated with available sources of data, and only collected if there is a predefined plan for their analysis and use to guide action.
Individual-level data	The type of data structured to link multiple data elements to a single person, over time and across different points of care. For example, records of an individual receiving TB care at a health facility and that individual's laboratory results. Note: Individual-level data can allow longitudinal and multivariate analysis of data on the same individual. Individual-level data should not be confused with case-based data, which is reserved for data related to a specific episode of TB. An individual could experience multiple episodes of TB disease.

Table 3.11 Data, data flow and the health system (continued)

Term	Definition
Master health facility list	A comprehensive and up-to-date list of ***ALL*** health facilities and providers that offer TB services (prevention, screening, diagnosis, treatment). See also *Health care facility*.
Monitoring	The ongoing and routine recording and reporting of priority information about the implementation of a programme's activities and performance over time. By providing continuous oversight of a programme's inputs and intended outputs, outcomes and impacts, the aim of monitoring is to track progress and assess if objectives are achieved and resources are used efficiently.
National TB programme (NTP)	The part of the ministry of health that is responsible for the prevention and care of people with TB disease. Countries with a low TB burden may not have a dedicated NTP, in which case responsibilities for functions such as guideline development, planning of services and surveillance may fall under the remit of a broader health care entity; for example, a health ministry unit responsible for communicable diseases.
Patient monitoring	The routine collection, compilation and analysis of data on patients over time and across service delivery points. The primary purpose of patient monitoring is to guide the clinical management of a patient over time and ensure continuity of care between health facilities.
People-centred care	An approach to care that consciously adopts the perspectives of individuals, families and communities and sees them as participants as well as beneficiaries of health systems. This includes ensuring that people are fully informed about the benefits and risks of treatment options and that health services respond to individual needs and preferences.
Programme management	The direction of and decision-making related to health programme services and resources, made on the basis of health information on programme inputs, outputs, outcomes and impact.
Rights-based care	An approach to care that is underpinned by the core principles of participation, accountability, non-discrimination and equality.
Surveillance	The systematic and continuous collection, analysis, reporting and use of data related to the health of a population.

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Chapter 4
Core indicators to report and use

This chapter sets out a **core set of TB indicators** to report and use based on surveillance data i.e. data that are systematically and continuously collected as part of a national health information system. These data comprise those collected during visits to health facilities, by mobile services provided in community or household settings, and by laboratories involved in diagnostic testing and treatment monitoring.

The data that need to be collected[1] so that the core set of TB indicators can be calculated, including how the individual data items that are required can be named, categorized, coded and recorded, are explained in Chapter 5.

The core set of TB indicators is based on the purpose, principles and scope set out in Chapter 2:

- The indicators cover the pathway of prevention and care for TB disease and TB infection.
- Indicators are required for at least one of the following objectives:
  - reliable monitoring of the TB epidemic at national and subnational levels in terms of the number of cases (TB incidence) in the population and trends;
  - detection and investigation of outbreaks or disruptions to services;
  - assessment of progress towards national, regional and global targets for reductions in TB disease burden and provision of TB treatment, prevention and care services;
  - assessment of the performance of TB services;
  - to inform the planning, budgeting, policy and programmatic actions necessary to ensure high-quality and coverage of TB prevention and care services.
- The frequency with which indicators need to be reported and used is clearly specified, distinguishing between weekly, monthly, quarterly and annual.
- The categorization of indicators takes into consideration whether a case-based digital or paper-based aggregated reporting system is in place.
- The categorization of indicators is informed by experience and lessons learned during more than 100 national TB epidemiological reviews and associated assessments of TB surveillance in 91 countries from 2013–2021 (Web Annex A).

The chapter is divided into five major sections, as follows:

1. Data governance, sources and compilation;
2. Frequency of reporting: an overview;
3. Indicator for rapid reporting (weekly or monthly) and use;
4. Indicators for regular reporting (quarterly) and use;
5. Indicators for annual reporting and use.

In the case of quarterly reporting (Section 4.4) and annual reporting (Section 4.5), a clear and important distinction is made between: a) **a minimum set of core indicators** that is applicable in all countries, regardless of whether a case-based digital or paper-based aggregated surveillance system is in place; b) **five additional indicators** that are recommended in countries with a case-based digital surveillance system; and c) **additional disaggregations of notification data** that may be relevant in subsets of countries and which could be considered in countries with a case-based digital surveillance system. A further prerequisite for collection of data related to additional disaggregations is that capacity already exists, or the necessary capacity can be created, to record, analyse and use the data.

For the core set of indicators that is recommended for all countries, numerators and denominators are defined in Table 4.6; **methods to calculate these indicators are explained in detail in Web Annex D**.

4.1 Data governance, sources and compilation

4.1.1 Data governance

In any country, all health facilities where TB prevention and care services are provided should report data to the national TB surveillance system. This includes health facilities in the public and private health sectors, at the primary, secondary and tertiary health care levels; and general practitioners (GPs) and specialists with individual practices.

Developing and maintaining a comprehensive master list of all reporting health facilities provides the foundation

[1] Either for all people diagnosed with TB, all people with presumptive TB, or all household contacts of people with bacteriologically confirmed TB.

for a well-functioning surveillance system, in terms of both coverage and quality *(1)*. Ensuring the availability of a list of reporting facilities relevant to TB prevention and care, and keeping this list up to date, should be among the priority activities for the national TB programme (NTP). This is necessary to ensure national coverage of the TB surveillance system and in turn to provide the most accurate picture of the TB epidemic and the programmatic response. These activities should be undertaken in collaboration with other parts of the ministry of health and other relevant ministries (e.g. interior, labour, social services, welfare), as well as the private sector and other national and international partners and stakeholders. Ideally, overall oversight should be provided by the team (or its equivalent) that is responsible for overall governance of the health information system.

An example of the establishment of a digitized version of a master health facility list, from Pakistan, is provided in Box 4.1.

In many countries, there may be more than one health authority responsible for collecting and using TB data. For example, the NTP (or its equivalent) is typically responsible for planning and delivering the programmatic response, while responsibility for monitoring TB epidemics and responding to public health emergencies and outbreaks may rest with a national centre for disease control (CDC). National systems for civil registration and vital statistics (CRVS) are usually responsible for recording and certifying deaths, including causes of death, using international classification systems *(2)*. Irrespective of how roles are assigned, it is recommended that countries develop a unified surveillance system for TB that addresses all national objectives and needs.[1]

Given that multiple organizations are likely to be involved in national TB surveillance, it is essential that the roles and responsibilities of the different authorities are clearly defined, including those related to the governance of data – what data to collect, how to collect data, who is responsible for data collection and validation, the frequency of data reporting, and data interpretation and use.[2] For example, the NTP might be responsible for analysis of the number of people diagnosed with a new episode of TB who were identified in a reporting unit over a given time period (data which may be used as the basis for planning the programmatic response and provision of care), while the national CDC might be responsible for analysing the same data as an entry point to an outbreak investigation that may involve appropriate community and household visits.

[1] See also Chapter 6, Section 6.3.

[2] Public health surveillance data governance and use must work within the national and international legal frameworks on the protection of personal and identification data.

Box 4.1 Establishing a digitized version of a master health facility list: the example of Pakistan

In Pakistan, health regulatory bodies at provincial level are responsible for developing and maintaining an up-to-date register of all health care facilities (public and private), as well as setting standards for the registration and licensing of these facilities. There is also a regulatory authority for health care in the capital city of Islamabad. Registration of a health care facility is the responsibility of the facility. The issuance and renewal of a health care facility's licence to practice and provide health care is linked with this registration. Regulatory frameworks are in place to allow provincial authorities to inspect facilities and monitor, among other things, their registration status.

In 2022, the National TB programme (NTP) and provincial TB programmes initiated the development of a digitized version of a master health facility list, for both the public and private sectors, to be used by the TB programme at national and provincial levels as well as by other disease-specific programmes. Development of the list required collaboration with regulatory authorities for health care at provincial level as well as the Health Systems Strengthening Department of the Ministry of Health.

By the end of 2022, the mapping and digital registration of health facilities had been completed in the province of Punjab and was in the planning phase in three provinces: Sindh, Balochistan and Khyber Pakhtunkhwa. The same process was underway in Islamabad.

4.1.2 Data sources and flow

The primary data sources for monitoring the provision of health services related to TB, as a person moves through the health system, are typically patient records, patient registers and laboratory records. All of these primary data sources contain information (in either paper or digital format) at the individual level.

Individual-level data are then aggregated at the level of a reporting unit, compiled and entered into a surveillance report. Each number in the report typically refers to the total number of events matching specific criteria, at a given location, such as a health facility or a household, for a given time period. Totals for reporting units can be used to gauge the level of activity in specific

geographical areas and guide clinical and programmatic planning and action.

Reports from each health care facility are combined according to an administrative hierarchy, such that information is aggregated upwards at, for example, district, regional and finally national levels. An illustration is provided in Fig. 4.1.

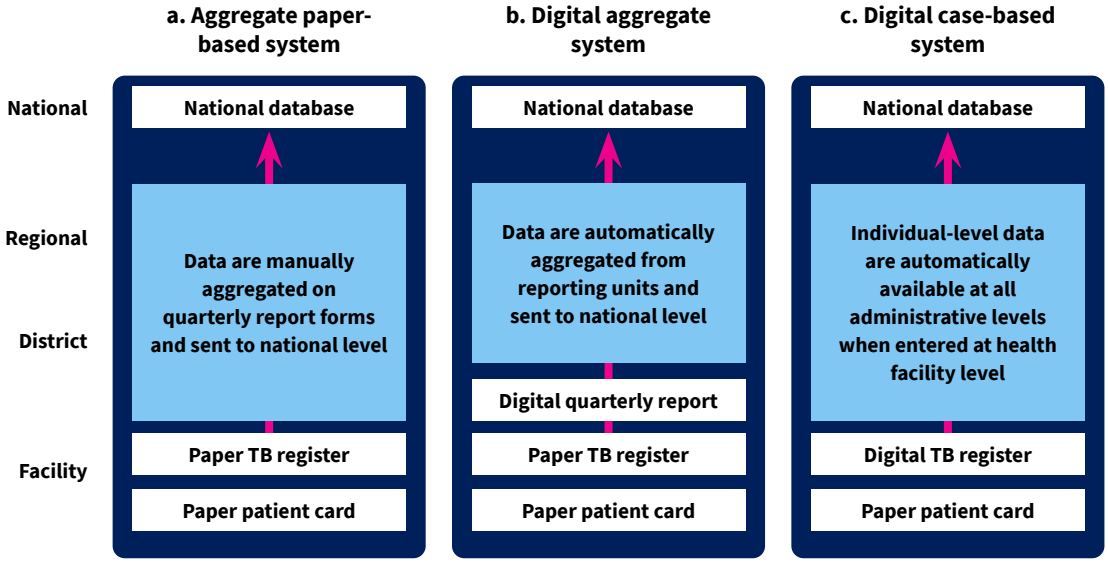
If the national TB surveillance system holds only aggregate totals (usually taken from paper forms, as shown in Fig. 4.1.a,b), then staff at the health facility level need to compile totals manually from their patient records and/or TB registers. This is a time-consuming and potentially error-prone activity. These totals then need to be entered into a periodic surveillance report (usually a standard template/form specifically designed for such reporting), at a defined frequency (e.g. monthly, quarterly). The totals in the paper-based report are then either entered directly in a national digital, aggregate reporting system; Fig. 4.1.a) or sent up the administrative hierarchy (Fig. 4.1.b). If the latter is done, then numbers for different levels of the administrative hierarchy (e.g. district, regional up to national) can be calculated automatically. If not, then staff at different subnational levels will need to aggregate the data at their level before reporting up the hierarchy. One of the limitations of a system that holds aggregated data (Fig. 4.1.a,b) is that it is prone to overreporting, due to the possibility of there being multiple records for the same person notified with the same episode of TB disease. Deduplication of records is an exercise that is recommended to avoid this, but can only be done in national digital, case-based TB surveillance systems.

If there is a national digital, case-based TB surveillance system in which data entry is done at the health facility level (Fig. 4.1.c), then the totals can be calculated automatically from individual-level records held in the system. There is no need for health facilities to report their aggregated data up the administrative chain by sending periodic reports. Nonetheless, reporting units should review their own data regularly (e.g., during supervision visits or quarterly review meetings) to monitor their own performance and to guide local clinical and programmatic planning and action. The digital, case-based system will also only operate effectively if data entry is timely (e.g. each person with a new episode of TB is recorded in the digital system as soon they are diagnosed, or at least no later than the end of the week after the diagnosis is made).

Traditionally, the main sites feeding data into a national TB surveillance system have been health facilities where TB prevention and care services are provided. TB surveillance also needs to encompass laboratories that conduct bacteriological testing of sputum specimens (Box 4.2) and provider-initiated care delivered in households or community settings (Box 4.3). Collaboration between the public and private sectors is also necessary (Box 4.4).

Additional databases with information about people diagnosed or notified with TB exist in many countries: for example, those used by health insurance schemes and by some private health care providers. These need to be identified in each country and then linked with the TB surveillance system as appropriate, so that they can feed data into the TB surveillance system. Such da-

Fig. 4.1 An illustration of the flow of TB data from health care facility to national level, by type of surveillance system



Box 4.2 Provision of TB care in laboratories

Laboratory facilities routinely process sputum and other specimens collected from patients and carry out bacteriological testing for TB (e.g. using rapid tests, culture and smear microscopy). Results are recorded in laboratory forms and registers. In laboratory systems with digital, case-based data that allow multiple test results to be registered for the same individual, results will be linked to individuals and hence be patient-based.

Care must be taken to ensure correct linkage of laboratory data with health facility data for the same individual. It is important to conduct regular cross-checks, and build strong data linkages, to verify that all people with a positive bacteriological test result who are listed in a laboratory register are followed up by a clinician and, if appropriate, started on treatment and notified to the routine TB surveillance system.

Box 4.3 Provision of TB care in community or household settings

Examples of provider-initiated care for TB infection and TB disease that can be provided in community or household settings include screening for TB (e.g. interview or test for TB infection), diagnosis of TB (e.g. using mobile vans with rapid tests and chest radiography), treatment support or provision of referrals to health facilities. The data these activities generate can be incorporated into the national surveillance system for TB using digital, case-based solutions.

Box 4.4 Provision of TB care in the private sector

In many countries, private providers of health care – ranging from informal providers and pharmacists through to well-resourced hospital systems – can be important sources of health care, including at the early stages of care seeking and among all socioeconomic groups. Capturing data from such providers in the TB surveillance system can be challenging but is feasible. In recent years, many NTPs have made good progress in engaging with private sector providers and integrating their data into the national TB surveillance system.

For the purposes of TB surveillance in the private sector, it is helpful to distinguish between for-profit and not-for-profit providers. Engagement with the faith-based or non-profit sector is often relatively straightforward; for example, many countries in Africa have long integrated such providers into their health systems. In contrast, for-profit providers are typically less organized and engaging with them is often more difficult. However, in many countries, for-profit providers are growing in number and importance.

Indicators related to private sector provision of TB care to be monitored include the number of people diagnosed with TB and started on treatment, and the proportion of notified patients who receive WHO-recommended rapid diagnostic tests and TB drugs.

tabases can be used to assess the level of underreporting of TB to the official TB surveillance system, through record-linkage exercises *(3)*, and to inform corrective actions as appropriate (see also Section 4.5.4 and Web Annex C).

There are also other national databases that can be used to bring TB-relevant data into the routine TB surveillance system. A good example is databases related to HIV prevention and care, which include data about the number of people living with HIV who are newly enrolled on TB preventive treatment.[1] Other examples include databases related to BCG vaccination, national provider-initiated TB screening programmes for specific subpopulations at particularly high risk of TB infection or disease (e.g. pre- and post-entry screening programmes for migrants from high- to low-burden countries), and social protection. In these instances, the NTP (or equivalent) would not have to collect data, but rather link to the databases that contain the relevant data (Section 4.5.4).

4.2 Frequency of reporting – an overview

It is important to consider the frequency of reporting that is needed to fulfil the main purposes of TB surveillance. Often there is a balance to be struck; on the

[1] People living with HIV are one of the priority populations for which WHO strongly recommends TB preventive treatment *(4)*.

Table 4.1 An overview of how rapid, regular and annual reporting of a core set of TB indicators serve the main purposes of TB surveillance

Purpose	Reporting frequency		
	Rapid (weekly or monthly)	Regular (quarterly)	Consolidated (annual)
Monitoring of TB epidemiological trends	X	X	X
Timely detection and investigation of sudden or unexpected changes	X		
Assessment of progress towards national and global targets			X
Assessment of the performance of TB services	X	X	X
Informing the planning, budgeting, policy, programmatic and clinical actions necessary to ensure high quality and coverage of TB services		X	X

one hand, data must be sufficiently comprehensive and timely to guide action, but on the other hand the recording, compilation, analysis and reporting of data should not generate an unmanageable and unnecessary workload, especially for front-line health care staff.

In this context, it is helpful to distinguish three frequencies of reporting: rapid reporting, regular quarterly reporting and consolidated annual reporting.

The primary purpose of **rapid reporting** is to detect and investigate sudden or unexpected changes (e.g. outbreaks, disruptions to health services, disruptions in reporting). In this chapter, rapid reporting is defined as either weekly reporting (if a national, digital, case-based system is in place) or monthly reporting (if paper-based registers for aggregated reporting are relied upon) of **one indicator only**.

The purpose of **regular reporting** is to monitor epidemiological trends and the programmatic response. Regular reporting is defined in this chapter as quarterly reporting (in both case-based digital and paper-based systems) of a **limited number of indicators** that are necessary for timely identification of potential problems and implementation of prompt corrective actions as appropriate.

The purpose of **consolidated annual reporting** is to allow assessment of epidemiological trends, programmatic performance and progress in response efforts at national and subnational levels (e.g. in the context of national, regional and global targets), and to estimate the burden of TB disease. Such reporting is based on consolidated and validated data for the calendar year and should ideally be made available annually in the form of an official national report. The dataset can also be used for official statistics and reporting to international agencies, such as WHO.

A summary of how these three types of reporting serve the main functions of a national TB surveillance system is provided in Table 4.1.

4.3 Indicator to report and use on a weekly or monthly basis

Weekly or monthly reporting facilitates the timely detection and investigation of sudden or unexpected changes. If a digital case-based surveillance system is in place, it is suggested that a suitable frequency for such reporting is weekly. If a paper-based system of aggregated reporting is in place, then the suggested frequency is monthly.

Only one indicator – the **total number of people diagnosed with a new episode of TB** who were notified during the reporting period – is recommended for weekly or monthly reporting. The data used to generate this indicator will typically be considered as provisional, but if sudden or unexpected changes are observed they should prompt investigation, even if all data quality processes to check their accuracy have not been completed.

Data on new episodes of TB are best reviewed at well-defined administrative levels (e.g. district, region/province, national). This is because event numbers at the health facility level, or even in small districts in countries with a low burden of TB disease, are often too small and/or highly fluctuating to allow meaningful interpretation and use. However, national TB surveillance teams will need to define what constitutes a meaningful change that warrants further investigation (in terms of an increase or decrease in episode numbers), for a given level of data aggregation.

Two examples of how weekly or monthly data could be interpreted and used to guide action at country level are provided in Box 4.5.

For the purposes of global TB surveillance, national totals of provisional monthly notifications can be reported to WHO *(5)*. An illustration is provided in Fig. 4.2. This shows provisional national data on monthly TB notifications that were reported to WHO by four high TB

Box 4.5 Two examples of the interpretation and use of weekly or monthly TB case notification data at country level

Example 1: A sudden increase in TB case notifications

A sudden increase in weekly or monthly notifications may be due to an outbreak and should prompt investigation. The source(s) of the increased case numbers should be identified and contact tracing investigations carried out. For the latter, individual-level data, including names and addresses, are required. Such investigations are typically the responsibility of the health authority responsible for the notifiable diseases register (e.g. the national CDC).

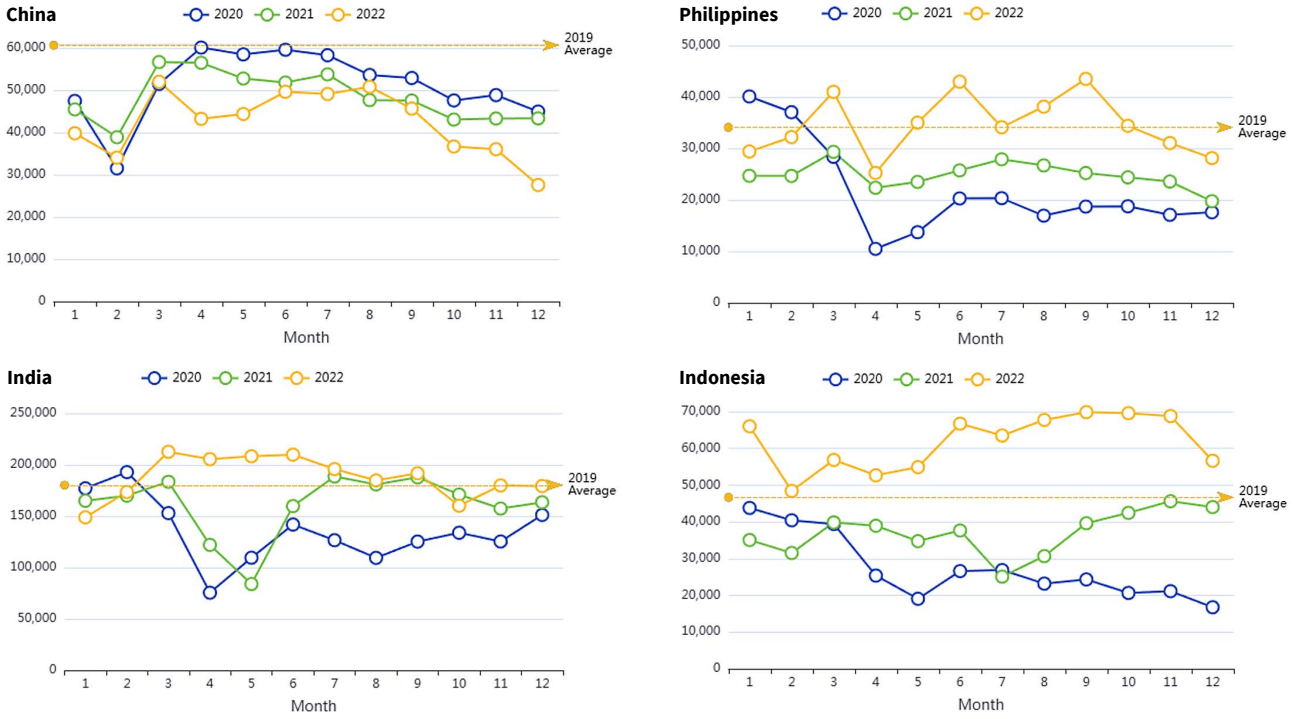
Example 2: A sudden change in TB case notifications

A sudden change in notifications may be due to one-off or periodic events. Examples include provider-initiated screening campaigns, or a change in the availability of or access to TB diagnostic and treatment services. Disruptions to diagnostic and treatment services due to stock outs, industrial action by workers, holidays, emergencies or lockdowns may cause a sudden decrease, while adding new facilities to the reporting network may cause a sudden increase.

Disruptions to reporting systems could also be an explanation for a sudden change in notifications. Reporting systems can be affected by a variety of factors: for example, staff shortages (such as those due to absences or strikes) and IT problems. In such cases, reductions are often followed by increases once reporting mechanisms are restored.

District or regional-level data are usually sufficient to detect sudden changes in notifications. Investigation of the cause(s) is typically the responsibility of the NTP or, in the case of reporting issues, the authority responsible for the national health information system. Remedies, if needed, may be within the remit of the NTP or may require a wider response.

Fig. 4.2 Provisional national data on monthly TB notifications in four high TB burden countries during the COVID-19 pandemic, as reported to WHO



burden countries during 2020, 2021 and 2022, relative to the average for 2019. These data clearly illustrate how TB notifications were impacted at different stages of the COVID-19 pandemic and where (and when) the biggest efforts were needed to ensure recovery of TB diagnostic and treatment services.

4.4 Indicators to report and use on a quarterly basis

Quarterly reporting is necessary for the regular monitoring of epidemiological trends and the programmatic response at national and subnational levels. It relies on a limited core set of indicators, and findings are used to prompt corrective actions if needed. For example, a noticeable change in the total number of TB notifications (or the notification rate per 100 000 population), or a marked change in the percentage of people diagnosed with bacteriologically confirmed pulmonary TB, or a marked change in the percentage of people tested for drug susceptibility, are all examples of observations that should prompt review and, if appropriate, corrective action.

The core set of indicators recommended for quarterly reporting (Section 4.4.1) represents a subset of those required for a national annual report (Section 4.5).[1] By convention, the four quarters are defined as follows: Q1: 1 January – 31 March; Q2: 1 April – 30 June; Q3: 1 July – 30 September; and Q4: 1 October – 31 December.

4.4.1 Core set of indicators for all countries

Table 4.2 lists the core set of indicators which **all countries** are recommended to report and use on a quarterly basis, irrespective of whether a paper-based aggregated or case-based digital surveillance system is in place. These indicators should be reported for all administrative units in the national TB surveillance system, down to the lowest appropriate level (e.g. districts, regions, provinces), and used at these administrative levels as well as nationally.

If a national digital case-based surveillance system is in place, individual-level data can be entered at health facility level. Automated dashboards and reports can be included in the system to enable timely calculation and interpretation of the core set of indicators, at all relevant administrative levels.

If a manual or paper-based system of aggregated reporting is still in use, a quarterly form can be used to collate and report the data required for the indicators listed in Table 4.2 at the health facility level, and to then produce aggregated reports at higher administrative levels (e.g. district, province, national). It is worth highlighting that **most of the indicators listed in Table 4.2 can be calculated from data compiled using the paper-based quarterly reporting templates that were provided in WHO guidance issued in 2013** *(6)*.

An example of a template that could be used to report the required data in a paper-based aggregated reporting system is provided in Web Annex D.

Table 4.3 provides examples of how the indicators recommended for quarterly reporting might be interpreted and used. In each of the examples listed, possible interpretations of noticeable changes (besides real changes in the underlying TB epidemiology) that may require action are suggested.

A country example of how the core indicators for quarterly reporting (Table 4.2) can be visualized and interpreted is provided in Fig. 4.3, using data from Pakistan.

The time periods for which notification data and treatment outcome data should be included in a quarterly report are different (Table 4.2, Fig. 4.4). Indicators related to notifications and diagnoses of new episodes of TB, as well as treatment initiation, should be based on data for the main reporting quarter. However, indicators for treatment outcomes will be for an earlier time period. For example, the percentage of people treated for drug-susceptible TB who were cured should be based on the cohort of people who started their treatment in the same quarter, 12 months previously (Fig. 4.4).

4.4.2 Additional indicators that are recommended, and additional disaggregations of notification data that may be considered, in countries with a case-based digital surveillance system

In countries with case-based digital surveillance systems, it may be appropriate to expand the core set of indicators for quarterly reporting.[2]

Five additional indicators are recommended if case-based digital surveillance is in place (Table 4.4): two for people with presumptive TB; one for people diagnosed with TB disease; and two for people who are contacts of people diagnosed with TB disease.[3]

Examples of **additional disaggregations** of data that **may be relevant** for the number of notifications of people diagnosed with a new episode of TB are provided in Table 4.5. These disaggregrations are recommended **only for countries with a case-based digital surveillance system**. Care should be taken not to add too

[1] Note that this is a **change from previous guidance** where quarterly reports were intended to be used at the end of the year to compile an annual report. In this guidance, quarterly reporting includes fewer indicators than those needed for the annual report.

[2] Experience has shown that trying to add systematic collection of the additional data required for the indicators shown in Table 4.4 and the disaggregations shown in Table 4.5 to existing paper-based aggregated reporting systems is complex and cumbersome, and risks making data collection, compilation and analysis overly time-consuming and prone to error. This problem was observed in many of the >100 national TB epidemiological reviews conducted 2013–2021. See Web Annex A.

[3] WHO has developed digital packages and tools to help countries to collect the data needed for the additional indicators included in Table 4.4; further details are provided in Chapter 6.

Table 4.2 Core set of TB surveillance indicators for quarterly reporting in all countries, irrespective of whether a case-based digital or paper-based aggregated surveillance system is in place

For definitions of indicator numerators and denominators, see Table 4.6.

Indicator	Recommended level of disaggregation
People diagnosed with TB disease	
Notifications: Number of notifications of people diagnosed with a new episode of TB[a]	Sex: male, female, intersex, unknown/unspecified Age group (in years): 0–4, 5–9, 10–14, 15–19, 20–24, 25–34, 35–44, 45–54, 55–64, ≥65 Geographic area: administrative unit[b] Type of TB: pulmonary bacteriologically confirmed, pulmonary clinically diagnosed, extrapulmonary Treatment history: new, recurrent, unknown
Notification rate: Number of people diagnosed with a new episode of TB per 100 000 population	Geographic area: administrative unit[b]
Bacteriological confirmation: Percentage of people diagnosed with a new episode of pulmonary TB whose disease was bacteriologically confirmed	Geographic area: administrative unit[b]
Documentation of HIV status:[c] Percentage of people diagnosed with a new episode of TB whose HIV status was documented	Geographic area: administrative unit[b]
HIV status:[c] Percentage of people with a new episode of TB who are HIV-positive, among those with documented HIV status	Geographic area: administrative unit[b]
Antiretroviral therapy for people living with HIV:[c] Percentage of people living with HIV diagnosed with a new episode of TB who were on or newly enrolled on antiretroviral therapy	Geographic area: administrative unit[b]
Testing for rifampicin resistance: Percentage of people diagnosed with bacteriologically confirmed pulmonary TB who were tested for rifampicin susceptibility	Geographic area: administrative unit[b]
Rifampicin-resistant TB (RR-TB): Number of people diagnosed with bacteriologically confirmed pulmonary TB that is resistant to rifampicin	Geographic area: administrative unit[b]
People treated for TB disease	
Treatment initiation: Percentage of people diagnosed with TB and registered as a TB case in each of the following categories: started on treatment, died before starting treatment, lost to follow-up before starting treatment	Geographic area: administrative unit[b]
Treatment outcome:[d] Percentage of TB patients in each of the following categories out of those who started treatment for drug-susceptible TB[e]: cured; treatment completed; treatment success (cured + treatment completed); treatment failed; lost to follow-up; died; not evaluated	Geographic area: administrative unit[b]

[a] New episodes of TB disease include both drug-susceptible and drug-resistant TB, unless otherwise stated.
[b] Administrative units are reporting entities such as provinces, regions and districts, as opposed to individual health facilities (which are too small a unit for meaningful analysis).
[c] Data required for this indicator are not available in all countries; for example, in some countries data on HIV testing, test results and antiretroviral therapy for people living with HIV are anonymized in surveillance databases. These indicators are of most relevance in countries with a high burden of HIV-associated TB.
[d] The reporting period for this indicator is the patient cohort registered in the quarter that ended 12 months previously, compared with all other indicators in this table. For example, if data for the indicators in this table are compiled for the second quarter of a given year, data for treatment outcomes are compiled for the patient cohort of the second quarter of the previous calendar year.
[e] Quarterly reporting of outcomes for people eligible for treatment for drug-resistant TB is only recommended in settings, and for cohorts, with high volumes of patients.

many additional disaggregations; these may overload those responsible for data entry and compilation, and compromise overall data quality.

It should also be highlighted that **measurement of the indicators and indicator disaggregations shown in Table 4.4 and Table 4.5 does not always have to rely on TB surveillance** i.e. it does not have to rely on the systematic and continuous collection and reporting of data. Data could also be compiled using periodic surveys (e.g. based on a random sample of patient records). Consideration of alternative approaches is particularly warranted if routine data collection, compilation and reporting is likely to significantly add to the size and complexity of the workload for those involved in these tasks, and if measured values for the indicators are unlikely to vary much within short time periods.

Table 4.3 Interpretation and use of core TB surveillance indicators for quarterly reporting: selected examples

Indicator	Possible interpretation of noticeable changes (other than real changes in TB epidemiology)
Number of TB case notifications or notification rate	Increases in notifications could be due to factors such as improvements to services, specific efforts made during the reporting period (e.g. launch of a provider-initiated screening campaign), recent inclusion of additional health providers into the reporting system, or an increase in the number of people clinically diagnosed. Decreases could occur for the opposite reasons. Causes need to be investigated, identified and acted upon as appropriate. In low-incidence countries with strong surveillance systems the TB notification rate is used to track progress towards TB elimination.
Percentage of people diagnosed with a new episode of pulmonary TB whose disease was bacteriologically confirmed	Decreases could be due to factors such as: • overdiagnosis of clinically diagnosed TB; • disruptions to diagnostic services resulting in shortages of cartridges for rapid tests or reagents for smear microscopy or culture testing; • issues with TB laboratory quality assurance resulting in high levels of false-negative results; and • disruptions to reporting, for example due to problems with data linkages between laboratories and health facilities. Increases could reflect recent improvements to diagnostic testing as well as potentially laboratory errors or data reporting errors. Causes need to be investigated, identified and acted upon as appropriate.
Percentage of people diagnosed with a new episode of TB whose HIV status was documented	Decreases could be due to factors such as disruptions to HIV testing services at TB centres, stock-outs of HIV test kits or staff shortages. Increases could result from better availability of tests or an increase in the number of facilities where testing is provided. Causes need to be investigated, identified and acted upon as appropriate.
Percentage of people diagnosed with bacteriologically confirmed TB who had a test for rifampicin susceptibility	Decreases could reflect disruptions to laboratory services (e.g. stock-outs of cartridges or consumables needed for testing, problems with sample transportation systems) as well as laboratory performance (e.g. errors or invalid results) and reporting issues. Increases may be expected following specific efforts to improve the coverage of testing for rifampicin susceptibility. Causes need to be investigated, identified and acted upon as appropriate.
Percentage of people diagnosed with TB who were started on TB treatment	Percentages below 100% should be investigated and corrected. Explanations may include initial losses to follow-up, deaths, data reporting issues, drug stock-outs or disruptions to TB treatment services.

4.4.3 Additional indicators based on other national databases

In some countries, it may be possible to make use of data compiled in other national databases (i.e. data not routinely collected by the TB surveillance system) to generate additional indicators for quarterly reporting. However, the benefits of using additional indicators generated in this way are usually only fully realized if they can be linked with data from the routine TB surveillance system.

One example is data on the number of people living with HIV who were started on TB preventive treatment, which are usually collected and reported by national HIV programmes. People living with HIV are one of the priority subpopulations for which WHO guidelines include a strong recommendation to screen for TB as part of routine HIV care *(8)*, and to provide TB preventive treatment to those eligible *(4)*. Regular reporting and use of such data are particularly relevant in countries with a high burden of HIV-associated TB.

4.5 Indicators to report and use on an annual basis

The purpose of annual reporting is to monitor epidemiological trends and the programmatic response at national and subnational levels, based on **finalized, consolidated and validated data for the latest calendar year**. These data, as well as comparable datasets for previous years, can also be used in the estimation of the burden of TB disease, including the absolute level of and trends in TB incidence and TB mortality.

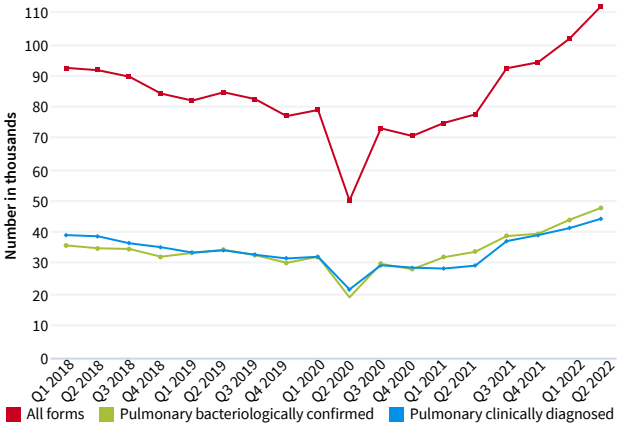
Unlike weekly, monthly and quarterly reporting which typically relies on provisional data, an annual report should be based on a finalized, validated set of data, i.e. data that have been subjected to corrective processes such as de-duplication of records for people notified with TB disease, de-notification of people whose diagnosis was changed from TB, inclusion of any data that were previously missing (e.g. due to the late arrival of test results), and accounting for transfers of patients between facilities.

Fig. 4.3 Visualization and interpretation of quarterly indicators for quarterly reporting: an example using data from Pakistan

Q1: January to March, Q2: April to June, Q3: July to September, Q4: October to December
Source of data: National TB Programme, Pakistan. Missing means either no data or a value could not be calculated.

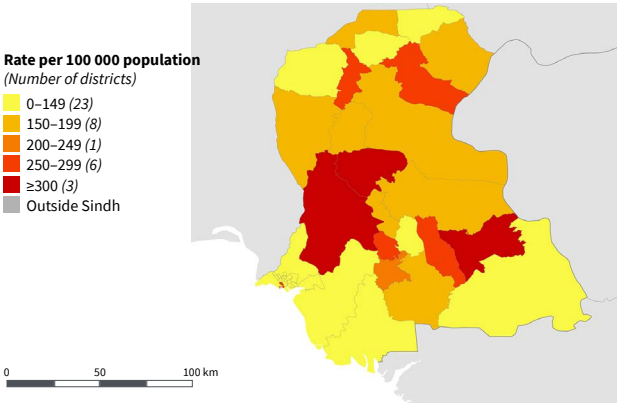
1. National number of people diagnosed and notified with a new episode of TB disease, overall and by type of diagnosis, Q1 2018 to Q2 2022

The drop in notifications for the period April–June 2020 was during the first national lockdown put in place at the start of the COVID-19 pandemic.



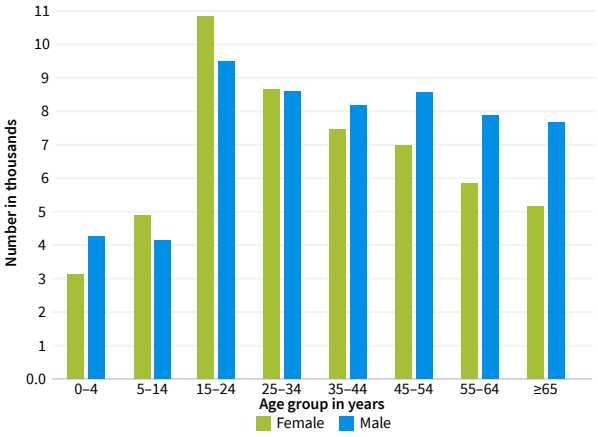
2. Notification rate per 100 000 population of people with a new episode of TB disease, Q2 2022, by district in Sindh province, Pakistan

There was geographic variation in notification rates in the districts of Sindh province. This warranted investigation, to understand if the variation reflected real differences in local TB epidemiology or different approaches to TB case finding and access to TB diagnostic networks.



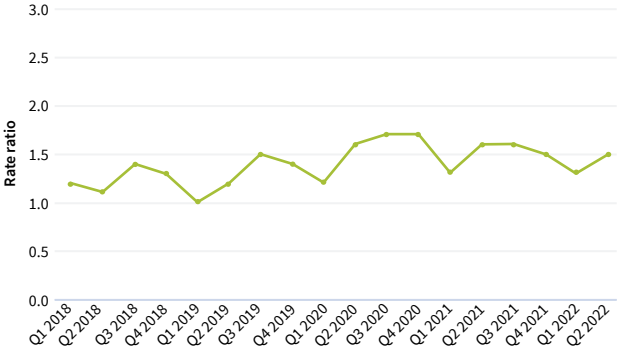
3. National number of people diagnosed and notified with a new episode of TB disease, Q2 2022, disaggregated by age group and sex

Most people notified with TB disease (85%) were aged 15 years and above; the male to female ratio ranged from 0.9 in the age group 5–14 years to 1.5 in those aged over 65 years.



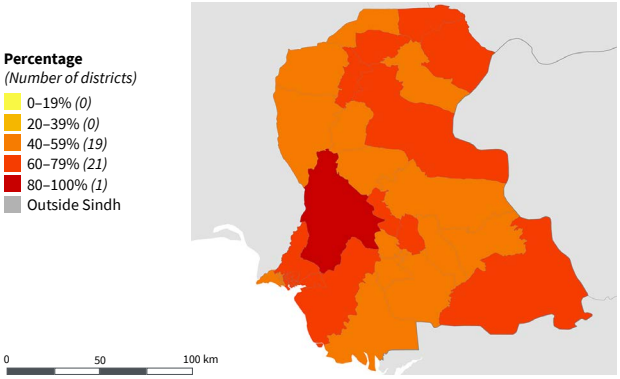
4. National notification rate ratio for children with a new episode of TB disease, comparing those aged under 5, to those aged 5–14 years, Q1 2018 to Q2 2022

The rate ratio remained within a range of 1.0 and 2.0 every quarter. Natural history of disease studies suggest a ratio of 1.5–3.0 in settings where TB is endemic. Countries achieving values within the expected range suggest strong programmatic capacity to identify and treat TB disease in children and particularly those aged under 5.



5. Percentage of people diagnosed with a new episode of pulmonary TB that was bacteriologically confirmed, Q2 2022, by district in Sindh province, Pakistan

Considerable geographical variation was observed. This warranted further investigation to understand if the variation reflected real differences in local TB epidemiology or lack of access to TB diagnostic networks, particularly in the 19 districts with low percentages (<60%).



6. Percentage of people diagnosed with a new episode of extrapulmonary TB disease, Q2 2022, by district in Sindh province, Pakistan

Considerable geographic variation was observed, with the highest (>30%) percentages observed in six districts in Sindh province. Possible explanations included over-diagnosis of extrapulmonary TB (especially in children) or under-diagnosis of pulmonary TB overall.

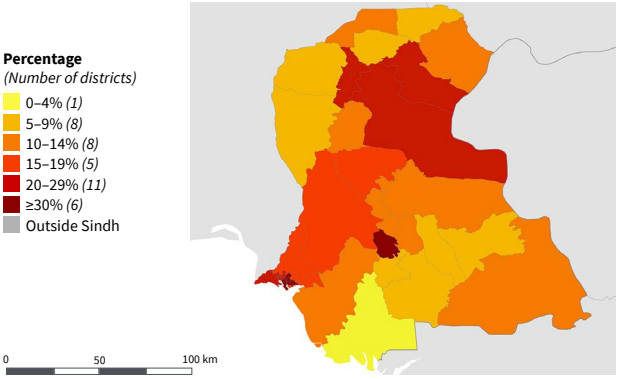
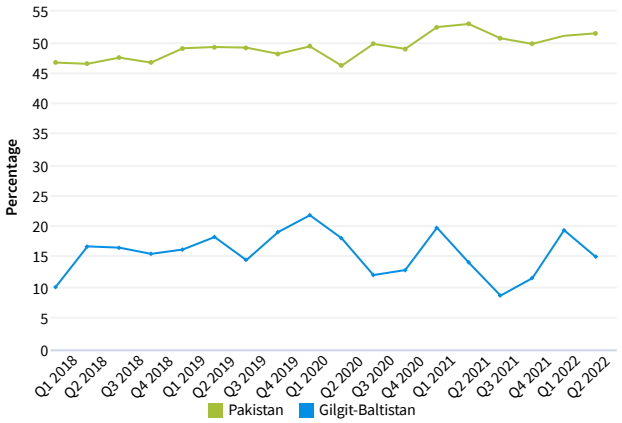


Fig. 4.3 Visualization and interpretation of quarterly indicators for quarterly reporting: an example using data from Pakistan (continued)

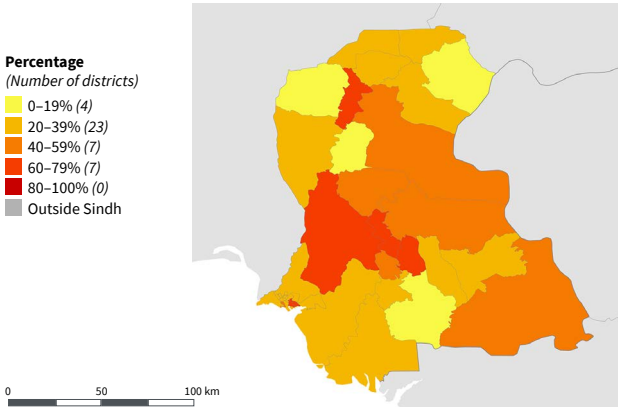
7. Percentage of people diagnosed with a new episode of pulmonary TB that was bacteriologically confirmed, Q1 2018 to Q2 2022: national level compared with Gilgit-Baltistan region

The percentages in Gilgit-Baltistan were consistently lower than the national average. An additional pattern that was observed was a lower percentage in Q3 each year in Gilgit-Baltistan. Such observations have been used to inform planning and resource allocation.



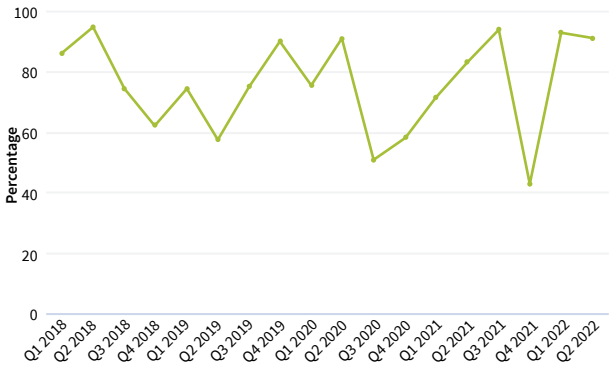
8. Percentage of people diagnosed with a new episode of TB disease with documented HIV status, Q2 2022, by district in Sindh province, Pakistan

There was considerable geographic variation; no district in Sindh province had at least 80% documented HIV status.



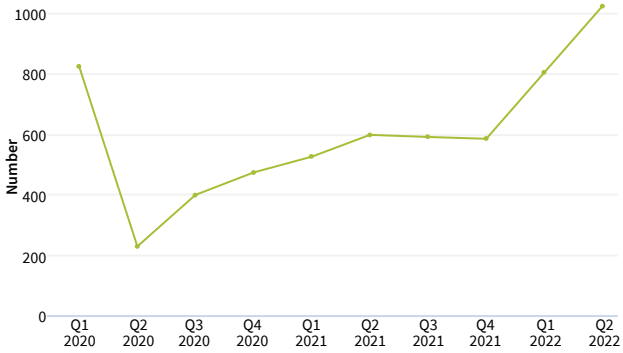
9. National percentage of people newly diagnosed with TB who were newly enrolled or already on antiretroviral therapy (ART), Q1 2018 to Q2 2022

The inconsistent trend was explained by the small number of people diagnosed with TB who were on or eligible for ART.



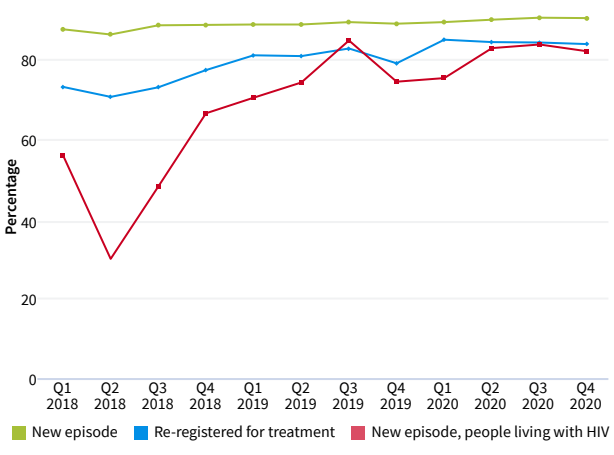
10. National number of people diagnosed with a new episode of pulmonary TB that was bacteriologically confirmed and resistant to rifampicin, Q1 2020 to Q2 2022

The increase in absolute numbers from Q2 2020 was due to improved coverage of testing for rifampicin resistance.



11. National percentage of people who were successfully treated for drug-susceptible TB, by treatment history and for those coinfected with HIV, Q1 2018 to Q4 2020

High levels of treatment success were consistently achieved. Levels were slightly lower for people who were re-registered for treatment. There was more variation among people living with HIV, but improvements were made over time.



12. National treatment outcomes for people treated for drug-susceptible TB, Q1 2018 to Q1 2021

Treatment outcomes were very consistent over time, with high levels of treatment success.

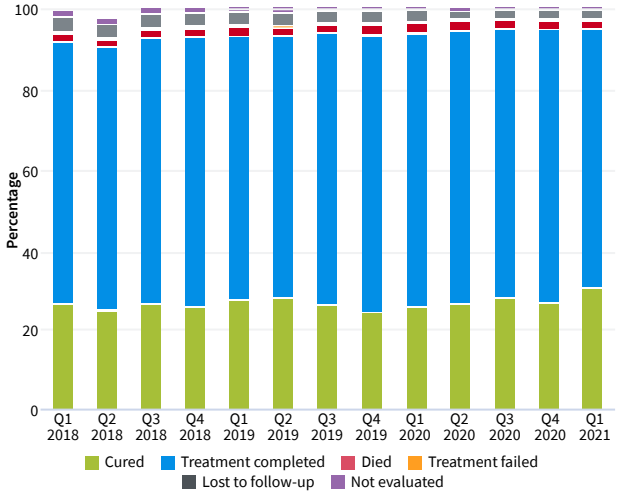


Fig. 4.4 Illustration of the time periods for which notification and treatment outcome data should be included in a quarterly report

This is an example for Q1, 2022 and a similar pattern can be followed for other quarters.

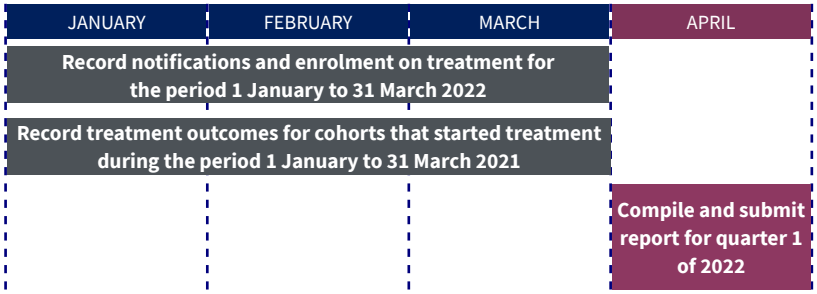


Table 4.4 Five additional indicators that are recommended for quarterly reporting in countries with a case-based digital surveillance system

Indicator	Comment
People with presumptive TB	
Number of diagnostic tests performed for TB using WHO-recommended rapid diagnostic tests (WRDs)	These indicators can be used to measure the level of effort made to diagnose TB. Digital laboratory databases can be used as the source of data for these indicators.
Percentage of tests for TB that were positive using WRDs	
People diagnosed with TB disease	
Rapid testing for TB: Percentage of people diagnosed with a new episode of TB who were initially tested with a WRD	Rapid testing is important in all countries. WRDs are highly accurate, reduce the time to treatment initiation, impact patient-important outcomes, and are cost-effective. A major consequence of insufficient use of WRDs is a large gap in the detection of drug resistance.
Contacts of people diagnosed with bacteriologically confirmed pulmonary TB disease	
Contact investigation coverage: Percentage of household contacts (or all close contacts) who were evaluated for TB (disease or infection)	WHO guidelines on TB preventive treatment recommend that all household contacts of a positive TB case should be evaluated for TB disease and infection *(4)*. Contact investigation coverage and the coverage of TB preventive treatment are two of the indicators recommended by WHO for monitoring implementation of the WHO End TB Strategy. Global targets have been set for TB preventive treatment that have been endorsed by all UN Member States. Of note, some national guidelines recommend investigation of all close contacts, with varying definitions among countries of what constitutes a "close" contact.
Preventive treatment of contacts: Percentage of household contacts (or all close contacts) who were started on TB preventive treatment, out of those eligible	

WRD: WHO-recommended rapid diagnostic test.

Given that annual reporting is based on validated data, the information published in a national annual report will **supersede that provided in quarterly reports**.[1] These annual data, and the associated indicators, form the basis of official statistics at both national and global levels, including the annual reporting of TB data by all Member States to WHO.

4.5.1 Core set of indicators for all countries

Compared with quarterly reports, an annual report is normally more comprehensive and includes a greater volume of data. It might also include data related to specific interventions, programmes, projects or initiatives that are not covered in quarterly reporting (e.g. provider-initiated TB screening programmes that are implemented on a continuous, systematic basis) and analyses of TB-relevant data obtained from outside the TB surveillance system (e.g. data related to deaths from TB that are recorded in a national or sample vital registration system). It may also include indicators that require a combination of surveillance data and estimates of TB disease burden.[2]

[1] Ideally and especially as TB surveillance is strengthened over time, the quarterly reports should be very close to the data published in annual reports.

[2] For example, the denominator of the indicator "treatment coverage" requires estimates of TB incidence; the indicator "case fatality ratio" requires estimates of the number of deaths caused by TB for the numerator and estimates of TB incidence for the denominator).

Table 4.5 Candidates for additional disaggregations of quarterly data about the number of notifications of people diagnosed with a new episode of TB disease in countries with a case-based digital surveillance system

Disaggregation	Comment
Sector of the health system (e.g. public, private for-profit, private non-profit provider)	Disaggregation of notifications by sector of the health system may be relevant in countries with large numbers of providers in the private sector (including private for-profit individual and institutional providers, as well as not-for-profit mission hospitals, nongovernmental organizations and faith-based organizations), and/or large numbers of providers in the public sector that are not within the NTP network (such as public hospitals, public medical colleges, prisons and detention centres, military facilities and public health insurance organizations). A global working group on public-private and public-public mix (PPM) for TB has identified a top priority group of countries for monitoring of TB case notifications by type of health provider *(7)*.
Level of the health system (e.g. community or level 0, primary care or level 1, secondary care or level 2, tertiary care or level 3)	Disaggregation of notifications for different levels of the health system can help programme managers to understand and act on variations in the coverage, provision and quality of TB services throughout the health system. This includes actions to help ensure diagnosis as early as possible in the care-seeking pathway and provision of treatment in a location that is geographically accessible (both of which also contribute to limiting costs faced by people with TB and their households).
Country of origin	This disaggregation is commonly used in low TB burden countries.
Ethnic group	This disaggregation is used in some low TB burden countries.
Risk factor (comorbidity or socioeconomic)	Examples of risk factors for TB disease (beyond age and sex) include comorbidities and socioeconomic risk factors. Examples of comorbidities (other than HIV status which is already part of the core set of indicators for all countries) are diabetes, undernutrition, mental health disorders, drug and alcohol use disorders, and smoking. The quarterly and annual reports of some low-burden countries include disaggregations for social risk factors (e.g. homelessness, imprisonment).
Source of referral (health facility/ community)	This indicator is of most relevance in countries where there is extensive engagement of community health workers and volunteers in TB care (e.g. initial referral to health services of people with presumptive TB and/or treatment support for those diagnosed with TB).

Table 4.6 shows a **recommended set of core indicators for annual reporting that applies to all countries, irrespective of whether a case-based digital or paper-based aggregated surveillance system is in place**. The core set for annual reporting includes all the indicators recommended for quarterly reporting (Table 4.2) plus additional indicators and disaggregations. Most of the additional indicators relate to testing for drug-resistant TB and results from this testing; and to treatment initiation and outcomes for people treated for drug-resistant TB.

If a national digital case-based surveillance system is in place, the core indicators can be directly generated from the national database. Ideally, automated dashboards to summarize and visualize values for the core indicators will be built into the system.[10] An example of an annual reporting form that could be used to report the same data in a paper-based aggregated surveillance system is provided in Web Annex D.

Examples of how the core indicators for annual reporting (Table 4.6) can be visualized and interpreted are provided for a variety of countries in Fig. 4.5.

Examples of analyses and use of the data associated with these recommended core indicators can also be found in a WHO handbook on understanding and using TB data *(9)* and recent editions of the annual WHO Global TB Report *(10)* as well the analytical dashboards of the WHO digital platform for historic TB data *(11)*. Analyses and interpretation of all these data should be conducted at national and subnational levels and used to inform and guide action. The WHO Global TB Report also presents examples of how these annualized data can be used to monitor progress towards national TB targets and milestones. Finally, WHO has developed a conceptual framework that provides guidance on interpreting and using TB surveillance and other relevant data, all along the pathway of prevention and care, to support TB programme planning and prioritization *(12)*.

4.5.2 Additional indicators that are recommended, and additional disaggregations of notification data that may be considered, in countries with a case-based digital surveillance system

As with quarterly reporting, in countries with a case-based digital TB surveillance system, the same five additional indicators in Table 4.4 are also recommended for annual reporting. These are reproduced, for ease of reference, in Table 4.7.

[10] Examples of such dashboards are provided in Chapter 6.

Table 4.6 Core set of TB surveillance indicators for annual reporting and use in all countries, irrespective of whether a case-based digital or paper-based aggregated surveillance system is in place

The indicators comprise all of the core indicators recommended for quarterly reporting and use (Table 4.2) as well as additional core indicators that are recommended only for annual reporting and use. The fourth column identifies whether an indicator is for quarterly reporting, annual reporting or both.

Indicator	Numerator and denominator	Recommended level of disaggregation	Reporting frequency
People diagnosed with TB disease			
Notifications: Number of notifications of people diagnosed with a new episode of TB[a]	*Numerator*: Number of notifications of people diagnosed with a new episode of TB[a] *Denominator*: 1	Sex: male, female, intersex, unknown/unspecified Age group (in years): 0–4, 5–9, 10–14, 15–19, 20–24, 25–34, 35–44, 45–54, 55–64, ≥65 Geographic area: administrative unit[b] Type of TB: pulmonary bacteriologically confirmed, pulmonary clinically diagnosed, extrapulmonary Treatment history: new, recurrent, unknown	Quarterly, annual
Notification rate: Number of people diagnosed with a new episode of TB per 100 000 population	*Numerator*: Number of people diagnosed with a new episode of TB × 100 000 *Denominator*: Number of people in the population	Sex: male, female, intersex, unknown/unspecified Age group (in years): 0–4, 5–9, 10–14, 15–19, 20–24, 25–34, 35–44, 45–54, 55–64, ≥65 Geographic area: administrative unit[b]	Quarterly, annual
Reregistration for TB treatment: Number of people re-registered for TB treatment	*Numerator*: Number of people re-registered for TB treatment *Denominator*: 1	Geographic area: administrative unit[b] Type of TB: pulmonary bacteriologically confirmed, pulmonary clinically diagnosed, extrapulmonary	Annual
Bacteriological confirmation: Percentage of people diagnosed with a new episode of pulmonary TB whose disease was bacteriologically confirmed	*Numerator*: Number of people diagnosed with a new episode of pulmonary TB whose disease was bacteriologically confirmed × 100 *Denominator*: Number of people diagnosed with a new episode of pulmonary TB	Geographic area: administrative unit[b]	Quarterly, annual
Rifampicin-resistant TB (RR-TB): Number of people diagnosed with bacteriologically confirmed pulmonary TB that is resistant to rifampicin	*Numerator*: Number of people diagnosed with bacteriologically confirmed pulmonary TB that is resistant to rifampicin *Denominator*: 1	Geographic area: administrative unit[b]	Quarterly, annual
		Treatment history: new, previously treated	Annual
Documentation of HIV status:[c] Percentage of people diagnosed with a new episode of TB whose HIV status was documented	*Numerator*: Number of people diagnosed with a new episode of TB whose HIV status was documented × 100 *Denominator*: Number of people diagnosed with a new episode of TB	Geographic area: administrative unit[b]	Quarterly, annual
HIV status:[c] Percentage of people with a new episode of TB who are HIV-positive, among those with documented HIV status	*Numerator*: Number of people with a new episode of TB who are HIV-positive × 100 *Denominator*: Number of people with a new episode of TB with documented HIV status	Geographic area: administrative unit[b]	Annual

[a] New episodes of TB disease include both drug-susceptible and drug-resistant TB, unless otherwise stated.
[b] Administrative units are reporting entities such as provinces, regions and districts, as opposed to individual health facilities (which are too small a unit for meaningful analysis).
[c] Data required for this indicator are not available in all countries; for example, in some countries data on HIV testing, test results and antiretroviral therapy for people living with HIV are anonymized in surveillance databases. These indicators are of most relevance in countries with a high burden of HIV-associated TB.

Table 4.6 Core set of TB surveillance indicators for annual reporting and use in all countries, irrespective of whether a case-based digital or paper-based aggregated surveillance system is in place (continued)

Indicator	Numerator and denominator	Recommended level of disaggregation	Reporting frequency
People diagnosed with TB disease (continued)			
Antiretroviral therapy for people living with HIV:[c] Percentage of people living with HIV diagnosed with a new episode of TB who were on or newly enrolled on antiretroviral therapy	*Numerator*: Number of people living with HIV diagnosed with a new episode of TB who were on or newly enrolled on antiretroviral therapy × 100 *Denominator*: Number of people living with HIV diagnosed with a new episode of TB	Geographic area: administrative unit[b]	Quarterly, annual
Coverage of testing for drug resistance among people with bacteriologically confirmed pulmonary TB[d]			
Testing for RR-TB: Percentage of people diagnosed with bacteriologically confirmed pulmonary TB who were tested for rifampicin susceptibility	Numerator: Number of people diagnosed with bacteriologically confirmed pulmonary TB who were tested for susceptibility to rifampicin × 100 *Denominator*: Number of people diagnosed with bacteriologically confirmed pulmonary TB	Geographic area: administrative unit[b] Treatment history: new, previously treated	Quarterly, annual Annual
Testing for multi-drug resistant TB (MDR-TB): Percentage of people diagnosed with bacteriologically confirmed pulmonary TB who were tested for susceptibility to both rifampicin and isoniazid	Numerator: Number of people diagnosed with bacteriologically confirmed pulmonary TB who were tested for susceptibility to both rifampicin and isoniazid × 100 *Denominator:* Number of people diagnosed with bacteriologically confirmed pulmonary TB	Geographic area: administrative unit[b] Treatment history: new, previously treated	Annual
Testing for isoniazid-resistant rifampicin-susceptible TB (Hr-TB): Percentage of people with documented test results for susceptibility to rifampicin who were tested for susceptibility to isoniazid	Numerator: Number of people diagnosed with bacteriologically confirmed pulmonary TB with documented test results for susceptibility to rifampicin who were tested for susceptibility to isoniazid × 100 *Denominator*: Number of people diagnosed with bacteriologically confirmed pulmonary TB with documented test results for susceptibility to rifampicin		Annual
Testing for pre-extensively drug-resistant TB (pre-XDR-TB) in rifampicin-resistant TB (RR-TB): Percentage of people with rifampicin-resistant pulmonary TB who were tested for susceptibility to fluoroquinolones	Numerator: Number of people diagnosed with bacteriologically confirmed pulmonary TB that is resistant to rifampicin who were tested for susceptibility to fluoroquinolones × 100 *Denominator*: Number of people diagnosed with bacteriologically confirmed pulmonary TB that is resistant to rifampicin		Annual

[b] Administrative units are reporting entities such as provinces, regions and districts, as opposed to individual health facilities (which are too small a unit for meaningful analysis).
[c] Data required for this indicator are not available in all countries; for example, in some countries data on HIV testing, test results and antiretroviral therapy for people living with HIV are anonymized in surveillance databases. These indicators are of most relevance in countries with a high burden of HIV-associated TB.
[d] Only results *susceptible* or *resistant* are considered when calculating indicators related to susceptibility testing.

Table 4.6 Core set of TB surveillance indicators for annual reporting and use in all countries, irrespective of whether a case-based digital or paper-based aggregated surveillance system is in place (continued)

Indicator	Numerator and denominator	Recommended level of disaggregation	Reporting frequency
Coverage of testing for drug resistance among people with bacteriologically confirmed pulmonary TB[d] (continued)			
Testing for extensively drug-resistant TB (XDR-TB) in pre-extensively drug-resistant TB (pre-XDR-TB): Percentage of people with pulmonary TB resistant to both rifampicin and fluoroquinolones (pre-XDR-TB) who were tested for susceptibility to bedaquiline and linezolid	Numerator: Number of people diagnosed with bacteriologically confirmed pulmonary TB that is resistant to both rifampicin and fluoroquinolones (pre-XDR-TB) who were tested for susceptibility to bedaquiline and linezolid × 100 *Denominator*: Number of people diagnosed with bacteriologically confirmed pulmonary TB that is resistant to both rifampicin and fluoroquinolones (pre-XDR-TB)		Annual
Testing for bedaquiline resistant TB in pre-extensively drug-resistant TB (pre-XDR-TB): Percentage of people with bacteriologically confirmed pulmonary TB resistant to both rifampicin and fluoroquinolones (pre-XDR-TB) who were tested for susceptibility to bedaquiline	Numerator: Number of people diagnosed with bacteriologically confirmed pulmonary TB that is resistant to both rifampicin and fluoroquinolones (pre-XDR-TB) who were tested for susceptibility to bedaquiline × 100 *Denominator:* Number of people diagnosed with bacteriologically confirmed pulmonary TB that is resistant to both rifampicin and fluoroquinolones (pre-XDR-TB)		Annual
Testing for linezolid resistance in pre-extensively drug-resistant TB (pre-XDR-TB): Percentage of people with bacteriologically confirmed pulmonary TB resistant to both rifampicin and fluoroquinolones (pre-XDR-TB) who were tested for susceptibility to linezolid	*Numerator*: Number of people diagnosed with bacteriologically confirmed pulmonary TB that is resistant to both rifampicin and fluoroquinolones (pre-XDR-TB) who were tested for susceptibility to linezolid × 100 *Denominator*: Number of people diagnosed with bacteriologically confirmed pulmonary TB that is resistant to both rifampicin and fluoroquinolones (pre-XDR-TB)		Annual
Results from testing for drug resistance among people with bacteriologically confirmed pulmonary TB[d]			
RR-TB: Percentage of people tested for RR-TB who were resistant to rifampicin	*Numerator*: Number of people diagnosed with bacteriologically confirmed pulmonary TB that is resistant to rifampicin × 100 *Denominator*: Number of people diagnosed with bacteriologically confirmed pulmonary TB who were tested for susceptibility to rifampicin	Geographic area: administrative unit[b] Treatment history: new, previously treated	Annual

[b] Administrative units are reporting entities such as provinces, regions and districts, as opposed to individual health facilities (which are too small a unit for meaningful analysis).
[d] Only results *susceptible* or *resistant* are considered when calculating indicators related to susceptibility testing.

Table 4.6 Core set of TB surveillance indicators for annual reporting and use in all countries, irrespective of whether a case-based digital or paper-based aggregated surveillance system is in place (continued)

Indicator	Numerator and denominator	Recommended level of disaggregation	Reporting frequency
Results from testing for drug resistance among people with bacteriologically confirmed pulmonary TB[d] (continued)			
MDR-TB: Percentage of people tested for MDR-TB who had MDR-TB	*Numerator*: Number of people diagnosed with bacteriologically confirmed pulmonary TB that is resistant to both rifampicin and isoniazid × 100 *Denominator*: Number of people diagnosed with bacteriologically confirmed pulmonary TB who were tested for susceptibility to both rifampicin and isoniazid	Treatment history: new, previously treated	Annual
Hr-TB: Percentage of people tested for Hr-TB who had Hr-TB	*Numerator*: Number of people diagnosed with bacteriologically confirmed pulmonary TB that is susceptible to rifampicin and resistant to isoniazid × 100 *Denominator*: Number of people diagnosed with bacteriologically confirmed pulmonary TB who were tested for susceptibility to both rifampicin and isoniazid		Annual
Pre-XDR-TB: Percentage of people tested for pre-XDR-TB who had pre-XDR-TB	*Numerator:* Number of people diagnosed with bacteriologically confirmed pulmonary TB that is resistant to both rifampicin and fluoroquinolones (pre-XDR-TB) × 100 *Denominator*: Number of people diagnosed with bacteriologically confirmed pulmonary TB that is resistant to rifampicin who were tested for susceptibility to fluoroquinolones		Annual
XDR-TB: Percentage of people tested for XDR-TB who had XDR-TB	*Numerator*: Number of people diagnosed with bacteriologically confirmed pulmonary TB that is resistant to both rifampicin and fluoroquinolones and also resistant to bedaquiline and/or linezolid (XDR-TB) × 100 *Denominator*: Number of people diagnosed with bacteriologically confirmed pulmonary TB that is resistant to both rifampicin and fluoroquinolones who were tested for susceptibility to bedaquiline and linezolid		Annual

[d] Only results *susceptible* or *resistant* are considered when calculating indicators related to susceptibility testing.

Table 4.6 Core set of TB surveillance indicators for annual reporting and use in all countries, irrespective of whether a case-based digital or paper-based aggregated surveillance system is in place (continued)

Indicator	Numerator and denominator	Recommended level of disaggregation	Reporting frequency
People requiring treatment for TB disease			
Treatment initiation: Percentage of people diagnosed with TB and registered as a TB case in each of the following categories: started on TB treatment, died before starting treatment, lost to follow-up before starting treatment	*Numerator*: Number of people diagnosed with TB and registered as a TB case who started TB treatment × 100 *Denominator*: Number of people diagnosed with TB and registered as a TB case *Numerator*: Number of people diagnosed with TB and registered as a TB case who died before starting TB treatment × 100 *Denominator*: Number of people diagnosed with TB and registered as a TB case *Numerator*: Number of people diagnosed with TB and registered as a TB case who were lost to follow-up before starting TB treatment × 100 *Denominator*: Number of people diagnosed with TB and registered as a TB case	Geographic area: administrative unit[b] Regimen type (for those started on treatment): • Regimens designed to treat rifampicin-susceptible TB (irrespective of HIV-status) • Regimens designed to treat rifampicin-susceptible TB (people living with HIV) • Short (≤12 months) regimens designed to treat rifampicin-resistant TB (RR-TB/MDR-TB/pre-XDR-TB/XDR-TB) • Long (>12 months and ≤24 months) regimens designed to treat rifampicin-resistant TB (RR-TB/MDR-TB/pre-XDR-TB/XDR-TB)	Quarterly, annual Annual
Treatment outcome: Percentage of TB patients in each of the following categories out of those who started TB treatment: cured; treatment completed; treatment success (cured + treatment completed); treatment failed; died; lost to follow-up; not evaluated	*Numerator*: Number of people who started TB treatment who were cured × 100 *Denominator*: Number of people who started TB treatment *Numerator*: Number of people who started TB treatment who completed TB treatment × 100 *Denominator*: Number of people who started TB treatment *Numerator*: Number of people who started TB treatment who were successfully treated (cured or who completed TB treatment) × 100 *Denominator*: Number of people who started TB treatment *Numerator*: Number of people who started TB treatment whose treatment failed × 100 *Denominator*: Number of people who started TB treatment	Geographic area: administrative unit[b] Regimen type: • Regimens designed to treat rifampicin-susceptible TB (irrespective of HIV-status)[e] Regimen type: • Regimens designed to treat rifampicin-susceptible TB (people living with HIV)[c,e] • Short (≤12 months) regimens designed to treat rifampicin-resistant TB[e] (RR-TB/MDR-TB/pre-XDR-TB/XDR-TB) • Long (>12 months and ≤24 months) regimens designed to treat rifampicin-resistant TB[f] (RR-TB/MDR-TB/pre-XDR-TB/XDR-TB)	Quarterly, annual Annual

[b] Administrative units are reporting entities such as provinces, regions and districts, as opposed to individual health facilities (which are too small a unit for meaningful analysis).
[c] Data required for this indicator are not available in all countries; for example, in some countries data on HIV testing, test results and antiretroviral therapy for people living with HIV are anonymized in surveillance databases. These indicators are of most relevance in countries with a high burden of HIV-associated TB.
[e] The reporting period for this indicator is for the patient cohort registered in the year immediately prior to that for all other indicators in this table.
[f] The reporting period for this indicator is for the patient cohort registered two years prior to that for all other indicators in this table.

Table 4.6 Core set of TB surveillance indicators for annual reporting and use in all countries, irrespective of whether a case-based digital or paper-based aggregated surveillance system is in place (continued)

Indicator	Numerator and denominator	Recommended level of disaggregation	Reporting frequency
People requiring treatment for TB disease (continued)			
Treatment outcome: Percentage of TB patients in each of the following categories out of those who started TB treatment: cured; treatment completed; treatment success (cured + treatment completed); treatment failed; died; lost to follow-up; not evaluated	*Numerator*: Number of people who started TB treatment who died for any reason during the course of TB treatment × 100 *Denominator*: Number of people who started TB treatment *Numerator*: Number of people who started TB treatment who were lost to follow-up during TB treatment × 100 *Denominator*: Number of people who started TB treatment *Numerator*: Number of people who started TB treatment to whom no treatment outcome was assigned, excluding those lost to follow-up × 100 *Denominator*: Number of people who started TB treatment		
Case outcome: Percentage of the total number of people diagnosed with TB and registered as a TB case in each of the following categories: cured; treatment completed; treatment success (cured + treatment completed); treatment failed; died; lost to follow-up; not evaluated	*Numerator*: Number of people diagnosed with TB and registered as a TB case who were cured × 100 *Denominator*: Number of people diagnosed with TB and registered as a TB case *Numerator*: Number of people diagnosed with TB and registered as a TB case who completed TB treatment × 100 *Denominator*: Number of people diagnosed with TB and registered as a TB case *Numerator*: Number of people diagnosed with TB and registered as a TB case who were successfully treated (cured or who completed TB treatment) × 100 *Denominator*: Number of people diagnosed with TB and registered as a TB case *Numerator*: Number of people diagnosed with TB and registered as a TB case whose treatment failed × 100 *Denominator*: Number of people diagnosed with TB and registered as a TB case	Geographic area: administrative unit[b]	Quarterly, annual

[b] Administrative units are reporting entities such as provinces, regions and districts, as opposed to individual health facilities (which are too small a unit for meaningful analysis).

Table 4.6 Core set of TB surveillance indicators for annual reporting and use in all countries, irrespective of whether a case-based digital or paper-based aggregated surveillance system is in place (continued)

Indicator	Numerator and denominator	Recommended level of disaggregation	Reporting frequency
People requiring treatment for TB disease (continued)			
Case outcome: Percentage of the total number of people diagnosed with TB and registered as a TB case in each of the following categories: cured; treatment completed; treatment success (cured + treatment completed); treatment failed; died; lost to follow-up; not evaluated	*Numerator*: Number of people diagnosed with TB and registered as a TB case who died for any reason before starting, or during the course of, TB treatment × 100 *Denominator*: Number of people diagnosed with TB and registered as a TB case *Numerator*: Number of people diagnosed with TB and registered as a TB case who were lost to follow-up before starting or during TB treatment × 100 *Denominator*: Number of people diagnosed with TB and registered as a TB case *Numerator*: Number of people diagnosed with TB and registered as a TB case to whom no treatment outcome was assigned, excluding those lost to follow-up × 100 *Denominator*: Number of people diagnosed with TB and registered as a TB case		

Table 4.7 Five additional indicators that are recommended for annual reporting in countries with a case-based digital surveillance system

Indicator	Comment
People with presumptive TB	
Number of diagnostic tests performed for TB using WHO-recommended rapid diagnostic tests (WRDs)	These indicators can be used to measure the level of effort made to diagnose TB. Digital laboratory databases can be used as the source of data for these indicators.
Percentage of tests for TB that were positive using WRDs	
People diagnosed with TB disease	
Rapid testing for TB: Percentage of people diagnosed with a new episode of TB who were initially tested with a WRD	Rapid testing is important in all countries. WRDs are highly accurate, reduce the time to treatment initiation, impact patient-important outcomes, and are cost-effective. A major consequence of insufficient use of WRDs is a large gap in the detection of drug resistance.
Contacts of people diagnosed with bacteriologically confirmed pulmonary TB disease	
Contact investigation coverage: Percentage of household contacts (or all close contacts) who were evaluated for TB (disease or infection)	WHO guidelines on TB preventive treatment recommend that all household contacts of a positive TB case should be evaluated for TB disease and infection *(4)*. Contact investigation coverage and the coverage of TB preventive treatment are two of the indicators recommended by WHO for monitoring implementation of the WHO End TB Strategy. Global targets have been set for TB preventive treatment that have been endorsed by all UN Member States. Of note, some national guidelines recommend investigation of all close contacts, with varying definitions among countries of what constitutes a "close" contact.
Preventive treatment of contacts: Percentage of household contacts (or all close contacts) who were started on TB preventive treatment, out of those eligible	

WRD: WHO-recommended rapid diagnostic test.

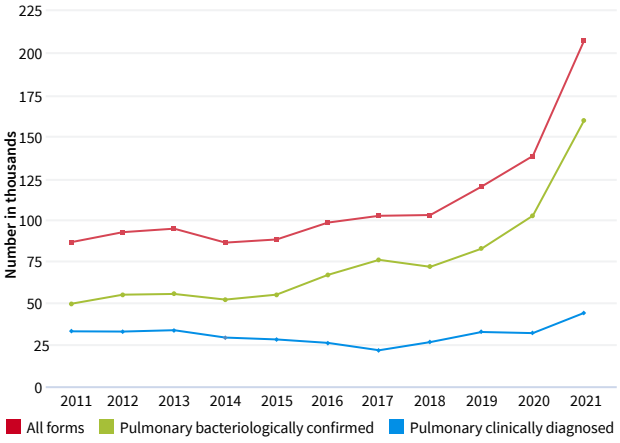
Table 4.8 Candidates for additional disaggregations of data about the annual number of notifications of people diagnosed with a new episode of TB disease in countries with a case-based digital surveillance system

Disaggregation	Comment
Sector of the health system (e.g. public, private for-profit, private non-profit provider)	Disaggregation of notifications by sector of the health system may be relevant in countries with large numbers of providers in the private sector (including private for-profit individual and institutional providers, as well as not-for-profit mission hospitals, nongovernmental organizations and faith-based organizations), and/or large numbers of providers in the public sector that are not within the NTP network (such as public hospitals, public medical colleges, prisons and detention centres, military facilities and public health insurance organizations). A global working group on public-private and public-public mix (PPM) for TB has identified a top priority group of countries for monitoring of TB case notifications by type of health provider *(7)*.[a]
Level of the health system (e.g. community or level 0, primary care or level 1, secondary care or level 2, tertiary care or level 3)	Disaggregation of notifications for different levels of the health system can help programme managers to understand and act on variations in the coverage, provision and quality of TB services throughout the health system. This includes actions to help ensure diagnosis as early as possible in the care-seeking pathway and provision of treatment in a location that is geographically accessible (both of which also contribute to limiting costs faced by people with TB and their households).
Country of origin	This disaggregation is commonly used in low TB burden countries.
Ethnic group	This disaggregation is used in some low TB burden countries.
Risk factor (comorbidity or socioeconomic)	Examples of risk factors for TB disease (beyond age and sex) include comorbidities and socioeconomic risk factors. Examples of comorbidities (other than HIV status which is already part of the core set of indicators for all countries) are diabetes, undernutrition, mental health disorders, drug and alcohol use disorders, and smoking. The quarterly and annual reports of some low-burden countries include disaggregations for social risk factors (e.g. homelessness, imprisonment).
Source of referral (health facility/community)	This indicator is of most relevance in countries where there is extensive engagement of community health workers and volunteers in TB care (e.g. initial referral to health services of people with presumptive TB and/or treatment support for those diagnosed with TB).

[a] Additional indicators for which disaggregation of data by type of provider could be considered are: the percentage of people diagnosed with a new episode of pulmonary TB who were bacteriologically confirmed, the percentage of people diagnosed with a new episode of TB whose HIV status was documented, the percentage of people living with HIV who were on or newly enrolled on ART, the percentage of people diagnosed with bacteriologically confirmed TB who had rifampicin susceptibility testing performed, the number of people diagnosed with RR-TB.

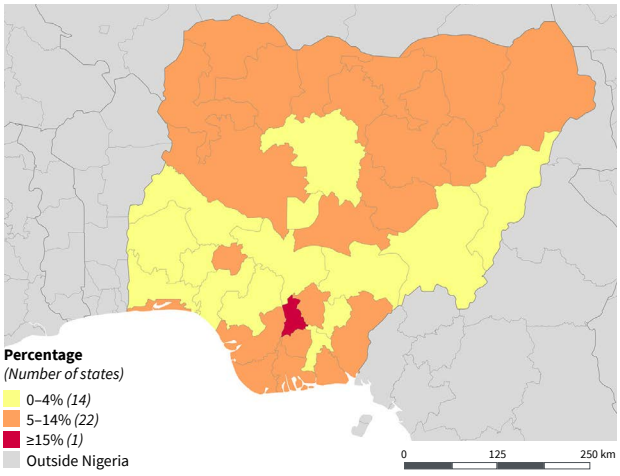
Fig. 4.5 Visualization and interpretation of core indicators for annual reporting, selected countries

1. National number of people diagnosed and notified with a new episode of TB disease, overall and by type of diagnosis, 2011–2021, Nigeria
After years of stagnating levels of case notifications, there was a very large increase between 2019 and 2021. This was consistent with a major expansion of TB screening and diagnostic services in health facilities, evidenced by a comparable increase in the percentage of people diagnosed with TB who were bacteriologically confirmed.



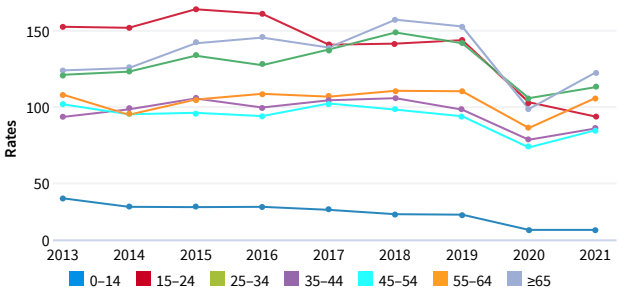
Source of data: National TB Programme, Nigeria

2. Percentage of people diagnosed with a new episode of TB disease who were children (aged 0–14 years), by state, 2021, Nigeria
There was considerable geographic variation. The high level in Anambra state (in red) followed the introduction of provider-initiated screening among orphanages and within child welfare clinics to improve case detection among children.



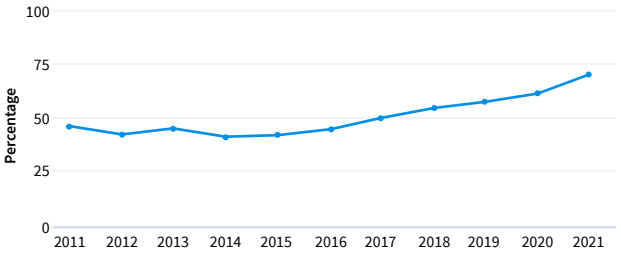
Source of data: National TB Programme, Nigeria

3. National notification rate per 100 000 population of people with a new episode of TB disease by age group, 2013–2021, Peru
There was a large decrease in notification rates among the age group 15–24 years. There was a smaller decrease in the age group 0–14 years. This warranted further investigation, to establish if decreases were due to a real reduction in TB burden among these age groups or changes in programmatic activities. The drop in 2020 occurred during disruptions to health services caused by the COVID-19 pandemic and was consistent across all age groups.



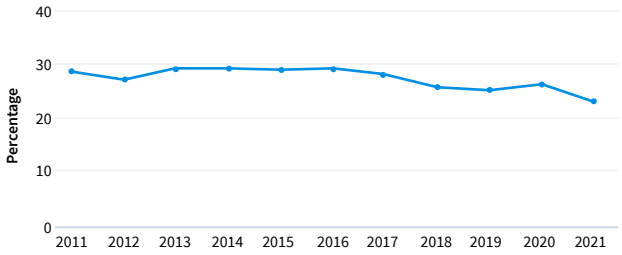
Source of data: Global TB Database

4. National percentage of people diagnosed with a new episode of pulmonary TB that was bacteriologically confirmed, 2011–2021, Uzbekistan
There was marked improvement in laboratory-based confirmation of TB disease, with the percentage rising from 42% in 2015 to 72% in 2021.



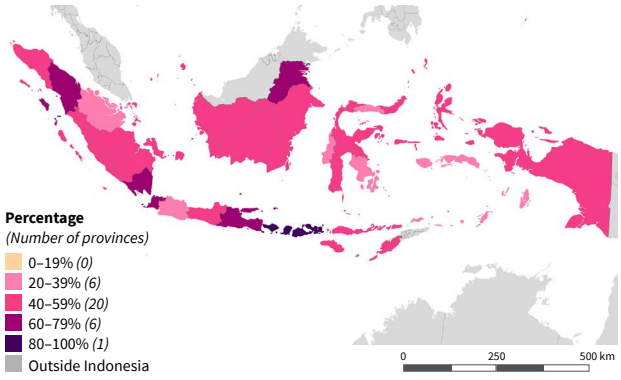
Source of data: Global TB Database

5. National percentage of people diagnosed with a new episode of extrapulmonary TB disease, 2011–2021, Iran
Overall, high levels of extrapulmonary TB disease were documented. The small decline from 2016 to 2021 was consistent with a reduction in the percentage of people diagnosed with TB disease who were living with HIV.



Source of data: Global TB Database

6. Percentage of people diagnosed with a new episode of TB disease with documented HIV status, 2021, by province, Indonesia
There was considerable geographic variation. The percentage was above 80% in two provinces but needed improvement in other parts of the country.

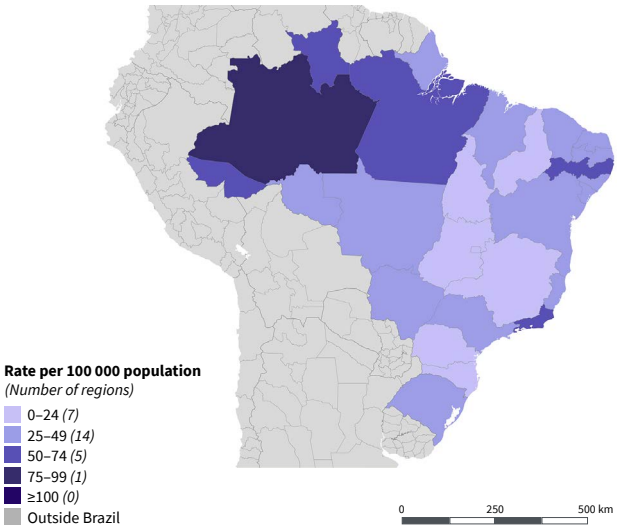


Source of data: National TB Programme, Indonesia

Fig. 4.5 Visualization and interpretation of core indicators for annual reporting, selected countries (continued)

7. Notification rate per 100 000 population of people with a new episode of TB disease, by region, 2021, Brazil

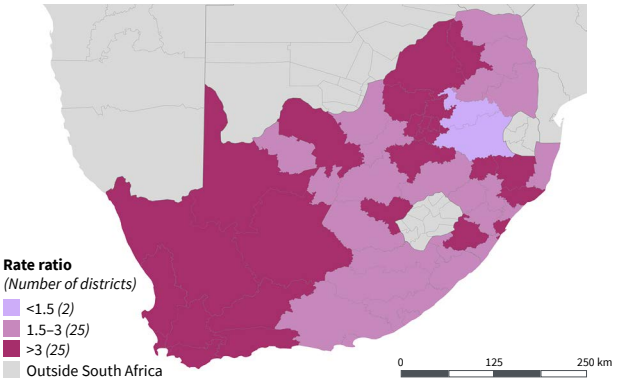
The Amazonia region had the highest notification rate.



Source of data: National TB Programme, Brazil

8. National notification rate ratio for children with a new episode of TB disease, comparing those aged under 5 to those aged 5–14 years by district, 2021, South Africa

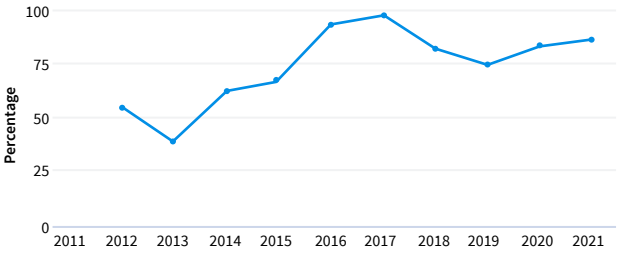
There was considerable geographic variation. Twenty-five districts had a ratio above 3 while two districts in the northeastern part of the country had ratios below 1.5. Natural history of disease studies suggest a ratio of 1.5–3.0 in settings where TB is endemic. Districts achieving values within the expected range suggest strong programmatic capacity to identify and treat TB disease in children and particularly those aged under 5.



Source of data: National TB Program, South Africa

9. National coverage of ART among people newly diagnosed with TB who were known to be living with HIV, 2011–2021, Papua New Guinea

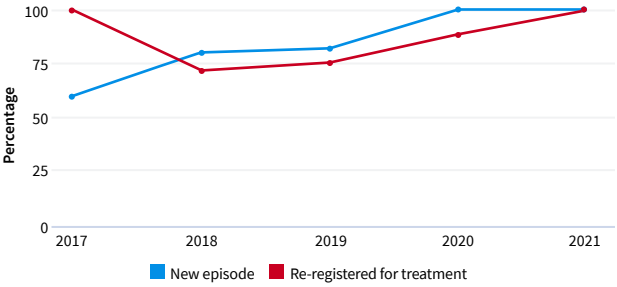
Programmatic efforts to document HIV status among people diagnosed with TB disease were intensified in 2017. This resulted in the identification of more people eligible for ART, and an associated decrease in ART coverage. Subsequently the coverage of ART began to improve.



Source of data: Global TB Database

10. National coverage of testing for rifampicin susceptibility among people diagnosed with pulmonary TB that was bacteriologically confirmed, by treatment history, 2017–2021, Mongolia

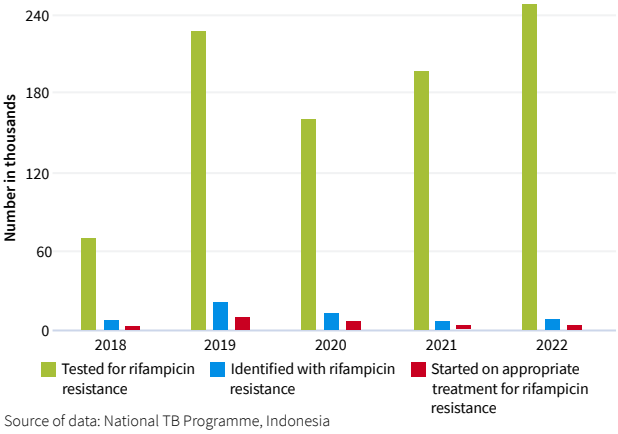
Noticeable improvements were made between 2018 and 2021.



Source of data: Global TB Database

11. National numbers of people with bacteriologically confirmed TB disease, who were tested for rifampicin resistance, identified with rifampicin resistance and started on appropriate treatment, 2018–2022, Indonesia

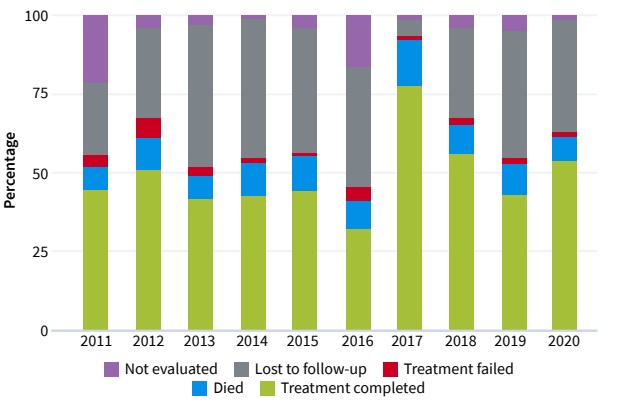
Testing coverage fell in 2020 due to disruptions caused by the COVID-19 pandemic but recovered by 2022. Levels of resistance remained consistently low but there were gaps in treatment enrolment.



Source of data: National TB Programme, Indonesia

12. National treatment outcomes for people treated for drug-susceptible TB, who were previously treated, 2011–2020, Colombia

Inconsistent trends in annual cohorts of treatment outcomes among people who were previously treated for TB were evident. There were high percentages of patients in the lost to follow-up or not evaluated categories. Strengthening support to patients to help them complete treatment was identified as a priority corrective action.



Source of data: Global TB Database

Similarly, countries with a case-based digital surveillance system may consider annual reporting of the additional disaggregations in Table 4.5 of the number of notifications of people diagnosed with a new episode of TB. Examples of such disaggregations, and comments related to the subsets of countries in which they may be relevant, are reproduced in Table 4.8.

There are additional indicators that countries with a case-based digital surveillance system may wish to consider including in their "core set" of indicators for annual reporting and use. Examples are provided in Table 4.9. As highlighted above, care must be taken not to add too many additional indicators; these may overload those responsible for data entry and compilation, and compromise overall data quality.

As also highlighted above, measurement of additional indicators does not always have to rely on TB surveillance i.e. it does not have to rely on the systematic and continuous collection and reporting of data. Data for additional indicators could also be collected using periodic surveys (e.g. based on a random sample of patient records). Consideration of alternative approaches is particularly warranted if routine data collection, compilation and reporting is likely to significantly add to the size and complexity of the workload for those involved in these tasks, and if measured values for the indicators are unlikely to vary much within short time periods.

4.5.3 Additional indicators for specific interventions, projects or programmes

Many countries implement specific interventions or programmes related to TB prevention, diagnosis and treatment for which data are collected separately from the routine TB surveillance system. The most obvious example is provider-initiated screening for TB disease and infection in specific subpopulations considered at particularly high-risk. Beyond the screening of contacts described in Table 4.4 and Table 4.7, subpopulations defined in WHO guidelines as high-risk include:

- people living with HIV;
- miners or other people exposed to silica dust;
- people in prisons or other penitentiary institutions; and
- people with structural risk factors for TB, such as the homeless, communities in remote or isolated areas, communities in urban poor areas, migrants, refugees and internally-displaced people.

Indicators relevant to provider-initiated screening programmes, initiatives or specific projects are listed in Table 4.10.

4.5.4 Additional indicators based on other national databases

To serve the needs of annual national reporting, data from other national databases can be used to supplement data obtained from the routine national TB surveillance system. Examples of additional indicators that it may be possible to report on an annual basis by accessing or linking with other national health data collection efforts and databases include:

- Social protection coverage among people diagnosed with TB disease.
- The number of people living with HIV who were initiated on TB preventive treatment. Data on the use of preventive treatment among people living with HIV are systematically collected and reported in many countries, including at the global level by UNAIDS.
- The completion rate for TB preventive treatment among people living with HIV. Data on the completion of preventive treatment among people living with HIV are systematically collected and reported in many countries, including at the global level by UNAIDS.
- National coverage of BCG vaccination. This can be assessed according to national policy (e.g. whether a policy of universal vaccination or vaccination for specific priority groups is in place).
- TB mortality. The number of deaths attributable to TB can be assessed using mortality data compiled within the national CRVS system, assuming this has sufficient coverage and quality, and causes of death are coded according to the International Classification of Diseases *(2)*. An alternative is to use data from a sample registration system that includes data on causes of death.

Potentially, data that would allow TB case numbers to be disaggregated by the risk factors listed in Table 4.5 and Table 4.8 (e.g. comorbidities such as diabetes, undernutrition, smoking) could also be obtained via data linkages, i.e. by linking individual records from the national TB surveillance database with those in databases managed by other national programmes (e.g. those for nutrition or noncommunicable diseases). However, if these data are considered a high priority, it is likely better to include the relevant variables in the TB surveillance system. Linkage exercises typically involve trying to match very large numbers of individual records, which is time-consuming and difficult to do.

4.5.5 Record linkage

In addition to the national TB surveillance system, there are other potential sources of data about people diagnosed with TB disease that may be useful for measuring

Table 4.9 Examples of additional candidates for inclusion in the core set of indicators for national annual reporting and use in countries with a case-based digital surveillance system

Indicator	Comments
People diagnosed with TB disease	
Percentage of people with a new episode of TB that is clinically diagnosed who had a WRD test **Numerator:** Number of people with a new episode of pulmonary TB that is clinically diagnosed who had a WRD × 100 **Denominator:** Number of people with a new episode of pulmonary TB that is clinically diagnosed	Experience in some countries has shown an unduly high proportion of clinically diagnosed cases had a negative WRD test result. In such settings, it may be important to monitor this indicator. The expected proportion when WRDs are widely used is in the range 10–20% (Web Annex B). Note that if a WRD result is positive then the person should be classified as having bacteriologically confirmed pulmonary TB.
Testing for bedaquiline resistance in people with rifampicin-resistant TB[a]: Percentage of people with pulmonary bacteriologically confirmed TB resistant to rifampicin who were tested for susceptibility to bedaquiline **Numerator:** Number of people with pulmonary bacteriologically confirmed TB that is resistant to rifampicin who were tested for susceptibility to bedaquiline × 100 **Denominator:** Number of people with pulmonary bacteriologically confirmed TB that is resistant to rifampicin	In 2022, WHO recommended a regimen containing bedaquiline and linezolid for the treatment of people with RR-TB. It is important to scale-up DST for these drugs among people with RR-TB to monitor the emergence of resistance.
Testing for linezolid resistance in people with rifampicin-resistant TB[a]: Percentage of people with pulmonary bacteriologically confirmed TB resistant to rifampicin who were tested for susceptibility to linezolid **Numerator:** Number of people with pulmonary bacteriologically confirmed TB that is resistant to rifampicin who were tested for susceptibility to linezolid × 100 **Denominator:** Number of people with pulmonary bacteriologically confirmed TB that is resistant to rifampicin	In 2022, WHO recommended a regimen containing bedaquiline and linezolid for the treatment of people with RR-TB. It is important to scale-up DST for these drugs among people with RR-TB to monitor the emergence of resistance.
People requiring treatment for TB disease	
Treatment outcomes disaggregated by age group and sex: Percentage of TB patients in each of the following categories out of those diagnosed with TB, disaggregated by age group and sex: cured; treatment completed; treatment failed; died; lost to follow-up; not evaluated	These disaggregations are helpful to monitor equity in the provision of quality of care. It also allows programmes to monitor acceptability and adherence to treatment in different population groups.
Treatment initiation for people diagnosed with TB and registered as a TB case who started treatment with regimens designed to treat rifampicin-resistant TB disaggregated by fluoroquinolone resistance status, i.e distinguishing between regimens designed to treat rifampicin-resistant but not fluoroquinolone-resistant TB and regimens designed to treat rifampicin-resistant and fluoroquinolone-resistant TB (pre-XDR-TB/XDR-TB)	These disaggregations are helpful to monitor access to treatment in countries with high levels of fluoroquinolone resistance among people with RR-TB.
Treatment outcomes for people treated with regimens designed to treat rifampicin-resistant TB disaggregated by fluoroquinolone resistance status, i.e distinguishing between regimens designed to treat rifampicin-resistant but not fluoroquinolone-resistant TB and regimens designed to treat rifampicin-resistant and fluoroquinolone-resistant TB (pre-XDR-TB/XDR-TB)	These disaggregations are helpful in countries with high levels of fluoroquinolone resistance among people with RR-TB.
Contacts of people diagnosed with bacteriologically confirmed pulmonary TB disease	
Completion rate for TB preventive treatment among contacts: Percentage of household contacts (or all close contacts) who completed TB preventive treatment (disaggregated by age <5, ≥5 years) **Numerator:** Number of household contacts (or all close contacts) of people diagnosed with a new episode of bacteriologically confirmed pulmonary TB disease who completed TB preventive treatment × 100 **Denominator:** Number of household contacts (or all close contacts) of people diagnosed with a new episode of bacteriologically confirmed pulmonary TB disease who started TB preventive treatment	

WRD: WHO-recommended rapid diagnostic test.
[a] Only results *susceptible* or *resistant* are considered when calculating indicators related to susceptibility testing.

Table 4.10 Indicators relevant to provider-initiated TB screening programmes, initiatives or projects

Indicator	Comments
Percentage of those eligible who were screened	These indicators can be constructed for one or more subpopulations considered at particularly high risk of TB disease or infection. Data for people living with HIV are already systematically compiled and reported in many countries as part of the HIV surveillance system (see also Section 4.4.3). Many low-burden countries have established TB screening programmes to test migrants from higher-burden countries, pre- or post-entry, for TB infection or disease.
Percentage of those screened who were diagnosed with TB disease	
Percentage of those screened who were diagnosed with TB infection	
Number of people started on TB treatment	
Number of people started on TB preventive treatment	

and addressing underreporting of cases to the national TB surveillance system. Annual analyses of underreporting, based on record linkage studies that use individual-level records from the national TB surveillance system and individual-level records available in other existing national databases that include data for people diagnosed with TB, are strongly encouraged. Detailed guidance on how to implement such record-linkage studies (using Link software) is provided in Web Annex C.

Examples of national data sources that can be used for record-linkage studies are:

- Databases maintained by other disease programmes that provide TB screening and diagnostic services e.g. the national programmes for HIV/AIDS, diabetes and nutrition.
- A notifiable diseases registry and reporting system.[1] This may include data for people diagnosed with TB. A caveat is that these systems may produce "noisy" data and often include unconfirmed cases. Numbers need to be interpreted with caution.
- Data on expenditures or reimbursements from health insurance systems.
- Data that adhere to the international classification of diseases (ICD) that are available from hospital networks, for example on TB diagnosis and TB treatment.
- A national reference laboratory information system. This may include data on bacteriological test results from TB screening and TB diagnosis. Laboratory data may be "noisy", and some laboratory systems may only be able to report on the number of positive tests rather than the number of people. A further caveat is that not all positive test results will result in TB notification and treatment; the latter is a decision for clinicians treating patients. There also needs to be a mechanism for exclusion of re-registered cases (i.e. people who failed their most recent treatment or who were lost to follow-up).

[1] For example, WHO's IDSR (Integrated Disease Surveillance and Response) system is in use in many countries in the African Region (https://www.who.int/publications/i/item/AFRO-IDSR2010).

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Chapter 5
Core data items to collect

This chapter defines the **core set of TB data items** that should be systematically and continuously collected for every person with TB disease by the TB surveillance system in all countries, so that the core indicators presented in Chapter 4 can be calculated. It also defines the data items that are required to calculate the five additional indicators that are recommended for reporting and use in countries with a case-based digital surveillance system; and provides examples of the data items required for additional disaggregations of notification data that may be relevant and could be considered for quarterly or annual reporting and use in countries with a case-based digital surveillance system.

Section 5.1 provides detailed specifications of how each of the data items required for the core set of indicators that are applicable to all countries[1] can be named, categorized, coded and recorded in either a digital or paper-based system.

Section 5.2 provides detailed specifications of how each of the data items required for the five additional indicators[2] that are recommended in countries with a case-based digital surveillance system can be named, categorized, coded and recorded.

Section 5.3 provides some examples of the data items required for the additional disaggregations of notification data that are discussed in Chapter 4,[3] which can also be considered in countries with a case-based digital surveillance system.[4]

Section 5.4 provides guidance on how to handle three specific issues that require attention during data collection. These are how to record and report data for a patient whose treatment regimen changes, how to record and report data for a patient who transfers to the care of a different heath facility during their TB treatment, and how to de-notify a case of TB.

Section 5.5 provides a short commentary about how to calculate and report aggregated totals. This is described in more detail in Web Annex D, which provides templates for annual and quarterly reporting forms, as well as a detailed explanation (including formulae) of how to calculate the aggregated totals required to complete these forms.

5.1 Data items to record for every person with TB, all countries

Box 5.1 provides an overview of the data items that need to be collected for every person diagnosed with TB disease so that the core set of TB surveillance indicators recommended for all countries can be calculated. All health facilities that provide TB services should contribute their data to the surveillance system.

Table 5.1 provides a detailed specification of the data items that need to be recorded for every person with TB disease so that the core set of TB indicators recommended for annual reporting (Chapter 4, Table 4.6) can be calculated. For each data item, Table 5.1 also provides a recommended short name, a variable or "code" name, possible valid values and a fuller description of the item.

The data items required for weekly/monthly reporting (Chapter 4, Section 4.3) and quarterly reporting (Chapter 4, Section 4.4) are **a subset** of the items shown in Table 5.1.

The data items defined in Table 5.1 are typically recorded in a "TB register". In a paper-based surveillance system, this is a line listing of case records in a paper book; in a case-based digital system, it consists of digital records for every individual diagnosed with TB. Treatment records for TB patients, laboratory forms and other medical records are among the sources of data that can be used for routine TB surveillance. It is important to clearly define the primary data sources that feed into each data collection form, for each data item. Monitoring data flow is also an important aspect of data quality assurance (Chapter 7).

All people diagnosed with TB should be notified and included in the TB case register, regardless of whether they started treatment and whether they had drug-sus-

[1] i.e. the indicators listed in Table 4.2 (for quarterly reporting) and Table 4.6 (for annual reporting) of Chapter 4.
[2] i.e. the indicators listed in Table 4.4 (which are duplicated, for ease of reference, in Table 4.7) of Chapter 4.
[3] i.e. the disaggregations discussed in Table 4.5 (which are duplicated, for ease of reference, in Table 4.8).
[4] At the same time, users of this guidance are reminded that collection of these additional data items should only be done if there is capacity to record, analyse and use the additional data, or this capacity can be created.

Box 5.1 Core set of data items that need to be collected for every person with TB disease at a given location so that the core TB surveillance indicators[a,b] defined in Chapter 4 can be calculated

- Notification
  - Person ID: this could include a nationally unique number (e.g. national health insurance number) as well as identifiers such as name and address
  - Health care facility that recorded the notification
  - Registration date
  - Age
  - Sex
  - History of previous treatment for TB
  - Anatomical site of disease (pulmonary, extrapulmonary)
  - Method of diagnosis (bacteriologically confirmed, clinically diagnosed)
  - Drug susceptibility test (DST) results
    - DST result for rifampicin
    - DST result for isoniazid
    - DST result for fluoroquinolones
    - DST result for bedaquiline
    - DST result for linezolid
  - Treatment regimen type eligibility
  - HIV status
  - Date started on antiretroviral therapy
- Enrolment on TB treatment
  - Was treatment started
  - Date treatment started
  - Treatment regimen type duration
- Result of TB treatment
  - Date outcome assigned
  - Treatment outcome

[a] i.e. those relevant to all countries, and to both case-based digital and paper-based aggregated surveillance systems, as defined in Chapter 4 (Table 4.2 and Table 4.6).
[b] While not essential, including the results of laboratory tests for diagnosis and monitoring of treatment response is useful to validate the variables listed above.

ceptible or drug-resistant TB. The TB register is a register of **all** people with TB disease, in a given time period.

5.2 Data items required for five additional indicators recommended for countries with a case-based digital surveillance system

Chapter 4 defined five additional indicators[1] that are recommended for all countries with a case-based digital surveillance system: two for people with presumptive TB; one for people diagnosed with TB disease; and two for people who are contacts of people diagnosed with TB disease.[2]

The data items that need to be recorded to calculate these five indicators (including a recommended short name, a variable or "code" name, possible valid values and a fuller description of the item) are provided in Table 5.2, Table 5.3 and Table 5.4.

5.3 Examples of data items required for additional disaggregations of the number of people notified with a new episode of TB disease, which can be considered in countries with a case-based digital surveillance system

Chapter 4 provided examples of additional disaggregations of data for people diagnosed with a new episode of TB that may be relevant in subsets of countries.[3] These included disaggregations by type of provider, level of the health system, country of origin, risk factors (including socio-economic status and comorbidities) and source of referral. With the prerequisite that a case-based digital surveillance system is in place, some countries may wish to routinely report and use these additional disaggregations as part of their routine surveillance system for TB.

Examples of the data items that would need to be recorded to routinely report and use data according to such disaggregations (including a recommended short name, a variable or "code" name, possible valid values and a fuller description of the item) are provided in Table 5.5. Before embarking on the collection of such data, it is essential that there is capacity (or such capacity can be created) to record, analyse and use the additional disaggregations that these data items generate.

[1] i.e. the indicators listed in Table 4.4 (which are duplicated, for ease of reference, in Table 4.7) of Chapter 4.
[2] WHO has developed digital packages and tools to help countries to collect the data needed for the additional indicators included in Table 4.4; further details are provided in Chapter 6.
[3] See Table 4.5 and Table 4.8.

Table 5.1 Core set of data items to record for every person with TB disease

This table is relevant for all countries, irrespective of whether a case-based digital or paper-based aggregated surveillance system is in place. Suggested codes have been included for each data item. The purpose of these codes is to show how indicators are calculated from the data items (see Section 5.5).

Data item name	Code	Possible values	Definition (for full details related to definitions, see Chapter 3)
Health facility ID	facility_id		Unique ID of the health facility that recorded the notification
Notification details of the person with TB disease			
Person ID	person_id		Unique ID of the person moving through the health system
Registration date	registered_date	(valid date)	Date when registration details of the person with TB were added to the TB register. This defines the cohort period in which the person will be included in treatment outcome monitoring (e.g. date between 1 January and 31 March = Quarter 1 of that year). If a person is re-registered (for example after needing a change of treatment regimen), the registration date refers to the date at which the person was re-registered.
Age	age		Age at last birthday at time of registration (in years)
Sex	sex	F	**Female**: Sex assigned at birth is female (ICD-11 code XX2V25)
		M	**Male**: Sex assigned at birth is male (ICD-11 code XX2UQ8)
		I	**Intersex**: The person was born with sex characteristics (including genitals, gonads and chromosome patterns) that do not fit typical binary notions of male or female bodies (ICD-11 code XX45B7)
		U	**Unknown/unspecified** (ICD-11 code XX2PX3)
Treatment history	tx_history	N	**New**: The person has never been treated for TB before or has only previously ever taken TB drugs for less than 1 month
		R	**Recurrent**: The person was previously treated for TB, was declared cured or treatment completed at the end of their most recent course of TB treatment and is now diagnosed with a new episode of TB
		P	**Re-registered**: The person had been notified previously as a TB case, started treatment and took TB drugs for at least 1 month but was not declared cured or treatment completed, and is now being registered for a new course of TB treatment
		U	Undocumented history of TB treatment
Anatomical site of TB disease	disease_site	P	Pulmonary
		E	Extrapulmonary
Method of diagnosis	diagnosis_ method	B	Bacteriologically confirmed
		C	Clinically diagnosed
HIV status	hiv_status	P	HIV-positive
		N	HIV-negative
		U	HIV status unknown
Date started on antiretroviral therapy	art_start_date	(valid date)	Date the person was started on antiretroviral therapy
Rifampicin susceptibility test result	rif_susceptibility	S	The result of drug susceptibility testing shows that the person is infected with a strain of *M. tuberculosis* **complex susceptible to rifampicin**
		R	The result of drug susceptibility testing shows that the person is infected with a strain of *M. tuberculosis* complex **resistant to rifampicin**
		U	Unknown: There is no documented result of drug susceptibility testing for rifampicin for this person or the test result was indeterminate
Date rifampicin susceptibility status determined	rif_susc_date	(valid date)	Date the rifampicin susceptibility status was determined

Table 5.1 Core set of data items to record for every person with TB disease (continued)

Data item name	Code	Possible values	Definition (for full details related to definitions, see Chapter 3)
Notification details of the person with TB disease (continued from previous page)			
Isoniazid susceptibility test result	inh_ susceptibility	S	The result of drug susceptibility testing shows that the person is infected with a strain of *M. tuberculosis* complex **susceptible to isoniazid**
		R	The result of drug susceptibility testing shows that the person is infected with a strain of *M. tuberculosis* complex **resistant to isoniazid**
		U	Unknown: There is no documented result of drug susceptibility testing for isoniazid for this person or the test result was indeterminate
Date isoniazid susceptibility status determined	inh_susc_date	(valid date)	Date the isoniazid susceptibility status was determined
Fluoroquinolone susceptibility test result	fq_susceptibility	S	The result of drug susceptibility testing shows that the person is infected with a strain of *M. tuberculosis* complex **susceptible to fluoroquinolones**
		R	The result of drug susceptibility testing shows that the person is infected with a strain of *M. tuberculosis* complex **resistant to fluroquinolones**
		U	Unknown: There is no documented result of drug susceptibility testing for fluroquinolones for this person or the test result was indeterminate
Date fluoroquinolone susceptibility status determined	fq_susc_date	(valid date)	Date the fluoroquinolone susceptibility status was determined
Bedaquiline susceptibility test result	bdq_ susceptibility	S	The result of drug susceptibility testing shows that the person is infected with a strain of *M. tuberculosis* complex **susceptible to bedaquiline**
		R	The result of drug susceptibility testing shows that the person is infected with a strain of *M. tuberculosis* complex r**esistant to bedaquiline**
		U	Unknown: There is no documented result of drug susceptibility testing for bedaquiline for this person or the test result was indeterminate
Date bedaquiline susceptibility status determined	bdq_susc_date	(valid date)	Date the bedaquiline susceptibility status was determined
Linezolid susceptibility test result	lzd_ susceptibility	S	The result of drug susceptibility testing shows that the person is infected with a strain of M. tuberculosis complex **susceptible to linezolid**
		R	The result of drug susceptibility testing shows that the person is infected with a strain of *M. tuberculosis* complex **resistant to linezolid**
		U	Unknown: There is no documented result of drug susceptibility testing for linezolid for this person or the test result was indeterminate
Date linezolid susceptibility status determined	lzd_susc_date	(valid date)	Date the linezolid susceptibility status was determined
Eligibility for TB treatment			
TB treatment regimen type eligibility	tx_regimen_type	ds	The person is eligible for treatment using a regimen designed for TB that is not resistant to rifampicin
		rr	The person is eligible for treatment using a regimen designed for TB that is resistant to rifampicin Note that if there is a need to distinguish between treatment based on fluoroquinolone resistance, this code could be split into two alternatives: rr_nfqr: The person is eligible for treatment using a regimen designed for TB that is resistant to rifampicin but not resistant to fluoroquinolones and rr_fqr: The person is eligible for treatment using a regimen designed for TB that is resistant to rifampicin and also resistant to fluoroquinolones

Table 5.1 Core set of data items to record for every person with TB disease (continued)

Data item name	Code	Possible values	Definition (for full details related to definitions, see Chapter 3)
Treatment for TB disease			
Was treatment started?	tx_started	Y	TB treatment was started
		N	TB treatment was not started
Date treatment started	tx_start_date	(valid date)	Date at which the patient started the anti-TB treatment regimen. This is needed to determine when treatment outcomes of cured, or treatment completed, can be assigned
Treatment duration	tx_duration		Number of months the chosen regimen is designed to be administered
Reason treatment was not started	notx_reason	died	The person died before TB treatment could be started
		lost	The person did not start treatment for any reason other than death
Result of TB treatment			
Treatment outcome	tx_outcome	cure	The patient was cured
		cmplt	The patient completed taking the treatment
		fail	The treatment failed
		died	The patient died for any reason after starting TB treatment
		lost	The patient was lost to follow-up after starting TB treatment
		neval	The outcome was not evaluated
Date outcome assigned	tx_outcome_ date	(valid date)	Date at which the patient's TB treatment outcome was determined

Table 5.2 Data items required for every person with presumptive TB, to calculate two indicators for people with presumptive TB

Data item name	Code	Possible values	Definition
WHO-recommended rapid diagnostic test result	wrd_result	P	Test result positive
		N	Test result negative
		U	Test result unknown or not done

Table 5.3 Data items required for every person diagnosed with TB, to calculate the coverage of rapid testing for initial diagnosis

Data item name	Code	Possible values	Definition
Use of a WHO-recommended rapid diagnostic (WRD)	wrd	Y	Yes, a WHO-recommended rapid diagnostic that employs molecular or biomarker-based techniques for the diagnosis of TB was used as the initial diagnostic test
		N	No, a WHO-recommended rapid diagnostic that employs molecular or biomarker-based techniques for the diagnosis of TB was not used as the initial diagnostic test

Table 5.4 Data items required for every household contact of every person diagnosed with a new episode of bacteriologically confirmed pulmonary TB disease, to calculate indicators related to contact investigation coverage and provision of TB preventive treatment[a]

Data item name	Code	Possible values	Definition
Index case ID	index_id		Unique ID of a person of any age with new or recurrent bacteriologically confirmed pulmonary TB initially identified in a specific household or comparable setting in which others may have been exposed
Household contact ID			Unique ID of a household contact of the index case. In some countries the recommendation is to investigate all "close" contacts
Age	age		Age at last birthday at time of screening (in years)
Has the person been screened for TB disease?	screened	Y	Yes, screened according to national guidelines
		N	No, not screened
Date screened for TB?	tpt_screen_date	(valid date)	Date the screening of the individual was conducted
Is the person eligible for TB preventive treatment according to national guidelines?	tpt_eligible	Y	Yes, the person is eligible for TB preventive treatment
		N	No, the person is not eligible for TB preventive treatment
TB preventive treatment started?	tpt_started	Y	Yes, TB preventive treatment started
		N	No, TB preventive treatment was not started
Date started TB preventive treatment	tpt_start_date	(valid date)	Date TB preventive treatment was started
Completion of TB preventive treatment	tpt_completed	Y	TB preventive treatment is completed
		N	TB preventive treatment is not completed

[a] These data items should be recorded for each person who shared the same enclosed living space as someone diagnosed with bacteriologically confirmed TB (the index case) for one or more nights or for frequent or extended daytime periods during the 3 months before the index case was diagnosed with TB. It should also include contacts who were not screened for TB.

5.4 Specific issues with patient and data flow that need attention

5.4.1 What to do when a patient's TB treatment regimen is changed

Treating a person with TB can be long and difficult. National TB programmes (NTPs) use several treatment regimens for people with TB disease depending on the case type, clinical presentation of individuals, and available resources. NTPs must be able to account for the number of people with TB disease who started (or who did not start) a particular treatment regimen, as well as what happened to them. This allows NTPs to monitor the overall effectiveness of their performance in treating individuals appropriately.

A person with TB disease may have to change treatment regimen multiple times, changes that the TB surveillance system needs to be able to record and monitor. When those managing a TB patient's treatment determine that a patient is not responding adequately, and that the treatment regimen needs to be changed (according to national treatment guidelines), this can be documented as follows:

1. Record outcome of current treatment as a failure (tx_outcome = fail);
2. Create a new treatment record for the person, now as a re-registered case (tx_history = P);
3. Record the new treatment regimen (tx_regimen) and new date of initiation (tx_start_date).

Web Annex E provides illustrative scenarios related to the reporting of people diagnosed with TB, when their treatment regimen is changed.

5.4.2 What to do when a patient transfers to another facility

As treatment for TB disease is lengthy, it is not unusual for people being treated to move to another part of the country during the period of their treatment. Traditionally, the health facility that originally notified a TB case (the "source" facility) would have been responsible for reporting the final treatment outcome and therefore would have needed to ask the facility at which the patient completed their treatment (the "destination" facility) for the final outcome. This is not always done, resulting in that patient being reported as "not evaluated" by the source facility.

Table 5.5 Examples of data items required for every person diagnosed with TB, for additional (optional) disaggregations of data for people diagnosed with TB

Data item name	Code	Possible values	Definition
Sector of the health care facility (health care provider)	facility_sector	public	Public
		pr_not_profit	Private not-for-profit
		pr_for_profi	Private for-profit
Level of the health care facility	facility_level	primary	
		secondary	
		tertiary	
Diabetes screening test result[a]		Diabetic	Person has documented evidence of diabetes
		Not diabetic	Person has documented evidence of no diabetes
		U	Unknown: There is no documented evidence of diabetic status for the person
Source of referral		community	Person identified with TB disease was referred to the health facility by a community worker
		self	Person identified with TB disease sought care themselves
		provider	Person identified with TB disease was referred to the health facility by another health provider
Country of birth/origin		native	
		other	

[a] Diabetes is one example of a risk factor for TB disease for which it may be useful to collect data. Other comorbidities or socioeconomic factors could be relevant, e.g. smoking, undernutrition, alcohol use disorders, depending on the country context (see also Chapter 4, Table 4.5 and Table 4.8).

This edition of WHO guidance on TB surveillance recommends that responsibility for reporting the notification remains with the source facility, but that responsibility for reporting the final treatment outcome switches to the destination facility. This means that the reporting responsibility lies with the facility that cares for, and has contact with, the patient at the relevant stage of their care pathway.

However, for this to work in practice, it is essential that the source facility receives confirmation that the destination facility has taken over responsibility for the treatment of the TB patient. The source facility should have already made the TB patient's details available to the destination facility.

The process is the same regardless of whether treatment was started at the source facility.

The data items related to patient transfers that need to be recorded in an aggregated reporting system based on a paper TB register are provided in Table 5.6 and Table 5.7.

Implementation of the recommended approach to reporting of data for people who transfer between health facilities during their TB treatment is much easier if a national, digital, case-based system is in place. The treatment record can be re-allocated to the destination facility, along with an audit trail of the re-allocation.

Web Annex D shows how transfers can be accounted for in quarterly and annual reports.

5.4.3 What to do when a TB case is de-notified

Sometimes people are treated for TB disease, and thus captured in a TB treatment register, when in fact they do not have TB. This can occur, for example, because of delays in receiving laboratory speciation results, and it subsequently transpires that an individual does not have TB but is instead infected with a non-tuberculous mycobacterium. It is also possible for the same episode of TB disease in a given individual to be recorded multiple times in the same register of a health facility, or across different registers of multiple facilities.

When any of these situations occur, records of a non-TB disease episode must be de-notified, and any duplicate records of the same episode of TB must be removed. Table 5.8 provides data items that need to be recorded.

Table 5.6 Data items required in the source facility TB register for tracking transfers between facilities

Data item name	Code	Possible values	Definition
Transferred out	transfer_out	Y	The patient has been received into the care of another facility for anti-TB treatment, as confirmed by that facility
Transfer date	transfer_out_ date	(valid date)	The date the 'destination' facility confirmed the person was now under their care for anti-TB treatment
Destination facility ID			Name or unique code of the facility to whose care the patient moved

Table 5.7 Data items required in the destination facility TB register for tracking transfers between facilities

Data item name	Code	Possible values	Definition
Transferred in	transfer_in	Y	The patient has been received into the care of this facility for anti-TB treatment and has confirmed this to the 'source' facility and copied notification and treatment details into its register
Transfer date	transfer_in_date	(valid date)	The date the facility registered the person to be under its care for anti-TB treatment
Source facility ID			Name or unique code of the facility from where the patient moved

Table 5.8 Data items related to case denotification

Data item name	Code	Possible values	Definition
De-notify case record	denotified	Y	Exclude the TB case record and related treatment outcomes from aggregate reports
Reason de-notified	denotified_ reason	dup	The record is a duplicate of another record relating to the same person's TB notification, whether at the same or another facility
		nottb	The person was found not to have TB

Paper register: Cross the record out so that it is not included in any aggregate report. If a report has already been sent, then the higher level will need to be informed.

Case-based digital: Complete the variables in Table 5.8 so that the record will be automatically excluded from any aggregate report. Recording de-notification is more transparent than physically deleting a record.

5.5 Compiling and reporting aggregated data

TB surveillance reports are composed of aggregated data (**totals)** rather than a listing of the details of each person with TB. The numbers in a surveillance report thus typically refer to the total number of events matching specific criteria, at a given location such as a health facility or a household, for a given time period. This might be, for example, the number of new episodes of TB detected at a given health centre during the first three months of the year 2022. The numbers from individual health facilities are then aggregated up an administrative hierarchy so that the same totals – the number of new episodes in the first quarter of 2022, are calculated, for example, at the district and then the regional level and finally at national level.

All health facilities that provide TB care services, including public and private hospitals or health centres, general practitioners and prisons, should report into the national TB surveillance system.

Totals are used to gauge the level of disease activity, and hence resource needs, in each geographical area.

If there is a national case-based digital TB surveillance system in place, then the aggregated totals can be calculated automatically from the individual case records held in the system. Consequently, there is no need for health facilities to report their aggregated data up the administrative chain. Nonetheless, individual reporting units are urged to protect time to generate and review their own performance indicators at regular intervals, during or outside supervision visits. This activity is recommended both in settings with a digital, case-based surveillance system and settings with paper-based surveillance systems.

In the absence of a case-based digital system (i.e. the national surveillance system only stores aggregated numbers), staff at health facilities must compile their totals manually from patient notes and/or TB registers (a time-consuming and potentially error-prone activity) and then feed these totals into the system. This is done either by sending paper-based reports up the administrative hierarchy or by entering the totals into a digital national system for reporting of aggregated data.

To make it possible to compare data fairly between areas with different numbers of people or patients, the aggregated totals are converted into **normalized indicators**. These typically present totals as rates, proportions or percentages of a given group: for example, the percentage of people with pulmonary TB who were bacteriologically confirmed in a given region during the year 2022. Indicators are discussed in detail in Chapter 4.

5.5.1 Annual and quarterly reporting forms for aggregated data

Templates for manual or paper-based reporting of aggregated data on a quarterly and annual basis are provided in Web Annex D. These templates are designed to ensure that all of the data required to calculate the core indicators applicable to all countries on a quarterly basis (Chapter 4, Table 4.2) and an annual basis (Chapter 4, Table 4.6) are reported.

Both templates are relatively long, and some sections may be full of zeros for facilities with low TB-related workloads.

Web Annex D also provides a detailed explanation (including formulae) of how the aggregated totals required for such reporting can be calculated. **These calculations should be automated in a digital case-based surveillance system.**

Chapter 6
Digital surveillance

National, digital, case-based surveillance systems for TB have several advantages compared with the more traditional paper-based aggregated systems. For this reason, one of the objectives of this guidance is to encourage countries to make the transition from paper-based aggregated to case-based digital TB surveillance, as well as to support countries that are seeking to strengthen their existing digital case-based systems.

This chapter highlights the main advantages of case-based digital surveillance systems. It then describes how national case-based digital TB surveillance should work in practice, with particular attention to three key design features. This is followed by an overview of WHO products and tools that are available to support countries to establish, sustain and strengthen digital case-based TB surveillance systems.

6.1 Advantages of case-based digital surveillance

The main advantages of case-based digital surveillance compared with paper-based surveillance are reductions in the recording and reporting workload of frontline workers, better data quality, faster access to data at all levels, more flexible data analysis and enhanced use of data through record linkage between databases.

6.1.1 Reductions in recording and reporting workload

Case-based digital systems spare frontline health care workers from the tedious, time-consuming and error-prone job of compiling aggregate reports from paper registers. If implemented well, case-based digital systems should free up staff time, especially in facilities with large numbers of patients.

6.1.2 Better data quality

Automated checks can be built into a digital system to ensure that data for any given patient are accurate, internally consistent and complete. Checks to detect duplicated entries for the same person can also be included.

6.1.3 Faster access to data at all levels

Case-based digital systems in which individual-level data are recorded as soon as possible (e.g. shortly after TB diagnosis) can provide close to real-time information, in turn enabling more timely data-informed decisions. This is in contrast to aggregated reporting systems, in which data are only updated periodically (for example, every quarter).

6.1.4 More informative data analysis without requiring an additional reporting workload

Case-based digital systems store individual-level records linked to each health facility. In addition to allowing the automatic generation of aggregated reports for each layer of the administrative hierarchy (from the lowest level such as district, up to national level), indicators within these reports can be disaggregated by any combination of variables. For TB surveillance, examples include disaggregations by location/area, age, sex, case type, previous treatment history, HIV status, drug resistance status and treatment regimen. This allows for more detailed analysis and understanding of TB epidemiology and the performance of TB services compared with aggregated reporting systems, in turn enabling better adaptation and targeting of programmatic responses geographically and for specific population groups.

Detailed disaggregation of indicators is very difficult in aggregated reporting systems and comes with significant costs that can include additional staff time, staff demotivation and poor data quality.

6.1.5 Enhanced use of data through record linkage between databases

Case-based digital systems rely on the use of unique personal identifiers. If different systems all use the same unique personal identifiers, it is possible to link data for the same individual with other digital datasets (e.g. national databases for TB can be linked with those for HIV, diabetes and health insurance; and with digital records of treatment adherence). This is what is referred to as deterministic linkage. It is also possible to carry out probabilistic record linkage, using dedicated software, with a combination of identifying variables (see Web Annex C).

Examples of the uses of such data linkages in the context of TB include assessment of the burden of HIV and diabetes among people with TB, measurement of underreporting of people diagnosed with TB to the national TB surveillance system *(1)* and informing outbreak investigations by matching TB surveillance data to TB genotyping data from laboratories.

6.2 How should national case-based digital TB surveillance work in practice?

One goal on which there is strong consensus among the global TB community is that all countries have national case-based and digitized surveillance systems for TB that function well.

In a well-functioning system, data for all individuals with or at risk of TB should be effectively and efficiently captured wherever and whenever they use health services for the prevention and care of TB disease or TB infection, and then consolidated, analysed, reported and used.

Key design features required for case-based digital TB surveillance to work well are the use of unique identifiers, an integrated system for TB surveillance that encompasses both drug-susceptible and drug-resistant TB, and interoperability between the TB surveillance system and other parts of the overall architecture for public health surveillance.

Prerequisites for the successful establishment and maintenance of a national system for case-based digital TB surveillance include standards for metadata, indicators and analytics, infrastructure and equipment, a competent core national health information and surveillance team, sufficient staffing and funding, and political commitment to the collection, routine analysis and use of TB data.

Eight case studies of national experience in establishing and enhancing case-based digital TB surveillance (from England, Wales and Northern Ireland; Georgia; Indonesia; Iran; Mongolia; the Netherlands; the Philippines; and the United Republic of Tanzania) are featured in Box 6.1, Box 6.2, Box 6.3, Box 6.4, Box 6.5, Box 6.6, Box 6.7 and Box 6.8.

6.2.1 Unique identifiers

Individuals access health care in various locations. These include public and private health facilities (e.g. general practitioners, clinics, hospitals, laboratories); in their household if health care or community health workers make home visits; and at the workplace. TB surveillance depends on being able to link data for the same individual, wherever they access care.[1] This is more efficient and accurate when the different information systems use the same, unique identifier for each individual.

Unique identifiers can be based on a single number that is assigned to all individuals accessing health services in a given country, for example, a national health insurance number.[2] Alternatively, it could be based on biometric data, for example, a fingerprint.

It is important that the unique identifier is easily accessible whenever an individual interacts with the health system, to limit the risk of losing or misclassifying critical surveillance data (e.g. laboratory results).

Individual-identifying data and information should be anonymous and confidential, and their collection and use should adhere to ethical standards *(3, 4, 5)*.

6.2.2 Integrated system for TB surveillance

There should be a single, comprehensive digital system for TB surveillance. Fragmentation, such as separate digital systems for people with drug-susceptible TB disease and people with drug-resistant TB disease, should be avoided.

Duplication of effort in collecting data, especially by frontline workers (e.g. more than one data collection process for the same data), also needs to be avoided. An example is collection of TB notification data by both the NTP and the notifiable diseases surveillance department of the ministry of health, through separate surveillance systems. Clear definition of the objectives, roles and responsibilities of the different stakeholders involved in collecting and using data can help to prevent unnecessary duplication.

As far as possible, project-based solutions should be limited; however, if unavoidable, there should be a clear and time-bound plan for their eventual integration into the national architecture for public health surveillance.

[1] See Chapter 2, Fig. 2.1.

[2] A good overview and specific recommendations for the use of unique identifiers for the provision of individual-level care is available in Chapter 4 of the Consolidated guidelines on person-centred HIV patient monitoring and case surveillance *(2)*.

Box 6.1 The national system for digital TB surveillance in England, Wales and Northern Ireland

Tuberculosis (TB) is a notifiable disease in the United Kingdom of Great Britain and Northern Ireland. Anyone with confirmed or presumptive TB must be notified within three days by registering details on the national TB surveillance (NTBS) web-based platform (Fig. B6.1.1). The NTBS is managed by a national TB team in the United Kingdom Health Security Agency (UKHSA). The NTBS platform specifications are a .NET application with a SQL server backend and a reporting system using Windows Power Bi. User authentication and identity are managed using Windows Active Directory. The national TB team provides user support in office hours through a dedicated inbox. User permissions can be set to different levels of access, for example to specific regions or TB services. An overview of the NTBS architecture is shown in Fig. B6.1.2.

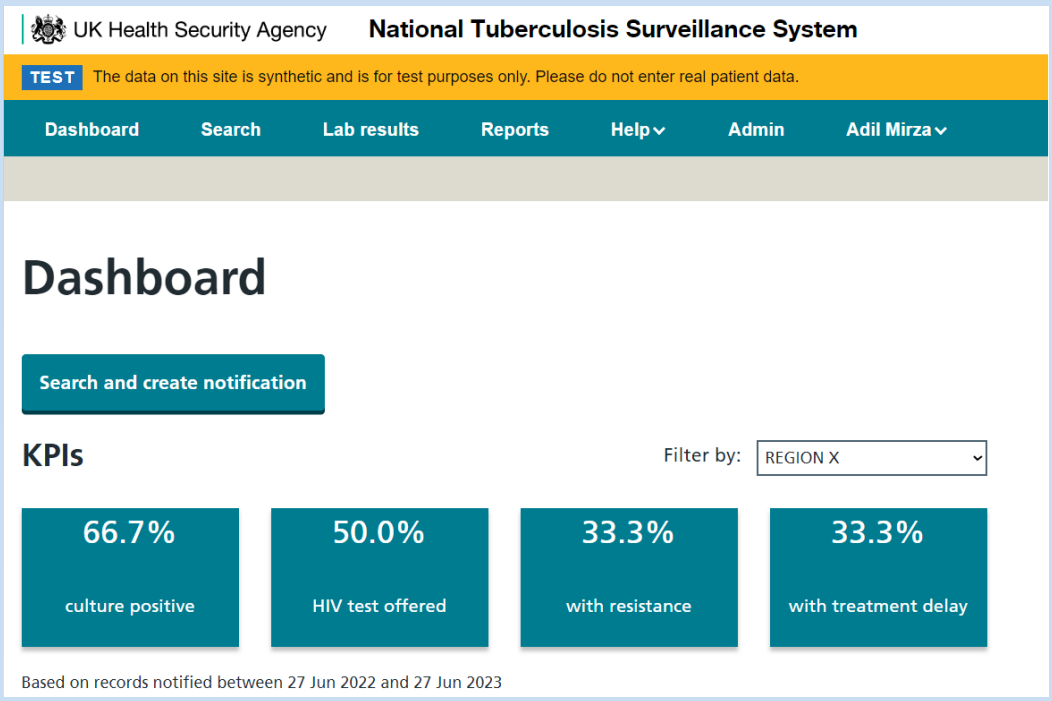
Information on TB notifications is entered by registered users, including TB case managers in the National Health Service. Members of local and national health protection teams and regional field services also have access permissions. TB case managers update information on case notifications as information becomes available, including local hospital test results from chest x-rays, PCR, sputum microscopy and histology. Information about the socio-demographic characteristics of cases, social risk factors, clinical comorbidities, and treatment outcomes are also entered. In total, each case notification contains up to 500 data items across 50 different tables within the NTBS.

Summary data are also collected on the number of contacts traced, screened and found to have active disease for each notification; however, identifiable information on these people is not included for data governance reasons. There is a separate, and currently unlinked, database for the programmatic screening of TB infection.

The NTBS receives automated feeds on information from the mycobacterial reference laboratories in London and Birmingham (which currently operate different laboratory information management systems) on samples matched to notifications using a matching algorithm. At the end of 2022, results from reference laboratories for Wales and Northern Ireland were being obtained via manual feeds. Results include culture positivity, species and drug resistance predictions based on whole genome sequencing (WGS) for all culture-positive samples.

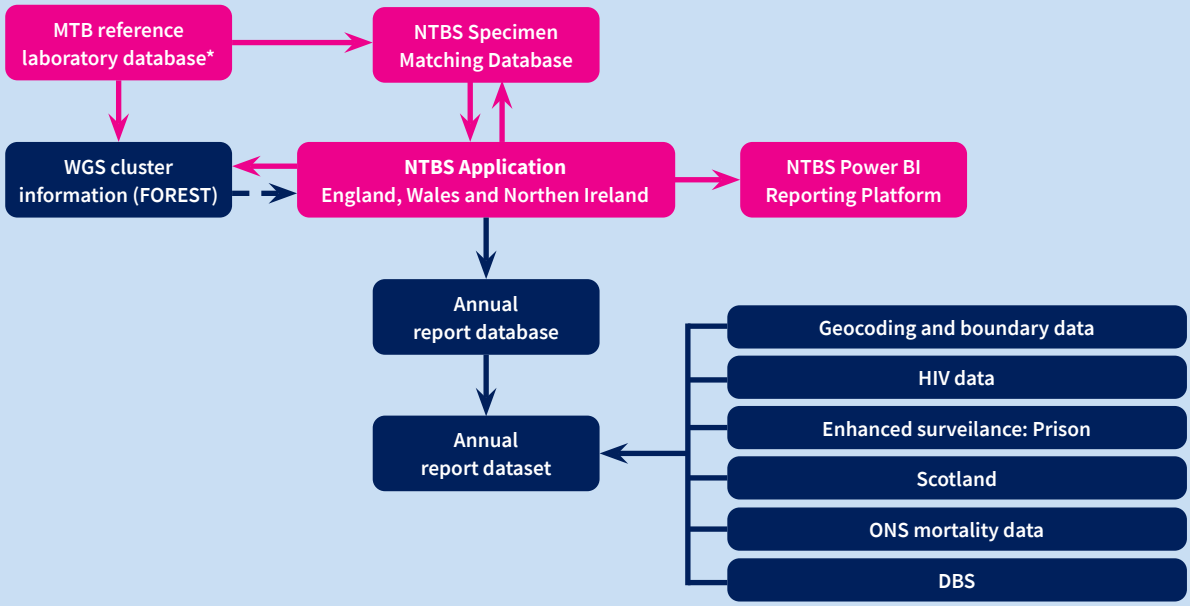
The NTBS has various in-built queries and automated reminders to help ensure data quality.

Fig. B6.1.1 Screenshot showing the front-page dashboard of the NTBS



Box 6.1 The national system for digital TB surveillance in England, Wales and Northern Ireland (continued)

Fig. B6.1.2 Overview of the National Tuberculosis Surveillance (NTBS) architecture



DBS: Demographics Batch Service; MTB: *M. tuberculosis*; ONS: Office of National Statistics; WGS: whole genome sequencing.
Application code is open source, available in github repository: https://github.com/publichealthengland/ntbs_Beta.

Outputs from the NTBS include summary bespoke reports and line lists that can be generated through the NTBS front-end by registered users according to their level of access (e.g., limited to their TB service or region) using Power Bi (Fig. B6.1.3).

A system is already in place for users to make user enhancement requests, which are considered by the NTBS management team with transparent prioritisation and tracking of progress.

The annual report dataset is extracted from the NTBS database and WGS cluster information (FOREST) by the national team and is used for official reporting. Further information from external data sources is appended (TB notifications from Scotland) or merged into the dataset during the process, again using matching algorithms. This includes seeking to find as complete information as possible on HIV-coinfection, deaths and prison history.

Front-end users can search for an existing notification using personal identifiers, including to check that a case has not already been notified prior to creating a new notification.

The tab for laboratory results provides a list of results from the reference laboratory feeds that could not be perfectly matched using the matching algorithm and provides suggested potential matches for TB case managers to review and assign a match.

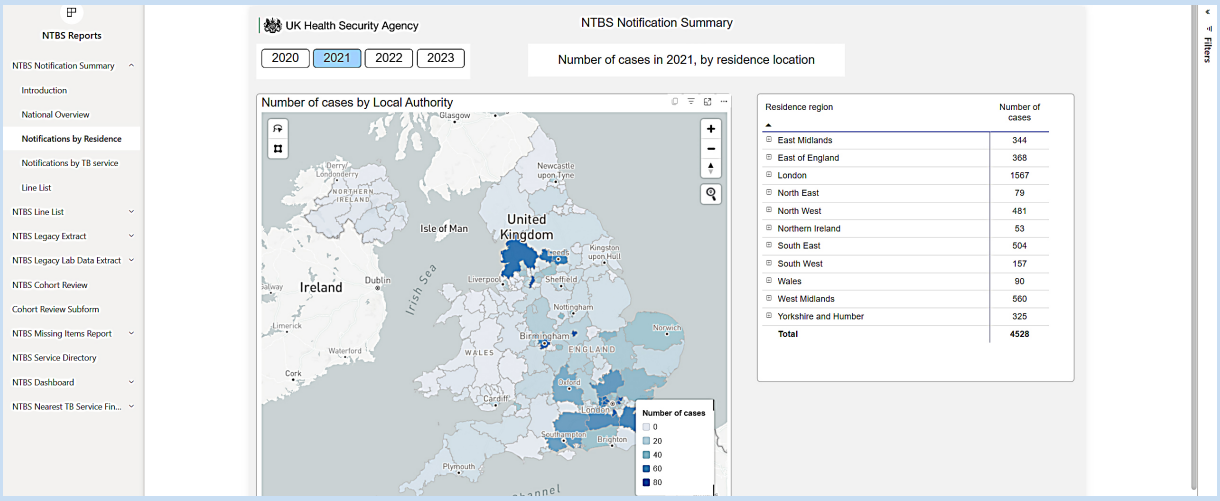
The Reports tab provides a link to the automated summary reports and line lists in Windows Power Bi that users can refine as desired (Fig. B6.1.3).

The Help tab provides a link to resources such as frequently asked questions, the data dictionary and related documentation and training materials held on SharePoint.

The dashboard shows selected Key Performance Indicators (KPIs) by the selected filter (and depending on access permissions). Culture-positive status is provided for all TB notifications. Resistance includes those with monoresistance to first-line anti-TB drugs as well as rifampicin resistance and multi-drug resistance. Treatment delay is defined as more than 60 days between reported symptom onset and start of treatment for all notifications.

Box 6.1 The national system for digital TB surveillance in England, Wales and Northern Ireland (continued)

Fig. B6.1.3 Screenshot of an example NTBS Power Bi report



The report shows the number of notified cases by UKHSA region in 2021 for a user who has access to data for all regions. On the right-hand side of the screen is a Filters tab, which can be expanded to allow further refinement of reports and line lists by setting logical statements using any of the NTBS variables.

Box 6.2 The Digital Health Management Information System for TB in Georgia

The Ministry of Internally Displaced People, Labour, Health and Social Affairs of Georgia has used information technology to streamline data systems, including those for TB. In 2022, with support from the Global Fund, a new TB Health Management Information System (TB HMIS) was developed to enable provision of real-time, reliable and comprehensive data. The new system is fully digital, follows the patient pathway from identification of a presumptive case to follow-up after treatment completion and covers people with active TB disease as well as those with TB infection. In addition, the system includes programmatic data for reimbursement of TB services and is linked with the civil registry and mobile apps used for surveillance (TraceTB) and Video Supported Treatment (AdhereTB).

The system provides information for a variety of purposes. These include epidemic surveillance and programmatic use by the National Center for Disease Control and Public Health; supervision of preventive, diagnostic and therapeutic services by the National Center for Tuberculosis and Lung Diseases and National Reference Laboratory; service reimbursement within the State TB Program for National Health Agency; and comprehensive data for decision makers to support evidence-based decisions. The inbuilt analytical module enables visualization of information (for example through dashboards) and supports assessment of health service performance and decision making. Based on routine health facility data collected from public and private entities, it can also generate indicators about outputs, outcomes and impact for local and international accountability.

A mobile application called TraceTB was developed locally in 2021, for contact tracing and surveillance of TB infection, with support from the Global Fund. It is a standalone Android-based application that can be used to record information for all TB contacts undergoing investigation and people initiated on TB preventive treatment (TPT register). It allows TB doctors and epidemiologists to work simultaneously to create a digital database containing surveillance, treatment and follow-up information for TB contacts and risk groups. All data are aggregated in a web-based platform, allowing users to have full information for each TB contact digitally. When aggregated, the data provide information for epidemiological surveillance and for monitoring the performance of TB preventive services in terms of access, coverage, and quality.

AdhereTB is a mobile application for video-supported treatment (VST) that was developed locally in 2017

Box 6.2 The Digital Health Management Information System for TB in Georgia (continued)

with the support of the Global Fund, as a standalone platform. It allows TB patients (and people on TB preventive treatment) to take medicines at any convenient time for them, record their intake of drugs and send the record daily to their supervisor nurse. Nurses can confirm or reject the process of the intake of drugs. The AdhereTB database collects all information related to adherence to treatment and allows its web users to see aggregated data in different dashboards.

TraceTB and Adhere TB are both linked to the TB HMIS using Application Programming Interface (API) services. This ensures all information is in the "general" database of the TB HMIS and enables health care workers to use a single appropriate application for data recording/import. After registering a new TB case in TB HMIS, information is automatically reflected in the TraceTB app. Similarly, if an epidemiologist registers contacts in the TraceTB app, the information is reflected in TB HMIS, where TB doctors can add information on medical examinations and treatment of contacts. Information on new TB cases registered in TB HMIS (including about treatment regimens) is also automatically reflected in the AdhereTB app. Nurses providing VST can confirm or reject information about treatment using the AdhereTB platform, which will also be reflected in TB HMIS.

Box 6.3 Developing a national system for digital TB surveillance in Indonesia

TB surveillance in Indonesia initially relied on a paper-based system for reporting of aggregated data. Data were compiled and transmitted from facility to national level using Excel spreadsheets.

A transition to a digital system was initiated in 2006, initially for drug-resistant TB. A system called "TB electronic" was introduced, which was replaced by e-TB manager in 2010. Digital surveillance for drug-susceptible TB, using a separate system, was initiated in 2012.

In 2016, in alignment with updates to screening and diagnostic algorithms stated in Permenkes (Regulation of the Minister of Health) No. 67, the integration of digital surveillance for drug-resistant and drug-susceptible TB in one unified system was recommended. Subsequently, the NTP initiated the development of a unified, case-based digital surveillance system for both drug-susceptible (DS) and drug-resistant (DR) TB called SITB (Sistem Informasi Tuberculosis/Tuberculosis Information System). This was done with support from the Challenge TB project (led by KNCV Tuberculosis Foundation) and a local developer.

The development of SITB was planned in two phases: 1) technical development of the system; and 2) pilot implementation. To guide its development, the Ministry of Health developed a blueprint for a national TB information system that included a detailed specification of requirements and an implementation plan that included training as well as pilot work and associated evaluation. The system was developed to fulfil the following functionalities that were defined in the blueprint:

1. Ability to capture TB surveillance data throughout the continuum of care, data related to logistics (drugs and non-drugs) and laboratory test results.
2. Data capture to be possible both online and offline to accommodate areas with insufficient network connection, computers or human resources.
3. As the system is scaled up, it should remain appropriate for use in any type of health facility and any geographical unit.
4. The system should be interoperable with existing TB digital systems (e.g. Wifi TB, a simplified digital reporting system with a much smaller number of data items, which was developed for use in the private sector) and other existing health information systems (e.g. Sistem Informasi Provinsi/provincial information system, Sistem Informasi HIV & AIDS/HIV & AIDS information system, PCare BPJS Kesehatan/Primary care information system of social security agency and Elektronik monitoring efek samping obat/electronic monitoring of adverse drug reaction).

SITB was officially launched for nationwide use on 1 January 2020. People already notified as a TB case in the older systems (Sistem Informasi Tuberkulosis Terpadu/Integrated tuberculosis information system and eTB Manager) were followed in the previous system until their treatment was completed.

Box 6.3 Developing a national system for digital TB surveillance in Indonesia (continued)

SITB is implemented in all primary health care facilities in the country, where case-level TB data are expected to be entered in real-time. Private facilities engaged with the NTP are encouraged to use SITB for recording and reporting of TB data. However, where SITB cannot be used, Wifi-TB is offered instead.

SITB captures data throughout the pathway of care, for people with presumptive TB up to recording of treatment outcomes for people diagnosed with TB and started on treatment. This ensures the monitoring of treatment enrolment and outcomes for all individuals diagnosed with TB. SITB includes a laboratory module that allows health workers to obtain laboratory results for people with presumptive TB as soon as their results are entered into the system by a laboratory technician. Where GxAlert is used, GeneXpert test results are automatically pushed by GxAlert into SITB. SITB also includes a household contact module that captures data related to screening of household contacts and associated provision of TB preventive treatment (TPT) to those eligible. SITB is also interoperable with SITK, a separate digital system for contact tracing and prevention used by community health workers.

In addition to Wifi-TB, SITK and GxAlert, there are other digital systems that collect and store TB data that can potentially be linked with SITB. These include electronic medical record systems, laboratory information systems, and a digital system related to sputum transportation and treatment adherence. Other national databases containing TB-related data, which can potentially be linked with SITB, include Pusdatin (managed by the central HMIS unit for disease reporting) and the database of the national health insurance system.

In 2020, the Minister of Health of Indonesia introduced legislation (Permenkes No. 21) requiring health governance reform, including digital health transformation across all health information systems. The *Blueprint for Digital Health Transformation Strategy 2024* sets out an architecture that leverages the interoperability standard, HL7 FHIR, to exchange data across multiple systems, under the Indonesia Health Services Platform, called Satu Sehat.[a] This includes the integration of SITB into the platform.

[a] Ministry of Health of the Republic of Indonesia (2021). Blueprint for Digital Health Transformation Strategy 2024. Jakarta: Ministry of Health of the Republic of Indonesia. (https://dto.kemkes.go.id/ENG-Blueprint-for-Digital-Health-Transformation-Strategy-Indonesia%202024.pdf).

Box 6.4 The digital TB surveillance system in Iran

Iran first developed a digital web-based TB register in 2014. It has been used alongside a paper register.

Case-level data are available at the University Medical Science and the national level. The system sub-modules comprise a TB registry, a culture registry and a drug-susceptibility testing (DST) registry. The system captures all key demographic and core TB-related variables, and treatment outcome information for all patients diagnosed with TB. The variables and structure of tables mirror the paper-based formats. The system enables users to create, read, update and delete TB-related data and search entered data. The system implements role-based access permission linked with an individual user's account.

Iran's national reference laboratory, regional DST laboratories and culture laboratories are all connected to the system and can enter data in real time. However, smear microscopy laboratories only record test results on paper.

A person's TB number is used as the key variable to link an individual patient record with the culture and DST laboratory tables. The system allows users at district or university level to display a line listing of TB patients, similar to the TB register. The system also enables the transfer of a TB patient from one facility to another. Alerts are sent to users at the receiving facility, to ensure continuity of care as well as accurate recording and computation of treatment outcomes.

The digital system for TB includes automated standard reports, which allow reporting of the number of cases and key indicators. The reporting function allows users to disaggregate data by variable and time period. A national surveillance report is routinely produced and disseminated on an annual basis.

Box 6.5 The digital TB surveillance system in Mongolia

A digital case-based surveillance system, TUBIS, was launched in 2011. It was initially implemented in parallel with a paper-based aggregated system[1] and continuously upgraded thereafter. TUBIS captures individual-level information for registered TB patients, including basic demographic and clinical information, and is used by TB dispensaries, national TB reference laboratories, the national TB surveillance and research division and the national TB supervisory division. It contains interactive dashboards, a search function and functions for data validation.

TUBIS has a TB laboratory module in which laboratory staff can enter smear, culture, Xpert and drug susceptility test results. The laboratory database is currently separate from the case registration module, resulting in some discrepancies in the number of laboratory-confirmed cases between the two databases (since some people are lost to follow-up after laboratory testing). To address this issue, a link between the two modules will be established to ensure that information on all confirmed cases in the laboratory module is automatically transferred to the case registration module.

As of 2022, a system upgrade was underway, to promote interoperability with other information systems. The aim is that TUBIS will be able to exchange data with the national notifiable diseases surveillance system (H-info) and a government information exchange platform (Khur system) where national registration and social welfare information are stored. This will reduce the workload of health care workers by discontinuing parallel reporting to TUBIS and H-info, and improve data quality by avoiding duplication of records.

The Ministry of Health also plans to launch a Health Information Exchange Platform (HIEP), so that data from multiple sources and sectors (including the private sector) can be gathered and managed in a unified platform. Data can be extracted from other systems including TUBIS.

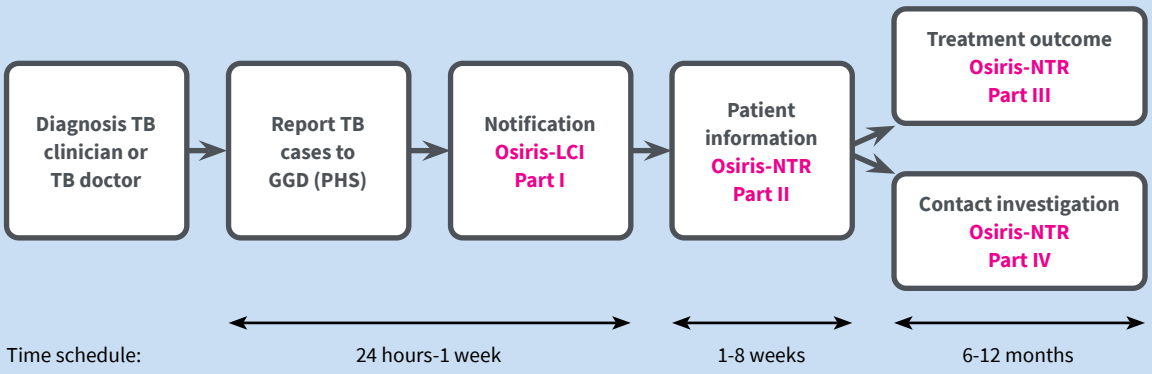
[a] The TB programme Mongolia is currently planning the phase out of the paper-based system for aggregated data and exclusive use of TUBIS.

Box 6.6 The digital TB surveillance system in the Netherlands

In the Netherlands, TB notifications are sent from municipal Public Health Services (PHS) to the National Institute for Public Health and the Environment (RIVM), using a digital registration system called Osiris. This system is used for the notification of all notifiable infectious diseases and allows for secure reporting of (pseudonymized) patient and disease characteristics. For each notification, the system generates a unique code that the PHS can link to their own patient information system, allowing PHS to trace the patient corresponding to the Osiris notification. At the national level, tracing back a notification in Osiris to an individual is not possible.

In the Osiris National TB Register (NTR), the notification process consists of four parts (Fig. B6.6.1). The first part is the legally required notification to

Fig. B6.6.1 The digital TB notification process in the Netherlands



TB: Tuberculosis; GGD (PHS): "Gemeentelijke Gezondheidsdienst" (municipal Public Health Service); LCI: National Coordination of Infectious Disease Control, as part of the National Institute of Public Health and the Environment (RIVM, Netherlands); NTR: National TB Register.

Box 6.6 The digital TB surveillance system in the Netherlands (continued)

the infectious diseases response unit of RIVM (the National coordination of infectious disease control; LCI) and should be completed within one week. This part covers only basic patient characteristics (e.g. sex, year of birth, date of diagnosis). The second part must be completed shortly thereafter; it contains more detailed data on the patient and the disease, including country of birth and duration of stay in the Netherlands, comorbidities, type of TB, laboratory confirmation and (if available) whole genome sequencing results. The last two parts are filled in at later stages: part 3 covers treatment and treatment outcome, and part 4 is used to register the results of source and contact tracing (including the number of contacts investigated and the number of TB cases and TB infections that were found).

Not all data that are collected in the notification system are mandated by the Dutch Public Health Act. For variables that are not covered by the Public Health Act (such as duration of stay in the Netherlands at the time of TB diagnosis; the reason for migrating to the Netherlands in the case of foreign-born patients; data on test results of hepatitis B and C, and HIV status; and details about treatment support), permission to register this information is requested from the patient.

At the RIVM, the notification data are used for national TB surveillance. Each year, on World TB Day (24 March), the key figures about TB epidemiology in the Netherlands for the previous year are presented in a factsheet.[a] In quarterly reports, trends are shown over time and feedback is provided to the different regions. In the annual surveillance report, more in-depth analyses of the data are summarized and results are interpreted in the context of the Dutch National TB control plan.[b]

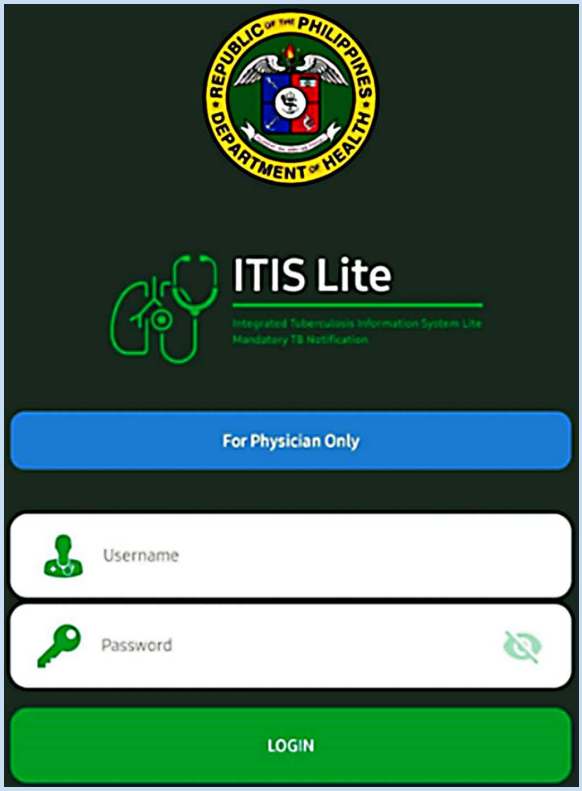
[a] Epidemiology of tuberculosis (factsheet). In: National Institute for Public Health and the Environment [website]. Ministry of Health, Welfare and Sport; 2023 (https://www.rivm.nl/en/tuberculosis/epidemiology-of-tuberculosis, accessed 25 July 2023).

[b] National Tuberculosis Control Plan 2016–2020. Towards elimination. National Institute for Public Health and the Environment. Ministry of Health, Welfare and Sport; 2018 (https://www.rivm.nl/documenten/national-tb-control-plan-0).

Box 6.7 Facilitating mandatory notification of TB in the Philippines through digital tools

The Philippines Department of Health started building an Integrated Tuberculosis Information System (ITIS) in the early 2010s. This is a web-based, case-based national TB surveillance system that is used to collect, process and report the information needed for the creation and monitoring of plans to end TB in the Philippines. It is based on the national health standards and implemented with the intention of increasing efficiency in the cascade of care delivery and improving accuracy in recording and reporting. Despite the establishment of ITIS, evidence from a national TB prevalence survey implemented in 2016 showed a high level of underreporting of people diagnosed with TB. The national TB registry only contained records for about half of those who reported being on TB treatment at the time of the survey, with the majority of reporting done by the public sector *(2)*. Among the interventions implemented were the development of a mandatory notification policy and a more user-friendly version of ITIS for reporting to the national registry.

Fig. B6.7.1 Landing page of ITIS lite application for mandatory notification



Box 6.7 Facilitating mandatory notification of TB in the Philippines through digital tools (continued)

In 2017, the Department of Health released Republic Act 10767 (Comprehensive TB Elimination Plan Act). This stipulated that all public and private health care providers must report all detected TB cases and their treatment outcomes, with the overall aim of boosting case finding and reporting and helping to ensure quality TB case management in both public and private sectors.

In 2018, the Department of Health released ITIS Lite (Fig. B6.7.1), as an official application for mandatory reporting, tailor-made to meet the needs of the private sector, with fewer data fields and more focus on case notification. ITIS Lite is available within ITIS, in both web and mobile format, and provides the same level of data security. The application has a dashboard on the home page showing the monthly number of cases reported per year. It can be used by physicians, clinic staff and facilities without TB-specific clinics. As of October 2022, there were more than 25 000 ITIS users, including 13 000 ITIS Lite users. Mandatory notification through ITIS Lite contributed 9.7% of total notifications in 2018, increasing to 22.2% in 2021.

Box 6.8 Developing a digital TB surveillance system in the United Republic of Tanzania

In 2014, the National TB and Leprosy Programme (NTLP) in the United Republic of Tanzania decided to digitize the reporting of aggregated TB data, with the aim of improving the availability and quality of TB surveillance data. DHIS2 software was chosen for this purpose.

In 2016, the NTLP embarked on the implementation of a case-based, digital recording and reporting system for TB, with support from the Global Fund, the United States Agency for International Development (USAID) and United States Centers for Disease Control and Prevention/United States President's Emergency Plan for AIDS Relief, with technical assistance from KNCV.

The process started with a needs assessment and a stakeholder workshop to define objectives and the desired system characteristics. DHIS2 Lab, a team from the University of Dar es Salaam, used the tracker module of the DHIS2 software to design the system (see also Section 6.3.1). Following a successful pilot of the system in three regions in 2017, it was decided to roll out the system nationally. Following training of relevant staff and the procurement of laptops for all 213 district TB and leprosy coordinators (DTLCs) who would need to enter facility level data for all facilities in their district, the system was officially launched in 2018. A total of 279 TB providers (DOT Providers) and data clerks from high volume public and private facilities were subsequently trained to use the system, to support the DTLCs.

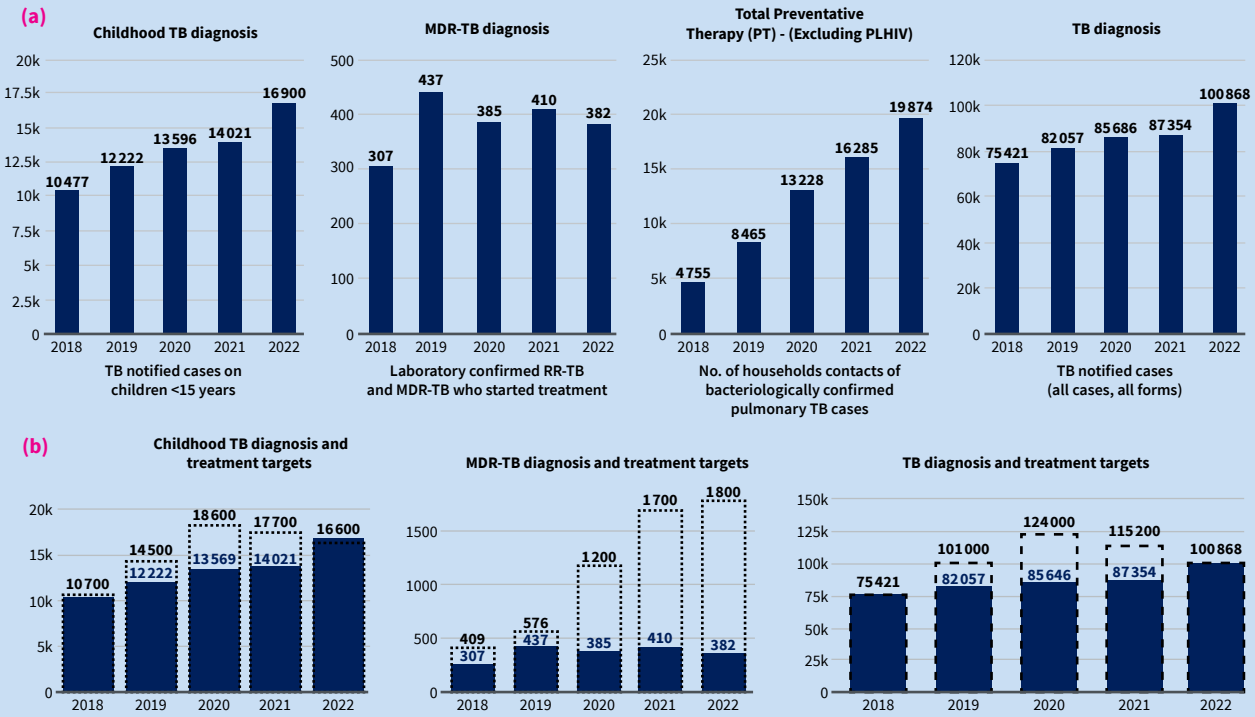
The national system is known as the Electronic TB and Leprosy Register (ETL). It comprises three functioning data entry forms; one for people diagnosed with drug-susceptible TB disease, one for people diagnosed with drug-resistant TB disease and one for bacteriological test results (e.g. from culture and drug-susceptibility testing). ETL generates reports and automatically populates standardised visualizations. It makes data readily available for planning and decision making at different levels, supports enhanced communication with people who are on care through SMS alerts, and facilitates reporting such as to WHO. The WHO TB surveillance standards and benchmarks assessment conducted in 2018 helped to identify gaps and ways to further strengthen the system. A new release of ETL/DHIS2, with enhanced data quality checks and data visualizations, was released in 2021. As of 2023, case-based data from about 3500 public and private health facilities in the United Republic of Tanzania were being captured in ETL.

ETL is a model in TB surveillance and its implementation provides valuable lessons for other disease programmes in the country. The system allows the NTLP to understand TB disease burden and risk factors for TB disease, and to monitor the performance of the provision of care, treatment outcomes and progress towards set targets (Fig. B6.8.1). Visualizations of case-based data from the facility level upwards make it possible to assess data quality and conduct in-depth analyses of key TB data.

Box 6.8 Developing a digital TB surveillance system in the United Republic of Tanzania (continued)

At the beginning of 2023, the NTLP was in the process of introducing an offline application to digitize the register for community-based TB activities, which will be linked with ETL and the national system for Hospital Electronic Management Recording. During the COVID-19 pandemic, the ETL played a crucial role in tracking the provision of TB services and the impact of the pandemic on people with TB disease, and informing actions needed in response.

Fig. B6.8.1 Example visualizations for (a) key indicators related to programmatic performance and (b) progress towards reaching targets set for 2018–2022 at the UN high-level meeting on TB (2018), translated at the national level



Dashed outline represents national targets from the 2018 UN high-level meeting on TB, bars in blue represent actual numbers of people diagnosed, treated and reported in the digital system.

Table 6.1 Architecture for national public health surveillance: pillars and key components[a]

	Pillars		
	Governance	**Health system**	**Financing**
Key components	Clear scope, purpose and objectives	Understanding systems (reviews and assessments)	Financial analysis and management
	Well-defined roles and responsibilities for all stakeholders	Data and digital technologies, including interoperability and integration solutions	Cost-effectiveness analyses – "for every US$ invested in surveillance…"
	Decision-making networks/committees	Data sharing, routine data use at all levels, by all stakeholders	Appropriate and sustainable levels of domestic financing
	Supportive legal frameworks	Workforce and capacity	Innovative international financing mechanisms
		Collaboration, coordination, collective action	

[a] This table draws on a white paper that was prepared in the context of efforts to strengthen the global architecture for health emergency preparedness, response and resilience *(6)*.

6.2.3 Interoperability or integration with the rest of the public health surveillance system

A digital surveillance system for TB should be interoperable with, or integrated into, the rest of the public health surveillance system.

Countries may find it helpful to establish a national committee or a technical working group to enable interoperability or integration of the TB surveillance system with the rest of the architecture for national public health surveillance. Examples of entities from which representation would be relevant include those responsible for disease surveillance (including TB), health information systems, health insurance, health statistics, health financing and health care in correctional facilities. The terms of reference of the committee should cover governance mechanisms, systems and financing, and associated components (Table 6.1).

6.3 WHO digital packages for TB surveillance

Departments within WHO have worked together to develop, and support country implementation of, digital systems and software packages for the routine collection, analysis, visualization and use of data from health facilities *(7)*. Packages have been developed in the open source DHIS2 platform *(8)*. These packages can be installed on a server, instantly providing data collection forms, dashboards and reports that can then be customised. DHIS2 was chosen because it is used as the main health information system by many low- and middle-income countries.

Each disease-specific package contains a machine-readable DHIS2 configuration file, an installation guide, an analysis guide referring to a core set of indicators and dashboards, and an accompanying exercise book. Disease-specific packages can be added in the national public health architecture of a country in a modular format, according to country needs.

The TB digital package is available on the WHO website *(7)*. It is based on WHO guidance on case-based digital TB surveillance *(9)*, WHO guidance on routine analysis and use of TB data *(10)* and the WHO TB surveillance checklist of standards and benchmarks *(11)*. The implementation and use of these packages in a country will need to be planned and budgeted appropriately. Consideration should be given to allowing enough time and funding for the necessary customization of the packages, according to the country context, as well as the longterm maintenance costs.

To support countries interested in using other software, WHO has also embarked on the development of software-agnostic digital adaptation kits (DAKs) which specify the metadata, indicators and analytical requirements to inform the design of digital systems. The development of a DAK for TB was initiated in 2022 and finalized in 2023. Also in 2022, to complement the digital packages based on DHIS2 and the DAK for TB, the development of a standardized framework for assessing a country's readiness to adopt and implement digital case-based surveillance systems for TB was initiated, in collaboration with stakeholders including national and local governments, technical agencies, funding agencies and civil society.

The WHO DHIS2 digital package for TB includes components for a) case-based data and b) aggregated data.

6.3.1 Digital TB package for case-based data

A DHIS2 case-based TB "tracker" package to manage a core set of data items for individuals with drug-susceptible and drug-resistant TB disease in a single system was made available in 2020 *(12)*. It is designed for registration and longitudinal tracking of individuals with TB disease throughout their care pathway, from the point of testing for TB to the final treatment outcome. Data for multiple episodes of TB disease in the same individual can be recorded.

The tracker can be used to capture baseline and demographic information about each person with TB and their risk factors, laboratory results, type of drug resistance (if any), treatment regimen(s) and outcome (Fig. 6.1). Data entry is at the health facility level; data can be entered by testing laboratories if needed. Depending on local infrastructure and resources, the tracker can also be used at district or higher levels to enter data from paper registers compiled at health facilities.

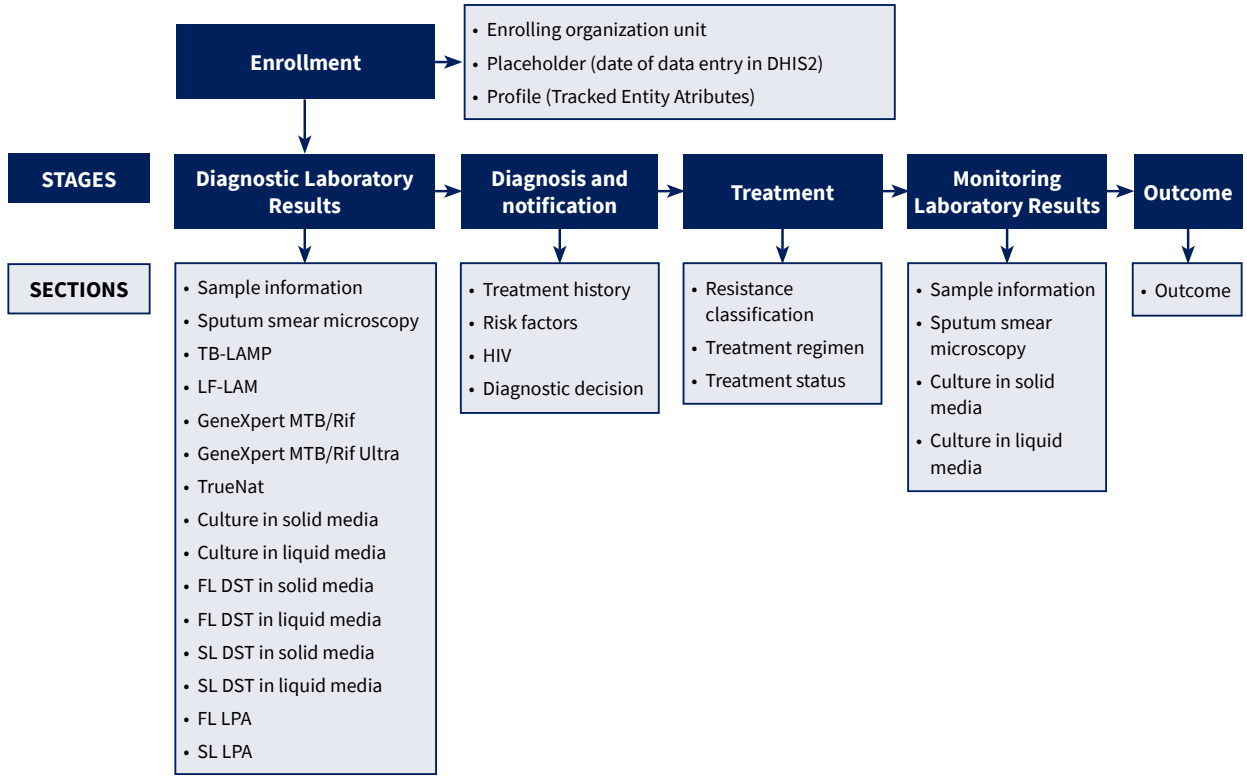
There are standard dashboards that include graphs, tables and maps for core TB surveillance indicators (e.g. notifications, coverage of testing for drug resistance and HIV, and treatment outcomes) and data quality indicators (e.g. completeness and internal consistency).

The tracker is not designed to support the clinical management of patient care.

Fig. 6.2 illustrates how data for an individual with presumptive TB might be recorded and the typical workflow involved. The tracker can be modified to suit the specific data needs and workflows in a country.

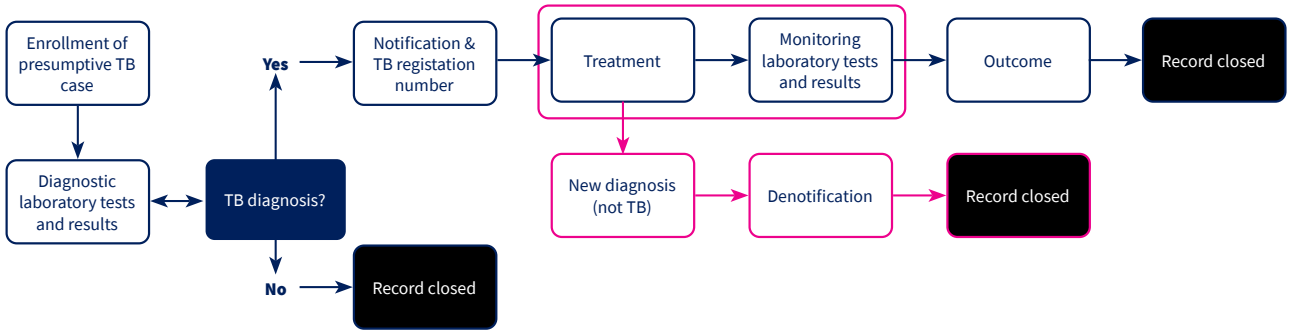
Best practices that can help to ensure a successful roll out and use of the DHIS2 TB tracker, from an evaluation in five countries (Ghana, Lao People's Democratic Republic, Pakistan, Rwanda, the United Republic of Tanzania), are highlighted in Box 6.9. A summary of the evaluation is provided in Web Annex F.

Fig. 6.1 System structure of the tracker for case-based TB surveillance (as of September 2023)[a]



DST: drug susceptibility testing; FL: first line; HIV: human immunodeficiency virus; LF-LAM: lateral flow urine lipoarabinomannan; LPA: line-probe assay; SL: second line; TB: tuberculosis; TB-LAMP: TB loop-mediated isothermal amplification.
[a] The most up-to-date structure and design of the tracker is provided on the WHO website *(7)*.

Fig. 6.2 Example of the workflow for an individual with presumptive TB[a]



[a] The most up-to-date structure and design of the tracker is provided on the WHO website *(7)*.

In 2023, the development of new content for the tracker, to allow linkage of data for TB "index" cases with household and other close contacts (for whom WHO recommends TB contact tracing and, if eligible, TB preventive treatment), was initiated. The design allows for data entry in the household or the community using the DHIS2 Capture App.

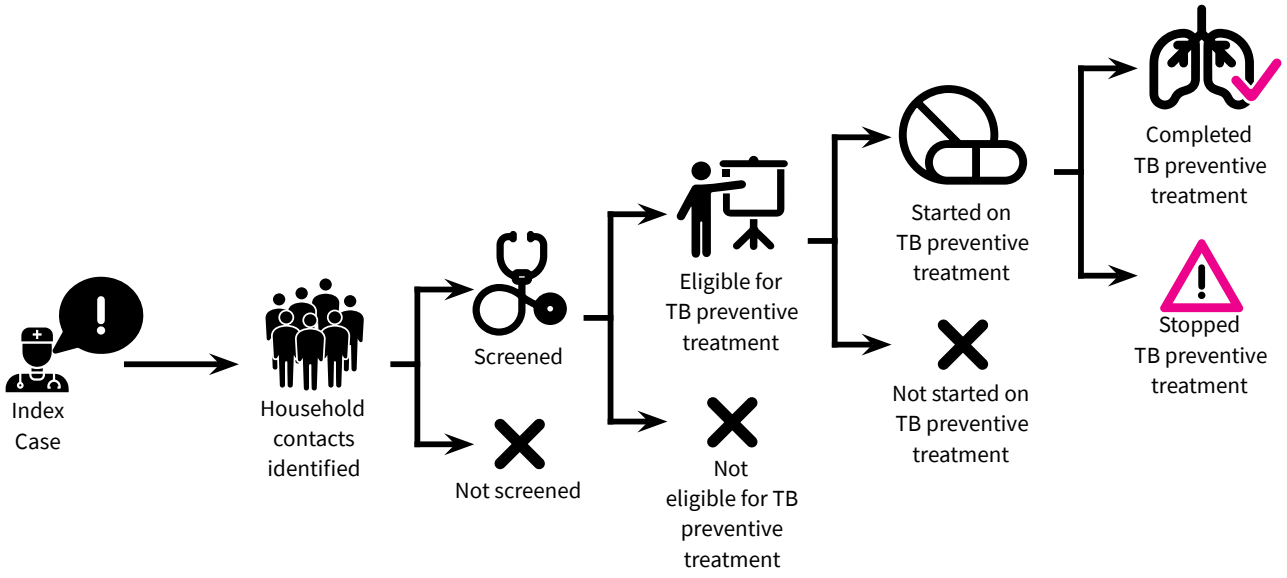
For countries without DHIS2 architecture, a standalone digital DHIS2 package is available for the collection of case-based data related to TB preventive treatment and screening *(13)*. Fig. 6.3 illustrates the data flow in this digital package. The package started as a prototype for household contact investigation but was subsequently adapted to accommodate other use-cases, such as occupational or clinic-based screening. It includes three modules: a platform to design the data collection framework; a data capture and retrieval interface as a mobile application; and a dashboard to summarize key indicators. The mobile app is optimized for Android data collection using the DHIS2 Capture App.[1]

6.3.2 Digital TB package for aggregated data

A WHO DHIS2 package for the management, analysis and use of core TB surveillance data in aggregated for-

[1] The app is free to download on the GooglePlay store.

Fig. 6.3 Data flow of a digital package for household-level TB preventive activities



Box 6.9 Implementing the DHIS2 TB tracker: lessons from the field

Implementation of the DHIS2 TB tracker was evaluated in five countries that piloted it: Ghana, Lao People's Democratic Republic, Pakistan, Rwanda and the United Republic of Tanzania.

This evaluation identified four best practices that can help to ensure a successful roll out and use of the TB tracker.

1. **Clear strategy for planning, design, implementation and use**

NTPs and partners should have a clear digital health information strategy that highlights the need for a patient-centric data platform, with both centralized elements for coordination and decentralized elements for implementation and support. The strategy must be complemented by a clear plan for implementation and monitoring and evaluation, to guide piloting and phased scale up of the system. Potential issues related to staffing, funding, maintenance and support need to be considered and planned for in advance.

2. **Strong governance of the process, coordinated by the NTP**

A multisectoral approach to governance should be taken, with buy-in from all relevant stakeholders at all levels and strong political commitment from the ministry of health. It is important to ensure that all stakeholders have a long-term aligned commitment to a chosen technology and approach to collaboration.

3. **Build on existing experience and knowledge of DHIS2**

If DHIS2 is to be adopted by the NTP for the recording and reporting of TB data, then it should be integrated within a coherent health system architecture in the country. The NTP should take advantage of opportunities for accessing high-quality technical support from experienced teams, either locally within the ministry of health (e.g. HMIS) or internationally from relevant partners (e.g. Health Information System Programme [HISP]) as needed.

4. **Strong supportive policies and processes**

A strong middle layer of support should be set up, with communication across the administrative layers to enable district coordinators to monitor and support staff within their administrative unit. Similarly, the NTP and partners should provide a platform for learning, feedback and support. This can be provided through a strong community of practice (e.g. forums) to support learning and development and/or a virtual working group to facilitate discussion of issues and challenges in real-time.

mat was developed in 2018 *(14)*. It was based on the data entry forms corresponding to the quarterly and annual reporting templates recommended by WHO in the 2006 (referred to as "old records") and 2013 reporting frameworks *(15)*. As this guidance went to press, the package was being updated to include data entry forms corresponding to the indicators and associated data items described in Chapter 4 and Chapter 5.

Data entry can be at a health facility or at a higher administrative level such as a district. Older TB surveillance data, for example datasets stored in Excel spreadsheets, can be imported so that a longer timeseries of TB data is available within the system for use at national and subnational levels.

If the necessary infrastructure and core national team are available, this package can be installed and operated on national servers. For countries that are still in the process of building national capacity but would like to use this package in the meantime, a global platform that has been established by WHO is available *(16)*.

In addition to the data entry forms, the package allows users to display the results of recommended analyses. The package also installs standard dashboards containing graphs, tables and maps for all the core surveillance indicators (e.g. notifications, coverage of testing for drug resistance and HIV, and treatment outcomes) and data quality indicators (e.g. completeness and internal consistency). The package includes training material on how to interpret and use these dashboards.

The dashboards can be viewed by visiting the global platform established by WHO *(16)* and logging into the account set up for demonstration purposes (full instructions are provided on the landing page of the website).

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Chapter 7
Data quality

As highlighted in Chapter 2, national TB surveillance systems are essential for:

- **reliable monitoring of TB epidemics** at global, regional, national and subnational levels in terms of the number of new episodes of TB disease (TB incidence)[1] in the population, and how this varies over time and according to factors such as age, sex and geographical location;
- **assessment of progress towards national, regional and global targets** for reductions in TB disease burden and provision of TB treatment, prevention and care services, including those set in national, regional and global TB strategies and political declarations adopted by all WHO or UN Member States;
- **assessment of the performance (e.g. quality, coverage, effectiveness of interventions) of TB services** along the full pathway of screening, diagnosis and treatment for TB infection and TB disease; and
- **informing the planning, budgeting, policy, programmatic and clinical actions** necessary to ensure high-quality and coverage of TB prevention and care services, including timely action in response to disease outbreaks.

To be most useful and to avoid unintended consequences of decisions based on poor or incomplete data, TB surveillance data need to be accurate, complete, consistent and timely, in other words to be of "high quality".

Poor quality data can have negative impacts at all levels of the health system, and at any point along the pathway of TB prevention and care. For instance, at the level of health facilities, errors in the recording of patient information can result in suboptimal treatment and provision of care, which in turn can have detrimental effects on the lives and livelihoods of people with TB disease. At the higher administrative levels, poor quality data can result in inappropriate planning decisions and distribution of resources, mislead policy makers about progress towards targets and ultimately compromise progress towards the global goal of ending the TB epidemic *(1, 2)*.

This chapter defines the six dimensions that are commonly used to assess data quality (accuracy, completeness, consistency, timeliness, validity and uniqueness); highlights general governance and design features of a TB surveillance system that can help to ensure data quality; provides examples of data validation checks that can be routinely implemented, first at the level of health facilities and then at the level of administrative units, to help ensure data quality; and describes how data quality can be periodically evaluated through self-assessments and audits. Two illustrative country case studies are also provided.

[1] The prevalence of TB disease and infection is measured using cross-sectional population-based surveys.

7.1 Dimensions of data quality

Six dimensions of data quality that are commonly used in the public health literature are accuracy, completeness, consistency, timeliness, validity and uniqueness *(3)*.

Accuracy means that data are a correct description of reality and free from errors.

Completeness refers to the extent to which expected data are available. For TB surveillance data to be considered complete, there should be no missing data (at least for core data items). At national level, all expected reports from all reporting units should be available.

Consistency means that data are both internally consistent (e.g. over time) and externally consistent (e.g. consistent with expected benchmarks or values derived from research studies, or comparable with data from similar countries).

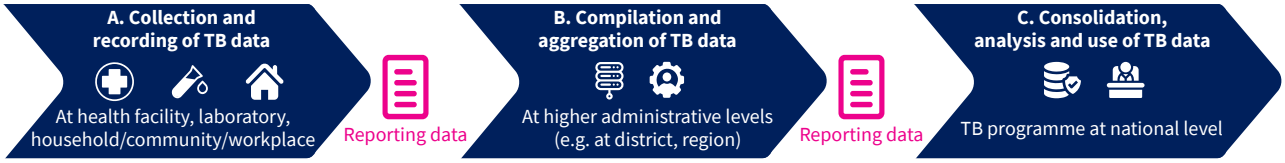
Timeliness means that data are available at the time that they are needed. In the context of TB surveillance, Chapter 4 defines indicators that should be available for reporting and use at three distinct frequencies: weekly/monthly; quarterly; and annual.

Validity is defined as the extent to which data conform to the expected format, type, and range.

Uniqueness means that there is not more than one record for any given observation. In the context of TB surveillance, this means that there is only one record for each TB treatment episode (in a given database).[2]

[2] This definition refers to when the unit of analysis is the treatment episode. It is in fact possible to have multiple records for a given patient within the same database representing different treatment episodes or different laboratory tests. Chapter 5 describes occasions when a single patient can have multiple records, e.g. re-registration after treatment failure or, depending on how surveillance is organized, re-registration after transfer to another treatment unit.

Fig. 7.1 An illustration of the recording and reporting process for TB data



7.2 Governance and design features of a TB surveillance system that can help to ensure data quality

Typically, TB data are recorded at health facilities or other TB service delivery sites (such as within the community, households, workplaces or the laboratory network), as illustrated in Fig. 7.1. Individual-level information (demographic, clinical, diagnostic and medical history) is recorded (for example, on a paper-based TB treatment card or as an electronic medical record). Depending on the type of TB surveillance system in place, these primary source data are then either transcribed or transmitted into TB registers (Fig. 7.1, step A).

The individual-level data are then compiled and aggregated into datasets for higher administrative levels (Fig. 7.1, step B). This may involve multiple steps within the reporting hierarchy (e.g. aggregation from subdistrict to district level, followed by district to regional level). In some countries, transmission happens in one step, from the health facility straight to the national level.

At the national level, multiple datasets are merged into a national consolidated database from which indicators are calculated and analysed (Fig. 7.1, step C).

A well-governed and designed TB surveillance system can help to ensure high data quality at all levels.

7.2.1 Data governance

A key part of data governance is the identification of which entities are responsible for data collection, compilation, analysis, reporting and use. In TB surveillance, the roles of the national TB programme (NTP) or its equivalent, those with overall responsibility for the health information system, and other relevant agencies such as those responsible for disease control and prevention should be clearly defined and agreed. This includes specification of how the TB surveillance system interacts or is integrated with the overall architecture for public health surveillance.

Clearly defined roles and responsibilities are also necessary to manage the processes of data validation.

Good governance should also include a requirement for periodic evaluations of the quality of TB surveillance data (see also Section 7.4).

7.2.2 Data sharing frameworks and agreements

In many countries, collection of data about people with TB disease and TB infection is not restricted to the official TB surveillance system managed by the NTP (or its equivalent). Examples of other sources of TB data include databases for notifiable diseases, databases managed by other national disease programmes within the ministry of health (such as those for HIV/AIDS) or other ministries (e.g. those responsible for correctional services), and databases managed by health insurance schemes.

Legal frameworks and formalized agreements for sharing of data are important to facilitate cross-checking of TB surveillance data.

7.2.3 Data confidentiality and safety

TB surveillance systems hold sensitive personal data for people who have received care. Many countries will have laws on how confidential or personal data should be stored and accessed, for example by restricting access to sensitive personal information to those directly involved in a patient's care. There are various aspects of a system's operations where data confidentiality could be compromised, such as:

- access to screens and reports;
- physical access to data files;
- data transmission via public networks or using portable media devices such as memory sticks, which can be lost or stolen.

Clear policies and processes must be in place to ensure the confidentiality of TB surveillance data.

Techniques to consider using to ensure data confidentiality include:

- Role-based access to data: users of the system get access on a need-to-know and need-to-use basis. This identifies:
  a. which data items, screens and reports a user is allowed to see;
  b. which data items a user is allowed to add, edit or delete;
  c. for which sets of patients the access rights above are defined.

For example, someone working at a TB treatment centre could be prevented from seeing any patient who is being treated at a different centre. Someone working at the regional level could be allowed to see, but not modify, patient records from all treatment centres in that region, but not be allowed to see any patient records from other regions. Someone working at the national level could be prevented from modifying individual patient records, and could be prevented from seeing a patient's HIV status, or even prevented from seeing any personal data.

- Training users in the importance of confidentiality and having them make a formal commitment by signing a document describing what they may and may not do with the data held in the system.
- Keeping automated detailed logs showing details of all user interactions with the system, including logging in, viewing and modifying data so that there are clear audit trails and so that security breaches can be traced.
- Excluding access to personal data for those not directly involved in patient care.
- Preventing direct access to physical data files so that the only access users have to the data is via screens and reports.
- Physical security such as locking server rooms.
- Secure data transmission methods to prevent others from seeing data sent from one computer to another by using data encryption across public networks (such as https[1]), by using a Virtual Private Network (VPN) across public networks or by using private networks.
- Data encryption of physical media such as memory sticks.

Some recommended approaches that promote data confidentiality and safety are:

- Identify all legal requirements regarding data confidentiality.
- For access to screens and reports, implement role-based access permissions combined with individual user accounts.
- Restrict access to physical data files: these are best held on a server with no direct end-user access and not on a shared hard drive so that the only access users have to the data is via screens and reports.
- Restrict access for users not directly involved in patient care to aggregated or anonymous data only. Care should be taken that individuals cannot be identified through using the other variables in the data, for example through a combination of age, sex and location.
- Ensure physical security (protection against theft) of all devices that store patient data.
- Use secure data encryption methods whenever possible to prevent others from seeing data transmitted between computers.

[1] Hypertext Transfer Protocol Secure. This allows web browsers to communicate in web servers securely and is commonly used in web-based commercial services such as banking.

7.2.4 Provision of feedback among all system users

A digital surveillance system gains better acceptance if it helps and informs all those who use it, not just those at the national level viewing aggregated outputs. It is important to enable those tasked with data entry to have a direct stake in, and an incentive to ensure, the accuracy of the data they enter. Think about who enters data: do they also need to use data in their work, for example to inform their decisions? Will they be adversely affected if data they see in the system are inaccurate? Will their work be made easier if they can correct data that are wrong? In other words, is there a feedback loop for those entering data so that data entry is not a passive, one-way activity?

Data entry should be an element of engaging users in an interactive system. Ensure data entry is not just a mandatory chore. If staff need to use the data they enter to carry out their daily tasks, data entry is no longer a passive, one-way process. The analyses needed for workflows, data quality processes and standard reports could identify feedback, such as: a) prompting users to act upon the data in the system, such as tracing missing data or contacting patients who have not attended a clinic; b) making reports on standard performance indicators, such as case notifications, treatment outcomes or data completeness rates, available to all users so that staff within individual health-care units or districts can compare their performance with those of others regionally or nationally. This encourages two-way communications and shows staff how their work fits into a larger picture; c) higher administrative levels informing lower levels about data problems to be corrected, for example if higher administrative levels detect duplicated patient records.

Automatically producing standard reports allows more staff at all levels to understand what is happening and reduces the need for individual, detailed analyses to be conducted. However, staff will need training to understand and interpret system outputs, and how best to act upon them. There are two key types of outputs to consider: operational, which are concerned with the daily activities of running a TB programme, and surveillance, which are concerned with epidemiological analyses and trends.

7.2.5 Software

A software that allows the creation of a database with functional capacity for storage, management, validation and analysis of data should be used, such as the purpose-built data management systems described in Chapter 6.

Web- and case-based digital systems that use unique identifiers for individuals are the reference standard.[1] Such systems provide the greatest scope for automating a range of routine data validation checks (see also Section 7.3).

Use of non-specialized software for data management (such as Microsoft Excel©) should be avoided.

7.2.6 Financial and human resources

The design, national roll-out and maintenance of a TB surveillance system, including its software and hardware, requires adequate and sustained financial and human resources. Data quality will be strongly influenced by the availability of adequately trained staff to implement data collection, management, reporting, analysis and use.

Staff with expertise in data management, infectious diseases epidemiology, statistics and information technology (IT) are all essential, especially at national level, to complement the work of those responsible for data entry at subnational levels.

Staff roles and responsibilities need to be clearly defined, well documented and understood. In addition to introductory trainings for new staff, regular refresher trainings of existing staff in data validation checks are important. Routine supervision visits and periodic data audits at health facility level should be part of the roles and responsibilities of teams at higher administrative levels.

7.2.7 Clear specification of indicators and data items to be collected, reported and used, and associated standardized tools and operating procedures

The indicators to be reported and used, and the data items that need to be collected, should be clearly specified. This can be done using the guidance provided in Chapter 4 and Chapter 5.

Standardized tools and standard operating procedures (SOPs) that can help to ensure data quality include:

- Standardized reporting tools for core data items. These could be part of national manuals and guidelines, supported by training materials and SOPs (e.g. for completion of data entry screens in a digital system, or reporting forms in a paper-based system).
- A document, either standalone or as part of a monitoring and evaluation plan, that provides clear guidance and protocols for data cleaning, including how to deal with common sources of errors in a standardized and systematic way.

SOPs can be developed and disseminated as manuals, posters or flip charts, and should be readily accessible to all staff involved in data recording and reporting processes, at all levels.

7.3 Routine data validation checks

Routine use of data validation checks, first at health facility level and then at the level of administrative units, can help to ensure data quality. It helps to describe in detail and in a systematic way such checks: the people involved, their responsibilities in the process, when they take place, how they happen, and what happens to records at each stage.

7.3.1 Facility level

Various checks of data quality can be done when TB-related data are collected and recorded at health facilities.

Digital systems

In digital systems, automated data validation checks can be built into the system. When a validation check fails during data entry, an error message should alert the user, prompt an investigation and lead to corrective action if necessary. A well-designed set of data validation checks at the time of data entry will help to ensure data accuracy, completeness and timeliness.

Examples of validation checks that can be implemented during data entry at health facility level are provided in Table 7.1.

Two case studies that illustrate the validation procedures that can be put in place in countries with digital case-based surveillance systems for TB are provided in Box 7.1 and Box 7.2.

Paper-based systems

In paper-based systems, data validation procedures require manual checks. Examples include checks for missing values, misclassifications and duplicate records for the same treatment episode of the same person; checks that all required data fields have been filled in; and checks that entered data are consistent within individual records. Such manual checks are labour-intensive, cumbersome, unlikely to be manageable for all available data, and prone to human error. Two of the several advantages of digital surveillance are reducing

[1] More detailed guidance on digital recording and reporting systems for TB is available elsewhere *(4)*.

Table 7.1 Examples of data validation checks that can be used in health facilities, for the six dimensions of data quality

Dimension of data quality	Validation check
Accuracy	• Enforcement of the correct data type (e.g. numeric fields do not accept text) • Checks for implausible values and misclassifications (e.g. negative values) • Definition and enforcement of valid formats for some data entry fields • Category options defined and enforced by using tick boxes or drop-down lists instead of free text fields • Reporting units and hierarchies moving up the administrative levels defined and enforced
Validity	• Checks for outliers (when data value is not within the expected range) • Automatic calculations provided wherever possible (e.g age automatically calculated when date of birth is entered; total number of cases automatically calculated as the sum of cases from all age groups)
Consistency	• Check that individuals' characteristics (gender, age) are similar across tables • Check DST results vs culture positivity (DST results should only be among individuals with a positive culture) • Check the dates (follow-up visit after initial visit) • Check that clinically diagnosed TB cases did not have a bacteriological test result that was positive
Uniqueness	• Checks for duplicates (exact and on specific key primary variables)
Completeness	• Provision and enforcement of mandatory fields that need to be completed (e.g. for core variables such as name, age, sex, type of TB disease) before data entry can be continued with the next field or the record can be saved • Defining "skip" or conditional fields (for example, do not ask about drug regimens if a patient has not started treatment yet)
Timeliness	• System-generated alerts to the user if data are not available (e.g. to enter treatment outcome results when treatment is due to have been completed) • Errors within the data should be detected as quickly as possible to allow for corrective action or follow up with original data sources

the workload of staff while also helping to enhance data quality (Chapter 6).

7.3.2 Higher administrative levels

Beyond health facilities, additional data validation checks should be implemented at the stage of data compilation and reporting, when data from individual reporting facilities are aggregated at the level of administrative units.

In some countries, this second stage involves multiple steps within the reporting hierarchy (e.g. aggregation from subdistrict up to district and then on up to regional levels), before a final national dataset is available for analysis and use.

In other countries, the upward transmission of data may only involve one step, in which health facility data are appended or merged into a national consolidated database in preparation for analysis and use. Merging or appending multiple datasets is often a source of error (for example, to append two datasets, they need to have the same structure and the variables should be named and encoded in the same way). To avoid these errors, it is recommended to write a detailed SOP for each step of the process. This should include use of an automated procedure using data management software (use of "copy paste" should be avoided).

Ensure adequate resources will be available to carry out data quality activities: train staff so that all are aware of their roles and responsibilities; develop clear SOPs for the various data quality processes. This helps to ensure uniformity of data quality mechanisms across all facilities using the system, especially when complemented by clear, up-to-date definitions of all terms and expressions used within the system. Some activities are specialized and time-consuming, so planning and budgeting for these staff is important.

Digital systems

Examples of data validation checks that can be implemented at higher administrative levels are provided in Table 7.2.

It is best to have data validation checks built into the digital surveillance system itself. In the absence of this functionality, data validation checks could also be performed on the raw data exported from a digital system with the use of standard code written for use by an external statistical package (e.g. Stata, R). Such checks can be automated easily and frequently reproduced to allow quick identification of common sources of error (e.g. one facility may not be recording one particular data item), to produce lists of data to check per facility (e.g. lists of missing data, lists of inconsistencies), and to emphasize potential problems at the facility level (e.g. potential overdiagnosis if there is evidence that people are being diagnosed with TB when they have a negative bacteriological test result). Such checks using a statistical package require the availability of staff with the relevant expertise and experience at higher administrative levels.

Box 7.1 Examples of data quality assurance procedures in the national TB surveillance system in the United Kingdom of Great Britain and Northern Ireland (UK)

The UK has a national TB surveillance system (NTBS). It is digitized and case-based (see also Chapter 6, Box 6.1).

Data quality is supported by ensuring front-end users are appropriately trained before registering an account on the live system. Training materials include videos, a user guide and access to a test version of the NTBS.

Automated application alerts have been built into the system and are visible to those with the appropriate permissions. Alerts are shown within a user's dashboard and also within a TB case record once data has been saved in the record. Dashboards display all notification events that the user needs to act upon; a selection of dashboard alerts from the training and testing platform is shown in Fig. B7.1.1.

Examples of alerts include:

Missing 12- and 24-month treatment outcomes: This is triggered from the available start date of the notification, in order of availability, treatment start date, diagnosis date or notification date. The 12-month outcome is due 1 year minus 1 day from the start date. Likewise, the 24-month outcome if treatment did not complete before 12 months is due 2 years minus 1 day from the start date. Transfer and treatment restart is not classed as a treatment outcome.

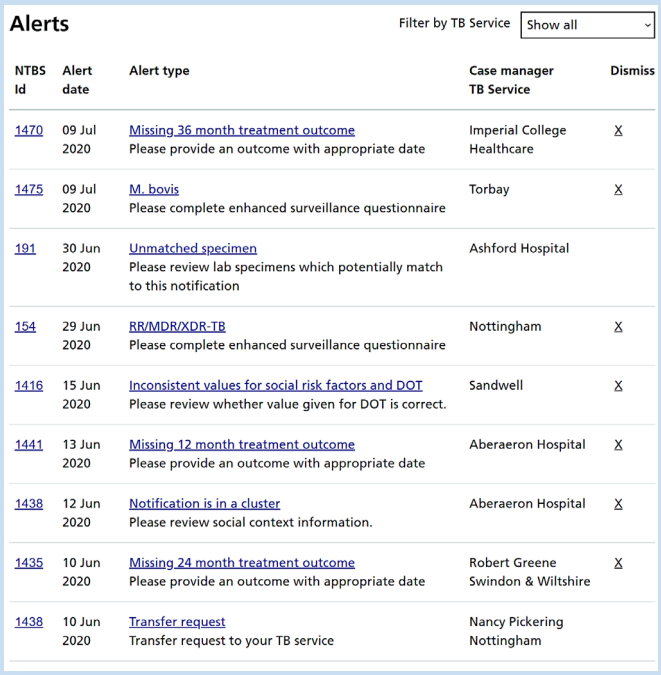
Potential duplicate notification: This is triggered when a record is matched on either National Health Service number, name or date of birth, but the records are not linked – i.e. they are classed as two separate events for the same person. This requires the case manager to either request that the notifications are linked, actioned by the national team, or that one or more cases is denotified if they are duplicates.

RR/MDR/XDR-TB: This is triggered if a record is matched to a reference laboratory result indicating one of these drug resistance categories or the user has specified that the planned course of treatment is MDR-TB treatment. The action is to complete the enhanced surveillance questionnaire for RR/MDR-TB cases.

Transfer request: This is triggered when a user in another facility is requesting that a notification belonging to their service is transferred to another user's service. Users from the receiving service can either accept or decline the request.

During data consolidation and analysis, the NTBS generates various reports to support data quality including an alerts summary report (Fig. B7.1.2) and a missing items report. These can be filtered in various ways and can be seen for each user's registered TB service/s or region/s.

Fig. B7.1.1 Examples of dashboard alerts



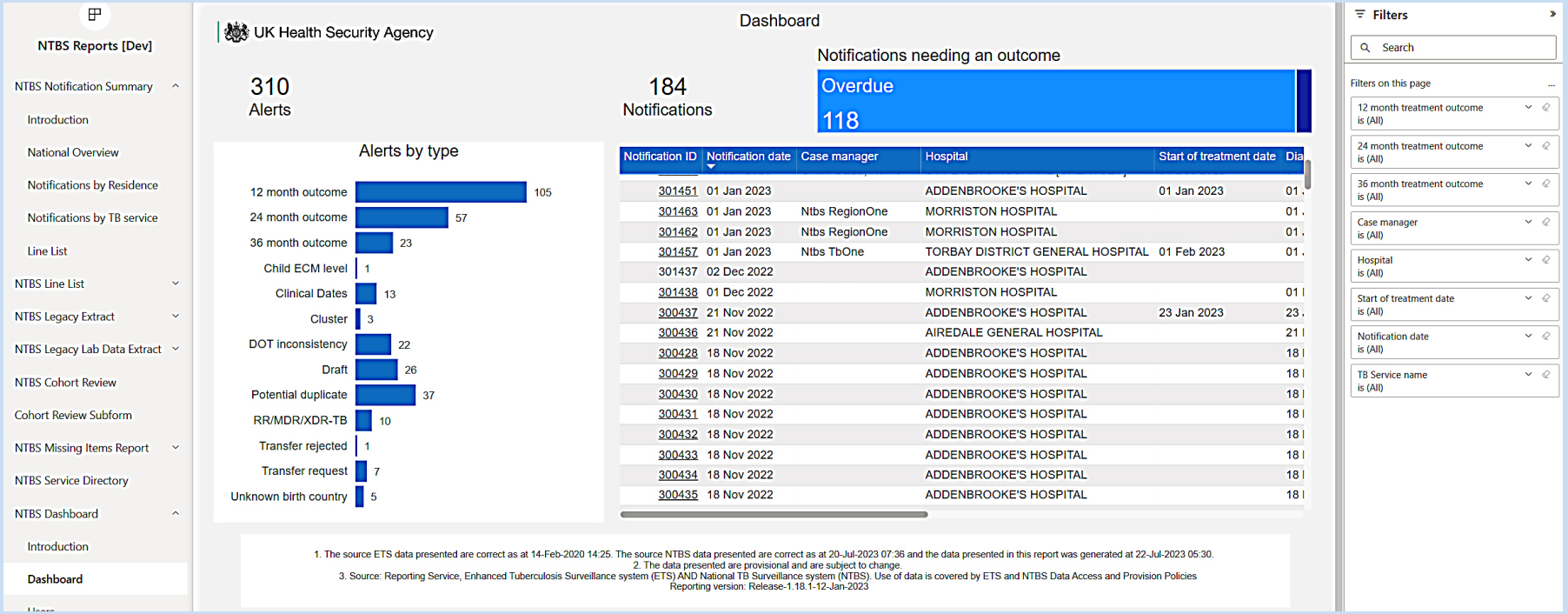
Alerts

Filter by TB Service: Show all

NTBS Id	Alert date	Alert type	Case manager TB Service	Dismiss
1470	09 Jul 2020	Missing 36 month treatment outcome Please provide an outcome with appropriate date	Imperial College Healthcare	X
1475	09 Jul 2020	M. bovis Please complete enhanced surveillance questionnaire	Torbay	X
191	30 Jun 2020	Unmatched specimen Please review lab specimens which potentially match to this notification	Ashford Hospital	
154	29 Jun 2020	RR/MDR/XDR-TB Please complete enhanced surveillance questionnaire	Nottingham	X
1416	15 Jun 2020	Inconsistent values for social risk factors and DOT Please review whether value given for DOT is correct.	Sandwell	X
1441	13 Jun 2020	Missing 12 month treatment outcome Please provide an outcome with appropriate date	Aberaeron Hospital	X
1438	12 Jun 2020	Notification is in a cluster Please review social context information.	Aberaeron Hospital	X
1435	10 Jun 2020	Missing 24 month treatment outcome Please provide an outcome with appropriate date	Robert Greene Swindon & Wiltshire	X
1438	10 Jun 2020	Transfer request Transfer request to your TB service	Nancy Pickering Nottingham	

Box 7.1 Examples of data quality assurance procedures in the national TB surveillance system in the United Kingdom of Great Britain and Northern Ireland (UK) (continued)

Fig. B7.1.2 An example of an alerts summary report from NTBS, for all regions on the training and testing platform



Box 7.2 Data quality assurance in the national TB surveillance system in Australia

In Australia, the surveillance of TB has been undertaken formally at the national level since 1991 through the National Notifiable Diseases Surveillance System (NNDSS). As a notifiable disease, clinicians and/or testing laboratories report TB cases to their designated jurisdictional health department, which then uploads de-identified data into the national system. The system was upgraded in 2021/2022 to improve its stability and security, as well as to increase its potential for interoperability.

Various procedures are in place to ensure high quality TB data in Australia. These include the availability of a written Standard Operating Procedures (SOP) manual for end users, automated data validation checks when entering/transferring data into the digital system, and periodic manual data checks. Quarterly data checks are performed by epidemiologists and data managers in each jurisdiction to identify any issues with data transference to the NNDSS. In addition, a TB data quality working group meets several times a year to review data quality issues and revise, where required, the national TB data specifications. Reviews of TB data, and their specifications, are undertaken by the National Tuberculosis Advisory Committee.

Australia's NNDSS uses two unique identifier numbers to protect patient privacy and to facilitate data review and de-duplication. One is assigned by each of the jurisdictional surveillance systems, while the other is generated by the NNDSS system in case the former ID number carries privacy concerns. Both numbers are different to other unique personal identifiers used in Australia, such as national ID numbers and health insurance/social security numbers.

Paper-based systems

As at the level of a health facility (see Section 7.3.1), in paper-based surveillance systems there are limits to what can be achieved in terms of routine data validation checks at the level of administrative units. Periodic audits of data collected in paper-based TB surveillance systems should be planned for and budgeted. Some of the checks listed in Table 7.2 could be implemented.

7.4 Periodic evaluations of data quality

Periodic evaluations of data quality are important. These can include self-assessments as well as external, independent audits. In the context of TB surveillance data, self-assessments could be done by NTPs. Audits would be done less frequently. Both should be institutionalized as part of the routine NTP workplan, and used to facilitate supervision, sustain or improve recording and reporting of data, and sustain or strengthen the quality and coverage of the surveillance system.

The main components of self-assessments and audits are shown in Table 7.3.

It is common to see the quality of data improve when corrective action is taken. During periods when major changes to the surveillance system are being made (e.g. during a transition from paper-based aggregated reporting to case-based digital surveillance), particular attention should be given to data quality, including through routine validation checks, regular self-assessments by the NTP, and independent audits.

An illustration of how routine validation checks (Section 7.3) and more periodic assessments can be part of NTP activities is provided in Fig. 7.2.

Table 7.2 Examples of data validation checks that can be used at the level of administrative units, for six dimensions of data quality

Dimension of data quality	Validation check
Accuracy and validity	• Data validation algorithms run routinely by designated staff at different levels checking for erroneous, misclassified or implausible values.
Completeness	• Datasets routinely checked for missing values • Routine checks that all reports and data have been submitted by all reporting units, according to the expected frequency (e.g. all reporting districts for the province on a quarterly basis) • Regular record-linkage exercises with external databases that hold individual-level data on people with TB disease (for example, laboratory databases) • Routine checks that all health facilities (public and private) that diagnose and treat TB disease, based on an exhaustive and up-to-date master health facility list, have reported data to the TB surveillance system
Uniqueness	• Checks for duplicated records of the same treatment episode • Record-linkage exercises (deterministic or probabilistic) to identify and remove duplicate records for the same individuals

Table 7.2 Examples of data validation checks that can be used at the level of administrative units, for six dimensions of data quality (continued)

Dimension of data quality	Validation check
Consistency	Recommended examples of data items and indicators to be reviewed over time for internal consistency include[a, b]: • male to female ratio, • extrapulmonary TB as a percentage of all forms, • childhood TB notifications as a percentage of notifications for all ages, • case notification rate for all forms of TB, • case notification rate for bacteriologically confirmed TB, • ratio of the number of people with presumptive TB to total notifications of TB cases, and • age distribution of the whole patient cohort Recommended indicators to be compared for external consistency with other settings include: • percentage of people with pulmonary TB disease that are bacteriologically confirmed is in the range of 70–90%, and • year-to-year change in the case notification rate for new, all forms of TB is consistent with the year-to-year change for new, pulmonary bacteriologically confirmed notification rates (the trajectories follow the same direction) For further details, see the WHO TB surveillance checklist in Web Annex B. Another process could be defined to monitor unusual trend detection, to be run on a fixed, frequent schedule: an outbreak detection algorithm. This identifies unusual clusters of cases (geographically and/or temporally) and procedures for immediate investigation. It is useful to display any unusual trend using graphs and/or maps.
Timeliness	• Routine checks that all reports and data have been submitted by all reporting units within a pre-defined timeframe (e.g. alerts generated at higher administrative levels when reporting units have not submitted their aggregated data by the end of certain reporting periods (in countries using digital systems, either for aggregated or case-based TB data))

[a] The time series of some of these indicators could be inconsistent in settings with a small number of TB episodes, due to stochastic variability. In situations such as these, this does not mean data are internally consistent, but rather that it is not appropriate to make the assessment.
[b] Some observed changes in the indicators listed here over time can be explained. For example, childhood TB notifications as a percentage of notifications for all ages is expected to reduce in settings where transmission in the community decreases and most new episodes of TB are due to the activation of an old infection.

Fig. 7.2 An illustration of how routine data validation checks and periodic assessments of data quality can be implemented as part of NTP plans

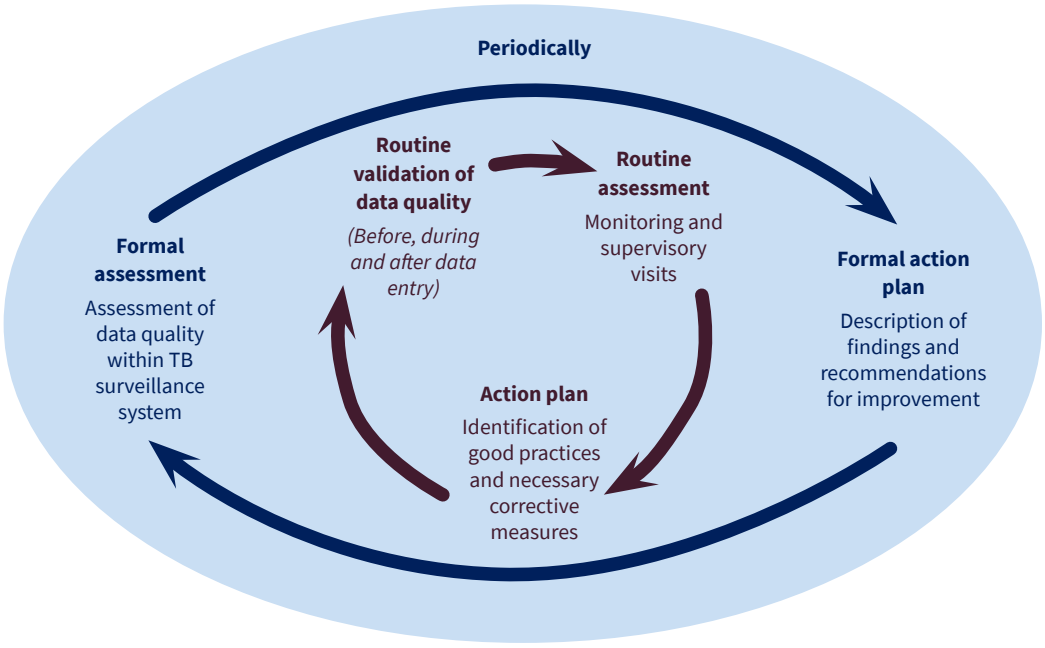


Table 7.3 Main components of routine self-assessments and external, independent audits

Characteristics	Routine self-assessments	External, independent audits
Description	Assessment of data quality from TB data reporting units	Assessment of data quality of the national TB surveillance system
Objective	Self-assessment of data quality and associated capacity strengthening in data recording and reporting, and data management	Comprehensive and independent assessment of data quality from all TB data reporting entities to evaluate the system's ability to record and report high-quality TB data
Frequency	Regularly, as part of routine data management and regular monitoring and supervision	Periodically (annually to every few years)
Implementation	By the NTP To include: • supervisory visits (for a quick snapshot assessment based on convenience sampling of a small number of health facilities) • Use of assessment tools and checklists according to the local context	By (programme-) independent, external auditors. To include: • desk reviews of forms and documents; and • supervisory visits (sites may be selected through random, cluster sampling or as part of a nationally representative sample of health facilities) Conducted using a standardized approach using tools and checklists
Resource requirements (time, finances, personnel)	Usually low-to-medium resource intensive, since assessments should be integrated into routine data quality and supervisory activities; however, this may depend on the local context and on what assessment tools are used	Medium-to-high resource intensive as assessment should be comprehensive and national in scope; personnel from all levels including senior staff involved
Output	Action plan detailing best practices, corrective measures, required resources and timelines to be implemented by selected entities or geographical areas, or nationally	Formal report of system performance detailing recommendations for the NTP and stakeholders; often informs development of national strategic plans, TB programme reviews, development of funding applications
Resources	• Manual on use of routine data quality assessment (RDQA) tool for TB monitoring *(5)*	• The WHO data quality assurance toolkit *(5–8)* • The WHO checklist of standards and benchmarks for TB surveillance and vital registration systems (see Web Annex B)[a]

[a] The first edition of the checklist is available elsewhere *(9)*.

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