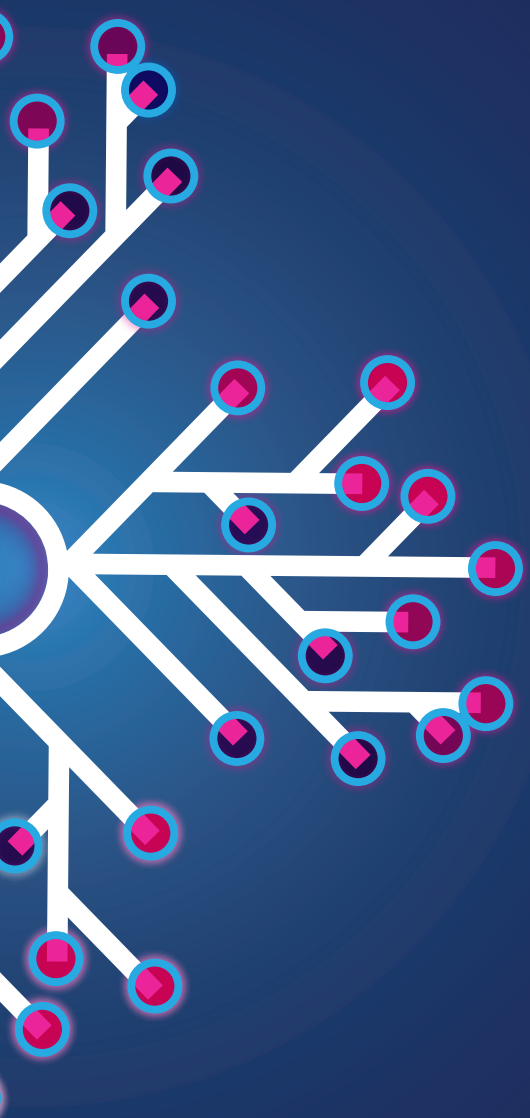
Consolidated guidance on tuberculosis data generation and use
Module 1

Tuberculosis surveillance

Web Annex B

Standards and benchmarks for tuberculosis surveillance and vital registration systems: checklist, 2nd edition



World Health Organization

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Contents

Chapter 1
Introduction

1.1 Background

A major goal in the surveillance of tuberculosis (TB) is to provide an accurate measure of the number of new TB cases and related deaths that occur each year, and to be able to assess these trends over time. In some countries, TB surveillance already meets the standards necessary to do this, but in others, there are important gaps in the TB surveillance system that make this impossible. Examples of gaps in surveillance found in many countries include TB cases that are diagnosed in the private sector going unreported; in countries with a high burden of TB, people with TB finding it difficult to access health care and therefore not being diagnosed; and countries lacking vital registration systems with the quality and geographical coverage that is required to accurately measure deaths caused by TB. In response to this situation, the *Checklist of standards and benchmarks for TB surveillance and vital registration systems* was developed; its two main objectives are to:

- assess a national surveillance system's ability to accurately measure TB cases and deaths; and
- identify gaps in national surveillance systems that must be addressed to improve TB surveillance.

The results of national assessments using the checklist can be used to identify which countries have surveillance systems that already provide an accurate measure of the number of TB cases and deaths that occur each year. The results can also be used to define the actions necessary to strengthen surveillance in countries in which gaps are identified.

The first edition of the checklist[1] was developed by a team of experts in disease surveillance, in conjunction with expert advice from meetings organized by the World Health Organization (WHO) in September 2011 and May 2012. The original checklist was revised following two rounds of field-testing in 11 countries: Brazil, China, Egypt, Estonia, Japan, Kenya, the Netherlands, Thailand, Uganda, the United Kingdom of Great Britain and Northern Ireland (United Kingdom) and the United States of America (USA).

This second edition contains updates to the original checklist based on an updated global analysis of TB surveillance data from 2015 to 2019, comparing outcomes for potential benchmarks with 10 reference countries that are considered to have high-functioning TB surveillance systems: Australia, Canada, Denmark, Germany, Japan, the Netherlands, New Zealand, Sweden, the United Kingdom and the USA. This edition was also informed by lessons learned from implementing the first edition of the checklist in over 90 countries. Where applicable, benchmarks have been updated to be better aligned with the Sustainable Development Goals (SDG) and monitoring and evaluation (M&E) indicators for updated WHO TB guidelines. The scope of the second edition of the checklist has been widened to cover more of the pathway of prevention and care, with the addition of two new standards related to programmatic management of TB preventive treatment (PMTPT) and treatment outcomes. Also, this edition of the checklist has received input from technical experts as part of the Global Task Force on TB Impact Measurement and has been piloted in seven countries: Cambodia, Indonesia, Nigeria, Pakistan, Lao People's Democratic Republic, Rwanda and South Africa.

1.2 What does the checklist assess?

The checklist has two parts:

- Part A has 18 questions designed to provide a general description of the TB surveillance system that is being assessed; the questions assess the characteristics of the national TB surveillance system and set the background for Part B.
- Part B has a total of 17 standards (i.e. general statements about the criteria for a high-performing TB surveillance system) and associated benchmarks, across four sections:
    - *Section 1 – Core standards for TB surveillance and vital registration systems* provides nine standards related to the measurement of TB cases (e.g. data quality and system coverage) and one related to the measurement of TB deaths (using TB mortality data from vital registration systems);

[1] Standards and benchmarks for tuberculosis surveillance and vital registration systems: checklist. Geneva: World Health Organization; 2014 (https://iris.who.int/handle/10665/112674).

- *Section 2 – Supplementary standards for specific populations* provides three supplementary standards on surveillance of TB and HIV coinfection, drug-resistant TB and childhood TB; the responses can be used to assess whether a national TB surveillance system can be certified as providing a direct measure of the number of rifampicin-resistant TB cases, HIV-positive TB cases or childhood TB cases;
- *Section 3 – Treatment outcomes* provides two standards that can be used to assess the quality of treatment outcomes data; and
- *Section 4 – Programmatic management of TB preventive treatment* provides two standards related to contact tracing and prevention; the responses can be used to assess the availability and quality of M&E data on PMTPT.

Benchmarks define (in quantitative terms where possible) the level of performance considered sufficient to meet respective standards. To ensure that the most complete data are available for review, the assessments are designed to use data from the most recent complete calendar year, unless otherwise stated. Depending on the timeliness of the reporting and finalization of data validation procedures in the system, the lag time may range from no delay to up to one year. In some instances, data from additional years are needed to assess trends over time, or data from a single quarter can be used, to reduce the burden of data collection. It is anticipated that an assessment of a TB surveillance system using the checklist would take place every 3–5 years.

For Parts A and B of the checklist, a detailed description should be provided, including a justification of the outcome. It is important to also record key actions that address gaps identified in the surveillance and vital registration systems that would prevent those systems from accurately measuring TB cases and deaths, and actions that could improve the quality of TB surveillance, based on established best practices. An estimated budget to support activities that could bridge these gaps will assist the national TB programme (NTP) in developing an M&E investment plan.

The standards and benchmarks related to health system coverage (Standard B1.9) and vital registration (Standard B1.10) are outside of the purview of the NTP. However, these two standards and their associated benchmarks are deemed necessary to assess the capacity of the surveillance system to accurately estimate TB burden.

This checklist was developed primarily for use at national level but may also be used at the subnational level. The checklist assesses only one part of system capacity; it is not intended to assess the system's ability to fulfil other programmatic requirements (e.g. patient care, delivery of laboratory results or management of drug stock). However, these other requirements may be discussed as part of the detailed description in the checklist, where appropriate. Another issue is that the standards assess the outputs rather than the inputs or processes of the surveillance system, which will vary by country. Using the results of Part B of the checklist, coupled with the information collected in Part A, countries can identify areas where additional resources can be targeted to effectively strengthen their surveillance systems.

1.3 What is a certified TB surveillance system?

For a country's TB surveillance system to be certified as providing a direct measurement of TB cases and TB deaths, the system should meet all 10 standards in Section 1 of Part B and their associated benchmarks. The three supplementary standards in Section 2 of Part B can be used to assess whether a TB surveillance system can be certified as providing direct and specific measures of the number of drug-resistant TB cases, HIV-positive cases of TB and TB in children. The two standards in Section 3 of Part B can be used to assess whether the TB surveillance system is accurately recording and monitoring treatment outcomes and the two standards in Section 4 to assess data quality related to contact tracing and prevention activities.

Certification provides an objective situational analysis of the current TB surveillance system. It is intended to provide a baseline and a framework that can be used to support improvements to the system, if required. Subsequent assessments can be used to determine whether targets have been met based on the initial assessments. Certification is based on the assessment of the system at the relevant time period. External peer review and endorsement of the findings by the WHO Global Task Force on TB Impact Measurement will be necessary for a country's system to be certified.

1.4 Who can implement the checklist?

The checklist is best implemented by an external technical assistant with knowledge of TB programmes and disease surveillance systems, in close collaboration with the NTP. This is to facilitate objectivity in the assessment and avoid any potential introduction of bias from a self-assessment, even if the bias is unintentional.

The checklist can still be used by in-country NTP staff for a self-assessment. All parts of the checklist should be undertaken by someone with an informed and

current knowledge of the system; for example:

- NTP manager;
- NTP programme officer;
- NTP monitoring and evaluation officer;
- NTP statistician or epidemiologist;
- NTP data manager; or
- WHO TB programme officer.

1.5 What is new in the second edition of the checklist?

The following is a summary of updates to the standards the second edition of the checklist:

A2. The question has been revised to explicitly include tools for screening, prevention and treatment outcomes.

A8. The question has been revised to explicitly include the data quality for screening, prevention and treatment outcomes.

B1.6 The benchmarks have been updated and they now assess external consistency using data on bacteriological confirmation.

B1.9 The benchmarks have been updated to align with the SDG universal health coverage (UHC) index (SDG Indicator 3.8.1). A UHC index score of 80 is required to meet this standard; however, the standard can be partially met if the UHC index score is above 60 but below 80.

B1.10 The benchmarks have been updated to align with WHO cause of death analysis, which systematically assesses the availability and quality of vital registration data. A quality score of either "1-High" or "2-Medium" is required to meet this standard. A quality score of either "3-Low" or "4-Very low" is enough to partially meet this standard. The standard is not met if vital registration data are not available.

B2.1 The standard and associated benchmarks have been updated to assess surveillance of rifampicin-resistant TB among both new and previously treated bacteriologically confirmed pulmonary cases. The threshold for meeting this standard through routine surveillance has been increased to at least 80%.

B2.2 The benchmark has been updated to include the documentation of HIV status for all TB cases through routine surveillance.

B2.3 The first benchmark is now assessed using the rate ratio of TB notifications for those aged 0–4 years to those aged 5–14 years.

Four standards have been added to the checklist. The rationale for each of the new standards is as follows:

B3.1 This standard has been added to assess adoption of updated definitions related to the M&E of treatment outcomes.

B3.2 This standard has been added to assess the quality of treatment outcomes data.

B4.1 This standard has been added to assess the adoption of updated definitions and ensure alignment of recommended M&E indicators for PMTPT.

B4.2 This standard has been added to assess the quality of PMTPT data.

Chapter 2
Checklist

2.1 Part A: Characteristics of the TB surveillance system

Before completing the checklist, it is important to characterize the national TB surveillance system. Please provide answers to the questions given below.

Questions	Outcomes (best practices are in bold)	Detailed descriptions and key actions required to address gaps
A1. How are data recorded for individual TB cases at the service delivery level (e.g. in TB diagnostic units, health centres and clinics)? *(Tick all that apply)*	☐ **Data are recorded on a national internet-based digital system** ☐ Data are recorded on a state, provincial or regional internet-based digital system ☐ Data are recorded on a local digital system ☐ Data are recorded on paper ☐ Data are not recorded	
A2. Do all service delivery points systematically use standardized TB data collection forms and tools, including those for screening of contacts and PLHIV, and for the provision of preventive treatment?	☐ **Yes, completely** ☐ Mostly ☐ Partially ☐ No, not at all	
A3. Which TB cases are included in the national TB surveillance data? *(Tick all that apply)*	☐ **All TB cases from all parts of the country are included** ☐ Some TB cases are excluded ☐ Some parts of the country are excluded ☐ Some case types are excluded ☐ Some care providers (e.g. non-NTP providers, prisons or private practitioners) are excluded ☐ Others (please specify): _____	
A4. What types of TB data are available at the national level? *(Tick all that apply)*	☐ **Patient level data that allow multiple episodes of TB in the same person to be identified are available** ☐ Case level data are available for the entire country ☐ Case level data are available for parts of the country ☐ Aggregated data are available (i.e. summaries for groups of cases)	
A5. What is the expected frequency of data transmission from the first subnational administrative level to the national level? *(Tick all that apply)*	☐ **Real-time** ☐ More often than monthly ☐ Monthly ☐ Quarterly ☐ Less often than quarterly	
A6. At what levels of the system are TB data systematically verified for accuracy, timeliness and completeness?	☐ **From the service unit upwards** ☐ From the first administrative level upwards ☐ From the second administrative level upwards ☐ Only at the national level ☐ Not at any level	

Questions	Outcomes (best practices are in bold)	Detailed descriptions and key actions required to address gaps
A7. What types of quality assurance procedures are systematically undertaken for TB data? *(Tick all that apply)*	☐ **Quality controls are in place for the digital surveillance system (automated checks at data entry and batch checking, plus SOPs)** ☐ Data are reviewed during supervisory monitoring visits to service units and subnational levels (how often? _____) ☐ Data are reviewed during meetings with TB staff (how often? _____) ☐ Other (please specify:_____)	
A8. Is feedback on TB data quality systematically provided to all lower reporting levels, for data recorded at all stages of the pathway of prevention and care?	☐ **Yes, completely** ☐ Mostly ☐ Partially ☐ No, not at all	
A9. When are national TB case data for a given calendar year considered ready for national analyses and reporting?	☐ **Before April of the following calendar year** ☐ Before May of the following calendar year ☐ Before June of the following calendar year ☐ On or after the beginning of June of the following calendar year	
A10. Are there national guidelines for recording and reporting of TB data (e.g. documentation or instructions)? *(Tick all that apply)*	☐ **Yes, they are posted on the internet** ☐ Yes, they are available in a manual or other reference document (e.g. training materials) ☐ No	
A11. Does the NTP have a plan for training staff involved in data collection and reporting at all levels of the reporting process?	☐ **Yes** ☐ No	
A12. How often do TB programme staff receive training specifically on TB surveillance (i.e. recording and reporting of TB data)? *(Tick all that apply)*	☐ **Training is routinely received at national and subnational levels (how often?_____)** ☐ Training is received on an ad hoc basis ☐ Staff receive training when they are appointed ☐ No routine training is received	
A13. How many staff work on TB surveillance at the national level? *(Tick all that apply)*	☐ **Epidemiologist, full-time (#_____)** ☐ Epidemiologist, part-time (#_____) ☐ Statistician, full-time (#_____) ☐ Statistician, part-time (#_____) ☐ Data manager, full-time (#_____) ☐ Data manager, part-time (#_____) ☐ Data quality officers, full-time (#_____) ☐ Data quality officers, part-time (#_____) ☐ Other (please specify: _____)	
A14. Is a national TB surveillance report routinely produced and disseminated on an annual basis?	☐ **Yes** ☐ No	
A15. Have the goals of the surveillance system been put in writing?	☐ **Yes** ☐ No	
A16. Are policies and procedures in place to protect the confidentiality of all surveillance data (e.g. records, registers)?	☐ **Yes, completely** ☐ Mostly ☐ Partially ☐ No, not at all	

Questions	Outcomes (best practices are in bold)	Detailed descriptions and key actions required to address gaps
A17. Is there a long-term financial plan and budget in place to support TB surveillance activities?	☐ **Yes** ☐ No	
A18. When was the last time the TB surveillance system was evaluated?	☐ **Within the past 5 years** ☐ Within the past 5–10 years ☐ Never	

NTP: national TB programme; PLHIV: people living with human immunodeficiency virus; SOP: standard operating procedure; TB: tuberculosis.

2.2 Part B: Checklist for TB surveillance and vital registration systems

For each standard, please assess whether the system is able to satisfy the associated benchmark or benchmarks, using the methods recommended in the user guide. Indicate "Met", "Partially met", "Not met" or "Not applicable" in the results column. Describe the key results and any action recommended to improve the quality of the system in the last two columns.

Standard	Benchmarks	Results	Results (description) including key actions required to address the gaps
Section 1 – Core standards			
TB surveillance system data quality			
B1.1 Case definitions are consistent with WHO guidelines	All three benchmarks should be satisfied to meet this standard: • Laboratory-confirmed cases[1] are distinguished from clinically diagnosed cases • New cases are distinguished from previously treated cases • Pulmonary cases are distinguished from extrapulmonary cases	☐ Met ☐ Partially met ☐ Not met	
B1.2 The TB surveillance system is designed to capture a minimum set of variables for reported TB cases	Data are routinely collected for each of the following variables, as a minimum: • Age or age group • Sex • Year of registration • Bacteriological results • History of previous treatment • Anatomical site of disease • For case-based systems, a patient identifier	☐ Met ☐ Partially met ☐ Not met	
B1.3 All scheduled periodic data submissions have been received and processed at the national level	*For paper-based systems:* • 100% of expected reports from each TB basic management unit have been received and data have been aggregated at national level *For national patient-based or case-based digital systems that import data files from subnational (e.g. provincial or regional) digital systems:* • 100% of expected data files have been imported	☐ Met ☐ Partially met ☐ Not met ☐ Not applicable	
B1.4 Data in quarterly reports (or equivalent) are accurate, complete, and internally consistent *(for paper-based systems only)*	All benchmarks should be satisfied to meet this standard: • Subtotals of the number of TB cases by age group, sex and case type equal the total number of reported TB cases in ≥95% of quarterly reports (or equivalent) from BMUs • The number of TB cases in >95% of quarterly reports (or equivalent) matches the number of cases recorded in BMU TB registers and source documents (patient treatment cards and laboratory register) • Data for a minimum set of variables are available for ≥95% of the total number of reported TB cases in quarterly reports	☐ Met ☐ Partially met ☐ Not met ☐ Not applicable	

[1] i.e. by smear, culture or WHO-recommended rapid diagnostic (e.g. Xpert MTB/RIF).

Standard	Benchmarks	Results	Results (description) including key actions required to address the gaps
B1.5 Data in national database are accurate, complete, internally consistent, and free of duplicates *(For digital case-based or patient-based systems only)*	All benchmarks should be met to reach this standard: • Data validation checks are in place at national level to identify and correct invalid, inconsistent, and missing data in the minimum set of variables (B1.2) • For each variable in the minimum set (standard B1.2), ≥90% of case records are complete, valid and internally consistent for the year being assessed • <1% of case records in the national dataset for the year being assessed are unresolved potential duplicates	☐ Met ☐ Partially met ☐ Not met ☐ Not applicable	
B1.6 TB surveillance data are externally consistent	All benchmarks should be met to reach this standard: • Percentage of bacteriologically confirmed cases among pulmonary new and recurrent cases ranges between 70% and 90% • Year-to-year change of TB notification rates (new and recurrent, all forms) is consistent with the year-to-year change in bacteriologically confirmed notification rates for pulmonary TB (i.e. the trajectories are in the same direction) • Overall percentage of decline in proportion of bacteriologically confirmed pulmonary TB cases over the 5 years preceding the year of the assessment does not exceed 5%	☐ Met ☐ Partially met ☐ Not met	
B1.7 Number of reported TB cases is internally consistent	*If vital registration data are available, then the following benchmark should be satisfied for this standard to be met:* • Year-to-year change in the national number of reported TB cases is consistent with year-to-year change in national TB mortality (HIV-negative, from national vital registration); that is, the trajectories are in the same direction) *If vital registration data are not available, then the following benchmarks should be satisfied for this standard to be met:* • Proportion of extrapulmonary TB cases out of all TB cases • Ratio of male to female TB cases • Proportion of childhood TB out of all TB cases • Year-to-year change in the case notification rate for all forms of TB • Year-to-year change in the case notification rate for new bacteriologically confirmed TB • Ratio of the number of people with presumptive TB to total notifications of TB cases (if data are available)	☐ Met ☐ Partially met ☐ Not met	
System coverage			
B1.8 All diagnosed cases of TB are reported	All benchmarks should be satisfied to meet this standard: • TB reporting is a legal requirement • All case types, including drug-resistant TB, are included in the overall number of cases reported • >90% of TB cases are reported to national health authorities, as determined by a national-level investigation (e.g. inventory study) conducted within the past 10 years	☐ Met ☐ Partially met ☐ Not met	
B1.9 Population has good access to health care	• UHC index score is ≥80 (SDG Indicator 3.8.1)	☐ Met ☐ Partially met ☐ Not met	

Standard	Benchmarks	Results	Results (description) including key actions required to address the gaps
Vital registration			
B1.10 Vital registration system has high national coverage and is of high quality	• Vital registration data provided by CRVS is evaluated as either "1-High" or "2-Medium" *(See WHO methods and data sources for country-level causes of death 2000–2019, at ghe2019_cod_methods.pdf (who.int))*	☐ Met ☐ Partially met ☐ Not met	
Section 2 – Supplementary standards for specific populations			
B2.1 Surveillance data provide a direct measure of rifampicin-resistant TB in bacteriologically confirmed pulmonary cases	One of these two benchmarks should be satisfied to meet this standard: • Rifampicin susceptibility testing results are documented for ≥80% of all bacteriologically confirmed pulmonary TB cases • Rifampicin susceptibility testing results are documented for a nationally representative drug resistance survey conducted in the past 5 years	☐ Met ☐ Partially met ☐ Not met	
B2.2 Surveillance data provide a direct measure of the prevalence of HIV infection in TB cases	One of these two benchmarks should be satisfied to meet this standard: • HIV status (positive/negative) is documented for ≥80% of all notified TB cases • HIV status is available from a representative sample from all TB cases notified, in settings where there is a low-level epidemic state[1] or in settings where it is not feasible to implement routine surveillance	☐ Met ☐ Partially met ☐ Not met	
B2.3 Surveillance data for children reported with TB (defined as ages 0–14 years) are reliable and accurate AND all diagnosed childhood TB cases are reported	Both these benchmarks should be satisfied to meet this standard: • Rate ratio of groups aged 0–4 to 5–14 years is in the range 1.5–3.0 • ≥90% of childhood TB cases are reported to national health authorities, as determined by a national-level investigation (e.g. inventory study) conducted in the past 10 years	☐ Met ☐ Partially met ☐ Not met	
Section 3 – Treatment outcomes			
B3.1 Monitoring treatment outcomes is consistent with WHO guidelines	Both these benchmarks should be satisfied to meet this standard: • Treatment outcome definitions for all TB cases are consistent with WHO guidelines • Treatment outcomes of TB patients at national level can be disaggregated by at least the following variables: treatment history, HIV status and drug resistance status	☐ Met ☐ Partially met ☐ Not met	
B3.2 Recording and reporting of TB treatment outcomes are accurate, complete and consistent	All these benchmarks should be satisfied to meet this standard: *For paper-based systems:* • Assignment of treatment outcomes is correct for >95% of TB patients recorded in the facility register • Number of treatment outcomes (for each outcome category) in >95% of quarterly reports (or equivalent) matches the number recorded in BMU TB registers • Reported number of the cohort of patients with an expected assigned[2] treatment outcome in any given year matches the number of patients notified the year before • <1% of cases are assigned an outcome of not evaluated	☐ Met ☐ Partially met ☐ Not met	

[1] Low-level epidemic state: HIV prevalence has not consistently exceeded 5% in and defined sub-population.
[2] This excludes people who are still on treatment at the time of reporting, e.g. those on longer than 12 months treatment regimens.

Standard	Benchmarks	Results	Results (description) including key actions required to address the gaps
	For case-based or patient-based digital systems: • Data validation checks are in place to ensure validity of assigned treatment outcome for individual cases • Reported number of the cohort of patients with an expected assigned[1] treatment outcome in any given year matches the number of patients notified the year before • <1% of cases are assigned an outcome of not evaluated		
Section 4 – Programme management of TB preventive treatment			
B4.1 Monitoring indicators for PMTPT are consistent with WHO guidelines	All these benchmarks should be satisfied to meet this standard: • M&E indicators for PMTPT are consistent with WHO guidelines in terms of: o Contact investigation coverage o TPT coverage (disaggregated by PLHIV, contacts <5 years of age and ≥5 years) o TPT completion (disaggregated by regimens lasting 6 months or more and others lasting <6 months) • PMTPT dataset contains the minimum variables for monitoring TPT at three important instances of PMTPT: o Assessment of contacts of TB patients o Assessment of PLHIV and other at-risk groups o Initiation and completion of TPT *(See WHO operational handbook on tuberculosis. Module 1: Prevention – tuberculosis preventive treatment, at https://apps.who.int/iris/bitstream/handle/10665/331525/9789240002906-eng.pdf)*	☐ Met ☐ Partially met ☐ Not met	
B4.2 PMTPT data are accurate, complete and consistent	All the benchmarks should be satisfied to meet this standard: *For paper-based systems:* • Number of individuals evaluated for TB disease and TB infection and recorded in the source registers at the health facility matches the number reported (disaggregated by PLHIV, contacts aged <5 years and those aged ≥5 years) • Number of individuals started on TPT in the source register at the health facility matches the number reported (disaggregated by PLHIV, contacts aged <5 years and ≥5 years) • Number of individuals who completed TPT in the source register at the health facility matches the number reported (disaggregated by PLHIV, and household contacts of all ages combined) *For case-based or patient-based digital datasets:* • Data validation checks are in place at national level to identify and correct invalid, inconsistent and missing PMTPT data in the minimum set of variables (B4.1) • For each variable in the minimum set (B4.1), ≥90% of individual records are complete, valid and internally consistent for the year being assessed	☐ Met ☐ Partially met ☐ Not met	

BMU: basic management unit; CRVS: civil registration and vital statistics system; HIV: human immunodeficiency virus; PLHIV: people living with human immunodeficiency virus; PMTPT: programme management of TB preventive treatment; TB: tuberculosis; TPT: TB preventive treatment; WHO: World Health Organization.

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