PBMEF National-Level Indicators: Standard Indicator Reference Sheets (IRS)

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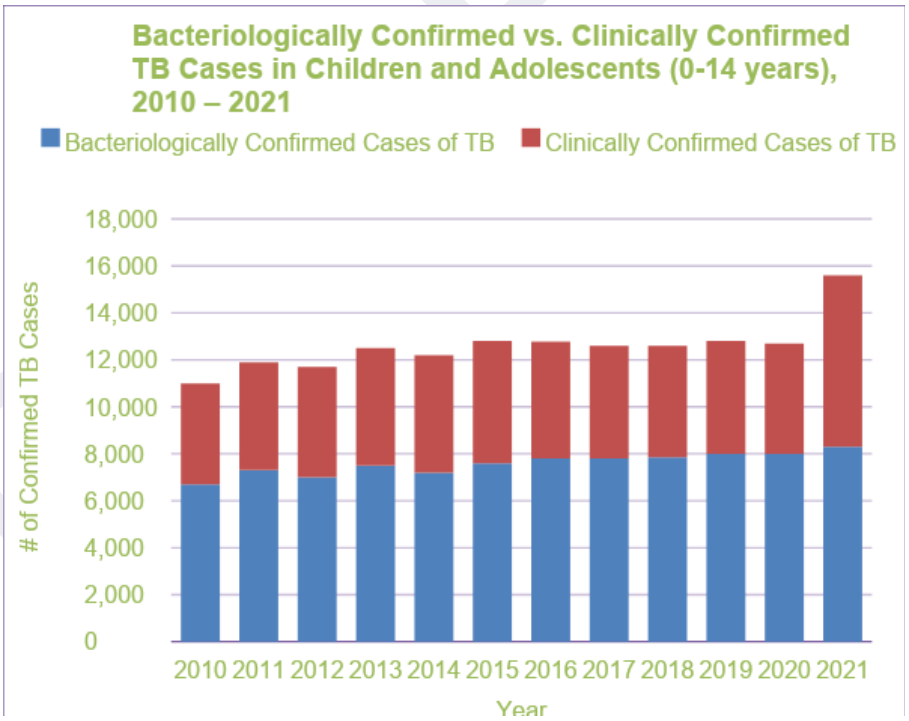
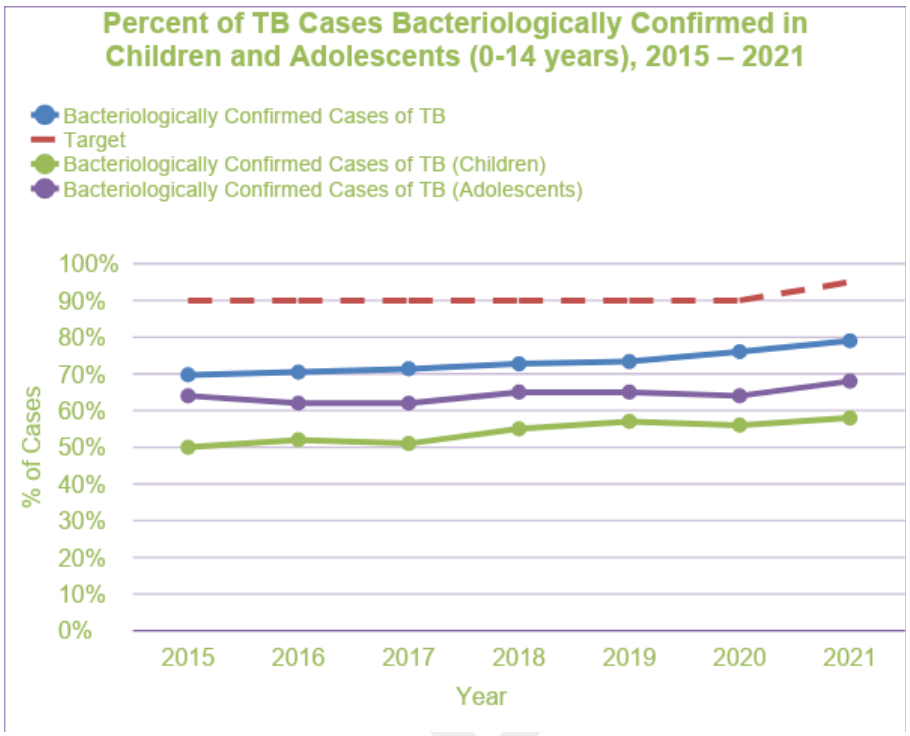
National-Level Indicators

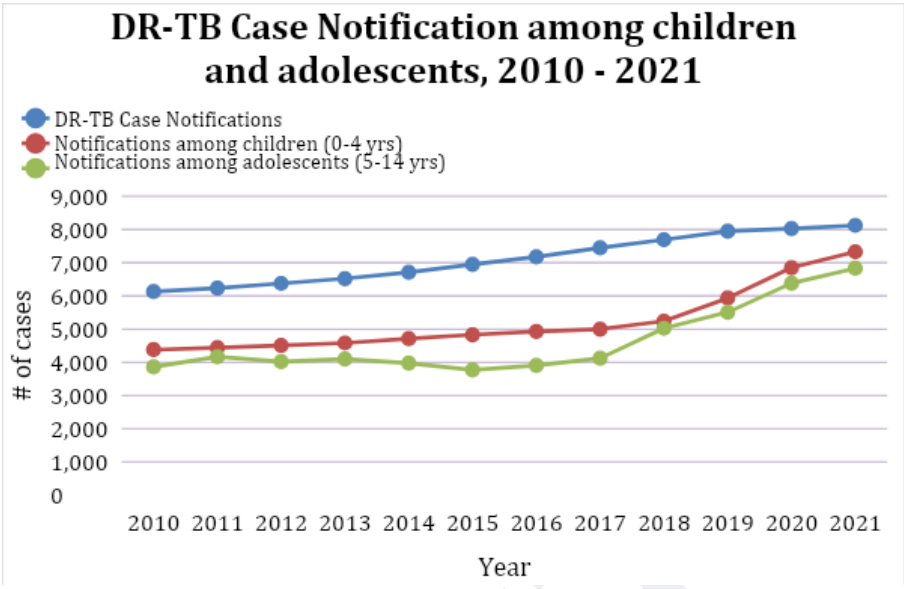
Indicator name and number	**PEDS_BAC_CON: Percent children and adolescents (0–14 years) bacteriologically confirmed** *Previously [CH-11]*
Definition	Percent of children and adolescents (0-14 years) with new and relapse pulmonary TB who are bacteriologically confirmed. Bacteriologically confirmed: Smear positive for TB or culture positive for TB or positive for TB by a World Health Organization-recommended rapid diagnostics test (WRD) such as Xpert MTB/RIF™, Truenat™, TB-LAMP™, Abbott™, BD™, Roche™, Hain™ or LF-LAM™. *Note: This is a subset of the core indicator "Percent Bacteriologically Confirmed".* According to 2022 WHO consolidated guidelines on tuberculosis (Module 5: Management of tuberculosis), the recommended initial diagnostic test in children and adolescents with signs or symptoms of pulmonary TB is either a WRD (Xpert MTB/RIF™, Truenat™, TB-LAMP™, Abbott™, BD™, Roche™, Hain™) for TB and rifampicin-resistance detection in sputum, gastric aspirate, nasopharyngeal aspirate and stool, rather than smear microscopy/culture and phenotypic DST and LF-LAM test (as a point-of-care test) for TB among children and adolescents (0-14 years) living with HIV. Of note, stool-based testing should be done using the Ultra cartridge on the Xpert platform which can detect trace amounts of *M.tb* (which should be interpreted as positive for children).
Numerator	Number of children and adolescents (0-14 years) with new and relapse pulmonary TB who are bacteriologically confirmed during a reporting period.
Denominator	Number of children and adolescents (0-14 years) with new and relapse pulmonary TB during the reporting period.
Category	Reach
Indicator type	Outcome
Level	National
Unit of measure	Percent of people
Data type	Percentage
Disaggregate by	Age (0-4, 5-14), sex
Reporting level	National level indicators should be reported at the national level; data may also be reported subnationally or at the project level if national data is not available.
Reporting frequency	This indicator should be reported on an annual basis at minimum. More frequent monitoring on a quarterly or monthly basis is recommended.
Data source(s)	Data sources may include the TB register, laboratory register and electronic management information systems at health facility and district level.
Importance	Improvements in reaching children and adolescents are needed to reach the United Nations High Level Meeting targets to provide TB diagnosis and treatment with the aim of successfully treating 3.5 million children with TB and 115,000 children with drug-resistant

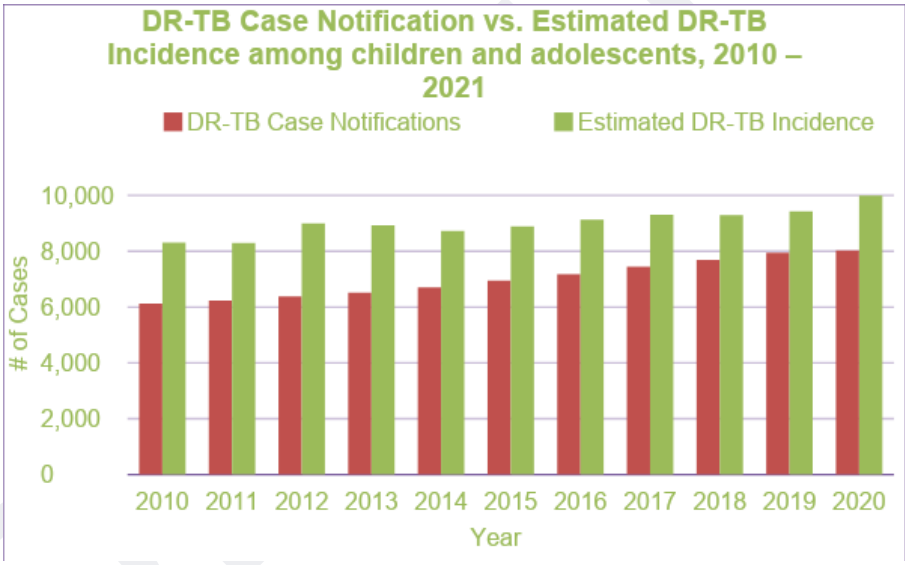
	TB by 2022. Recent advances in TB diagnosis for children, such as use of stool-based testing, will allow for more frequent bacteriological confirmation of TB among this population, which has traditionally been clinically diagnosed. These advances are important for avoiding overdiagnosis of TB based on symptoms only and for timely identification of drug resistant TB. National TB Programs that have prioritized TB diagnosis in children under 14 years old have begun piloting and scaling up these new approaches with USAID support, so monitoring changes in the indicator will allow stakeholders to determine whether or not they are being implemented well.
Data use	As new diagnostic approaches for childhood TB diagnosis are piloted and scaled up in high burden countries, this indicator should increase over time. This indicator can be analyzed as a trend over time and can be visualized in comparison to clinically diagnosed children and adolescents (0-14 years). It can also be compared to childhood and adolescent TB detection. Although the new diagnostic approaches are expected to improve bacteriological confirmation for children with TB, 40 to 50% of children with TB will continue to be diagnosed clinically due to suboptimal specificity. Low bacteriological diagnosis coverage among children and adolescents 0-14 years may be due to several contributing factors, including over-reliance on clinical diagnosis by the healthcare providers, gaps in referral for specimen testing with providers who are not familiar with new approaches such as stool-based testing, weak sample transport networks, breakdown of diagnostic platforms, stockout of consumables required for testing, and weaknesses in the system for reporting results to providers. Improved supervision and training, as well as improved supply chain, can help address these issues and improve performance on this indicator. 



Indicator name and number	**PEDS_MDR_NOTIF: MDR-TB notifications among children and adolescents (0-14 years)** *Previously [CH-13]*
Definition	Number of children and adolescents (0-14 years) with drug-resistant tuberculosis (DR-TB) notified during the reporting period (this includes rifampicin resistant (RR) and multidrug-resistant (MDR) TB diagnoses; pre-XDR/XDR-TB should not be reported in addition to the RR/MDR-TB notifications). RR/MDR TB: RR-TB is TB caused by Mycobacterium Tuberculosis (M. tuberculosis) strains that are resistant to rifampicin; MDR-TB strains are resistant to at least both rifampicin and isoniazid. Note: pre-XDR/XDR notifications should not be added to RR/MDR-TB notifications to avoid double counting of DR-TB notifications. Children who are diagnosed with pre-XDR and XDR-TB will already have been identified and recorded as having RR/MDR-TB. The number of RR/MDR-TB notifications should therefore equal the total number of DR-TB notifications.
Numerator	Number of children and adolescents (0-14 years) with notified DR-TB during the reporting period (both lab-confirmed and clinically diagnosed).
Denominator	N/A
Category	Reach
Indicator type	Outcome

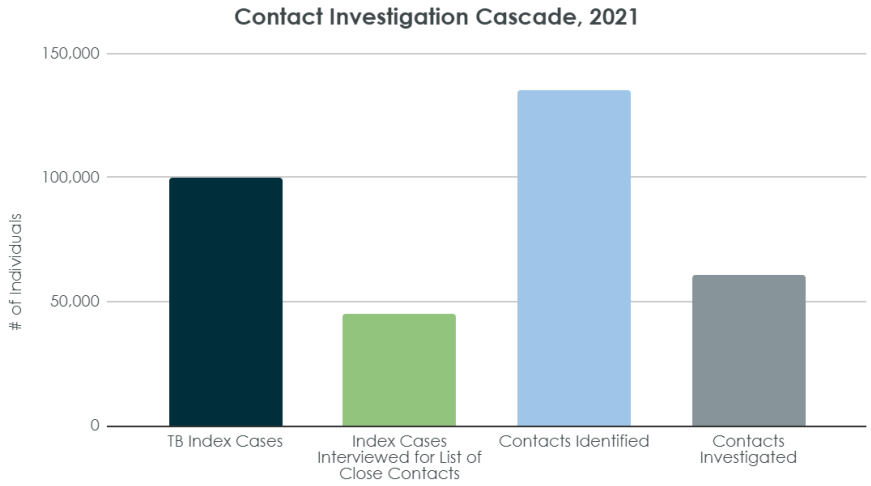
Level	National
Unit of measure	Number of children and adolescents
Data type	Integer
Disaggregate by	Age (0-4, 5-9, 10-14), sex
Reporting level	National level indicators should be reported at the national level; data may also be reported subnationally or at the project level if national data is not available.
Reporting frequency	This indicator should be reported on an annual basis at minimum. More frequent monitoring on a quarterly or monthly basis is recommended.
Data source(s)	Data sources may include the TB register, RR/MDR-TB register, or laboratory information and electronic medical record systems (LIMS, EMR) available at health facility and district level.
Importance	Understanding the burden of DR-TB in children is key for any NTP to respond accordingly. Researchers have estimated that between 25,000 and 32,000 children develop multidrug-resistant TB (MDR-TB) every year. MDR-TB, a form of TB that is resistant to two of the most potent anti-TB drugs (rifampicin and isoniazid), is a major contributor to antimicrobial resistance. Children acquire DR-TB mainly through transmission from household and/or close contact with an infectious adult or adolescent with MDR-TB. The diagnosis of DR-TB can be challenging, especially in young children, as they cannot easily produce a sputum sample for bacteriological testing, and because tests lack sensitivity to detect the low number of bacilli in samples of children. WHO now recommends the use of less invasive, non-sputum based, samples to test with rapid molecular diagnostics, to confirm the diagnosis of (rifampicin-resistant) TB, such as stool and naso-pharyngeal aspirates. Child and adolescent DR-TB notification measures a country's ability to detect drug resistance among children (0-14 years) who have TB disease.. Data on DR-TB child and adolescent notifications are also valuable for planning second line drug procurement and prioritizing supervision.Child-friendly second line drug formulations are difficult to manufacture; supply at a global level is fragile. Thus, accurate data on the number of children and adolescents notified with DR-TB is especially critical for ensuring the medications are available.
Data use	Child and adolescent DR-TB notifications can be analyzed as a trend over time to show the total number of children with TB detected within a given country. The number of child and adolescent DR-TB notifications can further be broken down by age categories to show the percent of child and adolescent with DR-TB occurring in children under five years of age and children between the ages of 5 and 14. Childhood and adolescent DR-TB notifications can be compared to the total number of DR-TB notifications within a country to see what percent of people who have DR-TB are children. Data can also be collected at the subnational level and used to learn from the geographic distribution of children with DR-TB, for example, to identify outbreaks of DR-TB. Data should be reported annually at a minimum but semiannually or quarterly reporting will improve the timeliness of data for decision-making. Example charts/graphs:

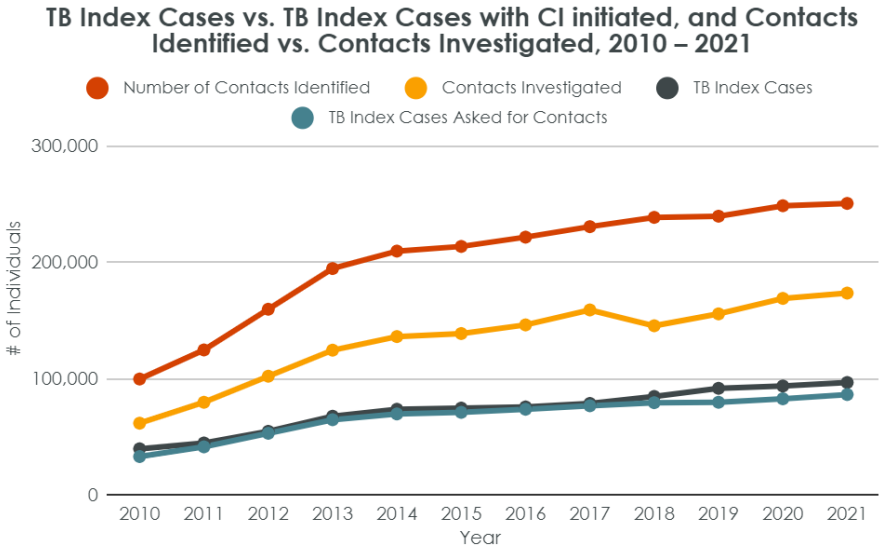


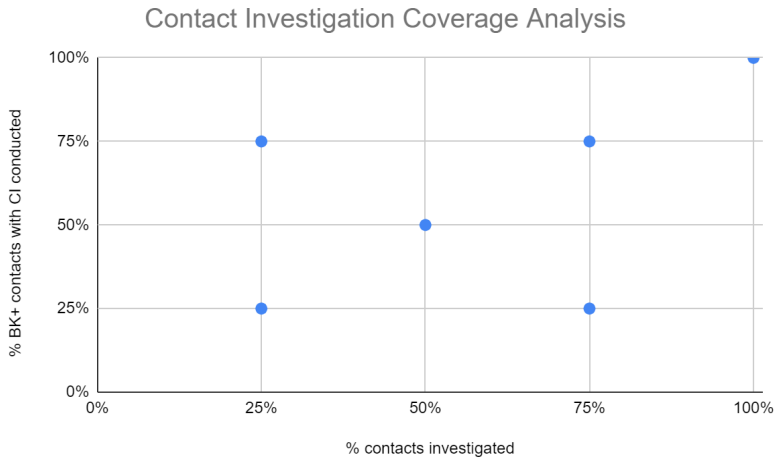


Indicator name and number	**DT_CI_INIT: Percent of people with notified TB with a contact investigation initiated** *Previously [CI-8]*
Definition	Percent of people with notified TB with a contact investigation initiated. Contact investigation initiated: The process of enumeration or listing of all known contacts to a person with notified TB (index case) and initiating an investigation to determine if those contacts have active TB disease or TB infection (TBI) through symptom screening, diagnostic testing, CXR or clinical evaluation. Index case: Person with pulmonary TB who is notified to health authorities.

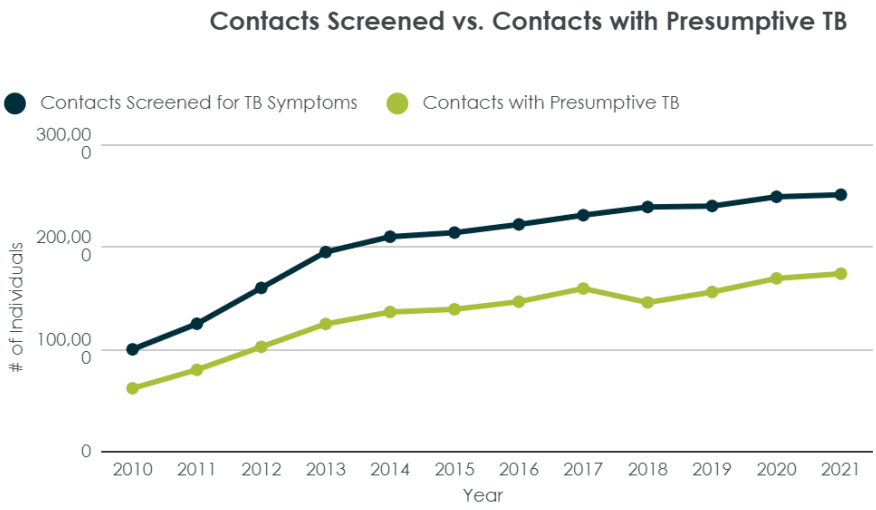
Numerator	Number of people with notified pulmonary TB with a contact investigation initiated.
Denominator	Number of people with notified pulmonary TB during the reporting period.
Category	Reach/Prevent
Indicator type	Outcome
Level	National
Unit of measure	Percent of people with TB
Data type	Percentage
Disaggregate by	Age (0-4, 5-14, 15+), sex
Reporting level	National level indicators should be reported at the national level; data may also be reported subnationally or at the project level if national data is not available.
Reporting frequency	This indicator should be reported on an annual basis at minimum. More frequent monitoring on a quarterly, monthly, or weekly basis is recommended.
Data source(s)	Data sources include the TB register, contact investigation register, laboratory testing register and electronic management information systems available at health facility and district level.
Importance	Contact investigation (CI) will reduce TB transmission in the community through early identification and treatment of people with active TB disease and identification and initiation of TPT for people with TB infection. A WHO guideline review found an effective CI yield of 3.4% (95% CI: 2.9,3.8) among contacts to bacteriologically confirmed (bac+) index cases, 3.9% (95% CI: 2.5, 5.4) among contacts <5 years old, 3.7% (95% CI: 2.4, 5.3) among MDR/XDR contacts, and 11.6% (95% CI: 8.2,15.4) among contacts who were also HIV infected. [2022 WHO consolidated guidelines on tuberculosis. Module 2: screening – systematic screening for tuberculosis disease. pg. 17]. This indicator provides data to identify gaps in the first step of CI service delivery.
Data use	The percent of people with TB with CI initiated (the number of people with notified TB who had a CI initiated divided by the total number of people with notified TB) provides a measure of how thoroughly programs are conducting CI activities. When analyzed over time, it can identify gaps and opportunities to find unrecognized people with TB. This is the first step in the CI cascade. Broader CI cascade analyses can be used to identify 'hot spots' for DS-TB and DR-TB in the community and trends over time to determine the number of contacts needed to screen (NNS) or the number of contacts needed to test (NNT) to find a new case. They can also provide information to understand contact-tracing performance and yield in health facilities and across subnational levels to guide implementation and planning for scale up. Example charts/graphs: ● Contact investigation cascade ● Trends over time of percent of people with notified TB who have a CI initiated comparisons ● Scatterplot comparing coverage of people with TB with CI done and CI completed for contacts identified


Contact Investigation Cascade, 2021
150,000
100,000
50,000
0
# of Individuals
TB Index Cases
Index Cases Interviewed for List of Close Contacts
Contacts Identified
Contacts Investigated


TB Index Cases vs. TB Index Cases with CI initiated, and Contacts Identified vs. Contacts Investigated, 2010 – 2021
Number of Contacts Identified
Contacts Investigated
TB Index Cases
TB Index Cases Asked for Contacts
300,000
200,000
100,000
0
# of Individuals
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
Year


Contact Investigation Coverage Analysis
100%
75%
50%
25%
0%
% BK+ contacts with CI conducted
0%
25%
50%
75%
100%
% contacts investigated

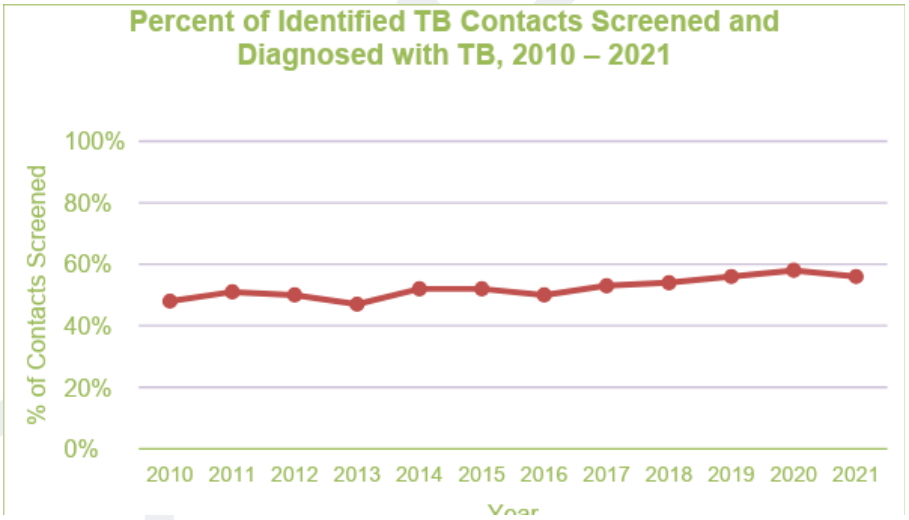
Indicator name and number	DT_CON_PRES: Number of contacts with presumed TB
Definition	Number of contacts to a person with notified pulmonary TB who have signs or symptoms of TB, as defined by the WHO four symptom screen or the NTP (i.e., have presumed TB). Presumed TB: a person who has one or more signs or symptoms of active TB disease and should be referred for diagnostic testing to diagnose or rule out active disease.
Numerator	Number of contacts
Denominator	N/A
Category	Reach
Indicator type	Outcome
Level	National
Unit of measure	Number of contacts
Data type	Integer
Disaggregate by	Age (0-4, 5-14, 15+), sex
Reporting level	National level indicators should be reported at the national level; data may also be reported subnationally or at the project level if national data is not available.
Reporting frequency	This indicator should be reported on an annual basis at minimum. More frequent monitoring on a quarterly or monthly basis is recommended.
Data source(s)	Data sources may include the TB register, contact investigation register, laboratory register and electronic management information systems available at health facility and district level.
Importance	Contact investigation (CI) will reduce TB incidence and transmission in the community through early identification and treatment of people with active TB disease and identification and initiation of TPT for people with TB infection. This indicator provides data for an important step in the CI cascade and allows users to measure the percent of contacts who are presumptive for active TB. Together with CON_TST and CON_DX, the percent of contacts with presumptive TB who receive diagnostic testing, and the percent who are diagnosed with active TB disease can be monitored over time. These trends are important measures of how well CI programs are functioning by documenting TB case finding yield of CIs.
Data use	The number of contacts with presumed TB can be used to calculate the percent of contacts with presumed TB by dividing this indicator by the number of contacts who were screened for TB (reported as the numerator in the core indicator on CI). When combined with the number of contacts diagnosed with active TB disease, this indicator can inform programs on the positive diagnostic yield of a CI program. Example charts/graphs: ● Contact investigation cascade ● Trends over time comparisons

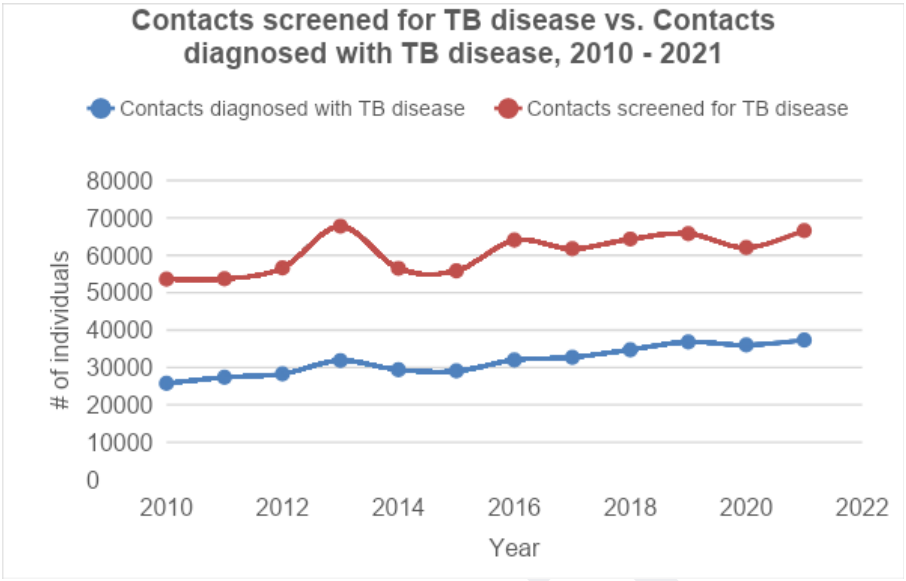


Indicator name and number	**DT_CON_TST: Number of contacts who received TB diagnostic testing** *Previously [CI-10]*
Definition	Number of contacts to a person with notified pulmonary TB with signs or symptoms of TB (ex. presumed TB) who received diagnostic testing for TB. Diagnostic testing includes smear, culture or a World Health Organization recommended rapid diagnostics test (WRD) such as Xpert MTB/RIF™, Truenat™, TB-LAMP™, Abbott™, BD™, Roche™, Hain™ or LF-LAM™.
Numerator	Number of contacts to a person with notified pulmonary TB who received diagnostic testing for presumed TB.
Denominator	NA
Category	Reach
Indicator type	Outcome
Level	National
Unit of measure	Number of contacts
Data type	Integer
Disaggregate by	Age (0-4, 5-14, 15+), sex,
Reporting level	National level indicators should be reported at the national level; data may also be reported subnationally or at the project level if national data is not available.
Reporting frequency	This indicator should be reported on an annual basis at minimum. More frequent monitoring on a quarterly, monthly, or weekly basis is recommended.

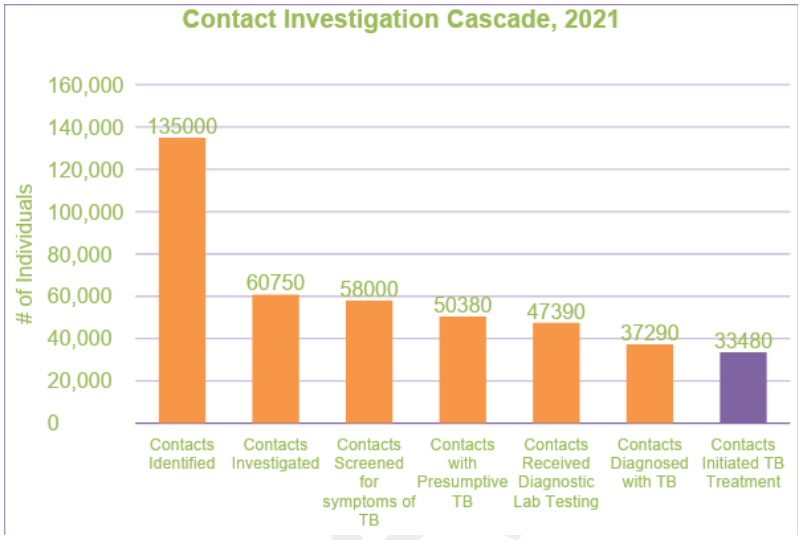
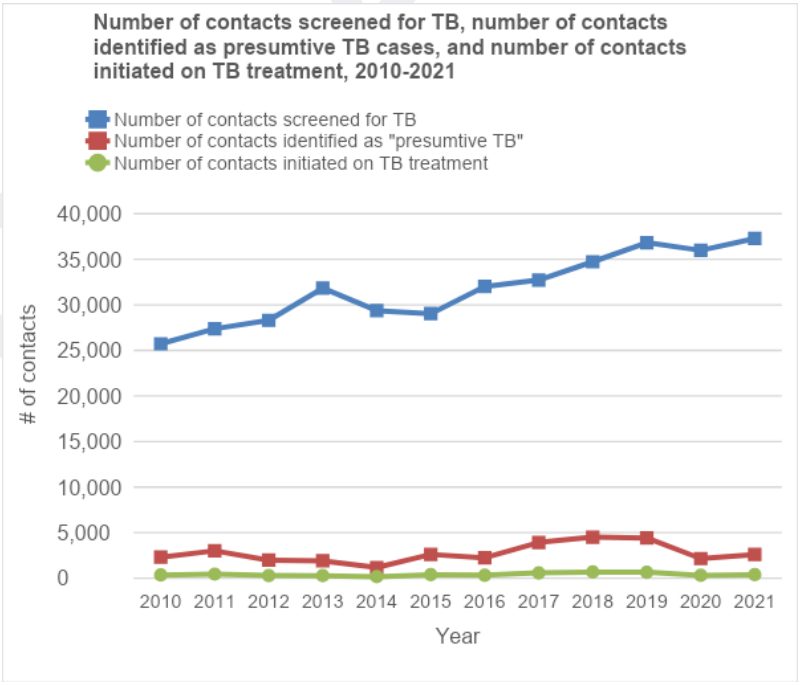
Data source(s)	Data sources may include the TB register, contact investigation register, laboratory register and electronic management information systems available at health facility and district level.
Importance	Contact investigation (CI) is important both for active case finding and TB preventive treatment (TPT). CI identifies people recently exposed to TB with a high risk of developing TB disease or TB infection and can help early detection and treatment and reduce the spread of TB in a community. This indicator along with the number of presumptive bacteriologically confirmed provides a measure of the yield of contact investigations, allowing a calculation of the numbers needed to screen (NNS) and the number needed to test (NNT) to find a person with TB.
Data use	The number of contacts with presumed TB who received diagnostic testing and who tested positive provides an important data point when analyzing the CI cascade. Example charts/graphs: ● Contact investigation cascade ● Trends over time comparisons

Indicator name and number	**DT_CON_DX: Number of contacts diagnosed with active TB disease** *Previously [CI-4]*
Definition	Percent of contacts diagnosed with TB disease (both bacteriologically and clinically confirmed) among all contacts who were screened for TB disease during the reporting period.
Numerator	Number of contacts who were diagnosed with TB disease (both bacteriologically and clinically confirmed).
Denominator	N/A
Category	Reach
Indicator type	Outcome
Level	National
Unit of measure	Percent of contacts
Data type	Percentage
Disaggregate by	Age (0-4, 5-14, 15+), sex
Reporting level	National level indicators should be reported at the national level; data may also be reported subnationally or at the project level if national data is not available.
Reporting frequency	This indicator should be reported on an annual basis at minimum. More frequent monitoring on a quarterly, monthly, or weekly basis is recommended.

Data source(s)	TB register, contact investigation register, laboratory register and electronic patient management information systems available at health facility and district level
Importance	Contact investigation (CI) is important both for active case finding and TB preventive treatment (TPT). CI identifies people recently exposed to TB with a high risk of developing TB disease or TB infection and can help early detection and treatment and reduce the spread of TB in a community. This indicator provides the yield of TB detection from all contacts evaluated for TB disease, which is an important indicator to monitor over time as different case finding approaches are used in context. Research suggests that up to 5% of all contacts of people with bacteriologically confirmed TB may be found to have TB disease, so this threshold could be used to identify major outliers and potential gaps in CI activities.
Data use	The number of contacts detected with active TB disease can be divided by the total number of contacts to provide the TB detection yield from contact investigation activities. When analyzed over time, it can provide insights on gaps in CI, for example, a sudden decrease or increase should be explored to identify any changes in CI that should be considered. It can be analyzed as a trend over time or to understand contact-tracing performance across subnational levels. Example charts/graphs: • Contact investigation cascade • Trends over time comparisons 

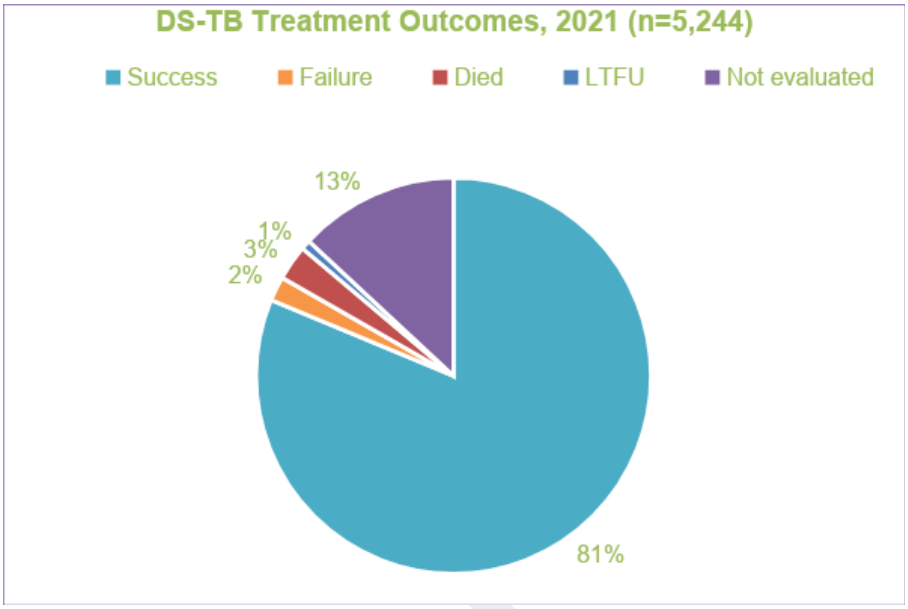
	

Indicator name and number	**DT_CON_TX: Number of contacts who initiated TB treatment** *Previously [CI-11]*
Definition	Number of contacts diagnosed with active TB disease who initiated TB treatment.
Numerator	Number of contacts who initiated TB treatment.
Denominator	NA
Category	Reach
Indicator type	Outcome
Level	National
Unit of measure	Number of contacts
Data type	Integer
Disaggregate by	Age (0-4, 5-14, 15+), sex
Reporting level	National level indicators should be reported at the national level; data may also be reported subnationally or at the project level if national data is not available.
Reporting frequency	This indicator should be reported on an annual basis at minimum. More frequent monitoring on a quarterly or monthly basis is recommended.
Data source(s)	TB register, contact investigation register, laboratory register and electronic management information systems available at health facility and district level.

Importance	Contact investigation (CI) is important both for active case finding and TB preventive treatment (TPT). CI identifies people recently exposed to TB with a high risk of developing TB disease or TB infection. This indicator provides information on how well a program's CI efforts are linking contacts who are diagnosed with TB to TB treatment. …
Data use	The number of contacts who were initiated on TB treatment provides an important data point when analyzing the CI cascade… Example charts/graphs: ● Contact investigation cascade ● Trends over time comparisons  

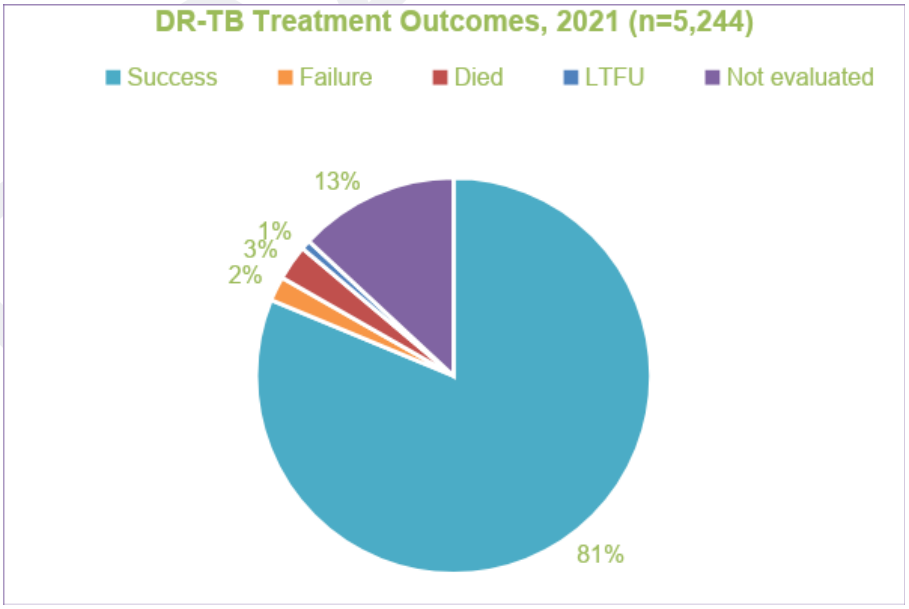
Indicator name and number	**TX_DS_OUT: DS-TB treatment outcomes** *Previously [SN-2 through SN-5]*
Definition	Number of people with DS-TB (new and relapse), all forms, with each defined DS-TB treatment outcome, among the cohort of people who were initiated DS-TB treatment during a reporting period. Cohort reporting: Treatment outcomes are defined by the time of initiation on treatment; e.g., “2018 cohort successfully treated” reflect those who were initiated on treatment in 2018, even though treatment may have extended into 2019. For this reason, reports of treatment outcome data lag by one year.
Numerator	Number of people with DS-TB (new and relapse), all forms, with each defined DS-TB treatment outcome (defined below), among the cohort of people who were initiated DS-TB treatment during a reporting period. DS-TB Treatment outcomes: Successfully treated: Cure or Completed treatment: Cure: A patient with pulmonary TB with bacteriologically confirmed TB at the beginning of treatment who completed treatment as recommended by the national policy, with evidence of bacteriological response and no evidence of failure. “Bacteriological response” refers to bacteriological conversion with no reversion: • “bacteriological conversion” describes a situation in a patient with bacteriologically confirmed TB where at least two consecutive cultures or smears taken on different occasions at least 7 days apart are negative; and • “bacteriological reversion” describes a situation where at least two consecutive cultures or smears taken on different occasions at least 7 days apart are positive either after the bacteriological conversion or in patients without bacteriological confirmation of TB. Completed treatment: A patient who completed treatment as recommended by the national policy but whose outcome does not meet the definition for cure or treatment failure. LTFU: A patient who did not start treatment or whose treatment was interrupted for 2 consecutive months or more. Treatment failed: A patient whose treatment regimen needed to be terminated or permanently changed to a new regimen or treatment strategy. Reasons for the change include: • no clinical response or no bacteriological response, or both (see note ‘b’); • adverse drug reaction; or • evidence of additional drug-resistance to medicines in the regimen Died: A patient who died for any reason before starting treatment or during the course of treatment. Not Evaluated: A patient for whom no treatment outcome was assigned. This includes cases “transferred out” to another treatment unit and whose treatment outcome is unknown; however, it excludes those lost to follow-up. (WHO revised treatment definitions for both DS and DR-TB (Ch.10): https://www.who.int/publications/i/item/9789240065116)
Denominator	N/A (cohort size reported under core DR-TB TSR indicator)
Category	Cure
Indicator type	Outcome

Level	National
Unit of measure	Number of people
Data type	Integer
Disaggregate by	Age (<15, 15+), sex, HIV status, treatment outcome (defined above)
Reporting level	National level indicators should be reported at the national level; data may also be reported subnationally or at the project level if national data is not available.
Reporting frequency	This indicator should be reported on an annual basis at minimum. More frequent monitoring on a quarterly or monthly basis is recommended.
Data source(s)	The data sources are the TB register or electronic management information systems available at health facility and district level. Quarterly cohort analysis reports may also be used if these analyses are being conducted. The following WHO indicators can be used to report this indicator: *Successfully treated: newrel_succ* *LTFU: newrel_lost* *Treatment failed: newrel_fail* *Died: newrel_died* *Not Evaluated: newrel_neval*
Importance	Systematic analysis of treatment outcomes for people initiated on DS-TB treatment is an important activity to track the quality of TB services and measures the NTP's ability to ensure successful completion of TB treatment. Monitoring various treatment outcomes reported under this indicator is useful in understanding reasons for suboptimal treatment success, which is a key outcome in the USAID TB strategy. As a WHO standard indicator, the percent of people with DS-TB who died during treatment allows countries to monitor their progress in reducing the number of deaths due to TB among those who are diagnosed and initiating treatment. High death rates in a treatment cohort may be indicative of long delays in diagnosis and treatment regimens, problems with selected treatment regimens, or lack of support for those on TB treatment.
Data use	Cohort analysis of treatment outcomes is a major management tool for monitoring the effectiveness of the national TB program. The treatment success rate (a core indicator) is a useful way to monitor success of treatment. The treatment success rate is a subset of data from this indicator. The data reported for each treatment outcome in this indicator should be compared to the cohort size which is reported with the core indicator for TSR; to determine the percent of people with each outcome, divide the number of people with the outcome by the number of people in the treatment cohort (*newrel_coh*). The percent LTFU can also be a useful metric for analysis. Ideally, there should be no LTFU during treatment, and a high rate of LTFU (5% or above) may warrant further investigation. The percent of people who died during TB treatment can also be analyzed as a trend showing whether the rate of death is increasing or decreasing over time. Monitoring this indicator is important as countries strive to reach zero deaths due to TB but it can also prompt NTPs to implement additional or better-targeted treatment support services with the aim of improving DS-TB treatment outcomes. This indicator should also be considered in the context of HIV prevalence or other co-infections, since a high percent of HIV-associated TB (or other comorbidities) will result in a greater number of deaths. Death rates above 5% may warrant a formal

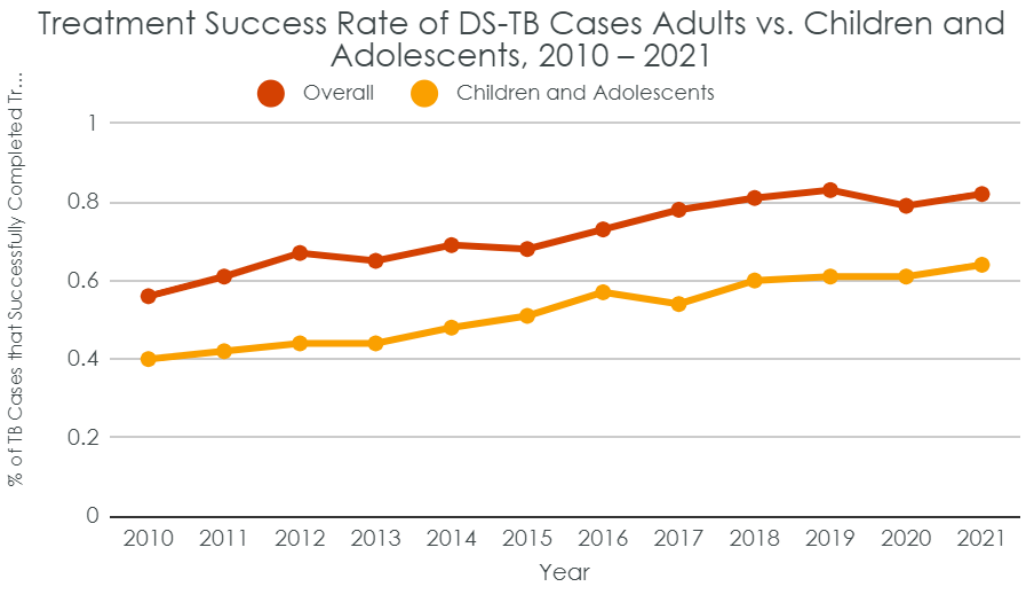
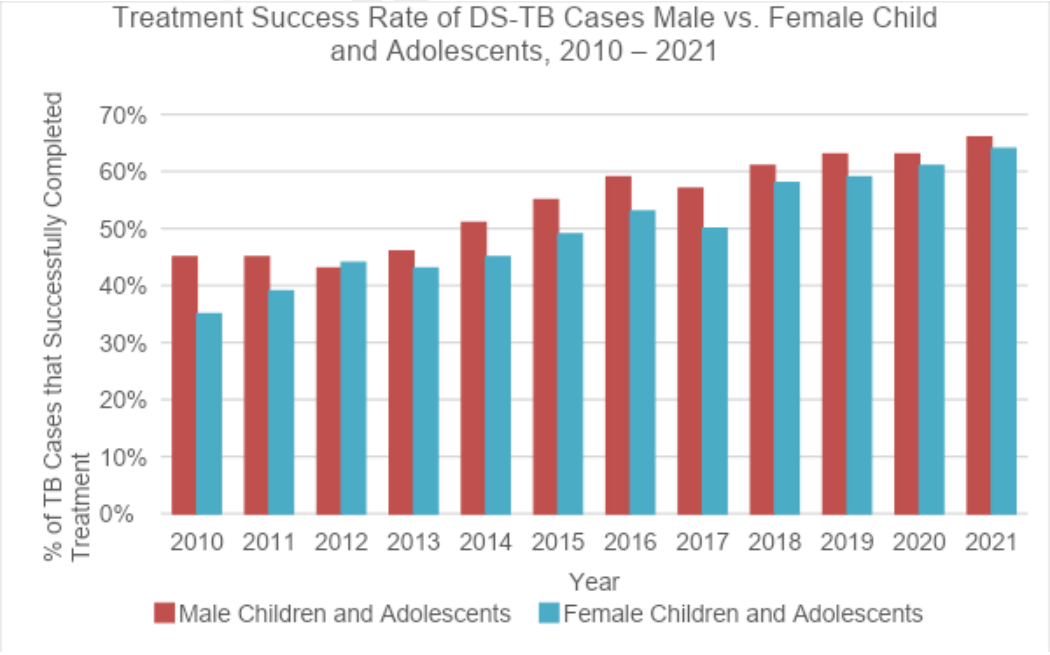
	analysis of deaths that occur while on treatment, to ensure those on DS-TB treatment do not have DR-TB. Example charts/graphs: ● TB outcome pie chart Trend over time comparisons ● TB treatment cascade 

Indicator name and number	**TX_DR_OUT: DR-TB treatment outcomes** *Previously [RS-2 through RS-5]*
Definition	Number of people with DR-TB with each of the defined DR-TB treatment outcomes, among the cohort of people who were initiated on DR-TB treatment during a defined reporting period. Cohort reporting: Treatment outcomes are defined by the time of initiation on treatment; e.g., "2018 cohort successfully treated" reflect those who were initiated on treatment in 2018, even though treatment may have extended into 2019 or 2020. For this reason, reports of DR-TB treatment outcome data lag by one-two years.
Numerator	Number of people with DR-TB with each of the treatment outcomes (defined below), among the cohort of people who were initiated on DR-TB treatment during a defined reporting period. DR-TB Treatment outcomes: Successfully treated: Cure or Completed treatment: Cure: A patient with pulmonary TB with bacteriologically confirmed TB at the beginning of treatment who completed treatment as recommended by the national policy, with evidence of bacteriological response and no evidence of failure. "Bacteriological response" refers to bacteriological conversion with no reversion: • "bacteriological conversion" describes a situation in a patient with bacteriologically confirmed TB where at least two consecutive cultures taken on different occasions at least 7 days apart are negative; and

	• "bacteriological reversion" describes a situation where at least two consecutive cultures taken on different occasions at least 7 days apart are positive either after the bacteriological conversion or in patients without bacteriological confirmation of TB. Completed treatment: A patient who completed treatment as recommended by the national policy but whose outcome does not meet the definition for cure or treatment failure. LTFU: A patient who did not start treatment or whose treatment was interrupted for 2 consecutive months or more. Treatment failed: A patient whose treatment regimen needed to be terminated or permanently changed to a new regimen or treatment strategy. Reasons for the change include: • no clinical response or no bacteriological response, or both (see note 'b'); • adverse drug reaction; or • evidence of additional drug-resistance to medicines in the regimen Died: A patient who died for any reason before starting treatment or during the course of treatment. Not Evaluated: A patient for whom no treatment outcome was assigned. This includes cases "transferred out" to another treatment unit and whose treatment outcome is unknown; however, it excludes those lost to follow-up. (WHO revised treatment definitions for both DS and DR-TB (Ch.10): https://www.who.int/publications/i/item/9789240065116)
Denominator	N/A (cohort size reported under core TSR indicator)
Indicator type	Outcome
Category	Cure
Level	National
Unit of measure	Number of people
Data type	Integer
Disaggregate by	Age (<15, 15+), sex, HIV status, treatment outcome (defined above)
Reporting level	National level indicators should be reported at the national level; data may also be reported subnationally or at the project level if national data is not available.
Reporting frequency	This indicator should be reported on an annual basis at minimum. More frequent monitoring on a quarterly or monthly basis is recommended.
Data source(s)	The data sources are basic management unit DR-TB register or electronic management information systems available at health facility and district level. Quarterly DR-TB cohort analysis reports may also be used if these analyses are being conducted. The following WHO indicators can be used to report this indicator: *Successfully treated: mdr_succ + xdr_succ* *LTFU: mdr_def + xdr_def* *Treatment failed: mdr_fail + xdr_fail* *Died: mdr_died + xdr_died* *Not Evaluated: c_mdr_neval + c_xdr_neval*
Importance	Systematic analysis of treatment outcomes for people initiated on DR-TB treatment is an important activity to track the quality of TB services and measures the NTP's ability or inability to support people to successfully complete DR-TB treatment.

	Monitoring various treatment outcomes reported under this indicator is useful in understanding reasons for suboptimal treatment success, which is a key outcome in the USAID TB strategy. High death rates may be indicative of people who were not identified with DR-TB early enough, problems with treatment regimens, or poor treatment management. High treatment failure rates can be indicative of problems with choice of second-line treatment regimen, drug quality, poor clinical management of DR-TB and/or a lack of treatment adherence support services. High LTFU can be indicative of poor treatment management and/or a lack of treatment support services; high numbers of people not evaluated can also be indicative of poor patient management or poor documentation practices.
Data use	Cohort analysis of treatment outcomes is a major management tool for monitoring the effectiveness of the national TB program. The data reported for each treatment outcome in this indicator should be compared to the cohort size which is reported with the core indicator for DR-TB TSR; to determine the percent of people with each outcome, divide the number of people with the outcome by the number of people in the cohort (*mdr_coh + xdr_coh*). The percent of people who experienced each DR-TB treatment outcome can be analyzed as a trend to show improvements in treatment outcomes over time. Monitoring this indicator is important as countries strive to reach zero deaths due to TB, but it can also prompt NTPs to implement additional or better-targeted treatment support services for people with DR-TB, with the aim of improving treatment outcomes. Example charts/graphs: ● DR-TB outcome pie chart ● Trend over time comparisons ● DR-TB treatment cascade 

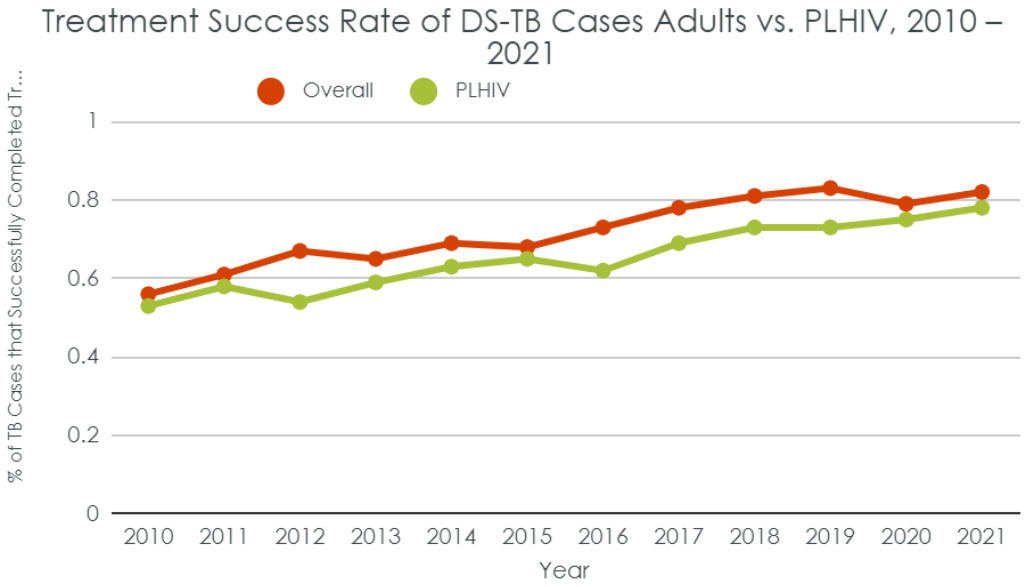
Indicator name and number	**PEDS_TSR: Treatment success rate in children and adolescents (0–14 years)**
Definition	Percent of people with new and relapse TB (bacteriologically confirmed or clinically diagnosed, pulmonary or extrapulmonary) among children and adolescents aged 0–14 years who were notified in a specified period that were cured or completed treatment for DS-TB, among the total number of people with new and relapse TB (bacteriologically confirmed or clinically diagnosed, pulmonary or extrapulmonary) among children and adolescents aged 0–14 who were initiated on treatment for DS-TB during the same reporting period (excluding those moved to RR-TB treatment cohort). Treatment outcomes are defined by the time of initiation on treatment; e.g., "2018 cohort successfully treated" reflect those who were initiated on treatment in 2018, even though treatment may have extended into 2019. For this reason, reports of treatment outcome data lag by one year. This indicator is a subset of the data reported in the core indicator "Treatment success rate".
Numerator	Number of children and adolescents (0-14) with new and relapse TB (bacteriologically confirmed or clinically diagnosed, pulmonary or extrapulmonary), who were registered in a specified period that were cured or completed treatment.
Denominator	Number of children and adolescents (0-14) with new and relapse TB (bacteriologically confirmed or clinically diagnosed, pulmonary or extrapulmonary) who initiated treatment in the same period.
Category	CURE
Indicator type	Core outcome
Level	Core
Unit of measure	Percent of children
Data type	Percentage
Disaggregate by	Sex
Reporting level	National level indicators should be reported at the national level; data may also be reported subnationally or at the project level if national data is not available.
Reporting frequency	This indicator should be reported on an annual basis at minimum. More frequent monitoring on a quarterly or monthly basis is recommended.
Data sources	This indicator is reported by national TB program (NTP) official records. *Quarterly report on TB treatment outcomes in the basic management unit* and *Form 07: Combined annual outcomes report for basic TB and for RR-/multidrug-resistant (MDR)-TB.*
Importance	Treatment success rate among children and adolescents aged 0–14 years is an important indicator of the quality of TB services, as it measures the NTP's capacity to support young patients through a complete course of treatment with a favorable outcome. Successful treatment requires a stable supply of appropriate, child-friendly TB medications, management of side effects and various efforts to support children with TB and their caregivers so they can complete the full course of treatment. This indicator measures the successful treatment of a cohort of people with TB, which is essential to reducing morbidity and mortality due to TB and to prevent the further spread of the infection. The treatment success rate allows countries to monitor progress towards meeting global and national targets and to determine whether more resources are required to improve treatment outcomes by reducing death, loss to follow-up (LTFU), and the percent of people with an outcome that is not evaluated. Detecting and successfully treating a large percent of people with TB should have an immediate impact on TB prevalence and mortality. Low treatment success rates may indicate inappropriate treatment regimens being administered, poor treatment management, adverse side effects, or comorbidities leading to death or LTFU. An understanding of why treatment success may be low is important to be able to implement solutions for improving patient care.

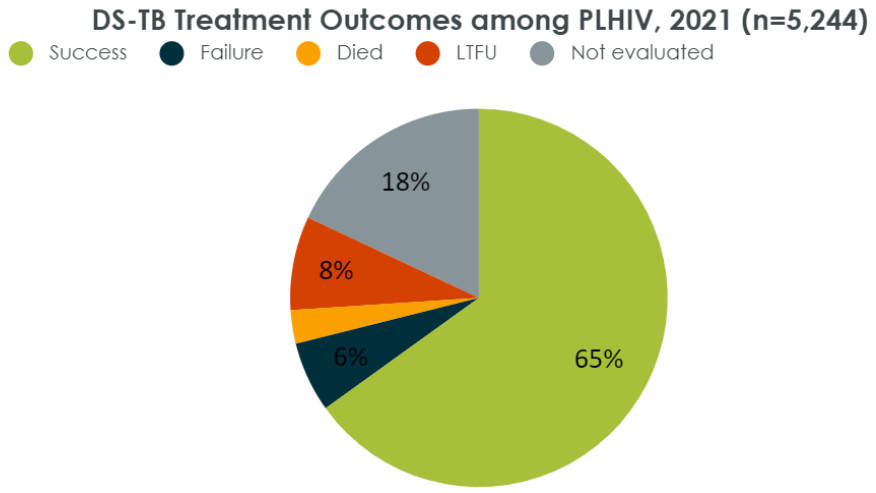
Data use and visualization	TB treatment success rate in children and adolescents can be analyzed as a trend showing whether treatment success is stable, improving or decreasing over time, and to compare the rate to national and global treatment success rate targets. A comparison of children with TB initiated on treatment and successfully completing treatment using a cascade of care will highlight the gap in the cascade where some people were lost during the treatment phase. The gap between treatment initiation and treatment success can be further broken down to understand why pediatric patients had unfavorable treatment outcomes (e.g., death, LTFU, treatment failure, or unknown outcomes). Below are examples one can use when presenting this indicator.  

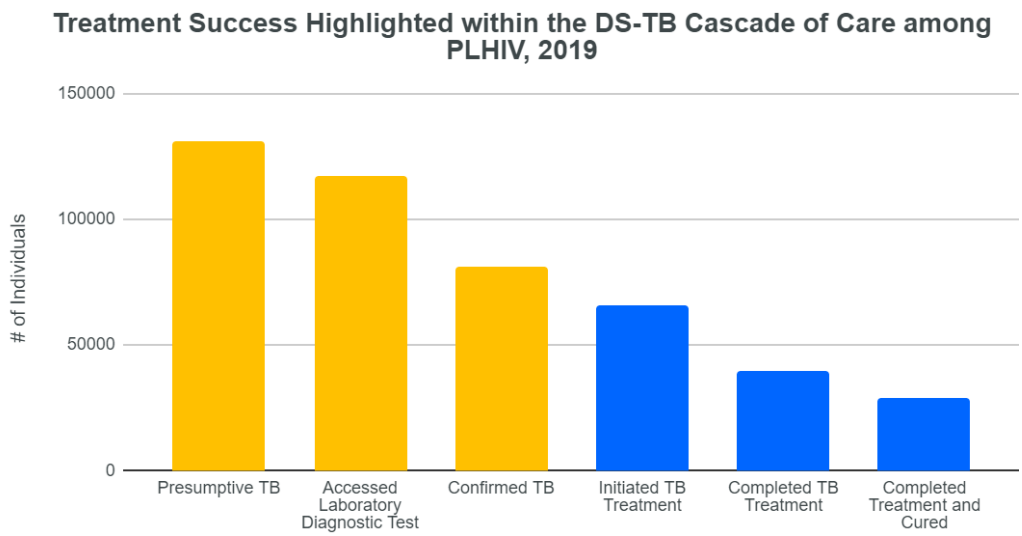
Indicator name and number	PLHIV_TSR: Treatment Success Rate among PLHIV
Definition	Percent of PLHIV with new and relapse TB among PLHIV (bacteriologically confirmed or clinically diagnosed, pulmonary or extrapulmonary) who were notified in a specified period that were cured or treatment completed, among the total number of people with new and relapse TB (bacteriologically confirmed or clinically diagnosed, pulmonary or extrapulmonary) who were initiated on treatment during the same reporting period (excluding those moved to RR-TB treatment cohort). Treatment outcomes are defined by the time of initiation on treatment; e.g., "2018 cases successfully treated" reflect those who were initiated on treatment in 2018, even though treatment may have extended into 2019. For this reason, reports of treatment outcome data lag by one year. Calculation: (Numerator/Denominator) x 100
Numerator	Number of PLHIV with new and relapse TB (bacteriologically confirmed or clinically diagnosed, pulmonary or extrapulmonary), who were registered in a specified period that were cured or treatment completed.
Denominator	Number of PLHIV with new and relapse TB (bacteriologically confirmed or clinically diagnosed, pulmonary or extrapulmonary) who initiated treatment in the same period.
Category	CURE
Indicator type	Core outcome
Level	Core
Unit of measure	Percent of PLHIV
Data type	Percentage
Disaggregate by	Age (<15, 15+), sex
Reporting level	National level indicators should be reported at the national level; data may also be reported subnationally or at the project level if national data is not available.
Reporting frequency	This indicator should be reported on an annual basis at minimum. More frequent monitoring on a quarterly or monthly basis is recommended.
Data sources	This indicator is reported by national TB program (NTP) official records. *Quarterly report on TB treatment outcomes in the basic management unit* and *Form 07: Combined annual outcomes report for basic TB and for RR-/multidrug-resistant (MDR)-TB.*
Importance	Treatment success is an important indicator of the quality of TB services, as it measures the NTP's capacity to support patients through a complete course of treatment with a favorable outcome. Successful treatment requires a stable supply of TB medications, management of side effects and various efforts to support people with TB so they can complete the full course of treatment. This indicator measures the successful treatment of a cohort of people with TB, which is essential to prevent the spread of the infection. The treatment success rate allows countries to monitor progress towards meeting global and national targets and to determine whether more resources are required to improve treatment outcomes by reducing death, loss to follow-up (LTFU), and the percent of people with an outcome that is not evaluated. Detecting and successfully treating a large percent of people with TB should have an immediate impact on TB prevalence and mortality. Low treatment success rates may indicate problems with the treatment regimens being administered, poor treatment management, adverse side effects, or comorbidities leading to death or LTFU. An understanding of why treatment success may be low is important to be able to implement solutions for improving patient care.
Data use and visualization	TB treatment success rate can be analyzed as a trend showing whether treatment success is stable, improving or decreasing over time, and to compare the rate to national and global treatment success rate targets. A comparison of people with TB who initiated treatment and successfully completed treatment using a cascade of care will highlight the gap in the cascade where some people were lost during the treatment phase. The gap between treatment initiation and treatment success can be further broken down to understand why people were unsuccessful with treatment (e.g., death, LTFU, treatment failure, or unknown outcomes). Treatment success

rates can also be compared between DS and drug-resistant TB (DR-TB) and TB/HIV. but differences in treatment outcomes among these cohorts should be interpreted with caution; differences in TB epidemiology at national level, resistance profile, HIV program context and other factors should be considered.

Below are examples one can use when presenting this indicator.







Indicator name and number	TX_DS_ENROLL: DS-TB Treatment Initiations
Definition	Number of people with laboratory-confirmed or clinically diagnosed DS-TB who initiated treatment for DS-TB during the reporting period.
Numerator	Number of people with laboratory-confirmed or clinically diagnosed DS-TB who initiated treatment for DS-TB during the reporting period.
Denominator	NA
Category	Reach/Cure
Indicator type	Outcome
Level	National
Unit of measure	Number of people
Data type	Integer
Disaggregate by	Age (<15, 15+), sex, HIV status, public or private
Reporting level	National level indicators should be reported at the national level; data may also be reported subnationally or at the project level if national data is not available.
Reporting frequency	This indicator should be reported on an annual basis at minimum. More frequent monitoring on a quarterly or monthly basis is recommended.
Data source(s)	The data sources are basic management unit TB register and electronic management information systems available at health facility and district level.

Importance	This indicator measures a TB program's ability to ensure people diagnosed with TB are initiated on TB treatment. This is a very important measure of the effectiveness of the NTP in terms of improving access to TB treatment. This indicator is also critical in monitoring progress towards the USAID TB Strategy goal of "90% of people with TB diagnosed and initiated on treatment". The indicator should be analyzed alongside the number of TB notifications to measure the gap between the number of people diagnosed with DS-TB and the subset of those diagnosed who are initiated on TB treatment, with the goal that all who are diagnosed are linked to treatment. The data are also valuable for planning first line drug procurement and prioritizing supervision. The indicator provides data for a critical step in cascade analysis for DS-TB case detection.
Data use	This indicator can be used to track performance of the NTP in linking people who are diagnosed with TB to treatment. It is important for guiding programmatic decisions on scale up of treatment services for management of DS-TB. It can be presented and visualized using tables, charts, line graphs, etc. This indicator can be compared to the number of TB notifications in the same year to assess what percent were initiated on treatment. It can also be compared to the DS-TB treatment cohort size (on a year lag, when cohort data is available), which is the denominator for all the DS-TB treatment outcomes (i.e. treatment success, lost-to follow-up, etc.). The gap between the number of people initiated on DS-TB treatment and the subsequent cohort size reported can also be visualized and sizable gaps should be interrogated to determine reasons for discrepancies.

Indicator name and number	**TPT_CON_04: Number of TPT initiations among contacts <5** *Previously [PT-7]*
Definition	Number of household contacts under 5 years old of bacteriologically confirmed pulmonary new and relapse TB cases notified in the reporting period who were started on TPT.
Numerator	Number of household contacts under 5 years old of bacteriologically confirmed pulmonary new and relapse TB cases notified in the reporting period who were started on TPT.
Denominator	N/A
Category	Prevent
Indicator type	Outcome
Level	Project
Unit of measure	Percent of contacts <5 years
Data type	Percentage
Disaggregate by	Sex
Reporting level	National and sub-national

Reporting frequency	Annually, quarterly, monthly
Data source(s)	The data sources for this indicator may vary country to country. In some settings, data will be found in basic management unit TB registers, TPT register, community health worker contact investigation registers or electronic management systems at health facility and district level. The numerator of this indicator is can me calculated using the WHO Global TB Programme Database variable: newinc_con04_prevtx
Importance	Analysis of TPT coverage for priority populations is important for national TB programs to monitor and manage TB prevention efforts. This indicator is a disaggregation of the core indicator, TPT Coverage (PT-4) that includes children under the age of five years old. Children under five years of age are at high risk of becoming infected with TB and progressing from infection to disease upon exposure to a bacteriologically confirmed household contact. This indicator provides information on how well the NTP is reaching this priority population.
Data use and visualization	Ongoing monitoring of the percentage of children under five years of age who are household contacts of TB cases and initiate TPT provides key information on the coverage and successful implementation of TPT services. This indicator can be visualized with basic graphs to show trends in TPT coverage for household contacts under five years of age over time. This data can also be plotted alongside TPT coverage for household contacts between the ages of five and fourteen years as well as TPT coverage for adult household contacts. Example charts/graphs: ● Graph of TPT coverage among household contacts under 5 ● Graph of TPT coverage among HH contacts for: Children under 5, children 5-14 and adults

Indicator name and number	**TPT_PLHIV_ENROLL: Number of TPT initiations among PLHIV** *Previously [PT-8]*
Definition	Number of PLHIV who were started on TPT during the reporting period
Numerator	Number of PLHIV who were started on TPT during the reporting period
Denominator	N/A
Category	Prevent
Indicator type	Outcome
PBMEF level	Project level
Unit of measure	Number of individuals
Data type	Integer
Disaggregate by	Age (0-4, 5-14, 15+), sex

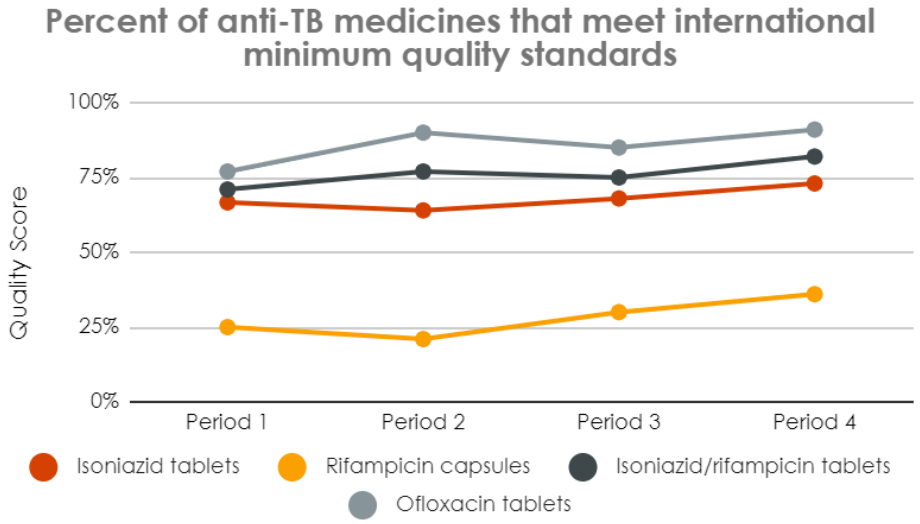
Reporting level	Project level indicators are expected to be reported at the subnational level for subnational units where the implementing partner is operating. National data may also be reported if available.
Reporting frequency	This indicator should be reported on an annual basis at a minimum. More frequent monitoring on a quarterly or monthly basis is recommended.
Data source(s)	The data sources for this indicator may vary country to country. In some settings, data will be found in basic management unit TB or HIV registers, TPT register, or electronic management systems at health facility and district level. Additionally this indicator can be calculated from two standard WHO indicator by using the WHO Global TB Programme Database variables: WHO database: *hiv_ipt_reg_all* and *hiv_reg_all*
Importance	Understanding the specifics of TPT coverage within a given country / region is key for national TB programs to monitor and manage TB prevention efforts. This indicator is a drilled down view into the core indicator, TPT Coverage (PT-4). Because PLHIV are at such a high risk of developing TB infection, it is essential that they have access to TPT. Thus, beyond overall TPT coverage, this indicator functions to specifically look at the TPT coverage among PLHIV. This is particularly important for a country's ability to assess the success of their TPT implementation strategies, particularly among PLHIV.
Data use and visualization	This indicator can be used to track the progress of efforts to increase and/or maintain TPT coverage among PLHIV. This indicator can be visualized using basic graphs to show trends in TPT coverage among PLHIV over time that can be presented for a particular region or country or alongside multiple regions and countries for comparison. It can also be plotted with TPT coverage among household contacts under the age of five years compared to adolescent and adult household contacts to show the trend for these three important populations over time. Example charts/graphs: ● TPT coverage among PLHIV over time for country X (maybe plot against global coverage TPT among PLHIV coverage) ● TPT coverage among PLHIV, Adult contacts, and child contacts over time

Indicator name and number	**SN_CQI: CQI programs in place**
Definition	Existence of a continuous quality improvement (CQI) platform(s) at all levels of the health system for 1) TB clinical care, 2) TB laboratory, 3) TB commodities, and 4) other whereby TB service delivery and relevant data and indicators are systematically monitored, their quality assessed and decisions are made to address any operational problems or challenges identified.
Numerator	Existence of a continuous quality improvement (CQI) platform(s) at all levels of the health system for the following : -TB clinical care CQI program? Yes/No -TB laboratory CQI program? Yes/No -TB commodities CQI program? Yes/No -Other CQI? Yes/No (if yes, please describe) CQI programs may take multiple forms; one example may be regular or systematic data review and monitoring meetings that NTPs conduct at district, provincial, and national levels where problems, gaps, bottlenecks, delays, etc. that impact patient care are assessed. Impacts on patient care could include impacts on case detection, treatment outcomes, TPT

	completion, etc., thereby encompassing multiple steps in the TB care and prevention cascade.
Denominator	NA
Category	Sustain
Indicator type	Outcome
Level	National
Unit of measure	Yes/no
Data type	Boolean
Disaggregate by	N/A
Reporting level	National level indicators should be reported at the national level; data may also be reported subnationally or at the project level if national data is not available.
Reporting frequency	This indicator should be reported on an annual basis at minimum. More frequent monitoring on a quarterly or monthly basis is recommended.
Data source(s)	Documented quality improvement processes and tools geared to increase and maintain quality implementation and performance (i.e.. Reports of Laboratory QMS, procurement and supply chain QMS, pharmacy QMS, program audits).
Importance	"CQI is a progressive incremental improvement of processes, safety, and patient care. The goal of CQI may include improvement of operations, outcomes, systems processes, improved work environment, or regulatory compliance." "CQI project development commonly includes defining the problem, benchmarking, setting a goal, then iterative quality improvement projects."[1] It is a means to determine & track program integrity and effectiveness. It is important because it guides quality operations; ensures safe environments and high quality of services; supports in meeting standards and regulations; and assists institutional programs and services to meet annual goals, objectives, and targets. [1]O'Donnell B, Gupta V. Continuous Quality Improvement. [Updated 2023 Apr 3]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK559239/
Data use	To pinpoint and address the gaps, analytical tools like run charts, fish-bone diagrams, and flow charts may be helpful. CQI processes are proactive and methods are able to identify and remediate latent or future program challenges and requirements. CQI programs should use performance data to inform an iterative and incremental transition towards an optimally performing system by building on successes and improving sub-optimal activities and outputs.

Indicator name and number	**SN_MQS: TB drugs meeting international minimum quality standards**
Definition	Percent of anti-TB medicines procured locally or internationally which meet international minimum quality standards within a country. Calculation: (Numerator/Denominator) x 100 "International minimum quality standards" are defined and documented in the batch certificate. Standards and the reference organizations considered to be acceptable

	include WHO Prequalification of Medicines Programme (PQP)/ stringent regulatory authorities (SRAs)/ Expert Review Panel (ERP).
Numerator	Number of batches of anti-TB medicines procured locally or internationally for which a batch certificate showed acceptable results during the reporting period
Denominator	Number of batches received of anti-TB medicines (procured during the reporting period)
Category	Sustain
Indicator type	Outcome
Level	National
Unit of measure	Percent of anti-TB medicines
Data type	Percentage
Disaggregate by	N/A
Reporting level	National level indicators should be reported at the national level; data may also be reported subnationally or at the project level if national data are not available.
Reporting frequency	This indicator should be reported on an annual basis at minimum. More frequent monitoring on a quarterly or monthly basis is recommended.
Data source(s)	Data for this indicator can be obtained from public and private sector procurement agents.
Importance	In accordance with Good Manufacturing Practices (GMP), a manufacturer should produce a batch certificate for each batch of its product. The batch certificate documents the results of quality analysis and inspection for each batch of the product. The agency that procures the medicine should request and review the batch certificate to ensure the data are acceptable. “Acceptable” data would demonstrate the batch is of adequate quality to be used in the TB program. In order to prevent emergence of DR-TB and to sustain the treatment successes achieved to date by using quality assured medicines, we must ensure countries procuring TB medicines with domestic funding should procure drugs according to these 'International minimum quality standards'.
Data use	The percentage of anti-TB medicines that meet international minimum quality standards can be analyzed as a trend over time either on its own or against country targets. Procurement agents should be sensitized to the importance of obtaining and reviewing this documentation as basic evidence of the quality of medicine that they procure. Receipt of this documentation can be specified as a requirement in procurement contracts to help ensure the quality of medicines on the market. Example charts/graphs: ● Trend over time comparisons



	Isoniazid tablets	Rifampicin capsules	Isoniazid/rifampicin tablets	Ofloxacin tablets
Period 1				
Total # of batches	45	40	42	39
# meeting adequate quality	30	10	30	30
Period 1 Quality Score	67%	25%	71%	77%
Period 2				
Total # of batches	50	38	48	39
# meeting adequate quality	32	8	37	35
Period 2 Quality Score	64%	21%	77%	90%