Aggregate Reports for Tuberculosis Program Evaluation

Attachment 3b

Targeted Testing and Treatment for Latent Tuberculosis Infection —

Form and Instructions

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Aggregate Reports for Tuberculosis Program Evaluation — Targeted Testing and Treatment for Latent Tuberculosis Infection

**Fields are optional*

Program Area: _____

Cohort Year: _____

Date Report Updated: Click to enter a date.

Part I. Testing Counts

Number of persons	Testing formats: Targeted testing project	*Targeted testing individual	*Administrative
Sought, enlisted, or registered			
*US-born			
*Non-US–born			
Evaluated			
*By TST			
*By IGRA			
TB disease			
Latent TB infection			

	Medical risk	Population risk	*Medical risk	*Population risk	
Latent TB infection					
Candidates for treatment					
Started treatment					
*3HP					
*RIF (4 months)					
*3HR					
*INH (6 months)					
*INH (9 months)					
Other					
Unknown					
Completed treatment					
*3HP					
*RIF (4 months)					
*3HR					
*INH (6 months)					
*INH (9 months)					
Other					
Unknown					

Public reporting burden of this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329; Attn: OMB-PRA (0920-0457).

Reason Treatment Not Completed

Active TB developed			
Adverse effect of medicine			
Death			
Patient chose to stop			
Patient is lost to follow-up			
Patient moved (follow-up unknown)			
Provider decision			

Part II. Evaluation Indices (auto-calculated)

Evaluation rate	N/A		N/A			N/A	
Disease rate	N/A		N/A			N/A	
Latent TB infection rate	N/A		N/A			N/A	
	Medical risk	**Population risk**	**Medical risk**	**Population risk**		N/A	
Candidate rate	N/A	N/A	N/A	N/A		N/A	
Treatment rate	N/A	N/A	N/A	N/A		N/A	
Completion rate	N/A	N/A	N/A	N/A		N/A	

Part III. Referral Counts

Referred, TB infection	* Medical risk	*Population risk	*Administrative
Referred			
US-born			
Non-US–born			
Evaluated			
By TST			
By IGRA			
TB disease			
Latent TB infection			
Candidates for treatment			
Started treatment			
*3HP			
*RIF (4 months)			
*3HR			
*INH (6 months)			
*INH (9 months)			
Other			
Unknown			
Completed treatment			
*3HP			
*RIF (4 months)			
*3HR			
*INH (6 months)			
*INH (9 months)			
Other			

Unknown			
Reason treatment not completed			
Active TB developed			
Adverse effect of medicine			
Death			
Patient chose to stop			
Patient is lost to follow-up			
Patient moved (follow-up unknown)			
Provider decision			

Part IV. Evaluation Indices (auto-calculated)

Evaluation rate	N/A	N/A	N/A
Disease rate	N/A	N/A	N/A
Latent TB infection rate	N/A	N/A	N/A
Candidate rate	N/A	N/A	N/A
Treatment rate	N/A	N/A	N/A
Completion rate	N/A	N/A	N/A

Note: The instructions for this report are not a substitute for guidelines about TB diagnosis, treatment, or control. Any contradictions between the content of these instructions and the health department's policies and practices should be discussed, according to the context, with a consultant from the local or state TB control program or CDC.

The report for **Targeted Testing and Treatment for Latent Tuberculosis Infection (Targeted Testing Report)** is an annual summary of activities to find and treat latent TB infection (LTBI) through targeted and other testing. Testing means diagnostic tests done primarily to find LTBI cases. Testing and follow-up of contacts, however, are not included in this report. Active case-finding (i.e., primarily seeking TB disease) also should not be included in this report, unless the person is being tested for LTBI also.

At its discretion, the health department may include testing activities that are performed by partner or contract entities on its behalf, if the health department has assurance that the data are satisfactory. Typically, this means that the health department has contributed to the partner or contract entity's work through training, consultation, supplies, funding, or direct assistance by health department personnel, and the quality of the testing, treatment, and data are monitored routinely and meet the expectations of the health department.

Systematic tuberculin skin testing (TST) or testing by interferon-gamma release assay (IGRA) that is done partly for infection control and partly for surveillance purposes (e.g., testing of health care personnel) is not included in this report unless the health department determines that such testing has mixed features of both targeted testing and surveillance. If persons have LTBI that is diagnosed during other types of testing programs (e.g., applicants screening for permanent resident status adjustment by the civil surgeons) and they are referred to the health department for other testing and for treatment, they should be counted under the second half of this report, **Referral Counts**.

The **Referral Counts** section of this report is intended for recording LTBI treatment when the denominator data (i.e., the number of persons tested) are unavailable or inappropriate for this report. The **Referral Counts** section sums up the follow-up of persons who are referred to the health department because of possible LTBI. This includes reporting or referral of persons diagnosed with LTBI by the civil surgeons from applicants screening during resident status adjustment. At its discretion, the health department also may include the data generated by other entities that perform these same activities on its behalf, if the health department somehow assists with the care of those patients (e.g., providing medication or monitoring adherence) and participates in the data collection.

Cohort year. The data are accumulated into a cohort over one calendar year. Depending on the circumstances, the year for entering an individual patient into a cohort is the date of registration at the health department or the date that a person was tested, listed for testing, or at least sought for testing as part of a target group. A person who was included in testing activities more than one time during a year should be counted for each event.

Date report updated. A preliminary report should be tabulated by March 31 after the cohort year (i.e., before all the completion of therapy data are available). The final results, including the completion-of-therapy data, are due for submission to CDC no later than March 31; one year after submission of the preliminary report.

Part I. Testing Counts

This section includes the count of persons who were sought, enlisted, or registered for testing and the outcomes of their testing and treatment.

Testing formats. The selection of a testing category (**Targeted testing** [**project** or **individual**] or **Administrative**) is determined by the structure of the testing activities and the public health intentions. The data in **Part I** flow down the columns under these categories.

Targeted testing. This is the sum of testing projects or testing of individual persons, with the testing focused on specific groups or persons who should be tested for LTBI according to guidelines in effect at the time of testing. The groups or persons should be at an increased risk for TB because of a high prevalence of latent infection, ongoing TB transmission, or concurrent medical conditions that promote progression of LTBI to active TB disease.

Project. Usually, testing projects for groups are done at sites outside the health department, as determined for the convenience or by the needs of the groups being tested. Such testing projects might be done only once during a limited period, or they might be recurrent (e.g., annual testing at a correctional facility) or ongoing (e.g., testing of all new admissions to a homeless shelter).

Note: The targeted testing projects that are supported by dedicated funding through a TB cooperative agreement should be included in the sum for the **Project** category. Separate counts for each project should be retained by the funding recipient for inclusion in the annual narrative for the TB cooperative agreement.

Individual. This is the sum of testing that is done one person at a time or by group but outside of testing projects, when testing is in accordance with national, state, or local guidelines for selecting persons who are at risk for TB and who are expected to be candidates for treatment if they have LTBI. The testing is often done at a health department clinic.

Administrative. This is the sum of testing for LTBI that is done when the testing is a low public health priority because the tested persons or groups are not at risk for TB and might not even be candidates for LTBI treatment. This testing often is required by regulations or policies created outside the TB control program. (Persons who are tested for administrative reasons should be counted under **Targeted testing individual** if the health department determines that they fit in a TB risk category.)

Note — Overextended contact investigations: As part of a contact investigation, persons who are tested because of mass screening after minimal or no TB exposure can be counted in the report for

Sought, enlisted, or registered. For **Project** under **Targeted testing,** this is the number of persons who should be tested as part of the project, regardless of

whether they can be evaluated (e.g., persons who decline testing should still be counted here because they were sought for testing). For the other testing formats, this is the number of persons who are listed or registered by the health department for testing, regardless of whether any further testing or evaluation is done.

US-born person. A *US-born person* is someone who was eligible for US citizenship at birth.

Non-US–born person. A person who was not eligible for US citizenship at birth, regardless of the actual country of birth.

Evaluated. This is the count of persons who have been evaluated and a determination can be made about the following outcomes: LTBI or TB disease (see the following sections). The majority of persons who are counted under **Evaluated** receive a tuberculin skin test (TST) or interferon-gamma release assay (IGRA). For persons who have a record of disease or latent infection that has been diagnosed previously, a TST or IGRA and other examinations might not be needed and the outcome can be classified; therefore, they are counted under **Evaluated.** Persons who receive a TST or IGRA are not counted under **Evaluated** until the TST has been read or known IGRA result obtained. Persons who have a positive TST or IGRA result are not counted under **Evaluated** until active TB disease has been excluded by any further tests and examinations, as indicated. (Tests for cutaneous anergy should not be considered for classifying outcomes for this report.)

By TST. Number of persons tested by using the tuberculin skin test (Mantoux).
By IGRA. Number of persons tested by using an interferon-gamma release assay.

TB disease. Persons are counted under this outcome if they have TB disease (i.e., active TB) at the time of the evaluation in the testing process, even if the illness has been previously diagnosed and reported, and regardless if the person is undergoing treatment at the time of the evaluation. Such cases should fit CDC's Report of Verified Case of Tuberculosis (RVCT) definition, and these cases should be referred for morbidity surveillance according to the local reporting requirements. Old, resolved TB cases that have been treated and cured or that have spontaneously healed should be counted under **LTBI** even if a TST or IGRA is not done.

Note: In the **Contact Follow-Up** report, previous TB disease is not counted as an evaluation outcome.

Latent TB infection. Persons are counted under this outcome if they have LTBI but not TB disease. LTBI is determined by (a) the result of a current TST or IGRA, as interpreted according to national, state, or local diagnostic guidelines; (b) a known LTBI that already has been diagnosed from a previous TST or IGRA result, regardless if treatment has been taken; or (c) resolved prior TB disease regardless if it has been treated. Persons who are still receiving anti-TB medication for a TB case should be counted under **TB disease**.

Note: In the **Contact Follow-Up** report, previously known LTBI is not counted as an evaluation outcome.

Note — In making a diagnosis of LTBI, only the results from TSTs or IGRAs should be considered, not from skin tests with other antigens (i.e., control antigens or an anergy panel). However, if persons with a negative TST or IGRA result, or an indeterminate IGRA result, are to be treated for presumed LTBI, they should be counted in this report as infected with TB.

Latent TB infection (sorted by risk). Under the **Project** and **Individual** formats of **Targeted testing**, the persons who have LTBI are divided into categories according to TB risk factors. Every person who is counted as infected with LTBI should be classified as either **Medical risk** or **Population risk**. Persons who have both a medical risk and a population risk should be counted under **Medical risk**. Persons who have no known risks should be counted under **Population risk**.

Medical risk. Persons with LTBI should be counted under this category if they have a condition that has been associated with predisposition to TB disease, usually a concurrent medical diagnosis (see the text box below). LTBI treatment has increased urgency for persons in this target category.

Population risk. Persons with LTBI should be counted under this category if they are members of socially or demographically defined groups that have been associated with high prevalence of TB infection or a high transmission rate (see the text box below).

Medical Risk Conditions	Population Risk Circumstances
• HIV infection • Tuberculin skin test conversion • Fibrotic lesions (on chest radiograph) consistent with old, healed TB • Injection-drug use • Diabetes mellitus • Prolonged high-dose corticosteroid therapy or other intensive immunosuppressive therapy • Chronic renal failure • Certain hematologic disorders (e.g., leukemia or lymphoma) • Specific malignant neoplasms (e.g., carcinoma of the head or neck) • Weight ≥10% less than ideal body weight • Pulmonary silicosis • Gastrectomy or jejunoileal bypass • Age 0–4 years • Recent exposure to TB	• Residency or occupation in congregate settings that might place persons at TB risk; for example, — prisons and jails — health care facilities — nursing homes and long-term–care facilities for older or infirm persons — shelters for homeless persons • Birth or residence in a country having a high prevalence or incidence of TB; for example, — immigrants — refugees — students — certain migrant workers • Socioeconomic predictors of TB exposure; for example, — low income — inner-city residence — migrant labor

Candidates for treatment. Persons with LTBI are counted in this category if they should receive treatment according to the treatment guidelines in effect at the time of testing. Counting under this category should be determined according to medical and epidemiological factors, even if treatment will not be prescribed because of other factors. Persons who are not candidates for treatment because of temporary conditions (e.g., treatment will be deferred because of pregnancy) should not be counted under this category, even if treatment is planned for the future. When the deferred treatment is administered, it can be counted in **Part III Referral Counts**.

Note: In the **Contact Follow-Up** report, the **Candidates for treatment** category is not included.

Started treatment. Persons with LTBI are counted under this category after the first dose of a planned full-treatment course. The determination of whether the first dose has been taken is based on the best available information, which is often the person's statement. If a person is lost to follow-up after treatment was prescribed and information is unavailable about whether any medication was taken, treatment can be considered started if it can be determined that the medicine was picked up from a clinic or pharmacy.

Treatment regimens:

3HP. Number of contacts for whom once-weekly isoniazid-rifapentine for 3 months (3HP) was prescribed and the regimen was started.

RIF (4 months). Number of contacts for whom 4 months of daily rifampin (RIF) was prescribed and the regimen was started.

3HR. Number of contacts for whom 3 months of daily isoniazid-rifampin (3HR) was prescribed and the regimen was started.

INH (6 months). Number of contacts for whom 6 months of isoniazid (INH) was prescribed and treatment was started.

INH (9 months). Number of contacts for whom 9 months of isoniazid (INH) was prescribed and treatment was started.

Other. Number of contacts for whom a regimen other than the ones listed previously was prescribed and treatment was started.

Unknown. Number of contacts started on treatment without the drug regimen being documented.

Completed treatment.

Note: This category is based partly on an arbitrary, operational definition of completion and therefore might not be equivalent to an adequate course of therapy.

All of the following criteria are required for counting under this category:

1. The prescribing provider, believing that an adequate regimen was received, discontinued treatment.
2. The patient completed ≥80% of the prescribed doses in the selected regimen.
3. The treatment was finished within a period of 150% of the selected duration of therapy.

The determination of whether the definition was met should be based on the best available information, which is usually the provider's records and the patient's statements about adherence to treatment.

Treatment regimens:

3HP. Number of patients who completed 3HP treatment.
RIF (4 months). Number of patients who completed 4 months of RIF treatment.
3HR. Number of patients who completed 3HR treatment.
INH (6 months). Number of patients who completed 6 months of INH treatment.
INH (9 months). Number of patients who completed 9 months of INH treatment.
Other. Number of patients who completed treatment under a drug regimen other than the ones listed previously.
Unknown. Number of patients who completed treatment but without a drug regimen being documented.

Reason treatment not completed. This section catalogues general reasons why LTBI treatment was not completed.

Active TB developed. If a patient is still receiving treatment for LTBI but has active TB disease that qualifies as a case under the standard surveillance definition (i.e., RVCT), the outcome is counted in this category. However, if the treatment regimen already has been stopped before active TB disease develops because of completion or for any other reason, the outcome should not be changed to *Active TB developed*.

Adverse effect of medicine. Persons who do not complete treatment because of presumed adverse effects (including drug–drug or drug–food interactions) of anti-TB medications should be counted in this group, but only if a health care provider documents the problem and determines that the medicine should be discontinued. If a person stops taking the medicine because of an adverse effect but a provider does not recommend the discontinuation, the reason for stopping treatment should be counted as *Patient chose to stop.*

Death. Persons who were receiving treatment on schedule but who died of any cause before completion are counted under this category.

Note: Health department staff should verify death using death certificates or medical record information to ensure reporting accuracy.

Patient chose to stop. Persons who do not complete treatment should be counted in this category if they decide to stop taking their medicine before they have received a complete regimen and a health care provider has not determined that the medicine should be discontinued for a medical reason.

Patient is lost to follow-up. Persons whose treatment status at the end of the expected treatment regimen is incomplete or indeterminate because the health department cannot locate them for determining a more specific outcome should be counted in this category.

Patient moved (follow-up unknown). Persons who do not complete treatment because they moved or migrated from the health department's jurisdiction should be counted in this category if follow-up information is unavailable. However, if the health department receives specific follow-up from a receiving jurisdiction (e.g., completed treatment or patient is lost to follow-up), the outcome should be reclassified accordingly.

Provider decision. If a health care provider determines that the treatment for LTBI should be stopped because of concerns about the benefits, the safety, or the practicality of treatment (e.g., a person has such erratic attendance at the clinic that the adequacy and the safety of the treatment cannot be monitored), this is the reporting category.

Part II. Evaluation Indices

This section of the report is the summary statistics that are calculated from the aggregate data entered into **Part I** of the report. The indices are calculated automatically and presented as percentages in the National TB Indicators Project (NTIP) system.

The calculations are as follows:

Evaluation rate = (# persons evaluated)/(# persons sought, enlisted, or registered) x 100
Disease rate = (# persons diagnosed with TB disease)/(# persons evaluated) x 100
Latent TB infection rate = (# persons diagnosed with LTBI)/(# persons evaluated) x 100
Candidate rate = (# persons who are candidates for treatment)/(# persons diagnosed with LTBI) x 100
Treatment rate = (# persons started treatment)/(# persons who are candidates for treatment) x 100
Completion rate = (# persons completed treatment)/(# persons started treatment) x 100

Part III. Referral Counts

Persons are included in this section when they are being evaluated for LTBI treatment, usually diagnosed with a positive TST or IGRA, and when they cannot be counted as part of the testing denominators in **Part I** of the report. **Part III** also includes persons with LTBI who had their treatment delayed beyond a reporting period after they were evaluated, and it includes certain contacts who cannot be counted under the treatment categories in the **Contact Follow-Up** report.

Referred. This is the number of persons who are registered for the confirmation (and often treatment) of presumed LTBI, regardless of whether TB disease already has been excluded.

TB disease. As defined for **Part I**.
Latent TB infection. As defined for **Part I**.
Candidates for treatment. As defined for **Part I**.
Started treatment. As defined for **Part I**.
Completed treatment. As defined for **Part I**.

Reason treatment not completed. All reasons as defined for **Part I**.

Part IV. Evaluation Indices for Referrals

This part is equivalent to **Part II**.