

Aggregate Reports for Tuberculosis Program Evaluation

Attachment 3b

**Targeted Testing and Treatment for Latent Tuberculosis Infection,
form and instructions**

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

Shaded fields are optional

Program Area: _____ Grantee _____
 Cohort Year: _____ 2020 _____

Part I. Testing Counts

	Targeted Testing Project		Testing Formats: Targeted Testing Individual		Administrative
			Medical Risk	Pop. Risk	
Sought, Enlisted, or Registered	(a1)		(a2)		(a)
U.S.-born	(a1a)		(a2a)		(aa)
Non-U.S.-born	(a2a)		(a2b)		(ab)
Evaluated	(b1)		(b2)		(b)
By TST	(b1a)		(b2a)		(ba)
By IGRA	(b1b)		(b2b)		(bb)
TB Disease	(c1)		(c2)		(c)
Latent TB Infection (LTBI)	(d1)		(d2)		(d)
LTBI	(e1 _m)	(e1 _p)	(e2 _m)	(e2 _p)	(e)
Candidates for Treatment	(f1 _m)		(f2 _m)		(f)
Started Treatment	(g1 _m)		(g2 _m)		(g)
INH (9 months)	(g1a _m)	(g1a _p)	(g2a _m)	(g2a _p)	(ga)
3HP	(g1b _m)	(g1b _p)	(g2b _m)	(g2b _p)	(gb)
RIF (4 months)	(g1c _m)	(g1c _p)	(g2c _m)	(g2c _p)	(gc)
Other	(g1d _m)	(g1d _p)	(g2d _m)	(g2d _p)	(gd)
Unknown	(g1e _m)	(g1e _p)	(g2e _m)	(g2e _p)	(ge)
Completed Treatment	(h1 _m)		(h2 _m)		(h)
INH (6 months)	(h1a _m)	(h1a _p)	(h2a _m)	(h2a _p)	(ha)
INH (9 months)	(h1b _m)	(h1b _p)	(h2b _m)	(h2b _p)	(hb)
3HP	(h1b _m)	(h1c _p)	(h2c _m)	(h2c _p)	(hc)
RIF (4 months)	(h1d _m)	(h1d _p)	(h2d _m)	(h2d _p)	(hd)
Other	(h1e _m)	(h1e _p)	(h2e _m)	(h2e _p)	(he)
Unknown	(h1f _m)	(h1f _p)	(h2f _m)	(h2f _p)	(hf)
Reasons Treatment Not Completed:					
Death					
Patient Moved (follow-up unknown)					
Active TB Developed					
Adverse Effect of Medicine					
Patient Chose to Stop					
Patient is Lost to Follow-up					
Provider Decision					

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 D-74, Atlanta, Georgia 30333; Attn: OMB-PRA (0920-0457)

Part II. Evaluation Indices (auto calculated)

Evaluation Rate	N/A		N/A		N/A	
Disease Rate	N/A		N/A		N/A	
LTBI Rate	N/A		N/A		N/A	
	Medical Risk	Pop. Risk	Medical Risk	Pop. Risk		
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

	Medical Risk	Pop. Risk	Admin.
Referred, TB Infection:			
Referred	(i _m)	(i _p)	(i)
U.S.-born	(ia _m)	(ia _p)	(aa)
Non-U.S.-born	(ib _m)	(ib _p)	(ab)
Evaluated	(j _m)	(j _p)	(j)
By TST	(ja _m)	(ja _p)	(ba)
By IGRA	(jb _m)	(jb _p)	(bb)
TB Disease	(k _m)	(k _p)	(k)
Latent TB Infection (LTBI)	(l _m)	(l _p)	(l)
Candidates for Treatment	(m _m)	(m _p)	(m)
Started Treatment	(n _m)	(n _p)	(n)
INH (9 months)	(ga _m)	(na _p)	(ga)
3HP	(gb _m)	(nb _p)	(gb)
RIF (4 months)	(gc _m)	(nc _p)	(gc)
Other	(gd _m)	(nd _p)	(gd)
Unknown	(ge _m)	(ne _p)	(ge)
Completed Treatment	(o _m)	(o _p)	(o)
INH (6 months)	(ha _m)	(oa _p)	(ha)
INH (9 months)	(hb _m)	(ob _p)	(hb)
3HP	(hc _m)	(oc _p)	(hc)
RIF (4 months)	(hd _m)	(od _p)	(hd)
Other	(he _m)	(oe _p)	(he)
Unknown	(hf _m)	(of _p)	(hf)

Reasons Treatment Not Completed:

Death			
Patient Moved (follow-up unknown)			
Active TB Developed			
Adverse Effect of Medicine			
Patient is Lost to Follow-up			
Provider Decision			

Part IV. Evaluation Indices (auto calculated)

Evaluation Rate	N/A	N/A	N/A
Disease Rate	N/A	N/A	N/A
LTBI 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

Basic Instructions for the Aggregate Reports for Tuberculosis Program Evaluation:

Targeted Testing and Treatment for Latent Tuberculosis Infection

Note: The instructions for this report are not a substitute for guidelines about TB diagnosis, treatment, or control. Any contradictions between the implied 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 program or the Division of Tuberculosis Elimination (DTBE).

This report is an annual summary of activities to find and treat LTBI through targeted and other testing. Testing means diagnostic tests done to find mainly LTBI. Testing and follow-up of contacts, however, are not included in this report. Active-case finding (i.e., seeking mainly TB disease) should not be included in this report, either, unless the individuals also are being tested for LTBI.

At its discretion, the health department may include testing activities that are carried out by partner or contract entities on its behalf if the health department has assurance that the data are satisfactory. (Generally, this means that the health department has contributed to the 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 skin testing that is done partly for infection control and surveillance purposes (e.g., the annual testing of healthcare workers) generally should not be included in this report unless the health department determines that this testing has mixed features of both targeted testing and surveillance. If latently TB-infected individuals are diagnosed during these other types of testing programs and 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 second half of this report, **Referral Counts**, mainly records the treatment of LTBI when the denominator data (i.e., the number of persons tested) are unavailable or inappropriate for this report.

Referral Counts sums up the follow-up of persons who are referred to the health department because of possible latent TB infections. At its discretion, the health department also may include the data generated by other entities that carry out these same activities on its behalf if the health department somehow assists with the care of the patients (e.g., providing medication or monitoring adherence) and participates in collecting the data.

Cohort Year. The data are accumulated into a cohort over 1 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 an individual is tested, listed for testing, or at least sought for testing as part of a target group. A person who is included in testing activities more than once in a year should be counted for each event.

Closure Date for Follow-up. A preliminary report should be tabulated by March 31 following the cohort year (i.e., before all the completion-of-therapy data are available) and, depending on the context, shared with the program consultant at the state health department or DTBE. The final results, including the completion-of-therapy data, are due at DTBE by March 31, 1 year later.

Part I. Testing Counts.

This section includes the count of persons who are sought or enrolled for testing and the outcomes of 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 individuals, with the testing focused on specific groups or individuals who should be tested for LTBI as per current guidelines. The groups or individuals should be at an increased risk for TB because of a high prevalence of latent infection, ongoing TB transmission, or a high prevalence of concurrent medical conditions that promote the progression of LTBI to active TB disease.

Project. Usually, testing projects for groups are done at sites outside of the health department, as determined by the convenience or needs of the groups being tested. Such testing projects might be done only once during a limited period, or they can 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 group-wise 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. Often the testing is 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 treatment of LTBI. Often this testing is required by regulations or policies created outside of the TB control program. (Persons who are tested for administrative reasons should be counted **under Targeted Testing** and **Individuals** if the health department determines that they would fit into a TB risk category.)

Note about overextended contact investigations: As part of a contact investigation, persons who are tested because of mass screening following minimal or no TB exposure also can be counted in the report for targeted testing (usually under Administrative) instead of in the report for contact follow-up, at the discretion of the health department.

Sought, Enlisted, or Registered. For Project under **Targeted Testing**, this is the count of individuals who should be tested as part of the project, whether or not they can be evaluated (e.g., persons who decline testing would still be counted here because they were sought for testing). For the other testing formats, this is the count of persons who are listed or registered by the health department for testing, whether or not any further testing or evaluation is done.

- **U.S.-born:** The U.S. Census Bureau defines a “U.S.-born” person to be someone born in 1 of the 50 states or the District of Columbia, or someone born outside the United States to at least one parent who was a U.S. citizen.
- **Non-U.S.-born:** Individuals who are born outside of the U.S. to parents who was not a U.S. citizen.

Evaluated. This is the count of persons who have been evaluated to the point where a determination can be made about these outcomes: LTBI or TB disease (see the outcome categories, below). Most persons who are counted under **Evaluated** receive a tuberculin skin test. For persons who have a record of

disease or latent infection that already has been diagnosed, a skin test and other examinations might not be needed and the outcome can be classified; therefore they are counted under **Evaluated**. Persons who receive a skin test are not counted under **Evaluated** until the test has been read. Persons who have a positive skin test 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 individuals tested using tuberculin (Mantoux) skin test
- **By IGRA:** Number of individuals tested using 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 whether or not the person is undergoing treatment at the time of the evaluation. Such cases should fit the CDC 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 already or that have spontaneously healed should be counted under **LTBI** even if a skin test is not done. (Note: In the other report, Contact Follow-up, previous TB disease is not counted as an evaluation outcome.)

LTBI. Persons are counted under this outcome if they have LTBI but not TB disease. LTBI is determined by the result of a current tuberculin skin test (as interpreted according to national, state, or local diagnostic guidelines); by a known LTBI that already has been diagnosed from a previous skin test result, whether or not treatment has been taken; or by resolved prior TB disease whether or not 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 other report, Contact Follow-up, previously known LTBI is not counted as an evaluation outcome.)

Note about anergy: In making a diagnosis of LTBI, only the results from tuberculin skin tests should be considered, not from skin tests with other antigens (i.e., control antigens, or an anergy panel). However, if persons with a negative tuberculin skin test result are to be treated for suspected LTBI, then they should be counted in this report as TB infected.

LTBI, (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 latently TB infected should be classified into one of these two categories: **Medical Risk** and **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. Latently TB-infected persons are counted under this category if they have a condition known to predispose to TB disease, usually a concurrent medical diagnosis (see box, below). The treatment of LTBI has increased urgency in this target category.

Conditions that are counted under **Medical Risk**

HIV infection
Tuberculin skin test conversion
Fibrotic lesions (on chest x-ray) consistent with old, healed TB
Injection drug use
Diabetes mellitus
Prolonged high-dose corticosteroid therapy or other intensive immunosuppressive therapy
Chronic renal failure
Some hematologic disorders, such as leukemia or lymphoma
Specific malignant neoplasms, such as carcinoma of the head or neck
Weight at least 10 percent less than ideal body weight
Pulmonary silicosis
Gastrectomy or jejunioileal bypass
Age < 5 years
Recent exposure to TB

Population Risk. Latently TB-infected persons are counted under this category if they are members of socially or demographically defined groups known to have a high prevalence rate of TB infection or a high transmission rate (see box, below).

Circumstances that are counted under **Population Risk**

Residency or occupation in high-risk congregate settings:
Prisons and jails
Healthcare facilities
Nursing homes and long-term facilities for the elderly
Shelters for homeless persons
Birth in a country having a high prevalence or incidence of TB: Includes
Immigrants
Refugees
Students
Some migrant workers
Socioeconomic predictors of exposure:
Low income
Inner-city residence
Migrant labor

Candidates for Treatment. Latently TB-infected persons are counted in this category if they should receive treatment according to the treatment guidelines in effect at the time. 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 given, it can be counted in **Part III. Referral Counts**. (Note: In the other report, Contact Follow-up, the **Candidates for Treatment** category is not included.)

Started Treatment. A person who has LTBI is counted under this category after the first dose of a planned full-treatment course for LTBI. 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, then treatment can be considered started if the medicine was picked up from a clinic or pharmacy.

- **INH (9 months):** This is the count of patients prescribed and started treatment using INH.
- **3HP:** Number of patients prescribed and started the 3HP.
- **RIF (4 months):** Number of patients prescribed and started 4 months of RIF.
- **Other:** Number of patients prescribed and started treatment with regimen other than one stated above.
- **Unknown:** Number of patients started treatment without drug regimen documented.

Completed Treatment. (Note: This category is based partly on an arbitrary definition of completion. It might not be equivalent to an adequate course of therapy.) A person is counted under this category (1) if the prescribing provider, believing that an adequate regimen has been received, discontinues treatment, and (2) if the person has taken at least 80 percent of the prescribed doses in a therapy course within a period of 150 percent of the selected duration of therapy. The determination about whether the definition is met is made from the best available information, which is generally the provider's records and the person's statements.

- **INH (6 months):** This is the count of patients completed 6 months of INH treatment.
- **INH (9 months):** This is the count of patients completed 9 months of INH treatment.
- **3HP:** Number of patients completed 3HP.
- **RIF (4 months):** Number of patients completed 4 months of RIF.
- **Other:** Number of patients completed treatment under drug regimen other than one stated above.
- **Unknown:** Number of patients completed treatment but without drug regimen documented.

Reasons Treatment Not Completed: This section catalogues some general reasons that the treatment for LTBI is not completed.

Death. Persons who were receiving treatment on schedule but who had treatment interrupted by death before completion are counted under this category. (Note: Because of the seriousness of this outcome and the unreliability of anecdotal reports, a verification of any deaths is helpful for accuracy in reporting.)

Patient Moved (follow-up unknown). Persons who do not complete treatment because they have moved or migrated from the jurisdiction of the health department should be counted under this category when follow-up information is unavailable. However, if the health department receives specific follow-up (e.g., **Completed Treatment** or **Lost to Follow-up**) from a receiving jurisdiction, then the outcome should be counted accordingly.

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

Adverse Effect of Medicine. Persons who do not complete treatment because of adverse effects (including drug-drug or drug-food interactions) of anti-TB medications should be counted in this group if a healthcare 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, then the reason for stopping treatment should be counted as **Patient Chose to Stop**.

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 healthcare 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.

Provider Decision. If a healthcare 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), then this is the reported reason.

Part II. Evaluation Indices for Testing.

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 by

TIMS. The formulae are shown in the paper-copy table to show the source figures for the calculations.

Part III. Referral Counts.

Persons are included in this section when they are being evaluated for treatment of LTBI, usually diagnosed with a positive tuberculin skin test result, and when they cannot be counted as part of the testing denominators in **Part I** of the report. **Part III** also includes the 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 report of contact follow-up.

Referred. This is the number of persons who are registered for the confirmation (and often treatment) of presumed LTBI, whether or not TB disease has been excluded already.

TB Disease. As defined for **Part I**.

LTBI. 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**.

Reasons Treatment Not Completed: All reasons as defined for **Part I**.

Part IV. Evaluation Indices for Referrals.

This part is similar to **Part II**, except that rates for evaluation and infection are not included.