

Aggregate Reports for Tuberculosis Program Evaluation
OMB# 0920-0457
(Exp. 9/30/2013)

Targeted Testing and Treatment for Latent TB Infection Form

Attachment 3b

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

Reporting Area: _____

Cohort Year: _____

Closure Date for Follow-up: ____/____/____ (August 15 of the first year after the cohort year)

Part I. Testing Counts

	Testing Formats:				Admin.
	Targeted Testing				
	Project		Individual		
Sought, Enlisted, or Registered.....	(a1)		(a2)		(a)
Evaluated.....	(b1)		(b2)		(b)
TB Disease.....	(c1)		(c2)		(c)
Latent TB Infection.....	(d1)		(d2)		(d)
	Medical Risk	Pop. Risk	Medical Risk	Pop. Risk	
Latent TB Infection, (sorted by risk).....	(e1 _{pop})	(e1 _{med})	(e2 _{pop})	(e2 _{med})	(e)
Candidates for Treatment.....	(f1 _{pop})	(f1 _{med})	(f2 _{pop})	(f2 _{med})	(f)
Started Treatment.....	(g1 _{pop})	(g1 _{med})	(g2 _{pop})	(g2 _{med})	(g)
Completed Treatment.....	(h1 _{pop})	(h1 _{med})	(h2 _{pop})	(h2 _{med})	(h)

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.....			

Part II: Evaluation Indices for Testing

	Project		Individual		Admin.
Evaluation Rate.....	(b1/a1)%		(b2/a2)%		(b/a)%
Disease Rate.....	(c1/b1)%		(c2/b2)%		(c/b)%
Latent Infection Rate.....	(d1/b1)%		(d2/b2)%		(d/b)%
	Medical Risk	Pop. Risk	Medical Risk	Pop. Risk	
Candidate Rate.....	(f1 _{pop} /e1 _{pop})%	(f1 _{med} /e1 _{med})%	(f2 _{pop} /e2 _{pop})%	(f2 _{med} /e2 _{med})%	(f/e)%
Treatment Rate.....	(g1 _{pop} /f1 _{pop})%	(g1 _{med} /f1 _{med})%	(g2 _{pop} /f2 _{pop})%	(g2 _{med} /f2 _{med})%	(g/f)%
Completion Rate.....	(h1 _{pop} /g1 _{pop})%	(h1 _{med} /g1 _{med})%	(h2 _{pop} /g2 _{pop})%	(h2 _{med} /g2 _{med})%	(h/g)%

Public reporting burden for this collection of information is estimated to average 3 hours per manual response by data clerks, 30 minutes per manual response by program managers, 30 minutes per electronic response by data clerks and program managers, 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 comment regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ASTDR Information Collection Review Office, 1600 Clifton Road, MS D-74 Atlanta, GA 30333. ATTN: PRA (0920-0457). Do not send this comment to the address.

TB Disease.....	(i_p)	(i_p)	(j)
Latent TB Infection.....	(k_p)	(k_p)	(k)
Candidates for Treatment.....	(l_p)	(l_p)	(l)
Started Treatment.....	(m_p)	(m_p)	(m)
Completed Treatment.....	(n_p)	(n_p)	(n)

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.....			

Part IV: Evaluation Indices for Referrals

	Medical Risk	Pop. Risk	Admin.
Disease Rate.....	$(j_p/i_p)\%$	$(j_p/i_p)\%$	$(j/i)\%$
Candidate Rate.....	$(l_p/k_p)\%$	$(l_p/k_p)\%$	$(l/k)\%$
Treatment Rate.....	$(m_p/l_p)\%$	$(m_p/l_p)\%$	$(m/l)\%$
Completion Rate.....	$(n_p/m_p)\%$	$(n_p/m_p)\%$	$(n/m)\%$

**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 tuberculosis (TB) diagnosis, treatment, or control. Any contradictions between the implied content of these instructions and the health departments 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 latent TB infection through targeted and other testing. "Testing" means diagnostic tests done to find mainly latent TB infection. 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 latent TB infection.

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 health care 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 latent TB infection 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 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 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 August 15 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 August 15 one 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 **Admin.**) 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 latent TB infection 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 latent TB infection 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 latent TB infection. Often the testing is done at a health department clinic.

Admin. (i.e., Administrative). This is the sum of testing for latent TB infection 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 latent TB infection. 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 **Admin.**) 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.

Evaluated. This is the count of persons who have been evaluated to the point where a determination can be made about these outcomes: latent TB infection, 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, and 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.)

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 Report of a 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 already or that have spontaneously healed should be counted under **Latent TB Infection** 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.)

Latent TB Infection. Persons are counted under this outcome if they have a latent TB infection but not TB disease.

Latent TB infection is determined by the result of a current tuberculin skin test (as interpreted according to national, state, or local diagnostic guidelines), by a known latent TB infection 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 latent TB infection is not counted as an evaluation outcome.)

Note about "anergy": In making a diagnosis of latent TB infection, 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 latent TB infection, then they should be counted in this report as TB infected.

Latent TB Infection, (sorted by risk). Under the **Project** and **Individual** formats of **Targeted Testing**, the persons who have latent TB infection 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 **Pop. 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 **Pop. risk**.

Medical Risk. Latently TB-infected persons are counted under this category if they have a condition known to

- 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% less than ideal body weight
- Pulmonary silicosis
- Gastrectomy, or jejunioileal bypass
- Age \leq 5 years
- Recent exposure to TB

predispose to TB disease, usually a concurrent medical diagnosis (see box, below). The treatment of latent TB infection has increased urgency in this target category.

Pop. (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).

<p>Residency or occupation in high-risk congregate settings</p> <ul style="list-style-type: none"> Prisons and jails Health care facilities Nursing homes and long-term facilities for the elderly Shelters for homeless persons <p>Birth in a country having a high prevalence or incidence of TB: Includes</p> <ul style="list-style-type: none"> Immigrants Refugees Students Some migrant workers <p>Socioeconomic predictors of exposure:</p> <ul style="list-style-type: none"> 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 latent TB infection is counted under this category after the first dose of a planned full treatment course for latent TB infection. 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.

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% of the prescribed doses in a therapy course, within a period of 150% 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.

Reasons Treatment not Completed: This section catalogues some general reasons that the treatment for latent TB infection is not being completed.

Death. Persons who were receiving treatment on schedule but who had treatment interrupted by death before completing 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 followup 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.

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 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, 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 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.

Provider Decision. If a health care provider determines that the treatment for latent TB infection 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 the treatment of a latent TB infection, usually diagnosed with a positive tuberculin skin test result, and when they cannot be counted as part of the testing denominators in the **Part I** of the report. **Part III** also includes the persons with latent TB infection who had their treatment delayed beyond a reporting period after they were evaluated, and it includes the 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 latent TB infection, whether or not TB disease has been excluded already.

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**.

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.