Aggregate Reports for Tuberculosis Program Evaluation

Attachment 3a

Follow-up and Treatment of Contacts to Tuberculosis Cases,

form and instructions

Form Approved
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Aggregate Reports for Tuberculosis Program Evaluation — Follow-Up and Treatment for Contacts of Tuberculosis Patients

**Fields are optional*

Program Area: _____

Cohort Year: _____

Date Report Updated: Click to enter a date.

Part I. Cases and Patient Contacts

Types of Cases for Investigation

	Sputum smear-positive	Sputum smear-negative/ culture-positive	Other
Cases reported in RVCT	(auto-populated)	(auto-populated)	N/A
Cases for investigation			N/A
Cases with no contacts			N/A
Number of contacts			
*US-born			
*Non-US–born			
Evaluated			
*By TST			
*By IGRA			
TB disease			
Latent TB infection			
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			
Contact chose to stop			
Contact lost to follow-up			
Contact moved (follow-up unknown)			
Death			
Provider decision			

Part II. Evaluation Indices (auto calculated)

No-contacts rate	N/A	N/A	
Contacts per case	N/A	N/A	
Evaluation rate	N/A	N/A	N/A
Disease rate	N/A	N/A	N/A
Latent infection 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 — Follow-Up and Treatment for Contacts of Tuberculosis Patients

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 from CDC.

The report for **Follow-Up and Treatment for Contacts of Tuberculosis Patients (Contact Follow-Up Report)** is an annual summary of the core activities of eliciting and evaluating contacts of TB patients and treating the contacts who have latent TB infection (LTBI). The health department also may include results that are provided by partner or contract health care entities if the health department has assurance that the data are satisfactory. This usually means that the other entities have cooperated with the health department in confirming the results from contact evaluations and in managing the treatment of contacts who have LTBI.

For the following 2 special circumstances, contact-related data can be reported in the other aggregate report: **Targeted Testing and Treatment for Latent Tuberculosis Infection (Targeted Testing Report)**:

1. If a health department is compelled to evaluate contacts who probably have not been exposed to the index TB patient whose case is under investigation, the results of this excess testing may be reported in the **Targeted Testing Report** instead of in the **Contact Follow-Up Report**. Consequently, the testing category is likely to be **Administrative** in **Part I** of the **Targeted Testing Report**, unless the contact has TB risk factors; in that instance, the contact should be grouped under **Targeted testing individual**.
2. If the contact has a previous record of TB disease (now inactive) or LTBI or is already being treated for LTBI, the data regarding treatment can be recorded in **Part III Referral Counts** of the **Targeted Testing Report**. The **Contact Follow-Up Report** does not have categories to record the diagnosis and treatment of these contacts. However, these contacts are still included in the counts for the **Number of contacts** and **Evaluated** (see the following) in the **Contact Follow-Up Report.**

Cohort year. The data are accumulated into a cohort throughout one calendar year. The contacts are assigned to the same count-year as the TB cases being investigated. A person who is included in more than one contact investigation within a year should be counted for each event, but exposures to multiple TB patients who are connected to a single contact investigation should be counted as one event only.

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. Cases and Patient Contacts

Cases reported in RVCT. The number of TB patients for the count year reported to CDC on the Reports of Verified Cases of Tuberculosis (RVCT). This field is auto-populated in the CDC data system. TB programs should compare this number to the data in their local surveillance registry to ensure the accuracy and completeness of data reported to CDC, and all cases that should be investigated are included and reported in the CDC surveillance count.

Cases for investigation. The TB patients, their contacts, and all of the subsequent results are grouped into 3 categorical columns, according to the type of each TB case that led to the contact investigation.

Sputum smear-positive. All three of the following criteria must be met for counting cases under this category:

1. inclusion in the overall surveillance count;
2. a disease site in the respiratory system, including the airways; and
3. a positive acid-fast bacilli (AFB) sputum-smear result, regardless if any culture result is positive.

Cases should be counted under this category even if contacts cannot be elicited for any reason (e.g., the patient left the area or died before an interview was done).

Sputum smear-negative/culture-positive. All four of the following criteria must be met for counting cases under this category:

1. inclusion in the overall surveillance count;
2. a disease site in the respiratory system, including the airways;
3. negative AFB sputum smear results; and
4. a positive sputum culture result or nucleic acid amplification test (NAAT) result that is positive for *Mycobacterium tuberculosis.*

Cases should be counted under this category, even if contacts cannot be elicited for any reason.

Other. This category includes contact investigations that were done because of any circumstances not included in the first 2 categories (e.g., associate-contact or source-case investigations done because of TB in a child). The number of contacts is counted, but the number of cases for investigation is not.

Cases with no contacts. Cases that are counted under one of the first two columns, as follows:

Sputum smear-positive or sputum smear-negative/culture-positive. See previous instructions. These cases are counted here if no contacts have been elicited, regardless of the reason.

Notes

- Persons should not be included in the contact count if they do not need to be evaluated, as the health department believes that the person has been exposed to TB as a patient's contact:
  1. The health department believes that the person has been exposed, which warrants an evaluation for TB disease or infection.
  2. The exposure was caused by a TB patient who was counted by the reporting jurisdiction.
  3. Enough identifying and locating information is available to facilitate a reasonable opportunity for contacting the person, regardless of whether the person is in the jurisdiction of the health department.

  The follow-up of an out-of-jurisdiction contact usually requires the assistance of the health department in the other jurisdiction.

  For example, this happens when the index patient's concentric circles is used. After evaluating some of the contacts who had high exposure (i.e., close contacts), the health department might determine that the other contacts who had less exposure do not need to be evaluated. The remaining contacts should not be included in the reported count of contacts because the health department believes that an evaluation is unwarranted for them.
- Sometimes contact investigations are done because of a possible TB case before the diagnosis of TB is confirmed. If TB is excluded (i.e., ruled out), the persons who initially were listed as contacts should still be counted as contacts, although a TB case is not counted. These persons and their test results are reported under the case category **Other**, which does not include a TB case denominator.
- The contacts who are associated with a TB

Number of contacts. All of the following three criteria must be met for counting a person who has been exposed to TB as a patient's contact:

1. The health department believes that the person has been exposed, which warrants an evaluation for TB disease or infection.
2. The exposure was caused by a TB patient who was counted by the reporting jurisdiction.
3. Enough identifying and locating information is available to facilitate a reasonable opportunity for contacting the person, regardless of whether the person is in the jurisdiction of the health department.

The follow-up of an out-of-jurisdiction contact usually requires the assistance of the health department in the other jurisdiction.

Note — Contacts who have had prior TB disease or latent infection: This **Contact Follow-Up Report** only includes the contact evaluation results that are determined through contact investigations. Contacts who already have known TB disease or latent infection already diagnosed before they were investigated are counted under **Number of contacts**, but the diagnostic outcomes are not counted in the **Contact Follow-Up Report**. These contacts usually can be counted under **Evaluated**, even if further tests and examinations are not done, because enough history is already available for determining their TB status. Therefore, they have been evaluated in the context of the contact investigation. If such contacts are to be treated, the treatment should be counted only in the other aggregate report, **Targeted Testing and Treatment for Tuberculosis Infection**, in the **Part III Referral Counts** section. (These contacts are counted on both reports. They are counted on this report as contacts and on the other form as referrals for treatment.)

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 contacts who have been tested and examined, as part of a contact investigation, to the point where a final determination can be made about two of the potential diagnostic outcomes: LTBI or TB disease (see the following for reporting definitions of these outcomes). Most contacts will receive a tuberculin skin test (TST) or interferon-gamma release assay (IGRA) unless their medical history indicates otherwise (see the following note). Contacts who receive a TST or IGRA should not be counted under **Evaluated** until the TST has been read or known IGRA result obtained. Contacts who need a second TST or IGRA because of recently ended exposure should not be counted under **Evaluated** until the second test has been read or obtained. Contacts who have a positive TST or IGRA should not be counted under **Evaluated** until active TB disease has been excluded by any further tests, as indicated.

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. Contacts should be counted under this outcome if they have TB disease (i.e., active TB) initially discovered as part of the contact investigation. Patients should fit CDC's RVCT definition, and they should be referred for morbidity surveillance according to the

reporting requirements. Active TB that develops after latent infection was diagnosed during the contact investigation should not be counted here. Patients with prior TB disease who have been treated already or who have spontaneously healed and TB disease discovered coincidentally (i.e., not because of the contact investigation) should not be counted in this category. (Of note, these instructions differ slightly from the ones for the report of **Targeted Testing and Treatment for Latent Tuberculosis Infection**.)

Note — Genotyping: The results of genotyping of *M. tuberculosis* isolates or whole genome sequencing should be ignored for counting contacts under **TB disease**, even if the results disprove a transmission link. The count for **TB disease** should be tabulated for this report as if genotyping data had not been available.

Latent TB infection. This is the count of contacts who have LTBI (not TB disease) that was diagnosed because of the current contact investigation. Both of the following criteria are required:

1. a positive result of a current TST or IGRA, as interpreted according to national, state, or local diagnostic guidelines; and
2. the exclusion of active TB disease through further tests or examinations.

LTBI that has been diagnosed coincidentally or previous to the contact investigation should not be included in this count.

Note — In determining whether to count a contact under **LTBI**, only results from a TST or IGRA should be considered, not from skin tests with other antigens (i.e., control antigens or an anergy panel). However, if a contact with a negative TST or IGRA is being treated with a full-course regimen for presumed LTBI, that contact should be counted under **LTBI**.

Started treatment. A contact who has LTBI is counted in this category after the first dose of a treatment for LTBI. The determination of been administered is based on the best which is often the contact's statement. If a up after treatment was prescribed and about whether any medication was taken, considered started if it can be determined that medicine from a clinic or pharmacy.

planned full-course whether the first dose has available information, contact is lost to follow- information is unavailable treatment can be the contact picked up the

Note — Window-period treatment: Contacts who are receiving treatment pending a second TST or IGRA (called *window-period treatment*) should not be counted under *Started treatment* unless LTBI is confirmed and counted for the report.

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 made based on the best available information, which is usually the provider's records and the contact'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 contacts who completed treatment under a drug regimen other than the ones listed previously.
Unknown. Number of contacts who completed treatment but without a drug regimen being documented.

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

Active TB developed. If a contact is still receiving treatment for LTBI but has developed 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. If contacts do not complete treatment because of presumed adverse effects of the anti-TB medication, including drug–drug or drug–food interactions, they 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 contact stops taking the medicine because of an adverse effect but a provider has not

recommended the discontinuation, the reason for stopping treatment should be counted as *Contact chose to stop.*

Contact chose to stop. Contacts should be counted in this category if they decide to stop taking their medicine before they have finished their regimen and a health care provider has not determined that the medicine should be discontinued for a medical reason.

Contact is lost to follow-up. Contacts whose treatment status at the anticipated end of the 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.

Contact moved (follow-up unknown). Contacts 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.

Death. Contacts 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.

Provider decision. If a health care provider determines that the treatment for LTBI should be stopped because of concerns about the benefits, safety, or practicality of treatment (e.g., a contact 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 part of the contact follow-up 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:

No contact rate = (# cases with no contact)/(# cases for investigation) x 100
Contact per case = (# contacts)/(# cases for investigation)
Evaluation rate = (# contacts evaluated)/(# contacts) x 100
Disease rate = (# contacts diagnosed with TB disease)/(# contacts evaluated) x 100
Latent TB infection rate = (# contacts diagnosed with LTBI)/(# contacts evaluated) x 100
Treatment rate = (# contacts started treatment)/(# contacts diagnosed with LTBI) x 100
Completion rate = (# contacts completed treatment)/(# contacts started treatment) x 100