Aggregate Reports for Tuberculosis Program Evaluation

**Attachment 3a**

# Follow-up and Treatment of Contacts to Tuberculosis Cases, form and instructions

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# Aggregate Reports for Tuberculosis Program Evaluation
## Follow-up and Treatment for Contacts to Tuberculosis Cases

*Shaded fields are proposed changes in this revision and are optional*

Program Area: Grantee
Cohort Year: 2020
Date report Updated:

**Part I. Cases and Contacts**

| | Types of Cases for Investigation: Sputum Smear + | | Sputum Smear - Cult. + | | Others | |
|---|---|---|---|---|---|---|
| Cases reported in RVCT | (auto calculated) | | (auto calculated) | | | |
| Cases for Investigation | | (a1) | | (a2) | | |
| Cases with No Contact | | (b1) | | (b2) | | |
| Number of Contacts | | (c1) | | (c2) | | (c) |
| U.S.-born | | (c1a) | | (c2a) | | (ca) |
| Non-U.S.-born | | (c1b) | | (c2b) | | (cb) |
| Evaluated | | (d1) | | (d2) | | (d) |
| By TST | | (d1a) | | (d2a) | | (da) |
| By IGRA | | (d1b) | | (d2b) | | (db) |
| TB Disease | | (e1) | | (e2) | | (e) |
| Latent TB Infection | | (f1) | | (f2) | | (f) |
| Started Treatment | | (g1) | | (g2) | | (g) |
| INH (9 months) | | (g1a) | | (g2a) | | (ga) |
| 3HP | | (g1b) | | (g2b) | | (gb) |
| RIF (4 months) | | (g1c) | | (g2c) | | (gc) |
| Other | | (g1d) | | (g2d) | | (gd) |
| Unknown | | (g1e) | | (g2e) | | (ge) |
| Completed Treatment | | (h1) | | (h2) | | (h) |
| INH (6 months) | | (h1a) | | (h2a) | | (ha) |
| INH (9 months) | | (h1b) | | (h2b) | | (hb) |
| 3HP | | (h1c) | | (h2c) | | (hc) |
| RIF (4 months) | | (h1d) | | (h2d) | | (hd) |
| Other | | (h1e) | | (h2e) | | (he) |
| Unknown | | (h1f) | | (h2f) | | (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 | | | | | | |

**Part II. Evaluation Indices (auto calculated)**

| | | | | | | |
|---|---|---|---|---|---|---|
| No-Contacts Rate | N/A | (b1/a1)% | N/A | (b2/a2)% | | |
| Contacts Per Case | N/A | (c1/a1)% | N/A | (c2/a2)% | | |
| Evaluation Rate | N/A | (d1/c1)% | N/A | (d2/c2)% | N/A | (d/c)% |
| Disease Rate | N/A | (e1/d1)% | N/A | (e2/d2)% | N/A | (e/d)% |
| Latent Infection Rate | N/A | (f1/d1)% | N/A | (f2/d2)% | N/A | (f/d)% |
| Treatment Rate | N/A | (g1/f1)% | N/A | (g2/f2)% | N/A | (g/f)% |
| Completion Rate | N/A | (h1/g1)% | N/A | (h2/g2)% | N/A | (h/g)% |

## Basic Instructions for the Aggregate Reports for Tuberculosis Program Evaluation:

## Follow-up and Treatment for Contacts to Tuberculosis Cases

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 the core activities of eliciting and evaluating contacts to TB cases and treating the contacts who have LTBI. The health department also may include results that are provided by partner or contract healthcare entities if the health department has assurance that the data are satisfactory. Generally, this 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 two special circumstances, contact-related data can be reported in the other aggregate report: Targeted Testing and Treatment for Latent Tuberculosis Infection.

1. If a health department is compelled to evaluate contacts who probably have not been exposed to the index case of TB that is under investigation, the results of this excess testing may be reported in the targeted-testing report instead of in the contact report. Then, the testing category is likely to be **Administrative** in **Part I** of the targeted-testing report unless some of the individuals have TB risk factors, and then these individuals usually will be grouped under **Targeted Testing** and **Individual**.

2. If the contacts having previous records of TB disease (now inactive) or latent infection are treated for LTBI, the data about treatment can be recorded in **Part III.**

**Referral Counts** of the targeted-testing report. The contact 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 below) in the contact report.

**Cohort Year**. The data are accumulated into a cohort over 1 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 in a year should be counted for each event, but exposures to multiple TB cases that are connected to a single contact investigation should be counted as one event only.

**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.

**Total TB Cases Reported**. This is the surveillance result for TB morbidity for the count year.

**Part I. Cases and Contacts**

**Cases for Investigation**. The TB cases, their contacts, and all the subsequent results are grouped into three categorical columns according to the types of TB cases that led to the contact investigations.

**Sputum smear +**. All 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, whether or not any culture result is positive.

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

**Sputum smear - culture +**. All 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. sputum culture result positive, or nucleic acid amplification (NAA) test result positive for *Mycobacterium tuberculosis.*

Cases should be counted under this category even if contacts could not be elicited for any reason.

**Other**. This category includes contact investigations that were done because of any circumstances not included in the other two categories. Example: 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

(**Sputum smear +** or **Sputum smear - culture +**, see above) are counted here if no contacts were elicited, regardless of the reason that contacts were not elicited.

**Number of Contacts**. All of the following criteria must be met for counting a person who has been exposed to TB as a contact for this report:

1. The health department believes that the person was exposed, warranting an evaluation for TB disease or latent infection;

2. the exposure was caused by a TB case that was counted by the reporting jurisdiction; and

3. enough identifying and locating information is available for a reasonable opportunity to contact the person, regardless of whether the person is in the jurisdiction of the health department.

The follow-up of out-of-jurisdiction contacts usually requires the assistance of the health departments in those other jurisdictions.

Note: Persons should not be included in the contact count if they do not need to be evaluated as judged by the health department. For example, this happens when the model of concentric circles is used. After evaluating some of the contacts who had more exposure (i.e., close contacts), the health department determines 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 not warranted for them.

Note: Sometimes contact investigations are done because of a suspected TB case before the diagnosis of TB is confirmed. If TB is excluded (i.e., ruled out), then 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.

Note: The contacts that are associated with TB cases in other jurisdictions are not counted by the jurisdiction with the contacts; they are counted by the jurisdictions that are reporting the TB cases.

- **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 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 below for reporting definitions of these outcomes). Most contacts will receive a tuberculin skin test unless their medical history indicates otherwise (see following note). Contacts who receive a skin test should not be counted under **Evaluated** until the skin test has been read. Contacts who need a second skin test because of recently ended exposure should not be counted under **Evaluated** until the second skin test has been read. Contacts who have a positive skin test result should not be counted under **Evaluated** until active TB disease has been excluded by any further tests as indicated. (Skin tests with other antigens, for cutaneous anergy, should not be considered for classifying outcomes for this report.) Note about contacts having prior TB disease or latent infection: This contact 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 are investigated are counted under **Number of Contacts**, but the diagnostic outcomes are not counted in the

contact report. Generally, these contacts can be counted under **Evaluated** even if further tests and examinations are not done because enough history is already available to determine their TB status and therefore they have been evaluated in the context of the contact investigation. If such contacts will be treated, then the treatment should be counted only in the other aggregate report, Targeted Testing and Treatment for Tuberculosis Infection, in the section headed **Part III. Referral Counts**. (These contacts are counted on both reports. They are counted on this report as contacts and then on the other form as referrals for treatment.)

- **By TST:** Number of individuals tested using tuberculin (Mantoux) skin test
- **By IGRA:** Number of individuals tested using 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. Cases should fit the CDC 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. Old TB cases that have been treated already or that have spontaneously healed, and TB disease discovered coincidentally (i.e., not because of the contact investigation), should not be counted in this category. (These instructions differ slightly from the ones for the report of Targeted Testing and Treatment for Latent Tuberculosis Infection.)

Note about DNA fingerprinting [i.e., restriction fragment length polymorphism (RFLP) or strain typing]: The results of DNA fingerprinting of *M. tuberculosis* isolates should be ignored for counting contacts under **TB Disease**, even if the fingerprinting results disprove a transmission link. The count for **TB Disease** should be tabulated for this report as though DNA fingerprinting were unavailable.

**LTBI**. This is the count of contacts who have LTBI (not TB disease) diagnosed because of current contact investigations. Both of the following criteria are required:

1. A positive result of a current tuberculin skin test (as interpreted according to national, state, or local diagnostic guidelines) and
2. the exclusion of active TB disease through further tests or examinations. Latent TB infections that have been diagnosed coincidentally or previous to the contact investigation should be not be included in this count.

Note about anergy: In determining whether to count a contact under **LTBI**, only results from a tuberculin test 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 tuberculin skin test result is being treated with a full-course regimen for suspected LTBI, then 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 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 contact's statement. If a contact 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 contact picked up the medicine from a clinic or pharmacy.

Note about window-period treatment: Contacts who are receiving treatment pending a second tuberculin skin test (i.e., window-period treatment) should not be counted under **Started Treatment** unless LTBI is diagnosed finally and counted for the report.

- **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, operational* definition of completion. It might not be equivalent to an adequate course of therapy.) The following criteria are required for counting under this category:

1. The prescribing provider, believing that an adequate regimen has been received, discontinues treatment;
2. the contact has taken at least 80 percent of the prescribed doses in the selected regimen; and
3. the treatment is finished 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 contact's statements about adherence to treatment.

- **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**. Contacts 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 check of any deaths is helpful for accuracy in reporting.)

**Patient Moved (follow-up unknown)**. Contacts who do not complete treatment because they have moved or migrated from the jurisdiction of the health department 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), then the outcome should be reclassified accordingly.

**Active TB Developed.** If a contact 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.** If contacts do not complete treatment because of an adverse effect (including drug-drug or drug-food interactions) of the anti-TB medication, they should be counted in this group if a healthcare 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, then the reason for stopping treatment should be counted as Contact

**Patient 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 healthcare 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.

**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 contact 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.

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 either ratios or percentages by TIMS. The formulae are shown in the paper-copy table to show the source figures for the calculations.