

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

## Introduction

This report is an annual summary of the core activities of eliciting and evaluating contacts to tuberculosis (TB) cases and treating the contacts who have latent TB infection. 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 generally 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 latent TB infection.

There are two forms used in California to report contact investigation aggregate data for TB program evaluation. Local health departments reporting one or more cases during the count year are required to complete and submit the “California ARPE: Follow-up and Treatment for Contacts to TB Cases (CA ARPE-CI) Preliminary and Final Report” forms. Jurisdictions with no cases counted during the calendar year are not required to submit an ARPE form.

**CA ARPE-CI Preliminary and Final Reports (*California instructions*).** CDPH TBCB modified the CDC ARPE-CI to create two CDPH forms. CDPH 8635 A is the **California ARPE-CI Preliminary Report form (CA ARPE-CI Prelim)**. CDPH 8635 B is the **California ARPE-CI Final Report form (CA ARPE-CI Final)**. Please use these forms when reporting contact data to the TBCB.

The **CA ARPE-CI Preliminary Report** (CDPH 8635 A) includes Part 1 through “Started Treatment” (row g), plus the corresponding Part II. Evaluation Indices (all indices excluding Completion Rate). The portions of the form which should not be included in the Prelim report are greyed out on the CA ARPE-CI Prelim form.

The **CA ARPE-CI Final Report** (CDPH 8635 B) comprises the complete ARPE form and includes the previously submitted CA ARPE-CI Prelim data for the given cohort.

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 Centers for Disease Control and Prevention (CDC) Division of Tuberculosis Elimination (DTBE).

**Reporting Schedule (*California instructions*).** Submission dates for the CA ARPE-CI Prelim reports are scheduled for approximately three and a half months after the end of the cohort. The CA ARPE-CI Final reports are due to TBCB one year after the CA ARPE-CI Prelim reports. CA ARPE-CI Prelim and Final report forms and instructions will be mailed to all local health departments two months prior to the submission deadline. Please refer to the [‘Schedule for Reporting Contacts to TB Cases in California’](#) for specific dates by which all local health departments in California should submit the CA ARPE-CI Prelim and Final reports.

LINK: <http://www.cdph.ca.gov/programs/tb/Documents/TBCB-ARPE-Schedule.pdf>

Local health departments wishing to internally track contact investigations in 6-month cohorts may request line listings from the TBCB at 6-month intervals.

### CA ARPE Form Instructions

#### 1. Cohort Year

ARPE data are accumulated into cohorts that cover one calendar year (i.e., January-December). Contacts are assigned to the year in which the index TB cases were counted and reported to the State using the count date (variable #6 "Date Counted" on the CDC Report of Verified Case of TB [RVCT]) for the case to which the contact is linked. A person included in more than one contact investigation in a cohort period should be counted for each event, but contacts exposed to multiple TB cases connected to a single contact investigation (i.e., index and secondary cases) should each be counted only once.

#### 2. Total TB Cases Reported

This is the total surveillance TB case count for the cohort year including cases without associated contact investigations.

### Part I. Cases and Contacts

#### 1. Types of Cases for Investigation (Columns)

The TB cases, their contacts, and all the subsequent results are grouped into the following three categories according to the type of TB index case. Cases for investigation include all respiratory cases, defined as pulmonary or laryngeal TB (variable #16 "Site of TB Disease") on the RVCT.

- **Smear (+)**

All of the following criteria must be met to count cases in this category:

- a) inclusion in the overall surveillance count,
- b) disease site in the respiratory system (pulmonary or laryngeal), and
- c) positive AFB smear result from sputum, or bronchial or tracheal fluids, whether or not any culture result is positive.

Cases should be counted in 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).

- **Smear (-), and culture (+) or nucleic acid amplification test (NAAT) (+)**

All of the following criteria must be met for counting cases under this category:

- a) inclusion in the overall surveillance count,
- b) disease site in the respiratory system (pulmonary or laryngeal),
- c) negative AFB smear results from sputum, or bronchial or tracheal fluids, and
- d) culture or NAAT<sup>1</sup> positive result for *Mycobacterium tuberculosis* complex, from sputum, or bronchial or tracheal fluids.

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<sup>1</sup> CDC. (2009). [Updated Guidelines for the Use of Nucleic Acid Amplification Tests in the Diagnosis of Tuberculosis](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5801a3.htm). MMWR 58(01);7-10. Can be found at: [www.cdc.gov/mmwr/preview/mmwrhtml/mm5801a3.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5801a3.htm). Provides information on the NAA tests that have been approved by the Food and Drug Administration for use with AFB smear-positive respiratory specimens.

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

- **Other Pulmonary (*California instructions*)**

This category includes contact investigations conducted for verified pulmonary/laryngeal TB cases not included in the other two case categories, e.g., clinically confirmed TB, or TB confirmed by a specimen obtained via bronchial wash. Cases should be counted under this category even if contacts could not be elicited for any reason. Please note that this box is shaded on the federal CDC ARPE-CI form but is not shaded on the California ARPE-CI forms.

## 2. Data Rows

- **Cases for Investigation (*California instructions*)**

TB cases for whom contact investigations are indicated are counted here whether or not an investigation was performed. The TB cases are grouped into the three categories above according to the type of TB case leading to the contact investigation. Please note that source case investigations for pediatric cases are not reportable on the ARPE-CI.

- **Cases With No Contacts (*California instructions*)**

Cases counted in “Cases for Investigation” are reported here if no contacts were elicited, regardless of the reason contacts were not elicited. Please note that the box for this count is shaded for the “Others” case category on the federal CDC ARPE-CI form but is not shaded on the California ARPE-CI forms.

- **Number of Contacts (*California instructions*)**

All the following criteria must be met to count a person exposed to TB as a contact for this report:

1. The health department believes the person was exposed, warranting an evaluation for TB disease or latent infection. The following list of factors should be considered when determining whether evaluation is warranted for a contact:
  - Infectiousness of source case
  - Proximity of contacts
  - Duration of exposure
  - Host susceptibility of contact (e.g., immunosuppression, child, other high risk factors)
  - Environmental characteristics affecting transmission (e.g., ventilation, size of space)
  - Evidence of transmission.
2. The exposure was caused by a TB case counted by the reporting jurisdiction.
3. Enough information is available to verify a current location or phone number for the named contact, 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, as judged by the health department, they do not need to be evaluated. This may occur, for example, when the concentric circle model is used. If evaluation of contacts with the greatest exposure (i.e., “close contacts”) revealed no evidence of

transmission, the health department may determine that other contacts, who are not high-risk, and had less exposure do not require evaluation. These contacts should not be included in the ARPE “Number of Contacts.”

Note: Contacts associated with a TB case located in another jurisdiction are counted by the jurisdiction reporting the TB case, not the jurisdiction in which the contact is located.

- **Evaluated (*California instructions*)**

This is the number of contacts for whom the indicated evaluation step listed below has been completed, as part of a contact investigation, to the point where a final determination can be made about three of the potential diagnostic outcomes: latent TB infection, TB disease (see below for reporting definitions of these outcomes), or neither.

| Indications  | Evaluation Step   |
|--|---|
| ALL CONTACTS   | Interview, <sup>2</sup> <b>and</b> Symptom review                               |
| Contacts with no documented history of positive Tuberculin Skin Test (TST) or Interferon Gamma Release Assay (IGRA) or TB disease  | TST #1 placed and read, <sup>3</sup> or IGRA #1 performed and results received. |
| Contacts with TST #1 placed or IGRA #1 performed <8 weeks from last exposure, and with a negative TST or IGRA #1   | TST #2 placed and read, <sup>2</sup> or IGRA #2 performed and results received. |
| Contacts with documented history of positive TST or IGRA   | Chest imaging study <sup>4</sup>  |
| Contacts with: <ul style="list-style-type: none"> <li>• TB symptoms present, <b>or</b></li> <li>• Positive TST or IGRA #1 or positive TST or IGRA #2, <b>or</b></li> <li>• History of TB disease, <b>or</b></li> <li>• HIV infection, risk for HIV infection, <b>or</b></li> </ul> Contacts age $\leq$ 4 years | Medical evaluation, <sup>5</sup> <b>and</b> Chest imaging study <sup>3</sup>    |

Note about contacts having prior TB disease or latent infection: CA ARPE-CI reports only include those contact evaluation results determined through contact investigations. Contacts with a known history of TB disease or latent infection prior to a contact investigation should, however, be included in the **Number of Contacts**. And generally, these contacts can also be counted under **Evaluated** if their evaluation is completed according to the ‘Evaluated’ table. However, the

<sup>2</sup> Interview includes query regarding: symptoms, history of latent TB infection or TB disease, documented previous TST results, previous treatment for latent TB infection or TB disease, risk factors for developing TB disease or, other conditions of immunosuppression that are associated both with anergy or false TST positive results, and that are associated with high risk of progression from infection to disease (e.g. patients who are undergoing immunosuppressive therapy, patients who have leukemia or Hodgkin’s disease).

<sup>3</sup> Skin tests with other antigens, for cutaneous anergy, should not be considered for classifying outcomes for this report.

<sup>4</sup> May not need to obtain a new chest radiograph if a chest radiograph was done within the preceding six months.

<sup>5</sup> Medical evaluation is an in-person evaluation by a physician or other appropriately licensed practitioner.

diagnostic and treatment outcomes are **not** counted in the CA ARPE-CI reports. Contacts with a known history of TB disease or latent infection prior to contact investigation should be included in the ARPE-CI count of contacts identified. However, their treatment for LTBI should NOT be included in this report. Also, see “**Started Treatment**” below.

- **TB Disease**

Contacts should be counted under this outcome if they have TB disease (i.e., active TB) diagnosed as part of the contact investigation. Cases must fit the CDC RVCT definition and should be referred for morbidity surveillance according to the reporting requirements. Persons with active TB disease that developed after latent infection was diagnosed during the contact investigation should not be counted in this category. Persons with a history of TB who have been previously treated or have spontaneously healed, and persons with TB disease diagnosed coincidentally (i.e., not because of the contact investigation) should also not be counted in this category.

Note about genotyping: results of genotyping of *Mycobacterium tuberculosis* isolates should be ignored when counting contacts under **TB Disease** even when results disprove a transmission link. The count for **TB Disease** should be tabulated for this report as though genotyping were unavailable.

- **Latent TB Infection**

This is the count of contacts with latent TB infection (not TB disease) diagnosed through current contact investigations. Both of the following criteria must be met:

- a) new positive result of a current tuberculin skin test or interferon-gamma release assay (IGRA) (as interpreted according to California diagnostic guidelines), and
- b) exclusion of active TB disease through further tests or examinations.

Latent TB infections diagnosed coincidentally or prior to the contact investigation (prior positive TST) should not be included in this count.

Note about “anergy”: in determining whether to count a contact under **Latent TB Infection**, only results from a tuberculin test should be considered, not from skin tests with other antigens (i.e., “control” antigens or an “anergy panel”). If, however, a contact with a negative tuberculin skin test result is being treated with a full-course regimen for suspected latent TB infection, that contact should be counted under **Latent TB Infection**.

- **Started Treatment**

A contact with latent TB infection is counted in 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 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 receiving treatment pending a second tuberculin skin test or IGRA (i.e., window-period treatment) should not be counted under **Started Treatment** unless latent TB infection is diagnosed

and counted for the report.

When contacts with a known history of TB disease or latent infection prior to contact investigation are treated, their treatment information should not be included in this report.

- **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:

- a) the prescribing provider, believing that an adequate regimen has been received, discontinues treatment,
- b) the contact has taken at least 80% of the prescribed doses in the selected regimen, and
- c) the treatment is finished within a period of 150% of the selected duration of therapy.

Determination of whether the definition of “completed treatment” 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.

- **Reasons Treatment not Completed**

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

- **Death**

Contacts receiving treatment on schedule 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 check of all deaths is helpful for accuracy in reporting.)

- **Contact Moved (follow-up unknown)**

Contacts who do not complete treatment because they have moved or migrated from the health department jurisdiction should be counted in this category when follow-up information is unavailable. If, however, the health department receives specific follow-up from another jurisdiction (e.g., **Completed Treatment** or **Patient is Lost to Follow-up**), then that outcome should be reported.

- **Active TB Developed**

If a contact who is receiving treatment for latent TB infection develops active TB, that qualifies as a case under the standard surveillance definition (i.e., RVCT), then the outcome is counted in this category. If, however, the treatment regimen has already been stopped before active TB developed, because of completion or any other reason, then the outcome should not be reported as **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 provided that 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, then the reason for stopping treatment should be counted as **Contact Chose to Stop**.

Note on reporting adverse events associated with treatment of LTBI: To monitor adverse effects, CDC has established an LTBI treatment adverse effects surveillance system. Adverse effects leading to hospital admission or death should be reported to Janice Westenhause (email address: [janice.westenhause@cdph.ca.gov](mailto:janice.westenhause@cdph.ca.gov)) at the California Department of Public Health for inclusion in this system. Adverse events or medication errors also should be reported to [FDA MedWatch](http://www.fda.gov/medwatch) at <http://www.fda.gov/medwatch>, by submitting a [MedWatch Form 3500](http://www.fda.gov/medwatch/safety/FDA-3500_fillable.pdf) (available at [http://www.fda.gov/medwatch/safety/FDA-3500\\_fillable.pdf](http://www.fda.gov/medwatch/safety/FDA-3500_fillable.pdf)) or by calling: 1-800-FDA-1088.

- **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 to determine a more specific outcome should be counted in this category.
- **Provider Decision**

Contacts whose treatment is discontinued because a health care provider determines that treatment for latent TB infection should be stopped due 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) should be counted in this category.
- **Still on Treatment**

Contacts who are still on treatment at the time the report is due should be counted in this category.

## Part II. Evaluation Indices

This part of the contact follow-up report contains the summary statistics calculated from the aggregate data in Part I. of the report. The formulae for each cell are shown in the paper-copy table.

**California instructions.** Calculation and reporting of these indices is encouraged when using the paper CA ARPE-CI reports. These indices can help evaluate contact investigation activities in local health jurisdictions.