Aggregate Reports for Tuberculosis Program Evaluation: Training Manual and User's Guide

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TB Elimination

Aggregate Reports for Tuberculosis Program Evaluation (ARPEs): Training Manual and Users Guide

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Prepared by John Jereb and Linda Leary
Field Services and Evaluation Branch,
Zachary Taylor, Branch Chief
Division of Tuberculosis Elimination
National Center for HIV, STD, and TB Prevention
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

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Bureaucrat's code:
That which gets measured, gets done.
If it was not recorded, it did not happen.

Introduction

Worldwide, the highest priorities for tuberculosis control are comprehensive case finding and case holding. This is how patients are cured of tuberculosis. Besides saving the lives and the productivity of the individuals who have tuberculosis, society gains an additional benefit: when the patients are cured, transmission is interrupted. Case finding and case holding in the United States are monitored through the national surveillance system, which is explained in separate guidance from the Division of Tuberculosis Elimination (DTBE) of the Centers for Disease Control and Prevention (CDC).

The Aggregate Reports for Tuberculosis Program Evaluation (ARPEs), the subject of these instructions, help you to evaluate some other activities that have a different approach. In the United States, resources for tuberculosis control are available for going beyond curing cases by preventing them in the first place. Examples of prevention activities are contact tracing, targeted tuberculin testing, and treating latent tuberculosis infection (LTBI). These activities accelerate tuberculosis elimination, but they are labor intensive and offer mainly remote return for the investment. Therefore, careful evaluation of these activities is critical for assessing their validity in your setting. ARPEs are the national summary tools for confirming the merit of these activities for you.

This manual will help you in three general tasks for ARPEs. The first task is collecting the best data that is feasible in your setting. The second is assembling the data, storing and combining the reports, and submitting them efficiently. The third is the most important: interpreting the results of your reports while considering their limitations. This final task creates the opportunities for improvements in your tuberculosis-prevention activities.

Who can use ARPEs

Tuberculosis control starts at the local level, at each health department and with each provider who cares for the patients who have tuberculosis or who are exposed to it. Everyone who undertakes prevention activities and contributes to the data collection should be empowered to understand the results of ARPEs and to respond with ideas for improvements. Within a local health department, the principal user of ARPEs is the tuberculosis program manager. Other workers in tuberculosis control, such as public health nurses, outreach workers, and physicians, should be kept aware of the results of ARPEs so that they can recognize their contribution to the overall efforts.
Within a state health department, the principal users of ARPEs are the regional supervisors, the program manager, and the tuberculosis controller. The reports are a

communication tool—the common language for evaluating and coordinating tuberculosis-prevention activities statewide. For policymakers, the reports are the documented summary of the work that has been accomplished and the improvements that are still needed. Epidemiologists also can take advantage of the reports, although they should be cautioned that the reports are not designed for epidemiological studies.

At CDC in Atlanta, the principal users of ARPEs are the DTBE program consultants, who administrate the Federal tuberculosis cooperative agreements with states, large cities, and U. S. Trust Territories and Protectorates. The DTBE program consultants use ARPEs to study program operations and progress toward the national objectives. DTBE as a whole uses the national ARPE results as documentation of progress toward program objectives and as a corroboration of nationwide funding needs.

Who should use this manual

If you generate or collect ARPE data, you should use this manual as a reference for defining these data. Also, if you need to assemble, submit, or interpret ARPEs, you will find useful hints in this guide.

At workshops, DTBE trains state ARPEs coordinators, and these coordinators should refer to this manual as a refresher or as a template for their own training workshops. The manual also can be used as stand-alone instructions for persons who are learning about ARPEs on their own or who need an explanation of the reporting instructions.

Administrative structure of tuberculosis control in the United States

Authority for tuberculosis control in the United States rests with state governments; some states devolve authority to local jurisdictions, such as districts, counties, townships, or cities. Public health officials are responsible for certain actions, which include gathering information about selected hazards and diseases and taking action to protect their citizens from these conditions.

With few exceptions, CDC does not have the authority to undertake public health activities directly unless it is invited to act on the behalf of a state or other jurisdiction. In its usual role, DTBE facilitates tuberculosis control by monitoring epidemiology, formulating strategy, offering consultation, promulgating guidance, and disbursing funds. Other components of CDC contribute to epidemiologic response, program development, laboratory services, training, and tuberculosis screening of international migrants.

Most CDC funding for tuberculosis control is distributed through cooperative agreements, a non-contractual mechanism. DTBE and the local or state health jurisdiction

set expectations for working together on the shared tasks of tuberculosis control. The health jurisdiction is obliged to carry out recipient activities that are outlined in the agreement—reporting with ARPEs is one of these recipient activities.

Federal approval for CDC to collect ARPEs

The U.S. Office of Management and Budget (OMB) approved a CDC application to collect and use ARPEs under OMB #0920-0457. OMB requires renewal of this approval every 3 years. CDC must seek additional OMB approval, subject to a public comment period, for any ARPEs amendments. Respondents have the option of commenting to OMB about the reports at any time. Please see the report form for instructions on how to do this.

Under the OMB approval, DTBE may request, collect, and use ARPEs from public health officials for the jurisdictions that receive federal tuberculosis cooperative agreements. ARPEs are stipulated in the cooperative agreements, but the reports are classified as voluntary/optional. Nonetheless, DTBE interprets a failure to submit ARPEs as evidence of potential program problems, possibly caused by insufficient resources or unbalanced priorities.

Strategies for finding and treating latent tuberculosis infection

Experienced tuberculosis controllers are keenly aware of the discrepancies between the theory and the reality of finding and treating latent tuberculosis infection (LTBI). Although the guidelines about LTBI appear to be straightforward on the surface, in truth the tasks are challenging, and efficiency and effectiveness are difficult to achieve. In this section, we review the general principles that influence the success of your prevention activities.

The success of your prevention activities is governed by three elements that we all need to balance simultaneously in order to have successful public health interventions. These elements are: (1) finding and accurately diagnosing LTBI, (2) determining the urgency of treatment, and (3) completely treating the patients who have LTBI. Problems in any of these three areas will detract from the success of your activities. For example, if you start a project that finds dozens of at-risk patients who have LTBI but none of the patients start or complete treatment, the project does not contribute to tuberculosis prevention. ARPEs give you a broad overview that helps you to find problems and to strike a balance among the three elements.

Finding and accurately diagnosing LTBI

Finding and accurately diagnosing LTBI depends on the prevalence rate of LTBI in the population that is under consideration. The prevalence rate refers to how common LTBI is,

and it is a population characteristic that reflects the tuberculosis history of the population. The prevalence rate controls how many infected individuals you will discover by testing. This is your yield of LTBI. The minimum prevalence rate for a successful strategy is unknown, but you need to take a critical look at the balance of the three elements if you are testing in a population having an LTBI prevalence rate less than 10 percent.

The LTBI prevalence rate also influences the accuracy of the tuberculin skin test.[1] This is because the predictive value of a positive test result depends on the prevalence rate. When the prevalence rate is low, the predictive value of a positive result is also low. For example, when the LTBI prevalence rate falls below 10 percent, most of the patients with positive results from the skin test actually will have false-positive results. Therefore, when the prevalence rate of LTBI is low, most of the patients who are being treated for LTBI are actually not at risk for tuberculosis because they do not even have LTBI. This is wasteful of resources and possibly hazardous to the patients.

Determining the urgency of treatment

The urgency of treatment for LTBI patients depends on how likely they are to get sick with active tuberculosis. If the likelihood of active tuberculosis is high, then the urgency of treatment is high. One example is the patients who have been recently exposed to contagious tuberculosis (i.e., contacts). We also worry about patients who have medical problems that change their immune capacity: co-infection with the human immunodeficiency virus (HIV) is a very serious example.

The urgency of treatment is relative. No one can predict which patients with LTBI are going to become sick with tuberculosis. The risk of tuberculosis might be high, medium, or low, and this determines the urgency of treatment. The current medical condition and the tuberculosis exposure history are factors to consider when determining the urgency of treatment for an individual. The final decision to treat rests with the individual patient and the prescribing provider.

Sometimes the urgency of treatment offsets the concerns about testing a population with a low LTBI prevalence rate. For example, infants who might have been exposed to contagious tuberculosis should be tested even if the exposure was minimal because infection could be very dangerous for them. In this example, the concern about the danger of tuberculosis overrides the low yield of testing.

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[1] Recent developments in blood tests for infection with *M. tuberculosis* offer the possibility that they might perform better than the tuberculin skin test. DTBE will send an amendment to these ARPEs instructions if these blood tests are implemented and if they substantially alter the way that contact investigations and targeted testing are done.

Completely treating the patients who have LTBI

Finally, LTBI patients who are good treatment candidates must start and complete treatment if prevention activities are to be effective. Activities for finding LTBI must be followed by decisions about treating patients (based on the urgency of treatment) and monitoring them for adverse effects and completion of therapy. **This does not mean that every single instance of LTBI should be managed with medical treatment.** It does mean that activities for finding LTBI should be undertaken with (1) a goal of finding patients who are most likely to benefit form treatment and (2) a strategy and support systems for getting patients all the way through treatment.

Targeted testing

You start targeted testing by choosing a population that has either a high prevalence rate of LTBI or a high risk of disease if infection is present. Having both conditions present gives maximal potential public health impact. The results of targeted testing are reported in the ARPE: Targeted Testing and Treatment for Latent Tuberculosis Infection.

Your activities for targeted testing often will be adapted to fit the population you have chosen. When the individuals can be tested as a group, your activities take the form of a project. For example, you might go to a nursing home twice a year to test any new residents.

Under different circumstances, you might be testing some individuals who are at risk for tuberculosis and who come to your clinic, perhaps for reasons besides tuberculosis. For example, you might test persons who attend prenatal clinic at your health department if they come from countries where tuberculosis is common. These activities are still targeted testing because you are selecting the individuals who should be tested. However, these activities are not a project, because you have not set up a system for finding and reaching the populations at risk for tuberculosis. The distinction is subtle, and it does not always have practical significance. When the distinction is vague for your situation, you and your colleagues should make a decision about how to count the data and then follow that decision consistently.

Contact investigations

One very special type of targeted testing, and the highest priority, is a contact investigation. In a contact investigation, you test a population that you selected because of recent exposure to a contagious tuberculosis patient. The prevalence rate of LTBI for contacts is likely to be greater than average. Also, the recent exposure means that some contacts might be sick already with tuberculosis disease at the time that they are evaluated, and the contacts who have LTBI are at a relatively high risk for tuberculosis

disease. The structure and the issues of a contact investigation are so distinctive that they have to be evaluated as a specific system of activities, separate from other types of targeted testing. The results of contact investigations are reported in the ARPE: Contact Follow-up and Treatment.

Accountability is different from responsibility

Health departments have responsibilities to protect their communities from certain threats to public health, as laid out in state and local laws. One of these threats is tuberculosis.

Health departments also have general responsibilities to evaluate their effectiveness and to account for their work. ARPEs are **accounting tools** designed for evaluating selected prevention activities. ARPEs help you to account for key processes that are important for monitoring tuberculosis-prevention activities.

You might feel reluctant to report on activities that make your program or your health department appear unsuccessful. Most of us would prefer to gather and classify data in a way that puts the emphasis on success. However, ARPEs cannot serve you unless they realistically reflect what happens with your activities. The only way to evaluate the prevention activities of your tuberculosis program is to account for the processes as accurately and consistently as possible.

Some of the events that appear in ARPEs are beyond your immediate control. Example: a patient who has LTBI after recent exposure seeks advice from a healthcare provider who advises against treatment for LTBI. This is problematic for tuberculosis control. You are responsible to **count** this event, even though you were not responsible for what happened. In this instance, the health department is accountable for an event but not immediately responsible for it. At least, you learned that you need to build a collaboration with the healthcare provider who does not like to treat LTBI, but in this instance, the purpose of reporting is more to keep track of important outcomes and less to measure the performance of the health department.

Structure of the ARPE Forms and Data

The report forms follow a common-sense flow of information from left to right and from top to bottom. The activities with higher priority are grouped in the left-most columns on each of the two forms. The sequence of outcomes flows from top to bottom, with the initial process steps recorded in the top rows of both forms and the later steps listed in lower rows. The bottom-line results for both reports are the absolute number and the percentage of LTBI patients who complete treatment for their infection.

You begin the ARPE reporting process with data for individuals and events, and you finish with the data in an aggregate format. This means that the data are lumped together, and you cannot study any factors separately without returning to the original records for those individuals and events. Sometimes you can overcome the limitations of aggregate data by keeping separate records and sub-reports that you predefine in accordance with your needs. This refinement is described in "How to Interpret and Use the ARPE Results" on page 99.

At the bottom of the reports, the calculated indices are listed. These indices are the rates and ratios that are calculated from the aggregate data, and they are an aid in comparing overall results with program objectives.

Data required for these reports

The specific minimum data elements that are required for ARPEs are listed in appendix 2 for the contact report and in appendix 4 for the targeted-testing report. With these data, you have all the information for filing representative reports and monitoring the prevention activities of your program.

For the contact reports, the data about source cases, that is, the tuberculosis cases that are at the center of contact investigations, are coded in the Report of a Verified Case of Tuberculosis (RVCT) in tuberculosis registries. Case registers are different from place to place, and you need to be familiar with your registry so that you can assemble essential data (unless automated links between case and contact data are available to you already).

Data about contacts are managed differently from site to site in accordance with local and state program needs. Routine contact-investigation flow sheets (i.e., tables showing the outcome of contacts when they are listed and evaluated) usually include all the data needed for the contact reports except for the treatment completion data and the reasons treatment is not completed. For contacts numbering fewer than approximately 200, original medical records are a feasible option for retrieving contact data, but data for greater numbers of contacts can be cumbersome when original medical records are the main source. For greater numbers of contacts, you probably need an automated tracking system, which also can help in many other ways.

Data for targeted testing are similar to data for contact investigations, but the absolute numbers of patients who are included in counts could be greater. Therefore, you need as much simplification and automation as possible to improve accuracy, efficiency, and feasibility.

For the targeted-testing report, the risk classification of patients who have LTBI is the most distinctive feature. Although the data are collapsed into two general risk categories (i.e., medical risks and population risks), each of these categories includes multiple conditions. Therefore, you might prefer a data worksheet that has check boxes related to the conditions listed on pages 21 and 22.

ARPEs are relatively simple tools, and they might not encompass all the data that you need. You and your colleagues might determine that more detailed information is needed for assessing certain aspects of your prevention activities. DTBE encourages collection of additional data for state and local program purposes if (1) the extra effort that you invest in data collection is balanced by the potential value of the data and (2) the results of the evaluation ultimately are used to improve the effectiveness and efficiency of prevention activities. As with any data collection, the challenge is to validate the extra work by showing a benefit for the program. The collection of additional data should be planned carefully with clear goals for program evaluation and improvement. Any of your personnel who are responsible for gathering or generating the data should be consulted about proposals for data elements that go beyond the minimum required for ARPEs.

How to classify data for these reports: motivation, uniformity, and coordinators

You will discover that the Basic Instructions for the Aggregate Reports for Tuberculosis Program Evaluation (pp. 13–26) do not include all possible situations and outcomes that you encounter. This is because the instructions and the reports were designed for simplicity and for ordinary day-to-day operations. Simple reports such as these cannot accommodate all the details of either your tuberculosis program activities or your individual patients.

The classification of most patients and most outcomes is straightforward after you are comfortable with the reporting instructions. Still, you will come across events that are not covered by the reporting instructions. For these situations, someone will need to move beyond the confusion and decide how to count the patients or events—this might seem arbitrary at first. In this section, we outline some general concepts to make this process more transparent.

By stepping back from the details, you often can answer your own questions by asking yourself and your colleagues, "Why are we collecting these data in the first place? What do the data mean? How will the results help us describe our program activities?" These are the justifications for collecting the data, and in most instances they will help resolve a dilemma.

On the other hand, the reason for having definitions in the first place is to explain how the data elements (e.g., patients, results, outcomes) should be classified. The goal is to have everyone in your program and in other programs classify specific data elements identically. This is **uniformity**, and uniformity should be guarded when making adjustments in the definitions for local purposes. ARPEs, the same as other data collection tools, require a careful, consistent balance between flexibility and uniformity.

ARPE **coordinators** should supervise the uniformity of reporting. For most jurisdictions, the coordinator is a member of the state tuberculosis program who has attended one of the ARPE workshops sponsored by DTBE. If local jurisdictions designate their own ARPE coordinators, then the state tuberculosis program should link the local coordinators with each other and with the state program so that everyone contributes to uniformity. The administrative details of how the coordinators work together should be determined.

Coordinators can monitor uniformity through routine communication with program personnel who are engaged in prevention activities and data collection. Keeping track of questions and answers in a simple log book allows a quick summary of the common problems plus a list of rare problems for future reference. This method makes the entire ARPEs process smoother.

At the national level, DTBE seeks overall uniformity of reporting. To this end, the DTBE program consultants work with ARPE coordinators in each state program. When state coordinators are considering variations on the standard definitions, they should contact their DTBE program consultant for a national perspective. The program consultants can offer helpful suggestions, and they can share solutions that the ARPE coordinators in other states have discovered.

The Basic Instructions and Definitions for Reporting

This section contains copies of the basic definitions for both reports, as approved by the U. S. Office of Management and Budget under package #0920-0457. CDC cannot change these instructions without an amendment approved by the Office of Management and Budget, which requires an extensive process of public comment and official review.

However, individual jurisdictions within the U. S. Trust Territories and Protectorates may adjust or expand the definitions to accommodate local or regional needs, as described in the previous section. Any changes to the definitions should be consistent with the intentions of the report, and if the revised definitions are printed for local use, they should be labeled as different from the national ones so that they are not misinterpreted.

Proposed changes should be discussed and coordinated with the corresponding program consultant, Field Services and Evaluation Branch, DTBE.[2]

The instructions and definitions generally follow the order of elements in the reports, from top to bottom and left to right. The instructions for the two reports are as similar as possible. However, the instructions are slightly different between the two reports in a few ways because contact investigations and targeted testing are different from each other. These differences are explained in **Extended Definitions: Understanding the Concepts**.

In **Extended Definitions: Understanding the Concepts** (see page 26), which is the section right after **The Basic Instructions and Definitions for Reporting**, the instructions and definitions are repeated and expanded one point at a time. **Extended Definitions** explains the definitions in a way that is helpful for meeting challenges of unusual situations.

[2] The TB controllers of each cooperative agreement site are familiar with the program consultants and can facilitate communications.

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 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, 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 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.

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.)

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.

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.

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.)

Contact 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 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.

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.

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 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, 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.

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.)

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 jejunoileal 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.

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.

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.

Extended Instructions and Definitions: Understanding the Concepts

This section is designed for ARPE coordinators and others who need in-depth discussions of the instructions. Each item from the basic instructions is quoted (in small font type) and then is expanded to encompass more details, the underlying concepts are reviewed, and practical issues are discussed. This section will help you when you encounter complex situations that do not fit into ARPEs in any obvious way.

When you encounter complex situations, a single question can resolve many dilemmas: why are we collecting this data? Or, how are we planning to use this data? The data and the reports are designed to serve the tuberculosis control program. If the reporting process itself becomes disruptive because the data are difficult to classify and interpret, then the issues should be resolved quickly with concise, consistent solutions.

Consistency is an important goal when making decisions about complex data. Consistency means that when a similar complex situation is encountered later, a similar process will be followed. (In contrast, uniformity means that a similar process is followed by your colleagues who are working in different settings.) Two methods will improve consistency: team work (i.e., consensus building) and record keeping. Team work builds a clearer perspective on difficult data. Record keeping, such as maintaining a reporting log book, provides a quick reference for reviewing both recurrent problems and the solutions that have been used previously.

Extended instructions: contact report

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).

ARPEs are a tool for program evaluation. A potential hazard of these reports is that the reporting instructions and the data definitions might be misconstrued as treatment recommendations or program guidelines. The reporting instruction and the data definitions are derived from national guidelines and recommendations, but they are much simpler.

For example, the data definitions for completion of therapy in ARPEs specify the number of doses and the duration of treatment. However, when therapeutic decisions are under discussion for individual patients, treatment recommendations and medical judgment must be followed instead of ARPEs instructions. Under unexpected circumstances, the appropriate treatment decisions might cause a problem with reporting, but patient care is more important than these reporting definitions.

In another example, the ARPE results for a certain contact investigation might suggest that too many contacts were evaluated, with a low yield. However, the decision about how far to extend a contact investigation should be based on judgment derived from experience and program guidelines and not on results in ARPEs.

ARPEs are not capable of accommodating all the issues that must be considered for making programmatic decisions. The aim of ARPEs is general results, and the ARPE coordinators and the program managers have to recognize how unusual circumstances caused peculiar results in the reports. This is critical for taking advantage of the reports.

State and local jurisdictions should consult with each other on the reports when questions arise. For example, the designated ARPE coordinator in the state tuberculosis control program might be responsible for tracking all ARPEs-related questions and responding to

them. At DTBE, the program consultants for each reporting area[3] are the main point of contact for questions that are directed to the national tuberculosis program. They have available a range of public health specialists to assist them.

> The contact report is an annual summary of the core activities of eliciting and evaluating contacts to tuberculosis 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 are cooperating with the health department in confirming the results from contact evaluations and in managing the treatment of contacts who have LTBI.

Contact investigations are the second most important element in the U.S. general strategy for tuberculosis control. Contact investigations are a direct method for finding recent LTBI, and they also are probably the most efficient, productive method for active-case finding in the United States.

In spite of these benefits, contact investigations present some of the biggest challenges that a tuberculosis program routinely encounters, and some investigations require an intensive, long-term investment of personnel and other scarce resources. Evaluation of these activities is important for validating the investigations. This is the purpose of the contact report.

The contact report is completely unable to detect one very serious type of problem: long-term consequences of incomplete contact investigations. If infected contacts are missed (this can happen because the contacts are not elicited in the first place or because contacts are listed but not found, evaluated, or started on treatment), then these contacts might have tuberculosis disease later on. This problem can be addressed with an integrated epidemiological investigation, which is separate from ARPEs.

In many jurisdictions, some or even all contacts receive their medical evaluations and treatments through providers besides the health department. Examples of other providers are private physicians; health maintenance organizations; and comprehensive systems such as correctional settings, military bases, and hospitals. Collecting data from other providers is difficult to initiate, but you should pursue the data anyway. In some settings, the only source of information about contacts is outside of the health department. By seeking the data, you become acquainted with other providers in your jurisdiction, and they learn about the services provided by the health department. Working with other

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[3]For most jurisdictions, the state TB controller or the TB nursing consultant is the point of contact for communications with the DTBE program consultants.

providers gives you an opportunity to educate them about tuberculosis control policies and procedures, and you can participate in decisions for individual patients.

For the contact report, you should regard ARPE data from providers outside of the health department as equivalent to data that you generate from your own patient care activities, although you can anticipate practical differences. Separate analyses of data from different sources might provide important information under certain circumstances. For example, you could measure the completion of therapy for contacts who go to private medical providers and compare the rate with that of patients who start treatment at the health department.

Please note that the instructions on data from other sources are slightly different for the targeted-testing reports because the purposes of the data collection are different.

For two special circumstances, contact-related data can be reported in the other aggregate report: Targeted Testing and Treatment for Latent TB 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.

Sometimes the health department has to do extraneous work in a contact investigation, but this extra work barely is related to the basic tasks of contact investigations. This extra work should not be counted in the contact report because it dilutes the meaning of the results. This report is intended to show the results that were achieved in seeking, evaluating, and treating persons who were likely to be exposed to tuberculosis and thus likely to be infected recently.

One example of extra work in Point 1 (above instructions) occurs when the health department is investigating a case of noncontagious (negative results from sputum smear and culture) tuberculosis in a grade-school child. Probably the initial investigation will find no evidence of transmission to household contacts (unless, of course, an actual contagious tuberculosis patient happens to be part of the household). Even though tuberculosis in grade-school children rarely is contagious, the health department might encounter pressure to test the child's schoolmates. Under these circumstances, the health

department is testing children who probably are not contacts, in the sense that that they were unlikely to have been exposed to tuberculosis. These pseudo-contacts should not be counted in the contact report. The health department has two main options for counting the grade-school contacts in this example: include them on the contact report anyway and later explain why the number of contacts is greater and the infection rate for contacts is much lower than anticipated, or report them as counts in low-priority testing on the targeted-testing report. The first option probably will increase the number of contacts in the third column of the contact report, where results from other types of contact investigations are counted. The second option is a better reflection of the work done by the health department and the reasons for doing it, but this second option does require more effort to sort out the data. (A third option would be not counting these contacts at all.)

Point 2 refers to a very different situation that appears only in unusual settings. Contact investigations can find contacts who had previous tuberculosis disease (self-resolved or incompletely treated) or previously diagnosed LTBI, and after a full evaluation these persons might be regarded as good candidates for treatment of LTBI. However, this diagnosis and treatment of LTBI (or old, healed tuberculosis) is not supposed to be counted on the contact report because the diagnosis was made before the contact investigation. The steps that **were** attributable to the contact investigation were finding and evaluating the contacts, and these steps **should** be counted on the contact report.

If the health department undertakes treatment of these contacts (in Point 2 of the above instructions) who have previously diagnosed LTBI, then the results can be counted in the targeted-testing report in the section called **Referral Counts**. The concept here is that the health department has referred these patients to itself for treatment.

Under both Point 1 and Point 2, transferring the data to the targeted-testing report for these special purposes improves the quality of the data but also increases the clerical work for the health department. Therefore, these options should be undertaken only with the intention that the improved data will be useful in evaluating the prevention activities. These options increase the complexity and effort of reporting, and the ARPE coordinator should monitor these points for consistency and uniformity.

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.

This brief instruction includes several major points. First, the reports are on an annual cycle. The contacts who are collected for one annual cycle are counted together in a cohort, which means a group that is traced in aggregate through the course of all outcomes for all contacts (within the bounds of the closure date for reporting). The counting cycle is based on the calendar year.

Next, the contacts are linked with the tuberculosis cases that are under investigation, and the contacts are assigned to their cohort year depending on the count-year of the index cases. Count-year for index cases is determined in RVCT, which is the national tuberculosis surveillance form.

Next, under unusual circumstances, some contacts are exposed to more than one tuberculosis case in the same year. For example, within 1 calendar year, a person might be exposed to a tuberculosis case that is counted in March and later to another tuberculosis case that is counted in November. In this instance, the person is counted as a contact for each exposure, that is, the person is counted independently twice as a contact. However, if LTBI or tuberculosis disease were diagnosed in the first contact investigation, then neither of these diagnostic outcomes could be counted for the second investigation, although the contact could be counted as evaluated in the second investigation because all the work (for listing and checking the contact in the second investigation) was done.

Lastly, under other unusual circumstances, one person might be a contact to two or more tuberculosis cases in the same investigation. This might occur during a tuberculosis outbreak, where one contact is connected to several different cases that are epidemiologically related as a case cluster. This is a dilemma because each tuberculosis case in the outbreak might require a separate contact investigation that should be reported in the contact report. The individual who potentially was exposed to several of the tuberculosis cases in the cluster should only be counted as a contact once, if only one medical evaluation is required for all the exposures. Generally, for counting purposes, such a contact should be assigned to the case that was being investigated at the time that the contact was listed first; however, these situations can be very complex, and they should be settled with assistance from an ARPE coordinator who can document the circumstances.

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, 1 year later.

The purpose of the closure date is to establish administrative finality for processes that might be prolonged beyond reasonable limits. This implies that arbitrary criteria have been set, because what is reasonable is subject to interpretation. However, the U.S. tuberculosis controllers who contributed to the development of ARPEs believed that the closure dates were acceptable for capturing most of the important prevention work, because most outcomes should be available before the stated closure dates.

Occasionally, outcome events might occur later than the closure dates. For example, a contact who starts treatment for LTBI much later than the contact investigation might not complete treatment until later than the second (i.e., final) ARPEs closure date. The contact reports still should be closed on August 15, and the report should not be revised for including this unusual completion of therapy after the closure date. In the example given, the contact will be counted as having started treatment but not as having completed treatment. You should note that this is an extreme example. If it occurred routinely, then it might indicate a systematic problem.

The contact report has two closure dates. The first closure date marks the end of the preliminary report. The preliminary report records the cohort of contacts that are included for the count-year. Most if not all of the contacts that are going to be counted should be counted by the first closure date. In addition, most of the data about evaluating/diagnosing contacts and starting treatment for contacts with LTBI should be ready also. The second closure date marks the end of the final report, which should include the outcomes for contacts who received treatment. The final report focuses on completion of therapy.

Even for reports that are delayed administratively, the closure dates should be observed in regards to classifying data for the report. Reports should not be revised for data from events that occur after the final closure date, because this causes inconsistencies.

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

The total tuberculosis cases that are reported should match what is reported to DTBE in routine surveillance via RVCT/SURVS/TIMS. The result is included on the report as a reference point, and it is not used in the calculation of any of the indices. When a contact report is entered into TIMS, the software has a validation check to confirm that the total of

the cases for investigation in the first two columns of the report does not exceed the total for the year. However, no software automatically enters or checks the counts for cases reported.

Sometimes, the total cases reported by a tuberculosis program changes by a small number. Ideally, the contact report should show the same case count that the tuberculosis program does for other purposes, but this is not a critical detail.

Please note that, within a state or big-city reporting area, the rules for counting tuberculosis cases (e.g., counting cases at the county level) can be different from one jurisdiction to the next. If this is a problem for the contact report, then the ARPE coordinator should discuss potential solutions with the program consultant at DTBE.

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.

The three columns are a distinguishing feature of the contact report. This structure reflects the levels of urgency for contact investigations, and it is fundamental to interpreting the results. The first column lists the results of investigations of respiratory tuberculosis cases with a positive AFB sputum smear. These cases are likely to be the most contagious; therefore the contact investigations take a high priority. The second column lists the results for respiratory cases with a negative AFB sputum smear but a positive culture result. These cases are likely to be less contagious, but transmission is still possible and therefore most tuberculosis programs undertake complete contact investigations. The third column includes a range of other activities with lower efficiency. The criteria for the three categories follow.

The important feature to note is that the three columns establish the data structure for the contact report. This is because data for contacts are grouped with the cases and listed under them. Data do not cross between the columns, although a tuberculosis case counted as a contact diagnosis/outcome in one column subsequently might be a case for investigation in a different column. This is a reflection of standard operations and it does not entail any transfer of data between columns.

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 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).

In most ways, these instructions match the reporting instructions for RVCT. For the contact report, three points are listed (above) and expanded here:

1. Only cases that are counted by the jurisdiction submitting the contact report should be included. In other words, the jurisdiction has to count a case before the contacts can be counted, and contacts from cases that are not counted for this column should not reported in this column. This can occur when the RVCT criteria are not met for any reason or when the criteria are met but the case is counted by a different jurisdiction.

2. For the contact report, the case should include tuberculosis disease somewhere in the respiratory system, which for these purposes extends from the epiglottis down to the alveolus and includes all the connecting airways. This is slightly different from the RVCT definition for pulmonary, which does not include the upper airway. The reason for the difference is that upper-airway tuberculosis, including laryngeal tuberculosis, can be a very contagious form, and this is relevant to setting priorities for contact investigations. In practical terms, upper-airway tuberculosis usually includes pulmonary disease anyway. On other points, the contact report follows the same reporting instructions as the RVCT. The hilum and the pleura are defined as extra-pulmonary structures for surveillance. Tuberculosis in these locations is unlikely to be directly transmissible. Therefore, pleural or hilar tuberculosis are not by themselves sufficient for counting in this category of a contact report, but a positive sputum smear or culture is not expected anyway if tuberculosis is solely in these sites.

3. The positive AFB sputum smear result can be read from a direct specimen smear or a sputum concentrate. The central word here is “sputum.” Sputum is the specimen that the patient expectorates, whether it is spontaneous or induced. Specimens that are collected via lavage or biopsy through a bronchoscope or any other route are not counted with sputum. This is compatible with the RVCT instruction. The reason for the distinction is that the epidemiological impact of tuberculosis cases that are diagnosed without a sputum AFB examination is not known. Please note that positive smear results from sputum specimens obtained before or after a bronchoscopic procedure are valid for counting in this category. The sputum culture result can be either positive or negative for this category. The reason that a negative result is accepted is that the culture has imperfect sensitivity. In approximately 3 percent of cases reported with a positive AFB smear result, the culture result is negative. All that is required for this category in the contact report is that the case is counted by the jurisdiction and the sputum AFB smear result is

positive.

It is important to include all cases in this category if they fit the requirements for counting, even when contacts were not found. This is because cases without contacts found can have serious implications for tuberculosis control. Numerous operational factors go into finding or not finding contacts, and although the reasons for this occurring are not part of the contact report, they should be sought out as part of routine operations.

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 for *Mycobacterium tuberculosis.*

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

As for the definition preceding this one, in almost every respect, this definition matches the reporting instruction for RVCT/SURVS tuberculosis. For the contact report, three points are listed (above) and expanded here:

1. Only cases that are counted by the jurisdiction submitting the contact report should be included. The jurisdiction has to count a case before its contacts can be counted, and contacts from cases that are not counted at the head of this column should not be reported in this column. This can occur when the RVCT criteria are not met for any reason or when the criteria are met but the case is counted by a different jurisdiction because of local arrangements or because of details in the RVCT instructions.

2. For the contact report, the case should include tuberculosis disease somewhere in the respiratory system, which for these purposes extends from the epiglottis down to the alveolus and includes all the connecting airways. This is slightly different from the RVCT definition for pulmonary, which does not include upper-airway tuberculosis, for example. The reason for the difference is that upper-airway tuberculosis can be the most contagious of all forms, and this is relevant to the purpose of the contact report. (Please note that upper-airway tuberculosis is uncommon without a positive sputum AFB smear result.) On other points, the contact report follows the same reporting conventions as the RVCT. The hilum and the pleura are defined as extra-pulmonary structures for surveillance. Tuberculosis in these locations is unlikely to be directly transmissible. Therefore, pleural or hilar tuberculosis are not by themselves sufficient for counting in this category of a contact report, but a positive sputum smear or culture is not expected anyway if

tuberculosis is solely in these sites.

3. The positive sputum culture result can be derived from any culture method for mycobacteria. In addition, a positive result from a direct genetic amplification method applied to sputum, even without a positive sputum culture result to corroborate it, can be counted in this category for the contact report, although the relative degree of contagiousness is undetermined for this unusual scenario. Also, the term sputum is meant strictly. Sputum is the specimen that the patient expectorates, whether expectoration is spontaneous or induced. Specimens that are collected via lavage or biopsy through a bronchoscope or any other route are not counted as sputum. This distinction is compatible with the RVCT instruction. The reason for the distinction is that the general epidemiological impact of tuberculosis cases that are diagnosed without a sputum AFB examination or culture is not known. Please note that positive culture results from sputum specimens obtained before or after a bronchoscopic procedure are valid for counting in this category. All that is required for the contact report is that the case is counted by the jurisdiction and the sputum culture result is positive for *M. tuberculosis* or *M. tuberculosis* complex.

It is important to include all cases in this category if they fit the requirements for counting, even when contacts were not found. This is because cases without contacts found can have serious implications for tuberculosis control. Numerous operational factors go into finding or not finding contacts, and although the reasons for this occurring are not part of the contact report, they should be sought out as part of routine operations.

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.

The first two columns of the contact report include the most important contact investigations that a health department undertakes. For a wide variety of reasons, health departments also undertake a number of contact investigations for the tuberculosis cases that they count when the cases in and of themselves are unlikely to be contagious. The reasons for doing these other types of contact investigations vary from jurisdiction to jurisdiction. The overall public health impact of doing these other investigations is indeterminate, but sometimes there are compelling reasons.

"**Other**" is a catch-all term that captures the contact investigative results that were not countable in the first two columns of the contact report. Note that this category does not

have a case denominator. That is, the number of cases for investigation is not reported and, therefore, the number of contacts per case is undefined. This is because the other investigations are of disparate types and DTBE currently does not intend to capture these data systematically. On the other hand, a state or local program might gain new insight by reviewing these data, and if numerous contacts are being reported in this category, then the reasons for these investigations, and their productivity, should be monitored.

Associate-contact investigations are done to find persons who might have been infected from the same source as an index case. The assumption is that the index case was caused by recent infection; therefore other persons who currently are associated with the index patient might have been exposed, too. One distinction here is that the source case and the site for the transmission are undetermined initially, and for this and other reasons the yield of associate-contact investigations is low on average. A typical example of an associate-contact investigation is evaluating the siblings of a child who has tuberculosis. The assumption is that the siblings might have been exposed and infected along with the sick child—not because of potential transmission from the sick child to the healthy siblings (i.e., pediatric tuberculosis cases usually are not contagious). Associate-contact investigations are similar to source-case investigations, and often these investigations are done in tandem.

Source-case investigations are designed to find the source of infection for a tuberculosis patient who probably was recently infected. The typical reason for a source-case investigation is tuberculosis in a young child. Because of the child's young age, the date of tuberculosis infection is certainly fairly recent; therefore the odds of finding the source case are better than average, although still poor.

Both associate-contact and source-case investigations sometimes are done for LTBI, especially if children are involved. The public health value of this work is uncertain, but the **Other** column of the contact report is available for these data.

Another reason for counting in the **Other** category is explained under **Number of Contacts** in the basic instructions and definitions. If the health department undertakes a contact investigation around a suspected tuberculosis case, but the culture later confirms a diagnosis of infection with a mycobacterium besides *M. tuberculosis* (e.g., *M. avium*) or tuberculosis is excluded in some other way, then the health department has the option of counting the contacts for this non-case under the **Other** column. (In some instances, the investigation is undertaken because the index patient has a positive sputum AFB smear result, but tuberculosis later is excluded.) Reporting these contacts has advantages and disadvantages. An advantage is that the health department has a standard measure of how much work was undertaken, while a disadvantage is that the results generally do not

reflect productive activities. If your program chooses to report these data, then the reasons for reporting should be determined in advance and the value of the data probably should be reviewed critically to determine whether the program derives benefits from this reporting practice.

Sometimes contact investigations are done for extrapulmonary tuberculosis cases. The reasons for this kind of investigation are defined poorly in most instances, but the concepts are related to associate-contact or source-case investigations. If these contacts are to be counted in the report, then they should be included under **Other**.

> **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.

Sometimes tuberculosis patients who are difficult to interview transmit a great deal of infection before being diagnosed. Sometimes these patients cannot, for many reasons, assist the health department in listing contacts.

Failure to find contacts can contribute to outbreaks. However, some of the reasons for not finding contacts are beyond the control of the health department. The challenge confronting the health department under these circumstances is to account for these events and to seek alternatives.

One requirement of the contact report can cause an artifact in this category. All the contacts who are related to a tuberculosis case cluster might be assigned to the index case, which means that no unique contacts remain for other cases in the cluster. (The instructions stipulate that the contacts are only counted once each even if multiple cases exposed them to tuberculosis.) In many instances, however, additional unique contacts are found for the other tuberculosis cases in a cluster.

> **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.

The contact count is the essence of the contact report. It is also one of the most difficult numbers to determine. This is mostly because contact ascertainment is challenging in the

first place. Contact ascertainment is an imprecise science combining various evidence about a presumed source case and the resulting exposures. The completeness of contact investigations depends on flexible pursuit of evidence, or else important contacts can be missed. On the other hand, excess inclusion of contacts causes unnecessary medical evaluation and treatment. Full guidance about contact investigations goes beyond the scope of this training manual. The instructions here focus on counting contacts.

1. The essential idea for counting a contact in this report is that someone in the health department has determined, from whatever evidence or rationale, that the person (who might have been exposed to tuberculosis) might have been infected, and an evaluation to exclude LTBI or active tuberculosis is justified. The contact report does not aid in determining how good or how poor the guess was, at least not directly for each contact (see **How to Interpret and Use the ARPE Results**). The evidence and the circumstances vary from contact to contact; all that is needed from the health department for counting in the contact report is the decision that a diagnostic evaluation is warranted.

2. The tuberculosis case under investigation must be included in the count for the reporting jurisdiction if the contacts are going to be counted also. This requirement usually simplifies the reporting because the records for cases and contacts can be tied together in either a paper file or a computer data system. However, it also means that the health department sometimes cannot count all the contacts that need evaluation. You do not count contacts to cases counted by another jurisdiction, even though you evaluate the contacts. For example, if a tuberculosis case is reported in a neighboring state and the patient absconds from treatment and spends several months in your jurisdiction before being rediscovered, the additional contacts in your state should not be counted on your contact report because your tuberculosis program is not counting the case. Contacts to cases that are not counted (anywhere) because of an RVCT instruction/definition also should not be counted for the contact report.

3. In the spirit of meaningful reporting of program activities, the contact report includes data only on contacts that the health department has a reasonable opportunity for locating and thereby evaluating. “Reasonable” is subjective. The idea is to collect data on contacts that are accessible within the United States. Verifiable data are seldom available for contacts who move abroad or for fugitives. Contacts who are incompletely identified (e.g., partial or inaccurate name or inaccurate address) cannot be confirmed to exist, and counting them for the contact reports would have unclear value. However, incomplete locating information can be pursued more or less rigorously, and the efforts that are allocated to find

contacts should be determined according to the circumstances and not according to the instructions for ARPEs.

The contact report assigns the accountability for contacts to the jurisdiction reporting the tuberculosis cases under investigation. Accountability does not mean responsibility for evaluating and treating every single contact; it is more an insistence to find data and results for contacts, wherever they might be. This can happen only if health departments exchange essential information about contacts. In some U.S. regions, this is already the standard practice. With the increasing emphasis on tuberculosis prevention, contact tracing and reporting between jurisdictions is likely to become more standard.

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.

The concentric-circles model is an iterative process of measuring the rates of tuberculosis infection (both LTBI and disease) around a contagious source case. This is done by arranging the investigation into stages called circles. The theory is that contacts who have had more intensive or prolonged exposure are more likely to be infected, and these contacts should be evaluated before others. The circles of contacts are determined by the estimated degree of exposure. The data from each stage of the investigation are used as evidence for making decisions for the next stage, until the results show that enough contacts have been evaluated—that is, no more evidence of recent transmission is found.

The concentric-circles model is a reasonable guide for planning investigations, but operational limitations seldom permit this approach to be followed in every detail. Sometimes, it cannot be used at all. In any instance, the contact report does not evaluate the use of the model because it does not distinguish degrees of exposure. The contact report makes no distinction between close and other-than-close contacts.

On the other hand, if you are using the concentric-circles model, then this sometimes helps you to decide how to count contacts for reporting. The contact report only includes contacts that you (i.e., the health department) believe should be evaluated for possible LTBI or tuberculosis disease. If the concentric-circles model provides you with evidence that no further contacts beyond a point need to be evaluated, only the contacts up to that point should be counted for reporting. However, the last set of contacts who are evaluated should be counted, if they were evaluated because of a concern that they could have been infected.

Example: You start a contact investigation in a high school because one of the students has culture-confirmed tuberculosis with acid-fast bacilli observed on sputum microscopy. The school has 600 students, but the results for 8 household contacts and 30 homeroom contacts at school show no evidence for transmission. Therefore, you decide that the rest of the high school students do not need to be tested. The best number of contacts for reporting is 8 + 30 = 38, which is how many persons you determined should be evaluated. If you reported 8 + 600 = 608 contacts, then you also would have to report that you evaluated 38 contacts and did not evaluate 570. This would be unhelpful information in the report. In fact, you determined that the 570 should not be evaluated, and the contact report should reflect your correct reasoning by showing only the 38 contacts.

> 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 being counted. These persons and their test results are reported under the case category **Other**, which does not include a TB case denominator.

Many if not all tuberculosis programs initiate a contact investigation as soon as a suspected tuberculosis case is found, especially if the suspected tuberculosis patient has a positive result on the sputum smear for AFB. In general, this is a good idea. However, sometimes investigations are done for non-cases, that is, tuberculosis later is excluded as a diagnosis for the index patient.

Whether or not these contacts should be counted for the contact report is controversial. Some tuberculosis controllers prefer to include the data because the results reflect the burden that is incurred with this extra work. Other tuberculosis controllers prefer to omit the data because the public health benefit of the extra work is uncertain.

For tuberculosis programs where these data are included in the contact report, the report permits the results to be added into the **Other** column of the report. If this option is used, then the ARPE coordinator should discuss this with the DTBE program consultant and should review these data to determine how the results contribute to program evaluation.

> 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.

If you did not count a tuberculosis case under investigation, then you do not count the contacts, either. You might have contacts from a case in a neighboring jurisdiction or from farther away, and although you are evaluating these contacts, you should not be counting them for the contact report because you are not counting the index case. Conversely, if the

contacts to a tuberculosis case that you are counting are in another jurisdiction, you count the contacts and all the results and outcomes. To do this, you need the data from your colleagues in the other jurisdiction.

You might receive just as much contact data as you share with other jurisdictions, but a perfect balance is unlikely. In various tuberculosis programs, the priority assigned to tracing contacts between jurisdictions and then sharing data runs from high to low. One reason for building this type of data sharing into the contact reports is to raise the visibility of these activities.

> **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.)

A truly complete definition for evaluated would be difficult because the story for each contact has subtleties of history, epidemiology, and test results. The contact report is too simple for distinguishing all the details for each contact. Therefore, the definition for counting a contact as evaluated for the report is based on final diagnostic decisions that are in turn based on the complete story for each contact.

A contact should be counted as evaluated for the report after all necessary tests and other evaluations for LTBI and tuberculosis disease are finished and the healthcare providers have determined a tuberculosis status for the contact. The general choices are (1) not infected, (2) infected with *M. tuberculosis* but no evidence of tuberculosis disease (i.e., LTBI), and (3) active tuberculosis disease. Note that the first choice, not infected, is not an explicitly counted category in the contact report.

In general, the initial steps involved in the evaluation process are an interview about the recent exposure and any previous tuberculosis history and a tuberculin skin test (for contacts who are not already known to be reactive to tuberculin).[4] Because the skin test

[4] Recent developments in blood tests for infection with *M. tuberculosis* offer the possibility that they might perform better than the tuberculin skin test. DTBE will send an amendment to these ARPEs instructions if these blood tests are implemented and if they substantially alter the way that contact investigations and targeted testing are done.

result might not convert to positive until up to 8 weeks after initial infection with *M. tuberculosis*, some contacts require a second skin test if the first result is negative.

Contacts who have a positive tuberculin test result, or current tuberculosis symptoms even if the skin test result is negative, require further evaluation because they might have active tuberculosis. The evaluation usually starts with a chest radiograph at a minimum, and the healthcare providers might arrange for other tests or procedures.

The above outline of evaluated is not a substitute for current guidelines for diagnosing LTBI and tuberculosis disease. For detailed information on diagnosis and case management, you should refer to publications by the American Thoracic Society, the Infectious Disease Society of America, the American Academy of Pediatrics, and CDC.

Until the presence or absence of either infection or disease is established, a contact should not be counted as evaluated. Some reasons for not counting a contact as evaluated are listed here, although this list is not intended to be complete:

1. A contact is never seen for evaluation,
2. a test for *M. tuberculosis* infection should be done but is not,
3. a tuberculin skin test is applied but not read,
4. a second test for infection should be done but is not, and
5. a positive test result is not followed by further testing for active tuberculosis disease.

The contact report is not a tool for determining whether contacts have been evaluated optimally, although you might encounter quality-of-care issues while you are collecting data for the report. The contact report has an implicit assumption that evaluations are done in accordance with local, state, and national policies or guidelines. Disagreements about medical evaluations for specific contacts should be resolved between your health department and the healthcare providers. The DTBE program consultants are available to assist ARPE coordinators in state or local health departments in resolving these types of issues.

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; 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.)

Generally contacts who already have had a documented positive tuberculin skin test result before the contact investigation would not receive another skin test. The same would hold for contacts who have had active tuberculosis in the past. If a healthcare provider determines that an evaluation is completed for such a contact, then the contact should be counted as evaluated for the contact report. In this scenario, historical information constitutes a major part of contact evaluation.

Treatment decisions for contacts with old, previously diagnosed LTBI are made individually, and practices vary. Also, contacts who were treated previously for LTBI are a similar issue. Because the practices are variable, previously diagnosed LTBI is not included under **LTBI** in the contact report. If your health department routinely treats contacts under these circumstances, then the count of LTBI can be added to the targeted-testing report in the section **Referral Counts** in the targeted-testing report, and the treatment should be counted there.

If the targeted-testing report is used in this way, the practice is irregular because an individual contact is counted (1) once as a contact who has been evaluated and (2) again as a referral for treatment of LTBI. Although this is irregular, the practice is allowed as long as the principles of consistency and uniformity are followed.

This type of transfer between the two ARPEs adds complexity to the reporting process. The ARPE coordinator should set standards for these practices.

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.)

Contact investigations are one of the better methods for active case-finding for tuberculosis in the United States. Active case-finding means seeking tuberculosis disease in a defined population. This contrasts with passive case-finding, which means waiting for individuals to seek medical attention because of tuberculosis symptoms. (These terms are not the same as active surveillance and passive surveillance, which are contrasting strategies for collecting tuberculosis case reports. Active and passive surveillance are not directly relevant to ARPEs.)

The reason that active case-finding is efficient in contact investigations is that tuberculosis cases are common among recent contacts to contagious tuberculosis—an average of 1 percent or more of these contacts have tuberculosis disease at the time they are evaluated. Active-case finding is a crucial component of contact investigations.

The case definition for counting tuberculosis disease is the same as that of the national case definition in the RVCT instructions. However, the counting instructions are different. For RVCT, the determination about jurisdiction and who counts the case is connected to the address of the patient and several other details. For the contact report, if you counted the contact because you also counted the index case, then you count the secondary tuberculosis case (of the contact) in this section of the contact report, even if another jurisdiction is counting the same case for RVCT national surveillance. This happens in contact investigations that cross jurisdictional borders. These reporting systems, ARPEs and RVCT national surveillance, are functionally independent, and counting the same case in each of the systems causes no problems.

The contact report is designed to show the results of contact investigations only. Findings from other, coincidental sources should not be counted as outcomes in this report. For example, if a contact has active tuberculosis and is diagnosed before the contact investigation starts, this is not a discovery/result of the contact investigation. At best it is a coincidence and at worst it is evidence that the contact investigation was delayed. Another example is tuberculosis that develops after a contact has been evaluated and found not to have tuberculosis. These kinds of data contribute to understanding the epidemiology of tuberculosis transmission, but the contact report is not designed for this depth of data.

In contrast, for the targeted-testing report, some coincidental findings are accepted. The reason for this is that the structure and purpose of targeted-testing projects are different from contact investigations.

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.

DNA fingerprinting (i.e., genotyping) is a valuable tool for detecting or confirming tuberculosis transmission and studying its epidemiology. Examples of DNA fingerprinting methods are RFLP and spoligotying. Occasionally, results from these methods show a mismatch between a contact who has culture-confirmed tuberculosis and the presumed source case. From this evidence, the conclusion is that the cases are not linked by recent transmission.

The contact report is designed to study the process/results of contact investigations and not the exact epidemiological links among cases. A primary result of contact investigations is that cases are discovered by active case-finding. The evidence from DNA fingerprinting is not relevant for making decisions about the contact report. The contact report is the report for showing that you sought the contacts, evaluated them, and discovered a tuberculosis case because you did an investigation. DNA fingerprinting results are not available on all cases. This is because testing was not done or culture results were negative. The results of DNA fingerprinting should not be considered in making decisions about counting cases among contacts in the contact report.

In conclusion, DNA fingerprinting (i.e., genotyping) results for *M. tuberculosis* isolates should be ignored for classifying data for the contact reports.

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.

For contacts, the average rate of LTBI is approximately 20 times greater than that of active tuberculosis disease. Sometimes more than half of contacts are infected by the time an investigation is undertaken. The purpose of finding LTBI is to treat it and prevent the progression to active tuberculosis.

Obtaining the diagnostic outcome of **LTBI** requires a range of activities, although only the outcome itself is counted in the contact report. First is an interview to determine whether the patient (i.e., the contact) already has symptoms of active tuberculosis and any previous

history of tuberculosis disease, infection, or exposure. Next is a tuberculin skin test, and sometimes another one, for detecting evidence of LTBI.[5] The skin test should be interpreted according to local policies or guidelines. Finally, if the skin test result is positive, a chest radiograph (i.e., x-ray) and sometimes other tests are needed to exclude active tuberculosis. The selection of tests for excluding active tuberculosis depends on the circumstances and the healthcare providers' judgment.

For each contact, the determination about the LTBI diagnosis is up to the healthcare provider. Discrepancies between guidelines and diagnoses should be resolved by public health officials. The contact report is not designed to evaluate diagnostic practices for LTBI; the report has a built-in assumption of correct practices.

The general rules for counting LTBI found in a contact investigation are the same as for active tuberculosis disease. The ARPE report is designed to capture the results of contact investigations. Occasionally, LTBI has been diagnosed before the contact investigation is undertaken, or it might be diagnosed accidentally when a contact receives a tuberculin skin test but the tuberculosis exposure is unknown to provider, who is unaware of the contact investigation. Although these events are unusual in most areas of the United States, when they occur, the LTBI should not be counted as such on the contact report. Even if the LTBI is not countable, the contact can be counted as **Evaluated** if enough information is available to confirm the LTBI diagnosis and active tuberculosis disease has been excluded.

> 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**.

Recent guidelines about finding and treating LTBI have discounted tests for cutaneous anergy. Cutaneous anergy is detected by various combinations of control antigens referred to as an anergy panel. The reasons for this trend of discontinuing anergy testing are beyond the scope of this manual. At present, the tuberculin skin test is the only type of test that is taken into consideration when counting outcomes of contact evaluation for the contact report, until and unless improved blood tests for *M. tuberculosis* change this.

Under special circumstances, health care providers occasionally prescribe a full course of

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[5] Recent developments in blood tests for infection with *M. tuberculosis* offer the possibility that they might perform better than the tuberculin skin test. DTBE will send an amendment to these ARPEs instructions if these blood tests are implemented and if they substantially alter the way that contact investigations and targeted testing are done.

treatment for LTBI for contacts who have persistently negative tuberculin skin test results. (This contrasts with window-period treatment, which is not intended to be a full course from the onset.) An example is full LTBI treatment of HIV-infected contacts who have negative tuberculin skin test results after exposure to contagious tuberculosis. For the contact report, such contacts can be counted as treated, but they also have to be counted as infected. This is because they are receiving full treatment for the reason that LTBI is presumed. In reality, this occurs rarely except under special circumstances, usually congregate settings.

> **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.

The two components of this instruction are (1) that the contact has been counted under **LTBI** for the evaluation outcome and (2) the contact receives at least the first dose of treatment. The concept for the first point is that treatment implies an LTBI diagnosis, and the details meet the ARPE definition for LTBI.

The second point can be difficult to determine with certainty unless a patient is receiving directly observed therapy (i.e., supervised doses). Sometimes you and other providers have to rely on substitute methods for ascertaining the start of treatment. The best and simplest method is asking the contact about it in an interview; if the response from the contact can be validated by a pill count, this is even better.

However, sometimes the information about starting treatment is inaccessible. For this circumstance, the only substitute is a confirmation that the patient filled a prescription for LTBI treatment. When even this information is unavailable, then treatment should not be counted as started. In particular, the existence of a prescription or a medical order to start treatment should <u>not</u> be considered adequate for counting under the category of **Started Treatment**.

> 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.

Window-period treatment is given to a contact when the transmission rate is believed to be substantial, or the contact is extra vulnerable to tuberculosis, but the result from the first tuberculin skin test is negative. This practice is based on the assumption that the

contact might have acquired LTBI recently but the infection is so new that delayed hypersensitivity to tuberculin (e.g., the skin test) has not developed yet. Window-period treatment is administered until sufficient time has passed and a second tuberculin skin test is administered. If the second test result is negative, then treatment is stopped because the contact probably does not have LTBI.

The contact report is incompatible with the intrinsic concept of window-period treatment. From the perspective of this report, a contact who is receiving window-period treatment pending a second skin test is still being evaluated, because a determination still has not been made about whether the contact has LTBI. If the result of the second skin test is negative, then LTBI would be excluded. If LTBI is not diagnosed, then the contact cannot be counted under **LTBI,** and a contact who is not counted under **LTBI** also cannot be counted under **Started Treatment**.

The frequency that window-period treatment is prescribed varies from place to place. Although the contact report cannot help in evaluating window-period treatment, the basic structure of the report could be adapted for studying this practice locally. A consultation with your ARPE coordinator or a DTBE program consultant is recommended.

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.

A simplistic definition is necessary for **Completed Treatment** because this element is intrinsically difficult to describe and measure. Even with this definition, **Completed Treatment** is likely to cause confusion and disagreement. Consistency should be your highest priority.

One overriding factor: The definition for **Completed Treatment** is not a substitute for guidelines for treating LTBI. Treatment practices should be based on local, state, and national policies or guidelines, and decisions for individual patients are between healthcare providers and their patients. None of the ARPE definitions are intended as references for medical care or case management.

The definition for **Completed Treatment** includes three requirements:

1. The provider discontinues treatment after concluding that the contact has completed a recommended treatment regimen. Decisions by the patient or program administrators are not equivalent for meeting the definition. Thus, administrative close-outs do not meet the definition. (An administrative close-out is a determination by a program administrator that enough treatment was given even though a prescribing provider has not discontinued it. This does not meet the definition for the contact report.)

2. The reason for the "80 percent" figure is that some tuberculosis treatment studies have used this as an arbitrary cut-point for specifying completion of therapy. When intensive monitoring methods such as pill counts or directly observed therapy are in effect, the achievement of 80 percent of doses is measurable directly. In most situations where contacts are being treated, however, data are not available to determine how many doses have been taken. In these situations, you need a combination of data to make a reasonable guess about the number of doses that were taken (and whether or not this constitutes 80 percent of what was prescribed). Typical factors you might consider are the start date for treatment, the number of prescription refills, clinic attendance, and the adherence rate reported by the patient.

3. Completion within 150 percent of the planned treatment period is a pragmatic component of the definition. The purpose is to get the reports closed with finality. The contact report is no longer relevant if every single open treatment record is pursued to the point of final determination. Contacts who are still on treatment at the time point that is one-and-one-half times (i.e., 150 percent of) the intended duration should be regarded as not completed for the sake of the contact report, even if completion might be reached at a later date.

A number of factors can complicate determinations about **Completed Treatment**. An example is contacts who require a change of regimen midway through a course. Another example is contacts who start and stop treatment several times. For the contact report, you sometimes have to make arbitrary decisions about how to count these events. As much as possible, you should make these decisions consistently when similar situations arise and uniformly across reporting sites. Consultation with your ARPE coordinator or a DTBE program consultant is recommended.

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

Although DTBE requests submission of information about incomplete treatment, the main purpose of this section of the report is to assist local and state tuberculosis control programs to assess the obstacles that prevent completion of therapy within their jurisdictions. A major shortcoming of these data is that they are peculiar to local context; therefore these data have uncertain meaning when combined with reports from other areas. In addition, tuberculosis controllers have reported that interpretations of the definitions vary substantially from site to site; therefore the data that are aggregated from multiple reporting areas consist of mixed information. The definitions used in the instructions still should be followed as closely as possible.

The categories under **Reasons Treatment Not Completed** have a relative hierarchy: in a situation where several reasons for incomplete treatment might apply to one contact, the most specific reasons should be selected. In general, the reasons near the top of the list are more specific and less subjective. Some of the reasons are more serious, for example, death during treatment or adverse effects of treatment. These events are likely to require further attention; therefore they should be captured for the report whenever possible.

You should set a goal of counting each instance of incomplete treatment under one of the categories of **Reasons Treatment Not Completed**. However, you can expect difficulties in doing this and accept that you might not be able to assign a reason for each contact. DTBE does not require that the sum of contacts who are counted under the categories of **Reasons Treatment Not Completed** equal 100 percent of all the contacts who do not complete treatment, although a local or state tuberculosis program might decide to require this. TIMS automatically checks the total count under all categories and signals an error if the total exceeds the number of patients who did not complete treatment.

> **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.)

Death is a rare reason that contacts with LTBI do not complete treatment. As estimated from previous reporting systems for treatment of LTBI, death occurs in less than 0.5 percent of contacts while they are receiving treatment. You should be alert to reports of death in contacts for two general reasons: (1) A report of death might be inaccurate, and you should verify it, and (2) if the report is accurate, you need to know whether the death might be somehow related to the treatment of LTBI or to active tuberculosis that escaped your attention.

For counting events under this category it is important to determine whether death was

the reason that treatment was stopped, that is, the proximate reason. For example, if a contact dies while still receiving treatment after 3 months, then **Death** is the appropriate category. However, if the contact decides to stop treatment after 1 month and then dies 2 months later (unless a complication of treatment caused a late death), the closest reason that treatment was incomplete was the patient's decision, which you should record in that category.

If the contact stops treatment because of an illness or injury that proves fatal, this outcome should be included under **Death**. Under these circumstances, the treatment of LTBI is likely to be suspended because of the contact's worsening condition, but the general understanding is that the treatment would have been resumed if the contact had survived. On the other hand, if the treatment is suspended because of illness (not including an adverse effect of the treatment) or injury, and the contact survives but the treatment is discontinued permanently by a provider, this probably would be counted as **Provider decision**.

Contact 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.

The programmatic goal for contacts who move is to obtain follow-up information whenever possible. Although **Contact Moved (follow-up unknown)** is a nonspecific outcome, the contact can be assumed to be unavailable for further public health monitoring and completion of therapy.

Gathering follow-up information about contacts who move while being treated for LTBI can be difficult. You might need to decide that the additional data that you gain from finding out what happens to contacts after they leave your jurisdiction does not have enough priority relative to your other tasks. This is a realistic approach, but it entails some loss of information for the contact report. Also, your effort in tracing the outcome of contacts has intangible benefits, such as increasing the odds that a contact who started treatment in your jurisdiction will come to the attention of public health providers in another jurisdiction.

For counting a contact in this outcome category, you should seek some form of confirmation that the contact indeed moved outside of your jurisdiction. One possibility that you want to avoid is a contact who claims to be moving (i.e., as an avoidance of public

health monitoring) when in fact this person is not planning to move. In this instance, the better category for counting would be **Contact Chose to Stop** because it is closer to the facts. Making this distinction requires extra effort, but the distinction is important.

Contact Moved (follow-up unknown) implies that you know the destination of the contact who is moving. Without this information, you cannot determine a more specific outcome because you have no way to make a referral for continued monitoring of treatment for the contact. If you believe that the contact probably moved but you do not know the destination, then you should classify the outcome as **Contact is Lost to Follow-up** because you are uncertain about what happened to the contact.

> **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**.

Large-scale trials of LTBI treatment proved that an occasional patient becomes sick with active tuberculosis even while under treatment for LTBI. This occurred even with drug-susceptible *M. tuberculosis* and in patients who were adherent to treatment. The reasons for this phenomenon are unknown; you can assume that this outcome is rare.

On the other hand, tuberculosis is more likely to develop in a contact who stops treatment for LTBI, and you should attempt to determine if this is the underlying reason for the failure of treatment. If you determine that treatment was stopped for some reason before active tuberculosis developed, then you should record the proximate reason for stopping treatment.

After treatment for LTBI, active tuberculosis can develop. None of the treatment regimens for LTBI is 100-percent effective in preventing tuberculosis, and this is even more true for contacts who fail to complete therapy. If tuberculosis develops after treatment has been stopped (because it was completed or any other reason), then the original reason for ending treatment should be retained.

Note: Sometimes contacts are started on treatment for LTBI before all results from medical evaluation are obtained. Delayed test results or reinterpretation of early results might change a diagnosis from LTBI to active tuberculosis. For example, a positive culture result for *M. tuberculosis* might not become available until 6 weeks after the collection of a specimen. Also for example, abnormalities might be noted in the review of chest radiographs that initially were read as normal. For these unusual instances, the initial

evaluation actually was not complete at the time that treatment for LTBI was undertaken. The contact should be classified under **TB Disease** instead of under **LTBI**. Thus, the treatment start itself should not be counted because the LTBI diagnosis was incorrect. The classification of **LTBI**, **Started Treatment**, and **Active TB Developed** would be incorrect in this scenario because the proper disposition of the contact (for counting in the report) would be **TB Disease**.

> **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 Chose to Stop**.

All regimens for treating LTBI cause adverse reactions in a few patients, and sometimes these reactions are severe or dangerous enough to end treatment. The judgment that is required to make this decision is beyond the scope of the contact report and these instructions, and in each instance the decision to stop treatment rests with a healthcare provider and a contact. You can reasonably assume that consistency and uniformity are lacking in how this decision is made, but this too is beyond the scope of the report.

The crucial detail for counting in this category is that a healthcare provider has documented the decision to stop treatment because of the adverse effect. In instances where a contact decides to stop treatment because of the adverse effect but a healthcare provider has not evaluated the contact and has not decided to discontinue treatment, then the reported outcome should reflect the patient's decision as **Contact Chose to Stop**. For example, some anti-TB medicines cause abdominal pain, and this can prompt a patient to stop treatment. This would only be counted under **Adverse Effect of Medicine** if a provider evaluated the situation and recommended treatment be stopped.

An average rate of stopping treatment because of adverse effects should be less than approximately five percent. If you find a higher rate, you should be concerned about the possibility that treatment is being stopped without sufficient reason or that information is being misinterpreted when it is classified for reporting purposes.

If the adverse effect of medicine for a contact is fatal, then the outcome should be counted under **Death** rather than under **Adverse Effect of Medicine**. These events are of particular concern, and you should monitor them closely.

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.

This category is almost self-explanatory, but it also has its confusing points. One example is a contact who moves from your jurisdiction and deliberately leaves incorrect locating information. You would be reasonable in believing that the contact chose to stop treatment because that message is implicit, but a better classification would be **Lost to follow-up**.

When you are counting a contact who did not complete treatment under the category of **Contact Chose to Stop**, you should be able to determine the whereabouts and the clinical condition of the contact. Whether or not you seek out the contact to encourage resumption of treatment or check on health status depends on your program resources

and priorities. However, when you count a contact under this category, you are implying that you have a way to check on the person.

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.

When you really cannot determine what became of a contact who was on treatment for LTBI, **Contact is Lost to Follow-up** is the category. You might be concerned that this category depends on how much effort is spent on finding a contact, and probably it does. It is likely that if you had the resources and information for finding all contacts who seem to vanish, some of them would tell you that they prefer not to return to clinic.

In fact, resources are limited, and you have to set priorities when it comes to tracing absconders. You would be correct in guessing that from place to place resource levels for tracing lost contacts are different, and the priority assigned to this activity varies. Also, the local context influences this factor. If you work in a small community where everyone knows everyone else, a contact is less likely to disappear than if you are in an urban setting with social anonymity. This shows why program-process evaluation reports such as ARPEs are not fully comparable from one place to the next.

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.

This is a narrow category among reasons that treatment was not completed. You should

not expect to encounter it often. You should count a contact under **Provider Decision** only if a healthcare provider has decided in good faith, prospectively, to discontinue treatment because of some medical concern. (If, however, the medical concern is brought about by an actual adverse effect, then the contact should be counted under that category instead.) **Provider Decision** cannot be defined for every circumstance because the situation for each contact is different, and each healthcare provider has a different sense of judgment.

The main problem to avoid for counting contacts under this category is the retrospective interpretation of data. **Provider Decision** should not be used as a default or an escape for counting outcomes when only incomplete information is available.

The following are some reasonable examples of **Provider Decision**. By comparing the outcomes for contacts in your program against these examples, you have a frame of reference for typical situations that could be counted under this category:

> An elderly woman who is a contact with LTBI has alcoholism. The healthcare provider is concerned about liver injury associated with isoniazid, and the plan is to check the patient in clinic and to do blood tests every other week to monitor for early evidence of liver injury. However, this person does not keep clinic appointments and is difficult to locate when outreach workers search for her. The healthcare provider is concerned that she either is skipping her treatment or is in jeopardy from adverse effects of isoniazid. Therefore, the provider discontinues treatment.
>
> A man who is a contact being treated for LTBI is found to have cancer and starts intensive chemotherapy, and this makes him very sick. The healthcare provider decides to postpone treatment of LTBI indefinitely until the more urgent medical issues are settled. This amounts to an indefinite discontinuation of treatment. The provider is concerned that this patient could become sick with tuberculosis; therefore careful monitoring is planned so that tuberculosis can be discovered early if it develops.
>
> A woman who is a contact being treated for LTBI becomes pregnant during the 4th month of isoniazid treatment. The patient and the healthcare provider agree to postpone treatment until well after the birth of the baby (although this is not quite in keeping with treatment guidelines). For practical purposes you determine that treatment for this contact should be counted as incomplete, and you assign the outcome to **Provider Decision**.

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.

Note that some specific indices are different between the contact report and the targeted-testing report, which reflects differences in the activities.

The purpose of the evaluation indices is to give you a synopsis of the data flow in the contact report. Each index reflects the average result of a specific process that is shown in the report. You could regard each index as a measurement of performance, but this interpretation generally is overly simple. Better that you regard the indices as general comparators (i.e., for comparison to national averages) and as clues for determining which activities in contact investigation need your closer scrutiny. (See page 99, **How to interpret and use the ARPE results**, for additional suggestions about interpreting the indices.)

ARPEs differ from some other or previous U.S. tuberculosis program reports in that the indices are not adjusted for mitigating factors. For example, the treatment completion rate does not exclude contacts who move from your jurisdiction after starting treatment, and therefore the treatment rate is diminished by the departure of these contacts. This is a controversial point, but you have the option of calculating indices with adjustments, for your purposes. In the national report, no adjustments are made.

When ARPEs are entered into TIMS, the software program will calculate indices initially and then will recalculate them when you edit/update the data. The formulae that appear in the printed ARPE forms are the basis for those built into TIMS. If you use paper-copy forms, or computer-screen mock-up forms, you must remember to recalculate the indices after counts are edited/revised in the upper sections of the forms. If you use spreadsheet software programs for recording ARPE data, you can incorporate the formulae that are shown in the paper-copy form.

Extended instructions: target testing report

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).

ARPEs are a tool for program evaluation. A potential hazard of these reports is that the reporting instructions and the data definitions might be misconstrued as treatment recommendations or program guidelines. The reporting instructions and the data definitions are derived from national guidelines and recommendations, but they are much simpler.

For example, the data definitions for completion of therapy in ARPEs specify the number of doses and the duration of treatment. However, when therapeutic decisions are under discussion regarding individual patients, treatment recommendations and medical judgment must be followed instead of ARPEs instructions. Under unexpected circumstances, the appropriate treatment decisions might cause a problem with reporting, but patient care is more important than these reporting definitions.

In another example, the ARPE results for a certain targeted-testing project might suggest that the population selected for testing is not appropriate because the prevalence rate of LTBI is low. However, the selection of targeted populations should be based on judgment derived from experience and program guidelines and not on results in ARPEs alone.

ARPEs simply are not capable of accommodating all the issues that must be considered for making programmatic decisions. The aim of ARPEs is general results, and it is up to the ARPE coordinators and the program managers to recognize how unusual circumstances caused peculiar results in the reports. This is critical for taking advantage of the reports.

State and local jurisdictions should consult with each other on the reports when questions arise. For example, the designated ARPE coordinator in the state tuberculosis control program might be responsible for tracking all ARPEs-related questions and responding to them. At DTBE, the program consultants for each reporting area[6] are the main point of

[6]For most jurisdictions, the state TB controller or the TB nursing consultant coordinates communications with the DTBE program consultants.

contact for questions that are directed to the national tuberculosis program. They have available a range of public health specialists to assist them.

> 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 tuberculosis disease) should not be included in this report, either, unless the individuals also are being tested for LTBI.

Targeted testing is the third element in the general U.S. strategy for tuberculosis control. The essence of targeted testing is preventing tuberculosis by selecting and evaluating individuals or groups who have risks for tuberculosis disease and treating individuals who have latent infection with *M. tuberculosis*. The public health impact of targeted testing is achieved only when individuals found to have LTBI are fully treated in order to prevent the emergence of active tuberculosis disease.

In spite of the benefits of preventing future tuberculosis cases, targeted testing is prone to inefficiency because of the large number of persons who have to be evaluated, the low risk of active tuberculosis in the general population, and the difficulties of completely evaluating and treating persons with LTBI. Targeted testing usually requires an intensive, long-term investment of personnel and other scarce resources. Evaluation of targeted-testing activities is important for validating these prevention activities. This is the purpose of the targeted-testing report.

Contact investigations are a special type of targeted testing, but in almost all instances, data for contacts should be counted in the contact report instead of the targeted-testing report. The notable exception is the extensive and generally unproductive testing of contacts beyond the limits of what the health department authorities recommend. These data can be entered into the targeted-testing report, as explained under the extended instructions for the contact reports (page).

Active-case-finding refers to projects that have the primary aim of detecting tuberculosis disease in the selected population. The targeted-testing report was not developed with the intention of capturing data from projects for active-case finding. Tuberculosis cases are comparatively rare in most U.S. populations. On average, fewer than 1 per 10,000 persons has tuberculosis at a given time. In selected populations, the prevalence rate might be greater than 1 in 1,000, and in these populations, active case-finding might be efficient. The tuberculin skin test is not a sensitive or specific method for active case-finding; therefore targeted-testing activities that include a component of active case-finding require an ancillary testing method, such as chest radiography. The typical methods of active case-finding projects are a rapid screen for tuberculosis symptoms; chest radiographs of all the

individuals or only of ill individuals; and sputum examinations for AFB, usually only on ill individuals or individuals with abnormal radiographic results. Tuberculin skin testing is a poor adjunct to active-case finding, but in some projects targeted testing for LTBI is combined with active-case finding. You can use the targeted-testing reports for tracking the results of projects that combine both active-case finding and targeted testing for LTBI, but you need to distinguish the data because the methods and motives are different from those of ordinary targeted testing 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.)

In many jurisdictions, some or even all persons who are tested for *M. tuberculosis* infection receive initial medical evaluation and treatment through providers besides the health department. Examples of other providers are private physicians; health maintenance organizations; and systems such as correctional facilities, military facilities, and hospitals. Collecting data from other providers is difficult, and the results you collect from those sources should be collected only if the data are helpful. You have to create opportunities for influencing practices and thus improving the efficiency and the impact of targeted testing, so that the data collection from outside of health department is meaningful.

However, by seeking targeted-testing data from activities outside of health department projects, you become acquainted with other providers in your jurisdiction, and they learn about the services provided by the health department. Working with other providers gives you an opportunity to educate them about tuberculosis-control policies and procedures, and you can participate in strategy, decisions, and case management. In some jurisdictions, health departments have negotiated partnerships for targeted testing and treatment of LTBI. Examples of partners are infirmaries in correctional settings and clinics of community-based organizations. Collecting data from collaborative projects enhances the health department's capacity for technical consultation. For collaborative projects, data collection and project evaluation should be negotiated at the beginning of the collaboration.

For the targeted-testing report, you can regard the ARPE data accepted from providers outside of the health department as equivalent to data that you generate from your own patient care activities if data quality meets your normal standards, although you can anticipate differences. Separate analyses of data from different sources might provide important information. For example, you could measure the completion of therapy for

patients who go to private medical providers and compare the rate with that of patients who start treatment at the health department.

Please note that the instructions on data from other sources are slightly different for the contact reports because the purposes of the data collection are different.

> 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**.

Many types of settings (e.g., hospitals, long-term convalescence homes, and hospices) have systematic tuberculin skin testing that sometimes is repeated at routine intervals for employees, clients, or both. These testing activities generally do not have primary aims of both finding and treating LTBI. Rather, they are implemented as epidemiological monitoring systems for determining the prevalence of LTBI and detecting potential transmission of *M. tuberculosis*. Sometimes the individuals undergoing testing are at very low risk for LTBI or tuberculosis disease. These types of testing systems generally do not have routine tracking of LTBI treatment because treatment is prescribed through other health-service systems. Therefore, the data usually are not suitable for the targeted-testing report.

The targeted-testing report has an implicit design assumption that individuals are only tested once for LTBI,[7] and the report does not include a special way for counting repeated tests. This is another reason that the targeted-testing report is ill-suited for data from infection control and surveillance systems.

In some communities, the health department administers and interprets the tuberculin skin tests for non-targeted-testing activities as described above. However, because these activities generally are not targeted toward individuals at specific current risk for LTBI or active tuberculosis disease, the data should not be entered into the targeted-testing report. If specific individuals at risk for tuberculosis are being evaluated for the purposes of both

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[7]In some targeted-testing projects (e.g., a project in a homeless shelter), individuals leave and enter the scope of the project repeatedly and sometimes are reevaluated. The targeted-testing report regards these persons as fresh, new entrants; it does not have a way of tracking them differently. Because this shortcoming can bias the overall results, you should consider it when interpreting the report.

finding and treating LTBI, then these might be counted along with other targeted-testing data.

Sometimes the individuals who are diagnosed with LTBI during these other types of skin testing activities are already in the health department or are referred to the health department for further evaluation and possibly treatment. If so, they should be counted in the second half, **Referral Counts**. This reflects that the health department was not engaged in targeted testing but is providing prevention services subsequently.

> 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.

In some jurisdictions the health department does not do tuberculin skin testing except when evaluating contacts. In many of these jurisdictions, tuberculin tests are applied by providers outside of the health department for a variety of reasons. If these outside providers refer the patients who have positive test results to the health department, then you can use the second page of the targeted-testing report, **Referral Counts**, for recording counts and results.

The major distinction between the second page (**Referral Counts**) and the first page of the targeted-testing report is the lack of target population denominator data. When you use the second page of the report, your starting point is the patient subset who are believed to have LTBI (or, rarely, active tuberculosis) when they are referred to the health department. You receive little or no information about the individuals who had negative test results or who did not return for test interpretation.

As with the first half of the report, you may include **Referral Count** data from sources outside of the health department if these data are comparable to health department data and the health department is participating in the evaluation with the good-faith anticipation of influencing the process. Because the specialized activities counted under **Referral Counts** are unusual outside of health departments, you should verify your plan with your ARPE coordinator before accepting these data from outside sources.

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.

This brief instruction includes several major points. First, the reports are on an annual cycle. The targeted individuals, or members of a targeted population, who are collected for one annual cycle are counted together in a cohort, which means a group that is traced in aggregate through the course of all outcomes from testing through treatment (within the bounds of the closure date for reporting). The counting cycle is based on the calendar year.

Next, the date of entry depends on the recruitment system, that is, how persons are gathered for testing. For example, if a targeted-testing project automatically enrolls an individual at a homeless shelter when he or she registers in the shelter for the first time, then the shelter registration date determines the entry date for inclusion in the targeted-testing cohort, even though the tuberculin skin test will not be administered until the county nurse makes a routine visit several days later. The strategy for dating patient entry should be determined by local policy and evaluation needs, but the strategy should be recorded and followed consistently for optimal reporting. In general, you need to determine the date rules for each targeted-testing system or project. Consultation with your ARPE coordinator is recommended.

Under special circumstances, individuals are recruited into the same or more than one testing system during 1 year. For example, within 1 calendar year, a person might be enrolled in a testing project at a homeless shelter in March, leave the shelter in May, and return in November. In this instance, the person is counted for each evaluation, that is, counted independently, twice, as though two different persons entered the project. However, if LTBI or tuberculosis disease were diagnosed in the first evaluation, then this influences the methods for the second evaluation because a test for infection probably will not be helpful or necessary. Note that the instructions for classifying persons who have previously diagnosed LTBI or tuberculosis are different from those of the contact report. See the definitions of **TB Disease** and **LTBI** for the contact reports and contrast these with the definitions of the targeted-testing report.

Note, however, that in jurisdictions where computerized tracking is used for individuals entering and leaving targeted-testing projects, the tracking programs might not be compatible with multiple counts reflecting multiple entries. Under these circumstances, only initial evaluations might be counted. This is not contrary to successful reporting as long as you and everyone who uses the reports understands the differences in counting

procedures.

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, 1 year later.

The purpose of the closure date is to establish administrative finality for processes that otherwise might be prolonged beyond reasonable bounds. This implies that arbitrary criteria are have been set, because what is reasonable is subject to interpretation. However, the U.S. tuberculosis controllers who contributed to the development of ARPEs believed that the closure dates were acceptable for capturing most of the important prevention work, because most outcomes should be available before the closure dates.

Occasionally, outcome events might occur later than the closure dates. For example, a patient who starts treatment for LTBI much later than the initial evaluation might not complete treatment until later than the second (i.e., final) ARPEs closure date. The targeted-testing reports still should be closed on August 15, and the report should not be revised for including this unusual completion of therapy after the closure date. In the example given, the patient will be counted as having started treatment but not as having completed treatment. You should note that this is an extreme example. If it occurred frequently, then it might indicate a systematic problem.

The targeted-testing report has two closure dates (that are the same as the ones for the contact report). The first closure date marks the end of the preliminary report. The preliminary report records the cohort of individuals that are included for the count-year. Most if not all of the individual patients that are going to be counted should be counted by the first closure date. In addition, most of the data about evaluating/diagnosing these patients and starting treatment for those with LTBI should be ready also. The second closure date marks the end of the final report, which records the outcomes for patients who received treatment. The final report focuses on completion of therapy.

Even for reports that are delayed administratively, the closure dates should be observed. Reports should not be revised for data from events that occur after the final closure date, because this causes inconsistencies.

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.

These counts set the fundamental denominator for each testing activity/project. For each

activity/project, a definition for counting is required. Three factors can help in setting the definition:

1. mission of the testing activity/project,
2. use of the data, and
3. local practices for similar situations.

Setting the definition for testing counts should be part of the design for a new testing activity or project. In general, the testing counts should be a reflection of your intentions in undertaking the activity/project, that is, the mission. For example, if your mission for a testing project at a shelter for homeless persons is "to test every new entrant to the shelter," then the testing count should be matched to the number of new registrations at the shelter. However, after assessing the turnover of residents at the shelter, you might learn that less than half of the new registrants stay for longer than 2 days. Counting all new registrants would not give meaningful information because few of them would be available for diagnostic evaluation. You even might alter your mission to fit the situation: "To test every new entrant who plans to stay in the shelter for at least 1 week."

The purposes for collecting the data, that is, the uses of the data, also can guide your decisions about counting. If the data are used only by the health department, then you might decide on a narrow definition for the testing count, such as persons who are tested. If you have collaborators in a testing project, you might want to count persons who somehow miss being tested so that you can bring attention to increasing the number of persons who are tested.

Within your jurisdiction or in nearby jurisdictions, activities/projects similar to yours might be underway already. When a comparison of similar projects is desired, the counting definitions should be matched as closely as possible. Consistency of definitions increases the comparability of the results.

> **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.

The **Testing Formats** determine how data are grouped for the targeted-testing report. The grouping of the data then determines the structure and the flow of the data in each of the columns in this report. After you group the data into a particular column, the results move down that column to their final outcome, completion of therapy. You can transfer data from column to column if you decide to change testing categories for some of the data, but this could be very difficult if you are doing the tabulations by hand. Therefore, you should try to assign data to the best-fitting categories for **Testing Formats** at the start of data

collection. The notes that follow this one describe each testing category, [**Targeted Testing** (**Project** or **Individual**) and **Administrative**], in detail.

When you are deciding about how to group data under **Testing Formats**, you should seek input from collaborators and others who have a stake in the projects/activities and the evaluation of the activities. You also should strive for consistency between projects and within your jurisdiction or region so that results are comparable as much as possible. Consultation with the ARPE coordinator is advised.

> **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.

Targeted testing is a strategy for increasing the yield, the efficiency, and the benefit-to-risk ratio of these types of tuberculosis-prevention activities. The populations or individuals who are selected for targeted testing are likely to have at least one of two characteristics: (1) a likelihood of LTBI because of an exposure history or historical markers for exposure to tuberculosis, and (2) health conditions that promote the progression from LTBI to active tuberculosis. The greater the fraction of persons who have both characteristics, the greater the prevention impact that the testing activity is likely to have, that is, if patients with LTBI start and complete treatment.

The initial yield of a testing activity depends on the prevalence rate of LTBI in the population. The prevalence rate, in turn, depends on the population's exposure history.

The prevalence rate of LTBI also influences the predictive positive value of tuberculin skin test results. With greater rates of LTBI, positive skin test results are more likely to indicate LTBI instead of nonspecific reactions (i.e., false-positive reactions). If the predictive value of skin test results is greater, then more patients who truly have LTBI receive treatment, and this increases both the efficiency of the activities and the benefit-to-risk ratio.

Generally, persons who have health conditions that increase the likelihood of tuberculosis disease (if they are infected with *M. tuberculosis*) receive the most potential benefit from treatment of LTBI. Probably the most important health condition in this class is HIV infection. Treating these persons can give a good benefit-to-risk ratio because the likelihood of tuberculosis disease, without treatment, is greater than average.

Guidelines for targeted testing occasionally change, and the changes might affect whom

you include for targeted testing. However, you should not apply the guideline changes retroactively to data derived from activities that you already completed. Mid-year guideline changes can be accommodated by changes in data collection at that point in time.

> **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.

Under the broader heading of **Targeted Testing**, you need to distinguish between **Project** and **Individual**. The distinction is somewhat arbitrary for some situations, but usually you will be able to distinguish between the two and assign testing activities to one or the other. As for other ARPEs sections, consistency in how you classify data is an important consideration. You can improve consistency by working with an ARPE coordinator and documenting the decision process.

Testing in the **Project** format involves a strategy that captures a group of persons because of their similar risks of tuberculosis. In some targeted-testing projects, you can skip the person-by-person initial screening for tuberculosis risks because most persons in the group have increased tuberculosis risk.

For many targeted-testing projects, the targeted group has mutual social characteristics that link the individuals to specific locations where you can reach many of them at one time. For example, many of them might work at the same factory. Thus, targeted-testing projects often take place outside of health department clinics because it is more sensible to deliver the services to the targeted group at a common setting.

One common feature of targeted-testing projects is that they should include collaborators for achieving optimal effectiveness. For example, a project at a prison would include the correctional system health care workers. For some settings, the collaborators are the unique advocates or guardians for the targeted group, for example, a volunteer agency for homeless services. Collaborations with groups like these are necessary for effective interactions with the targeted populations. They have a stake in the results of targeted-testing projects for preventing tuberculosis, and they should be included in discussions about how data are collected, interpreted, and shared.

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.

If the predominant strategy for targeted testing is selecting individuals who should be tested and then treated if they have LTBI, then this category, **Individual**, is the choice for the testing data. For this category, an individual risk assessment is done for each person before the testing is done.

Individual risk assessments sometimes are built into targeted-testing projects, but in a targeted-testing project, you start with the assumption that the targeted group members are candidates for testing and possibly for treatment, and you do the individual risk assessment for refining the risk information and perhaps for excluding those persons who should not be included. Contrast this with the individual testing format, wherein you do the individual risk assessments for deciding whom to include in targeted testing.

In the individual testing format, the individual risk assessment is the starting point for selecting targeted individuals who have characteristics that make them good candidates for testing and possibly treatment. Someone outside of the health department might be doing the initial risk assessment and then sending the patient to the health department for testing. For example, a physician at a private clinic might send patients who have diabetes to the health department for a tuberculin skin test. Testing these patients probably would be in keeping with guidelines. At the health department, a provider can confirm whether the patient has tuberculosis risks.

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.)

This category of testing for LTBI, **Administrative**, is representative of low-priority testing activities that usually are required because of policies not directly related to public health or tuberculosis control. For example, mandatory tuberculin testing of all child day-care providers probably prevents very few tuberculosis cases; it mainly addresses a general public perception that children might be endangered if the testing is not done, whether or not this is true. The **Administrative** category represents this extra public health expenditure that is probably not in the public's best interest, in spite of perceptions.

On the other hand, some child day-care providers (for example) might have characteristics that put them at risk for tuberculosis; therefore the testing might be valid from the public health perspective. If it is feasible and helpful, you have the option of reclassifying data from the **Administrative** category to the **Individual** category. If you consider this practice, you should determine whether the extra paperwork is likely to improve the utility of the data and whether the idea is appropriate for your jurisdiction. If you decide to reclassify, then you should do it consistently.

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.

Occasionally tuberculosis control programs cannot avoid including excessive numbers of contacts in an investigation. From a public health perspective, you might not consider some of the "contacts" to be contacts at all because evidence shows that they were not exposed to tuberculosis or that they had trivial exposure. You have the option of reclassifying the data off of the contact report and onto the targeted-testing report, usually in the **Administrative** category, although individual contacts might have tuberculosis risk factors that might justify classification under the **Individual** category.

For example, if a child has scrofula, you realize that the contacts of this child are not at risk of infection (unless they share a common source case with this child, which is a different type of investigation). If many so-called contacts of the child are included in an investigation anyway, for example because of misplaced public concern, you have some options about how to classify the data for reporting. You can decide whether or not these data should be counted in the first place, and if you count them, you should decide whether they should be on the contact report (in the **Other** category for this example) or on the targeted-testing report. Consultation with an ARPE coordinator is advised.

Note: The instructions for **TB Disease** and **LTBI** are different for the targeted-testing report than for the contact report. If the data are reclassified from contact investigation to targeted testing, the definitions for the targeted-testing report should be used when classifying the results for counting in the reports.

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.

For a targeted-testing project, the count in this category should be the total number of persons who would be included if the project could meet its full potential. For example, if your project is designed to include all new employees at a factory in your jurisdiction, then the count of new employees defines your count for this category. This reinforces the need for determining data systems while the project is being designed. If you discover that the number of persons who are evaluated is far fewer than the number of persons who are sought, then you know either that the project itself is unfeasible or that you need new strategies.

The counting of persons in the **Individual** category usually is simpler. If you register someone for testing, you should count that person, whether or not the evaluation proceeds any further.

Within your jurisdiction or in nearby jurisdictions, activities/projects similar to yours might be under way already. When a comparison of similar projects is sensible, the conventions for counting should be matched as closely as possible. Consistency of definitions increases the comparability of the results.

> **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.)

A truly complete definition for evaluated would be difficult because the story for each person has subtleties of history, epidemiology, and test results. The targeted-testing report is too simple for distinguishing all the details for each person who is included. Therefore, the definition for counting persons as evaluated for the report is based on final diagnostic decisions that are in turn based on the story for each person.

A person should be counted as evaluated for the report after all necessary tests and other evaluations for LTBI and tuberculosis disease are finished and the healthcare providers have determined the tuberculosis status of the person. The general choices are (1) not infected, (2) infected with *M. tuberculosis* but no evidence of tuberculosis disease (i.e., LTBI), and (3) active tuberculosis disease. Note that the first choice, not infected, is not a counting category in the targeted-testing report.

Until healthcare providers have determined the tuberculosis status of a person, the person should not be counted as evaluated for the contact report. In general, the initial steps involved in this process are an interview about tuberculosis exposure and any previous tuberculosis history and a test for infection with *M. tuberculosis*, such as a tuberculin skin (for persons who are not already known to be reactive to the skin test).[8]

Persons who have a positive test for infection or current tuberculosis symptoms, even if the test result is negative, require further evaluation because they might have active tuberculosis. Although the evaluation for disease usually starts with a chest radiograph at a minimum, the healthcare providers might arrange for other tests or procedures.

The above outline of evaluated is not a substitute for current guidelines for diagnosing LTBI and tuberculosis disease. For detailed information on diagnosis and case management, you should refer to publications by the American Thoracic Society, the Infectious Disease Society of America, the American Academy of Pediatrics, and CDC.

Until the presence or absence of either tuberculosis infection or disease is established, a person should not be counted as evaluated. Some reasons for not counting a person as evaluated are listed here, although this list is not intended to be complete:

1. the person is never seen for evaluation,
2. a test for infection should be done but is not,
3. a tuberculin skin test is administered but not read, and
4. a positive test result is not followed by further evaluation for active tuberculosis disease.

The targeted-testing report is not a tool for determining whether persons have been evaluated optimally, although you might encounter quality-of-care information while you are collecting data for the report. The targeted-testing report has an implicit assumption that evaluations are done in accordance with local, state, and national policies or guidelines. Disagreements about medical evaluations for specific persons should be resolved between your health department and the healthcare providers. The DTBE program consultants are available to assist ARPE coordinators in state or local health departments in resolving these types of issues.

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[8] Recent developments in blood tests for infection with *M. tuberculosis* offer the possibility that they might perform better than the tuberculin skin test. DTBE will send an amendment to these ARPEs instructions if these blood tests are implemented and if they substantially alter the way that contact investigations and targeted testing are done.

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.)

Note that this definition for **TB Disease** is different than the one used for the contact report. The main difference is that you also should count prevalent cases, that is, cases that already have been diagnosed, as **TB Disease** in the targeted-testing report.

Targeted testing is not designed for active case-finding for tuberculosis. Active case-finding means evaluating the individuals in a defined population for tuberculosis disease. This contrasts with passive case-finding, which means waiting for individuals to seek medical care because of tuberculosis symptoms. (These terms are not the same as active surveillance and passive surveillance, which are contrasting strategies for collecting tuberculosis case reports.)

Active case-finding usually is not efficient as a part of targeted-testing activities because tuberculosis cases are comparatively rare in most U.S. populations. On average, fewer than 1 per 10,000 persons has tuberculosis at a given time. In selected populations, the prevalence rate might be greater than 1 in 1,000, and in these populations, active case-finding might be efficient. The tuberculin skin test is not a sensitive or specific method for active case-finding; therefore targeted-testing activities that include a component of active case-finding require an ancillary testing method, such as chest radiography. The targeted-testing report is not designed for evaluating active case-finding projects. However, projects that combine targeted testing with active case-finding can be evaluated with the targeted-testing report.

The case definition for **TB Disease** is the same as that of the national case definition in the RVCT instructions. However, the counting instructions are different. For RVCT, the determination about jurisdiction and who counts the case is connected to the address of the patient and several other details. For the targeted-testing report, if you counted the person for the report, then you count the tuberculosis case under **TB Disease**, even if another jurisdiction is counting the case for RVCT national surveillance. This happens in targeted-testing projects that include persons who reside in different jurisdictions.

The targeted-testing report is designed to include prevalent tuberculosis disease and LTBI. Therefore, findings from sources apart from the targeted testing can be counted as

outcomes in this report. For example, if a person who is included in a testing project has active tuberculosis and the case was diagnosed before the person was enrolled in the testing project, this case should be counted in the targeted-testing report. However, if a person is initially diagnosed as having LTBI after the complete diagnosis but active tuberculosis develops in that person later, then the classification should remain as LTBI because that was the determination of the targeted testing.

If a person who is included in targeted testing has a history of resolved tuberculosis disease, treated or not, and if the history for tuberculosis disease is documented to the extent that meets local standards, then this person should be classified as having LTBI after the diagnostic evaluation is completed. Depending on the circumstances and the judgment of the healthcare providers, a test for *M. tuberculosis* infection might not be necessary for the evaluation because it would it would not be helpful. Such a person also might be classified as a candidate for treatment of LTBI if the tuberculosis was not treated before or was not treated completely.

> **LTBI**. Persons are counted under this outcome if they have a 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.)

The goals of targeted testing are finding LTBI and getting it treated in order to prevent future tuberculosis cases. For these activities to be efficient, the prevalence rate of latent infection should be greater than the national average, which might be on the order of one to five percent (averaged) for adults in the United States. The efficiency of the prevention activities is increased even more if the infected individuals also have risk factors for progression to active TB.

Obtaining the diagnostic outcome of **LTBI** requires a range of activities, although only the outcome itself is counted in the targeted-testing report. First is an interview to determine whether the patient already has symptoms of active tuberculosis or a history of tuberculosis exposure, infection, or disease. Next is a tuberculin skin test to detect evidence of LTBI.[9] The skin test should be interpreted according to local policies or

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[9] Recent developments in blood tests for infection with *M. tuberculosis* offer the possibility that they might perform better than the tuberculin skin test. DTBE will send an amendment to these ARPEs instructions if these blood tests are implemented and if they substantially alter the way that contact investigations and targeted testing are done.

guidelines. Finally, if the skin test result is positive, a chest radiograph (i.e., x-ray) and sometimes other tests are needed to exclude active TB. The selection of tests for excluding active tuberculosis depends on the circumstances and the healthcare provider's judgment.

A two-step skin test is not recommended for targeted testing. Two-step testing is necessary for initial testing upon entry to infection-control surveillance programs, with the individuals being retested according to a routine schedule, e.g., annually. The targeted-testing report is not recommended for tracking surveillance systems.

For each individual, the determination about the LTBI diagnosis is up to the healthcare provider. Discrepancies between guidelines and diagnoses should be resolved by jurisdictional public health officials. The targeted-testing report is not designed to evaluate diagnostic practices for LTBI; the report has a built-in assumption of correct practices.

This counting category (**LTBI)** can include individuals who did not have LTBI diagnosed directly as part of a current testing activity. This instruction is different from that for the contact report. For the targeted-testing report, individuals who have historical information about tuberculosis infection can be counted under **LTBI** (as having possible prevalent infection). The two examples are

1. Previous positive skin test result, whether or not LTBI was treated
2. Previous tuberculosis disease that is healed now, whether or not it was treated

You and other ARPEs contributors who work with you should set the documentation standards for counting under these instructions. For example, you might require that each claim of a previous positive skin test result be backed by documentation before it is counted under **LTBI** in the report. With so many subtleties to counting prevalent infection from historical information, you should strive for consistency by working with your colleagues and establishing the counting criteria for your jurisdiction.

Probably a small fraction of individuals who are counted under **LTBI** because of historical information will turn out to be candidates for treatment of LTBI. You should take this into account when interpreting results from the targeted-testing report.

> 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.

Recent guidelines about finding and treating LTBI have discounted tests for cutaneous anergy. Cutaneous anergy is detected by various combinations of control antigens referred to as an anergy panel. The reasons for this trend of discontinuing anergy testing are

beyond the scope of this manual. At present, the tuberculin skin test is the only type of test that is taken into consideration when counting outcomes for the targeted-testing report. (However, the discovery of improved blood tests for diagnosing *M. tuberculosis* infection is likely to change this practice.)

Occasionally persons who have a negative tuberculin skin test result are prescribed a full course of treatment for LTBI. If such persons are to be counted as treated for the targeted-testing report, they also have to counted as infected under **LTBI**, because they are receiving full treatment for presumed LTBI. In reality, this hardly ever happens in connection with targeted testing. It is more likely with contact investigations, especially with HIV-infected contacts.

> **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**.

This stratification (i.e., branch point) is a distinctive feature of the targeted-testing report. All persons who have LTBI are grouped into one of two categories. Although some preliminary information about tuberculosis risks usually is collected as part of initial screening for infection, complete information usually is collected after a diagnosis of LTBI has been made. This is why the **LTBI (sorted by risk)** section is located at this point in the report.

Usually you can classify individuals who have LTBI into one of the two categories from information on hand, and the records for targeted-testing activities should include tuberculosis risks as routine information. For instances where the information is incomplete, then the default assignment should be to **Population Risk** because this is the more common reason for targeted-testing activities.

Sometimes an individual has multiple risk factors for LTBI or tuberculosis disease. If any of the reasons fits under **Medical Risk**, then this should be the classification. For example, if targeted testing is done at a county jail, where the general reason for testing is the population-based tuberculosis risk associated with correctional facilities, but an individual inmate who has LTBI also has diabetes, which is a medical risk for tuberculosis disease, then the individual should be counted under **Medical Risk**. This category is at higher priority because the indication for treatment generally is clear and the opportunity for preventing cases is greater.

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 jejunoileal bypass
Age < 5 years
Recent exposure to TB

Each of the conditions listed in the box has been reported to promote the progression from *M. tuberculosis* infection to tuberculosis disease. (The conditions that could be included under the categories in the list are numerous, and consultation with medical experts is necessary for including all possibilities.) Sometimes the conditions that qualify for counting under this category are noted before the diagnostic evaluation for LTBI because the information is helpful for interpreting the tuberculin skin test results. The information always should be pursued after the diagnosis of LTBI has been made. Record-keeping systems that routinely include this information will facilitate reporting.

The presence of any of these medical risks increases the likelihood of tuberculosis developing and thus increases the potential benefit of treating LTBI. In general, the completion of treatment for these individuals is a higher priority than it is for the other risk category, **Population risk**, although other factors come into setting priorities.

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

The social situations that are grouped under **Population Risk** are highly heterogeneous. Each has been associated with increased incidence rates of tuberculosis or prevalence rates of LTBI. The reason in each example is the particular likelihood of exposure to contagious tuberculosis.

On average, more persons are included in targeted-testing activities because of population risks than because of medical risks. The heterogeneous content of this category means that the interpretation of aggregated data is limited. The local interpretation of data, when the content can be described specifically, is more meaningful. Specific local data should be studied for assessing whether a testing activity is productive, because the social situations listed in the box (above) are for general guidance purposes only and do not predict the risk of infection equally well in every setting.

Sometimes an individual is included in a targeted-testing project, but after the diagnosis of LTBI has been made, the determination about risk category is impossible or unfeasible. For reporting purposes, the individual should be counted in the **Population Risk** category as a default.

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.)

This category is an important part of the targeted-testing report. It is not part of the contact reports because all contacts who have LTBI are assumed to be candidates for treatment. In successful targeted-testing activities, most persons who are found to have LTBI are also candidates for treatment. However, in any circumstance, some persons who have LTBI are not candidates for treatment for various reasons, such as previous tuberculosis treatment, contraindications against specific medicines, high risk of adverse effects from treatment, or a very low risk for active TB.

The guidelines for selecting candidates for treatment of LTBI are context sensitive, and they are dependent on judgment; ultimately someone has to make a determination about whether an individual should be considered a candidate, at least for counting purposes. This ambiguity creates the possibility for inconsistency in reporting, which is a reflection of the uncertainty in the recommendations for treatment of LTBI. For reporting purposes, you should seek optimal consistency by working with an ARPE coordinator.

In some jurisdictions, the guidelines for selecting treatment candidates are different from the national guidelines. The operational treatment guidelines are the ones that should be used for counting **Candidates for Treatment**. If treatment guidelines change during the course of a reporting year, then the guidelines in effect at the particular moment can be used for counting purposes. (The distinction has little effect in most instances, and a decision can be made to consider all the patients under one set of guidelines or the other for efficiency, as long as the potential discrepancy is noted.)

In contrast, sometimes a provider will recommend against treating LTBI because that patient has unstable circumstances or expresses reluctance to participate. This decision not to treat is up to the provider and the patient; however it is different from the criteria for **Candidates for Treatment**. **Candidates for Treatment** is based on the medical and epidemiological criteria for deciding when to recommend treatment to a patient, and a reluctance to prescribe or to be treated should not be considered for reporting purposes.

Possibly patients could be started on treatment for LTBI when they are not actually, by guidelines or recommendations, candidates for treatment. If the treatment is to be counted

on the targeted-testing report, then the individuals also should be counted as treatment candidates in order to maintain flow of data. Such events represent a potentially inefficient use of resources and also a risk to patients, and therefore further inquiry is warranted.

> **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.

The two components of this instruction are (1) that the patient has been counted under **LTBI** for the evaluation outcome and (2) the patient receives at least the first dose of treatment. (The patient also has to be counted as a candidate for treatment.) The concept for the first point is that treatment implies that LTBI has been diagnosed, and the details meet the ARPE definition for LTBI.

The counting requirement about the first dose of treatment can be difficult to determine with certainty unless a patient is receiving directly observed therapy, which is provided more often for contacts than for TB-infected persons found during targeted testing. Sometimes you and other providers have to rely on substitute methods for ascertaining the start of treatment. The best and simplest method is asking the patient about it in an interview, and if the response from the contact can be validated by a pill count, this is even better.

However, sometimes the information about starting treatment is inaccessible. For this circumstance, the only substitute is a confirmation that the patient filled a prescription for treatment of LTBI. When even this information is unavailable, then treatment should not be regarded as started. In particular, the existence of a prescription or a medical order to start treatment should <u>not</u> be considered adequate for counting under the category of **Started Treatment**.

> **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.

A simplistic definition is necessary for **Completed Treatment** because this element is intrinsically difficult to describe and measure. Even with this definition, **Completed**

Treatment is likely to cause confusion and disagreement. Consistency should be your highest priority. The instructions here are the same as for the aggregate report of contacts, but you should be aware that the circumstances of targeted-testing projects are different from contact investigations, and the information that is available to you in determining completion of treatment is likely to be different.

One overriding factor: The definition for **Completed Treatment** is not a substitute for guidelines for treating LTBI. Treatment practices should be based on local, state, and national policies or guidelines, and decisions for individual patients are between healthcare providers and their patients. None of the ARPE definitions are intended as references for medical care or case management.

The definition for **Completed Treatment** includes three requirements:

1. The provider discontinues treatment after conclusing that the patient has completed a recommended treatment regimen. Decisions by the patient or program administrators are not equivalent for meeting the definition. Thus, administrative close-outs do not meet the definition. (An administrative close-out is a determination by a program administrator that enough treatment was given and therefore the treatment is being classified as **Completed Treatment** even though a provider has not discontinued it. This does not meet the definition for the targeted-testing report.)

2. The reason for the "80 percent" figure is that some tuberculosis treatment studies have used this as an arbitrary cut-point for specifying completion of therapy. When intensive monitoring methods such as pill counts or directly observed therapy are in effect, the achievement of 80 percent of doses is measurable. In most situations of targeted testing, however, data are not available to determine how many doses the patients have taken. In these situations, you need a combination of data to make a reasonable guess about the number of doses that were taken (and whether or not this constitutes 80 percent of what was prescribed). Typical factors you might consider are the start date for treatment, the number of prescription refills, clinic attendance, and the adherence rate reported by the patient.

3. Completion within 150 percent of the planned treatment period is a pragmatic component of the definition. The purpose is to get the reports closed with finality. The targeted-testing report is no longer relevant if every single open treatment record is pursued to the point of final determination. Patients who are still on treatment at the time point that is one-and-one-half times (i.e., 150 percent of) the intended duration should be regarded as not completed for the sake of the contact report, even if completion might be reached at a later date.

A number of factors can complicate determinations about **Completed Treatment**. An example is patients who require a change of regimen midway through a course. Another example is patients who start and stop treatment several times. For the targeted-testing report, you sometimes have to make arbitrary decisions about how to count these events. As much as possible, you should make these decisions consistently when similar situations arise and uniformly across reporting sites. Consultation with your ARPE coordinator or your DTBE program consultant is recommended.

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

The instructions here are nearly to identical those for the aggregate report of contacts, with the exception of the omission of the word "contact" here. However, in the broader perspective, you should be aware that the circumstances of targeted-testing projects are different from contact investigations, and the information that is available to you is likely to be different. Also, the priority that is placed on treating LTBI found during targeted testing sometimes is lower than the priority placed on treating LTBI found during contact investigations. Therefore, less energy will be spent on tracing these patients if, for example, they appear to be nonadherent to a treatment regimen.

Although DTBE encourages submission of this information about incomplete treatment to the national tuberculosis program, the main purpose of this section of the report is to assist local and state tuberculosis control programs to assess the obstacles that prevent completion of therapy within their jurisdictions. A major shortcoming of these data is that they are peculiar to local context; therefore these data have uncertain meaning when combined with reports from other areas. In addition, tuberculosis controllers have reported that interpretations of the definitions vary substantially from site to site; therefore the data that are aggregated from multiple reporting areas consist of mixed information. The definitions used in the instructions should be followed as closely as possible under the circumstances.

The categories under **Reasons Treatment Not Completed** have a relative hierarchy: in a situation where several reasons for incomplete treatment might apply to one patient, the most specific reasons should be selected. In general, the reasons near the top of the list are more specific and less subjective. Some of the reasons are more serious, for example, death during treatment or adverse effects of treatment. These events are likely to require further attention; therefore they should be captured whenever possible.

You should set a goal of counting each instance of incomplete treatment under one of the categories of **Reasons Treatment Not Completed**. However, you can expect difficulties in doing this and accept that you might not be able to assign a reason for each patient. DTBE does not require that the sum of patients who are counted under the categories of **Reasons Treatment Not Completed** equal 100 percent of all the patients who do not complete treatment, although a local or state tuberculosis program might decide to do so.

> **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.)

Death is a rare reason that patients with LTBI do not complete treatment. As estimated from previous reporting systems for treatment of LTBI, death occurs in less than 0.5 percent of patients while they are receiving treatment. You should be alert to reports of death in patients for two general reasons: (1) The report might be inaccurate and you should verify it and (2) if the report is accurate, you need to know whether the death might be somehow related to the treatment of LTBI or to active tuberculosis that escaped your attention.

For counting events under this category it is important to determine whether death was the reason that treatment was stopped, that is, the proximate reason. For example, if a patient dies while still receiving treatment after 3 months, then **Death** is the appropriate category. However, if the patient decides to stop treatment after 1 month and then dies 2 months later (unless a complication of treatment caused a late death), the closest reason that treatment was incomplete was the patient's decision, which you should record in that category.

If the patient stops treatment because of an illness or injury that proves fatal, this outcome should be included under **Death**. Under these circumstances, the treatment of LTBI is likely to be suspended because of the events events, but the general understanding is that the treatment would have been resumed if the patient had survived. On the other hand, if the treatment is suspended because of illness (not including an adverse effect of the treatment) or injury, and the patient survives but the treatment is discontinued permanently by a provider, this would be counted as **Provider decision**.

> **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.

The programmatic goal for patients who move is to obtain follow-up information as often as possible, although treating patients who are found through targeted testing usually has lower priority than treating contacts. Although **Patient Moved (follow-up unknown)** is a nonspecific outcome, the patient can be assumed to be unavailable for further public health monitoring and completion of therapy.

Gathering follow-up information about patients who move while being treated for LTBI can be difficult. You might need to decide that the additional data that you gain from finding out what happens to patients after they move from your jurisdiction does not have enough priority relative to your other tasks. This is a realistic approach, but it entails some loss of information for the report. Also, your effort in tracing the outcome of patients has intangible benefits, such as increasing the odds that a patient who started treatment in your jurisdiction will come to the attention of public health providers in another jurisdiction.

For counting a patient in this outcome category, you should seek some form of confirmation that the patient indeed moved outside of your jurisdiction. One possibility that you want to avoid is a patient who claims to be moving (i.e., as an avoidance of public health monitoring) when in fact this person is not planning to move. In this instance, the correct category for counting would be **Patient Chose to Stop** because it is closer to the facts. Making this distinction requires extra effort, but the distinction is important.

Patient Moved (follow-up unknown) implies that you know the destination of the person who is moving. Without this information, you cannot determine a more specific outcome because you have no way to make a referral for continued monitoring of treatment. If you believe that the person probably moved but you do not know the destination, then you should classify the outcome as **Patient is Lost to Follow-up** because you are uncertain about what happened to the patient.

> **Active TB Developed**. If a patient 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**.

Large-scale trials of LTBI treatment proved that an occasional patient becomes sick with active tuberculosis even while under treatment for LTBI. This occurred even with drug-susceptible *M. tuberculosis* and in patients who were adherent to treatment. The reasons for this phenomenon are unknown; for purposes of ARPEs you should assume that this

outcome is rare.

On the other hand, tuberculosis is more likely to develop in a patient who stops treatment for LTBI, and you should attempt to determine if this is the underlying reason for the failure of treatment. If you determine that treatment was stopped for some reason before active tuberculosis developed, then you should record the proximate reason for stopping treatment.

After incomplete or even complete treatment for LTBI, active tuberculosis can develop. None of the treatment regimens for LTBI is 100-percent effective in preventing TB, and this is even more true for patients who fail to complete therapy. If tuberculosis develops after treatment has been stopped (because it was completed or any other reason), then the original reason for ending treatment should be retained.

Note: Sometimes patients are started on treatment for LTBI before all results from medical evaluation are obtained. Delayed test results or reinterpretation of early results might change a diagnosis from LTBI to active TB. For example, a positive culture result for *M. tuberculosis* might not become available until 6 weeks after the collection of a specimen. Also for example, abnormalities might be found in the review of chest radiographs that initially were interpreted as normal. For these unusual instances, the initial evaluation actually was not complete at the time that treatment for LTBI was undertaken. The patient should be classified under **TB Disease** instead of under **LTBI**. Thus, the treatment start itself should not be counted because the LTBI diagnosis was incorrect. The classification of **LTBI**, **Started Treatment**, and **Active TB Developed** would be incorrect in this scenario because the proper disposition of the patient (for counting in the report) would be **TB Disease**.

> **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**.

All regimens for treating LTBI cause adverse reactions in a few patients, and sometimes these reactions are severe or dangerous enough to end treatment. The judgment that is required to make this decision is beyond the scope of the targeted-testing report, and in each instance the decision to stop treatment rests with a healthcare provider and a patient. You can reasonably assume that consistency and uniformity are lacking in how this decision is made, but this too is beyond the scope of the report.

The crucial detail for counting in this category is that a healthcare provider has documented the decision to stop treatment because of the adverse effect. In instances where a patient decides to stop treatment because of the adverse effect but a healthcare provider has not evaluated the patient and has not decided to discontinue treatment, then the reported outcome should reflect the patient's decision as **Patient Chose to Stop**. For example, many anti-TB medicines cause abdominal pain, and this can prompt a patient to stop treatment. This would only be counted under **Adverse Effect of Medicine** if a provider evaluated the situation and recommended treatment be stopped.

An average rate of stopping treatment because of adverse effects should be less than approximately five percent. If you find a higher rate, you should be concerned about the possibility that treatment is being stopped without sufficient reason or that information is being misinterpreted as it is being classified for reporting.

If the adverse effect of medicine for a patient is fatal, then the outcome should be counted under **Death** rather than under **Adverse Effect of Medicine**. These events are of particular concern, and you should monitor them closely.

> **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.

This category is almost self-explanatory, but it also has its confusing points. One example is a patient who moves from your jurisdiction and deliberately leaves incorrect locating information. You would be reasonable in believing that the patient chose to stop treatment because that message is implicit, but a better classification would be **Lost to follow-up**.

When you are counting a patient who did not complete treatment under the category of **Patient Chose to Stop**, you should be able to determine the whereabouts and the clinical condition of the patient. Whether or not you seek out the patient to encourage resumption of treatment or check on health status depends on your program resources and priorities. However, when you count a patient under this category, you are implying that you have a way to check on the person.

> **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.

When you really cannot determine what became of a patient who was on treatment for LTBI, **Patient is Lost to Follow-up** is the category. You might be concerned that this

category depends on how much effort is spent on finding a patient, and probably it does. It is likely that if you had the resources and information for finding all patients who seem to vanish, some of them would tell you that they prefer not to return to clinic.

In fact, resources are limited, and you have to set priorities when it comes to tracing absconders. You would be correct in guessing that from place to place resource levels for tracing lost patients are different, and the priority assigned to this activity varies. Also, the local context influences this factor. If you work in a small community where everyone knows everyone else, a patient is less likely to disappear than if you are in an urban setting with social anonymity. This shows why program-process evaluation reports such as ARPEs are not fully comparable from one place to the next.

> **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.

This is a narrow category among reasons that treatment was not completed. You should not expect to encounter it often. You should count a patient under **Provider Decision** only if a healthcare provider has decided in good faith, prospectively, to discontinue treatment because of some medical concern. (If, however, the medical concern is brought about by an actual adverse effect, then the patient should be counted under that category instead.) **Provider Decision** cannot be defined for every circumstance because the situation for each patient is different, and each healthcare provider has a different sense of judgment.

The main problem to avoid for counting patients under this category is the retrospective interpretation of data. **Provider Decision** should not be used as a default or an escape for counting outcomes when only incomplete information is available.

The following are some reasonable examples of **Provider Decision**. By checking the outcomes for patients in your program against these examples, you have a frame of reference for typical situations that could be counted under this category:

> An elderly woman with LTBI has alcoholism. The healthcare provider is concerned about liver injury associated with isoniazid, and the plan is to check the patient in clinic and to do blood tests every other week to monitor for early evidence of liver injury. However, this patient does not keep clinic appointments and is difficult to locate when outreach workers search for her. The healthcare provider is concerned that the patient either is skipping her treatment or is in jeopardy from adverse effects of isoniazid. Therefore, the provider discontinues treatment.

A man who is being treated for LTBI is found to have cancer and starts intensive chemotherapy, and this makes him very sick. The healthcare provider decides to postpone treatment of LTBI indefinitely until the more urgent medical issues are settled. This amounts to an indefinite discontinuation of treatment. The provider is concerned that this patient could become sick with TB; therefore careful monitoring is planned so that tuberculosis can be discovered early if it develops.

A woman who is being treated for LTBI becomes pregnant during the 4th month of isoniazid treatment. She and the healthcare provider agree to postpone treatment until well after the birth of the baby (although this is not quite in keeping with treatment guidelines). For practical purposes you determine that treatment for this patient should be counted as incomplete, and you assign the outcome to **Provider Decision**.

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.

The instructions here are identical to those for the contact report, except that the terms are changed to reflect the different purposes of the reports. Note also that some specific indices are different between the two reports, which reflects the different activities.

The purpose of the evaluation indices is to give you a synopsis of the data flow in the targeted-testing report. Each index reflects the average result of a specific process that is shown in the report. You could regard each index as a measurement of performance, but that interpretation generally is overly simple. Better that you regard the indices as general comparators (i.e., for comparison to national averages) and as clues for determining which activities in targeted-testing projects need your closer scrutiny. (See page 99, **How to interpret and use the ARPE results**, for additional suggestions about interpreting the indices.)

ARPEs differ from some other or previous U.S. tuberculosis program reports in that the indices are not adjusted for mitigating factors. For example, the treatment completion rate does not exclude patients who move from your jurisdiction after starting treatment, and therefore the treatment rate is diminished by the departure of these patients. This is a controversial point, but you have the option of calculating indices with adjustments, for your purposes. In the national report, no adjustments are made.

When ARPEs are entered into TIMS, the software program will calculate indices initially and then will recalculate them when you edit/update the data. The formulae that appear in the printed ARPE forms are the basis for those built into TIMS. If you use paper-copy forms, or computer-screen mock-up forms, you must remember to recalculate the indices after counts are edited/revised in the upper sections of the forms. If you use spreadsheet software programs for recording ARPE data, you can incorporate the formulae that are shown in the paper-copy form.

Part III. Referral Counts.
Persons are included in this section when they are being evaluated for the 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 the **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 the certain contacts who cannot be counted under the treatment categories in the report of contact follow-up.

You can use this section of the targeted-testing report for many purposes, but all the uses are related to one general concept: data are initiated with the diagnosis of LTBI, and not with enrollment into screening or testing. Ideally, the number of persons who were sought for testing or who were tested would be recorded, because this information is vital to determining the validity of prevention activities. However, circumstances sometimes do not allow this.

Health care providers outside of the public health system offer tuberculin skin testing. In some settings or jurisdictions, these other providers even do most or all testing. If they refer the patients who have positive skin test results to the health department for additional diagnostic tests and treatment, then this section of the report, **Part III Referral Counts**, can be used for keeping track of the activities and the results. (If the health department arranges with the other providers to keep track of the number of persons sought for testing and the number tested, then the first page, **Part I Testing Counts**, of the targeted-testing report is a more comprehensive way of recording the information.)

Particular details in the definitions for other sections of both the contact report and the targeted-testing report allow for unusual events (that do not fit into those other sections) to be recorded in this part of the targeted-testing report. The typical example is a contact who has a previously recorded diagnosis of LTBI before the current contact investigation. The previous LTBI diagnosis is not counted as LTBI for the contact report; the contact is considered evaluated, but the data flow for that individual ends at that point (i.e., treatment for LTBI should not be recorded on the contact report because infection is not being counted there). If treatment is recommended for that contact, then the process steps can be recorded in the targeted testing report, in **Part III Referral Counts**. Whether or not

these activities warrant the extra effort of using the targeted-testing report is a decision for local and state health tuberculosis control officials, in consultation with the DTBE program consultant.

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.

In general, the persons who are referred to the health department already have had a skin test for *M. tuberculosis* infection and sometimes further evaluation for TB. Some arrive after full evaluation for LTBI, but a more common scenario is arriving with a positive tuberculin skin test result and no other medical evaluation yet. In some settings, even the reading of the skin test can be questionable.

The count for **Referred** depends on how the local systems are arranged. If health care providers (external to the health department) are notifying the health department before sending patients, then the notifications can trigger counting. Alternatively, if providers ask patient to make their own arrangements with the health department, then the initial communication (e.g., telephone request for appointments) with patients can trigger counting. Another method would be counting patients when they actually arrive and register. You should select the method for counting that fits the circumstances and the needs for evaluation. Feasibility/efficiency of data collection is another factor you should take into account. DTBE does not recommend any specific method, but the DTBE program consultants can offer suggestion for your specific circumstances.

One factor you can consider is the loss rate in the referral process. For example, if an HIV clinic refers its patients that have positive skin test results for further tests and treatment, but only 50% of the patients come to the health department for the tuberculosis evaluation, then this loss rate might be important statistically. The targeted-testing report does not have a way to do this because it does not include an evaluation rate. In contrast, if the referrals are for food service workers who have pre-employment testing, and the urgency to provide treatment for LTBI is comparatively minor, then the loss rate might not be such an important number. The decision really depends on what you are trying to measure, and of what value could the statistics be to your program.

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

The description presented here is identical to that for Part I. In general, patients who are referred because of positive tuberculin skin test results rarely have tuberculosis disease. Therefore, if a substantial fraction (e.g., > 1%) have tuberculosis disease, then this alerts you of a need for further exploration.

Note that this definition for **TB Disease** is different than the one used for the contact report. The main difference is that you also should count prevalent cases, that is, cases that already have been diagnosed, as **TB Disease** in the targeted-testing report.

Targeted testing is not designed for active case-finding for TB. Active case-finding means evaluating the individuals in a defined population for tuberculosis disease. This contrasts with passive case-finding, which means waiting for individuals to seek medical care because of tuberculosis symptoms. (These terms are not the same as active surveillance and passive surveillance, which are contrasting strategies for collecting tuberculosis case reports.)

Active case-finding usually is not efficient as a part of targeted-testing activities because tuberculosis cases are comparatively rare in most U.S. populations. On average, fewer than 1 per 10,000 persons has tuberculosis at a given time. In selected populations, the prevalence rate might be greater than 1 in 1,000, and in these populations, active case-finding might be efficient. The tuberculin skin test is not a sensitive or specific method for active case-finding; therefore targeted-testing activities that include a component of active case-finding require an ancillary testing method, such as chest radiography. The targeted-testing report is not designed for evaluating active case-finding projects. However, projects that combine targeted testing with active case-finding can be evaluated with the targeted-testing report.

The case definition for **TB Disease** is the same as that of the national case definition in the RVCT instructions. However, the counting instructions are different. For RVCT, the determination about jurisdiction and who counts the case is connected to the address of the patient and several other details. For the targeted-testing report, if you counted the person for the report, then you count the tuberculosis case under **TB Disease**, even if another jurisdiction is counting the case for RVCT national surveillance. This happens in targeted-testing projects that include persons who reside in different jurisdictions.

The targeted-testing report is designed to include prevalent tuberculosis disease and LTBI. Therefore, findings from sources apart from the targeted testing can be counted as outcomes in this report. For example, if a person who is included in a testing project has active tuberculosis and the case was diagnosed before the person was enrolled in the testing project, this case should be counted in the targeted-testing report. However, if a person is initially diagnosed as having LTBI after the complete diagnosis but active tuberculosis develops in that person later, then the classification should remain as LTBI because that was the determination of the targeted testing.

If a person who is included in targeted testing has a history of resolved tuberculosis disease, treated or not, and if the history for tuberculosis disease is documented to the extent that meets local standards, then this person should be classified as having LTBI after the diagnostic evaluation is completed. Depending on the circumstances and the judgment of the healthcare providers, a test for *M. tuberculosis* infection might not be necessary for the evaluation because it would it would not be helpful. Such a person also might be classified as a candidate for treatment of LTBI if the tuberculosis was not treated before or was not treated completely.

LTBI. As defined for **Part I**.

The description presented here is identical to that in **Part I**. In general, patients who are referred because of positive tuberculin skin test need further diagnostic history and tests before the LTBI determination can be made. The history should include questions about tuberculosis risks, as pertains to the risk categories used in the targeted-testing report, and the tests usually include a chest radiograph at a minimum for excluding tuberculosis disease. In some instances you might need to recheck the skin test reading or even repeat the skin test, and these details would be part of the evaluation process. The decisions about how to diagnose or verify LTBI in referred patients are dependent on numerous factors that are beyond the scope of ARPEs.

The goals of targeted testing are finding LTBI and getting it treated in order to prevent future tuberculosis cases. For these activities to be efficient, the prevalence rate of latent infection should be greater than the national average, which might be on the order of one to five percent (averaged) for adults in the United States. The efficiency of the prevention activities is increased even more if the infected individuals also have risk factors for progression to active TB.

Obtaining the diagnostic outcome of **LTBI** requires a range of activities, although only the outcome itself is counted in the targeted-testing report. First is an interview to determine whether the patient already has symptoms of active tuberculosis or a history of tuberculosis exposure, infection, or disease. Next is a tuberculin skin test (generally this has been done already for patients referred to the health department) to detect evidence of LTBI. The skin test should be interpreted according to local policies or guidelines. Finally, if the skin test result is positive, a chest radiograph (i.e., x-ray) and sometimes other tests are needed to exclude active TB. The selection of tests for excluding active tuberculosis depends on the circumstances and the healthcare provider's judgment.

A two-step skin test is not recommended for targeted testing. Two-step testing is necessary for initial testing upon entry to infection-control surveillance programs, with the

individuals being retested according to a routine schedule, for example, annually. However, the targeted-testing report usually is not suitable for these types of surveillance data.

For each individual, the determination about the LTBI diagnosis is up to the healthcare provider. Discrepancies between guidelines and diagnoses should be resolved by jurisdictional public health officials. The targeted-testing report is not designed to evaluate diagnostic practices for LTBI; the report has a built-in assumption of correct practices.

This counting category (**LTBI)** can include individuals who did not have LTBI diagnosed directly as part of a current testing activity. This instruction is different from that for the contact report. For the targeted-testing report, individuals who have historical

information about tuberculosis infection can be counted under **LTBI** (as having possible prevalent infection). The two examples are

1. Previous positive skin test result, whether or not LTBI was treated
2. Previous tuberculosis disease that is healed now, whether or not it was treated

You and the other ARPE contributors should set the documentation standards for counting under these instructions. For example, you might require that each claim of a previous positive skin test result be backed by documentation before it is counted under **LTBI** in the report. With so many subtleties to counting prevalent infection from historical information, you should strive for consistency by working with your colleagues and establishing the counting criteria for your jurisdiction.

Probably only a small fraction of individuals who are counted under **LTBI** because of historical information will turn out to be candidates for treatment of LTBI. You should take this into account when interpreting results from the targeted-testing report.

Candidates for Treatment. As defined for **Part I**.

The description presented here is identical to that for **Part I**. For referred patients, the likelihood that they will be candidates for treatment depends on the reasons that they are being tested. Patients who are referred after "routine" (i.e., non-targeted) testing are less likely to be candidates for treatment.

This category is an important part of the targeted-testing report. It is not even part of the contact reports because all contacts who have LTBI are assumed to be candidates for treatment. In successful targeted-testing activities, most persons who are found to have LTBI are also candidates for treatment. However, in any circumstance, some persons who

have LTBI are not candidates for treatment for various reasons, such as previous tuberculosis treatment, contraindications against specific medicines, high risk of adverse effects from treatment, or a very low risk for active TB.

The guidelines for selecting candidates for treatment of LTBI are context sensitive, and they are dependent on judgment; ultimately someone has to make a determination about whether an individual should be considered a candidate, at least for counting purposes. This ambiguity creates the possibility for inconsistency in reporting, which is a reflection of the uncertainty in the recommendations for treatment of LTBI. For reporting purposes, you should seek optimal consistency by working with an ARPE coordinator.

In some jurisdictions, the guidelines for selecting treatment candidates are different from the national guidelines. The operational treatment guidelines are the ones that should be used for counting **Candidates for Treatment**. If treatment guidelines change during the course of a reporting year, then the guidelines in effect at the particular moment can be used for counting purposes. (The distinction has little effect in most instances, and a decision can be made to consider all the patients under one set of guidelines or the other for efficiency, as long as the potential discrepancy is noted.)

In contrast, sometimes a provider will recommend against treating LTBI because that patient has unstable circumstances or expresses reluctance to participate. This decision not to treat is up to the provider and the patient; however it is different from the criteria for **Candidates for Treatment**. **Candidates for Treatment** is based on the medical and epidemiological criteria for deciding when to recommend treatment to a patient, and a reluctance to prescribe or to be treated should not be considered for reporting purposes.

Possibly patients would be started on treatment for LTBI when they are not actually, by guidelines or recommendations, candidates for treatment. If the treatment is to be counted on the targeted-testing report, then the individuals also should be counted as treatment candidates in order to maintain flow of data. Such events represent a potentially inefficient use of resources and also a risk to patients, and therefore further inquiry for program evaluation is warranted.

Started Treatment. As defined for **Part I**.

The description presented here is identical to that for **Part I**.

The two components of this instruction are (1) that the patient has been counted under **LTBI** for the evaluation outcome and (2) the patient receives at least the first dose of treatment. (The patient also should be counted as a candidate for treatment.) The concept

for the first point is that treatment implies that LTBI has been diagnosed, and the details meet the ARPE definition for LTBI.

The point about the first dose of treatment can be difficult to determine with certainty unless a patient is receiving directly observed therapy, which is provided more often for contacts than for TB-infected persons found during targeted testing. Sometimes you and other providers have to rely on substitute methods for ascertaining the start of treatment. The best and simplest method is asking the patient about it in an interview, and if the response from the contact can be validated by a pill count, this is even better.

However, sometimes the information about starting treatment is inaccessible. For this circumstance, the only substitute is a confirmation that the patient filled a prescription for treatment of LTBI. When even this information is unavailable, then treatment should not be regarded as started. In particular, the existence of a prescription or a medical order to start treatment should not be considered adequate for counting under the category of **Started Treatment**.

Completed Treatment. As defined for **Part I**.

The description presented here is identical to that for **Part I**.

A simplistic definition is necessary for **Completed Treatment** because this element is intrinsically difficult to describe and measure. Even with this definition, **Completed Treatment** is likely to cause confusion and disagreement. Consistency should be your highest priority. The instructions here are the same as for the aggregate report of contacts, but you should be aware that the circumstances of targeted-testing projects are different from contact investigations, and the information that is available to you in determining completion of treatment is likely to be different.

One overriding factor: The definition for **Completed Treatment** is not a substitute for guidelines for treating LTBI. Treatment practices should be based on local, state, and national policies or guidelines, and decisions for individual patients are between healthcare providers and their patients. None of the ARPE definitions are intended as references for medical care or case management.

The definition for **Completed Treatment** includes three requirements:

1. The provider discontinues treatment after concluding that the patient has completed a recommended treatment regimen. Decisions by the patient or program administrators are not equivalent for meeting the definition. Thus, administrative close-outs do not meet the definition. (An administrative close-out is a

determination by a program administrator that enough treatment was given and therefore the treatment is being classified as **Completed Treatment** even though a provider has not discontinued it. This does not meet the definition for the targeted-testing report.)

2. The reason for the "80 percent" figure is that some tuberculosis treatment studies have used this as an arbitrary cut-point for specifying completion of therapy. When intensive monitoring methods such as pill counts or directly observed therapy are in effect, the achievement of 80 percent of doses is measurable. In most situations of targeted testing, however, data are not available to determine how many doses the patients have taken. In these situations, you need a combination of data to make a reasonable guess about the number of doses that were taken (and whether or not this constitutes 80 percent of what was prescribed). Typical factors you might consider are the start date for treatment, the number of prescription refills, clinic attendance, and the adherence rate reported by the patient.

3. Completion within 150 percent of the planned treatment period is a pragmatic component of the definition. The purpose is to get the reports closed with finality. The targeted-testing report is no longer relevant if every single open treatment record is pursued to the point of final determination. Patients who are still on treatment at the time point that is one-and-one-half times (i.e., 150 percent of) the intended duration should be regarded as not completed for the sake of the contact report, even if completion might be reached at a later date.

A number of factors can complicate determinations about **Completed Treatment**. An example is patients who require a change of regimen midway through a course. Another example is patients who start and stop treatment several times. For the targeted-testing report, you sometimes have to make arbitrary decisions about how to count these events. As much as possible, you should make these decisions consistently when similar situations arise and uniformly across reporting sites. Consultation with your ARPE coordinator or your DTBE program consultant is recommended.

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

The description presented here matches that for **Part I**. However, the specific reasons are not defined separately here. Their definitions should be the same here as there.

The instructions here are nearly identical to those for the aggregate report of contacts, with the exception of the omission of the word "contact" here. However, in the broader perspective, you should be aware that the circumstances of targeted-testing projects are

different from contact investigations, and the information that is available to you is likely to be different. Also, the priority that is placed on treating LTBI found during targeted testing sometimes is lower than the priority placed on treating LTBI found during contact investigations. Therefore, less energy will be spent on tracing these patients if, for example, they appear to be nonadherent to a treatment regimen.

Although DTBE encourages submission of this information about incomplete treatment to the national tuberculosis program, the main purpose of this section of the report is to assist local and state tuberculosis control programs to assess the obstacles that prevent completion of therapy within their jurisdictions. A major shortcoming of these data is that they are peculiar to local context; therefore these data have uncertain meaning when combined with reports from other areas. In addition, tuberculosis controllers have reported that interpretations of the definitions vary substantially from site to site; therefore the data that are aggregated from multiple reporting areas consist of mixed information. The definitions used in the instructions should be followed as closely as possible under the circumstances.

The categories under **Reasons Treatment Not Completed** have a relative hierarchy: in a situation where several reasons for incomplete treatment might apply to one patient, the most specific reasons should be selected. In general, the reasons near the top of the list are more specific and less subjective. Some of the reasons are more serious, for example, death during treatment or adverse effects of treatment. These events are likely to require further attention; therefore they should be captured whenever possible.

You should set a goal of counting each instance of incomplete treatment under one of the categories of **Reasons Treatment Not Completed**. However, you can expect difficulties in doing this and accept that you might not be able to assign a reason for each patient. DTBE does not require that the sum of patients who are counted under the categories of **Reasons Treatment Not Completed** equal 100 percent of all the patients who do not complete treatment, although a local or state tuberculosis program might decide to do so.

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

These instructions are similar to the analogous indices instruction for other ARPEs parts. Because the testing denominators are not included, the indices for evaluation and infection cannot be calculated. A greater potential difference lies in the interpretation of results, because the public health issues of referral counts are likely to be different than those for contact investigations or targeted testing.

The purpose of these evaluation indices is to give you a synopsis of the data flow in the referral section of the targeted-testing report. Each index reflects the average result of a specific process that is shown in the report. You could regard each index as a measurement of performance, but that interpretation generally is overly simple. Better that you regard the indices as general comparators (e.g., for comparison to national averages) and as clues for determining which activities need your closer scrutiny. (See page 99, **How to interpret and use the ARPE results**, for additional suggestions about interpreting the indices.)

ARPEs differ from some other or previous U.S. tuberculosis program reports in that the indices are not adjusted for mitigating factors. For example, the treatment completion rate does not exclude patients who move from your jurisdiction after starting treatment, and therefore the treatment rate is diminished by the departure of these contacts. This is a controversial point, but you have the option of calculating indices with adjustments, for your purposes. In the national report, no adjustments are made.

When ARPEs are entered into TIMS, the software program will calculate indices initially and then will recalculate them when you edit/update the data. The formulae that appear in the printed ARPE forms are the basis for those built into TIMS. If you use paper-copy forms, or computer-screen mock-up forms, you must remember to recalculate the indices after counts are edited/revised in the upper sections of the forms. If you use spreadsheet software programs for recording ARPE data, you can incorporate the formulae that are shown in the paper-copy ARPEs forms.

ARPEs and TIMS

The Tuberculosis Information Management System (TIMS) initially had a design requirement that it should be able to generate reports, such as ARPEs, for program evaluation. However, technical problems in the overall system ultimately precluded any capacity to generate reports. Even if data on individual contacts are saved in TIMS in the Client Module, the system cannot generate a contact report by itself. Generating a report would require exporting the data and designing a system to analyze them.

However, the Evaluation Module in TIMS has programs for recording, storing, combining, and transmitting ARPEs. In general, you will find that these programs are straightforward if you already are fluent in both ARPEs and TIMS, but if you are not, you should consider contacting DTBE for user support.

The TIMS version of ARPEs is an electronic facsimile of the paper forms. You enter aggregate counts of your data directly into the data fields. You can complete a report partially and save it for editing/updating later. When you save a report, TIMS initiates the

calculated indices if the report is new, and it recalculates the indices if you saved the report before and returned to edit it. TIMS assigns a unique number to a report the first time that you save it, but the program also prompts you to name the report. You should adopt a naming convention that makes sense to you and others who look at the report. For example, you could include your state, a particular district within your state, and the cohort year.

In general, the more distinct reports that you save for your overall jurisdiction, the more flexibility you will get in return for the extra effort. At the extreme, you can save a separate contact report for each contact investigation. Later, you can combine any or all reports representing a given year. The disadvantage of saving a greater number of reports is the work burden and the administrative complexity. Approaches, needs, and capabilities differ from place to place, and you should use a team approach to determine a strategy for saving reports in your overall jurisdiction. One practical system is reporting separately for each county within a state.

You can combine reports (a contact report with a contact report; a targeted-testing report with a targeted-testing report) from the same cohort year by selecting them and using the combine-report function. When combined, a new report is created, but the component reports remain. You will be prompted to name the combined report. You can edit the component reports, which automatically revises the combined report, but you cannot edit the combined report. The indices are calculated automatically in the combined report. The system does not set a limit on the number of reports that you can combine.

You can submit ARPEs in TIMS to DTBE by using the same data transmission rules that apply to case surveillance data. When you submit a summary (i.e., combined) report, it "drags along" all of the component reports that you combined into it. For example, if you set up separate reports for each county in your state, and you add them together for the state report, all of the county reports remain distinct and transmit with the state report. Someone who is reviewing your state report also can view all the county reports. Again, you should name each report with reference to its origins so that an unfamiliar reader will be able to determine its source.

Also, you can print the reports from TIMS at any point during their creation. You can use printed reports for discussions, for paper-copy files, and for submission.

Reporting schedule: the preliminary and final reports

The National Tuberculosis Controllers Association and DTBE negotiated the reporting dates for ARPEs, which represent a compromise between administrative constraints and

practical utility. The main administrative concerns are (1) the time required to gather and collate information from numerous sources and (2) the other administrative priorities, such as preparation of annual reports, which compete with ARPEs for staff time. The practical utility of the reports, however, decreases when they are delayed for administrative purposes. Therefore, DTBE and the National Tuberculosis Controllers Association recommend that you review information in the reports as soon as it becomes available to learn more about the issues in your tuberculosis control programs.

Each of the reports has a 2-year reporting cycle. The cycle is based on the calendar year, and it is prolonged by the long duration of treatment for LTBI. During the first year in the life of a report, you delimit and document the cohort of patients who are included in the report, and by August 15 of the following year, you submit the "preliminary" report to DTBE through your routine reporting routes (e.g., the state epidemiologist or tuberculosis control official). Data on the number of patients who started treatment should be available to you by that time, but not on the final number of patients who completed. Therefore, you and your team have the option of deciding how much, if any, treatment completion results you enter in the preliminary report.

You should submit the "final" report on August 15 of the year following the preliminary report, that is, in the second year after the cohort period. The final report should include all treatment completion results and the reasons that treatment was not completed, if your program is collecting these. If you were unable to submit a preliminary report before the final report comes due, then a single report, the final report, is sufficient.

DTBE anticipates that jurisdictional programs can submit reports on schedule if reliable program systems are in place. DTBE will contact state or big city program officials if reports have not been received by August 15. The DTBE program consultants are authorized to work with jurisdictional program officials in negotiating alternative reporting schedules if deadlines cannot be met.

How to Interpret and Use the ARPEs Results

The reports that you generate in the ARPE systems are tools—they are only inert collections of numbers until you put them to work for you. How you do this will define their worth and simultaneously will strengthen your reporting systems, because after you apply the ARPE results to program evaluation, you will imagine better ways to collect the data and coordinate the reports.

The counts

The actual numbers of persons or events that are included in your system have several

implications. These numbers give a general indication of how much work was done or is underway. For example, listing a thousand contacts in a single year gives an idea of substantial work, and if a quarter of those contacts have latent infection, you have an overview of the commitment of resources required for completion of therapy. Knowing how much work has been done, you have an indirect indication of costs. Monitoring the counts from year to year, you have an opportunity to note changes. Although the reports do not show the reasons for change, they notify you of potential problems that might require closer review.

You should also look at the counts for assessing the statistical strength of your calculated indices, because small denominators or numerators can cause unstable estimates. For an example of a small denominator, if three of four contacts who started treatment for latent infection completed it, then the completion of therapy rate is 75%, but if only one less contact had completed treatment, the completion rate would have been 50%. For an example of a small numerator, if two contacts out of two hundred (total) has active tuberculosis disease diagnosed in contact investigations in one year, then the disease rate is 1%, but if four contacts out of two hundred have tuberculosis disease in the following year, then the disease rate is 2%—a doubling and yet possibly not a meaningful change.

The counts are the starting point for calculating the indices, and relatively minor errors in the counts can generate misleading indices. Errors can creep into your reporting systems at each step along the way to completed reports. Although the reports themselves are very simple, the events and all the many steps in counting the events are very complex, which requires many detailed operations along the way to a completed report, and any unreliable details can have "ripple effects" that cause errors to propagate into your reports. The definitions for counting/including events can be misunderstood, events can be missed, and systematic bias can influence counts. Although ARPEs are not scientific tools, you should invest constant, steady effort in maintaining the accuracy of the reports. This effort includes training yourself and your colleagues about the reporting process and monitoring it regularly.

Idiosyncratic details in the reporting definitions can affect the counts in frustrating ways. If you notice patterns that seem to be specific to your jurisdiction or problematic in any way, you should record the details as part of your operational information and refer back to these issues when interpreting the results and sharing the reports.

The indices

The calculated indices in the reports are not adjusted for any operational contingencies. For example, the calculation of completion of therapy does not deduct patients who move

out of your jurisdiction, even though you might not be able to influence treatment after the individuals leave. This serves to underscore the simplicity of the indices and the necessity of looking at many issues when interpreting them.

The order of the indices in the reports reflect the data flow of the processes in contact investigations or targeted testing. Thus, they show the relative losses at each of the steps, for example, from contact evaluation through treatment initiations to completion.

You can compare between the indices for two or more regions within a jurisdiction and for two or more jurisdictions. You also can compare the indices of a jurisdiction and the average for the United States. Although the comparisons provide perspective and should raise questions, they should not be overly interpreted as indicative of "performance." The results in a report are reflective of the entire context that was the source for the data, and the context is unique to each site. For example, a treatment completion rate of 40% in one site does not imply worse performance than in a jurisdiction that achieved 60%, because the situations probably are completely different.

You should take advantage of longitudinal (year-to-year) comparisons for your own programs. Even these comparisons need to be interpreted carefully, because changes in the indices reflect many influences beyond program performance. However, you should determine the likely causes of the changes, because the causes might require programmatic interventions.

Each index is a simple average that reflects only the aggregate data and none of the details that are embedded in the aggregate data. As such, an index can either conceal extreme results or it can be deviated by extreme results. For example, if some contact investigations include far too many contacts and others include too few, the average contact-to-case ratio can appear unremarkable. This is why the reports are most informative when they are subdivided to the basic operational unit, usually the local health department. Even at the local health department, the averaging effect can obscure significant issues, and subdividing the data as much as possible improves utility.

The indices are dependent on correct counts, especially when the numerators or denominators are small. Correct interpretation of the indices requires understanding the reliability of the source data, and the first step for investigating an index that appears out of range is verifying the data.

Process and outcomes

Most of the ARPE data items reflect processes and not outcomes. The long-term purpose

of both contact investigations and targeted-testing projects is prevention of tuberculosis cases, and this is the best outcome measurement for these activities, but neither report measures prevention or failure of prevention. The only major outcome that is measured in the reports is completion of treatment for latent infection, which at least is an indirect indication of cases prevented.

Besides completion of therapy, finding tuberculosis cases is another true outcome that sometimes takes on greater consequence. Generally, cases are found as part of contact investigations; targeted-testing projects rarely focus on active case finding. On average, 1% of contacts to contagious tuberculosis have tuberculosis disease at the time of the contact investigation, but when transmission is intense or the contacts are more susceptible than usual, the rate of disease can be larger.

Productivity and efficiency

From an ARPEs perspective, productivity is indicated by the aggregate counts. For example, if you list 1,000 contacts and evaluate 900 of them, this implies a substantial investment of resources and a substantial amount of work that your team accomplished. This shows productivity. However, if the jurisdiction with 1,000 contacts only had two contact investigations, this raises concern over the efficiency of the activities. Even though you accomplished a large amount of work, the number of contacts per case far exceeded the typical number of 10 to 15 contacts for each contagious case. Listing, finding, and evaluating too many contacts is inefficient because many contacts who are unlikely to be infected are being included. (However, some scenarios have great numbers of contacts who are large odds of being infected, and the epidemiological evidence should guide the size of a contact investigation.)

For another example, suppose you start a targeted-testing program that enrolls 1,500 persons in its first year. Later, when you are reviewing the final data, you notice that only 3 persons completed treatment for latent infection. The end-point productivity was small, and the efficiency might be poor, but you have to analyze the step-by-step flow of data for the project before you commit to any conclusions.

Sometimes productivity and efficiency are apposing goals that you have to balance as elements of program management. The measurements and principles of productivity and efficiency are undefined for tuberculosis program managements, but ARPEs provide you with a convenient descriptive overview for exploring these factors.

<u>Going back to the source and subsets of the data</u>

The broad overview that ARPEs give you is you starting point for more focused

exploration of the data and its sources. You should look to the results recorded in the ARPE system as the source of questions instead of answers. Finding the answers requires that you trace back the ARPE data to its sources, the daily operations of the programs in your jurisdiction. The sources vary from situation to situation. In one scenario, you might find answers by reviewing patient records in a clinic. In another, you might find answers in the flow sheets being used for contact investigations. Finally, you should coordinate with your colleagues, the persons who work in your programs. They have perspectives that go beyond ordinary paperwork.

The reports are easier to trace back if the data are grouped into subsets by local jurisdiction or whatever administrative divisions fit the context of your area. For example, if you notice that (overall) a large fraction of tuberculosis patients with positive sputum-smear results do not have contacts, you need to know where to search first for the underlying problems. If you have a separate report for each public health clinic, you can select the one with the largest fraction and begin your exploration there.

ARPEs as a medium and a catalyst for communication

Your reports are a tool for sharing. One of the advantages of a standard report for all U.S. jurisdictions is that program officials from quite different jurisdictions can discuss their ARPE results and have confidence that they are discussing the same types of results, measured with the same definitions, albeit under different conditions.

You are encouraged to pay attention to the extremes in the ARPE results (e.g., a great completion-of-therapy rate or a poor evaluation rate) to initiate communications within your system and with your colleagues in other jurisdictions. Raising questions is a critical step toward finding answers.

Providing feedback to program personnel

The data for ARPEs start with the daily tuberculosis control activities of local programs. In some places, the personnel who carry out these activities also have to gather the data for ARPEs; in other places, separate administrative personnel gather these data. Regardless, you should provide each contributor to ARPEs with routine opportunities to discuss results and solve problems. When each worker understands how his or her contribution affects the reported results, then the reports are serving their best role.

Limitations

ARPEs are the first steps for evaluating your key activities for tuberculosis prevention: contact investigations, targeted testing, and treatment of LTBI. The reports do not, however, provide comprehensive insight into any of these activities, which should be

evaluated in the context of local communities, tuberculosis programs, and epidemiology. In addition, the intrinsic limitations of the report have to be taken into account.

Limitations of aggregate data

Aggregate data tend to conceal extreme ratios because diverse results are likely to converge on an overall average result, and in the calculation of indices, the result is a mean (i.e., simple average) instead of a median, which generally is a better representation of non-randomly distributed data.

Limitations of the definitions

For ARPEs to have broad utility, they have to be relatively simple, yet the realities that they encompass, that is, contact investigations and targeted-testing projects, are extensively complex, with layers of details that are distributed over extended time periods. Because of this tension between simplicity and complexity, the reports fail to capture nuances. The simplistic approach to reporting is most obvious in the definitions, which fail to reflect many subtleties. Another source of limitations in the definitions is the need for consistency with other data systems, especially the national tuberculosis case surveillance RVCT system.

Inexact results for epidemiological study

ARPEs were not designed for epidemiological study and analysis. The data definitions favor operational factors over epidemiological ones, and the data collection should not be subjected to the intensive quality control and review that is necessary for epidemiological studies, because this would be very inefficient. However, you can use ARPEs as a starting point for focused investigations using more stringent definitions and data collection.

Inaccuracies of reporting

With the many complex activities covered by the reports, and the number of steps required for data collection, opportunities for misinterpretations are numerous. You should check any extreme results in ARPEs for potential misconceptions/errors before searching for programmatic problems.

Inconsistency of reporting from site to site

From jurisdiction to jurisdiction, and from site to site within a jurisdiction, inconsistencies of reporting are likely because of different contexts and different interpretations of instructions. The inconsistencies also can arise from intentional modifications of ARPEs instructions for meeting local needs.

Appendix 1

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

CDC
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL CENTER FOR HIV, STD, AND TB PREVENTION
DIVISION OF TUBERCULOSIS ELIMINATION
ATLANTA, GEORGIA 30333

Form Approved
OMB No. 0920-0457
Exp. Date 08/31/2006

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

Reporting Area: _____

Cohort Year: _____

Closure Date for Follow-up: 8 / 15 / _____ (August 15 of the second year after the cohort year)

Total TB Cases Reported: _____

Part I. Cases and Contacts

	Types of Cases for Investigation:		
	Sputum smear +	**Sputum smear - cult. +**	**Others**
Cases for Investigation	(a1)	(a2)	
Cases With No Contacts	(b1)	(b2)	
Number of Contacts	(c1)	(c2)	(c)
Evaluated	(d1)	(d2)	(d)
TB Disease	(e1)	(e2)	(e)
Latent TB Infection	(f1)	(f2)	(f)
Started Treatment	(g1)	(g2)	(g)
Completed Treatment	(h1)	(h2)	(h)

Reasons Treatment Not Completed:

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

Part II. Evaluation Indices (Automated in TIMS, and converted to percentage as indicated by "%")

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

CDC xx.xx

Appendix 2. Recommended minimal data for contact reporting, items listed in approximate order of appearance in report and logical sequence. See instructions for explanations of terms.

For the jurisdiction

- Name of jurisdiction
- Cohort (calendar) year of the report
- Total number of tuberculosis cases for the cohort year
- Preliminary or final report
- User-assigned label for the report

For the individual case

- Count year and count status (counted or not)
- Anatomical sites of tuberculosis disease
- Sputum smear results for acid-fast bacilli
    - If smear results negative, results for sputum culture
- Whether or not any contacts were listed for the case

For the individual contact

- Linkage to specific case counted by the jurisdiction
    - ARPE category of the specific case
- Medical/diagnostic evaluation final determination (or lack thereof):
    - Latent tuberculosis infection
    - Active tuberculosis disease
    - Both above conditions excluded
    - Prior or coincidental tuberculosis

For the infected contact

- Treatment started or not

For the contact starting treatment

- Completion of treatment or not (number of doses, duration of treatment)

For the contact not completing treatment

- Disposition: reasons treatment not completed

Appendix 3

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

CDC
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL CENTER FOR HIV, STD, AND TB PREVENTION
DIVISION OF TUBERCULOSIS ELIMINATION
ATLANTA, GEORGIA 30333

Form Approved
OMB No. 0920-0457
Exp. Date 08/31/2006

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

Reporting Area: _____

Cohort Year: _____

Closure Date for Follow-up: 8 / 15 / _____ (August 15 of the second year after the cohort year)

Part I. Testing Counts

	Testing Formats:				
	Targeted Testing				Admin.
	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)	($e1_m$)	($e1_p$)	($e2_m$)	($e2_p$)	(e)
Candidates for Treatment	($f1_m$)	($f1_p$)	($f2_m$)	($f2_p$)	(f)
Started Treatment	($g1_m$)	($g1_p$)	($g2_m$)	($g2_p$)	(g)
Completed Treatment	($h1_m$)	($h1_p$)	($h2_m$)	($h2_p$)	(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 (Automated in TIMS, and converted to percentage)

	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	($f1_m$÷$e1_m$)%	($f1_p$÷$e1_p$)%	($f2_m$÷$e2_m$)%	($f2_p$÷$e2_p$)%	(f÷e)%
Treatment Rate	($g1_m$÷$f1_m$)%	($g1_p$÷$f1_p$)%	($g2_m$÷$f2_m$)%	($g2_p$÷$f2_p$)%	(g÷f)%
Completion Rate	($h1_m$÷$g1_m$)%	($h1_p$÷$g1_p$)%	($h2_m$÷$g2_m$)%	($h2_p$÷$g2_p$)%	(h÷g)%

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
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NATIONAL CENTER FOR HIV, STD, AND TB PREVENTION
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ATLANTA, GEORGIA 30333

Aggregate Reports for Tuberculosis Program Evaluation:
Targeted Testing and Treatment for Latent Tuberculosis Infection (continued)

Part III. Referral Counts

Referred, TB Infection:	Medical Risk	Pop. Risk	Admin.
Referred	(i_m)	(i_p)	(i)
TB Disease	(j_m)	(j_p)	(j)
Latent TB Infection	(k_m)	(k_p)	(k)
Candidates for Treatment	(l_m)	(l_p)	(l)
Started Treatment	(m_m)	(m_p)	(m)
Completed Treatment	(n_m)	(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
(Automated in TIMS, and converted to percentage)

Referred, TB Infection:	Medical Risk	Pop. Risk	Admin.
Disease Rate	(j_m÷i_m)%	(j_p÷i_p)%	(j÷i)%
Candidate Rate	(l_m÷k_m)%	(l_p÷k_p)%	(l÷k)%
Treatment Rate	(m_m÷l_m)%	(m_p÷l_p)%	(m÷l)%
Completion Rate	(n_m÷m_m)%	(n_p÷m_p)%	(n÷m)%

CDC xx.xx

Appendix 4. Recommended minimal data for targeted-testing reporting, items listed in approximate order of appearance in report and logical sequence. See instructions for explanations of terms.

For the jurisdiction
- Name of jurisdiction
- Cohort (calendar) year of the report
- Preliminary or final report
- Types of testing activities for inclusion in report
- User-assigned label for the report

For the individual patient
- Reason for inclusion
  - Targeted testing project
  - One-by-one (individual) enrollment
  - No risks for infection; inclusion in administrative testing
- Medical/diagnostic evaluation final determination (or lack thereof):
  - Latent tuberculosis infection
  - Active tuberculosis disease
  - Both above conditions excluded
  - Prior tuberculosis and testing history

For the infected patient
- Medical risks for progression of infection to disease
- Social/historical risks for latent infection
- Treatment recommended by guidelines and provider judgment (candidate)

For the treatment candidate
- Treatment started or not

For the patient starting treatment
- Completion of treatment or not (number of doses, duration of treatment)

For the patient not completing treatment
- Disposition: reasons treatment not completed