Appendix D: Report of Verified Case of Tuberculosis Questions and Clarifications

This appendix consists of a list of questions and clarifications regarding the RVCT instructions. **This document is updated periodically.** To download the RVCT Instruction Manual and to see the most current version of the document, visit

http://www.cdc.gov/tb/programs/rvct/default.htm

Report of Verified Case of Tuberculosis (RVCT) Questions and Clarifications on RVCT Items September 26, 2013

| RVCT | Item | Question | Answer |
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| Item# | 200111 | Question | |
| 3, | Case Numbers | How should the RVCT be completed for a recurring TB case for the following | The answer is indicated in the document "Additional CDC Guidance for Reporting Recurrence of TB Disease for TB Programs and Pacific Island |
| 5, | Count Status | Case numbers | Jurisdictions," attached at the end of this document. |
| 6, and | Date Counted | Count statusCount date | |
| 7 | Previous Diagnosis of TB Disease | Previous diagnosis of TB diseaseLaboratory test results | |
| 4 | Reporting Address for Case | A patient is diagnosed with TB in the hospital and shortly thereafter dies. He has no | The "Reporting Address for Case Counting" should be the hospital. This should be done only in lieu of having a patient address of residence. |
| | Counting | reported relatives, friends, or next of kin, nor any record of residence in any location or facility like corrections, long-term care centers or shelters. What should be used for "Reporting Address"? | |
| 4 | Reporting Address for Case Counting | If we are not reporting outcomes from other countries, what about the territories and outlying areas that do report cases to CDC? For example, if we have a case that moves to Guam, and we know they completed treatment there, should we include that outcome on the RVCT? Would this group be | Outcomes for patients who move to other countries will not be included in the funding formula. However, we suggest reporting those patient's final outcome results (if received from those countries). For Completion of Therapy (COT) criteria for funding, we will base that number on the assumption that if someone who moves from the mainland (50 states & D.C.) to a Pacific Island jurisdiction (or outlying areas), they have not "moved out of the country." |
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| RVCT | Item | Question | Angwon |
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| Item# | Item | Question | Answer |
| 5 | Count Status | Which of the following cases diagnosed in the United States should be counted as a case of TB? 1) A person on a U.S. student visa, receives a TB diagnosis in the United States and is receiving anti-TB therapy, and has been or plans to remain here for | It depends on the situation of the person. For more information, see Appendix B (section d), page 208 in the RVCT Manual. Several examples are provided below. Yes, because he has been or plans to remain in the United States for 90 days or more after diagnosis. |
| | | 90 days or more after diagnosis 2) An immigrant living in the United States who receives a TB diagnosis for less than 90 days | Yes, immigrants and refugees should be counted regardless of time in the United States. They are required to complete treatment before entering the United States per 2007 technical instructions (only border crossers and other foreign visitors have time constraints). |
| | | 3) Entered the United States illegally, detained by Immigration and Customs Enforcement (ICE) and is in the United States less than 90 days after diagnosis | No, because he is in the United States for less than 90 days after diagnosis. |
| | | 4) A person is visiting the United States and is here for less than 90 days | No, foreign visitors who are in the country for less than 90 cumulative days before and/or after diagnosis should not be counted. |
| | | 5) A refugee arrives with class B1 status, and reports completion of treatment for pulmonary TB. The person's records indicate that he/she received inadequate treatment due to an allergic reaction. It was decided to restart TB treatment in the United States. Does this person have a countable case? | No, it is not countable because he/she was diagnosed and counted by another country. The case should be reported as non-countable for national TB surveillance as therapy was initiated in another country. Please note the following in Appendix B (section d), page 208 in the CDC TB Surveillance Data training manual: Immigrants and refugees who are examined after arriving in the United States and diagnosed with clinically active TB requiring anti-TB medications should be reported and counted by the locality of their current residence at the time of diagnosis regardless |

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| RVCT | Item | Question | Answer |
| Item# | | | |
| | | 6) A patient was diagnosed with culture-positive TB in State A in February 2009. At that time the patient refused treatment. The patient moved to State B during May 2010. While being treated for cancer, the patient was diagnosed with TB using the clinical case definition. State B received the medical information from State A for culture. Is it ok for State B to use State A's diagnosis and count the case? | Yes, State B may count the case because the patient was lost to supervision for more than 12 months. State A should have counted the case in 2009, even though the patient refused treatment. However, State B can count the case in 2010. State B should use the clinical diagnosis determined in that state (not the diagnosis from State A). State B should also link the case to the Item 3 Case Number from State A. |
| 11 | Race | How should Tibetans be coded? Tibetans are Asians and therefore we need to identify a "sub" code for them. Some Tibetans were born in China and some in India. They are ethnic Tibetans, but there is not a NEDSS category for that. This is analogous to Hmong, which is a NEDSS choice. Your advice? | We suggest they check Asian and no subcategory. For additional information access the CDC Race and Ethnicity Code Set. http://www.cdc.gov/nchs/data/dvs/Race_Ethnicity_CodeSet.pdf |

| Item | Question | Answer |
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| Country of Birth 1 | Are the following considered U.Sborn or NOT 1) Child born on Guam to Filipino parents who are only naturalized U.S. citizens (parents migrated to Guam, then became U.S. citizens by virtue of residing on Guam for so many years 2) Child born on Guam to a Filipino parent who was born on Guam 3) Child born on Guam to an FSM national now currently living on Guam 4) Child born on Guam to parents from CNMI | Country of birth can be very tricky and complicated depending on the scenario. Many people ask questions on this issue and we are happy that they ask us for clarification instead of filling out the variable incorrectly. Definition: A "U.Sborn" person is someone born in 1 of the 50 states or the District of Columbia, OR someone born outside the United States to at least one parent who was a U.S. citizen. CDC uses the U.S. Census Bureau population data to calculate TB rates, therefore the CDC uses the same definition for "U.Sborn" that the U.S. Census uses. Some persons are "U.S. citizens," yet not "U.Sborn." Any child born in Guam is a U.S. citizen (but not necessary U.S. born). If parents arrive in Guam seeking U.S. citizenship status, but have not completed that process and have a child in the interim, the child is NOT U.S born. Specific answers: 1) Yes, the child is U.S. born because this person was born abroad to a parent who was a U.S. citizen (the naturalized Filipinos). 2) Yes, the child is U.S. born if the parent born in Guam is a U.S. citizen because of being born in Guam. If a parent is a U.S. citizen, it does not matter if he or she is naturalized or not. 3) Yes, the child is U.S. born if the FSM national is a U.S. citizen at the time of birth. But in this case, if we are assuming the FSM parents have not been in Guam long enough to be U.S. citizens, the child would not be U.Sborn. 4) Yes, the child is U.S. born if the parents are U.S. citizens, the child is not U.S. born. |
| | Country of Birth | Country of Birth Are the following considered U.Sborn or NOT |

| RVCT | Item | Question | Answer |
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| Item# | Item | Question | THISWEL |
| 12 | Country of Birth | This has to do with a parent of a child (the TB patient). The father was born in a foreign country. He moved to the United States and became a U.S. citizen. The child was born in the father's country of origin. Is the father considered U.Sborn or foreign born? Is the child U.Sborn because the father is now a U.S. citizen? | The parent (Joe) of the patient (Kim) is U.S. born only if at least one of Joe's parents was a U.S. citizen at the time of Joe's birth. If neither of Joe's parents was a U.S. citizen at the time of Joe's birth, then Joe is considered foreign-born. HOWEVER, since Joe moved to the United States and became a citizen, any of his children after he became a citizen would be considered U.Sborn. Joe is foreign-born and his child (Kim, the patient) is U.Sborn (only if the child was born AFTER Joe became a U.S. citizen). U.Sborn does NOT mean the same thing as U.S. citizen. There are only two ways someone can be classified as U.Sborn: If the person was born 1. In 1 of the 50 U.S. states or the District of Columbia Or 2. Abroad to a parent who was a U.S. citizen (at the time of the child's birth) Not all U.S. citizens (e.g., naturalized citizens) are U.Sborn, as in Joe's case. Foreign-born means the following The person was born 1. Abroad (Not in 1 of the 50 U.S. states or the District of Columbia) And 2. Neither parent was a U.S. citizen |
| 18 | Sputum Culture | Molecular beacons are currently not reportable as drug susceptibility test (DST) results on the RVCT. Can they be reported as evidence of <i>M. tuberculosis</i> complex? | Molecular beacons or line-probe assays are one type of molecular tests detecting mutations associated with drug resistance. Yes, some line-probe assays, like the Hain test, can detect MTBC in clinical specimens. http://www.cdc.gov/tb/topic/Laboratory/rapidmoleculartesting/MolDSTreport.pdf |

| RVCT | Item | Question | Answer |
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| Item# | Teelii | Question | TAILD II CI |
| 17, | Sputum Smear | The Kinyoun stain which is in the "Smear" test result section is used for both AFB | Some confusion appears to stem from the use of Kinyoun staining for confirmation of AFB in positive cultures. This should not be confused with the initial |
| 18, | Sputum Culture | stain and preliminary culture tests. Currently, all tests done by Kinyoun stain are being | smear that is done from the clinical specimen to determine the presence of AFB and relative bacterial burden (Item 17 – Sputum Smear, or Item 19 – |
| 19, | Smear/ Culture | placed into the "Smear" test result section. However, when a preliminary culture | Smear/Pathology/Cytology of Tissue and Other Body Fluids depending on the source). |
| 20, and | Smear/ Pathology/ Cytology of Tissue and Other Body Fluids | positive test is done (which is done by the same method), when placed in the "Smear" test result page, it would appear that the patient is again infectious, when indeed they are not (smears indicate | Laboratories will perform an AFB smear from the clinical specimen (usually fluorescence staining). Then the specimen is inoculated for culture. If the culture becomes positive, the first step performed is usually a microscopic examination to confirm the presence of AFB in the culture. Kinyoun is one example of the staining that may be used for this |
| 21 | Culture of Tissue and Other Body Fluids | infectivity, cultures do not). In addition, this test is populating into the "Smear" section of the RVCT, not the "Culture" area. This makes the RVCT go from a Negative Smear to a Positive Smear when, in fact, the result should be a preliminary culture. This is causing confusion for field staff and they are unsure as to whether or not these results should be moved over to the "Culture" field. | purpose. Others are Zeihl-Neelsen and fluorescence staining methods. After confirmation of AFB in the culture, laboratories will proceed with identification. The AFB smear from the culture would not be captured on the RVCT. Items 18 and 20 would refer only to the culture result. |
| 18, and | Sputum Culture and | The sputum culture variable specifies that results from specimens collected after the patient has been on therapy | Yes, sputum should have been collected during diagnostic work-up or shortly thereafter. Do not record specimens collected after the patient has received treatment for more than 2 weeks. It is |
| 41 | Sputum Culture Conversion Documented | for more than 2 weeks should not be reported. The positive sputum culture is from the initial specimens collected after the patient has been on therapy for more than 2 weeks. Does this mean that Sputum Culture Conversion results will not be captured on the RVCT, since this field requires a positive culture result? | possible that for a few patients, "Sputum Culture Conversion" will not be documented. |

| RVCT | Item | Question | Answer |
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| 1tem # 21 | NAA Test Result | Can some PCR test results that are not FDA approved be reported on the RVCT? | Yes. DTBE infers that any laboratory performing tests for <i>M. tuberculosis</i> complex has validated the assay according to appropriate FDA and Clinical Laboratory Improvement Amendments (CLIA) regulations and use of the assay has been approved by the laboratory accreditation agency. For a tool that describes the Nucleic Acid Amplification Tests see the Quality Assurance for Tuberculosis Data: A Guide and Toolkit 2013, Chapter 10: Toolkit for Quality Assurance, Data Accuracy Tool 5. |
| 21 | NAA Test Result | Can an NAA test be used alone to count the case of TB? For surveillance purposes, CDC will accept results obtained from NAA tests approved by the Food and Drug Administration (FDA) and used according to the approved product labeling on the package insert, or a test produced and validated in accordance with applicable FDA and Clinical Laboratory Improvement Amendments (CLIA) regulations. Would a positive MTD result meet the laboratory criterion to classify a case as | http://www.cdc.gov/tb/programs/rvct/default.htm Yes, a positive MTD result from your state lab ("Amplified MTD Test Positive") is sufficient to classify a patient as a confirmed case. Please note: Culture confirmation is preferable to NAAT confirmation. We are concerned that TB programs will get the NAAT result and feel that it's adequate to report, and not wait or look for a culture result to subsequently record into their reporting software. In addition, culture is needed for DST and genotyping. |
| 21 | NAA Test Result | confirmed? Should only NAA test done on direct clinical specimens be reported on RVCT (item 21) NAA Test Result? | Yes. Clinical specimen means material taken directly from the patient (e.g., sputum, cerebral spinal fluid, and pleural fluid). |
| 22A, 22B | Initial Chest Radiograph Initial Chest CT Scan or Other Chest Imaging Study | If a chest radiograph or chest CT scan shows normal lungs but picks up another type of extrapulmonary abnormality (e.g., spine, rib, pericardial effusion), should it be coded as "abnormal consistent with active TB"? Or is this to be used only when something is | A physician (presumably a radiologist) has to interpret the abnormality as consistent with TB. A surveillance administrator would not make that decision. |
| | | found in the lungs or pleural cavity? | |

| RVCT | Item | Question | Answer |
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| Item# | Item | Question | Allswei |
| 25 | Primary Reason Evaluated for TB Disease | A child was given a PPD as part of a 12-month well-baby check-up. Since it was positive, he had a CXR. What should be selected for Item 25 – Primary Reason Evaluated for TB Disease? Should it be targeted testing? None of the other categories seem to apply here and there is no "Other" category. | Yes, select Targeted Testing since the chest radiograph was performed during a workup for TB disease because of a positive TST result obtained during targeted testing. |
| 26 | HIV status | If a patient's HIV status is negative at time of TB diagnosis and then changes to positive 6 months later, how does this get coded on the RVCT? | The patient's HIV status should pertain to the status at time of diagnosis with TB. Therefore it should be recorded as HIV negative at time of diagnosis. |
| 27 | Homeless within past year | Which patients should be considered homeless within the past year? 1) Is a patient who spent 4 years in a refugee camp considered "homeless" on the RVCT? 2) A patient who had been staying in shelters during the past year was hospitalized with TB-related symptoms. After a 3-month hospitalization during which he received a concurrent diagnosis of cancer, he was discharged to a nursing home to complete treatment for TB and begin chemotherapy and radiation treatment. The patient was reported as living in a long-term care facility at the time of diagnosis. | It depends on the situation of the person. For more information, see pages 125–126 in the RVCT Manual. Several examples are provided below. A patient's experience outside of the United States should not be considered for this question. The patient was incorrectly reported as living in a long-term care facility at the time of diagnosis, and was not reported as homeless. Report the patient as homeless within the past year. |

| RVCT | Item | Question | Answer |
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| Item # | Item | Question | AllSWCI |
| | | 3) A patient who had been staying in shelters during the past year began "couch-surfing" with friends when he became ill with TB-related symptoms. Upon admission to the hospital for symptoms, he gave his friend's address as his address. | The RVCT should reflect that the patient had been homeless during the year before diagnosis. Report the patient as homeless within the past year. |
| | | 4) A patient who had been staying in shelters during the past year was diagnosed with TB during his stay at a local jail. | The patient should be reported as being in a correctional facility at the time of diagnosis, and the RVCT should reflect that the patient has been homeless during the year before diagnosis. The patient should be reported as homeless within the past year. |
| | | 5) A patient who had been staying in homeless shelters did not acknowledge that he had been homeless when interviewed by the health department. Upon searching electronic homeless shelter logs, it was found that the patient had stayed in shelters multiple times during the year before diagnosis. | The patient should be reported as homeless within the past year. |
| | | 6) A patient who had been staying with family and friends multiple months prior to diagnosis and then again after starting treatment was unstably housed before and during treatment, resulting in multiple interruptions in therapy. There were many instances documented in the chart in which she did not have stable housing and was moving among friends. | The patient should be reported as homeless within the past year. |

| RVCT | Item | Question | Answer |
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| Item# | | 7) A patient who was | The patient should be reported as living in a long |
| | | diagnosed while living in | term care facility at the time of diagnosis. In addition, |
| | | a mental health facility | the patient is most likely homeless. Further |
| | | had been in and out of | investigation may be needed to confirm his status as |
| | | his mother's house over | homeless. |
| | | the year preceding | |
| | | diagnosis. He would disappear for weeks to | |
| | | months, and had no | |
| | | address to provide. He | |
| | | was a known | |
| | | schizophrenic and had | |
| | | stays at a mental health | |
| | | hospital, again with no | |
| | | permanent address listed. | |
| | | He was not listed as | |
| | | homeless in the RVCT. | |
| | | 8) A patient provided an address which | The patient should be reported as homeless within the |
| | | subsequently turned out | past year. |
| | | to be a halfway house / | |
| | | transitional housing | |
| | | program, and the patient | |
| | | had been homeless | |
| | | within the previous 12 | |
| | | months. The program | |
| | | only realized the address | |
| | | was a halfway house | |
| | | after 4 months of treatment. | |
| 28 | Resident of | What correctional facility | Select "Other correctional facility" for persons who |
| | Correctional | should be selected for a | are on home detention with ankle monitors. |
| | Facility at | person who is diagnosed with | |
| | Time of | TB when he or she is on | |
| | Diagnosis | home detention with an ankle | |
| •0 | | monitor? | V 1(01 |
| 28 | Resident of | Should a person who is on | Yes, select "Other correctional facility" for persons |
| | Correctional Facility at | ICE home detention with an ankle monitor be reported as | with ICE home detention with ankle bracelets. |
| | Time of | resident of "other | |
| | Diagnosis | correctional facility?" This | |
| | | would enable us to capture | |
| | | the ICE detention in the | |
| | | second part of this question. | |
| 34 | Additional TB | Can you clarify the meaning | The literature describes patients who develop active |
| | Risk Factors | of "recently received" in the | TB while on tumor necrosis factor (TNF) therapy. |
| | | Alpha TNF antagonists | CDC does not collect data on onset of TB, so |
| | | instruction? What does the | consider obtaining a decision by the clinical provider |
| | | literature suggest about how long a person remains | of the individual case if there are concerns. We would expect therapy to have been "recent" as within |
| | | immunosuppressed following | a few months (arbitrarily, no more than 1 year) of |
| | | this therapy? | initial TB symptoms. |

| RVCT Item # | Item | Question | Answer |
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| 34 | Additional TB Risk Factors | Why are only solid organ transplants specified? Should a bone marrow transplant recipient be reported under "Post-organ transplant" or "Immunosuppression"? | Record only solid organ transplant under "post-organ transplant" and capture bone marrow transplant under immunosuppression. Most solid organ transplant patients will also be on immunosuppressive medications. The distinction may be somewhat arbitrary re: transplantation. However, historically, this is related to case reports of TB in transplanted solid organs, where the transplant patient had no history of TB exposure but the donor did. |
| 34 | Additional TB Risk Factors | Can "Incomplete LTBI Treatment" be selected for a patient who had a previous diagnosis of latent TB infection, but was never started on LTBI treatment, and therefore did not complete LTBI treatment? | Document only those LTBI patients who started but did not complete LTBI treatment (in the Incomplete LTBI treatment field). Persons who did not start treatment for LTBI should be placed in the "Other: Specify" fields. |
| 34 | Additional TB Risk Factors | If diabetes mellitus was diagnosed after TB diagnosis, should this be reported here? | The instructions on page 145 of the RVCT Manual indicate that diagnosis of diabetes mellitus should occur before or during the time of diagnosis. In the rare case that diabetes was diagnosed later during TB treatment, use the "Other" box and specify in the comment section. |

| RVCT | Item | Question | Answer |
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| 1tem # 35 | Immigration Status at First Entry to the U.S. | The RVCT question added in 2009 that asks about immigration status at first entry to the United States is inconsistently reported across jurisdictions. Some reporting areas are unable to report this information due to directives or policies that prohibit asking the question, while others have made an internal decision not to report this information to CDC. How can this be addressed? | DTBE recommends the following activities to promote consistency in reporting: • If your state is unable or unwilling to report immigration status at first entry to the United States, please ensure those cases are reported as "Unknown," and not left blank or reported as "Not Applicable." The "Not Applicable" response should be reserved for U.Sborn patients (by definition) or those born in one of the U.S. Territories, U.S. Island Areas, or U.S. Outlying Areas. • If a state is unable to report due to directives or policies that prohibit asking the question, please notify DTBE/SEOIB of which ones they are so that SEOIB can footnote those states when reporting these data in the annual report of surveillance report. • If your state can report the data but still has a majority of responses as "N/A", "unknown," or missing altogether, please be aware that these data can potentially be informative to policy makers who make decisions that affect TB. For instance, "undocumented" TB patients would not be covered under the Affordable Care Act, yet the states will still be in a position to provide treatment utilizing other funds. Accurately counting these patients under the "Other immigration status" response would help quantify this unreimbursed fiscal responsibility. • Please review the RVCT instructions for this variable. If the instructions are not clear, please let DTBE know so that we can provide additional |
| 36 | Initial Drug Regimen | Why is the Initial drug regimen entry period limited to 2 weeks? | guidance to mitigate the issue. The 2-week period is intended to allow the record updates necessitated by changes in regimen when treatment is begun. |
| 36, | Date Therapy Started | A patient starts three TB drugs on 05/01/2011 and another drug is added on | Yes, all four drugs should be entered as part of the initial drug regimen. The date therapy started would be 05/01/2011. ALL drugs started within the initial 2- |
| 37 | Initial Drug Regimen | 05/04/2011. Should all four drugs be entered as part of the initial regimen? Also, what is the date therapy is started? Is it the day any of | week period should be counted in the initial regimen and start date. This is regardless of whether or not the patient stayed on the drugs for 2 weeks. Any drugs added within the 2-week period are a part of the initial drug regimen but will not change the |
| | | the first three drugs were ingested (05/01/2011)? Or the first day that the fourth drug was ingested (05/04/2011)? | Any drugs added after the initial 2-week period is not a part of the initial drug regimen and does not change the treatment start date. |

| RVCT | Item | Question | Answer |
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| 39 40 | Initial Drug Susceptibility Testing Initial Drug | Should ethambutol (EMB) and pyrazinamide (PZA) be included in the list of drugs for initial drug susceptibility testing (DST)? | DTBE recommends jurisdictions to include EMB but not PZA in the list of drugs required for initial DST for both the NTIP and funding formula calculations. While the inclusion of PZA in the NTIP calculation of DST reporting is not recommended at this time, |
| 40 | Susceptibility Results | testing (DST)? | CDC and its partners should encourage public health laboratories to add PZA to the list of drugs tested for initial DST. |
| 41 | Sputum Culture Conversion Documented | Should a patient who moved out of the country be included in the NTIP indicator calculation for sputum culture conversion documented? | The new NTIP indicator calculation for sputum culture conversion documented excludes patients who moved out of the country. The calculation also includes the following: 1. Remove the objective for attaining culture conversion within 60 days. 2. Revise the RVCT instruction on the "sputum culture conversion" variable stipulating that the first consistently negative culture should be a least 7 days after the last positive culture. 3. Exclude patients with cavitary disease. See the Quality Assurance for Tuberculosis Surveillance Data: A Guide and Toolkit, Chapter 10: Cross-cutting Tool–7 NTIP Decision Memo: Sputum Culture Conversion Documented www.cdc.gov/tb/programs/rvct/default.htm |
| 42 | Moved | May we use the Moved variable for intra-state movement (county to county) and documentation? | Yes, reporting jurisdictions may document TB patient movement from county to county. Some reporting jurisdictions are centralized so that where all case documentation and coordination of care is monitored from one central area. Others have county, health district, or Big city-level reporting. At the national level, CDC is primarily focused on patient movement across reporting jurisdictions (state to state). |
| 42 | Moved | Should we continue the U.S. transnational referral when most deported patients become lost or cannot be reached by other country health officials? | Yes, coordination of patient care is most important. There are services that help with coordination of care for patient movement. CureTB is a referral and continuity-of-care program for tuberculosis patients and their contacts that travel between the United States and Mexico. Services are available for patients, their families, and providers from any state in the United States or Mexico. CureTB accepts referrals from health departments, correctional facilities, and other entities that diagnose or treat patients with tuberculosis. |

| RVCT | Item | Question | Answer |
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| Item# | 100111 | Question | Tank WOL |
| 44 | Reason Therapy Stopped or Never Started | If the provider removes a patient from TB treatment because death is imminent, should "Died" be reported as Reason therapy is stopped? If death follows shortly after treatment is stopped, it is reported as "Died." If treatment is stopped and the patient survives for a "long" period of time, it could be reported as "Other." How should "short" and "long" be defined? In Item 15, Status at TB | CDC recommends a clinical decision by the provider or MD. These are unique cases for which there is no one standard response. For Item 15, select "Dead" if diagnostic specimens |
| and 44 | Diagnosis Reason Therapy Stopped or Never Started | Diagnosis, the patient was marked "Dead" because he was never started on TB medications and the culture confirmation was reported after the patient had died. Is this correct? For Item 44 Reason Therapy Stopped or Never Started, should we mark "Died," if the patient was dead at diagnosis and had not started on TB medications? | were collected for evaluation of TB prior to death, but positive results to make a diagnosis of TB were not available until after death, and patient did not start TB therapy. Classify as Dead at TB diagnosis. For Item 44, select "Dead" only if the patient was alive at diagnosis but died before the start or completion of treatment. This also applies to a patient classified as Alive for Status at TB Diagnosis (Item 15) if the patient was taking at least 2 anti-TB drugs before the day of death, even though the TB case was not verified and counted until after death. The Case Completion Report (Follow up Report–2) (Items 41-49) should only be completed for cases that are alive at diagnosis. Thus, you would not complete Item 44 (Reason therapy stopped or never started) since the patient was NOT alive at diagnosis. The following table might help clarify the issue. |

| RVCT | Item | Question | A | nswer |
|-------|------|----------|--|---|
| Item# | | | Item 15 Status at TB Diagnosis | Item 44 Reason Therapy Stopped or Never Started |
| | | | Select "Alive at Diagnosis" if Laboratory results confirm a TB diagnosis and were known by the provider, or TB medications were started. | Select "Died" if Patient was alive at diagnosis but died before the start or completion of treatment, or The patient was taking at least 2 anti-TB drugs before the day of death, even though the TB case was not verified and counted until after death. Note: Do not enter the date of death on Item #15. |
| | | | Select "Dead at Diagnosis" if patient was deceased at the time laboratory results confirming a TB diagnosis were known to the provider. Enter the date of death. | Do not fill out Item 44. |

Additional CDC Guidance for TB Programs and Pacific Island Jurisdictions

Reporting TB Disease That Recurs Within a Consecutive 12-Month Period after the Patient Completed Therapy

If the patient completes treatment and has a recurrence of TB <u>within</u> a consecutive 12-month period <u>after</u> he/she completed therapy (see the RVCT Self-Study Manual, Facilitators Guide, page 30-31), record all RVCT information for the case into your reporting system according to instructions below:

Complete a second RVCT entry in your reporting system (only the initial TB episode is countable).

- 1. Insert new State Case Number for the second RVCT form.
- 2. Place original (countable) CDC State Case Number in the Linking State Case Number space.
- 3. Mark "1" for Reason Code in the Linking State Case Number option.
- 4. Mark Uncountable TB Case, option #3, "Verified case counted within 12 months..." under Count Status.

Note: The second RVCT record will have new relevant information for this event (e.g., new sputum smear results and initial and final susceptibility results (if available).

For example: Date counted (RVCT #6)—would be left blank. Note: For all noncountable TB cases, leave the date counted blank.

Previous diagnosis of TB disease (RVCT #7) –would be the initial TB episode that was counted as TB (see the RVCT Self-Study Manual, Facilitator Guide, page 51).

HIV status at the time of diagnosis (RVCT #26) –if the patient has a prior negative test results, please follow the guidance for time limits in the RVCT Self-Study Manual, Facilitator Guide, page 123. If the patient is HIV positive, no further testing is necessary.

Reporting TB Disease That Recurs More Than a Consecutive 12-Month Period after the Patient Completed Therapy

If the patient completes treatment and has a recurrence of TB <u>more</u> than a consecutive 12-month period <u>after</u> the patient completed therapy (see the RVCT Self-Study Manual, Facilitators Guide, pages 30-31), record all RVCT information for the case into the your reporting system according to instructions below:

Complete a second RVCT entry in your reporting system (both TB episodes are countable).

- 1. <u>Insert new State Case Number.</u>
- 2. Place original CDC State Case Number in the Linking State Case Number place.
- 3. Mark "1" for Reason Code in the Linking State Case Number option.
- 4. Mark Counted TB Case under Count Status.

Examples for Reporting and Counting TB Cases

| Case Status for CDC | | | | Case Description | CDC Clarification |
|----------------------|----|---------------------|----|---|--|
| Is it Reportable? | | Is it Countable? | | Description | Clarification |
| Yes | No | Yes | No | | |
| X | | X | | Case 1 Maria is diagnosed with TB disease and completes therapy with the health department. | This is reportable and countable (see Appendix B of the RVCT Self-Study Manual, Facilitator Guide, and also page 205). |
| | | | | Case 2 | Complete 2 RVCT forms |
| X | | X | | Esteban is diagnosed with TB disease and completes therapy with the health | Only the initial TB episode is countable. |
| X | | | X | department, and is diagnosed again 3 months after he completes treatment. | The second episode is noncountable due to recurrence within 12 months of completion of therapy (see the RVCT Self-Study Manual, Facilitator Guide, pages 29-31). |
| X | | X | | Case 3 Leilani is diagnosed with TB disease and starts therapy, but is lost for 3 months and then returns to the clinic for treatment. | TB programs have two choices on how to report this scenario. 1. If patient is lost before treatment completion but returns or is found within 12 months of the initial diagnosis, the initial, previously established RVCT form may continue to be used. Any updates to the RVCT in regards to the treatment or diagnosis information upon the patient's return should be compatible with the RVCT instructions. For example, if the initial drug regimen (RVCT #37) was established for at least 2 weeks, do not change (update) the RVCT to reflect a new treatment regimen. 2. The initial RVCT record may be closed due to treatment interruption ("Lost, record in RVCT #44) and a new RVCT record initiated for the noncountable TB episode. |

| Case Status for CDC | | | | Case Description | CDC Clarification |
|----------------------|----|---------------------|----|---|---|
| Is it Reportable? | | Is it Countable? | | • | |
| Yes | No | Yes | No | | |
| X | | X | | Case 4 Mika is diagnosed with TB disease and completes therapy with the health | Complete 2 RVCT forms Both TB episodes are countable. The second case is countable due to TB recurrence |
| X | | X | | department. He is diagnosed with TB disease 14 months after he completed treatment. | more than a consecutive 12-month period after the patient completed therapy (see the RVCT Self-Study Manual, Facilitator Guide, pages 29-31). |

Note: A verified TB case is always reportable to CDC. Case Studies 2 & 4 will have 2 RVCTs.