Appendix SUR I RVCT Form Completion Instructions

The Report of Verified Case of Tuberculosis (RVCT) form is designed to collect information on cases of tuberculosis (TB). The expanded RVCT form was approved by the Office of Management and Budget (OMB) in 1992, and a minor revision involving only the Race and Ethnicity variables was approved in 2002 (to become effective January 1, 2003). The expanded RVCT consists of three data collection forms printed in triplicate on carbonless paper:

1. **Report of Verified Case of Tuberculosis** - Questions 1 - 22 are printed on page 1, and questions 23 - 32 and user Comments on page 2. Patient demographics, laboratory and risk behavior data are collected on these pages. Complete this form for all patients.
2. The **Initial Drug Susceptibility Report** (Follow Up Report - 1) - Includes Questions 33, 34 and a space for user Comments. Susceptibility results are collected on this page. Complete this form for all patients who had a culture that was positive for *Mycobacterium tuberculosis* (*M. tuberculosis*) complex.
3. The **Case Completion Report** (Follow Up Report - 2) - Includes Questions 35 - 41 and a space for user Comments. Treatment outcomes are collected on this page. Complete this form for all patients who were alive when TB was diagnosed.

Note: All questions on the forms should be completed according to these instructions. A question should be left blank if the information requested is pending.

Data obtained from RVCT forms are entered into the Tuberculosis Information Management System (TIMS) and then transferred electronically to CDC.

While a case of TB is required to be reported to CDC only if active disease is verified and the case is to be part of the annual morbidity count, CDC encourages the use of the RVCT forms and TIMS for the collection of data on suspected cases of TB. Verification of suspected cases can be accomplished through periodic updates of the records in TIMS. TIMS will automatically verify a case as data are entered or updated in the databases and flag the record for transmission to CDC.

Note: Completed RVCT forms should *never* be sent to CDC. Forms should be stored in a secure (locked) location designated by each state or local health department. Refer to the Confidentiality and Data Security section in the Introducing TIMS chapter of this User Guide for additional information on protecting patient confidentiality.

Case Definition[1]

Note: A verified case of TB is a case that is laboratory confirmed or, in the absence of laboratory confirmation, a case that meets the clinical case definition.

A clinically verified case of TB is a case that meets *all* of the following criteria:

- A positive tuberculin skin test;

  and

- Other signs and symptoms compatible with TB, such as an abnormal, unstable (worsening or improving) chest x-ray, or clinical evidence of current disease;

  and

- Treatment with two or more antituberculosis medications;

  and

- Completed diagnostic evaluation.

The laboratory criteria for the diagnosis of TB are as follows:

- Isolation of *M. tuberculosis*[*] from a clinical specimen;

  or

- Demonstration of *M. tuberculosis* from a clinical specimen by nucleic acid amplification test;[†]

  or

- Demonstration of acid-fast bacilli in clinical specimen when a culture has not been or cannot be obtained.

[*] Use of rapid identification techniques for *M. tuberculosis* (e.g., DNA probes and mycolic acids high-pressure liquid chromatography performed on a culture from a clinical specimen) are acceptable under this criterion.

[†] Nucleic acid amplification (NAA) tests must be accompanied by culture for mycobacteria species. However, 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.

Case Counting

A case must not be counted more than once within any consecutive 12-month period. A case in which the patient had verified disease in the past **should** be counted again if the patient was discharged from supervision (e.g., completed therapy) or lost to follow-up for more than 12 months and disease can be verified again. A patient should not be counted a second time if 12 months have not passed since the patient was discharged from supervision. Consider the following.

> A case of TB was reported to the health department in February 1993, and began therapy on February 1, 1993. The health department verified and counted the case in March 1993, and the patient completed therapy and was closed to supervision on July 27, 1993. The patient returned to the clinic in April 1994, and was diagnosed with TB again. This new episode should not be reported or counted as a new case of TB because the previous episode was closed to supervision less than 12 months prior.

Note: ***Mycobacterium tuberculosis* complex** includes three mycobacterial species*: M. tuberculosis*, *M. bovis*, and *M. africanum*. These species are identical in DNA homology studies. In terms of their ability to cause clinical disease and to be transmissible from person to person, *M. bovis* and *M. africanum* behave like *M. tuberculosis*. Therefore, all three organisms should be reported as tuberculosis, using the RVCT. The only exception is the BCG strain of *M. bovis*, which may be isolated from persons who have received the vaccine to protect against tuberculosis or as cancer immunotherapy.

Confidentiality

Because of the sensitive nature of some of the data collected, CDC has obtained an Assurance of Confidentiality for the expanded surveillance system. Information on the RVCT forms and in the TIMS databases that would permit identification of any individual will be held in confidence and not released without the consent of the individual in accordance with Sections 306 and 308(d) of the Public Health Services Act (42 U.S.C. 242k and 242m(d)). Local patient identifier information, although collected by state and local health departments, will not be reported to CDC. Surveillance information reported to CDC will be used for statistical and analytic summaries in which no individual can be identified, and for special investigations of the natural history and epidemiology of TB. Refer to the Confidentiality and Data Security section in the Introducing TIMS chapter of this User Guide for additional information on protecting patient confidentiality.

Data Security

Note: Data security is the responsibility of the state or local health department.

Access to the RVCT forms and TIMS should be restricted only to individuals authorized to perform TB surveillance activities. Completed forms and backup copies of the local TIMS databases should be stored in a secured (locked) area. Access to TIMS is controlled through the use of a local user identifier (User ID) and password. All other electronic surveillance files should also be protected with passwords known only to designated surveillance staff. Refer to the Introducing TIMS and System chapters in this User's Guide for additional information on protecting patient confidentiality and exporting data from the databases.

Record Management

It may be necessary to update existing RVCT forms if a case is re-opened (e.g., a patient lost to follow up is found). CDC recommends that changes made on the forms be highlighted to facilitate data entry into TIMS. When the updated data are entered into an existing TIMS record, the new data will automatically overwrite the old.

PROTECT PATIENT CONFIDENTIALITY!

Case numbers must not include personal identifiers
Do not use names, initials, social security numbers, addresses, phone numbers, or other information that could potentially identify a client.

Getting Started

The SOUNDEX code is not determined by the individual completing the forms. The Soundex code is a feature included in the TIMS software, and will be automatically calculated and displayed by the software during data entry of the patient's last name. However, to assist in accurate record keeping, the Soundex code calculated by TIMS should be copied into the boxes at the top of the forms at the time of data entry.

A 2-digit numeric code (date code) should be entered for all day and month dates. Enter leading zeros when necessary (e.g., 01, 09, 12). Enter a 4-digit numeric code (e.g., 1952, 1993) for year. Questions 3, 28, 33, 35, 36, and 40 allow the entry of a 2-digit numeric code (e.g., 02, 03, 04) for the year when completing the form.

For Questions 1 through 16 on the RVCT form, if a valid value cannot be determined, the person completing the form should write the word "unknown" in the box surrounding the question. This will assist the person entering the data into TIMS to know that the person who completed the form attempted to collect the information, but was not able to do so. The data entry person will thus be able to distinguish better between data that are truly "unknown" (data not known) and data that are "missing" (data still being investigated).

Note: Patient history without medical documentation should not be accepted for clinical, treatment, and laboratory information requested on the RVCT forms. Date information can be obtained from documented medical records, such as those found in hospitals, clinics, directly observed therapy records, pharmacy and prescription records.

Instructions

The RVCT must be completed for all verified cases of TB that are to be included in the reporting area's annual morbidity count. CDC also encourages the use of RVCT forms for the collection of data on suspected cases of TB.

1. State Reporting

Indicate the name of the reporting area and the two-letter abbreviation of the area reporting this case (see Appendix SUR VII).

2. Case Numbers

Both the state case number and the city/county case number accept a maximum of 9 alphanumeric characters.

Note: **Case numbers must not include personal identifiers**. In order to maintain patient confidentiality, do not use names (neither patient nor provider), initials, social security numbers, addresses, phone numbers, or other information that could potentially identify a patient. Case numbers are transferred to CDC, and therefore must not include personal identifying information.

The **state case number** is the official state identification number for the case. If additional communication is required about a record between CDC and the state, this number is used to identify the record.

The **city/county case number** should also be listed if it exists.

Case numbers cannot be repeated during a calendar year (January 1 through December 31). Once a case number has been assigned, entered into TIMS and transferred to the next level, it cannot be changed or reused. Every case reported, whether from a city/county or state surveillance system, must have a unique case number for identification purposes. A **city/county case number** may not be assigned to more than one case during a calendar year. Similarly, a state case number may not be assigned to more than one case during a calendar year. However, a single case may be assigned identical city/county and state case numbers.

Case numbers should be assigned using a logical, standardized scheme. Although the requirements may vary, a sample case number may consist of a two-digit year code (e.g., for the year the case was submitted), followed by a three-digit location or facility code (for the location or facility reporting the case), followed by a four- digit, counting number for the case (e.g., 0001 for the first case reported in the year, 0002 for the second case, etc.).

Acceptable Case Numbers		Unacceptable Case Numbers	
Case Number	Explanation	Case Number	Explanation
93FLT0001	The first case (0001) reported from Fulton County (FLT) in 1993 (93)	MCCRAYEUG	Client name used for case number.
93FLT0002	The second case, etc.	049226142	Social Security Number used as case number.

3. Date Submitted

Indicate the date the RVCT form (Questions 1 - 32) was submitted to or completed by the reporting area (e.g., state health department). Also, enter the name of the person who should be contacted if there is a question about data on the form.

4. Address for Case Counting (Reporting Address)

Indicate the city, county, and zip code of the patient's residence. Also indicate if the patient lives within the city limits. To the extent possible, the address for case counting should represent the home address (whether permanent or temporary) of the patient.

Follow these guidelines within a reporting area:

If a person is diagnosed in the community which they consider their home, he or she should be included in the morbidity count for that area, and the city, county, and zip code of residence should be entered in this field.

If a newly diagnosed patient is an out-of-area resident who will return to his or her home for treatment, they should be included in the morbidity count of their home area, and the city, county, and zip code of their home area should be entered in this field.

For example, a patient in a community only for hospitalization and diagnosis is not considered a case in that community, but rather in the area in which he or she resides. Communication between health departments may be necessary to decide which jurisdiction will count the case. Immigrants (i.e., resident aliens living in the United States), migrants, United States military personnel, and other transient individuals should be counted in the community in which they reside at the time of diagnosis. The city, county, and zip code of residence at the time of diagnosis should be entered in this field. If a foreign visitor is diagnosed with TB in the United States, is receiving antituberculosis drug therapy, and is to remain in the country for at least 90 days, the case should be counted in the area of current residence, and the city, county, and zip code of his or her current residence should be entered in this field. Persons arriving in the United States who were diagnosed with TB before arriving here should not be counted as a case of TB in the United States. Such cases are considered to have occurred in another country, even if therapy is continued or completed in the United States.

Patients who are residents of long term care facilities or correctional facilities at the time of diagnosis should be counted in the area in which the facility is located, and the city, county and zip code of the facility should be entered in this field.

Homeless persons or others without any fixed residence should be counted in the community in which they are living at the time of diagnosis (e.g., the locality of the shelter in which the patient was living). Enter the city, county and zip code of that locality.

Transfer Cases (Patients who move from one reporting area to another)

Sixty reporting areas are responsible for reporting cases of TB to CDC. These reporting areas are: the 50 states, the District of Columbia, New York City, Puerto Rico, Guam, the Republic of Palau, the U.S. Virgin Islands, the Federated States of Micronesia, the Commonweatlh of the Northern Mariana Islands, the Republic of the Marshall Islands, and American Samoa. Because of the additional follow-up reporting requirements for expanded surveillance, specific instructions are necessary for the submission of forms for patients who move within a reporting area, and for those who move from one reporting area to another during the course of treatment.

To minimize the number of TB patients who are lost to follow-up, street address information should be updated regularly during the course of treatment.

In addition, patients should be asked periodically if they anticipate moving, so that necessary arrangements can be made to maintain continuity of care and ensure submission of follow up reports for the RVCT. Patients who anticipate moving should be encouraged to report their new address, so that necessary patient information can be forwarded to health care providers and to the TB control program in the area to which the patient is moving.

Communication between TB control programs to ensure continuity of care and submission of follow-up reports regarding a patient who is moving from one area to another should be conducted in the most efficient manner possible (e.g., by telephone or express courier).

If a TB patient for whom an RVCT record exists moves within the reporting area that initially reported the case (e.g., from county A to county B within a state), communication between county or local health departments may be all that is necessary to maintain continuity of care and ensure submission of follow up reports for the RVCT. In this instance, the responsibility for following the case to closure and the submission of follow up reports to CDC does not change, and remains with the reporting area (e.g., the state) that initially reported the case to CDC. The state may need to coordinate with counties A and B the submission of surveillance forms to avoid duplicate case reporting.

If a TB patient for whom an RVCT record exists moves from one reporting area to another (e.g., from state A to state B, or from Washington, DC to New York City, etc.), the responsibility for submitting follow up reports to CDC remains with the state that initially reported the case to CDC and counted it (e.g., state A). This responsibility remains with the initial area for surveillance purposes only, in order to minimize duplication of case reports and to simplify the reporting of the final disposition of the case. In other words, State B will be managing and following the patient, and will need to share follow up surveillance information with State A, which will officially submit follow up information to CDC using TIMS.

To facilitate in this process, state A should inform state B that the case has been reported to CDC and counted. State A should also inform state B of the surveillance information that has been reported to CDC, and the information that will need to be collected by state B and forwarded to state A for reporting to CDC.

Surveillance information requested on the follow up reports to the RVCT can be exchanged by telephone, or through the mail, following CDC's Recommended Guidelines for Maintaining Confidentiality of the TB Surveillance System (see the Confidentiality and Data Security section in the Introducing TIMS chapter of the User's Guide), and all laws applicable in the state and local jurisdictions involved.

5. Month-Year Reported

The month-year reported is the month and year that a health department (county or state) first became aware that the patient might have TB. If the patient has had a previous diagnosis of tuberculosis, month-year reported applies to the current episode.

6. Month-Year Counted

The month-year counted is the month and year that the health department responsible for counting TB cases (usually the state health department) verified the case as TB and included it in the official case count. Cases for which bacteriologic results are pending or for which verification of disease is questioned for any other reason should be counted only after they are determined to be verified cases. This could mean that a case that was reported in one year may not be counted until the following year.[2] For example, if a patient is reported to the health department in December 1993, but bacteriologic or clinical evidence of TB is not available until January 1994, the case should be counted in January 1994 (when TB was verified), not in 1993.

7. Date of Birth

Indicate the month, day, and year of birth for the patient. For example: 04/26/1968. A complete date of birth is required. Partial dates are not acceptable. If the month, day, and year of birth are not all known, enter "99/99/9999" on the form.

8. Sex

Male or Female. Check the appropriate box for the biological sex of the patient.

9. Ethnicity

The answer to this question should be based on the individual's self identity or self reporting. Indicate the ethnicity that the person considers themselves to be – select one.

Check **"Hispanic or Latino"** if the patient considers themselves to be of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin" can be used in addition to "Hispanic or Latino."

Check **"Not Hispanic or Latino"** if the patient does not consider themselves to be "Hispanic or Latino."

10. Race

The answer to this question should be based on the individual's self identity or self reporting. Patients shall be offered the option of selecting one or more racial designations. Indicate the race that the person considers themselves to be – select one or more.

Check **"American Indian or Alaska Native"** if a person has origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.

Check **"Asian"** if a person has origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

If **"Asian"** use the NEDSS Person Race Categories and Codes (see table below) to complete **"*Specify (optional): _____*".**

Check **"Black or African American"** if a person has origins in any of the black racial groups of Africa.

Check **"Native Hawaiian or Other Pacific Islander"** if a person has origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

If **"Native Hawaiian or Other Pacific Islander"** use the NEDSS Person Race Categories and Codes (see table below) to complete **"*Specify (optional): _____*".**

Check **"White"** if a person has origins in any of the original peoples of Europe, the Middle East, or North Africa.

NEDSS Person Race Categories and Codes for Asian and Native Hawaiian or Other Pacific Islander*

Asian		Native Hawaiian or Other Pacific Islander	
Code	**Description**	**Code**	**Description**
2028-9	Asian	2076-8	Native Hawaiian or Other Pacific Islander
2029-7	Asian Indian	2092-5	Carolinian
2030-5	Bangladeshi	2088-3	Chamorro
2031-3	Bhutanese	2097-4	Chuukese
2032-1	Burmese	2101-4	Fijian
2033-9	Cambodian	2087-5	Guamanian
2034-7	Chinese	2086-7	Guamanian or Chamorro
2036-2	Filipino	2096-6	Kiribati
2037-0	Hmong	2093-3	Kosraean
2038-8	Indonesian	2089-1	Mariana Islander
2048-7	Iwo Jiman	2090-9	Marshallese
2039-6	Japanese	2100-6	Melanesian
2040-4	Korean	2085-9	Micronesian
2041-2	Laotian	2079-2	Native Hawaiian
2052-9	Madagascar	2104-8	New Hebrides
2042-0	Malaysian	2500-7	Other Pacific Islander
2049-5	Maldivian	2091-7	Palauan
2050-3	Nepalese	2102-2	Papua New Guinean
2043-8	Okinawan	2094-1	Pohnpeian
2044-6	Pakistani	2078-4	Polynesian
2051-1	Singaporean	2095-8	Saipanese
2045-3	Sri Lankan	2080-0	Samoan
2035-4	Taiwanese	2103-0	Solomon Islander
2046-1	Thai	2081-8	Tahitian
2047-9	Vietnamese	2083-4	Tokelauan
		2082-6	Tongan
		2098-2	Yapese

* NEDSS Logical Data Model Data Dictionary: Appendix B, 1. Standardized Vocabulary, 1.4 Person Race Categories and Codes (last updated 11-19-2001) http://www.cdc.gov/nedss/DataModels/NEDSS_LDM_Dictionary_II.pdf

11. Country of Origin

Check the "If U.S., check here" box if the patient was born in the United States or born overseas to U.S. parents (e.g., born on a military installation). If the country of origin is not the United States, enter the appropriate two-letter abbreviation selected from the list provided (see Appendix SUR VIII). For this question, outlying U.S. areas (e.g., Puerto Rico, Guam, Virgin Islands) are not considered part of the United States; they should be listed as separate countries and their codes entered. Country of origin is the country in which the patient lived and probably held citizenship during the early years of life.

12. Month-Year Arrived in U.S.

If the patient was not born in the U.S., enter the month and year arrived in the U.S. If only the year of arrival is known, enter 99 for the month and the 4-digit year. For example, if the patient arrived in 1963, but the month cannot be determined, enter "99 1963". If both the month and year of arrival are not known, enter "99 9999".

The following instructions apply when the Reporting Area (Question 1) is one of the jurisdictions that report TB cases to CDC, other than the 50 states, New York City, and the District of Columbia (i.e., American Samoa, Guam, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Puerto Rico, Republic of the Marshall Islands, Republic of Palau, U.S. Virgin Islands).

If the Country of Origin is one of the 50 states of the United States, or if the client were born overseas to U.S. parents (e.g., born on a military installation):

Question 11: Check the "If U.S., check here" box. Leave the boxes for "If not U.S., enter country code (see list)" blank.

Question 12: Leave "Month-Year Arrived in U.S." blank.

If the Country of Origin is one of these Reporting Area jurisdictions AND is the same jurisdiction that is reporting the case (e.g., the country of origin is Puerto Rico and Puerto Rico is reporting the case):

Question 11: Leave the "If U.S., check here" box blank. Enter the two-letter code for the country of origin [see Appendix SUR VIII] in the boxes for "If not U.S., enter country code (see list)."

Question 12: Enter '99' for the month and '9999' for the year in "Month-Year Arrived in U.S."

If the Country of Origin is one of these Reporting Area jurisdictions BUT is not the same jurisdiction that is reporting the case (e.g., the country of origin is Federated States of Micronesia, but Guam is reporting the case):

Question 11: Leave the "If U.S., check here" box blank. Enter the two-letter code for the country of origin (e.g., Federated States of Micronesia in this example [see Appendix SUR VIII] in the boxes for "If not U.S., enter country code (see list)").

Question 12: Enter the month and year that the patient arrived in the jurisdiction that is reporting the case (e.g., Guam, in this example) in "Month-Year Arrived in U.S."

If the Country of Origin is not the United States, and is not one of the other U.S. reporting jurisdictions listed above (e.g., the country of origin is the Philippines, and Guam is reporting the case):

Question 11: Leave the "If U.S., check here" box blank. Enter the two-letter code for the country of origin (e.g., Philippines in this example [see Appendix SUR VIII] in the boxes for "If not U.S., enter country code (see list)").

Question 12: Enter the month and year that the patient arrived in the jurisdiction that is reporting the case (e.g., Guam, in this example) in "Month-Year Arrived in U.S."

13. Status at Diagnosis of TB

Check alive if the patient was alive at the time of diagnosis. Patients whose TB was suspected and who were started on at least two antituberculosis drugs prior to the day of death are classified as alive at the time of diagnosis even though the case may not be verified and counted until after death. Check **dead** if the patient was deceased at the time the investigation of possible TB was initiated. Patients who were only on one antituberculosis drug prior to the day of death because TB disease was not suspected, and who were then diagnosed with TB after death are classified as dead at the time of diagnosis.

For example, if a person who was taking isoniazid as preventive therapy for TB infection dies, and is found after death to have had TB disease, this person should be classified as dead at diagnosis.

14. Previous Diagnosis of Tuberculosis

Check **yes** if the patient has had a previous diagnosis of TB. A patient is considered to have had a previous diagnosis of TB if they had verified disease in the past, had been discharged (e.g., completed therapy) or lost to supervision for more than 12 consecutive months, and has verified disease again. If **yes**, provide the year in which the patient's previous episode of disease was diagnosed. For example, if the patient was diagnosed in 1985, was discharged or lost to supervision in 1986, and is found to have verified disease again in 1994, enter the number "1985" in the boxes provided. If the patient had more than one previous episode, enter the year of the most recent previous episode, and check the "If more than one previous episode, check here" box. Check **no** if the patient has not had a previous diagnosis of TB.

15. Major Site of Disease

Check the box corresponding to the one major site of disease. Lymphatic: Intrathoracic includes hilar, bronchial, mediastinal, peritracheal, and other lymph nodes within the thorax.

Note: If the patient has **miliary** tuberculosis, check **miliary** in question 15 and do not complete question 16, **Additional Site of Disease**.

If the major site is **other**, enter the anatomic code in the box provided (see Appendix SUR V). The Anatomic Codes for **other** are marked with an asterisk (*). Select only from those items. Anatomic codes without an asterisk (*) are parts of organ systems corresponding to Major Site of Disease values of 00 - 70.

16. Additional Site of Disease

If the patient's TB is known to affect additional sites, mark all the appropriate boxes. If an additional site is **other**, enter the Anatomic Code in the boxes provided (see Appendix SUR V). Select only from the Anatomic Code items marked with an asterisk (*) on the list. The same anatomic codes cannot be entered for both Major Site of Disease and Additional Site of Disease. Anatomic codes without an asterisk (*) are parts of organ systems corresponding to Additional Site of Disease values of 00 - 70. Indicate if more than one additional site is involved by marking the appropriate box.

17. Sputum Smear

Note: If several examinations have been done, check positive if any one is positive for acid-fast organisms.

Sputum includes spontaneous and induced sputum. *Do not include* the results of microscopic examination of pulmonary secretions obtained by tracheal suction, bronchoscopy procedures (e.g., bronchial washing, scrapings, biopsies), or gastric aspiration (see questions 19 and 20). If the results of the smear are pending, leave this field blank.

Check **negative** if the results of all examinations (or the only examination) were negative.

Check **not done** if a sputum smear is known not to have been done.

Check **unknown** if it is not known if a sputum smear was performed, or if the results are not known for a reason other than pending results (e.g., result was lost or specimen contaminated, and no other specimens can be obtained).

18. Sputum Culture

Note: Positive culture means positive for *M. tuberculosis* complex. If the culture grows organisms other than *M. tuberculosis*, *M. bovis* or *M. africanum*, check **negative**. If several examinations have been done, check **positive** if any one is positive for *M. tuberculosis* complex.

If the results of the culture are pending, leave this field blank.

Check **negative** if the results of all examinations (or the only examination) were negative for *M. tuberculosis* complex.

Check **not done** if a sputum culture is known not to have been done.

Check **unknown** if it is not known if a sputum culture was performed, or if the results are not known for a reason other than pending results (e.g., result was lost or specimen contaminated, and no other specimens can be obtained).

19. Microscopic Exam of Tissue and Other Body Fluids

Note: Check **positive** if any tissue or fluid (e.g., tracheal aspirate, bronchoscopy procedures (e.g., bronchial washing, scrapings, or biopsies), gastric aspirate, pleural fluid, urine, bone marrow, cervical lymph node, etc.) other than sputum was positive for acid-fast organisms.

If positive, select the appropriate code from the Anatomic Code list (see *Appendix SUR V Anatomic Codes* and *Appendix SUR VI Site of Disease/Anatomic Code Validations*), and enter the code in the boxes provided. Up to two tissue or fluid codes may be entered.

If the results of the microscopic exam are pending, leave this field blank.

Check **negative** if all such microscopic exams were negative for acid-fast organisms.

Check **not done** if exams are known not to have been done.

Check **unknown** if it is not known if such exams were performed or if the results are not known for a reason other than pending results (e.g., result was lost or specimen contaminated, and no other specimens can be obtained).

20. Culture of Tissue and Other Body Fluids

Note: Check **positive** if *any* tissue or fluid (e.g., tracheal aspirate, bronchial washing, gastric aspirate, pleural fluid, urine, bone marrow, cervical lymph node, etc.) culture other than sputum was positive for *M. tuberculosis* complex.

If the results of the culture are pending, leave this field blank.

If positive, select the appropriate code from the Anatomic Code list (see *Appendix SUR V Anatomic Codes* and *Appendix SUR VI Site of Disease/Anatomic Code Validations*), and enter the code in the boxes provided. Up to two tissue or fluid codes may be entered.

Check **negative** if all cultures were negative for *M. tuberculosis* complex.

Check **not done** if cultures are known not to have been done.

Check **unknown** if it is not known if cultures were performed or if the results are not known for a reason other than pending results (e.g., result was lost or specimen contaminated, and no other specimens can be obtained).

21. Chest X-Ray

Indicate the result of the chest radiograph taken during the diagnostic evaluation. If abnormal, indicate if any of the chest radiographs obtained at any time during this episode of TB showed a cavity or cavities, was noncavitary consistent with TB, or was noncavitary not consistent with TB. If abnormal, also indicate if a series of chest radiographs initially show the disease to be **stable**, **worsening**, or **improving**.

Check **not done** if chest radiographs are known not to have been done.

Check **unknown** if it is not know if chest radiographs were done, or if the results of chest radiographs are unknown.

Do not update chest radiograph information throughout the course of patient follow-up. For instance, if initial radiographs show the patient's disease to be worsening, but later improving in response to therapy, check **worsening** on the form. Do not update **worsening** to **improving** in response to therapy. Similarly, do not change an **abnormal** radiograph to **normal** because it resolved during therapy

22. Tuberculin (Mantoux) Skin Test at Diagnosis

Indicate the result of the Mantoux (tuberculin, PPD, 5TU) test performed during the diagnostic evaluation. **Positive** indicates that the patient is probably infected with *M. tuberculosis* (see Appendix SUR IX for criteria for a positive tuberculin skin test).

Negative means that the skin test did not meet current criteria for a positive test, as defined in Appendix SUR IX.

Indicate **not done** if the skin test was not performed.

Indicate **unknown** if it is not known whether the skin test was performed, or if the results are not known.

In addition to the above, indicate the millimeters of induration in the boxes provided. If the available skin test result indicates only that the result was "positive" or "negative," but does not give the millimeters of induration, indicate whether the test is recorded as positive or negative and code the millimeters of induration as "99."

If the tuberculin skin test was negative, you may choose to indicate whether or not the patient was known to be anergic.[3]

Note: If skin testing was not performed during the current diagnostic evaluation because the patient has a history of a past *positive* tuberculin skin test, **AND** the previous positive test is documented in the medical record, the previous positive test result may be reported in this field. Patient self-report of a previous positive PPD is not acceptable. A history of a previous *negative* tuberculin skin test, whether documented or not, and a patient self-report of a negative previous or current skin test are also not acceptable.

23. HIV Status

Definitions for **positive**, **negative**, and **indeterminate** HIV test results have been published.[4]

HIV status is **positive** if the patient is tested for HIV and the laboratory result is interpreted as positive according to published criteria.

HIV status is **positive** if the patient has a documented medical history of a previous positive HIV test, or a previous diagnosis of HIV infection or AIDS.

HIV status is **positive** if the patient gives a history (e.g., oral statement) of a previously positive HIV test, or AIDS.

If **positive**, check whether based on **medical documentation**, **patient history**, or **unknown** basis.

Check **Medical documentation** if an HIV test reported by a laboratory is positive, a physician or health department record indicates that the patient is HIV positive, or if AIDS or other manifestations of HIV infection are documented in medical records.

Check **Patient history** if an oral statement is given by the patient, a relative or a friend.

If HIV status is based on both, list as based on medical documentation.

If positive, list:

CDC AIDS Patient Number (If AIDS reported before 1993);

State HIV/AIDS Patient Number (If AIDS reported 1993 or later);

City/County HIV/AIDS Patient Number (If AIDS reported 1993 or later).

AIDS Patient Numbers and HIV/AIDS Patient Numbers can be obtained from the state or local AIDS surveillance program.

HIV status is **negative** if the patient has had a documented negative HIV antibody test within the past year before diagnostic evaluation for TB. Patient history that an HIV test result was negative is not acceptable. Such patients should be offered the opportunity to be tested for HIV.

HIV status is **indeterminate** if the patient has had a documented indeterminate HIV antibody test within the past year before diagnostic evaluation for TB. Patient history is not acceptable.

HIV status is **refused** if the patient was offered the test at the time of the TB diagnostic evaluation, but declined to be tested.

HIV status is **not offered** if the patient was not offered the test at the time of the TB diagnostic evaluation. If the patient had a documented negative HIV test more than a year ago and was not given an opportunity to be re-tested, consider the test as not offered.

HIV status is **test done, results unknown** if the patient has been tested and the results are not known to the TB program.

HIV status is **unknown** if it is not known if the patient has had an HIV antibody test, or was ever offered a test.

24. Homeless within Past Year

Check **yes** if the patient was homeless at any time during the 12 months prior to the time when the TB diagnostic evaluation was performed.

A homeless person may be defined[5] as:

(1) An individual who lacks a fixed, regular, and adequate nighttime residence;

or

(2) An individual who has a primary nighttime residence that is:

(a) A supervised publicly or privately operated shelter designed to provide temporary living accommodations (including welfare hotels, congregate shelters, and transitional housing for the mentally ill);

or

(b) An institution that provides a temporary residence for individuals intended to be institutionalized;

or

(c) A public or private place not designated for, or ordinarily used as, a regular sleeping accommodation for human beings.

A **homeless** person may also be defined as a person who has no home, e.g., is not paying rent, does not own a home, and is not steadily living with relatives or friends. Another definition is a person who lacks customary and regular access to a conventional dwelling or residence.[6] Included as homeless are persons who live on streets or in nonresidential buildings. Also included are residents of homeless shelters, shelters for battered women, welfare hotels, and single room occupancy (SRO) hotels which are not designated for permanent long-term housing.

Check **no** if the patient was not homeless in the past year. Check **unknown** if it is not known whether the patient was homeless in the past year.

25. Resident of Correctional Facility at Time of Diagnosis

Note: Any questions regarding classification of a specific correctional facility as federal, state, local, juvenile, or other should be referred to the department of corrections within the state.

Check **yes** if the patient was an inmate of a correctional facility at the time when the TB diagnostic evaluation was performed.

Check **no** if the patient was not an inmate when the TB diagnostic evaluation was performed.

Check **unknown** if it is not known if the patient was an inmate when the TB diagnostic evaluation was performed.

If **yes**, indicate the type of institution:

A **federal prison** is a confinement facility administered by a federal agency.

A **state prison** is a confinement facility administered by a state agency.

A **local jail**[7] is a confinement facility usually administered by a local law enforcement agency, intended for adults but sometimes also containing juveniles, which holds persons detained pending adjudication and/or persons committed after adjudication for sentences of usually a year or less. Temporary holding facilities, or lockups, that do not hold persons after being formally charged in court are excluded. Both city and county jails are included in this category. Federal and state prisoners who are boarded at local jails should be reported as residents of the local jail.

A **juvenile correctional facility**[8] is a public or private residential facility, including juvenile detention centers, reception and diagnostic centers, ranches, camps, farms, and halfway houses or group homes. The juveniles served by these facilities include those accused or adjudicated as delinquents; status offenders (runaways, truants, or incorrigibles); and those committed or detained for treatment of abuse, dependency, neglect, or other reasons. Juveniles who are boarded at federal or state prisons or local jails should be reported as residents of the sites at which they are boarded.

Other correctional facility includes: federal detention centers run by the Immigration and Naturalization Service, Indian reservation facilities, military stockades and jails, federal Park Police facilities, privately operated state and local correctional facilities, and police lockups (temporary-holding facilities for persons who have not been formally charged in court).

Check **unknown** if the patient was an inmate, but the type of correctional facility is not known.

26. Resident of Long-Term Care Facility at Time of Diagnosis

Note: The state-licensing agency for long-term care places can assist in determining under which of these categories a facility is classified.

Check **yes** if the patient was a resident of a long-term care facility at the time the TB diagnostic evaluation was performed.

Check **no** if the patient was not a resident of a long-term care facility when the TB diagnostic evaluation was performed.

Check **unknown** if it is not known if the patient was a resident of a long-term care facility when diagnostic studies were performed.

If **yes**, indicate the type of facility:

Nursing home[9]**:** A facility having 3 beds or more is classified as a nursing home if it meets one or more of the following criteria:

- Certified as a skilled nursing facility, or
- Certified as an intermediate care facility, or
- Not certified, but licensed as a nursing home, or
- Identified as a nursing care unit of a retirement center, or
- Determined to provide nursing or medical care and/or provide supervision over medications that may be self-administered.

Hospital-based facility[10]: A facility having 3 beds or more is classified as hospital-based if it meets one or more of the following criteria:

- Was identified as such by the Health Care Financing Administration, or
- Reported itself to be exclusively hospital-based on the ILTCP (Inventory of Long-Term Care Places) questionnaire.

Residential facility[11]**:** A facility having 3 beds or more is classified as a residential facility if it meets both of the following criteria:

- Was not classified as a nursing home or hospital-based facility as described above, and
- Provided personal care or supervision to its residents in addition to room and board (for example, help with bathing, dressing, eating, walking, shopping, or corresponding).

Included under residential facilities are:

- Homes for mentally retarded or developmentally disabled persons.
- Board and care homes (such as residential care homes, group homes, homes for the aged, family care homes, adult foster care homes, personal care homes, adult congregate living facilities, residential community care facilities, and domiciliary care homes).

Mental health residential facility[12] includes: State and local mental hospitals, private psychiatric hospitals, non-federal general hospitals with separate psychiatric services, VA medical centers, multiservice mental health organizations with residential treatment programs, and residential treatment centers for emotionally disturbed children. *Excluded* are other federal psychiatric facilities, such as those of the Department of Defense, Bureau of Prisons, Public Health Service, and Indian Health Service. Also excluded are Indian reservation facilities which are not federal.

Alcohol or drug treatment facility[13] includes only long-term rehabilitation/residential facilities designated for treatment of 30 days or longer. *Excluded* are: all ambulatory or outpatient facilities, hospital inpatient detoxification units, free-standing residential detoxification units, hospital inpatient units not for detoxification, and short-term rehabilitation/residential units designated for less than 30 days of treatment. The state alcohol and drug treatment agency can assist in determining if a facility is considered residential. Other long-term care facility includes facilities not mentioned above which are designated for treatment of 30 days or longer.

Check **unknown** if the patient was a resident of a long-term care facility, but the type of facility is unknown.

27. Initial Drug Regimen

Indicate the drug regimen initially prescribed for treatment of the disease and taken for at least two weeks. The two-week requirement should eliminate most of the record updates necessitated by changes in regimen when treatment is begun. Check **yes** if the drug is known to be part of the initial regimen. Check **no** if the drug is known not to be part of the initial regimen. Check **unknown** if it is not known whether the drug is part of the initial regimen. If it is not feasible to determine the initial regimen of at least two weeks duration, record the initial regimen on which the patient was known to have been placed.

See Appendix SUR XVIII for a list of anti-tuberculosis drug abbreviations.

28. Date Therapy Started

Enter the 2-digit month, day and year of the date the patient began therapy for TB or suspected TB. This may be one of several dates:

(1) Date patient first ingested medication, if documented from a medical record, such as hospital or clinic or directly observed therapy record;

or

(2) Date medication was first dispensed to patient, as documented by medical or pharmacy record;

or

(3) Date medication was first prescribed to patient by health care provider, as documented by medical record or by prescription given to patient.

Date of ingestion is the preferred date for this field. If date of ingestion is not known, enter date of dispensation. If neither of those dates is known, enter date of prescription. Patient history without medical documentation is not acceptable.

If an exact date cannot be determined based on the above guidelines, a partial date may be entered in this field. The 2-digit "month" and "year" of the date must be valid values, but "99" may be entered for the 2-digit "day" of the date if the exact day therapy was started is not known. For example, if after following the above guidelines an exact Date Therapy Started cannot be determined, enter "08/99/94" on the form for a patient know to have started therapy in August of 1994. If the month or year therapy started is not known enter "99/99/99" on the form.

29. Injecting Drug Use Within Past Year

The purpose for collecting this information is to assess the patient's ability to adhere to antituberculosis drug therapy. Use of injecting drugs within the past year should be sought as an indicator of recent activity (e.g., when did the patient last inject drugs).

Injecting drug use involves the use of hypodermic needles and syringes for injection of drugs not prescribed by a physician. Route of administration may be intravenous, subcutaneous (skin popping), or intramuscular. Drugs injected may include: heroin or other opiates (demerol, dilaudid), cocaine, heroin and cocaine (speedball), amphetamines or other stimulants, PCP, LSD, or other hallucinogens, barbiturates, steroids or other hormones, other drugs or unknown drugs.

Check **yes** if it is known that the patient injected drugs within the past 12 months.

Check **no** if the patient has not injected drugs within the past 12 months.

Check **unknown** if it is not known if the patient injected drugs within the past 12 months.

Medical documentation or other indices of a history of enrollment in a drug treatment program (e.g., methadone detoxification, methadone maintenance, outpatient drug free, residential or inpatient, halfway house, prison or jail treatment, narcotics anonymous, cocaine anonymous, or other self help), medical or laboratory documentation of injecting drug use (e.g., urine testing, if done), or physical evidence (e.g., needle tracks) may be useful in answering this question.

Since the patient interview for injecting drug use is often negative initially, it may be necessary to inquire of the patient at multiple visits and consider urine toxicology.

30. Non-Injecting Drug Use Within Past Year

The purpose for collecting this information is to assess the patient's ability to adhere to antituberculosis drug therapy. Use of non-injecting drugs or illicit drugs within the past year should be sought as an indicator of recent activity (e.g., when did the patient last use non-injecting drugs).

The intent of this question is not to require a detailed systematic interview of each patient but to identify those patients whose drug use might interfere with their ability to complete antituberculosis drug therapy.

Note: Alcohol is *not* included as a drug in this section.

Non-injecting drug use involves the use of licensed or prescription drugs or illegal drugs that were not injected and were not prescribed by a physician. The drugs may be ingested, inhaled, or smoked. Non-injected drugs may include: Heroin or other opiates (demerol, codeine, dilaudid, or non-prescription methadone), cocaine (snorting), crack (smoking cocaine), ingested amphetamines (speed, uppers, bennies), ice or glass (smoking amphetamine), Valium or other benzodiazepams, PCP, LSD, or other hallucinogens, barbiturates, marijuana, hashish, or THC (weed, grass, reefers), nitrites (poppers, rush, hardware), inhalants (gasoline, spray paint), steroids, other drugs, or unknown drugs.

Check **yes** if it is known that the patient used non-injecting drugs within the past 12 months.

Check **no** if the patient did not use non-injecting drugs within the past 12 months.

Check **unknown** if it is not known whether the patient used non-injecting drugs within the past 12 months.

A history of enrollment in a drug treatment program (e.g., outpatient drug free, residential or inpatient, halfway house, prison or jail treatment, cocaine anonymous, or other self help), as well as medical or laboratory documentation of drug use (e.g., urine toxicology), may be useful in answering this question.

Since the patient interview for non-injecting drug use is often negative initially, it may be necessary to inquire of the patient at multiple visits and consider urine toxicology.

31. Excess Alcohol Use Within Past Year

This information is intended to assess the ability of the patient to adhere to antituberculosis drug therapy. Excessive use of alcohol within the past year should be sought as an indicator of recent activity (e.g., when did the patient last have a drink). Since the patient interview for excess alcohol use is often negative initially, it may be necessary to inquire of the patient at multiple visits.

Check **yes** if the patient has used alcohol to excess within the past 12 months.

Check **no** if the patient has not used alcohol to excess within the past 12 months.

Check **unknown** if it is not known if the patient used alcohol to excess within the past 12 months.

Reliable indicators of excess alcohol use include participation in Alcoholics Anonymous or alcohol treatment programs (e.g., outpatient, residential or inpatient, halfway house, prison or jail treatment, or other self help). There are also numerous screening instruments that can be helpful in identifying persons who may use alcohol to excess.[14]

A multiple option approach[15] to identifying excess alcohol use may also be useful, and includes: (a) a description by the patient, the patient's family or acquaintances, or a health care provider of chronic, high intake of alcohol with behavior associated with alcohol abuse; or (b) repeated visits to health care facilities during which alcohol intoxication was observed; or (c) report of alcohol use coupled with the existence of organic, alcohol-associated disease (e.g., pancreatitis, cirrhosis); or (d) a diagnosis of alcoholism on available medical records (e.g., discharge summaries or medical referral information).

32. Occupation

Check all that apply within the past 24 months:

Health Care Worker includes *any* person who has worked in a medical facility (e.g., hospital, clinic, health maintenance organization, infirmary, dispensary, long-term care facility, dental office, drug treatment center, medical laboratory, morgue, etc.) within the 24 months before the TB diagnostic evaluation was performed. Also included are students, trainees and volunteers who spend time in a health care facility, as well as persons who deliver health care in the community (e.g., public health nurse, visiting nurse, outreach worker, etc.).

Correctional Employee includes any person who has worked in a correctional facility. The facility may be a federal or state prison, local jail, juvenile correctional facility, or other correctional facility (see variable on correctional institution, Question 25).

Migratory Agricultural Worker[16] includes any individual whose principal employment is in agriculture on a seasonal basis, and who establishes for the purpose of such employment a temporary place of abode. Excluded are seasonal agricultural workers who are not migratory agricultural workers.

Other Occupation includes any person who has been employed for pay or outside the home at any job within the 24 months before the TB diagnostic evaluation was performed.

Not Employed within Past 24 Months includes any person who was not employed for pay or outside the home during the entire 24 months before the TB diagnostic evaluation was performed (e.g., student, retiree, homemaker, unemployed, institutionalized).

Check **unknown** if the employment history of the patient during the 24 months prior to the initiating of the TB diagnostic evaluation is not known.

If a patient performed an occupation described above in the setting of another occupation described above, check both appropriate boxes. For example, if the patient is a physician who has worked in both a hospital setting and a prison medical clinic, check both "Health Care Worker" and "Correctional Employee".

Comments

Additional space is provided at the bottom of the form to write comments regarding the case of tuberculosis reported on the RVCT (e.g., directions to the patient's house or place of employment, etc.).

Follow Up Report - 1
Initial Drug Susceptibility Report

This report should be completed for culture-positive cases only. Complete and submit this report within 2 months after the initial RVCT was submitted, or when drug susceptibility results are available, whichever is later.

- Copy patient name, address, zip code, state reporting, year counted and case number(s) information from page 1 of the initial RVCT form.
- The SOUNDEX code is not determined by the individual completing the form. The Soundex code is a feature included in the TIMS software, and will be automatically calculated and displayed by the software during data entry of the patient's last name. However, to assist in accurate record keeping, the Soundex code calculated by TIMS should be copied into the boxes at the top of the forms at the time of data entry.

33. Initial Drug Susceptibility Results

Was drug susceptibility testing done?

Check **yes** if the patient has any isolate upon which drug susceptibility testing was performed.

Check **no** if no susceptibility testing was performed.

Check **unknown** if it is not known whether susceptibility testing was performed.

Note: If the answer is **no** or **unknown**, *do not* complete the remainder of the Initial Drug Susceptibility Report.

Date first isolate collected: If drug susceptibility testing was done, enter the collection date of the first isolate on which drug susceptibility testing was performed. This information may be available from medical records or laboratory reports. A complete date is required. Partial dates are not acceptable. If the month, day, and year the isolate was collected are not all known, enter "99/99/99" on the form.

34. Susceptibility Results

Record the results of susceptibility testing on the first isolate for which drug susceptibility testing was performed.

For each drug listed:

Check **resistant** if there was any degree of resistance, even partial resistance or resistance at a low concentration of the drug.

Check **susceptible** only if completely susceptible.

Check **not done** if susceptibility testing was not done for this drug.

Check **unknown** if it is not known whether the test was performed or the results were unavailable.

A list of the drugs and commonly used abbreviations can be found in Appendix SUR XVIII.

For other drugs include only antituberculosis drugs; do not include pyridoxine (vitamin B6).

Comments

Additional space is provided at the bottom of the form to write comments regarding the case of tuberculosis reported on the Initial Drug Susceptibility Report (e.g., name of the laboratory that performed drug susceptibility testing, etc.).

Follow Up Report - 2
Case Completion Report

This form should be completed for all cases in which the patient was alive at diagnosis. Enter data into this report as information becomes available during patient follow up. This report should be completed when the case is closed to supervision.

Copy patient name, address, zip code, state reporting, year counted and case number(s) information from page 1 of the initial RVCT form.

The SOUNDEX code is not determined by the individual completing the form. The Soundex code is a feature included in the TIMS software, and will be automatically calculated and displayed by the software during data entry of the patient's last name. However, to assist in accurate record keeping, the Soundex code calculated by TIMS should be copied into the boxes at the top of the forms at the time of data entry.

35. Sputum Culture Conversion Documented

Provide information on sputum culture conversion only for patients with initially positive sputum cultures.

Note: Do not complete this question if the patient was not sputum culture positive, as indicated on question 18. Do not complete this question for patients without initially positive sputum cultures who have positive cultures from other pulmonary specimens (e.g., bronchoscopy fluid).

For **Sputum Culture Conversion Documented**, check **yes** if a patient had an initially positive sputum culture followed by one or more consistently negative sputum cultures.

Check **no** if a patient with an initially positive sputum culture had no subsequent consistently negative sputum cultures (e.g., all follow-up cultures were positive, patient could not produce sputum after therapy started, or no follow-up sputum cultures obtained).

Check **unknown** if the results of all follow-up cultures are unknown, or if it is not known if follow-up cultures were obtained.

Provide date codes for **Date Specimen Collected on Initial Positive Sputum Culture** *only* for patients who had one or more positive sputum cultures and who subsequently had one or more consistently negative sputum cultures documented. This information may be available from medical records or laboratory reports. A complete date is required. Partial dates are not acceptable. If the month, day, and year the first positive sputum culture was obtained are not all known, enter "99/99/99" on the form.

Provide **Date Specimen Collected on First Consistently Negative Culture** *only* for patients who had one or more positive sputum cultures and who subsequently had at least one documented negative culture. This date should be at least 1 week after the last positive culture was obtained. There should be no positive cultures after this date. This information may be available from medical records or laboratory reports. A complete date is required. Partial dates are not acceptable. If the month, day, and year the first consistently negative sputum culture was obtained are not all known, enter "99/99/9999" on the form.

36. Date Therapy Stopped

Enter the 2-digit month, day and year of the date the patient stopped taking therapy for TB or suspected TB. The time period represented by the interval between Date Therapy Started (Question 28) and Date Therapy Stopped is meant to encompass the entire period (including interruptions in therapy) that the patient was receiving medication to treat TB disease or suspected TB. Treatment with anti-TB medications of disease caused by mycobacteria other than *M. tuberculosis* complex (i.e., mycobacteria other than *M. tuberculosis*, *M. bovis* and *M. africanum*) should not be included in the time period from Date Therapy Started to Date Therapy Stopped.

Consider the following: A patient with suspected TB starts therapy on March 13, 1994. The culture obtained at the time of the diagnostic evaluation is returned on April 12, 1994 having grown *M. avium*. If therapy is continued to treat the *M. avium*, Date Therapy Stopped should still be completed to reflect that treatment for TB was stopped because TB disease was ruled out. In this example, Date Therapy Stopped should be April 12, 1994. Alternatively, the date that the laboratory identified the organism as not *M. tuberculosis* complex should be used.

For patients being treated for TB disease or suspected TB, Date Therapy Stopped should be completed as outlined below:

(1) Date that the patient last ingested medication;

or

(2) Date that the medication dispensed to the patient would have run out, if the patient had taken all the medication;

or

(3) Date that the medication prescribed to the patient would have run out, if the patient had taken all the medication from the date of prescription.

Date of last ingestion is the preferred date for this field. If date of ingestion is not known, enter the date that the medication would have run out, based on the date of dispensation. If neither of the above dates is known, enter the date that the medication would have run out based on the date of prescription. While there may be interruptions in antituberculosis drug therapy, the final date when the patient took medication for TB disease or suspected TB should be given. Date Therapy Stopped should be updated if a patient is lost to follow-up and then returns and completes therapy. Patient history without medical documentation is not acceptable.

If an exact date cannot be determined based on the above guidelines, a partial date may be entered in this field. The 2-digit "month" and "year" of the date must be valid values, but "99" may be entered for the 2-digit "day" of the date if the exact day therapy was stopped is not known. For example, if after following the above guidelines an exact Date Therapy Stopped cannot be determined, enter "08/99/94" on the form for a patient know to have started therapy in August of 1994. If the month or year therapy stopped is not known enter "99/99/99" on the form.

37. Reason Therapy Stopped

Provide the primary reason that therapy was ended and not resumed. This question should be completed when the case is closed. If the case is reopened (e.g., patient lost to follow up is found, restarts therapy, and completes therapy), the Case Completion Report form should be updated (e.g., to reflect that the patient completed therapy).

Check **completed therapy** if the patient successfully completed the prescribed course of therapy.

Check **moved** if the patient moved to another jurisdiction with a known forwarding address before treatment was completed. Reasonable attempts to first ascertain a final outcome (e.g., completed, lost) should be made for patients moving within the United States. See discussion of Transfer Cases in this appendix for surveillance data requirements for persons with TB who move from one reporting area to another.

Check **lost** if the patient cannot be located prior to the completion of treatment (e.g., the patient moved to an unknown location)

Check **uncooperative or refused** if the patient refused to complete therapy (e.g., stopped taking drugs). If patient restarts treatment, the Case Completion Report form report should be updated as appropriate.

Check **not TB** if the completed diagnostic evaluation determined that the diagnosis of TB is not substantiated (e.g., *M. avium* is isolated from a clinical specimen).

Check **died** if the patient died before therapy was completed.

Check **other** if therapy was discontinued for another reason.

Check **unknown** if the reason that therapy stopped is not known.

38. Type of Health Care Provider

Check **Health Department** if all outpatient care was provided by the state or local health department (e.g., TB program, primary care clinics, field nurses, outreach workers, etc.).

Check **Private/Other** if all care (except for contact investigation and dispensing of medication) was provided by non-health-department providers, such as: private providers, hospital, correctional institution, long-term care facility, federal program, Veteran's Administration, alcohol or drug treatment programs, or other health care providers that are not part of the state or local health department.

Check **Both Health Department** and **Private/Other** if both sectors were involved in care of the patient (e.g., private provider cares for patient who receives diagnostic tests and/or directly observed therapy from the health department, etc.). Also enter both if the patient was initially under health department care and was subsequently under private/other care (or vice versa).

39. Directly Observed Therapy

Directly observed therapy (DOT) or supervised therapy involves the direct visual observation by a health care provider (e.g., outreach worker or nurse) or other reliable person (e.g., homeless shelter worker) of a patient's ingestion of medication.[17] Delivering medication to a patient without visual confirmation of ingestion does not constitute DOT.

Confirmation that the medication has been swallowed may sometimes be necessary. Using such techniques as having the patient swallow a glass of water or talk following ingestion, inspecting the oral cavity with the tongue raised by the patient, or using a tongue blade to inspect between the cheek and the gums are helpful in determining if the medication has been swallowed. DOT regimens may be administered daily, or intermittently such as three times a week, or twice weekly.

Check **no, totally self-administered** if no doses of medication were given under supervision.

Check **yes**, **totally directly observed therapy** if all doses of medication were given under supervision.

Check **yes, both directly observed and self-administered** if one or more doses of medication were given under supervision and one or more doses were not.

Check **unknown** if it not known whether any doses of medication were given under supervision.

If any medication was administered under DOT, indicate the **site(s) of directly observed therapy**.

Check **in clinic or other facility** if DOT was given at a health department or private provider facility (e.g., TB clinic, community health center, migrant clinic, drug treatment center, hospital outpatient setting, HIV/AIDS clinic) or at an institution, such as a nursing home or correctional facility.

Check **in the field** if DOT was given solely outside a facility, such as at the patient's home, work, or other site.

Check **both in facility and in the field** if both were used (e.g., patient received DOT at a clinic and in the field when patient did not show up at the clinic).

Check **unknown** if the sites of DOT are not known.

For **number of weeks of directly observed therapy**, write the total number of calendar weeks (Sunday through Saturday) that the patient received the following minimum amounts of medication under supervision in clinic or other facility or in the field:

For patients on a twice-weekly DOT regimen, count the week only if both the week's doses were administered under DOT.

For patients on a thrice-weekly DOT regimen, count the week only if all three of the week's doses were administered under DOT.

For patients on a daily DOT regimen, count the week only if five or more of the week's doses were administered under DOT.

If the patient does not receive the above minimum number of doses under DOT, do not count the week. The number of weeks of DOT indicated must be less than or equal to the number of weeks in the time period between Date Therapy Started (Question 28) and Date Therapy Stopped (Question 36).

40. Final Drug Susceptibility Results: Was follow-up drug susceptibility done?

This variable will help assess the frequency of acquired drug resistance.

Check **no** if no follow-up drug susceptibility testing was done.

Check **yes** if drug susceptibility testing was performed on an isolate that was collected ≥30 days after the isolate for which initial drug susceptibility testing was performed.

Check **unknown** if it is not known whether follow-up drug susceptibility testing was performed.

Note: If the answer is no or unknown, do not complete the remainder of the form.

Date of final isolate: If follow-up susceptibility testing was done, indicate the collection date of the last isolate for which drug susceptibility testing was performed. This date should be 30 days or more after the collection date of the initial isolate for which drug susceptibility was done (Question 33). This information is available from medical records or laboratory reports. A complete date is required. Partial dates are not acceptable. If the month, day, and year the isolate was collected are not all known, enter "99/99/99" on the form.

41. Final Susceptibility Results

Record results for the last isolate for which drug susceptibility testing was performed.

For each drug listed:

Check **resistant** if there was any degree of resistance, even partial resistance or resistance at a low concentration of the drug.

Check **susceptible** only if completely susceptible.

Check **not done** if susceptibility testing was not done for this drug.

Check **unknown** if it is not known whether the test was performed or the results were unavailable.

A list of the drugs and commonly used abbreviations can be found in Appendix SUR XVIII. For other drugs include only anti-tuberculosis drugs; do not include pyridoxine (vitamin B6).

Comments

Additional space is provided at the bottom of the form to write comments regarding the case of tuberculosis reported on the Case Completion Report (e.g., name of the laboratory that performed drug susceptibility testing, etc.).

Appendix SUR XVIII lists the antituberculosis drugs that are on the RVCT, and some common abbreviations used to identify them. These abbreviations may also be helpful in completing questions regarding Susceptibility Results (Question 34 and Question 41).

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