

# Tuberculosis Case Report Form Instructions

## General Information

The purpose of the Tuberculosis Case Report form is to collect surveillance data on TB suspects and cases. The data collected on this form are reported to CDC, and analyzed locally.

The instructions for this report are not a substitute for expert clinical opinion and CDC guidelines on the medical management of TB. As always, feel free to consult with the State for assistance in TB diagnosis and case management.

## Submission of Tuberculosis Case Report Forms

A Tuberculosis Case Report form should be completed for each suspect or confirmed TB case.

Reports should be made when either:

1. TB is one of the primary differential diagnoses. This often occurs when:
  - signs and symptoms of TB are present and/or
  - the patient has an abnormal chest x-ray consistent with TB or
  - the patient is started on multidrug therapy for TB
2. When specimen smears are positive for acid fast bacilli (AFB)
3. When the patient has a positive culture for *M. tuberculosis* complex (e.g. *M. tuberculosis*, *M. bovis*, *M. canetti*, *M. africanum*)
4. When a pathology report is consistent with tuberculosis.

### ***When to submit:***

A copy of the case form will be submitted by the local health department 3 times (initial, verification, and closure reports).

#### Initial Report:

Send a copy within one week of notification of the suspect or confirmed case. Enter the date the report is submitted to the State in the section 'Report and Date' on the top right hand corner of the form.

#### Verification Update:

Send an updated copy of the form when a determination of TB disease status can be made (after cultures results are received, or after 2 months treatment for clinical cases). The verification section must be filled out for all patients for whom an initial report was submitted. Enter the date the verification update was submitted to the State in the space next to "Verification" in the section 'Report and Date' on the top right hand corner of the form. If the case is laboratory-confirmed at the time of the initial report, you do not need to send the form in twice. Send one copy of the form using the same date as the initial date and verification date.

#### Closure Report:

Send a final updated copy when the case has been closed. The closure section must be filled out for all patients with an initial report. Enter the date the form is submitted in the space next to "Closure" in the section 'Report and Date' on the top right hand corner of the form. If the case is closed at the same time as the verification update (verified as NOT TB) then you do not need to send the form twice. Send one copy of the form using the same date as the verification date and closure date.

**Where to submit:**

Mail: TB Program  
Oregon Health Department  
Department of Human Services  
800 NE Oregon Street, Suite 1105  
Portland, OR 97232

-or- Fax: (971) 673-0178  
Send attention TB Program

**How to fill out the Tuberculosis Case Report Form**

The Tuberculosis Contact Investigation Form is divided into 9 sections: Administrative Information (the header of the form), Case Identification, Demographics, Basis of Diagnosis, Bacteriology, TB Risks, Treatment, Verification, and Closure. Details of the data elements collected in each section of the form are outlined below.

**ADMINISTRATIVE**

**County**

Enter the name of the county with jurisdiction of the case. This should be the county in which the case resides. See "address" below for more information on establishing jurisdiction of the case, or contact the State for assistance.

**Case Manager**

Enter the name of the case manager. This should be the person the State would call for questions on the case.

**Treating Physician**

Enter the name and phone number of the physician(s) treating the TB case.

**Report and Date**

Enter the date the case report form is submitted to the State (initial, verification update, and closure). See above "When to submit" for more detail.

**CASE IDENTIFICATION**

**Name and Phone**

Enter the full name (last, first MI) and phone number(s) of the case

**Address**

Indicate the street, city, county, and zip code of the patient's residence at the time of diagnosis. To the extent possible, the address should represent the home address (whether permanent or temporary) of the patient.

*Please follow these guidelines:*

- If a person is diagnosed in the community they consider their home, he or she should be included in the morbidity count for that area, and the street, 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 street, city, county, and zip code of their home area should be entered in this field. For example, a patient in a community due to hospitalization 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 U.S.), migrants, U.S. 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 U.S., is receiving antituberculosis drug therapy, and has been, or plans to remain in the country for at least 90 days, the case should be counted in the area of current residence, and the street, city, county, and zip code of his or her current residence should be entered in this field. Persons arriving in the U.S. who were diagnosed with TB before arriving here should not be counted as a case of TB in the U.S. Such cases are considered to have occurred in another country, even if therapy is continued or completed in the U.S.
- Patients who are residents of correctional facilities (e.g., local, state, federal, military) should be counted in the area in which the correctional facility is located, and the street, city, county and zip code of the facility should be entered in this field.
- Patients who are residents of long term care facilities at the time of diagnosis should be counted in the area in which the facility is located, and the street, 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 street, city, county and zip code of that locality.

#### **Institution**

If the case lives in a correctional facility, long-term care facility, or shelter at the time of diagnosis enter the name of the facility.

#### **Sources of Report**

Select the source of the report to the local health department (LHD): lab, physician, infection control or other. Enter the contact information of the source and the date reported to the LHD. Indicate whether the patient was reported at death.

### **DEMOGRAPHICS**

#### **Sex**

Enter the biological sex of the patient

#### **Date of Birth**

Enter the date of birth of the patient.

#### **Race and Hispanic Ethnicity**

Select the appropriate boxes to indicate self-identified race(s) and Hispanic or Latino ethnicity.

#### **Country of Birth**

If the person was born in one of the 50 United States or born abroad of a U.S. citizen parent (e.g., born on a military installation), select "US" as the country of birth.

If the person was born in the U.S. Territories, U.S. Island Areas, and U.S. Outlying Areas (e.g., American Samoa, Federated States of Micronesia, Guam, Republic of the Marshall Islands, Commonwealth of the Northern Mariana Islands, Republic of Palau, Puerto Rico, U.S. Virgin Islands) mark the box "US Territory" and write-in the location.

#### **Date of Entry to US**

For patients who were **NOT** born in one of the 50 United States or **NOT** born abroad of a U.S. citizen parent, enter the month and year the patient **first** arrived in the U.S. If month is unknown, enter year only.

## Immigration Status

Enter the immigration status at first entry to the US and currently.

If a TB patient was born in one of the 50 United States, born abroad of a U.S. citizen parent (e.g., born on a military installation), or born in one of the U.S. Territories, U.S. Island Areas, or U.S. Outlying Areas (e.g., American Samoa, Federated States of Micronesia, Guam, Republic of the Marshall Islands, Commonwealth of the Northern Mariana Islands, Republic of Palau, Puerto Rico, U.S. Virgin Islands) then a visa would not be issued and “**Not Applicable/U.S.-born**” should be checked. Of note, people born in Puerto Rico, U.S. Virgin Islands, and Guam are U.S. citizens.

For persons not under the option of “**Not Applicable/US-born**,” *select one* of the following choices:

**NOTE:** If the patient had a visa at first entry to the U.S., specify the type of visa. A reliable verbal source is acceptable. There are 2 main types of legal immigration status: permanent residents and non-immigrants (visa issued for specific purpose and time period). Permanent residents (e.g., immigrants) are issued an alien resident card (i.e., green card) and should carry this card with them. Non-immigrants with visas (e.g., student, tourist, employment, “V” visa, “K” visa) should be aware of their visa type which is stated in their passport (e.g., I-94 arrival document stapled in passport). Refugees are separate from the two main categories above; they should have an arrival document (I-94 card) showing their status as a refugee and they should carry this card with them.

### Immigrant Visa

Check for foreign-born TB patients who first entered the U.S. with permanent resident status (e.g., immigrants).

### Student Visa

Check for foreign-born TB patients who entered the U.S on a student visa. This is a non-immigrant visa and is obtained by an alien coming temporarily to the U.S. to pursue a full course of study in an approved institution.

### Employment Visa

Check for foreign-born patients who entered the U.S with a non-immigrant employment visa (an alien coming to the U.S. to work for a temporary period of time). There are many different non-immigrant employment visas depending upon type of work. (Note: Some persons entering the U.S. for work are immigrants; they should be checked as “immigrants”).

### Tourist Visa

Check for foreign-born TB patients who entered the U.S temporarily for business or pleasure. This is a non-immigrant visa.

### Family/Fiancé Visa

Check for foreign-born TB patients who entered the U.S with a “V” visa or “K” visa. A “V” visa is a non-immigrant category that allows a spouse or child of a U.S. lawful permanent resident to live and work in the U.S. A “K” visa is a non-immigrant category that allows a fiancé of a U.S. citizen to temporarily enter the U.S. for a specific purpose (i.e., marriage).

### Refugee

Check for foreign-born patients who first entered the U.S as refugees. A refugee is a person who is outside his or her country of nationality who is unable or unwilling to return to that country because of persecution or a well-founded fear of persecution.

### Asylee or Parolee

Check for foreign-born patients who first entered the U.S seeking asylum or who are parolees. An asylee is an alien in the U.S. who is unable or unwilling to return to his or her country of

nationality because of persecution or a well-founded fear of persecution. An asylee must meet the same criteria as a refugee; the only difference is the location of the person upon application – the potential asylee is in the U.S. or applying for admission at a port of entry, and the potential refugee is outside the U.S. A parolee is an alien, appearing to be inadmissible to the inspecting officer, allowed to enter the U.S. under urgent humanitarian reasons or when that alien's entry is determined to be for significant public benefit.

#### Other Immigration Status

Check for foreign-born TB patients who first entered the U.S with other immigration status, which is not Immigrant, Refugee, Asylee, Parolee, Student, Tourist, Employment, "V" visa, or "K" visa status, and is not "Unknown." This includes foreign-born persons who were not required to obtain a visa (e.g., foreign-born visitors from specific countries such as Canada that are part of the U.S. visa waiver program and are not required to obtain visas if visiting the U.S. for short periods of time (e.g., ≤90 days)), or those who entered the U.S. with no official immigration status at entry (e.g., "undocumented

#### Unknown

Check for jurisdictions with policies forbidding asking a TB patient their immigration status; foreign-born TB patients who do not know their immigration status at first entry; those who may have had a visa at entry to the U.S., but the type of visa is unknown; and those who refuse to respond.

### **Pediatric TB**

For patients <15 years of age, check whether the patient lived outside the US for more than 2 uninterrupted months, and if yes, write-in where. Indicate the country of birth of the guardians.

### **Occupation**

Within the past 12 months of the diagnostic TB evaluation, select the primary occupation of the patient. If more than one occupation option is applicable to the patient, choose the occupation that the patient performed for the longest period of time within the past 12 months. For example, if the patient was a health care worker and a student (e.g. taking night classes), then the patient's primary occupation would be classified as "Health Care Worker."

#### Health Care Worker

Mark if the patient was a paid or unpaid person working in healthcare settings with potential for exposure to *M. tuberculosis*. These may include but are not limited to physicians, nurses, aides, dental workers, technicians, staff in labs and morgues, emergency medical personnel, students, temporary and contract staff, and persons not involved directly in patient care but potentially at risk for occupational exposure (e.g., volunteers, dietary, maintenance, clerical, and janitorial staff). Also included are persons who deliver health care in the community (e.g., public health nurse, visiting nurse, outreach worker).

#### Correctional Facility Employee

Mark if the patient has worked in a correctional facility. The facility may be a federal or state prison, local jail, juvenile correctional facility, ICE

#### Migrant/Seasonal Worker

Mark if the patient was any individual who is required to be absent from a permanent place of residence for the purpose of seeking employment or who may vary their employment for the purpose of remaining employed while maintaining a permanent place of residence [e.g. seasonal agricultural worker, migrant factory worker, migrant construction worker, migrant service industry worker, migrant sporting worker (e.g., horse racing, dog racing)].

#### Other Occupation

Mark if the patient was regularly employed for pay at any occupation not included in the above choices within the 12 months before the TB diagnostic evaluation.

### Retired

Mark if the patient was retired within the 12 months before the TB diagnostic evaluation was performed.

### Unemployed

Mark if the patient was not employed during the past 12 months prior to the diagnostic TB evaluation. This should not include persons ineligible for employment such as infants, children, students, housewives, and persons receiving disability benefits or persons institutionalized. Such individuals should be included in the options "Retired" or "Not Eligible for Employment". "Unemployed" should be checked if the person was unemployed for the majority of the prior 12 month period; shorter time frames, such as 1 week of unemployment in the past 12 months such not be marked as "Unemployed."

### Not Seeking for Employment

Mark if the patient was not employed for reasons other than unemployment within the 12 months before the TB diagnostic evaluation, such as infants, children, students, homemakers (e.g., housewife, househusband), and persons receiving disability benefits or persons institutionalized.

### **Health Insurance**

Indicate if the patient's health insurance is private, public (e.g. Medicare/Medicaid) or none. If both public and private, mark both corresponding check boxes.

## **BASIS OF DIAGNOSIS**

### **Site of disease**

Select all that apply. If not pulmonary, pleural and/or lymphatic, write the site(s) in the space provided.

### **Symptomatic**

Mark whether the patient experienced TB symptoms. If yes, enter the date of onset. Mark yes or no or unknown for the following symptoms: cough (also indicate intensity and duration), hemoptysis, fever, night sweats, weight loss (indicate amount). If the patient experienced a TB symptom that is not listed (e.g. lymphadenopathy, chest pain) use the space provided to write-in. Indicate the date medical care was sought for TB symptoms and where the patient first presented.

### **If the patient did not present due to symptoms, primary reason for evaluation**

Select the primary or initial situation or reason that led to the initial suspicion that the patient may have TB disease. See options below. Note: if a TB patient was referred, but the reason is unknown, an attempt should be made to identify that reason.

### Contact Investigation

Mark if the patient was diagnosed with TB disease as a result of a contact investigation or source case finding.

### Targeted Testing

Mark if the patient was evaluated for TB disease due to a positive tuberculin skin test or positive interferon gamma release assay administered because the patient was specifically considered high risk for TB (e.g., persons from areas of the world with high rates of TB) or as part of a targeted testing screening program. For the purpose of this question, targeted testing should not be selected if another more appropriate reason exists, such as contact investigation, immigration medical examination, or employment/ administrative testing, or health care worker status.

### Employment/Administrative Testing

Mark if the patient was diagnosed with TB disease during a routine employment physical examination, employment tuberculin skin testing requirement, or school mandate for tuberculin skin testing. This category reflects an administrative requirement (e.g., a tuberculin skin testing

program applied to all 5<sup>th</sup> graders in a school or to all job applicants) rather than targeted testing of a group of individuals considered high risk. If skin testing was performed because the individual was considered high risk, check "Targeted testing". Indicate if employment testing was for a health care worker. "Health care worker" refers to all paid and unpaid persons working in healthcare settings who have the potential for exposure to *M. tuberculosis*. These may include but are not limited to physicians, nurses, aides, dental workers, technicians, staff in laboratories and morgues, emergency medical personnel, students, temporary and contract staff, and persons not involved directly in patient care but potentially at risk for occupational exposure (e.g., volunteers, dietary, maintenance, clerical, and janitorial staff). Also included are persons who deliver health care in the community (e.g., public health nurse, visiting nurse, outreach worker).

Immigration Medical Exam

Mark if the patient underwent a medical examination as part of the immigration application process and was found to have TB disease. A medical examination is mandatory for specific persons seeking admission to the U.S. (e.g., immigrants, refugees, asylees). These medical examinations may occur overseas or in the U.S. depending on the situation.

Incidental Abnormal Chest Radiograph

Mark if the patient had an incidental chest radiograph consistent with TB disease. The reason for taking the chest radiograph should be independent of the other choices listed in the question and should not have been done to rule out TB disease. For example, if the chest radiograph was taken as a result of a workup for TB disease due to a positive tuberculin skin test obtained during targeted testing, select "targeted testing." However, if a chest radiograph was taken as part of preoperative testing, where there was no suspicion of TB disease, then select "abnormal chest radiograph."

Incidental Lab Result

Mark if incidental specimen is positive for acid fast bacilli (AFB) or an incidental culture is positive for *Mycobacterium tuberculosis* (e.g., when the specimen was tested for AFB or cultured for TB without suspicion of TB disease or when TB disease was not considered a possible diagnosis, such as during a bronchoscopy, autopsy, organ donation, hospitalization or analysis for other disease].

Other

Mark if reason for evaluation is not listed above. Please write-in the reason.

**TST at diagnosis**

Enter the date and result of the TST placed at the time of diagnosis. If not placed, mark "Not Done".

**QFT at diagnosis**

Enter the date and result of the interferon gamma release assay (ie Quantiferon (QFT)) placed at the time of diagnosis. If not placed, mark "Not Done".

**Prior TST/QFT**

Enter the date and result of the last prior TST/QFT test.

**Chest imaging at diagnosis**

Enter the x-ray and/or CT date in the spaces provided. Select the result from the following:

Negative for TB

Check if the study did not show abnormalities consistent with TB.

Abnormal

Check if the study showed any abnormalities associated with TB (e.g., hilar adenopathy, infiltrate(s), cavity, scarring)

Cavitary

Check this box if the imaging shows evidence of 1 or more cavities, otherwise leave blank

Miliary

Check this box if the imaging shows evidence of miliary disease, otherwise leave blank

Not Done

Check if the test not performed

Note: Please attach copies of all CXRs or CTs.

**BACTERIOLOGY**

For specimens submitted for bacteriology during the diagnostic work-up, please enter the date collected, lab results (AFB (acid-fast bacilli) smear, NAAT (nucleic acid amplification test (Direct Test/PCR test), and MTB culture) and name of lab. Note: specimens collected after the patient has been on treatment (e.g. 2-3 weeks) should not be recorded here. This section is designed to collect at least the first positive smear result (or if smears are all negative, the first negative result), and the first positive culture result.

**TB RISKS**

**TB History**

**Previous diagnosis of TB Disease**

Check “Yes” if the patient has had a previous diagnosis of TB disease. A previous diagnosis of latent TB infection (i.e., LTBI) should not be entered. A patient is considered to have had a previous diagnosis of TB disease if he had verified disease in the past, had completed therapy or was lost to supervision for more than 12 consecutive months, and now has disease again. Often, TB disease is confused with latent TB infection (LTBI); therefore, documentation of the previous episode of TB disease is important. Written documentation of previous TB diseases is ideal. However, when written documentation is not available, reliable verbal documentation of a previous episode of TB disease is acceptable (e.g., medications taken, length of medication, sputum smear examination results).

If “Yes”, provide year which patient’s previous episode of TB disease was diagnosed. For example, if the patient was diagnosed with TB disease in 1985, was reported to have completed therapy or was lost to supervision in 1986, and is found to have verified disease again in 2005, enter "1985" in the boxes provided. If patient had more than one previous episode of TB disease, enter year of most recent episode. Indicate if treatment was completed and where.

Check “No” if the patient has not had a previous diagnosis of TB disease.

**Previous treatment for LTBI**

Check “Yes” if the patient was treated for LTBI in past. If yes, provide year LTBI treatment was started. Indicate if the treatment was completed and where. Written documentation is ideal; but reliable verbal documentation is acceptable.

**Previous contact to an infectious TB patient**

Check yes if patient was ever a contact to an infectious TB patient. If yes, enter year of exposure. Indicate if the index case was MDR (multi-drug resistant). Enter any other relevant details (where exposure occurred, etc).

**CONGREGATE SETTINGS**

**Homeless in the past year**

A homeless person is defined as a person who is not regularly paying rent, does not own a home, and is not steadily living with relatives or friends. Also includes residents of any shelter, SRO hotel or other facility not designated for permanent long-term housing. Indicate if the patient was homeless in the past 12 months.

**History of homelessness**

Check “Yes” if the patient has a history of homelessness. Specify details (when and where) in the space provided.

**Resident of a correctional facility at diagnosis**

Check “Yes” if patient was an inmate of a correctional facility (including Federal, State, Local, Juvenile Detention Centers, etc) when the TB diagnostic evaluation was performed. Indicate the facility in space provided.

**History of incarceration**

Check “Yes” if the patient has a history of incarceration. Specify details (when and where) in the space provided.

**Resident of long-term care facility**

Check “Yes” if patient was a resident of long-term care facility (including nursing homes, assisted living facilities, mental health facilities, alcohol or drug treatment facilities (designated for treatment 30 days or longer)) at the time when the TB diagnostic evaluation was performed. Indicate the facility in the space provided.

**SOCIAL FACTORS****Excess alcohol use in the past year**

Indicate if patient had excessive alcohol use in the past year.

There is no standard definition for excess alcohol use. Indications of excess alcohol use may include participation in treatment programs, loss of family/friends/job/assets due to drinking or hospitalization for alcohol related medical conditions. There are also numerous screening instruments that can be helpful in identifying persons who may use alcohol to excess (e.g., CAGE, AUDIT, MAST). Other strategies to determine alcohol use are to assess the frequency and amount of alcohol use. Some define drinking five or more drinks on the same occasion on each of 5 or more days in the past 30 days as considered excessive.

Since patients may minimize extent of alcohol use initially, it might be necessary to ask this question multiple times. If information changes during course of TB treatment, please update this question.

**IV drug use in the past year**

Indicate if the patient has used needles for self-injection of drugs not prescribed by a physician within the past 12 months. Route of administration may be intravenous, subcutaneous (skin popping), or intramuscular.

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.

As the patient may initially deny injecting drug use, it may be necessary to inquire of the patient at multiple visits. If information changes during course of TB treatment, please update this question.

**Non-IV drug use**

Indicate if the patient used non-IV drugs within the past year. This involves the use of prescription drugs or illegal drugs that were not injected or prescribed by a physician. The drugs may be smoked, snorted or swallowed.

A history of enrollment in a drug treatment program as well as medical or laboratory documentation of drug use (e.g., urine toxicology), may be useful in answering this question.

As the patient may initially deny drug use, it may be necessary to inquire of the patient at multiple visits. If information changes during course of TB treatment, please update this question.

**Currently smoking tobacco**

Indicate whether or not the patient currently uses tobacco. Indicate the type (cigarettes, cigars, pipe) and amount per day (e.g. 1PPD for 2 packs/per day). Also indicate the estimated start year.

**If not currently smoking, past tobacco smoking**

Indicate whether or not the patient has ever smoked tobacco (minimum >100 cigarettes in a lifetime, or similar amount of tobacco). Indicate the type (cigarettes, cigars, pipe) and amount per day (e.g. 1PPD for 2 packs/per day). Also indicate the estimated start year and quit year.

**Travel outside the US longer than 30 days**

Indicate if the patient traveled outside the US for longer than 30 consecutive days. If yes, please specify when and where.

**MEDICAL RISKS****HIV at diagnosis**

CDC recommends that **ALL** TB cases receive HIV counseling, testing, and referral at the time of TB evaluation or TB diagnosis. Indicate the status and the date of HIV test.

Pending

HIV status is "Pending" if the patient had a HIV test at the time of the TB diagnostic evaluation or TB diagnosis and the results are not yet known to the TB program. Please update the form with HIV status once it becomes known (usually by verification report)

Positive

HIV status is "Positive" if one of the following is applicable:

- 1.the patient is tested for HIV and the laboratory result is interpreted as positive according to published criteria.
- 2.the patient has a documented medical history of a previous positive HIV test, or a documented previous diagnosis of HIV infection or AIDS.

Negative

HIV status is "Negative" if the patient has had a documented negative HIV test at the time of TB diagnostic evaluation or at TB diagnosis. Undocumented patient history that an HIV test result was negative is not acceptable. Such patients should be offered the opportunity to be tested for HIV. In addition, if a patient has had a negative test in the past, regardless of when the HIV test was performed, the patient should be offered HIV counseling and testing at the time of TB diagnostic evaluation or TB diagnosis.

Not Done

If HIV status is not obtained, mark this box and indicate the reason why the test was not performed (e.g. refused, not offered).

**Other medical factors**Diabetes

Check if the TB patient has diabetes mellitus (Type I or Type II) at the time of TB diagnosis.

Immunosuppressive Therapy

Check this box for immunosuppressive therapy, such as prolonged use of high dose adrenocorticosteroids (e.g., prednisone).

TNF  $\alpha$  Antagonist Therapy

Check if the TB patient had recently or has been receiving tumor necrosis factor-alpha (TNF- $\alpha$ ) antagonist therapy at the time of TB diagnosis. TNF- $\alpha$  antagonist therapy is used for treatment of rheumatoid

arthritis and other selected autoimmune diseases. TB disease is a potential adverse reaction from treatment with TNF- $\alpha$  antagonists. The three FDA approved TNF- $\alpha$  antagonists are infliximab (Remicade<sup>®</sup>), etanercept (Enbrel<sup>®</sup>), and adalimumab (Humira<sup>®</sup>).

#### End Stage Renal Disease

Check if the TB patient has end-stage renal disease or chronic renal failure at the time of TB diagnosis

#### Post Organ Transplant

Check if the TB patient has a history of solid organ transplantation (e.g., renal, cardiac).

#### Weight < 90% of Ideal Body Weight

Check for patients who are undernourished

#### Cancer/malignancy

Check if patient has hematological or reticuloendothelial malignancies (e.g., leukemia, Hodgkin's lymphoma, carcinoma of the head or neck)

#### Other

Check if patient has TB risk factor not included in the above choices (e.g., intestinal bypass surgery for obesity, gastrectomy, jejunioileal bypass, chronic malabsorption syndromes, silicosis)

## **TREATMENT**

### **Date therapy started**

Enter the date (month, day, year) the patient began multi-drug therapy for TB disease or suspected TB disease. 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.

### **Regimen**

Indicate the drug regimen initially prescribed for treatment of TB disease, and taken for at least 2 weeks (if drug regimen changes in the first two weeks please update the form). Indicate the dosage and frequency (e.g. daily) in the space provided.

### **Is therapy directly observed?**

Indicate if therapy will be directly observed. Directly observed therapy (DOT) is the standard of care in Oregon. If not DOT, please indicate the reason in the space provided.

### **Height, weight, allergies, history of hepatitis, kidney or liver dysfunction**

Indicate height, weight, allergies, and history of hepatitis, kidney or liver dysfunction. Specify any relevant details in the space provided.

## **VERIFICATION**

Once it is known (e.g. once culture results are received, or after 2 months of treatment for clinical cases), indicate the verification status of the case. For non-laboratory cases, obtain status from treating physician. Mark only one.

#### Laboratory confirmed

Select this box if MTB complex has been isolated from a culture of a clinical specimen, or if MTB complex has been demonstrated from a respiratory specimen via nucleic acid amplification test (NAAT).

Clinical Case

Select this box if the culture negative case meets the following criteria:

- a. Full diagnostic evaluation
  - i. Tuberculin Skin Test (TST) or Quantiferon (QFT) test
  - ii. Chest X-ray/imaging
  - iii. Clinical specimens for culture/NAAT
  - iv. Risk factor evaluation: host factors (e.g. documented immunosuppression) and environmental factors (e.g. contact to an active case, born in a county endemic with TB, travel to endemic country)

**and**

- b. Lab test indicative of infection
  - i. Positive TST

**and/or**

  - ii. Positive QFT

**or**

  - iii. Negative TST or QFT with reason for not positive (immunosuppression)

**and**

- c. Signs or symptoms compatible with TB disease

**and**

- d. Improvement of signs or symptoms after treatment with 2 or more anti-TB drugs

Provider treating empirically

Select this box if the above definitions of laboratory confirmed or clinical case have not been met, and the provider is continuing TB treatment (TB not ruled out).

Not TB

Select this box if TB is no longer considered as a diagnosis. Indicate other diagnosis in space provided.

**CLOSURE**

**Reason**

Select the reason for closure of the TB case from the choices below (select one):

Not TB

TB is no longer a diagnosis. 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).

Completed therapy

Adequate treatment for TB disease has been completed.

Lost

Check if the patient cannot be located prior to the completion of treatment (e.g., the patient moved to an unknown location or when the address forwarding address is known, but the patient is not found at that address).

Refused/non-compliant

Check if the patient refused to complete therapy (e.g., stopped taking drugs).

### Died

Check if the patient was alive at diagnosis but died before therapy was completed, if started on at least two antituberculosis drugs prior to the day of death.

### Adverse treatment event

Check if therapy was permanently stopped due to an adverse treatment event from antituberculosis medications (e.g., life threatening drug reaction).

If started on treatment (even if later deemed not to be TB), please fill out the following sections.

### **Date stopped**

Enter date (month, day, year) the patient stopped taking therapy for TB disease or suspected TB disease. The time period represented by the interval between "Date Therapy Started" 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 disease. Date of last ingestion is the preferred date for this field. If date of ingestion is not known, enter date that medication would have run out, based on the date of dispensation. 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 was lost to follow-up and then returns and completes therapy. Patient history without medical documentation is not acceptable.

If patient completed adequate therapy but later experienced disease recurrence resulting in additional treatment, please fill out a new form. (If disease recurs within 12 months of completing therapy, this will not result in the person being counted as a new case. However, if disease recurs after 12 months of completing therapy, the episode is considered a new case.)

### **If treatment greater than 12 months, why?**

Specify the reason for treatment length of greater than 12 months (from start to finish). Reasons include but are not limited to: rifampin resistance, significant adverse drug reaction, non-adherence, failure to convert sputum culture beyond month 4 of treatment, TB meningitis, severe liver disease, etc).

### **Type of outpatient healthcare provider**

For the purpose of this variable, "**Type of Outpatient Health Care Provider**" is defined as the provider who has primary responsibility for clinical outpatient decision making (excluding diagnostic work-up, contact investigations, anti-TB medications, and DOT). An outpatient facility refers to a setting such as a clinic or medical office. Inpatient refers to an acute-care setting such as a hospital. Some institutions, such as a hospital, correctional facility, or long-term care facility, may have both outpatient and inpatient settings. For patients that have had multiple primary providers during their TB care, select all that apply. **Example:** If a private provider was the primary outpatient caregiver and made all the clinical decisions, but the local/state health department was providing DOT, conducting the contact investigation, and was periodically contacting the private provider for information, check "Private" for this variable. If however, this same patient after a period of time (e.g., 3 months), lost their medical insurance and then switched providers and now the local/state health department had primary responsibility for the outpatient decisions, then both "Private" and "Local/State Health Department" should be checked.

### Local/State Health Department

Check if the primary responsibility for clinical outpatient decision making (*excluding* diagnostic work-up, contact investigations, anti-TB medications, and DOT) is the local or state health department (e.g., TB program, health clinic).

### Private

Check if the primary responsibility for clinical outpatient decision making (*excluding* diagnostic work-up, contact investigations, anti-TB medications, and DOT) is a private provider [e.g., private physician or health care provider, private Health Maintenance Organization (HMO), or private managed care provider]. This category also includes the private provider that has the primary responsibility for clinical outpatient

decision making for a TB patient, even though the TB control program or local/state health department may be periodically contacting the private provider to ensure proper TB case management.

IHS, Tribal Health Department or Tribal Corporation

Check if the primary responsibility for clinical outpatient decision making (*excluding* diagnostic work-up, contact investigations, anti-TB medications, and DOT) is the Indian Health Service (IHS) or an American Indian or Alaska Native Tribal Health Department or Tribal Healthcare Corporation.

Institutional/Correctional

Check if the primary responsibility for clinical outpatient decision making (*excluding* diagnostic work-up, contact investigations, anti-TB medications, and DOT) is an institution such as, a correctional facility or a long-term care facility (e.g., nursing home, assisted living facility).

Inpatient Care Only

Check if the patient did not receive any outpatient TB care. Such situations could include TB diagnosed at autopsy, patients who died prior to receiving outpatient TB care, and patients that received all of their TB care as an inpatient in a hospital.

Other

Check if the primary responsibility for clinical outpatient decision making (*excluding* diagnostic work-up, contact investigations, anti-TB medications, and DOT) is a provider that is not included in any of the other categories and is not "Unknown" (e.g., State TB Chest Hospital providing outpatient care, city/county/state owned hospitals that are not part of the health department providing outpatient care, private hospital providing outpatient care, Veterans Administration, federal program, military facility, or community-based organization (CBO)).

## Response to treatment

### Did sputum culture convert?

**If "Yes":**

Enter the date (month, day, year) **when the first consistently negative sputum culture was collected**. This should be done *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 one week after the last positive culture was obtained. There should be no positive cultures after this date. A complete date is required.

**If "No"**, enter reason for not documenting sputum culture conversion. Reasons include clinically improved, no follow-up sputum was obtained despite induction, no follow-up sputum collection attempted, died, patient lost, patient refused.

Enter NA if there were no positive sputum cultures or sputums were not done.

### Did CXR or CT improve?

Indicate if follow-up CXR or CT improved. Enter NA if extrapulmonary and/or CXR not performed. Please attach reports.

### Did symptoms improve?

Indicate if symptoms improved. Enter NA if patient was asymptomatic.

## Treatment weeks and doses

In reporting county:

Enter the number of directly observed treatment weeks (for patients on daily regimens a full DOT week is 5 or more observed doses in a 7 day week, with the exception of government holiday weeks where 4 doses in a 7 day week is acceptable). Enter the total weeks of treatment taken while in the reporting jurisdiction.

Enter the number of directly observed doses and the total doses taken while in the reporting jurisdiction.

Outside reporting county (for transfer cases):

For cases that transfer out of the reporting jurisdiction, please record the treatment DOT and total weeks while the patient was under treatment in the transfer county or state.

Enter the number of DOT doses and total doses taken while under treatment in the transfer jurisdiction.

**DOT**

Directly observed therapy (DOT) or supervised therapy involves the direct visual observation by a health care provider (e.g., public health nurse, outreach worker, nurse, nurse's aid) or other reliable person (e.g., homeless shelter worker) of a patient's ingestion of medication.

Fully directly observed

Check if the patient received full DOT. For patients on daily regimens a full DOT week is 5 or more observed doses in a 7 day week, with the exception of government holiday weeks where 4 doses in a 7 day week is acceptable. Also allowable for classification as full DOT is self-administered therapy for 1 vacation week during the continuation phase. Any self-administered therapy greater than 1 week must be added on to the end of the regimen in order for treatment to be considered fully directly observed.

Self-administered

Check if the patient did not receive any directly observed doses during their treatment regimen

Both directly observed and self-administered

Check if the patient received both directly observed and self-administered therapy (i.e. the requirements of full DOT as specified above were not met).

**Comments**

Enter any comments in the space provided.