

Tuberculosis Case Report Form Instructions

We use the tuberculosis (TB) case report form to collect surveillance data on TB suspects and cases. We report the data to CDC, and analyze it locally.

These instructions tell you how to fill out the report form. They aren't a substitute for expert clinical opinion or CDC guidelines on medical TB management. Please contact us with questions on TB diagnosis and case management.

I. Submitting the TB Case Report Form

A report should be made whenever:

1. A patient is started on multidrug therapy for TB
2. A patient has a positive nucleic acid amplification test (NAAT, MTD, Xpert MTB/RIF) or positive culture test for *M. tuberculosis* complex
3. A patient has a pathology report consistent with tuberculosis

When to submit:

You need to submit the case report form three times:

Initial Report:

Send within *one week* after you are notified of a suspect or confirmed case.

Enter the initial submit date in the "Report and Date" section (top right hand corner).

REPORT AND DATE (sent to State)	
Initial	___/___/___
Verification	___/___/___
Closure	___/___/___

Verification Update:

Send an update when TB disease status is determined - usually after cultures results are received or after two months treatment for clinical cases. Enter the verification submit date in the "Report and Date" section.

If the case is lab-confirmed at initial report, you do not need to send the form in twice. Send one copy of the form and enter the same date for the initial and verification date.

Closure Report:

Send a final update when the case is closed. Enter the closure date in the "Report and Date" section.

If the case is closed at the same time as the verification update (verified as NOT TB) you do not need to send the form twice. Send one copy of the form and enter the same date for the verification and closure date.

Submit to:

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

Mail: TB Control Program
Oregon Health Authority
800 NE Oregon Street, Suite 1105
Portland, OR 97232

Section 3: DEMOGRAPHICS

Sex

Enter the biological sex of the case.

Date of Birth

Enter the case's date of birth.

Race and Hispanic Ethnicity

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

Country of Birth

Select "US" if the case was born in the United States, or born abroad to a U.S. citizen parent (e.g., born on a military installation).

Select "US Territory" and enter the location if the case was born in a US territory, island area, or outlying area (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).

Select "Other" if the case was born outside the US or a US territory, and enter the patient's birth country.

Date of Entry to US

If the case was born outside the US, enter the month and year the case **first** arrived in the US. If you don't know the month, enter the year only.

Pediatric TB – *only fill out if the case is less than 15 years old*

Select "Yes" if the case lived outside the US for two or more months. Enter where the case lived.
Select "No" or "Unknown" as appropriate.

Enter the country of birth for each of the case's guardians.

Occupation

Select the case's primary occupation within the past 12 months. If the case had multiple occupations, choose the one the case performed the majority of the time.

Health Insurance

Indicate if the case has health insurance (Yes/No). If yes, list the plan name.

- Negative for TB
- Abnormal non-cavitary, non-miliary
- Abnormal, cavitary
- Abnormal, miliary
- Not done

NO abnormalities consistent with TB
 TB-associated abnormalities, but **not** cavitary or miliary findings
 TB-associated abnormalities, including cavitary findings
 TB-associated abnormalities, including miliary findings
 N/A

Note: Please attach copies of all initial CXRs and CTs.

Section 5: BACTERIOLOGY

BACTERIOLOGY						
Source of Specimen*	Date Collected	AFB Smear	NAAT/PCR	Culture/DNA Probe	Pathology Notes	Lab Name (If not OSPHL submit copies of labs)
_____	___/___/___	4+ 3+ 2+ 1+ Neg <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Pos Neg NA Pend <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Pos Neg Pend <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	_____	_____
_____	___/___/___	4+ 3+ 2+ 1+ Neg <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Pos Neg NA Pend <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Pos Neg Pend <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	_____	_____
_____	___/___/___	4+ 3+ 2+ 1+ Neg <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Pos Neg NA Pend <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Pos Neg Pend <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	_____	_____
_____	___/___/___	4+ 3+ 2+ 1+ Neg <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Pos Neg NA Pend <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Pos Neg Pend <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	_____	_____

*Please indicate results of diagnostic specimens (e.g. include the first positive AFB smear and first positive MTB culture)

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Enter the specimen source, date collected, lab results, and laboratory name for all specimens collected as part of the TB diagnostic evaluation. If done, indicate:

- AFB smear result
- NAAT/PCR/Xpert MTB/RIF assay result (from clinical specimens only)
- Culture/DNA probe result (from culture specimens only)
- Brief notes on any pathology (e.g., lymph node biopsy)

Example:

BACTERIOLOGY						
Source of Specimen*	Date Collected	AFB Smear	NAAT/PCR	Culture/DNA Probe	Pathology Notes	Lab Name (If not OSPHL submit copies of labs)
Sputum	1/10/13	4+ 3+ 2+ 1+ Neg <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Pos Neg NA Pend <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Pos Neg Pend <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	_____	Legacy
Lymph node	1/7/13	4+ 3+ 2+ 1+ Neg <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	Pos Neg NA Pend <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	Pos Neg Pend <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	necrotizing granuloma	Legacy
Sputum	1/11/13	4+ 3+ 2+ 1+ Neg <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Pos Neg NA Pend <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	Pos Neg Pend <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	_____	Legacy

Since all testing in the example above took place at Legacy, you would submit all initial lab reports to us:

- 1/10/13 sputum smear, NAAT, and culture
- 1/7/13 lymph node smear and culture AND pathology report
- 1/11/13 sputum smear and culture

Section 6: TB RISKS

TB HISTORY

TB RISKS					
TB HISTORY					
Previous diagnosis of TB disease?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unk	If yes, year _____	Was treatment completed? _____ If yes, where _____
Previous treatment for LTBI?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unk	If yes, year _____	Was treatment completed? _____ If yes, where _____

Previous diagnosis of TB Disease



Check "Yes" if the case had TB disease (not LTBI) in the past. If yes, enter the year of diagnosis, if TB treatment was completed, and where.

Previous treatment for LTBI

Check "Yes" if the case was treated for LTBI in the past. If yes, provide year LTBI treatment was started. Indicate if the treatment was completed and where.

CONGREGATE SETTINGS

CONGREGATE SETTINGS			
Homeless in the past year?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unk _____
History of homelessness?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unk Describe _____
Resident of correctional facility at diagnosis?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unk If yes, where _____
History of incarceration?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unk If yes, when and where _____
Resident of longterm care facility at diagnosis?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unk If yes, where _____

Homeless in the past year

Indicate if the case was homeless in the past 12 months.

There are many definitions for homeless. A homeless person may be an individual who has

1. No fixed, regular, and adequate nighttime residence

and

2. 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). Persons in unstable housing situations (e.g., alternating between multiple residences for short stays of uncertain duration) may also be considered homeless.

History of homelessness

Check "Yes" if the case has a history of homelessness. Give details (when and where) if known.

Resident of a correctional facility at diagnosis

Check "Yes" if the case was evaluated for TB while in a correctional facility (federal, state, local, or juvenile detention center, etc.). Provide the facility name.

History of incarceration

Check "Yes" if the case has a history of incarceration. Specify details (when and where) if known.

Resident of long-term care facility

Check "Yes" if the case was evaluated for TB while in a long-term care facility (nursing home, assisted living, residential mental health or alcohol/drug treatment facility, etc.). Provide the facility name.

SOCIAL FACTORS

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Excess alcohol use in the past year? Yes No Unk
 IV drug use in the past year? Yes No Unk
 Non-IV drug use in the past year? Yes No Unk
 Currently smoking* tobacco? Yes No Unk Tobacco type (cigarette, cigar, pipe) _____ Amount per day _____ Start year _____
 If not currently smoking, past tobacco smoking*? Yes No Unk Tobacco type _____ Amount per day _____ Start year _____ Quit year _____
 Travel outside the US longer than 30 days? Yes No Unk If yes, when and where _____

* >100 cigarettes or equivalent amount in lifetime

Excess alcohol*, IV drug use, and non-IV drug use

Indicate if the case had excess alcohol use, IV drug use, and/or non-IV drug use in the past year. If information changes during the course of TB treatment, please update this question.

*There is no standard definition of excess alcohol use. Reliable indicators include:

- Participation in self-help programs (e.g., Alcoholics Anonymous) or alcohol treatment programs
- Medical record documentation of excess alcohol use or hospitalization for alcohol-related medical conditions (e.g., delirium tremens [DTs], pancreatitis, cirrhosis)

The National Household Survey on Drug Abuse defines heavy alcohol use as “five or more drinks on the same occasion on each of 5 or more days in the past 30 days”.

A standard drink in the United States is equal to 13.7 grams (0.6 ounces) of pure alcohol or

- 12 ounces of beer
- 8 ounces of malt liquor
- 5 ounces of wine
- 1.5 ounces or a “shot” of 80-proof distilled spirits or liquor (e.g., gin, rum, vodka, or whiskey)

Currently smoking tobacco

Indicate whether the case currently uses tobacco. List the type (cigarettes, cigars, pipe), amount per day, and estimated start year.

If not currently smoking, past tobacco smoking

If the case does not smoke now, indicate if the patient ever smoked tobacco. List the type (cigarettes, cigars, pipe), amount per day, and estimated start and quit year.

Travel outside the US longer than 30 days

If the case traveled outside the US for longer than 30 consecutive days, enter when and where.

MEDICAL RISKS

MEDICAL RISKS
 HIV at diagnosis ___/___/___ Pending
 Pos
 Neg
 Not done If not done, why? _____

Medical and Other Risk Factors (select all that apply)
 Diabetes Post organ transplant
 Immunosuppressive therapy Weight <90% of ideal body weight
 TNF α antagonist therapy Cancer/malignancy
 End stage renal disease Other _____

Previous contact to an infectious TB patient? Yes No Unk
 If yes, year _____ MDR? _____ Name of case _____

HIV at diagnosis

Enter the date and result of the case’s HIV test. All cases should receive HIV counseling and testing at TB diagnosis. A recent test result (within the last year) may be used. Update and resubmit as needed.

Medical and Other Risk Factors

Indicate if the case has any of the following conditions:

- Diabetes mellitus (Type I or Type II) at diagnosis
- Immunosuppressive therapy, such as high dose corticosteroids (e.g., prednisone)

- TNF α antagonist therapy for rheumatoid arthritis or other autoimmune diseases. Drugs may include infliximab (Remicade), etanercept (Enbrel), adalimumab (Humira), and golimumab (Simponi).
- End stage renal disease at diagnosis
- Post organ transplant – history of solid organ transplantation (e.g., renal, cardiac)
- Weight less than 90% of ideal body weight (case is undernourished)
- Cancer/malignancy – specifically immunosuppressive malignancies (e.g., leukemia, Hodgkin’s lymphoma, carcinoma of the head or neck)
- Other – TB risk factor not included in the above choices (e.g., intestinal bypass surgery for obesity, gastrectomy, jejunioileal bypass, chronic malabsorption syndromes, silicosis)
- Previous contact to an infectious TB patient
 - Check yes if the case 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).

Section 7: TREATMENT

TREATMENT				
DATE THERAPY STARTED ____/____/____				
Drug	Dosage	Frequency	Is therapy directly observed? <input type="checkbox"/> Yes <input type="checkbox"/> No	
<input type="checkbox"/> Isoniazid	_____	_____	If no, why _____	
<input type="checkbox"/> Rifampin	_____	_____	Pt height _____	Pt weight _____
<input type="checkbox"/> Pyrazinamide	_____	_____	<input type="checkbox"/> History of hepatitis or other liver dysfunction	
<input type="checkbox"/> Ethambutol	_____	_____	If yes, provide details:	
<input type="checkbox"/> Rifater	_____	_____		
<input type="checkbox"/> _____	_____	_____		
<input type="checkbox"/> _____	_____	_____		
<input type="checkbox"/> _____	_____	_____		

Date therapy started

Enter the date (month, day, year) the case started multi-drug therapy for treatment of TB disease.

Regimen

Indicate the initial drug regimen prescribed for TB treatment. List the dosage and frequency of each drug.

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 state the reason in the space provided.

Height, weight, history of hepatitis or liver dysfunction

Indicate the case’s height, weight, and history of hepatitis or liver dysfunction. List any relevant details.

Section 8: VERIFICATION

VERIFICATION (Please also update bacteriology section and HIV status if no longer pending)			
<input type="checkbox"/> Laboratory confirmed	<input type="checkbox"/> Clinical case	<input type="checkbox"/> Provider treating empirically	<input type="checkbox"/> Not TB: Other diagnosis _____

Indicate the case's verification status. For non-laboratory confirmed cases, obtain status from treating physician.

Laboratory confirmed

Select this box if the case has a culture or NAAT result that is positive for M tuberculosis complex.

Clinical case

Select this box if the case is culture/NAAT negative, but the clinical picture (including positive TST or QFT, complete diagnostic evaluation) indicates TB, and case improves on treatment.

Provider treating empirically

Select this box if the case is not laboratory confirmed or clinical, 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.

Section 9: CLOSURE

CLOSURE						
REASON	<input type="checkbox"/> Not TB	<input type="checkbox"/> Completed therapy	<input type="checkbox"/> Lost	<input type="checkbox"/> Refused/noncompliant	<input type="checkbox"/> Died: Cause(s) of death _____	<input type="checkbox"/> Adverse treatment event

Select the reason for closure of the TB case from the choices below:

Not TB: The completed diagnostic evaluation indicates the case does not have TB.

Completed therapy: Treatment for TB disease has been completed.

Lost: The case cannot be located prior to the completion of treatment (e.g., the case moved and no locating information is available, or the case can't be located based on available information).

Refused/non-compliant: The case refused to complete therapy (e.g., stopped taking drugs).

Died: The case was alive at diagnosis, but died before therapy was completed.

Adverse treatment event: Therapy was permanently stopped due to an adverse treatment event from TB medications (e.g., life threatening drug reaction).

If the case started treatment, fill out the following sections.

TREATMENT STOP DATE Date stopped ____/____/____ If tx >12 months, why? _____ _____	Type of outpatient healthcare provider w/ primary responsibility for clinical decision making <input type="checkbox"/> LHD <input type="checkbox"/> Inpatient care only <input type="checkbox"/> Private <input type="checkbox"/> Indian Health Services <input type="checkbox"/> Institutional/correctional <input type="checkbox"/> Other _____	RESPONSE TO TREATMENT Did sputum culture convert? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA Enter date of conversion ____/____/____ If no, why not _____ Did CXR or CT improve? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA Did symptoms improve? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
TREATMENT DOSES In reporting LHD: DOT doses Non-DOT doses <i>Outside reporting LHD (for transfer cases):</i> Daily* _____ _____ _____ # weeks DOT _____ # doses DOT Bi-weekly _____ _____ _____ # weeks _____ # doses Other schedule _____ Describe dose schedule (ie, 3x/wk) : _____ <small>*Daily DOT includes weekday doses and excludes weekends and federal holidays</small>		DOT <input type="checkbox"/> Fully directly observed <input type="checkbox"/> Self administered <input type="checkbox"/> Both directly observed and self administered If not full DOT, why? _____

COMMENTS

Treatment stop date

Enter the date the case stopped taking therapy for TB disease or suspected TB disease.

If treatment greater than 12 months, why?

Possible reasons for extended treatment include rifampin resistance, significant adverse drug reaction, non-adherence, failure to convert sputum culture in 2 months, TB meningitis, severe liver disease, etc.

Type of outpatient healthcare provider

Choose the provider(s) with primary responsibility for clinical outpatient decision making (*excluding* diagnostic work-up, contact investigations, anti-TB medications, and DOT).

Response to treatment

Did sputum culture convert? (*Only answer for cases with at least one positive sputum culture*)

If “Yes”, enter the date **when the first consistently negative sputum culture was collected** (no positive cultures collected after this date). It should be ≥ 7 days after the last positive culture collection. If “No”, enter reason for non-conversion (e.g., case died, lost, or refused; case clinically improved, no follow-up sputum collection attempted, patient unable to produce sputum).

Enter NA if there were no initial 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 doses

In reporting LHD

Enter the number of directly observed doses taken while on daily, biweekly, or alternative schedule DOT. If the case is on full DOT, do not list doses taken on weekends or federal holidays as non-DOT doses. Non-DOT doses only need to be entered for cases on self-administered therapy.

Outside reporting LHD (for transfer cases)

For transfer cases treated outside the reporting LHD, please record weeks of DOT and total weeks of treatment (if not all DOT) taken outside the reporting LHD. Enter number of DOT doses and total doses (if available).

DOT

Fully directly observed

Check if the case 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 case did not receive any directly observed doses during treatment.

Both directly observed and self-administered

Check if the case 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.