

OREGON HEALTH AUTHORITY

Tuberculosis Program

TB Case Report & Data Entry Manual

Preface

Beginning January 1, 2019, LPHAs must submit all TB case reports electronically via Orpheus (The Oregon Public Health Epidemiologists' User System). After this date, the TB Program, Oregon Health Authority (TB-OHA) will no longer accept paper reports.

Suspected or confirmed TB cases must be reported to TB-OHA via Orpheus within 5 business days after the report is received by the LPHA. TB-OHA uses the TB module in Orpheus to collect data on TB cases and contacts. This data is reported to the CDC and analyzed internally for statewide TB control and prevention activities.

These instructions describe using Orpheus to report TB cases and give detailed instructions on how to open a case and complete data entry. More detail about data definitions are available on the CDC website at https://www.cdc.gov/tb/programs/rvct/default.htm. These instructions are not a substitute for expert clinical opinion or CDC guidelines on medical TB management. Please contact TB-OHA with questions on TB diagnosis and case management.

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The TB Case Report: Overview

Beginning January 1, 2019, all TB case reporting will be completed in Orpheus. Faxed or e-mailed paper reports will no longer be accepted after this date.

When to report

Make a report in Orpheus within 5 business days whenever:

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

When to update

The case record should be updated when the case is confirmed to have TB disease or TB is ruled out. If the case did not have a positive lab but was started on treatment, a TB diagnosis is typically confirmed if the patient improves after two months of treatment. Update and close the record when treatment is complete.

How to report

Report confirmed cases of TB by opening a TB case in Orpheus and completing data entry. If an LPHA receives a lab confirmation of TB disease or a report from a provider indicating TB treatment is being started, the LPHA should open a case in Orpheus and complete patient demographic information and the following tabs in their entirety according to the information available at the time of report:

- 1. Admin
- 2. Labs
- 3. Clinical
- 4. Treatment
- 5. Risks
- 6. Follow-up

Contact data entry is covered in <u>Section 4</u> of this guide.

If an LPHA receives a confirmed or presumptive report from a provider or lab

The LPHA should attach to the Docs tab copies of the radiology report, pathology reports, and/or lab reports generated at any lab other than the Oregon State Public Health Lab. If the above documents are not available at time of report, attach them immediately upon receipt.

If the case is laboratory confirmed at time of report (i.e., there a positive NAAT or culture

lab result), enter verification status "Confirmed." If the case is not confirmed at time of initial report, enter status as follows:

- If the case has started treatment but is not a confirmed case, enter "Unconfirmed, started Tx";
- If the case is neither confirmed nor started on treatment, status can be entered as "Presumptive" at the LPHA's discretion. This status is optional and for LPHA tracking purposes only. Data collection and entry for Presumptive cases is not required.

If TB-OHA receives a confirmed lab report via ELR or fax

The TB Epidemiologist will open a case in Orpheus and enter the verification status, lab results, and demographic information from the lab report.

The TB Epidemiologist will notify via e-mail the LPHA responsible for the case.

The LPHA nurse case manager will complete demographic information and the following tabs in their entirety, as applicable, within five business days of report:

- Admin
- Labs
- Clinical

- Treatment
- Risks
- Follow-up

Case confirmation

Once a TB case is confirmed (whether confirmed at time of report or after confirmation by subsequent lab report or provider verification), the TB Epidemiologist assigns a case number and count date. The Epidemiologist follows-up with the LPHA to complete any information missing in the case record.

LPHA staff attaches to the Docs tab supporting documentation (e.g., radiology reports, case notes, or lab reports originating from labs other than OSPHL) as deemed relevant by the TB nurse case manager and/or TB-OHA staff;

- The TB Epidemiologist processes ELRs, edits ELRs, and attaches them to the case Labs tab unless another arrangement has been made with the LPHA in advance;
- LPHA staff documents completion of treatment in Orpheus.

If TB is ruled out

If an unconfirmed case on treatment or a presumptive case is ruled out as TB, the LPHA or TB-OHA changes the case status to "No case" and creates a note in the Orpheus case record explaining and documenting the change of status.

Data Quality Assurance (QA)

TB-OHA conducts case QA review of Orpheus case and contact investigation records to ensure completeness and accuracy. Based on QA review, TB-OHA may request data completion by an LPHA to meet deadlines for CDC reporting and local surveillance analysis.

Case Closure

The LPHA enters case closure information on the Treatment tab including date treatment stopped, reason treatment was stopped, and DOT status. The TB Epidemiologist will calculate and enter weeks of DOT.



Case reporting in Orpheus

Case reporting in Orpheus requires completion of the following information and tabs

- ✓ Demographic information
- ✓ Admin Tab
- ✓ Labs Tab
- ✓ Clinical Tab
- ✓ Treatment Tab
- ✓ Risks Tab
- ✓ Follow-up Tab

Case creation and data entry are outlined in detail in the following sections.

Creating the case report

✓ On the Orpheus home page, click on New Case Investigation to create a new case record. A pop-up window will appear. Complete the following fields:

Disease	Select TB from the dropdown.	Disease
Case Status	Enter case confirmation status. See page 5 for status assignment guidelines. Confirmed Unconfirmed, started tx Presumptive	Case Status 🔻
Name	Enter first and last name.	Last Name First Name Middle
Date of Birth	Enter date of birth.	DOB
Sex	Enter current sex.	Sex OF OM
Institution of Residence	Enter institution of residence at diagnosis if applicable (correctional facility, long-term care facility or shelter).	Institution of residence
Address	Enter residence address. This will usually be the case's home address, whether permanent or temporary.	Patient's Address Zip Code City, State County
	County will auto-populate based on Zip co	de.

Click "Create Case".

Orpheus will search name and DOB for matching person records. If a list of potential matches appears, check the list for an exact match. If a match appears, click "create case" (1) next to the name to create the new case. If no match appears, click "Ignore Matches – Create Person and Case" (2). If no potential matches are found, the new case window will appear without displaying the potential matches.



Demographic Information

✓ Enter demographic information on the central panel that appears on every page of the TB module. Every field above the "STATE USE ONLY" area is required. Most fields are filled by choosing from the drop-down options. Choose from the drop-down options only. Do not overwrite drop-down options with free text. Do not enter any information in the "STATE USE ONLY" fields.

Auto-populated based on information entered in the New Case Investigation window. Pediatric case If the case is less than 15 years old, a pediatric information box will appear. If the pediatric case lived outside the U.S. for two months or more, select "yes" and indicate where the case lived. Enter birth country for guardian(s).





Deceased

Enter "No" if case was alive at diagnosis. If the case dies during treatment, update this field with date and cause of death.

Current Sex

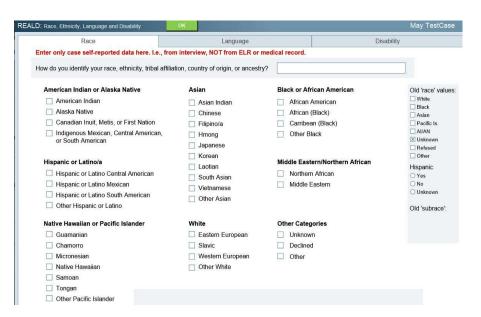
Sex auto-populates as "Current Sex." Sex at birth and gender are optional fields.

Pregnancy

If the case is a female, a Pregnancy box will appear. Enter yes, no, or unknown. If yes, enter estimated due date if known.

Race (REALD)

Enter self-identified race as free text and/or choose from the check box options. Be sure to ask the case to self-identify race. Do not guess or assume.



Language (REALD)

Answer language questions displayed below. Of self-reported language is not available, use the box on the right to enter observed preferred language.

Race	Language	Disability
Do you speak a language other than English at ho What language do you speak at home?	me? If so:	Old language field - use this when the source of info is not self-reported
In which language would you feel most comfortable How well do you speak English?	e speaking with your doctor or nurse?	
Very Well Not Well Unknown Well Not at all Declined		
Do you need an interpreter for us to communicate	with you?	
○ Yes ○ No ○ Unknown ○ Declined		
Are you deaf or do you have serious difficulty hear	ing?	
○ Yes ○ No ○ Unknown ○ Declined		

Disability (REALD)

Answer disability questions displayed below.

Race	Language	Disability
Your answers to the questions below help us find hea	alth and service differences among people with di	sabilities or limitations. Your answers are confidentia
Questions for all ages:	Questions	for ages 5 and up:
Are you blind or do you have serious difficeven when wearing glasses? Yes No Unknown Decline	○ Yes ○	re serious difficulty walking or climbing stairs? No Unknown Declined
Does a physical, mental, or emotional con limit your activities in any way? Yes No Unknown Decline	dition Yes O	re difficulty dressing or bathing? No Ounknown Opecimed
	do you hav a. Concent	f a physical, mental, or emotional condition, e serious difficulty: rating, remembering or making decisions? No Unknown Declined
	b. Doing e shopping?	rrands alone such as visiting a doctor's office or

Country of Birth and Residency

Select country of birth from the drop-down options. Do not enter free text. Select "United States" if the case was eligible for U.S. Citizenship at birth. If the case is known to be a refugee, click the "Refugee" box. The Residency box is used to record the country of usual residence. "Usual residence" means the country



where the case lived most of the time in the year prior to diagnosis. *This question is not intended nor used as a proxy for legal residence in the U.S.*

Worksite and Occupation

Enter Occupation category from the dropdown options. Enter the case's <u>primary</u> occupation within the past 12 months. If the case had multiple occupations, choose the one the case performed the majority of the time. Enter a brief description of the worksite or job description as free text.

Address and Phone number

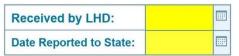
Address and phone number auto-populate from the Case Creation Window if entered at case creation. Check and confirm address and LPHA jurisdiction. If jurisdiction appears incorrect, contact TB-OHA. If address and phone number are not entered at case creation, enter these items.

TAB: Administrative

✓ Enter report dates, case epidemiologists, and treating provider information on the Admin tab.

Report Dates

Enter the date the initial report is received by the LPHA. Enter the date the report is made to the State.



Case Epis

By default, the Epi is automatically assigned to the person creating the case. The State Epi is always the State TB



Epidemiologist (currently Kiley Ariail). The Local Epi is the nurse case manager responsible for the case. Make sure this information is correct in the EPIs dropdown boxes.

Treating Provider

Specify the treating provider, if known. Clicking the "+ Provider" button allows you to search for and select the provider name.

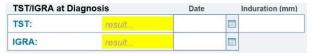


TAB: Lab Summary

✓ Enter preliminary lab results. All fields are required. Spaces are provided for TST and/or IGRA, Radiology, Sputum smear and culture, NAAT test, and tests of other tissue and body fluids. Do not overwrite any drop-down choices. The choices are set to conform to CDC reporting requirements.

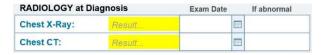
TST/IGRA at Diagnosis

TST: Enter the date placed and result of the TST placed during the current



diagnostic evaluation. Previous positive test results may be entered if the result is documented. Include the reading in millimeters. If not placed, mark "Not Done".

IGRA (Quantiferon or Tspot): Enter the date drawn and result of the IGRA drawn during the current diagnostic



evaluation. If not drawn, mark "Not Done".

Chest imaging at Diagnosis

Enter the chest x-ray and/or chest CT date in the spaces provided.

Enter the imaging result:

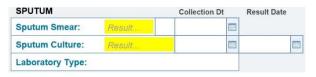
- Normal: NO abnormalities consistent with TB
- Abnormal: TB-associated abnormalities
- Unknown: Imagine done, result unknown
- Not done

If the result is abnormal, enter the descriptor:

- Cavitary: Cavitary findings
- Miliary: Miliary findings
- Both: Both cavitary and military findings
- Neither: abnormal findings, neither cavitary nor military

Sputum Bacteriology

Enter results of sputum examinations collected as part of the diagnostic evaluation or shortly



thereafter. Do not record results of specimens collected after case has been on treatment for more than 2 weeks.

Sputum Smear:

- Enter "positive" if the result of **any** sputum smear is positive for acid-fast bacilli (AFB). If several sputum samples were collected and the result of one or more smear tests is positive, enter the date and result for the first sputum specimen with a positive result.
- Enter "negative" if the results of **all** sputum samples examined are negative. If several sputum samples were collected and all results are negative, enter the date the first negative sputum sample was collected.
- Enter "not done" if it is known that a sputum smear was not done.
- Enter "unknown" if it is not known whether a sputum smear was done OR if results are not known for a reason other than pending results (e.g., result was lost or specimen was contaminated and no other specimen can be obtained).
- If an initial sputum specimen was collected and results are unknown, but later become known, update the results.

Sputum Culture:

- Enter "positive" if **any** sputum culture is positive for *M. tuberculosis* complex. If several sputum samples were cultured and the result of one or more cultures is positive for *M. tuberculosis* complex, enter the date and result for the first sputum culture with a positive result.
- Enter "negative" if the results of **all** sputum cultures are negative. If several sputum samples were collected and all results are negative, enter the date the first negative sputum culture was collected.
- Enter "not done" if it is known that a sputum culture was not done.
- Enter "unknown" if it is not known whether a sputum culture was done OR if results are not known for a reason other than pending results (e.g., result was lost or specimen was contaminated and no other specimen can be obtained).
- If an initial sputum specimen was collected and results are unknown, but later become known, update the results.

Collection Dates:

- Enter the date the **first** specimen with a positive smear or culture result was collected. If several specimens were tested and one or more were positive, enter the date the **first** specimen with a positive result was collected.
- If no positive result was obtained, enter the date the **first** specimen with a negative result was collected. If several specimens were tested and all were negative for M. tuberculosis, enter the date the **first** specimen with a negative result was collected.

Result Date:

- Enter the date the **first** positive culture result was reported. This date can be found on the laboratory report as the report date or release date.
- If more than one specimen was tested, and all are negative, enter the date the **first** negative result was reported.

Laboratory Type: Select the option that best describes the reporting laboratory type

- Public Health Lab: Most often Oregon State Public Health Lab. Any laboratory associated with a state or local health department
- Commercial Lab: Any lab that charges a fee for each specimen processed or test performed (e.g., Quest, Interpath)
- Other: Any other laboratory that is not considered a public health lab or commercial lab. Most often, hospital labs (e.g., Providence, Legacy, OHSU, Kaiser, National Jewish). Also labs associated with federal public health agencies (e.g., CDC, Indian Health Service, or Bureau of Prisons).

Nucleic Acid Amplification Testing (NAAT)

NAAT testing may be done on sputum or other primary clinical



specimens. NAAT testing is not done on culture isolates. NAAT results may reference GeneXpert, PCR, or RT-PCR. If a NAAT is performed on more than one primary clinical specimen, enter the results of the first positive test.

Do not overwrite any drop-down choices. The choices are set to conform to CDC reporting requirements.

Result:

- Enter "positive" if **any** NAAT result was positive for M. tuberculosis complex.
 - Any positive result supersedes all other test results (e.g., 1 positive and 2 negatives = positive; 1 indeterminate and 1 negative and 1 positive = positive).
- Enter "negative" if **no** NAAT result was positive for M. tuberculosis complex and at least one result was negative.
 - A negative result supersedes an indeterminate (e.g., 1 negative and 1 indeterminate = negative).
- Enter "indeterminate" if **all** NAAT results were indeterminate (e.g., inconclusive or inhibited).
- Enter "not done" if NAAT was **not** performed.
- Enter "unknown" if it is not known whether a NAAT was performed or if NAAT results are not known for a reason other than pending results.

Collection Date:

- Enter the date the first specimen with a positive result was collected. If several specimens were tested and one or more were positive for M. tuberculosis, enter the date the first specimen with a positive result was collected.
- If no positive result was obtained, enter the date the first specimen with a negative result was collected. If several specimens were tested and all were negative for M. tuberculosis, enter the date the first specimen with a negative result was collected.

Result Date:

• Enter the date the first positive NAAT result was reported. This date can be found on the laboratory report as the report date or release date.

• If more than one specimen was tested, and all are negative or indeterminate, enter the date the first negative or indeterminate result was reported.

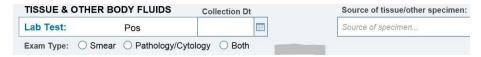
Specimen Source:

• Select specimen source from the dropdown options. Do not overwrite options. If you need assistance selecting specimen source, contact the TB Epidemiologist.

Laboratory type:

• See options above in Sputum Bacteriology.

Smear/Pathology /Cytology of Tissue & Other Body Fluids This section is for recording results of a smear, pathology, or cytology of tissue and/or other body fluids not including sputum. Examples of other tissue/fluid types include bronchial cells and fluid, tracheal aspirate, lymph node, lung tissue or fluid, pleural fluid, cerebral spinal fluid, etc. The specimen entered for smear, pathology, or cytology should have been obtained during a diagnostic workup or shortly thereafter. Do not record specimens collected after the patient has received treatment for more than 2 weeks.



Do not overwrite any drop-down choices. The choices are set to conform to CDC reporting requirements.

Result:

- Enter "positive" if any tissue or body fluid other than sputum tests positive by smear examination or shows granulomas, granulomatous inflammation, or other pathologic or histologic findings consistent with TB disease during a pathologic/cytologic examination.
 - o If more than one specimen is examined, any positive result supersedes a negative result.
- Enter 'negative' if all specimens of tissue or body fluid other than sputum tested negative by smear examination or showed no evidence of granulomas, granulomatous inflammation, or other pathologic or histologic findings consistent with TB disease during a pathologic/cytologic examination.
- Enter "not done" if no pathologic/cytologic examinations are done.
- Enter "unknown" if it is not known whether tissues or fluid other than sputum were examined or results are not known for a reason

other than pending results (e.g., result was lost or specimen was contaminated and no other specimen can be obtained).

Collection date:

- Enter the date the first specimen with a positive result was collected. If several specimens were tested and one or more were positive, enter the date the first specimen with a positive result was collected.
- Enter the date the first specimen with a negative result was collected. If several specimens were tested and all were negative, enter the date the first specimen with a negative result was collected.

Specimen Source:

• Select specimen source from the dropdown options. Do not overwrite options. If you need assistance selecting specimen source, contact the TB Epidemiologist.

Exam Type:

- Select the type of exam that corresponds to the result selected above.
- o Smear
- Pathology/Cytology
- o Both
- ✓ Any positive result supersedes a negative result in reporting TB diagnostic criteria. If the results are discrepant (e.g., smear negative, pathology positive) then Type of Exam should correspond to the positive result. If both smear and pathology are positive, "both" should be checked under Exam Type. Likewise, if both smear and pathology are negative, "both" should be checked under Exam Type.

Culture of Tissue & Other Body Fluids "Tissue and Other Body Fluids" does not include sputum. Examples of other tissue/fluid types include bronchial cells and fluid, tracheal aspirate, lymph node, lung tissue or fluid, pleural fluid, cerebral spinal fluid, etc. The specimen entered for culture should have been obtained during a diagnostic workup or shortly thereafter. Do not record specimens collected after the patient has received treatment for more than 2 weeks.



Do not overwrite any drop-down choices. The choices are set to conform to CDC reporting requirements.

Result:

- Enter "positive" if **any** tissue or body fluid culture other than sputum is positive for *M. tuberculosis* complex. If an initial specimen was collected and results are unknown, but later become known, update the results.
 - o If more than one specimen is cultured, any positive result supersedes a negative result.
- Enter 'negative' if **all** tissue or body fluid cultures other than sputum are negative for *M. tuberculosis* complex.
- Enter "not done" if it is known that no tissue or fluid cultures other than sputum were done.
- Enter "unknown" if it is not known whether tissue or fluid cultures other than sputum were performed or results are not known for a reason other than pending results (e.g., result was lost or specimen was contaminated and no other specimen can be obtained).
 - o If an initial specimen was collected and results are unknown, but results later become known, update the results.

Collection date:

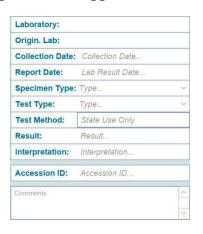
- Enter the date the first specimen with a positive result was collected. If several specimens were cultured and one or more were positive for *M. tuberculosis* complex, enter the date the first specimen with a positive culture result was collected.
- If no positive result was obtained, enter the date the first specimen with a negative result was collected. If several specimens were tested and all were negative, enter the date the first specimen with a negative result was collected.

Specimen Source:

- Select specimen source from the dropdown options. Do not overwrite options. If you need assistance selecting specimen source, contact the TB Epidemiologist.
- ✓ The notes box can be used to record any additional detail on tests, tissue specimens, or results.

TAB: Labs

- ✓ This is the tab where lab reports are displayed. Completion of the labs tab <u>is not required</u> to report a case.
- ✓ Reports received and processed via ELR will be displayed. Manual addition of reports received via fax or other method can also be uploaded to display here. Processing of ELRs is not covered in this manual.
- ✓ To manually add a lab report received via fax or other method
 - Click ** Specimen . A window with fields for lab report details appears.
 - Fill in the laboratory performing the test, the specimen collection date and the report dates.
 Choose Specimen Type from the dropdown.
 Overwrite dropdown choices as needed. Fill in Test Type, Result, and Interpretation.

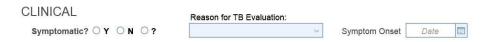


TAB: Clinical

✓ Enter clinical information. All fields are required.

Symptomatic

Indicate whether the case displayed symptoms at initial evaluation. If symptomatic, enter date of symptom onset if known.



Reason for TB Evaluation

Enter reason for TB evaluation from the dropdown choices. Do not overwrite dropdown choices.

- TB Symptoms: Case sought medical care for signs and symptoms consistent with TB (e.g., prolonged persistent cough, fever, lymphadenopathy, night sweats, weight loss).
- Contact Investigation: Case was evaluated as a result of contact investigation.
- Targeted testing: Case was evaluated after a positive TST or IGRA administered specifically because the case was considered high risk for TB (e.g., persons from area of the world with high risk for TB) or as a part of a testing program focused on specific groups at high risk for TB. Do not select if another reason (e.g., contact investigation, immigration medical exam, etc.) is more appropriate.
- Employment/Admin screening: Case was evaluated for employment. Refers to an administrative requirement rather than testing a group considered at high risk.
- Health Care Worker screening: Case was evaluated after a positive TST or IGRA administered for employment at a health care facility. Includes paid and unpaid workers. For health care workers being evaluated for TB disease, this choice supersedes targeted testing and employment/administrative screening. Other situations (e.g., TB symptoms, contact investigation) supersede health care worker.
- Immigration: Case was evaluated as an immigrant or refugee (B-waiver) on entry to the U.S. or as a status adjuster.
- Incidental Abnormal CXR/CT or Incidental Abnormal lab result: Case was identified as a result of a clinical evaluation for something other than TB (e.g., bronchoscopy or autopsy). Specimens were collected and tested for diagnostic completeness. TB was not expected.

- Unknown: Reason for evaluating the case was not known.
- Other: Enter reason in pop-up box.

Clinical Questions

Enter answers to clinical questions by clicking Ask Clinical Questions and answering the questions in the pop-up boxes. Mark yes, no, or unknown for the following symptoms:

CLINICAL QUESTIONS

- Cough enter how long the patient has been coughing
- Fever
- Night sweats
- Hemoptysis (bloody sputum)
- Weight loss enter amount of weight lost
- If the case had a symptom not listed (e.g. lymphadenopathy, chest pain, fatigue), enter under "other clinical symptoms".

Site(s) of Disease

Indicate site(s) of disease by checking the most appropriate option. If site of disease is not listed, choose the site from the dropdown choices in the Other box. Do not overwrite these choices.

Ask Clinical Questions

Contact the TB Epidemiologist for help with choosing the site if needed.

HIV Status at Diagnosis

Enter HIV status at diagnosis. All cases must be tested for HIV. An undocumented report of



HIV status is NOT acceptable. If the case is HIV positive, contact the TB Epidemiologist.

TAB: Treatment

Treatment Start Date	Enter date patient started multi-drug therapy.	Date Started
Deceased at Diagnosis	Select the radio button indicating whether the patient was deceased at time of diagnosis.	Deceased at TB Diagnosis O Y O N
Height & Weight	Enter the patient's height and weight at time of diagnosis. Check <90% Ideal Body Weight if appropriate.	Height Weight <a> < 90% Ideal Body Weight
Expected Length of Treatment	Enter the expected length of treatment if known. Use free text.	Expected Tx Length

✓ <u>Date stopped</u>, <u>closure</u>, <u>treatment extension</u>, <u>DOT</u>, <u>DOT weeks</u>, <u>and Provider(s)</u> will be entered when the case completes treatment.

Initial Drug Regimen

These fields are for initial drug treatment/initiation phase regimen only. Enter only initial/initiation phase regimen.



Do not change these fields when the drug regimen changes to continuation phase or if treatment changes for any other reason.

The RIPE+B6 regimen is auto-populated in the drop-down boxes. Enter the dosage as numbers only. Enter the dose frequency.

If the case is taking an alternative initial regimen, add a drug to the regimen by clicking ** Treatment*. An additional drop-down will appear. Choose the drug from the dropdown choices. Do not overwrite dropdown choices.

Remove drugs from the initial regimen as needed by clicking the \boldsymbol{x} at the end of the drug row

TAB: Risks

Enter answers to <u>risk questions</u> by clicking O Ask Risk Questions and answering the questions in the pop-up boxes. Guidance for answering each question is included on the question interface.

TAB: Follow-Up

✓ Enter answers to <u>follow-up questions</u> by clicking and answering the questions in the pop-up boxes.

Immigration	ì
Status	

TB-OHA does not collect or report immigration status information. If a case was born outside of the United States, Immigration Status at Entry to U.S. and

Immigration - At Entry to US
Immigration - Current

Question

Immigration Status Current should be entered as "Unknown."

Immigration Date Enter date of entry to US if known. Enter Date of Entry to US month and year in the format MM/YYYY. If month is unknown but year is known, enter 99/YYYY. If both month and year are unknown, enter 99/9999.

Health Insurance

Indicate if the case has health insurance. If yes, enter plan name in free text.

Health Plan
Health insurance



Closing a Case in Orpheus

When treatment is complete, close the case by completing information in the following tabs:

- ✓ Treatment
- ✓ Central Static Pane
- ✓ Admin

CLOSURE TAB: Treatment

Treatment Stop Date

Enter the date the patient stopped treatment. This is the date on which the patient last ingested medication.

date on which the patient last ingested medication for TB disease or suspected TB.

Closure Reason

Enter <u>Closure reason</u>. Select <u>Closure</u> closure reason from the dropdown choices. Do not overwrite choices.

- Completed therapy: Case completed prescribed course of treatment.
- Lost: Case could not be located before the start or end of treatment (e.g., the case moved to an unknown location or the forwarding address is known but the case could not be located at that address). Code cases who move outside the U.S. and cannot be followed up as "Other".
- Uncooperative/refused: Case refused to complete treatment (e.g., stopped taking drugs).
- Adverse treatment event: Treatment was permanently stopped because of an adverse event due to anti-TB medications.
 - o If the case died because of an adverse TB treatment event, select:
 - o Closure reason: "Died" and then select
 - o Deceased: "Yes" in the static demographic panel and "Related to Treatment" for reason for death.
- Not TB: Diagnostic evaluation did not substantiate the diagnosis of TB (e.g., M. avium was isolated from a clinical specimen).
- Died: Case was alive at diagnosis but died before the start or completion of treatment.
- Dying: Treatment was stopped prior to imminent death.
- Other: Treatment was discontinued for a known reason not included in the above choices and is not unknown. A case who moved out of state and the receiving state never followed up would fall into this category, as would cases who move internationally and are lost to follow-up due to international relocation.

Treatment Extension

Enter <u>reason for treatment</u> extension if duration of

Treatment Ext.

treatment was greater than 12 months. Select closure reason from the dropdown choices. Do not overwrite choices.

- Rifampin resistance: Rifampin-resistant or multi-drug resistant TB requiring a treatment protocol lasting more than 12 months.
- Adverse drug reaction: Adverse drug reaction that prolonged therapy.
- Non-adherence: Non- adherence resulted in treatment beyond 12 months (e.g., treatment interruption).
- Failure: A sputum specimen tested culture positive four or more months after treatment began.
- Clinically indicated other reasons: Clinical indications other than adverse drug reactions include CNS TB, severe liver disease, or other criteria specified by clinician.
- Other: Reason does not include any of the choices listed above.

Provider Type

Enter the type(s) of medical provider(s) that provided treatment.

Provider(s)	
Local/State Health Department (HD)	
☐ Private Outpatient	
☐ IHS, Tribal HD, or Tribal Corporation	
☐ Institutional/Correctional	
☐ Inpatient Care Only	
Unknown	
Other	

Directly Observed Treatment (DOT)

Enter <u>Directly Observed</u>
<u>Therapy</u>. Select observation type from the dropdown choices. Do not overwrite choices.

DOT	×
DOT Weeks	

_

• Totally directly observed: Applies if DOT was used for all doses for a case who was taking medication. Also applies if a case was taking medication 7 days a week and DOT was used for at least 5 of those days (e.g., case self-administered on weekends and holidays).

- Totally self-administered: Applies if NO doses of medication were given under direct supervision.
- Both: Applies if the case self-administered any doses while taking medication. Does not apply if the case was taking medication 7 times a week and DOT was used for at least 5 of those doses. Response also applies if case took several months of DOT and several months of self-administered treatment.
- ✓ DOT weeks will be calculated and entered by the TB Epidemiologist.

CLOSURE: Central Panel

Deceased

If closure reason on the Treatment tab is "Died", enter Deceased = "Yes" and

DOB:

Age:

Deceased?

Yes No Date

Cause

Cause

indicate date of death and cause of death from the dropdown choices. Do not overwrite dropdown choices.

- Related to TB Disease: TB was the immediate cause, TB was an underlying cause, or TB was another significant condition contributing to death (even if TB was not the main cause of death).
- Related to TB Therapy: An adverse treatment event was related to the cause of death.
- Unrelated to TB disease: TB was NOT the immediate cause, an underlying cause, or another significant condition contributing to death.
- Unknown: Cause of death was unknown.

CLOSURE TAB: Admin

LHD Completion Date

Enter the date case was closed and case record completed by the Local Public Health Authority.

The TB Epidemiologist will enter the State Completion Date.

LHD Completion Date:	
State Completion Date:	

Moved During Treatment

If case changed primary residence during treatment, enter that information.



- Enter "No" if case did not move during treatment.
- Enter "No" if the patient moved within the same local public health authority jurisdiction during treatment.
- Enter 'Yes" if the case moved to another jurisdiction.
 - Select "In-state, out of jurisdiction" if case moved within the state but out of the original treating jurisdiction. Enter the city and county to which the case moved.
 - Select "Out of state" if case moved from the original treating state to another of the 50 United States or the District of Columbia or to a U.S. Territory, U.S. Island Area, or a U.S. Outlying Area. Enter the name of the state or reporting area to which the case moved.
 - Select "Out of the U.S." if the case moved from the U.S. to another country. Enter the name of the country to which the case moved. Also check the "Out of US-Trasnational Referral" box if a transnational referral was made.



Contact Investigation Data Entry

Three Essential Points

- ✓ LPHAs are required to enter contact investigation information directly into the Contact Investigation tab in Orpheus. LPHAs are not required to submit the TB Contact Investigation Form to the State TB Control Program.
 - ✓ LPHAs are free to use the TB Contact Investigation Form to 1) prioritize the follow-up of contacts and 2) track the evaluation and treatment of contacts, however, use and submission of the form is not required. The form is available on the State TB Control Program website at:

https://www.oregon.gov/oha/PH/DISEASESCONDITI ONS/COMMUNICABLEDISEASE/TUBERCULOSIS/ Documents/formdoc/contactform.pdf

✓ The following data entry instructions are not a substitute for guidelines about TB diagnosis, treatment, or control. Please refer to "Guidelines for the Investigation of Contact of Persons with Infectious Tuberculosis" (MMWR December 16, 2005 vol. 54, no. RR-15) for the current CDC guidelines on conducting a contact investigation. Always feel free to consult with the TB Program, OHA for technical assistance or advice on conducting a contact investigation.

Contact Investigation Data Entry comprises the following types of information in the Contacts Tab:

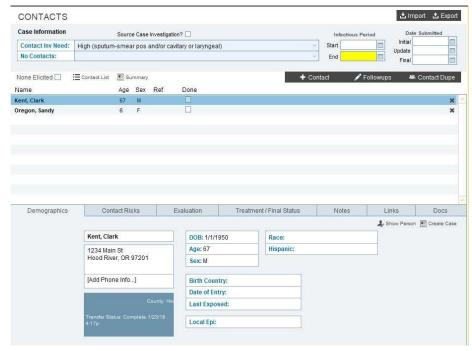
- ✓ Case Infectiousness Information
- ✓ Data Submission Dates
- ✓ Contact Demographics
- ✓ Contact Risks
- ✓ Contact Medical Evaluation
- ✓ Contact Treatment and Final Status

Please note that all screenshots contain fictitious data

CONTACTS TAB: Layout

The Contacts tab has four distinct areas:

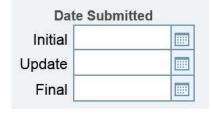
- ✓ An administrative area ("Date Submitted")
- ✓ A case-specific area ("Case Information" and "Infectious Period")
- ✓ A clickable list of contacts
- ✓ A contact-specific detail screen with seven tabs.



Submission Dates

Initial Data:

Enter initial data within 4 weeks of case report and after first round screening (<8 week TST/IGRA). Document initial data entry in the Date Submitted field.



Follow-up Data:

Enter follow-up data within 4 months of case report, after evaluation is complete for all contacts. Document follow-up data entry in the Date Submitted field.

Final Data:

Enter final data after all contacts who started treatment for LTBI have completed treatment or have stopped treatment for other reasons. Document final data entry in the Date Submitted field after all contacts have been fully evaluated and finished treatment, as applicable.

Case Specific Information: Contact Investigation Need

The State TB Epidemiologist will review each case of active TB and assign a Contact Investigation Need level (CI Need). This information is located at the top of the Contacts tab on the Case record in Orpheus.

Priority level for a contact investigation is assigned on the basis of disease characteristics and lab test results. Contact investigation is required for any potentially infectious case.

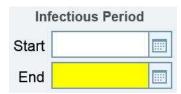
- High: Case is sputum-smear positive and/or has radiologically confirmed cavitary disease and/or laryngeal disease. Contact investigations must be initiated within 72 hours in these cases.
- Medium: Case has sputum-smear negative, culture positive pulmonary and/or laryngeal disease. Contact investigations must be initiated within 72 hours.
- Low: Case has sputum-smear negative, culture negative pulmonary or pleural disease. A contact investigation is recommended. If resources do not allow, please notify TB Program, OHA.
- None: All others, pulmonary involvement ruled out. Contact investigation is not indicated.

Case Specific
Information:
Infectious Period

An estimate of the infectious period start date and end date is required.

Infectious Period Start Date

A conservative method to estimate the start date is to use the date three months prior to either the onset of symptoms or the first positive finding consistent with TB disease, whichever is first. Positive findings



consistent with TB include, but are not limited to: positive AFB smear, positive NAAT, positive culture for MTB, abnormal CXR consistent with TB, and initiation of treatment for TB.

Infectious Period End Date

The end date can be determined as the date on which the patient

- has been on 4 drug TB treatment given by DOT for a minimum of 5 days <u>and</u>:
- has 3 consecutive AFB sputum-smear negative or equivocal specimens collected a minimum of 8 hours apart OR has a negative culture result.

Note: this end date is for the purposes of contact investigations only; clinical decisions for removing patients from isolation may differ from the above.

For more information on estimating the infectious period, refer to guidance located at

https://www.cdc.gov/tb/education/ssmodules/pdfs/Module8.pdf and https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm.

Case Specific Information: No Contacts

If no contacts were identified, complete this field to document the reason.

- No contacts identified despite effort to do so
- Contact follow-up was not done
- Contacts the same as for another case. Choose this option only
 if all the contacts for this case are the same as those for another
 case. In the Notes tab, identify the Orpheus Case ID of the
 related case.

Checkbox: No Contacts

Check this box if the case could not or would not identify any contacts for the contact investigation.

CONTACTS TAB: Adding Contacts

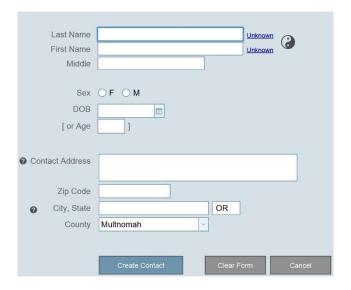
✓ Contacts can be entered into Orpheus in two ways. For smaller contact investigations, individual contacts can be entered directly. To save time in larger contact investigations, the Contact Investigation Upload Form may be used. This is a formatted Excel spreadsheet that can by uploaded to Orpheus to auto-populate contact records. For more information about this option, contact the TB Epidemiologist at 503-487-7031.

Adding a Contact

A contact is a person whom the health department believes had significant exposure and for whom identifying/contacting information is available.

Add a contact by clicking + Contact above the contact list.

In the next window, enter all known demographic information and click "Create Contact."

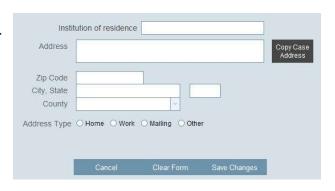


Orpheus will search all person records and display a list of possible name and birthdate matches. If a match appears, click "Link this Contact". If no match appears, click "Ignore Match, Create New Person". The new contact now appears in the Contact List.

CONTACTS TAB: Contact Demographics

Contact Address

Clicking the Address field pulls up an Address card. If the contact shares a residence with the case, click "Copy Case Address" to auto-populate the case's residence address into the Contact record. Otherwise, enter all known address information and Save Changes.



Age & Sex

Enter the Date of Birth, age and sex of the contact if not already filled.

DOB: 3/4/1956	
Age: 62	
Sex: F	

Birth	Country	&
Date	of Entry	

Birth Country and Date of Entry are essential risk factors and must be completed if possible.

Birth Country:	
Date of Entry:	
Last Exposed:	

Race & Ethnicity

Enter Race and Ethnicity from the dropdown choices. Do not overwrite dropdown choices.

Race:	
Hispanic:	

Date of Last Exposure

Date of Last Exposure is important for timing of the first and second round tests. If exposure is ongoing, as for a household member, indicate by checking the box.

Date Last Exposed	
Ongoing Exposure	

CONTACTS TAB: Contact Risks

Risk Level

Contact Risk is divided into two categories indicating high or low risk of infection for the contact. Level of risk relates directly to the contact's exposure to the case and the individual contact's medical conditions or other risks.

"High Risk of Infection" usually indicates the contact has either a significant exposure to the case or a medical risk that increases the contact's chances of becoming sick with TB after infection.

For example, if a contact is a member of the case's household, in most situations this indicates a great deal of direct exposure to the case and the contact's risk of infection would be high. Likewise, while an HIV-positive contact may have had less exposure to the case than a household contact, the fact that the contact is HIV-positive means the contact's personal risk of developing TB disease is high.

✓ Contacts assigned to the "High Risk of Infection" category should be prioritized in contact follow-up. Note: Contacts initially classified as "Low" may be moved into the "High" group as the investigation progresses or expands. This is likely to occur when the case is highly infectious and you suspect lower levels of exposure are causing infection (evidence of >10% latent infection rate among contacts tested, or evidence of secondary active cases).

Select low-High Risk Low Risk risk or highrisk for Household Congregate Setting ☐ No Exposure infection ☐ Age < 5
</p> ☐ Exceeds Exp Limits Other Low ☐ HIV Other Medical Risk based on Other risks ☐ CXR consistent Other: exposure Other risks. type.

Household: Contact lives in the same residence as the case.

<u>Age<5</u>: Contact is <5 years old. After infection, TB disease is more likely to occur in younger children. Contacts <5 years of age should be started on window treatment after a chest x-ray is obtained.

<u>HIV/AIDS</u>: Contact is HIV positive or has AIDS. Consider starting contacts with HIV/AIDS on window treatment or completing a full course of treatment for LTBI. Untreated HIV infection results in the progression of TB infection to TB disease more frequently and rapidly than any other known factor.

CXR c/w Inactive TB: Fibrosis on a CXR may indicate prior or current TB disease. Contacts with CXRs indicating healed primary TB (e.g. a calcified pulmonary nodule) are not at higher risk for later developing active TB disease.

Note: The activity of TB CANNOT be determined from a single CXR, and unless there are previous CXRs showing the abnormality has not changed, it is recommended sputum be sent for examination to assess the possibility of active TB disease. Once active TB disease is excluded by sputum culture, these patients are high priority for treatment for LTBI.

Congregate setting: Exposure to the case occurred in a congregate setting, either occupational or residential (e.g. high school, correctional facility, homeless shelter, nursing home, workplace). If you believe that the contacts in a congregate setting fall into the category of "Low Risk of Infection", please check the box "Other Low Risk" in the next column and write the setting in the space provided. Please consult with the State TB Control Program for assistance in determining if contacts are at high or low risk of infection if you have any questions. The State TB Control Program is available for onsite and/or technical assistance with all investigations in congregate settings.

Exceeds exposure limits: Contact is an otherwise healthy individual age ≥5 with exposure to the case that exceeds exposure limits (i.e., you believe the risk is high enough that the contact's level of exposure could result in infection). Examples of exceeds exposure limits might include a close friend, a coworker that shares an office with the case, daily carpool member, etc.

The North Carolina TB Control Program Manual (http://epi.publichealth.nc.gov/cd/lhds/manuals/tb/toc.html) specifies exposure limits to assist in determining if a contact "exceeds environmental limits". These limits are provided below should you wish to use them in your contact investigation. A contact is not required to meet the limits below, these are for guidance only.

- ≥ 4 cumulative hours in small, poorly ventilated space such as a car or enclosed room
- ≥ 8 cumulative hours in small well-ventilated space such as an apartment
- ≥ 12 cumulative hours in a large space such as a classroom or house
- ≥ 50 cumulative hours in large open area such as an auditorium or church

Other medical risk factor: Contact has a significant medical risk (other than HIV/AIDS). Examples:

- Those on immunosuppressive agents, including multiple cancer chemotherapy agents, antirejection drugs for transplants, TNF-alpha antagonists
- Someone receiving >15 mg of prednisone or its equivalent for >4 weeks
- Those with silicosis, uncontrolled diabetes mellitus, gastrectomy or jejunoileal bypass surgery, etc.

All patients taking prednisone or a TNF-alpha antagonist inhibitor (Enbrel, Remicade, Humira) should be treated during the window period. Consider starting all other contacts with significant medical risk(s) on treatment during the window period.

Other: Check this box if you believe the contact has a risk factor that contributes to their high risk of infection and progression to TB disease that is not listed above. Write in the risk factor in the space provided.

No Risk: Contact has no known risk factors, i.e., no actual exposure to the case.

Other Low Risk: Contact has limited exposure to the case, and you believe the risk of infection is truly low. Please note the exposure setting in the space provided. An example might be contacts from a school investigation (congregate setting) with little or no exposure to the case, and no other medical risks, that were tested as part of the investigation. Please feel free to consult with the State TB Control Program for assistance in determining if a contact's risk of infection is high or low.

CONTACTS TAB: Contact Evaluation

Symptomatic	and symptoms of sweats, hemoptysis	Check "Symptomatic" if contact is showing signs and symptoms of TB such as cough, fever, night sweats, hemoptysis, weight loss, etc. If the contact is symptomatic, work up for TB disease.			
History of Prior TB or LTBI	If the contact has a history of TB or LTBI and	Prior Positive TST/QFT? Prior Treatment (TB/LTBI)? Eval Complete	Prior Test/Treatn	nent Notes	
	you believe adequate prior treatment was completed for TB disease or LTBI, mark the box for "Prior Tx". In absence of a documented course of therapy, some questions to ask the patient to assess whether treatment was adequate include:				
	and color wereHow long wereDid you take mDid you miss n		v pill? How often?		
be screened for symptoms, offering LTB1	or symptoms. A chest x or if the case is highly to prior positives who	positive and/or prior tre -ray is recommended fo infectious (i.e., in an ou have not completed the	or contacts watbreak situa rapy.	rith medical risks	
		w LTBI" and "Eval Complete" boxes will autoding to the values entered in the evaluation tab. New LTBI			

1st Round Test (<8 week test)

Enter the results of the first round TST or IGRA. Tests done less than 8 weeks after last known exposure should be entered in this section. Tests administered more than 8 weeks after last exposure should be entered in the 2nd Round Test box, below.



2nd Round Test (>8 week test)

Enter the results of the second round TST or IGRA. A follow-up test done 8 or more weeks after a first round test should be entered here. Information should also be entered here if only one test was done and it was administered more than 8 weeks after last exposure to the case.



Chest X-ray

If a chest X-ray is completed, enter date of exam and results here.



CONTACTS TAB: Treatment/Final Status

✓ Complete for all contacts for whom LTBI treatment has been initiated. This may include persons with newly diagnosed LTBI, window treatment, prior positives, and immunocompromised persons being treated with a full course of preventive therapy (regardless of TST/QFT result).

Treatment Start Date

Enter date treatment for LTBI started

Treatment Start:

Treatment Stop:

Treatment Regimen:

Other Regimen:

Treatment Stop Date

Enter date treatment for LTBI ended

Treatment Regimen

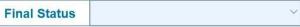
Choose the treatment regimen from the drop-down options. Do not overwrite options. Choose from the following options:

- INH daily 6 months
- INH daily 9 months
- INH biweekly DOT 6 months
- INH biweekly DOT 9 months
- RIF daily 4 months
- INH+Rifapentine 12 weeks
- Window Prophylaxis
- Other (specify)

If the treatment regimen is not listed, choose "Other" and describe as free text in "Other Regimen".

Final Status

Choose the final status of the contact after completing evaluation and/treatment if



indicated. Choose from the dropdown options. Do not overwrite dropdown options.

- 1- Active TB Diagnosed
- 2- Died
- 3- Moved

- ✓ If contact moved out of the jurisdiction, please submit an "Interjurisdictional Transfer Notification" located at: http://www.tbcontrollers.org/docs/resources/IJN Form May2015.pdf
- 4- Refused Treatment
- 5- Lost to follow-up
- 6- Provider decision (to stop or not start LTBI tx) toxicity
- 7- Provider decision (to stop or not start LTBI tx)- other
- 8- Refused evaluation
- 9- Completed LTBI treatment

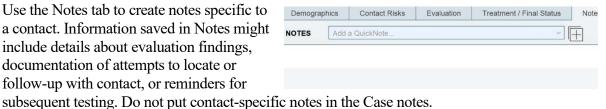
Treatment or other comments

Use this area to enter any contactspecific details or complications of treatment, details about incomplete evaluations, explanation for Final Status 7-Provider decision: other, etc.

Treatment comments or other contact information	Treatment	comments	or other	contact in	nformatio
---	-----------	----------	----------	------------	-----------

CONTACTS TAB: Notes

✓ Use the Notes tab to create notes specific to a contact. Information saved in Notes might include details about evaluation findings, documentation of attempts to locate or follow-up with contact, or reminders for



CONTACTS TAB: Links

✓ The links tab displays other Orpheus case records or contact records for the current contact.

CONTACTS TAB: Docs

✓ The Docs tab is a convenient location to upload and store documents related to the specific contact. Documents might include chart notes or radiology reports.



APPENDIX 1: DATA ENTRY TIMELINE for CASES and CONTACTS

	What	When	How	To Whom	What Else
Si	Initial presumptive/case report*	Open case in Orpheus within one week if: -medication is started for TB disease or - NAAT or culture is MTB positive or - pathology report is consistent with TB	Create case record and complete required data elements in Orpheus (see Case Report and Data Entry Manual)	TB Epidemiologist via Orpheus	Attach to Orpheus case record initial lab reports (if not from OSPHL), pathology, and CXR reports
Disease Cases	Verification update**	Update Orpheus case record within one week if: - NAAT or culture is MTB positive or - 2 months treatment completed if clinical case	Complete in Orpheus data elements required for verification (see Case Report and Data Entry Manual)	TB Epidemiologist via Orpheus	Attach to Orpheus case record verification lab reports (if not from OSPHL)
TB D	Completion of treatment update	Update Orpheus case record within one week if: -TB medications are stopped or - Lab results are negative for TB and TB disease is ruled out	Complete in Orpheus data elements required for closure (see Case Report and Data Entry Manual)	TB Epidemiologist via Orpheus	Attach to Orpheus case record final CXR (if indicated and available)
ation	Initial report	Within 4 weeks or after 1st round test			
Contact Investigation	Update	In 8 weeks or after 2nd round test (include CXR & treatment start data for LTBI)	Complete in Orpheus Data elements for each contact	TB Epidemiologist via Orpheus	For assistance with contact data entry, call TB Program at 503-487-7031.
Contac	Completion	After all contacts on treatment for LTBI are completed, treatment is stopped, or contact lost to follow-up			

^{*}Case Report and Data Entry Manual is located on the TB-OHA website under Program Forms at http://healthoregon.org/tb

^{**} Initial TB case report and verification update may be combined if first notification of case is at time of verification (e.g., first notification is a positive culture result)