Washington Disease Reporting System Tuberculosis Manual

Report of Verified Case of Tuberculosis Version 3



October 2023 DOH 343-148



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*Reason TB disease therapy extended >12 months (select all that apply)	
Was original treatment course altered due to drug resistance or adverse events?	
*Treatment administration (select all that apply)	
*Was phenotypic/growth-based drug susceptibility (DST) testing done?	
*Was genotypic/molecular drug susceptibility testing done?	
Was the patient treated as an MDR TB case (regardless of DST results)?	
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*Contact investigation conducted for this case	
**Contact investigation start date	
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*Please enter state case numbers for all known TB and LTBI cases epidemiologically linked to this case	
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About the WDRS TB Manual

Purpose and Audience

Per the Division of Tuberculosis Elimination (DTBE), "Tuberculosis (TB) is a nationally notifiable disease, and reporting is mandated in all states. In 1953, a national surveillance system was established to collect information on new cases of active TB disease. Since 1985, all states have been reporting TB cases to the Centers for Disease Control and Prevention (CDC) using the Report of Verified Case of Tuberculosis (RVCT), for national TB surveillance. Data are collected by state and local TB programs and submitted electronically to CDC, Division of Tuberculosis Elimination (DTBE). These data are used to monitor national TB trends, identify priority needs, and create the DTBE annual surveillance report, Reported Tuberculosis in the United States.

To control and eventually eliminate TB, state and local TB control programs must be able to monitor trends in TB disease in high-risk populations, as well as identify new patterns of disease and possible outbreaks. The last major revision of the RVCT was completed in 2009. Since 2016, members of a DTBE-sponsored workgroup consisting of nearly 30 public health professionals from 15 TB control programs, DTBE, and the National TB Controllers Association (NTCA) have been working to revise the RVCT. Modifications to the RVCT data collection [released in Washington state January 2023] now accommodate the changing epidemiology of TB in terms of risk factors, new drug treatments, and enhanced laboratory capacity for diagnostic tests."

The Washington Disease Reporting System (WDRS) is an electronic disease surveillance system that allows public health staff in Washington to receive, enter, manage, process, track, and analyze disease-related data from various sources. WDRS allows secure communication and coordination among state and local health departments.

The purpose of this manual is to provide local health jurisdiction (LHJ) partners with detailed orientation to the TB model in WDRS, and a comprehensive resource for how to navigate the TB reporting data elements in this system including definitions and answers to frequently asked questions. These resources are meant to support effective state and federal reporting of TB disease and any subsequent contact investigation.

Eliminating Stigmatizing Language

Judgmental terms and negative connotations of words such as 'defaulter' and 'suspect' may be perceived to place blame for the disease and responsibility for adverse treatment outcomes on the patient. To assist in implementing a change in the use of stigmatizing language the Heartland TB Center of Excellence, the International Union Against TB and Lung Disease, the National Society of TB Clinicians, the global TB community and the Treatment Action Group developed the <u>Stop the Stigma: Eliminating Stigmatizing Language</u> reference tool to aid in identifying suggested replacement language as a reminder of how our words may affect others.

Use This	Not that	Use This	Not that
Adherence /	Compliance /	Undocumented	Illegal; Illegal alien
Non-adherence	Non-compliance		
Person lost to follow up	Defaulter	Person with TB disease	TB case
TB Prevention and Care	TB Control	Treatment failed	Treatment failure
Person to be evaluated	TB Suspect	Missed doses/	Delinquent
for TB		Non-adherent	
HIV-Positive	HIV-infected	Contact Analysis;	Investigation;
		Contact Elicitation;	Investigate
		Contact Identification	
Immigrant	Alien	Exposed to TB	TB Contact
Lack of housing; Under-	Homeless/	Tuberculosis	Consumption; White
housed; People	Homelessness		Plague
experiencing			
homelessness			

Adapted from: <u>https://www.heartlandntbc.org/wp-content/uploads/2021/12/FactSheet_Final_5_19_16.pdf</u>

Stop TB Partnership's <u>Words Matter Language Guide</u> is an additional resource available to encourage positive change, sensitize, promote appropriate language, end the stigmatization, and empower people affected by TB.

How to Use This Manual

lcons

Throughout the manual, these icons quickly cue you about important information and other resources:



This warns about high-consequence information you must understand when performing the task.



This signals when you should call to report or to consult on the task.

💽 Тһ

This highlights special considerations for pediatric patients.



This suggests another relevant area in the manual or another resource that you may want to review.



This alerts you that a form is available for the task.



Reminder to save the patient record.

Definitions and Frequently Asked Questions

TB reporting often has nuance to it, and additional clarification is helpful in some circumstances. The DOH TB team has gathered CDC definitions, clarifications, and answers to frequently asked questions and included those in this manual. They will be distinguished by rounded boxes included after initial instructions for each question, if available.

Definitions will be found in blue boxes like this.

Answers to frequently asked question(s) will be found in orange boxes like this.

Getting Started in WDRS

The Washington Disease Reporting System (WDRS) is accessed through <u>Secure Access</u> <u>Washington (SAW)</u> (<u>https://secureaccess.wa.gov/</u>). Please contact your local data steward to request access.

Once you are logged into WDRS through SAW, search for a patient or create a new patient record from the WDRS Home Screen. For guidance on how to **Create a New Event** (Patient Record) or **Search for a Person** in this reporting database, refer to the <u>general WDRS Reference</u> <u>Guide (https://doh.wa.gov/sites/default/files/legacy/Documents/5600//200-004-WDRSReferenceGuide2017.pdf</u>).

WDRS Features

WDRS pages

Event Summary Dashboard

The Event Summary dashboard displays basic information about the event. The dashboard opens when a new event is created or an existing event is opened. To exit the Event Summary dashboard, click the X at the upper right of the page.

Sasic Information						Notes (Add/Edit	Show My Notes)	
event ID;	105584679						<u> </u>	
Disease:	TB disease							
Person:	TB TB Birth Date: 01/1	13/2003 (19 v	/o Male)					
Dates:	Create Date: 10/18/202	22						
lype:	Interactive							
nvestigation Status:	Active (Change to Clos	sed)						
inked Events/Contacts:	1 linked event(s)/conta	ct(s) (View)						
inked Exposure Sites:	0 linked exposure site(s) (View)						
Attachments:	0 attachment(s) (Add)							
lotices:	CustomConcerns (1) Issues exist in this	record, chec	k the Con	cerns tab for	details.			
	Workflow Status (1)	s [View List]						
General Notifications (1)								
Edit Event Properties	Vital Status: Alive Copy Event							
Edit Event Properties	Vital Status: Alive Copy Event Results Concerns	Persons	Tasks	Surveys	Calendar	Event Properties	Event History	
Edit Event Properties	Vital Status: Alive Copy Event Results Concerns	Persons	Tasks	Surveys	Calendar	Event Properties	Event History	
Edit Event Properties	Vital Status: Alive Copy Event Results Concerns	Persons	Tasks	Surveys	Calendar	Event Properties	Event History	
Edit Event Properties	Vital Status: Alive Copy Event Results Concerns	Person	Tasks	Surveys Last Update	Calendar	Event Properties	Event History	Status
Edit Event Properties Event Data Lab F Question Package Administrative	Vital Status: Alive Copy Event Results Concerns	Persons TB TB	Tasks	Surveys	Calendar	Event Properties	Event History By nder [test.txt5303]	- Status
Edit Event Properties Event Data Lab P Question Packages Administrative Demographics	Vital Status: Alive Copy Event Results Concerns	Persons Person TB TB TB TB	Tasks	Surveys	Calendar	Event Properties Updated Leiann Ki Leiann Ki	Event History By nder [test.txk5303] nder [test.txk5303]	Status Incomplete Incomplete
Edit Event Properties Event Data Lab I Duestion Packages Duestion Package Administrative Demographics Risk	Vital Status: Alive Copy Event Results Concerns	Person TB TB TB TB TB TB TB TB	Tasks	Surveys Last Update 01/03/2023 10/18/2022 10/18/2022	Calendar	Event Properties Updated Leiann Ki Annah O	Event History By nder [test.txk5303] nder [test.txk5303] stberg [AM00303]	Status Incomplete Incomplete
Edit Event Properties Event Data Lab I Duestion Packages Question Package Administrative Demographics Risk Diagnostics and Evaluat	Vital Status: Alive Copy Event Results Concerns	Persons Person TB TB TB TB TB TB TB TB	Tasks	Surveys Last Update 01/03/2023 01/03/2023 10/18/2022 01/03/2023	Calendar	Event Properties Updated Leiann Ki Annah Ci Leiann Ki Leiann Ki	Event History By nder [test.txk5303] nder [test.txk5303] stberg [AMO303] nder [test.txk5303]	Status Incomplete Incomplete Incomplete
Edit Event Properties Event Data Lab F Question Packages Question Package Administrative Demographics Risk Diagnostics and Evaluat Treatment	Vital Status: Alive Copy Event Results Concerns	Persons Person TB TB TB TB TB TB TB TB TB TB TB TB	Tasks	Surveys Last Update 01/03/2023 01/03/2023 10/18/2022 01/03/2023	Calendar	Event Properties Updated Leiann Ki Annah O Leiann Ki Leiann Ki	Event History By nder [test.txk5303] nder [test.txk5303] nder [test.txk5303] nder [test.txk5303]	Status Incomplete Incomplete Incomplete Incomplete Incomplete
Edit Event Properties Event Data Lab f Duestion Packages Administrative Demographics Risk Diagnostics and Evaluat Treatment Additional Information	Vital Status: Alive Copy Event Results Concerns	Person TB TB TB TB TB TB TB TB TB TB TB TB TB TB TB TB	Tasks	Surveys Last Update 01/03/2023 01/03/2023 10/18/2022 01/03/2023 01/03/2023 01/04/2023	Calendar	Event Properties Updated Leiann Ki Annah O Leiann Ki Leiann Ki Leiann Ki	Event History By nder [test.txk5303] nder [test.txk5303] nder [test.txk5303] nder [test.txk5303] nder [test.txk5303]	Status Incomplete Incomplete Incomplete Incomplete Incomplete Incomplete Incomplete Incomplete

The Event Summary dashboard contains links to all the screens and Question Packages associated with the event. The top section displays basic information and notes about the case. It also provides links to a person's summary page (Person page), linked events, and attachments (these links are in blue and take you to new screens). Important warnings or messages may also be seen under the basic information section.

Users can view and add notes in the upper right box by clicking Add/Edit. If you add a note, you may set the note to **Public** (meaning that anyone with permission to see the event can see the note), or **Sensitive** (meaning that only you or people with enhanced security can see the note.)

The bottom section of the Event Summary dashboard contains Question Packages for the case, as well as tabs with additional event information and a drop-down list of available Wizards.

Tab	Notes
Event Data	The Event Data tab is where the Question Packages for this event are located. Question Packages are used to view and edit information on an event.
Lab Results	The Lab Results tab is where you add and review labs for this event. This is also where electronic lab reports will be viewable.
Concerns	The Concerns tab is where you can view any Concern for the event. A Concern is an important issue that could affect the event. There are two types of Concerns: 1) a system-generated Concern is automatically generated by WDRS and is used to highlight important characteristics of the event (potential data entry issues, pediatric case, MDR, etc.); and, 2) a user- generated Concern is created by the user to bring attention to an issue.
Persons	The Persons tab provides details about the person associated with the event, and is used to add or update identifying and contact information about the person.
Tasks	The Tasks tab provides information about any Task associated with an open event. You can or view add Tasks here.
Calendar	The WDRS Calendar tab provides a simple solution for organizing team meetings, client appointments, and resources usage.
Event History	This tab provides a history of when the event was created and updated, including details about what changes were made to a Question Package and who made them. It can provide a helpful snapshot about who has done what on the event. This history is displayed at the Question Package level, not by individual question.

Tabs on the Event Summary dashboard include:

Person Page

The Person page can be accessed directly from the Event Summary dashboard by clicking the link on the person's name.

ent Summary	
Basic Information	
Event ID:	105584679
Disease:	TB-disease
Person:	TB TB Birth Date: 01/13/2003 (19 yo Male)
Dates:	Create Date: 10/18/2022
Туре:	Interactive
Investigation Status:	Active (Change to Closed)
Linked Events/Contacts:	0 linked event(s)/contact(s) (View)
Linked Exposure Sites:	0 linked exposure site(s) (View)
Attachments:	0 attachment(s) (Add)
Notices:	CustomConcerns (1) Issues exist in this record, check the Concerns tab for details.
	Workflow Status (1) Event is in workflows [View List]
	General Notifications (1) Vital Status: Alive

The person summary section of the Person page contains demographic and contact information. The event information section lists other events for the person as well as linked events and contacts. The labs section contains lab test and result information.

mographic Information (Vie	w History)				Notes (Add/Edit)		
rst Name:	TB				Notes (<u>Pidd/Edit</u>)		
iddle Name:	10						
et Name:	TB						
iffiv:	10						
th Date:	01/12/2002						
v assigned at hith:	Mala						
assigned at birth.	Ividie						
cial Security Number.							
ain Dale.	DKEKEZAMOVD						
tel status:	Alive						
tal status:	Alive						
ame alternate first:							
DB alternate:							
ex alternate:							
SN alternate last 4 only:							
ione number:							
nail:							
ectronic contact:							
rson identifier:							
evious WDRS person IDs:							
ever match (DOH-use only);							
ever match WDRS Person ID							
IE:	19						
dunlication Status:	Done						
					internation butta		2011 201010
t Information							
ents ent ID	Person		Status	Cre	ate Date	Dis	sease
5584679	IB, IB		Active	10/	18/2022	IB	disease
nked Events/Contacts	Person	Status	Create Date		Disease	Link Type	Linked From
	Test, TB	Active	12/28/2022		TB disease	Contact	105584679
5592190 🔬							
15592190 🕥 nked People					Birth Date		Address
15592190 🕥 nked People elationship			Full Name				
95592190 എ nked People elationship dended Family		-	Full Name Test, TB		01/04/2022		WA
5592190 இ Iked People Ilationship tended Family		1	Full Name Test, TB		01/04/2022		WA
5592190 🔬 Iked People Iationship tended Family			Full Name Test, TB		01/04/2022		WA

Linked Events Page

From the Event Summary screen, click "View" adjacent to "Linked Events/Contacts:"

ent Summary	
Basic Information	
Event ID:	105424244
Disease:	TB disease
Person:	TB TEST ()
Dates:	Create Date: 11/18/2022
Type:	Interactive
Investigation Status:	Active (Change to Closed)
Linked Events/Contacts:	1 linked event(s)/contact(s)(View))
Linked Exposure Sites:	0 linked exposure site(s) (View)
Attachments:	0 attachment(s) (Add)
Notices:	Concerns (2) Please fill in sex at birth information on Person screen. Please fill in the birth date information on Person Screen.
	Workflow Status (1) Event is in workflows [View List]
	General Notifications (1) Vital Status: Alive

Any existing TB-related events (e.g. cases, contacts, infection) already linked to the case will be displayed in the "Linked Events" line list at the top of the screen.

Linked Events - TB TEST - TB disease									
Filter Linked Events									
Disease:							 Statu 	s: 🗸	
Apply Filter	Apply Filter Reset Filter								
Linked Even	ts								
Event ID	Full Name	Status	Create Date	Disease	Event Date	Text1	Туре	Relationship	
105424850	Case, Test	Open	01/06/2023	TB contact	01/06/2023		Contact	Other	

This line list can also be filtered by type of linked event by selecting the appropriate event type (i.e. TB contact, TB disease, TB infection) from the drop-down list for "Disease:." The line list can also be similarly filtered by "Status:" of the event (i.e. open, closed, deleted).

Below the line-list, a separate "Link Events" section allows you to either, (1) create a new TB event linked to the case, or (2) link existing event(s) to the case. **Note:** the default "Operation:" is "Create Linked Event." This can be changed accordingly whether you are linking a new or existing WDRS event.

For detailed instructions on how to link TB events, see <u>WDRS Quick Tips: Linking TB Contact &</u> <u>Infection¹</u> or this <u>"Linking TB Events in WDRS" training video²</u>.

https://stateofwa.sharepoint.com/sites/DOH-tuberculosispartners/Shared%20Documents/WDRS%20Quick%20tips%20-%20Linking%20TB%20Contact%20&%20Infection.pdf?cid=1f27fc97-fa2a-4b10-9f6b-dc1c67bd3a99

^{2.} https://www.youtube.com/watch?v=1a sD3GR AM

Wizards

Wizards are a way to make data entry or data viewing easier. They are disease-specific and take relevant questions from the different Question Packages to create one spot for data entry (instead of going into each Question Package separately to do the data entry). Data entered in the Wizards will copy into the appropriate fields within the Question Packages. Wizards are often based on common data-entry questions and either match investigator forms, official WA DOH case reporting forms, CDC forms or match a shortlist of questions applicable to certain data-entry situations.

When in the Event Summary dashboard, a dropdown of available Wizards can be found below the individual Question Packages in the Event Data tab. The user will select which Wizard to view from the dropdown menu.

Some of the Wizards in TB events include:

- Suspect TB Wizard
- Report of Verified Case of Tuberculosis (RVCT) Wizard
- TB Contact Wizard
- LTBI Wizard

Workflows

Workflows are important in WDRS because they organize events and identify items that need user action. Each Workflow is a question or query asked about events in WDRS.

Workflows may ask questions specific to a disease or condition, general questions, or questions about a pending status. In this way, the system organizes lists of events with similar pending actions, such as deduplication, address verification, or open outbreaks.

Since one event may fit several questions, an event may appear in more than one Workflow. Closed events can appear in some Workflows, but not in others, depending on the specifications of the Workflow.

WDRS runs queries intermittently throughout a 24-hour period. Most Workflow queries run every 15 minutes, while others run once in 24 hours. The frequency with which the Workflow query runs is based on the criticality of the Workflow, as well as the burden on the system. Some queries look at more data and, therefore, take longer to run than those that look at only one or two pieces of information. The latest result of each of these queries is displayed on the Workflow queues page and is tagged with the time the query was last run. Workflows will not immediately be removed from the queue when the associated questions are updated, they will only disappear when the next refresh happens.

On the WDRS home screen, note the "Workflow Queue." To add a Workflow to your favorites list from this screen, click the star icon $\stackrel{\text{res}}{\longrightarrow}$ to the left of the name of the Workflow.

Was	shington Dise	ase Reporting System (Cobalt	1.10 Stag	ing (Pre Production) 👘 😭 🕻	Enter Case	BID or Search Term Search
	2 ् रि 🛙						
Ale	rts and Notifica	ations		•	Quick Links		
Ree	cent Records			•	Welcome To Washington Disease Reporting Sys	tem Cobalt 1.10	Staging (Pre Production)
	Event ID	Full Name	Dis	ease	Have comments or questions? Contact us:		
分	100847753	The Dog, Winston	TB disea	50	Business Area	Dhome	Email
☆					Dusiness Area Tuberculosis:	208.418.5500	thereoices@dob.wa.nov
☆					STD (Surveillance and HIV/STD Partner Services):	360.236.3445	STD Surveilance@dob wa cov
				More	HIV Surveillance:	360-236-3427	HIV Surv@doh.wa.gov
_					Hepatitis B and D:	206-418-5500	CommDisEpi@doh.wa.gov
Wo	rkflows			•	Hopatitis C:	360-236-3390	hepatitis@doh.wa.gov
		Workflow Queue	Events	Assigned	General Communicable Diseases:	206-418-5500	CommDisEpi@doh.wa.gov
4	My Groups' Open	9620	0	0	Blood Lead:	360-236-4280	lead@doh.wa.gov
~	My Onen Tesks	0.00	0	0	WDRS Administration Office:	360-236-4229	wdrs.community@doh.wa.gov
H	My Open Tasks		0	0	Calandar		
W I	My Overdue Tasks		0	0	Calendar		
R	Open Cases - Assi	gned to Current User	0	0	Manage appointments		
Ŷ	Open Tasks Create	ed by Me	0	0			
	Overdue Tasks Cre	ated by Me	0	0	WDR'S Helpful Resources		
立	Shared Cases - Ca	ises shared by me	0	0	DOH Notifishia Conditions	OH WODS WW	olio
分	Shared Cases - Ca	ses shared with me or my group(s)	0	0	WDRS User Community (WUG) SharePoint Site S	Submit a WDRS (Change Request
☆	TB Contact events [LHJ]	that are not evaluated >60 days	343	0	Help Desk		and the second second
	TB Contact events	that need county assigned [DOH]	66	0	DOU Device Control 200 205 4257 or Device Co		
				More	DOH Service Central: 360-236-4357 or ServiceCer	ntrai@doh.wa.g	ov

The complete set of all your workflows can be viewed in two ways:

- By clicking on the workflows icon
- By clicking on "More..." at the bottom of the "Workflow Queue"

The "Workflow Queues" page lists the entire set of all Workflows. A Workflow can be added to your favorites list from this screen by clicking the star icon 🔂 to the left of the name of the Workflow.

Wo	rkflow Queues (Hide empty workflows)			
	Workflow Queue	Total Count	Priority	Last Update
Cas	e Specific Monitors			
습	Open Cases - Assigned to Current User	0	Medium	02/12/2020 11:20 AM 1
습	Shared Cases - Cases shared by me	0	Medium	02/12/2020 11:20 AM
介	Shared Cases - Cases shared with me or my group(s)	0	Medium	02/12/2020 11:20 AM 1
TB.0	105 - Open Events [LHJ]			
☆	TB Events open in my LHJ [LHJ]	494	Medium	02/12/2020 11:25 AM 🚺
☆	TB Events with Investigator of current user [LHJ]	0	Medium	02/12/2020 11:29 AM 1
TD (MC Astion Derived II U II			
18.0	TR Disease suggist that are still suggest > 60 days 0 H 0	0	Many Linh	00/10/0000 11/05 AM
и А	TB Disease events that are still suspect >60 days [LHJ]	8	Very High	02/12/2020 11:25 AM
14	TB Events with ELR fields to resolve [LHJ]	10	Very High	02/12/2020 11:15 AM
12	TB Disease events that have not been submitted by LHJ >60 days [LHJ]	3	High	02/12/2020 11:25 AM
2	TB Disease events that need susceptibilities [LHJ]	9	High	02/12/2020 11:25 AM
Ŷ	TB Contact events that are not evaluated >60 days [LHJ]	343	Medium	02/12/2020 11:25 AM 🚦
ŵ	TB Disease events that need a contact investigation [LHJ]	19	Medium	02/12/2020 11:25 AM 🚺
☆	TB Events with lab reports for review [LHJ]	42	Medium	02/12/2020 11:25 AM
습	TB Infection events that have not completed treatment >9 months [LHJ]	12	Medium	02/12/2020 11:25 AM 1
습	TB Disease events with legacy data unresolved [LHJ]	110	Low	02/12/2020 11:25 AM 🚦
las	(Specific Monitors (Add Task)			
	My Groups' Open Tasks	0	Medium	02/12/2020 11:20 AM
	My Open Tasks	0	Medium	02/12/2020 11:20 AM 1
	My Overdue Tasks	0	Medium	02/12/2020 11:20 AM 🚦
	Open Tasks Created by Me	0	Medium	02/12/2020 11:20 AM
	Overdue Tasks Created by Me	0	Medium	02/12/2020 11:20 AM 🚦

TB-Specific Workflows

	Short description
Workflow name	How to clear records from this Workflow
	Refresh rate
TB Events open in my LHJ [LHJ]	TB events (Disease, Contact, and Infection) with your LHJ listed as the Accountable County, where 'LHJ close' has not yet been answered Yes.
	Clear events from this Workflow by marking 'LHJ close' field as Yes (if appropriate) or updating reporting address to change Accountable County to another LHJ (if appropriate).
	Refresh rate: 10 minutes
TB Events with Investigator of current	TB events (Disease, Contact, and Infection) with the current user listed as the Investigator in the event record.
user [LHJ]	Refresh rate: 10 minutes
TB Disease events that are still suspect >60	TB disease events that were created >60 days from today and still show a verification status of Suspect.
days [LHJ]	Clear events from this Workflow by either entering enough diagnostic and treatment data for the case to become verified, or if the case is not TB, select "Not TB" for the Reason treatment stopped or never started, indicate "No" for case counting, and select "Not a verified case" as the reason.
	Refresh rate: 2 hours
TB Events with ELR fields to resolve [LHJ]	Tuberculosis events where 'Automated process-unresolved' is in a standardized ELR field.
	Clear events from this Workflow by reviewing the Electronic Lab results and resolve any fields that state "Automated process – unresolved".
	Refresh rate: 15 minutes
TB Disease events that have not been	This Workflow identifies TB disease events that meet the criteria for counting but have not yet been submitted to the state TB team for counting.
submitted by LHJ >60 days [LHJ]	Clear events from this Workflow by selecting "Yes" for counting (if applicable).
	Refresh rate: 2 hours
TB Disease events that need susceptibilities	TB disease events with a positive culture result entered but drug susceptibility questions have not yet been answered.
[[[]]	Clear events from this Workflow by entering data regarding drug susceptibility testing.
	Refresh rate: 10 minutes

	Short description
Workflow name	How to clear records from this Workflow
	Refresh rate
TB Contact events that are not evaluated	TB contact events that were created >60 days from today but have not yet been dispositioned.
>60 days [LHJ]	Clear events from this Workflow by entering data into the record, including a final disposition determination (infected, not infected, etc.)
	Refresh rate: 10 minutes
TB Disease events that need a contact investigation [LHJ]	TB disease events with a positive sputum smear documented, but a contact investigation start date and/or an answer to whether a contact investigation was conducted for this case is unanswered.
	Clear events from this Workflow by answering whether a contact investigation was conducted for this case (for records after Jan 8, 2023) or by entering a contact investigation start date (for records prior to Jan 8, 2023), if applicable. If no contact investigation was conducted, add a comment to the case record indicating why not.
	Refresh rate: 10 minutes
TB Events with lab	TB events where the question "Lab report reviewed – LHJ" is unanswered.
reports for review [LHJ]	Clear events from this Workflow by reviewing the Electronic Lab Report and marking the lab report as reviewed.
	Refresh rate: 10 minutes
TB Infection events that have not completed treatment	TB infection events where treatment initiation is documented, but no treatment completion has been entered and it has been >9 months since treatment start.
>9 months [LHJ]	Clear events from this Workflow by completing Date therapy stopped and Reason therapy stopped.
	Refresh rate: 2 hours
TB Disease events with legacy data unresolved [LHJ]	TB disease events that were historically migrated into WDRS and some data values did not have a clean landing spot, which have not yet been reviewed by the LHJ.
	Clear events from this Workflow by reviewing data in the Legacy Data Question Package in the event. Enter any non-missing values into the corresponding field of the WDRS event record, as appropriate (either in an existing field or as a comment). Then mark "Yes" for the question "Legacy data are resolved as possible" in the Legacy Data Question Package. <i>For most</i> <i>LHJs, this Workflow will be empty and will remain empty</i> .
	Refresh rate: 10 minutes

Expand Details

Within each Question Package, and within the Wizards, details of total number of questions and incomplete required questions within the Question Package or Wizard may be viewed by clicking "Expand Details" in the top right corner of the screen.



Lab information, including Electronic Lab Report (ELR) results, can also be viewed in the expanded details section, allowing for convenient reference when entering diagnostic test results into the event record.

Tooltips

Tooltips provide additional context about a question. When a Tooltip accompanies a question, an icon to alert the user will appear to the right of the question.



View the Tooltip by hovering your mouse over the icon.

Country of usual residence	
Preferred language	Usual residence is defined as the place where the person lives and
Interpreter needed?	residence, legal residence, or the place where they became infecte

Comment boxes

Each Question Package contains an area at the bottom where comments may be entered if the user wishes to provide additional information related to the subject content of the question package. Upon saving the Question Package, the date/time and user's name will be automatically populated. Multiple comments may be made by clicking the "Add New" link to the right of the comment box.

	Comments	
Comments ⊟	test comment	Add New
Comments date/time	01/06/2023 01:38 PM	Add New M
Comments user	Leiann Kinder	
* Indicates required field	Add New Add Ne	
Save Cancel Help	0	

The use of comment boxes is a great way to communicate to the state TB team about unique situations that impact how answers are selected in the event record. One example is a circumstance where drug susceptibility testing is marked as Not Done but there is a positive culture result entered; detailing the reason why in a comment box allows the state TB team to distinguish a special situation from a data entry error.

Tasks

Tasks can be used to capture important information related to activities with target turnaround times.

Tasks can be viewed in three places:

1. From the Tasks tab in the event information section

Ever	nt Data	Lab Results	Concerns	Persons	Tasks	Surveys	Calendar	Event Properties	Event History
Tasks									
Туре	Status	Priority	Due Dat	e D	escription	As	signed To	Assigned To G	roup

2. From the Workflows page

Tas	Task Specific Monitors (Add Task)		
	My Groups' Open Tasks		
	My Open Tasks		
	My Overdue Tasks		

3. From the Tasks icon [™] in the toolbar on the home page



The State TB team uses the Tasks function within WDRS to alert LHJ partners to new labs that come in by fax that need review. For detailed instructions on how to access these Tasks, what steps to take next, and how to clear them from your Workflows, see <u>WDRS Quick Tips:</u> <u>Receiving TB Labs via 'Tasks'</u>.¹

More details about the Tasks function can be found in the WDRS Quick Reference Guide.²

2. https://doh.wa.gov/sites/default/files/legacy/Documents/5600/420-223-WDRSQuickReference.pdf?uid=633f583e53754

^{1. &}lt;u>https://stateofwa.sharepoint.com/sites/DOH-tuberculosispartners/Shared%20Documents/WDRS%20Quick%20tips%20-%20Receiving%20TB%20Labs%20via%20%E2%80%98Tasks%E2%80%99.pdf?cid=32949715-609d-4002-83d1-8a611e9fb059</u>

Reports

Reports allow users to pull data out of WDRS and can be customized to define which fields should be contained in the report results.

To run a report:

1. From the WDRS Dashboard, click the **Reports** button



- 2. Click the "Category" dropdown list and select "Tuberculosis."
- 3. Click the "Select Report" dropdown list and select the desired report.
- 4. The "Description" box contains text which describes what the report is used for and how it works.

Maven Reporting	9
Category:	Tuberculosis 🗸
Select Report:	TB Contact Report (events 8/29/2019 - present)
Description:	TB contact events pulled by case create date. This report applies to contact events created after 8/28/2019 which was when several new contact fields were added.
Report Period*:	● Date Range ○ Period
	Start Date: MM/DD/YYYY E End Date: MM/DD/YYYY
Output Type:	HTML V
This report has b	een configured to run on the reporting database.
Run Report	Dashboard Help

- 5. Select applicable report parameters. An asterisk (*) indicates a required parameter.
 - Report Period: The report may ask for a "Date Range" or "Period" for data to be reported. Note that these dates are **EXCLUSIVE**. If the current day's data is needed, set the end date to the following day's date.
 - Output Type: You may select between <u>displaying</u> the report in a non-editable format within the browser window (HTML) or <u>exporting</u> it to an external application such as Excel. Exporting the data allows for the data to be manipulated, formatted, or graphed.
 - When "Output Type" displays, select from the dropdown list.
 - The "Excel w/Parameters" option is available for line list and tabular reports to facilitate the exporting of the report parameters and name.
 - Note: If you plan to import the data into statistical software programs such as SAS or R, it is recommended exporting the data as a CSV.

Reports may take a while to run and have been configured to queue rather than run while the user waits. This enables the user to get back to other tasks while waiting. After choosing to run the report, the user will see a message indicating that the report has been queued and that the status is "Pending."

The selected rep	oort has been scheduled for execution	
Maven Reportin	g	
Category:	Tuberculosis 🗸	
Select Report:	TB Contact Report (events 8/29/2019 - present)	
Description:	TB contact events pulled by case create date. This report applies to contact events created after 8/28/2019 which was when several new contact fields were added.	
Report Period*:	○ Date Range ● Period 1 Week ▼ Start Date: 01/01/2022 ■ End Date: 12/31/2022	
Output Type:	HTML 🗸	
This report has	been configured to run on the reporting database.	
Run Report	Dashboard Help	
Report Schedu	e (<u>Refresh)</u>	_
Scheduled Time 01/06/2023 03:0	Frequency Created By 8 PM Queued Leiann Kinder [test.lxk5303]	Status Pending

The "Refresh" link is provided for the user to click after having waited for a period of time (which varies depending on the report). The reports process will continue to run in the background when users leave the "Reports" screen, allowing users to perform other tasks in WDRS without impacting the report process. To determine if the report is ready to be downloaded, the user can go back to the reports screen and select the same report again and click the "Refresh" link. If the report is ready to be downloaded at that point, the user will see a link which says "Download" and can click to download the report results.

Report Schedule (Refresh)	
Scheduled Time	Frequency
01/06/2023 03:08 PM	Queued

eate Date	Created By	File				Action
/06/2023 03:09 PM	Leiann Kinder [test.bxk5303]	TB_CONTACT_REPOR	T_EVENTS_8_2	9_2019_PRESENT	test.bxk5303_20230106	150929.html Downloa
					\leq	
						Action
					ol 🥖	Download Belete

Concerns

A Concern is an issue that could affect the event, such as a problem with that record or something important for the user to be aware of (e.g. pregnancy or pediatric patient). There are two types of Concerns in WDRS: system-generated Concerns and user-generated Concerns. A system-generated Concern is automatically generated by WDRS based on rules written into the system and is used to highlight potential data entry issues. A user-generated Concern is created by the user to bring attention to an issue.

Concern are flagged in the Basic Information pane of the Event Summary screen. Details of the Concern are visible on the Concerns tab and it is important to check it regularly.

vent Summary							X
Basic Information				I	Notes (Add/Edit Show	w My Notes)	
Event ID:	105584679						
Disease:	TB disease						
Person:	TB TB Birth Date: 01/13/2	003 (19 yo Male)					
Dates:	Create Date: 10/18/2022						
Type:	Interactive						
Investigation Status:	Active (Change to Closed)						
Linked Events/Contacts:	1 linked event(s)/contact(s) (View)					
Linked Exposure Sites:	0 linked exposure site(s) (View)					
Attachments:	0 attachment(s) (Add)	,					
Notices:	CustomConcerns (1) Issues exist in this rec details.	ord, check the Cor	cerns tab for				
	Workflow Status (1) Event is in workflows [M	iew List]					
	General Notifications (1) Vital Status: Alive						
Edit Event Properties	Copy Event						
Event Data Lab	Results Concerns F	Persons Tasks	Surveys	Calendar	Event Properties	Event History	
6							
Concerns		Decertet	lan	Dereer	Lest Ledate	- Councilia	Status
CONCERN NAANU AL 4	Concern		ION	TETE	Last Opdate	Seventy	Active
MANUALI	CONCERN	Test Col	al Diala	TP TP	01/06/2023	Medium	Active
KISK_FACTORS_RULE	CONCERN	Factors selected "None". in the Ri	ai rosk need to be l or marked Information is isk QP.	16 18	01/03/2023	wedium	Active

Description of fields in the Concerns tab:

Concern Field	Description
Concern	Unique name of the Concern in the database.
Description	Provides a detailed description of the Concern, including information on how to resolve the Concern.
Person	The person about whom the event is based.
Last Update	The date upon which the Concern was last updated. If no updates have been made to the Concern this date is the date the Concern was created.
Severity	Displays the severity level of the Concern (Very Low, Low, Medium, High, Very High).
Status	Refers to the current state of the Concern – either active or resolved.

Adding a User-Generated Concern

To add a user-generated Concern, click the "Add Concern" button on the Concerns tab.

Event Data Lab Res	ults Concerns	Persons	Tasks	Surveys	Calendar	Event Properties	Event	History
Concerns							_	
Concern			Descripti	ion	Person	Last Update		Severity
>MANUAL1			Test Con	cern	TB TB	01/06/2023		Medium
RISK_FACTORS_RULE_CC	DNCERN		Additional Factors in selected "None". I in the Ris	al Risk need to be or marked Information is sk QP.	TB TB	01/03/2023		Medium
Add Concern Update C	Concern							

In the Add Concern screen, a user can set the severity of the Concern. Setting the severity level to "Very High" causes the Concern to display in bright red in the Event Summary section. The status of the Concern can be "Active" or "Resolved." Enter a short description and any additional "Notes" and click the "Save" button to create the Concern. Note: Any user that views this event will see the Concerns you have created.

Resolving Concerns

To resolve a system-generated Concern, simply correct the data entry issue provided in the "Description" field.

To resolve a user-generated Concern, highlight the Concern on the Concerns tab and select "Update Concern."

	Event Data	Lab Results	Concerns	Persons	Tasł
Co	oncerns oncern DATE_VALIDATI	ONS_RULE_INVE	ESTIGATION_	COMPLETE,	_DATE
> N	IANUAL1				
A	dd Concern	Update Concer	n		

Change the status from "Active" to "Resolved." The notes field is available to notate how the Concern was resolved. *Please note: User-generated Concerns remain in the Concerns table even after they have been resolved*.

Troubleshooting

What if I created the wrong event type on accident? (creating a TB disease event when you meant to create a TB contact event, for example)

Please reach out to the <u>DOH TB Program</u> (<u>tbservices@doh.wa.gov</u>) for assistance. This is a common mistake and is easy to resolve when reported quickly.

General Reporting Guidance

Data Security

Data security is an important responsibility shared by CDC, state, and local health programs. Access to data entry software should be restricted to individuals authorized to perform TB surveillance activities. Access to approved data entry software, local databases, and all other electronic surveillance files should be controlled using a local user ID and password.



County case numbers must not include personal identifiers. Do not use names, initials, Social Security numbers, addresses, telephone numbers, or other information that could identify a patient.

To help protect the confidentiality of a person's health information when communicating with DOH or other WDRS users, it is recommended to use either the WDRS Event ID or State Case ID for identifying the event record(s) in question.

Partial Dates

There are several reporting elements that include dates. When entering dates in the RVCT, supply as much known information as possible. If the month and/or day is unknown, enter your best estimate or do the following:

• Some fields have guided specifications for what to enter if a date is unknown. Pay attention to Tooltips whenever they are available for a question.



- If the day is unknown, enter the first day of the known month as the date (e.g., if a case was reported in February 2021, but the exact date is unknown, enter 02/01/2021 as the date reported).
- If the month and day are unknown, enter the first day of the known year as the date (e.g., if the year of report is 2021, but the month is unknown, enter 01/01/2021 as the date reported).

Pending vs. Unknown Information

Leave the item blank if the information requested is pending. If the information may be pending for a longer duration than normal, consider adding a comment to the record to alert other users to the delay.



Answers of 'Unknown' should be used sparingly. **If a diagnostic test was not done, it is preferred to select 'Not done' rather than 'Unknown'.** Unknown should only be selected when the information is truly unknown.

Country Selection Options

Why can't I find South Korea in the list of options?

WDRS uses the CDC reference code list for country selection options. Clarifying text has been added to this reference list in RVCT V3 to assist with locating and differentiating some selection options.

- South Korea is officially known as "Republic of Korea"
- North Korea is officially known as "Democratic People's Republic of Korea"

When a patient reports "Congo" for country, how should it be recorded in RVCT?

If a patient reports "Congo" for a country question, please follow up with the patient to clarify whether they mean the *Republic of Congo* or *Democratic Republic of the Congo*.

• Note that sometimes these are referred to by their capitals, Brazzaville for Republic of the Congo and Kinsasha for Democratic Republic of the Congo.

TB Disease Events

In TB disease events in WDRS, there are two Wizards available to users for convenient data entry; these are the Suspect TB Wizard and the RVCT Wizard. Wizards can be accessed from the **Event Summary** screen by selecting the desired Wizard from the drop down at the bottom of the page, and then selecting "View Wizard":

ent Summary							
one outline y							
Basic Information							
Event ID:	105592	491					
Disease:	TB dise	ase					
Person:	Snow W	/hite ()					
Dates:	Create I	Date: 01/05/202	23				
Туре:	Interact	ive					
Investigation Status:	Active (Change to Clos	sed)				
Linked Events/Contacts:	0 linked	event(s)/conta	ct(s) (View)				
Linked Exposure Sites:	0 linked	exposure site(s) (View)				
Attachments:	0 attach	ment(s) (Add)					
Notices:	Concer Pleas Pleas	ns (2) se fill in sex at se fill in the bir	birth inform th date infor	ation on P mation on	erson screer Person Scre	n. een.	
	Workflo	ow Status (1)	N/Laure L Sault				
	Event		s [View List]				
	Genera	Status: Alivo	(1)				
Event Data Lab	Results	Concerns	Persons	Tasks	Surveys	Calendar	Event Properties
Question Packages							
Question Package						Person	
Administrative						Snow Wh	ite
Demographics						Snow Wh	ite
Risk						Snow Wh	ite
Diagnostics and Evalua	and Evaluation Snow White						
Treatment Snow White							
rreatment	Snow White						
Additional Information						Snow Wh	ite
Additional Information CDC Notification						Snow Wh Snow Wh	ite ite
Additional Information CDC Notification View Question Package	Wizar	rds Report of N	/erified Case	of Tubercu	Ilosis (CDC R	Snow Wh Snow Wh VCT V3 Form	ite ite View Wizard

Users can also choose to open each Question Package and enter data that way, if preferred. In both Wizards and Question Packages, required questions are marked with an asterisk.

Suspect TB Wizard

After a new TB disease event is created, but before the event is confirmed as a verified case of TB, initial event data can be entered through the Suspect TB Wizard tool, if desired. The Suspect TB Wizard includes a minimal subset of information necessary to record and monitor a suspect case until it is verified as TB disease or ruled out. Once a record is verified as TB disease, the RVCT Wizard or individual Question Packages should be used for subsequent data entry.

RVCT Wizard

The "Report of Verified Case of TB (RVCT)" Wizard contains the minimum required reporting variables for CDC reporting of cases of TB disease. Many users find this more convenient for case data entry than using individual Question Packages.

All required questions are marked with an asterisk (*) and also shaded yellow until they are answered. Fields not marked in at least one of these ways are optional and available for documentation if desired.

	Place of Residence	
*	Lived outside of the United States for >2 months (uninterrupted)?	~
*	Has experienced homelessness in the past 12 months 🚹	~
*	Has experienced homelessness ever 🚹	~
*	Resident of correctional facility at diagnostic evaluation	~
*	Resident of correctional facility ever	~
*	Resident of long-term care facility at diagnostic evaluation	~

TB Disease Question Packages

To open a Question Package, double click on the Question Package name or single click to highlight the name and click on the "View Question Package" button at the bottom of the list.

	Event Data	Lab Resi		
Q	estion Packag	es		
Qu	estion Package)		
>A	dministrative			
D	Demographics			
R	Risk			
D	Diagnostics and Evaluation			
Т	Treatment			
A	Additional Information			
C	DC Notification			
V	iew Question Pa	ackage		

Answer questions in order, from the top to bottom of the page. Some questions have additional drop-down questions that may not be visible until you select and answer the question in view.

The following sections provide detailed descriptions and guidance for each question in the TB Disease Question Packages.

Administrative Question Package

*Accountable county

Accountable county is the jurisdiction currently managing the clinical care of the patient with TB disease. This can change over the course of the patient's TB disease treatment if the person moves their home residence to a different jurisdiction.

This field is auto filled based on the <u>reporting address</u> of the patient, as entered when the event is first created, or added after a case is transferred to another jurisdiction. To populate this field, an address entered for the person on record must be selected as the <u>Reporting Address</u>. Whenever possible, the address selected should be the person's home address.

Whenever a case is transferred to another jurisdiction in Washington, please contact <u>tbservices@doh.wa.gov</u> so the record can be shared with the new jurisdiction and Accountable county can be overridden to the new jurisdiction.

Reporting source

Reporting source is the type of facility or provider associated with the source of information sent to Public Health.

This new field has been added as part of the National Notifiable Diseases Surveillance System (NNDSS) Modernization Initiative (NMI). One of the goals of this initiative is to develop interoperable, standardized data collection and exchange mechanisms across notifiable conditions.

Investigator

This field is entered based on the primary data case manager for this record. This can be changed over time if the case manager changes (either within-jurisdiction updates or between-jurisdiction transfers).

Adding an investigator helps the DOH TB Program know who to contact regarding data in the record, and also affects the Workflow titled "TB Events with Investigator of current user."

To find the investigator username, you can search by selecting the magnifying glass icon next to the field:



A separate search window will appear. It is easiest to search by Last Name and/or First Name, and then click the "Search" button. Once you have located the correct name you can select it in the right-hand pane and either double click the name or click the "Select" button.

Search User				
Search Criteria	Search Results			
Last Name: hubber First Name:	Username > JHubber	Full Name Jennifer Hubber		Status Active
Status: Active V Role: V	Showing 1 to 1 of 1 entries		First	Previous 1 Next Last
Group: Search Clear	Select Cancel Help			

What do the selection options mean for "Role" or "Group"?

It is not required to use either of these filter options to search and is often easiest not to use them. If you have a large number of search results and would like to filter on "Role," the selection option of "TB LHJ Investigator" is likely to be the most useful. The selection options for "Group" are based on complex permissions details in the back end of the surveillance system; we recommend not using this filter.

*LHJ notification date

Primary Purpose: The LHJ notification date is used to determine when the health department was first notified that a person may have TB.

Date format	Description	Comment
Month, day, and year (e.g., 01/17/2020)	Date that a health department first thought that the patient may have TB. or	If the month and/or day is unknown, enter your best estimate or do the following: • If the day is unknown enter the
	Date the health department received notification (verbal or written) from a health care provider that a patient might have TB.	 If the day is unknown, enter the first day of the known month as the date reported (e.g., if a case was reported in February 2021, but the exact date is unknown, enter 02/01/2021 date reported). If the month and day are unknown, enter the first day of the known year as the date reported (e.g., if the year of report is 2021, but the month is unknown, enter 01/01/2021 as the date reported). If the patient had a previous
		diagnosis of TB, the LHJ notification date applies to the current TB episode.

Note: If this case is counted by a different jurisdiction, the non-counting jurisdiction should still complete the date they were notified of the case by the counting jurisdiction (e.g., when an interjurisdictional notification from the other reporting area was received).

LHJ notification date based on

Indicate the way in which your LHJ received notification of the case. This question is optional and is not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.
*Verification status (auto-calculated)

This data element is auto-calculated based on diagnostic data entered into the case record, and defaults to 'Suspect' when a TB disease event is first created.

The assignment of case verification follows a hierarchical order:

- Not a verified case
- Positive culture
- Positive nucleic acid amplification (NAA) test
- Clinical case definition
- Provider diagnosis
- Suspect

A record that satisfies the criteria for more than one case verification method will be classified in the verification level that appears first in the hierarchy. For example, a record that meets the criteria for both positive culture and clinical case definition will be classified as being verified by positive culture.



A <u>Case Verification Tool</u> is available both on the TB Partners SharePoint and in <u>Appendix A</u> that outlines the required fields needed in WDRS to meet each case verification category.

What is "Provider Diagnosis"?

In situations where clinical and diagnostic data are not sufficient to otherwise verify the case but based on the provider's clinical judgment they strongly believe a patient to have TB disease, a verification type of "Provider Diagnosis" may be considered.

If the verification status needs to be overwritten to "Provider Diagnosis," please contact <u>tbservices@doh.wa.gov</u> to discuss.

*Countable TB case (LHJ)

When a case is ready to be counted, the accountable LHJ must select 'Yes.' This will send the case to a Workflow managed by the state TB program for further review. Alternatively, if the case will not be counted, select 'No', and specify the reason.

How do I know if a case is countable?

There are some basic rules of case counting:

- Only **verified cases** should be counted (those with a <u>Verification Status</u> other than Suspect or Not a Case)
- If a person did not stay in the United States for at least **90 days**, the case should not be counted.
- Cases are generally counted in the area where the TB diagnostic evaluation was initiated, though there are exceptions.
 - General CDC guidelines on case counting in unique situations are available in <u>Appendix B</u> for reference.
- Disease caused by **any member of the Mycobacterium tuberculosis complex** meets the TB surveillance case definition **except for the BCG strain of M. bovis**. Disease caused by any of the following is potentially countable:
 - o M. tuberculosis
 - M. africanum
 - M. bovis ***EXCEPT BCG strain***
 - o M. canetti
 - o M. caprae
 - $\circ \quad \text{M. microti}$
 - $\circ \quad \text{M. mungi}$
 - \circ M. orygis
 - o M. pinnipedii
 - M. suricattae
- If recurrent TB is diagnosed >12 months after the last dose, the case can be counted.
 - If recurrent TB is diagnosed <12 months after the last dose, the case cannot be counted and would be reported as a 'burden' case. Select for the <u>reason</u> <u>case not countable</u> "Recurrent TB within 12 months after completion of therapy".

If you have questions regarding case counting, please contact <u>tbservices@doh.wa.gov</u> to discuss

*Reason case not countable

Option (select one)	Description	Comment
Verified case: counted by another U.S. reporting area Verified case:	The case has already been counted by another U.S. reporting area such as another state (e.g. transfer). TB case has been	If you select this option, you will also be prompted to enter the State case number in the counting jurisdiction. This number is often included on the interjurisdictional notification (IJN) paperwork you may have received. If you need assistance locating this number, reach out to tbservices@doh.wa.gov. It may be difficult to verify whether a case has
TB treatment initiated in another country	counted by another country and is not a U.S. reporting area.	been counted in another country. If confirmation that the case was counted cannot be obtained, consider the case to have been counted in the other country if the diagnostic evaluation was completed and the patient was prescribed anti- TB medications before arriving in the United States. If you select this option, you will also be prompted to indicate the country that counted the case.
Verified case: Recurrent TB within 12 months after completion of therapy	Recurrence is considered the same TB episode if TB disease recurs within a consecutive 12-month period after the patient completed therapy.	Recurrent cases within 12 months of completion of therapy should be considered noncountable, regardless of whether the initial and subsequent genotypes are the same or different. 12 months refers to 12 consecutive months, not a calendar year. If you select this option, you will also be prompted to enter the Prior state case number for the previous TB episode. If you need assistance locating this number, reach out to <u>tbservices@doh.wa.gov</u> .

Option (select one)	Description	Comment
Not a verified	Case has been	In addition to selecting this option, please do the
case	determined to not be a countable case for a reason not included above. Most often this is because the person was determined to not have TB after further diagnostic evaluation.	 following: Select 'Not TB' for Reason therapy stopped or never started. This will automatically update the Verification status to 'Not TB.' Select 'Yes' for the LHJ close case field. This will remove this record from your Workflows.

U.S. reporting areas include the 50 United States, the District of Columbia, New York City (separate from New York State), five U.S. territories (i.e., Puerto Rico, American Samoa, Guam, Commonwealth of the Northern Mariana Islands, U.S. Virgin Islands), and three freely associated states (i.e., Federated States of Micronesia, Republic of the Marshall Islands, and Republic of Palau). These freely associated states are independent countries but are considered U.S. reporting areas for TB surveillance purposes.

*Countable TB case (completed by DOH)

The DOH TB Program will be notified via a Workflow that a case is ready to be counted and will review the case information. Cases are counted at the beginning of each week if they meet counting requirements as detailed by CDC. The DOH TB Program will contact the listed investigator if further information is needed prior to counting a case.

*Date counted (completed by DOH)

Primary Purpose: Used to determine the approximate date that the state TB program reviewed the RVCT and determined that the case meets the official TB surveillance case definition for reporting to the National Tuberculosis Surveillance System (NTSS).

This is the date that DOH uses in a weekly count to send data to CDC and will be reflected in the CDC MMWR. This date is only for surveillance and reporting purposes and is not clinically relevant to the case.

*Counting county (completed by DOH)

Generally speaking, most TB disease cases are counted by the jurisdiction in which the TB diagnostic evaluation was initiated, but there are <u>exceptions</u>. Counting jurisdiction assignment can be a conversation with the state TB program and involved jurisdictions.

*MMWR week and year (auto-calculated)

These fields are only visible in the back-end data, calculated automatically, and are based on the Date counted. MMWR year is used to determine the year in which the case is included for TB case counts and incidence rates.

For more information on MMWR weeks and how they are used, see link below:

https://ndc.services.cdc.gov/wp-content/uploads/MMWR Week overview.pdf

*State case number (auto-calculated)

Primary Purpose: Used to uniquely identify case reports to facilitate communication between reporting areas and CDC.

The state case number is the official identification number for the case and can be used for communication with the state TB program or other jurisdictions if the person transfers locations.

This field is hidden until both the LHJ and DOH select 'Yes' to officially count the case. When both fields are selected 'Yes,' a state case number auto-generates and the case number will appear.

The state case number, or RVCT number, takes the following format:

4 digit year + state (WA) + nine-character string = state case number

Example: 2022WA123456789

The nine-character string can contain letters or numbers and is assigned by the reporting area. In Washington, this portion of the state case number only contains numbers, but if you are receiving transfers from other states, they may have numbers or letters in this portion of the state case number.

*County case number (optional)

Primary Purpose: Used to uniquely identify case reports to facilitate communication between local health departments, reporting areas, and CDC.

This field is optional and can be used to include a locally-assigned case number if your jurisdiction generates such a number.

County case numbers must not include personal identifiers. Do not use names, initials, Social Security numbers, addresses, telephone numbers, or other information that could identify a patient. A county or local case number may not be assigned to more than one case during a calendar year.

*Reporting address

Primary Purpose: To document the approximate location of the patient's residence for the purpose of geographic analyses.

The reporting address is intended to represent the location of the patient's "usual residence" as described in the Council of State and Territorial Epidemiologists (CSTE) Position Statement 11-SI-04 ("Revised Guidelines for Determining Residency for Disease Notification Purposes") and the previous Position Statement 03-ID-10.

In general, "**usual residence**" is defined as "...the place where the person lives and sleeps most of the time, which is not necessarily the same as the person's voting residence, legal residence, or the place where they became infected with a reportable disease."

In most cases, determining a patient's usual residence is unambiguous; however, there are various scenarios where the determination might not be as straightforward. The table of scenarios in <u>Appendix B</u> presents the more common scenarios for which special guidelines for determining usual residence have been established.

The CSTE Position Statement also established the concept of a "reference point" in time at which the patient's usual residence would be established for surveillance reporting purposes. For the purposes of the RVCT, for consistency with historical practice, the reference point is the date when the TB diagnostic evaluation was initiated.

In cases where determining usual residence is not straightforward and where specific guidelines have not been established, reporting areas should confer with the state TB team to determine the most appropriate reporting address to report on the RVCT.

Populating the reporting address in WDRS:

1. On the Person page, either when initially creating the record or at any point in the data entry process, select "Edit Person".

P	erson Summary		
	Demographic Inform	ation (<u>View History</u>)	
	First Name:	Tester	
	Middle Name:		
	Last Name:	Testerton	
	Suffix:		
	Suffix:		
VDRS TB	Manual		
RVCT field	d **WA-specific fi	eld	

Contact Information	n
Туре	
Home * Primary	

 If no address information has yet been entered, you can enter it in the "Edit Address" section and hit "Save". If an address has already been entered, you can enter an additional address by selecting "Add Address Type"

Addresses	
Туре	Address
> Home	WA
Add Address Type	
Edit Address	
Start Date:	
10/28/2022	
End Date:	
01/01/2030	
Address Type:*	
Home Y	
Street 1:	
Street 1.	
Street 2:	
City: State: Zip Co	de:
WA 🗸	
County: Country:	
✓ USA	~
Survey Email:	
Desidence Trans. Add. Stat	
Residence Type: Address Statu	IS:
► Incomplete ►	
Geocode Status:	
Incomplete Data 🛩	
Save Cancel Help	

3. Navigate back to the TB disease event and click the link for "select reporting address."



4. A pop-up window will appear, listing all addresses that have been entered for this person. Select the most appropriate address from this list by clicking "Select as Official Address."

Available C	ontact Point	s				
Start Date	End Date	Address Type	Address	Residence Type	Address Status	Solact
10/28/2022	01/01/2030	Home	123 Pretend Street Spokane, WA 55555 Spokane County		Incomplete	Select as Official Address
01/01/1900	10/28/2022	Home	WA		Incomplete	Select as Official Address
01/01/1900	01/01/2030	Other	WA			Select as Official Address

5. This will populate the address elements into the event record.

Select reporting address	
Street address	123 Pretend Street
City	Spokane
* Within city limits	~
County	Spokane County
State	WA
Zipcode	55555
Census Tract (11-digit GEOID)	
Country	USA
B 11 .	

How do I enter reporting address if a person is experiencing homelessness?

If a person is experiencing homelessness, enter the City, County, and Zip Code of the shelter or area where the patient was living at the time the TB diagnostic evaluation was initiated. Also indicate "Residence Type" as "Homeless," and make sure to answer the <u>risk factor questions</u> pertaining to homelessness in the Risk Factors section of the RVCT wizard or the Risk Question Package.

City:		State:	Zip Code:	
Pretend City		WA 🗸	55555	
County: Spokane County Survey Email:		Country: USA		
Residence Type:		Addr	ess Status:	
Homeless		Veri	fied ❤	

*Within city limits

This field is a requirement from CDC and must be selected on an individual basis.

How do you classify what is within city limits? What if a patient has a city mailing address but does not technically live within the city limits?

Please report this information when possible. In some situations, this information affects how NTIP reports are generated or how TB funding is allocated. Apply the technical definition of city limits to where the person lives (not the mailing address). For example, if the person resides at a location that is subject to city property taxes (in addition to county and state taxes), that person likely lives within city limits.

What about Tribes whose land is partially in a city?

If the patient lives on land that falls within the city limits (even if Tribal members are exempted from paying city taxes), then "within city limits" = yes.

*Census tract/GEOID

This new data element will populate automatically based on address in the future, though that functionality is not yet available.

Census Tracts are small, relatively permanent statistical subdivisions of a county or statistically equivalent entity that can be updated by local participants prior to each decennial census as part of the Census Bureau's Participant Statistical Areas Program (PSAP). The primary purpose of census tracts is to provide a stable set of geographic units for the presentation of statistical data.

GEOID stands for Geographic Identifier. GEOIDs are numeric codes that uniquely identify all administrative/legal and statistical geographic areas for which the Census Bureau tabulates data. From Alaska, the largest state, to the smallest census block in New York City, every geographic area has a unique GEOID.

What is the rationale for collecting GEOID?

The rationale for collecting GEOID is to increase specificity of geospatial analyses, particularly in the context of genotype cluster detection. Census tracts are also held stable over time, while ZIP codes change boundaries based on the needs of the postal service.

Wouldn't this potentially identify individual TB patients if somebody had these GEOIDs? How is privacy protected (this is especially a concern in rural areas and with Tribal members)?

A census tract is roughly the size of an average city neighborhood, and it is an even bigger area in sparsely populated regions, so it is not a direct identifier. It could be an indirect identifier, but we have multiple indirect identifiers in the National TB Surveillance System (NTSS), which is why the NTSS has an Assurance of Confidentiality to prevent release of information that would permit any individual's identification. CDC has strict data security requirements to prevent inappropriate disclosure of identifiable information.

Is treatment address different than reporting address?

This question is optional and is not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.

Select Yes if the patient is being treated at a different location than the reporting address and select that address location.

Is current address different than reporting address?

This question is optional and is not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.

Select Yes if the patient has moved and is now residing at a different location than the reporting address and select that address location.

Demographics Question Package

*First, middle, last name

Fields autofill from contact names entered on the Person page. To edit name information, return to the Event summary page and select the "Persons" tab. Click the "Edit Person" button to manage information about the patient.

*Country of birth

Primary Purpose: To establish the patient's country of birth for evaluation of epidemiologic trends.

Enter the name of the geographic country in which the person was born (regardless of citizenship).



Do not enter 'United States' unless the person was born in one of the 50 U.S. states or the District of Columbia. Otherwise, specify the name of the U.S. territory, freely associated state, or other non-U.S. reporting area/country.

Why can't I find South Korea in the list of options?

WDRS uses the CDC reference code list for country of birth selection options. Clarifying text has been added to this reference list in RVCT V3 to assist with locating and differentiating some selection options.

- South Korea is officially known as "Republic of Korea"
- North Korea is officially known as "Democratic People's Republic of Korea"

When a patient reports "Congo" as country of birth, how should it be recorded in RVCT?

If a patient reports "Congo" as their country of birth, please follow up with the patient to clarify whether they were born in the *Republic of Congo* or *Democratic Republic of the Congo*.

• Note that sometimes these are referred to by their capitals, Brazzaville for Republic of the Congo and Kinsasha for Democratic Republic of the Congo.

For someone born in Puerto Rico or another U.S. territory, what should be selected for "country of birth?"

Please select the U.S. territory name where the patient was born (i.e., Puerto Rico, American Samoa, Guam, Northern Mariana Islands, or U.S. Virgin Islands). These should all be available in the dropdown menu of selection options.

*Month and year arrived in U.S.

For persons not born in the United States (U.S.), enter the month and year the person first arrived in one of the 50 U.S. states or the District of Columbia. This date should be provided regardless of whether the patient was already a U.S. citizen at the time of first arrival in the United States.

Please note: If month arrived in U.S. is unknown, there is a selection option in the dropdown for 'Unknown'. If Year arrived in U.S. is unknown, enter '1900'.

*Eligible for U.S. citizenship/nationality at birth (regardless of country of birth)

Primary Purpose: To establish the patient's citizenship status at birth for evaluation of epidemiologic trends.

Option (select one)	Description	Comment
Yes	Eligible for U.S. citizenship at birth.	In certain circumstances, a person might be eligible for U.S. citizenship at birth, but the parents must take additional steps to acquire citizenship for their child. More information is available at: <u>https://travel.state.gov/content/travel/en/legal/travel- legal-considerations/us-citizenship/Acquisition-US-</u> <u>Citizenship-Child-Born-Abroad.html</u> .
No	Not eligible for U.S. citizenship at birth.	Answer 'No' if the patient was not eligible for U.S. citizenship at birth, regardless of the patient's current citizenship status.
Unknown	Not known if patient was eligible for U.S. citizenship at birth.	Answer 'Unknown' if it is not known whether the person was eligible for U.S. citizenship at birth.

Why are we collecting this information?

This information is requested because the U.S. Census Bureau bases its "native-born" and "foreign-born" population estimates on this characteristic. As CDC uses the U.S. Census Bureau population estimates as denominator data in calculating incidence rates, this information is needed to correctly categorize people with TB as U.S.-born or non-U.S.-born.

*Country of birth for primary guardian(s)



This question only appears for persons <15 years of age.

Please specify the country of birth for up to two primary guardians.

Who is considered a child's guardian if the pediatric patient was brought into the United States without a traditional guardian (e.g. parent, family member)?

Please try to ascertain the birth country for the child's primary guardian(s) at the child's usual or previous home residence.

Why can't I find South Korea in the list of options?

WDRS uses the CDC reference code list for country of birth selection options. Clarifying text has been added to this reference list in RVCT V3 to assist with locating and differentiating some selection options.

- South Korea is officially known as "Republic of Korea"
- North Korea is officially known as "Democratic People's Republic of Korea"

When a patient or guardian reports "Congo" as guardian country of birth, how should it be recorded in RVCT?

If a patient or guardian reports "Congo" as guardian country of birth, please follow up to clarify whether they were born in the *Republic of Congo* or *Democratic Republic of the Congo*.

• Note that sometimes these are referred to by their capitals, Brazzaville for Republic of the Congo and Kinsasha for Democratic Republic of the Congo.

For someone born in Puerto Rico or another U.S. territory, what should be selected for "country of birth?"

Please select the U.S. territory name where the patient or guardian was born (i.e., Puerto Rico, American Samoa, Guam, Northern Mariana Islands, or U.S. Virgin Islands). These should all be available in the dropdown menu of selection options.

*Country of usual residence

Primary Purpose: To determine whether a patient was a resident of the United States at the time of diagnosis.

Country of usual residence is the country where the patient lives or sleeps most of the time.

Do not enter 'United States' unless the person resides in one of the 50 U.S. states or the District of Columbia. If a person resides in one of the five U.S. territories or other three U.S. reporting areas, name that reporting area.

Country of usual residence: The Council of State and Territorial Epidemiologists (CSTE) recommends that cases of nationally notifiable diseases be reported to CDC by the jurisdiction of the person's "usual residence" at the time of disease onset. For the purposes of the RVCT, for consistency with historical practice, this is defined as the date when the TB diagnostic evaluation was initiated.

The following information has been adapted from CSTE position statement 11-SI-04 ("Revised Guidelines for Determining Residency for Disease Notification Purposes"). In addition, because notifiable disease data are often combined with population data, case notification guidelines based on census residence rules will contribute toward greater consistency in the numerator and denominator data used in disease rates.

Usual residence is defined as the place where the person lives and sleeps most of the time, which is not necessarily the same as the person's voting residence, legal residence, or the place where they became infected with a notifiable disease. Determining usual residence for most people is easy and unambiguous. However, the usual residence for some people is not obvious.

Persons (regardless of citizenship) who have established a household or are part of an established household (i.e., a "usual residence") in the United States should be reported with a country of usual residence of "United States." This includes persons who are in the United States for an extended period for work or study, even if they do not consider the United States to be "home."

Persons (including U.S. citizens) whose established household is outside of the United States (e.g., they are "just visiting" the United States) should be reported with a country of usual residence that is the country where they have established a household.

Persons with established households in more than one country should have country of usual residence determined based on the country where they spent the most time during the year preceding diagnosis.

U.S. reporting areas include the 50 United States, the District of Columbia, New York City (separate from New York State), five U.S. territories (i.e., Puerto Rico, American Samoa, Guam, Commonwealth of the Northern Mariana Islands, U.S. Virgin Islands), and three freely associated states (i.e., Federated States of Micronesia, Republic of the Marshall Islands, and Republic of Palau). These freely associated states are independent countries but are considered U.S. reporting areas for TB surveillance purposes.

Why can't I find South Korea in the list of options?

WDRS uses the CDC reference code list for country selection options. Clarifying text has been added to this reference list in RVCT V3 to assist with locating and differentiating some selection options.

- South Korea is officially known as "Republic of Korea"
- North Korea is officially known as "Democratic People's Republic of Korea"

When a patient reports "Congo" for country of usual residence, how should it be recorded in RVCT?

If a patient reports "Congo" as their country of usual residence, please follow up with the patient to clarify whether they mean the *Republic of Congo* or *Democratic Republic of the Congo*.

• Note that sometimes these are referred to by their capitals, Brazzaville for Republic of the Congo and Kinsasha for Democratic Republic of the Congo.

For someone reporting Puerto Rico or another U.S. territory, what should be selected for "country of usual residence?"

Please select the U.S. territory name where the patient usually resides (i.e., Puerto Rico, American Samoa, Guam, Northern Mariana Islands, or U.S. Virgin Islands). These should all be available in the dropdown menu of selection options.

*Remained in United States for ≥90 days after report date

This question will appear if the answer to Country of usual residence is not a U.S. reporting area. The calculation of 90 days from report date will be done by the system and will appear in the text of the question.

What is the purpose of asking about country of usual residence and length of time in the United States? Any suggestions for how to ask these questions? It feels kind of like asking about immigration indirectly, which might be uncomfortable with some patients.

The purpose of these variables is to confirm whether a person met public health reporting criteria (resident of US or remained in US >= 90 days). This was also added at the recommendation of CSTE. In terms of how to ask about it, asking in a straightforward way can be best in most situations. It's also fine to explain why this is being asked and let someone know that this is for public health reasons and doesn't have any influence on immigration, legal, or other services.

**Preferred language

<u>Chapter 246-101</u> of the Washington Administrative Code (WAC) outlines required information that regulated entities must report with each case of a notifiable condition. In March 2021, the Washington State Board of Health <u>adopted amendments</u> to this chapter. Among the numerous changes is the addition of patient race, ethnicity, and preferred language (REaL) as required data reporting components, along with defined reporting categories for each.

Indicate the language the patient prefers for communication by selecting the search icon and entering for the name of the language.

Pre	ferred	lang	uage

If you are unsure of spelling, you can use the wildcard function; enter the first couple of letters of the word you are searching for followed by an asterisk (e.g. for a search of Burmese you could type bu*), while choosing the Match Type as 'Starts With.' This would pull up all languages that start with 'Bu').

Search Reference Code				
Preferred language				
Search term(s):	bu*			
Match Type:	Starts With 🗸			
Search C	lear			
Buginese				
Bulgarian				
Buriat				
Burmese				
Showing 1 to 4	4 of 4 entries			

Once you have found the language desired, select from the list generated by double clicking on the language or single click on the language and click the "Select" button. You can remove languages with the trash icon next to the window.

Burmese	
~	Clear
~	

Interpreter needed?

This question is optional and is not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.

Marital status

This question is optional and is not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.

* **Ethnicity

Primary Purpose: To establish the patient's ethnicity for evaluation of epidemiologic trends associated with ethnicity.

Option (select one)	CDC Description
Hispanic, Latino/a, Latinx	Patient considers himself or herself Cuban,
	Mexican, Puerto Rican, South or Central
	American, or of other Latin American culture
	or origin, regardless of race.
	Note: Some patients prefer the term
	"Spanish origin" to Hispanic or Latino
Non-Hispanic, Latino/a, Latinx	Patient does not consider himself or herself
	Hispanic or Latino.
Unknown	
**Patient declined to respond	

Washington state updates

<u>Chapter 246-101</u> of the Washington Administrative Code (WAC) outlines required information that regulated entities must report with each case of a notifiable condition. In March 2021, the Washington State Board of Health <u>adopted amendments</u> to this chapter. Among the numerous changes is the addition of patient race, ethnicity, and preferred language (REaL) as required data reporting components, along with defined reporting categories for each. State requirements have been integrated and harmonized with current federal reporting requirements for race and ethnicity for Tuberculosis.

Self-identity or self-reporting

The response to this item should be based on the patient's self-identity or self-reporting. It should not be based on physical appearance or surname.

* **Race

Primary Purpose: To establish the patient's race(s) for evaluation of epidemiologic trends associated with race.

<u>Chapter 246-101</u> of the Washington Administrative Code (WAC) outlines required information that regulated entities must report with each case of a notifiable condition. In March 2021, the Washington State Board of Health <u>adopted amendments</u> to this chapter. Among the numerous changes is the addition of patient race, ethnicity, and preferred language (REaL) as required data reporting components, along with defined reporting categories for each. State requirements have been integrated and harmonized with current federal reporting requirements for race and ethnicity for Tuberculosis.

Race	Patient declined to respond
	Unknown
	American Indian or Alaska Native
	🗆 Asian
	Black or African American
	Native Hawaiian or other Pacific Islander
	White
Specify whether American Indian and/or Alaska Native (required if available)	American Indian
	Alaska Native
Specify Asian (required if available)	~
Specify Native Hawaiian and/or other Pacific Islander (required if available)	~
Additional race(s)	· ·

In order to align with both federal and state reporting requirements for Race, there are several fields available for selecting one or more answers. Please select an answer or answers (select all that apply) based on what the patient self-reports for their race.

Please note these new selection options:

- Patient declined to respond
- Unknown
- Other (under Additional race(s)) can then be further specified in a free text field:

Additional race(s)	Other
Specify	

Self-identity or self-reporting

The response to this item should be based on the patient's self-identity or self-reporting. It should not be based on physical appearance or surname.

*Sex at birth

Primary Purpose: To establish the biological sex recorded for the patient at birth for evaluation of epidemiologic trends.

This field will autofill based on the sex selected on the Person page. It should be entered as the biological sex recorded for the patient at birth.

To edit Sex at birth information, return to the Event Summary page and select the 'Persons' tab. lick the 'Edit Person' button to manage information about the patient.

If you selected 'Other' for Sex at birth on the Person page, you will be prompted to further specify in the event if Sex at birth is best described as 'Other' or 'Unknown.'



*Was patient pregnant at time of diagnostic evaluation

This field is available regardless of the selection for Sex at birth and is required to be answered if Sex at birth is answered 'Female.'

How do we define the timing of the "TB diagnostic evaluation" for determining whether a person was pregnant?

Please use your best judgment. If their last menstrual cycle occurred before they began the medical evaluation that led to their TB diagnosis, and they were subsequently determined to have a positive urine or blood pregnancy test, then the answer is likely yes.

*Did patient move during therapy?

Primary Purpose: To facilitate efficient communication between TB programs in providing continuity of care for the patient.

Option (select one)	Description	
Yes	Patient moved to an area where another reporting area/jurisdiction must now provide or coordinate TB care.	
Νο	Patient did not move, orPatient moved within the same jurisdiction.	

If Yes, specify details about the move(s). Multiple moves can be documented using the "Add New" link:

* Did patient move during therapy?	Yes 🗸	
* Where did patient move? ⊟	Out of state 🗸	Add New

*Where did patient move?

Option (select all that apply)	Description	Comment	
**In state (out of jurisdiction) *Out of state	Patient moved within the state, but out of the local health department jurisdiction, such as moved to different county or city. Enter the county and city to which the patient moved. Patient moved from one U.S. reporting area to another U.S.	After selecting a value for county, city options should appear in the next dropdown. If a city you are looking for does not exist in the dropdown, please let the state TB team know so that field can be updated. U.S. reporting areas include: • The 50 U.S. states • District of Columbia	
	reporting area. For this item, "state" refers specifically to U.S. reporting areas. Moves from state to state within a U.S. reporting area (e.g., Federated States of Micronesia) should not be reported as an "out of state" move. Enter the name of the state or reporting area to which the patient moved.	 New York City (separately from New York State) Puerto Rico U.S. Virgin Islands Guam American Samoa Commonwealth of the Northern Marianas Islands Republic of the Marshall Islands Federated States of Micronesia Republic of Palau 	
*Out of the U.S.	Patient moved from a U.S. reporting area to a country not considered a U.S. reporting area. Enter the name of the country to which the patient moved.	For the purposes of this question, "U.S." refers to all U.S. reporting areas, not just the 50 states and the District of Columbia	

*If moved during treatment, was referral for continuing care completed (e.g. IJN, CureTB transnational referral, etc.)?

Communication between programs is important:

- To help ensure continued case management after a patient leaves their current jurisdiction.
- For completing a case management transfer and obtaining information from TB programs or physicians outside the United States for case completion (if applicable).

Three items have been included below this question to support the referral process when a TB patient transfers jurisdiction:

* If moved during treatment, was referral for continuing care completed (e.g. IJN, CureTB transnational referral, etc.)?
 Link to Interjurisdictional TB Notification (IJN) Forms
 Link to TB Manual Travel and Transfers Chapter
 Please fill in the new address information on the Person Screen



- 1. Link to the Interjurisdictional TB Notification (IJN) forms. (<u>https://www.tbcontrollers.org/resources/interjurisdictional-transfers/</u>)
 - a. NTCA encourages use of the IJN system to promote uninterrupted TB treatment and case management of persons confirmed with or thought to have TB disease; evaluation, testing and treatment of persons identified as close contacts to a person with infectious TB; and evaluation of persons referred by the Centers for Disease Control and Prevention, Division of Global Migration and Quarantine.
 - b. This link will take you to a resource page with links to all applicable forms for this process.



- 2. Link to WA DOH TB Services and Standards Manual chapter on Travel and Transfers.
 - a. This document provides additional details, guidance, and policies regarding jurisdictional transfer of TB records.
 - b. If you are unable to access this document via our TB Partners SharePoint page, contact <u>tbservices@doh.wa.gov</u>.
- 3. Reminder to update this person's address information on the Person Screen in WDRS.



- a. If a record needs to be transferred to another jurisdiction in Washington State, please notify the state TB team (<u>tbservices@doh.wa.gov</u>) so the WDRS record access permissions can be updated.
- b. Please remember to make the WDRS case record as complete as possible before transferring to another jurisdiction.

Date interjurisdictional notification sent

Specify date sent.

*Case meets binational reporting criteria

These selection options parallel the CSTE 2013 statement on inclusion of a binational reporting variable into the generic data set for infectious conditions, and have been tailored to those criteria relevant to Tuberculosis: www.cste.org/resource/resmgr/PS/13-SI-02.pdf

Broader and additional background is provided in these documents:

- Technical Guidelines for United States Mexico Coordination on Public Health Events of Mutual Interest: <u>https://www.cdc.gov/USMexicoHealth/pdf/us-mexico-guidelines.pdf</u>
- Development of a Surveillance Definition for United States Mexico Binational Cases of Tuberculosis: <u>https://pubmed.ncbi.nlm.nih.gov/29570435/</u>

Option (select all that apply)	Description	
Exposure to suspected product from Canada or Mexico	Patient exposed to a product (e.g., dairy product for M. bovis case).	
Has case contacts in or from Mexico or Canada	Patient has case contacts who live in Mexico or Canada.	
Potentially exposed by a resident of Mexico or Canada	Patient was potentially exposed to a person with TB from Mexico or Canada.	
Potentially exposed while in Mexico or Canada	Patient was potentially exposed to TB while physically in Mexico or Canada.	
Resident of Canada or Mexico	The patient is a resident of either Mexico or Canada.	
Other situations that may require binational notification or coordination of response	 Select this option if the case meets one of the following descriptions: The patient crossed the border into the United States from Mexico during TB treatment, or The patient was referred to a U.S-funded, binational TB program for treatment continuity (i.e., a patient who was being treated in the United States, but it was known that they would cross the border to Mexico). 	
No	The case does not meet binational reporting criteria.	
Unknown	It is not known if the case meets binational reporting criteria.	

If a person with TB disease meets more than one of these binational reporting criteria, record additional selections using the "Add New" link:

* Case Meets Binational Reporting Criteria[^] I Has Case Contacts in or From Mexico or Canada

What sort of time frame should be considered for these selection options? For example, if an adult was born in Mexico and has no other risk factors for TB, would that be considered meeting binational reporting criteria?

Please use your best judgment in answering this question. The Council of State and Territorial Epidemiologists asked that we use the same definitions for TB as is used for all other infectious diseases, most of which have much shorter incubation periods. If you believe, based on available epi information (e.g., patient interview, genotyping results) that this patient was plausibly infected while in Mexico/Canada or by somebody from Mexico/Canada, irrespective of timing, then please indicate that selection.

It may help to think about whether an exposure is a "likely scenario" rather than "within the realm of possibilities." For most cases, having been born in Mexico does not necessarily meet the binational criteria, but being born and living in a home for 1 year with a grandparent that had TB before migrating to the US would meet the criteria.

*Birth date

Primary Purpose: To calculate the patient's age at the time of relevant events in the patient's lifetime.

Age at time of case report

Patient's age at the time the LHJ was notified. This field is read-only.

Was patient pediatric at time of case report?

If patient was ≤15 years of age, they are considered pediatric. There are a few fields and functions in WDRS TB events that appear or trigger only for pediatric patients. This field is read-only.

Parent/legal guardian phone number

This question is optional and is not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.

*Status at TB diagnosis

Primary Purpose: To determine if the patient was alive at the time of TB diagnosis.

Option (select one)	Description	Comment
Alive	Patient was alive at time laboratory results confirming a TB diagnosis (e.g., positive culture or nucleic acid amplification [NAA] test result consistent with TB) were known to the provider Or TB medications were started	 If the patient Was known to be culture or NAA test result positive consistent with TB before the date of death, but did not start TB treatment per ATS/CDC/IDSA guidelines, classify the patient as alive at TB diagnosis, or Started empiric therapy for TB disease (per ATS/CDC/IDSA guidelines), but TB was not verified until after the patient's death, classify as alive at TB diagnosis, or Started TB therapy, regardless of laboratory or clinical confirmation for TB diagnosis, classify the patient as alive at TB diagnosis.
Dead	Patient was deceased at the time laboratory results confirming a TB diagnosis (e.g., positive culture, NAA test result consistent with TB) were known to the provider	 If diagnostic specimens were collected for evaluation of TB before death, but positive results to make a diagnosis of TB were not available until after death, and patient did not start TB treatment, classify as dead at TB diagnosis If TB diagnosis was made after death based on a constellation of clinical and other findings (e.g., symptoms, TST, and imaging studies) in the absence of laboratory confirmation, and the patient did not start therapy, classify as dead at TB diagnosis If patient was receiving treatment for latent TB infection at death because the patient was not believed to have TB disease, and TB was diagnosed after death, classify as dead at TB diagnosis If patient was diagnosed with TB at autopsy, classify as dead at TB diagnosis

*Did the patient die (either before diagnosis or at any time while being followed by TB program)?

Option (select one)	Description
Yes	The patient died (for any reason) either before the TB diagnosis was made or at any point after TB diagnosis while the TB program was following the status of the patient, even after treatment completion. If this option is selected, record the date of death.
No	The patient was alive at the time that the TB program stopped following up with the patient.
Unknown	It is unknown whether the patient was alive or dead at the time that the TB program stopped following up with the patient.

Primary Purpose: To collect information on mortality among people with TB

If Yes, indicate whether or not TB or complications of TB treatment contributed to death and enter the date of death.

*Did TB or complications of TB treatment contribute to death?

Option (select one)	Description	Comment
Yes	TB or complications of TB treatment contributed to death.	Written documentation of the cause of death (e.g., death certificate, autopsy report, medical record) is recommended. However, oral information from a reliable source (e.g., a health care provider) will be accepted. A death certificate is not necessarily required to complete this field, and TB does not need to be listed as a cause of death on the death certificate to conclude that the death was TB- related for the purposes of the RVCT.
		It is recommended to have your local health officer review the medical details for any patient with TB who has died, to help inform the answer to this question.

No	TB or complications of TB treatment did not contribute to death.	TB was not the immediate cause, an underlying cause, or another significant condition contributing to death.
Unknown	It is not known if TB or complications of TB treatment contributed to death.	Every effort should be made to determine if the death was related to TB disease before classifying as unknown.

*Date of death

To record date of death, navigate to the Person page and enter this information there. You should then see this appear in a view-only format in the Question Packages and Wizards for the record. A reminder to do this appears in red text when you select Yes for "Did the patient die?"

* Did the patient die (either before diagnosis or at any time while being followed by TB program)?	Yes 🗸
* Did TB or complications of TB treatment contribute to death?^^	~
Date of death	10/13/2022
Please fill in the death date information on Person Screen	



If you have added a date of death to the Person page and are not seeing that populate in the Question packages or Wizards for the record, try selecting "Save & Stay" in the top right corner of the page.



*Has the patient ever worked as one of the following? (select all that apply)

Primary Purpose: To evaluate potential associations between workplace exposures and TB by collecting information about the person's current occupations and industries.

This question appears for all persons regardless of age. For most children, the correct answer will be "none of the above."

Option (select all that apply)	Description
Healthcare worker	Also known as "health care personnel." Paid or unpaid person working in a health care setting.
	Includes volunteers, as well as persons who did not work in direct patient care, such as housekeepers and other support staff, as long as they were also potentially around patients with TB.
Correctional facility employee	Person working in a correctional facility. Persons who have worked as health care personnel within a correctional facility should have both the "Health care worker" box and the "Correctional facility employee" box checked.
Migrant/seasonal worker	Person 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.
None of the above	Select if confirmed that the individual never worked as a health care worker, correctional facility employee, or migrant/seasonal worker.
Unknown	Select only when it cannot be confirmed or denied that the individual ever worked as a health care worker, correctional facility employee, or migrant/seasonal worker.

What defines a volunteer?

If somebody is a volunteer with a recurring commitment or schedule (a "regular volunteer"), please include that work when completing this question. For example, volunteering at most 1 or 2 days per **year** is not an occupation.

Would a travel nurse be considered both a healthcare worker and a migrant/seasonal worker? And what if the travel nurse filled a temporary staffing shortage in a prison infirmary?

Please use your best judgment when answering occupational questions. The definition is broad. In this example, yes, a travel nurse would be considered both a healthcare worker and a migrant/seasonal worker. If the travel nurse was working in a prison infirmary, they would also fulfill the criteria for correctional facility employee.

Do tech workers here on contract count as migrant/seasonal workers?

It would depend on the definition of the contract. For example, if the contract is for 5 years or so, then no. If it is for 6 months, then this could count as a migrant/seasonal worker, or if it is for a specific time each year (say summers, or tax time) then also could count as a migrant/seasonal worker.

Are there other examples of migrant/seasonal workers?

A common example is a seasonal farmworker who works in different areas depending on the crops and type of farm work needed at a given time. However, this could also be related to tourism seasons, such as someone who works at a ski resort during a specific season but returns to a different residence the rest of the year.

*Patient's current occupation(s) and industry(ies)

Primary Purpose: To evaluate potential associations between workplace exposures and TB by collecting information about the person's current occupations and industries.

Occupation and industry questions appear only for persons aged 14 and older.

Enter the patient's current occupation. **Please do not include potentially identifiable information such as the specific name of a business or organization**. Once you enter the patient's current occupation, the field for the patient's current industry will appear.

Because many U.S. adults work multiple jobs, the flexible 'repeating group blocks' allow you to list all the patient's current (or most recent) jobs, whether paid or unpaid. You can add additional occupation/industry pairs by using the 'Add new' link that appears next to this question after an initial answer is entered:

* Patient's Current Occupation(s) (enter one per iteration using the Add New link)^^ 🖂 🖬	Nurse	Add New	-
* Patient's Current Industry 🚹	Hospitals		
Search for examples of industry and occupation here			

There is a red hyperlink included that takes you to a <u>search tool</u> that can be used to help generate ideas both for occupation and industry, as it may not be intuitive to think about a person's job in this way. Suggestions found in this tool include both a free-text option and the standardized code; either can be entered into the occupation and industry fields in WDRS. A training course on how to collect occupation and industry data can be found here: <u>https://rise.articulate.com/share/hVkoDJCSAr7ox4EsJXDiz_I8QP3ROrD9#/</u>.

DTBE will send free-text answers to these fields through a translation engine to standardize them into the NIOSH NIOCCS codes downstream.

What defines a volunteer?

If somebody is a volunteer with a recurring commitment or schedule (a "regular volunteer"), please include that work when completing this question. For example, volunteering at most 1 or 2 days per **year** is not an occupation.

Why are we collecting this information?

The rationale for asking about other occupations was discussed extensively by the RVCT revision workgroups. The Council of State and Territorial Epidemiologists (CSTE) has pushed for occupation and industry to be included with the other demographic characteristics collected with notifiable disease notifications; TB is one of the few nationally reportable conditions that did not already collect occupation/industry. This question can help determine if there are other occupations/industries associated with a higher risk of workplace exposure to TB.

Current occupation is the type of job that the patient has been doing most recently, whether paid or unpaid (volunteer).

Ask this question: "What kind of work do you do? For example, registered nurse, custodian, cashier, auto mechanic, barber, civil engineer, volunteer firefighter, etc."

If the patient has more than one current job, collect information on all of the patient's jobs for entry in the repeating group.

If the patient is unemployed and is not currently seeking employment (e.g., patient is retired, disabled, or a full-time student), do not leave the Current Industry and Current Occupation fields blank; instead enter "unemployed," "disabled," or "student." Include the level of study for students, e.g., "college student" or "high school student."

If he or she works on a voluntary basis, record what they do in the occupation field (e.g., zoo volunteer, school volunteer, library volunteer).

Tips for getting the best information on occupation that can be coded:

- Be descriptive: Clearly describe the kind of work.
 - Unhelpful: "teacher"
 - Helpful: "preschool teacher," "high school teacher"
- Be specific: General or vague terms do not always provide enough information to code.
 - Unhelpful: "laborer"
 - Helpful: "bricklayer"
 - Unhelpful: "worked in a warehouse," "worked in a shipping department"
 - Helpful: "forklift operator"

If the patient is not working because of their TB, but was working prior to getting sick, should that occupation be considered current occupation?

Yes, whatever they were doing before they got sick is their current occupation.

Current industry is the kind of business or industry the patient works in. For each of the patient's current occupations, the corresponding current industry should be reported.

This is **not** the name of the employer, although if the correct industry is not apparent, it is acceptable to enter the name, city, and state of the employer unless the name of the business would be sensitive or potentially identifiable.

Ask this question: "What type of business or industry do you work in? For example, a hospital, dairy farm, restaurant, trade school, library, etc."

Tips for getting the best information on industry that can be coded:

- If industry is not obvious, ask what is the main focus or product of the employer for which the person works. For example, if a patient says they work in manufacturing, ask what was made at the manufacturing plant. For example:
 - Unhelpful: "manufacturing"
 - Helpful: "automobile manufacturing"
- Be specific: General or vague terms do not always provide enough information to coded:
 - Unhelpful: "food industry"
 - Helpful: "restaurant" or "grocery store"

You can use the search tool at <u>https://csams.cdc.gov/nioccs/Default.aspx</u> to determine the NIOCCS categories and codes

Select NIOSH NIOCCS examples:

Occupation	Industry
Volunteer (9020)	Unpaid (9890)
Retired (9060)	Retired (9880)
Students (9070)	Elementary and Secondary Schools (7860)
Students (9070)	Colleges, Universities, and Professional Schools (7870)

If currently employed, specify employer

This question is optional and is not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.

If currently a student, student status

This question is optional and is not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.

Risk Question Package

*Does patient have	e previous	history	of TB	disease?
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History of Previous Illness (select one)	Description
Yes	The patient has a history of previous TB disease diagnoses.
	Note: Written documentation of the previous episode of TB disease is ideal. When written documentation is not available, self-report of a previous episode is acceptable (e.g., medication taken, length of course of medication).
No	The patient did not have previous TB disease diagnoses
Unknown	It is not known if the patient had previous TB disease diagnoses.

If yes, enter the following:

Year of previous diagnosis

Enter year of previous diagnosis. If truly unknown, enter 1900.

Previous state case number

Provide previous TB state case number, if available. Start with year of report date, then the 2letter state abbreviation, and then the within-state case number.



If you need support obtaining this state case number, reach out to the state TB team at <u>tbservices@doh.wa.gov</u>.

Completed treatment

Written documentation of the previous episode of TB disease is preferred. If the patient had a previous episode of TB that was reported to U.S. surveillance, contact the state in which the case was counted to obtain information about previous diagnoses and case outcomes. Otherwise, self-report is acceptable.

For TB disease, multiple prior episodes may be documented using the "Add New" link:

* Does patient have previous history of TB disease?	Yes 🗸	\frown
* Year of previous TB disease diagnosis (yyyy) ⊡	2007	Add New
Previous State Case Number^^		
* Completed TB treatment?^^	~	
*Does patient have previous history of TB infection?

History of Previous Illness (select one)	Description
Yes	The patient has a history of previous LTBI diagnoses.
	Note: Written documentation of the previous episode of LTBI is ideal. When written documentation is not available, self-report of a previous episode is acceptable (e.g., medication taken, length of course of medication).
No	The patient did not have previous LTBI diagnoses
Unknown	It is not known if the patient had previous LTBI diagnoses.

If yes, enter the following:

Year of previous diagnosis

Enter year of previous diagnosis. If truly unknown, enter 1900.

Previous state case number

Provide previous LTBI state case number, if available. Start with year of report date, then the 2letter state abbreviation, and then the within-state case number. If the jurisdiction did not assign state case numbers to LTBI cases, you may still complete the report year and 2-letter state abbreviation.



If you need support obtaining this state case number, reach out to the state TB team at <u>tbservices@doh.wa.gov</u>.

Completed treatment

Written documentation of the previous episode of LTBI is preferred. If the patient had a previous episode of TB that was reported to U.S. surveillance, contact the state in which the case was counted to obtain information about previous diagnoses and case outcomes. Otherwise, self-report is acceptable.

If a class B2 immigrant or refugee is evaluated by the U.S. health department, who repeated the TST or IGRA and determined that they did not have LTBI, how should this question be answered?

The answer to this question depends on whether the patient was diagnosed with LTBI. It should not be based solely on a positive TST or IGRA test result. If no LTBI diagnosis was made, the answer is "no." If the patient was diagnosed with LTBI, the answer is "yes."

*Case identified during the contact investigation of another case

Option (select one)	Description	
Yes	Case was identified during the contact investigation or source case investigation of another case.	
	If Yes, remember to record the state case number for the source case in the <u>epidemiologically-linked cases field</u> !	
No	Case was not identified during the investigation of another case.	
Unknown	It is not known if the case was identified during the investigation of another case.	

If a case/contact was missed during a previous case's contact investigation (like the old RVCT question "Missed contact"), should that be reported here? For example, the person was not mentioned during the previous case's interview and therefore never identified or evaluated.

No. The answer should only be Yes for cases that were prospectively identified (known about) through a contact or source case investigation. The "Missed contact" question is no longer on the RVCT.

Should cases identified during a source case investigation for a child with TB disease or LTBI, or for a healthcare worker with a TST/IGRA conversion be reported here?

Yes. If this case was identified through a source case investigation, answer Yes to this question.

Option (select one)	Description
Yes	Patient was evaluated for TB during that investigation, regardless of whether the patient was diagnosed with TB as part of that evaluation.
No	Patient was not evaluated for TB during that investigation.
Unknown	It is not known if patient was evaluated for TB during that investigation.

What if the patient was named as a contact but only had partial screening for TB during a previous contact investigation? For example, if they had a first TST but did not return for their second TST 8-10 weeks later.

In this example the patient had some amount of *screening* for TB, but they were not fully *evaluated*, so you would select "No" for whether the patient was evaluated for TB during that contact investigation.

History of BCG

This question is optional and is not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.

Previous exposure to TB before this incident

This question is optional and is not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.

*Lived outside of the United States for >2 months (uninterrupted)?

Primary Purpose: To determine the extent to which persons with TB have lived or traveled to countries that might pose a higher risk of TB exposure.

Option (select one)	Description
Yes	Patient indicates that they have lived or traveled outside the United States (1
	of the 50 states or the District of Columbia) for >2 months (uninterrupted).
No	Patient did not live or travel outside the United States (1 of the 50 states or
	the District of Columbia) >2 months (uninterrupted).
Unknown	No information is available about patient's travel history.

Examples:

Answer "Yes," if patient traveled outside the United States and visited multiple countries for a total of more than 2 uninterrupted months.

- From January 1 to March 15, the patient lived outside the United States
- Lived in Zambia for 4 weeks, then
- Lived in South Africa for 3 weeks, then
- Lived in Botswana 3 weeks, then
- Returned to the United States

Answer "No," if patient lived outside the United States for a total of more than 2 months, but travel was interrupted, and had no other international travel during lifetime.

- From January 1 to March 15, the patient lived outside the United States
- Lived in Zambia for 5 weeks, then
- Returned to the United States for 2 weeks, then
- Lived in South Africa for 5 weeks, then
- Returned to the United States

"**Lived**" refers to the place where a person stayed or slept most of the time, or the place the person considered home during the stated period.

What about travel to Puerto Rico or another U.S. territory? That's not "outside the United States," right?

Even though Puerto Rico, American Samoa, Guam, Northern Mariana Islands, and the U.S. Virgin Islands are part of the USA, the definition of the "United States" in this question is limited to the 50 U.S. states and District of Columbia. Therefore, please consider any travel to a U.S. territory to be "travel outside the United States."

Is this question asking if someone lived outside the U.S. for >2 months *since first arrival to the U.S.,* or will this be Yes for most persons born outside the U.S.?

This applies to any time the person lived outside the U.S., not just after initial U.S. arrival. Most people born outside the U.S. will have a "Yes" response to this question.

Specify country of residence (optional)

This specification is optional and is not a federal or state reporting requirement, but may be helpful for LHJ documentation purposes.

More than one country may be entered using the "Add New" link that appears after a selection is made.

* Lived outside of the United States for >2 months (uninterrupted)?	Yes 🗸	\sim
Specify country of residence (optional)	Aland Islands	Add New

*Has experienced homelessness in the past 12 months

Patient has experienced homelessness within the 12 months preceding the TB diagnostic evaluation.

*Has experienced homelessness ever

Patient has ever experienced homelessness.

Homelessness

A person experiencing homelessness 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 person experiencing homelessness 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.

A person experiencing homelessness may be a person who lacks customary and regular access to a conventional dwelling or residence. Included as homeless are persons who live on streets or in nonresidential buildings. Also included are residents of homeless shelters and shelters for battered women. Residents of welfare hotels and single room occupancy hotels could also be considered homeless. In the rural setting, where there are usually few shelters, a homeless person may live in nonresidential structures, or substandard housing, or with relatives. Homelessness does not refer to a person who is incarcerated or in a correctional facility.

For migrants who do not have a stable home, are they considered to be experiencing homelessness?

Any person without a fixed residence, or with unstable housing of uncertain duration, could be considered to be experiencing homelessness.

*Resident of correctional facility at diagnostic evaluation

Patient was incarcerated or detained in a jail, prison, or other detention center when TB diagnostic evaluation was performed or initiated.

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Option (select one)	Description	
Federal	Confinement facility administered by a federal agency (except Immigration	
prison	and Customs Enforcement); includes privately operated federal correctional facilities.	
State prison	Confinement facility administered by a state agency; includes privately operated state correctional facilities.	
Local jail	Confinement facility usually administered by a local law enforcement agency, intended for adults but sometimes also containing juveniles; holds persons detained pending adjudication and/or persons committed after adjudication, typically for sentences of 1 year or less.	
Juvenile	Public or private residential facility; includes juvenile detention centers,	
correctional	reception and diagnostic centers, ranches, camps, farms, boot camps,	
facility	residential treatment centers, and halfway houses or group homes	
	designated specifically for juveniles.	
Other	Includes Immigration and Customs Enforcement (ICE) detention centers, Indian reservation facilities (e.g., tribal jails), military stockades and jails, federal park police facilities, police lockups (temporary holding facilities for persons who have not been formally charged in court), or other correctional facilities that are not included in the other specific choices.	
Unknown	Inmate when the TB diagnostic evaluation was performed, but the type of correctional facility is not known.	

*Type of correctional facility

If the person with TB was a resident of **more than one facility** during the diagnostic evaluation, select the facility where the initial TB diagnostic evaluation was performed.

*Resident of correctional facility ever

Patient has ever been incarcerated or detained in a jail, prison, or other detention center at any point in their lifetime.

How should we report the correctional facility type for a TB patient who is being held in a local jail but is actually in federal custody (such as ICE or the U.S. Marshals Service)?

In this situation, please choose "Local Jail" because the facility itself is administered by the local law enforcement agency. In other words, this RVCT item refers to the type of facility, and not to the legal situation of the TB patient temporarily residing there.

*Resident of long-term care facility <u>at diagnostic evaluation</u>

Patient was a resident of long-term care facility when TB diagnostic evaluation was performed or initiated.

Option (select one)	Description	Comment
Nursing home	Freestanding facility with three or more beds (i.e., is classified as a residential facility or congregate residential setting) that provides nursing care services (e.g., nursing or medical care or supervision of medications that may be self- administered).	Facilities may be certified by Medicare or Medicaid or may be licensed by the state as a nursing home (e.g., skilled nursing facility, intermediate care facility, nursing care unit of a retirement center). This does not include assisted living facilities.
Hospital- based facility	Distinct unit with three or more beds that is physically attached to, or managed by, a hospital.	Facilities may be certified by Medicare or Medicaid or may be licensed by the state.
Residential facility	 Facility with three or more beds (i.e., classified as a residential facility or congregate residential setting) and meets both of the following criteria: 1. Not classified as a nursing home, hospital-based facility, mental health residential facility, or alcohol or drug treatment facility, as described above 	This includes assisted living facilities. This option should only be used for facilities that are not for mental health, treatment, or alcohol or drug treatment.
	 and Provides personal care or supervision (not nursing care services) to its residents, in addition to room and board (e.g., help with bathing, dressing, eating, walking, shopping). 	

*Type of long-term care facility

Mental health residential facility	Facility that provides 24-hour care in a hospital, residential treatment, or supportive setting.	Include state, local, and private psychiatric hospitals, general hospitals, Department of Veterans Affairs facilities, residential mental health treatment centers for children, and multiservice mental health residential treatment programs.
		For other mental health residential facilities, select "Other" long-term care facility. Examples include the Department of Defense, Bureau of Prisons, Public Health Service, Indian Health Service, and Indian reservation facilities.
Alcohol or drug treatment facility	Only long-term rehabilitation or residential facilities designated for treatment of 30 days or longer.	Exclude all ambulatory or outpatient facilities, detoxification units, and facilities designated for fewer than 30 days of treatment. The state agency responsible for alcohol and drug treatment can assist in determining whether a facility is considered residential.
Other	A facility not mentioned above that is designated for treatment of 30 days or longer and facility type is not Unknown.	Select if the type of long-term care facility is something other than the settings listed in this table. Select if the type of long-term care facility is something other than the settings listed in this table.
Unknown	Patient known to be a resident of a long-term care facility, but the type of facility is not known.	Select if the type of long-term care facility is not known.

If the person with TB was a resident of more than one facility during the diagnostic evaluation, select the facility where the initial TB diagnostic evaluation was performed.

*Injecting drug use in the past 12 months

Patient used injection drugs in the past 12 months not prescribed by a health care provider.

Injecting drug use

Injecting drug use involves the use of hypodermic needles and syringes for the injection of drugs not prescribed by a health care provider. Route of administration may be intravenous, subcutaneous (e.g., skin popping), or intramuscular.

*Noninjecting drug use in the past 12 months

Patient used noninjection drugs in the past 12 months not prescribed by a health care provider or approved by FDA for over-the-counter dispensing.

Noninjecting drug use

Marijuana use should always be recorded as noninjecting drug use, regardless of whether marijuana is legal for medicinal or recreational use in the state of residence.

Noninjecting drug use also includes misuse of licensed or prescription drugs, including opioids, or other drugs that were not injected and were not prescribed for the patient by a health care provider or approved for over-the-counter use by FDA. The drugs may be ingested, inhaled, sniffed, or smoked.

For more information, see Substance Abuse and Mental Health Services Administration, SAMHSA, Opioid Overdose Prevention Toolkit, 2018 at https://store.samhsa.gov/sites/default/files/d7/priv/opioid-use-disorder-facts.pdf

*Heavy alcohol use in the past 12 months

Patient heavily used alcohol in the past 12 months.

Heavy alcohol use

The National Institute on Alcohol Abuse and Alcoholism defines heavy alcohol use as binge drinking on 5 or more days in the month preceding diagnosis.

Binge drinking is defined as a pattern of drinking that brings blood alcohol concentration levels to 0.08 g/dL. This typically occurs after four drinks for women and five drinks for men in about 2 hours.

More information available from the National Institute on Alcohol Abuse and Alcoholism: https://www.niaaa.nih.gov/

*Current smoking status at diagnostic evaluation

Primary Purpose: Surveillance and patient management. To assess factors that might complicate testing, treatment, and follow-up.

Option (select one)	Description
Current every day smoker	Patient currently uses tobacco every day.
Current some day smoker	Patient uses tobacco some days, but not every day
Former smoker	Patient has smoked at least 100 cigarettes/cigars in his/her lifetime and has quit.
Never smoker	Patient has not smoked at least 100 cigarettes/cigars in his/her lifetime.
Smoker, current status unknown	Patient was a smoker (or tobacco user), but current status is unknown
Unknown if ever smoked	Patient's tobacco use history is not known.

Smoking

The definition of smoking includes consumption of tobacco (or nicotine) through combustible tobacco products (e.g., cigarettes) or electronic nicotine delivery systems (ENDS; e.g., vapes, e-cigarettes). It does not include chewing tobacco.

Smoking of substances other than tobacco (e.g., marijuana) should be recorded under noninjecting drug use.

Source: U.S. Food and Drug Administration. (2018). Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS). Retrieved from:

https://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm456610.htm

*Diabetic at diagnostic evaluation

Patient had diabetes when TB diagnostic evaluation was performed or initiated.

If Yes, please enter either or both Fasting blood glucose (mg/dL) and/or Hemoglobin A1c (%). At least one Hemoglobin A1c or Fasting blood glucose result should be reported, as close to the time of TB diagnostic evaluation as possible. Subsequent results may be reported but are optional.

* Diabetic at diagnostic evaluation	Yes 🗸
Fasting blood glucose (mg/dL)	
Hemoglobin A1c (%)	

Diabetic

The American Diabetes Association (American Diabetes Association. *Dia Care*. 2014;37:S81-S90) has established the following criteria for a diagnosis of diabetes:

- Hemoglobin A1c ≥6.5%, or
- Fasting (defined as no caloric intake for ≥8 hours) plasma glucose ≥126 mg/dL (7.0 mmol/L), or
- 2-hour plasma glucose ≥200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test, as described by the World Health Organization, **or**
- In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dL (11.1 mmol/L)

Persons who do not meet the above criteria only because they are currently receiving treatment for diabetes should still be reported as diabetic.

Is this question inclusive of type 1 and type 2 diabetes?

The RVCT does not distinguish between Type 1 and Type 2 diabetes, so please report either type of diabetes mellitus

*TNF-a antagonist therapy

Patient recently received, or was receiving, tumor necrosis factor-alpha (TNF- α) antagonist therapy when TB diagnostic evaluation was performed or initiated.

*Post-organ transplantation

Patient has ever received a solid organ transplant (e.g., kidney, heart).

WDRS TB Manual

*RVCT field **WA-specific field

*End stage renal disease

Patient had end-stage renal disease when TB diagnostic evaluation was performed or initiated (e.g., patients on dialysis).

*Viral hepatitis (B or C only)

Patient has ever had a diagnosis of Hepatitis B or C (acute or chronic).

*Other immunocompromise (other than HIV/AIDS)

Patient is immunocompromised because of either a medical condition (e.g., leukemia, Hodgkin's lymphoma, carcinoma of the head or neck), or immunosuppressive therapy, such as prolonged use of high doses of corticosteroids.

*Other risk factors

Additional risk factors as defined by the reporting area may be entered as "Other." The particular risk factor being reports should be identified in the "specify" field. An unlimited number of "other" risk factors may be reported. A Tooltip has been added to this question to provide some examples, but this is not an exhaustive list.





Please note that <u>pregnancy status</u> and <u>HIV</u> are risk factors documented elsewhere in the RVCT and should not be listed here.

Special guidance for unique risk factors:

- If you have an arriver through **Operation Allies Welcome** who is determined to have TB Disease, in the Other risk factors specification field please enter "ALLIESWELCOME."
- If an arriver from Ukraine has an attestation requirement, assume that they are part of the **U4U program**. If you have an arriver through Uniting for Ukraine who is determined to have TB Disease, in the Other risk factors specification field please enter "**U4UKRAINE**."
- If you know a TB patient has or has had SARS-CoV-2 coinfection within 1 year before or after TB report date, in the Other risk factors specification field please enter the term "COVID" followed by an underscore and then the CDC 2019-nCoV ID Number as reported on the patient's COVID-19 case report form. For example "COVID_WA123456." If the CDC 2019-NCoV ID number is not available, please use "UNKNOWN" in place of the ID number after the underscore.

**Contact of MDR TB patient (2 years or less)

Patient for whom the RVCT form is being completed is a contact of a patient with multidrugresistant (MDR) TB, within 2 years or less, regardless of whether the patient with MDR TB was infectious.

**Contact of infectious TB Patient (2 years or less)

Patient for whom the RVCT form is being completed is a contact of an infectious TB patient within 2 years or less.

Patient lived or worked in a country with high prevalence of TB disease in the past 5 years?

This question is optional and is not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.

Medical History (optional)

All of the data elements in this section are optional and available only for your own documentation. None of these data elements transmit to CDC.

Diagnostics and Evaluation Question Package

Date patient presented to health care system

This question is optional and is not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.

*Initial reason the patient was evaluated for TB

Primary Purpose: To ascertain trends in how TB cases come to the attention of the medical or public health establishment.

Select the **single initial reason** the patient was evaluated for TB disease. The definition of "initial reason" is the situation or reason that led to the initial evaluation for TB disease. If the patient was referred for evaluation, but the reason for the evaluation is unknown, try to determine that reason.

Option (select one)	Description	Comment
Contact investigation	A health department investigation to identify persons who had close contact with an infectious TB case. This also includes source case investigations (e.g., to identify the source of TB transmission to a child with TB disease or LTBI).	Select if TB diagnosis was made based on a contact investigation evaluation and testing results from this investigation.
Targeted testing	Positive result of TST or IGRA administered because the patient was specifically considered as high risk for TB (e.g. persons from area of the world with high rate of TB) or as part of a testing program focused on specific groups at risk for TB.	Targeted testing of populations at higher risk for TB not otherwise included in this list. Do not select if another reason is more appropriate.
Healthcare worker	Positive result of TST or IGRA administered because the patient was a health care worker.	Refers to all paid and unpaid persons working in health care settings who have the potential for exposure to <i>M</i> . <i>tuberculosis</i> .

Option (select one)	Description	Comment
Employment/ administrative testing	Results from routine physical examination before or periodically during employment, TST or IGRA required by employer, or primary or secondary school program for routine TST.	Reflects an administrative requirement rather than testing of a group considered at high risk.
Immigration medical exam	Findings of a medical examination that was part of the immigration application process.	A medical examination is mandatory for specific categories of persons seeking admission to the United States. These medical examinations may be performed overseas or in the United States depending on the situation. In addition, a medical examination may be required for some persons applying for nonimmigrant visas or special status (e.g. parolees) for temporary admission to the United States.
TB symptoms	Signs and symptoms consistent with TB (e.g., prolonged persistent cough, fever, lymphadenopathy, night sweats, weight loss).	TB symptoms should only be selected if the patient has TB symptoms at the time of diagnostic evaluation and neither Contact Investigation nor Screening apply to the case. This response is most appropriate when the reason that the patient came to the attention of the medical community was because of the patient's TB symptoms.
Abnormal chest radiograph	Incidental chest radiograph consistent with TB disease.	Reason for the chest radiograph should be independent of the other choices listed and should not have been the result of suspicion of TB disease.

Option (select one)	Description	Comment
Incidental lab result	The clinical evaluation was for something other than TB (e.g. bronchoscopy or autopsy). Specimens were collected and submitted for evaluation of TB and other diseases for diagnostic completeness. TB was not expected.	
Other not included above	Reason that does not fit into any of the above categories.	
Unknown	Reason for evaluating the patient not known.	Select if the reason the person was evaluated for TB is not known.

Example: If a person with TB was initially encountered via a contact investigation and during that investigation was also noted to have TB symptoms, select "**Contact Investigation**" as the initial reason for the evaluation. However, if a patient seeks medical care because of TB symptoms, select "**TB Symptoms**" as the initial reason for the evaluation.

Symptomatic?

Symptom list

These questions are optional and are not a federal or state reporting requirement for TB. You may choose to complete this question for documentation purposes.

*Date of illness onset/symptom start date

Primary Purpose: To establish the approximate symptom start date to facilitate estimation of infectious period¹.

Enter the date signs and symptoms started for this TB episode.

If the month and/or day is unknown, enter your best estimate or do the following:

- If the day is unknown, enter the first day of the known month as the symptom start date (e.g., if symptoms started in March 2020, enter 03/01/2020 as the symptom start date).
- If the month and day are unknown, enter the first day of the known year as the symptom start date (e.g., if symptoms started in 2020, enter 01/01/2020 as the symptom start date).

Some symptoms of TB can be nonspecific. The symptom onset date should be recorded as the approximate time when the patient first noticed any sign or symptom consistent with TB, such as the following:

- Severe cough that lasted at least 3 weeks
- Chest pain not explained by another condition
- Coughing up blood or sputum
- Night sweats
- Persistent fever not explained by another condition
- Unintentional weight loss not explained by another condition

If the patient reports not having experienced TB signs or symptoms, record date of earliest clinical finding consistent with TB disease, such as date of first medical encounter for evaluation of cough or other TB signs or symptoms, or date in medical records that unintentional weight loss was first recorded, or date of first abnormal chest radiograph consistent with TB.



¹ Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis Recommendations from the National Tuberculosis Controllers Association and CDC. MMWR 2005. 54(RR-15):7. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm

Patient hospitalized during current disease episode?

This question and the questions that appear if you select Yes are optional and are not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.

*HIV

Serologic test for human immunodeficiency virus infection. Patient self-report of HIV status is not acceptable. HIV serology results must be documented.

A documented positive test result can be from any date; a negative test result must be documented ≤12 months before the TB diagnostic evaluation.

*CD4 count

This field is available regardless of answer to HIV testing question, and becomes required if person has HIV positive test result reported.

At least one CD4 count should be reported for HIV-positive patients, as close to the time of TB diagnostic evaluation as possible. Subsequent CD4 counts may also be reported.

*TB Lab Results (non-DST)

Always enter initial TST, initial IGRA, initial sputum smear, initial sputum culture, initial NAAT, and initial HIV test. Enter "Not Done" for any tests that were not done.

If a type of test was done on different specimen sources, include the initial result for each unique combination of test type and specimen source.

Follow-up testing should be done according to CDC guidelines and local clinical judgment. For tests that are done multiple times, results for each combination of test type and specimen source where the result changed (e.g., positive to negative) are requested. Any additional results entered are optional.

Test Type	Description	Comment
TST	Tuberculin skin test Also report mm of induration • If mm induration unknown, enter "99"	Routinely reporting TST conversions is highly recommended. In the context of an outbreak, previous negative test results or TST conversions should be captured in the RVCT for outbreak-related cases. If a person has a documented previous negative test result and now has a positive result, record both the previous negative and current positive results.
		Results of the tuberculin skin test (TST) should be interpreted according to Table 7 of the currently accepted guidelines (www.cdc.gov/mmwr/PDF/rr/rr4906.pdf) A patient's undocumented self-report of a previous positive TST result is not acceptable
IGRA	Interferon-gamma release assay Specify test type: • T-Spot • QFT • Unknown	Routinely reporting IGRA conversions is highly recommended. In the context of an outbreak, previous negative test results or IGRA conversions should be captured in the RVCT for outbreak-related cases. If a person has a documented previous negative test result and now has a positive test result, record both the previous negative and current positive results.

Test types

smear specimen using smear qualitative section, select "Positiv	
tachnique results were interpreted by the d	e" if these
lecinique. lesuits were interpreted by the cr	inician
caring for the patient as consister	it with TB.
Soutum Mycobacterial culture of	
culture specimen to determine	
nresence of M tuberculosis	
complex (not nontuberculous	
mycobacteria)	
Smear/ Microscopic examination of When reporting these results in the second se	1e
pathology/ specimen using qualitative section, select "Positiv	e" if these
cytology of histopathological or results were interpreted by the cl	inician
tissue and cytological methods. caring for the patient as consister	it with TB.
other bodily	
fluids Specify type of exam:	
Smear	
Pathology/cytology	
Specify anatomic code	
Culture of Mycobacterial culture of	
tissue and specimen to determine	
other body presence of M. tuberculosis	
fluids complex (not nontuberculous	
mycobacteria).	
Specify anatomic code	
Nucleic acid Nucleic acid amplification When reporting these results in the	1e
amplification testing (only when the qualitative section, select "Positive	e" if these
test (NAAT) specimen is tested directly; results were interpreted by the cl	
do not include results from caring for the patient as consister	it with TB.
tests on isolates obtained via	
culture).	
Specify specimen type:	
Specify specimen type: • Sputum	
Specify specimen type: • Sputum • Other (specify	

Test details

Test detail	Comment
*Date collected	This date can be found on the laboratory report as the date the specimen was collected or TST placed.
or *Date placed	If the month and/or day is unknown, enter your best estimate or do the following:
	 If the day is unknown, enter the first day of the known month as the date collected (e.g., if a specimen was collected in March 2020, enter 03/01/2020 as the date collected). If the month and day are unknown, enter the first day of the known year as the date collected (e.g., if a specimen was collected in 2020, enter 01/01/2020 as the date collected).
Date lab received	This question is optional and is not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.
*Date read or	This date can be found on the laboratory report as the date the report is released or made available.
*Date result reported	In many instances, the result date and report date are the same; if not, provide the earliest date available.
	If the month and/or day is unknown, enter your best estimate or do the following:
	 If the day is unknown, enter the first day of the known month as the date collected (e.g., if a specimen was collected in March 2020, enter 03/01/2020 as the date collected).
	 If the month and day are unknown, enter the first day of the known year as the date collected (e.g., if a specimen was collected in 2020, enter 01/01/2020 as the date collected).
Specimen accession number	This question is optional and is not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.
**Reporting laboratory type	Completion of this field supports holistic program evaluation activities, including retrospective review of laboratory turnaround times to guide future process improvements.
Reporting laboratory	This question is optional and is not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.

Reviewing Electronic Lab Reports (ELR)

Electronic lab results (ELR) do NOT automatically populate TB disease event question packages in WDRS. Electronic and paper labs must be reviewed by the LHJ investigator, and appropriate results manually entered into the RVCT Wizard or Question Packages for the TB disease event in order for that data to be reported to CDC.

There are two Workflows in WDRS that can support your review of electronic lab reports. See the <u>Workflows section of this manual</u> for more details about Workflows in general and criteria for these specific Workflows:

- TB Events with ELR fields to resolve [LHJ]
- TB Events with lab reports for review [LHJ]



Detailed instructions on the general review of Lab Results in WDRS can be found in the "Washington Disease Reporting System Lab Results Instruction Manual."

https://doh.wa.gov/sites/default/files/legacy/Documents/5600/420-231-WDRSLabResultsInstructionManual.pdf

Isolate submitted for genotyping

This field and questions that appear if this question is answered "Yes" will be completed by state TB team staff.

Plain chest X-ray

Primary Purpose: To verify that the case meets the surveillance definition for TB and to identify imaging test characteristics of TB cases.

Standard radiological study resulting in a 2-dimensional projection of internal thoracic structures onto film or a screen.

Minimum requirements: Initial plain chest radiograph. Enter "Not Done" if applicable. Subsequent results should be entered if the result changed.

The minimum requirement is the initial plain chest radiograph or initial chest CT scan result; however, multiple results may be entered. Additional results can be added using the "Add New" link:

* Plain Chest X-Ray ⊟	Normal (including abnormal not consistent w/TB) 🗸	Add New	
* Date chest radiograph done	MM/DD/YYYY		7

Result (select one)	Description
Abnormal (consistent with TB)	Any initial results showing abnormalities (e.g., hilar adenopathy, effusion, infiltrate[s], cavity, scarring) consistent with TB.
Normal (including abnormal not consistent w/TB)	Results showed no abnormalities consistent with TB. This category includes any other abnormalities that are not consistent with TB.
Not done	Used to indicate that a chest radiograph was not done in this case.
Unknown	Result of chest imaging is not known.

What if a patient has an abnormal chest X-ray, but the abnormality is only related to old, healed TB disease?

The "Abnormal (consistent with TB)" response option includes not only current active TB disease but also scarring and calcifications from old TB.

How should a patient with multiple differing test results from different locations (hospitals, clinics) be reported on the RVCT?

If possible, enter all test results. At a minimum, please record a result for chest x-ray and chest CT scan (even if the answer for either of these is "Not Done"). In addition, please record any result where the test result changes from "Not Consistent with TB" to "Consistent with TB".

Evidence of a cavity

Cavity (select one)	Description
Yes	The chest imaging study showed evidence of one or more cavities.
No	Results did not show evidence of one or more cavities.
Unknown	It is not known if results showed evidence of one or more cavities.

Evidence of Miliary TB

Miliary (select one)	Description
Yes	Results showed evidence of miliary disease (e.g., miliary TB, or miliary or bilateral micropodular pattern)
No	Results did not show evidence of miliary disease (e.g., miliary TB, or
	miliary or bilateral micronodular pattern).
Unknown	It is not known if results showed evidence of miliary disease (e.g., miliary TB, or miliary or bilateral micronodular pattern).

Miliary TB is a serious type of TB disease. It is a clinical or radiologic finding, rather than a site of disease. Miliary TB is the result of a TB infection eroding into the bloodstream and from there disseminating throughout the body to multiple organs. It appears on radiographs as a great number of small (1- to 2-mm), well-defined nodules that look like millet seeds scattered throughout the lungs, hence the name "miliary."

CT Scan or other chest imaging

Primary Purpose: To verify that the case meets the surveillance definition for TB and to identify imaging test characteristics of TB cases.

Minimum requirements: Initial CT scan, if applicable. Also include the initial result of any other chest imaging studies performed that are in the test type value set (i.e., MRI, PET). Enter "Not Done" if applicable. Subsequent results should be entered if the result changed.

The minimum requirement is the initial chest imaging result; however, multiple results may be entered. Additional results can be added using the "Add New" link:



Result (select one)	Description
Abnormal (consistent with TB)	Any initial results showing abnormalities (e.g., hilar adenopathy, effusion, infiltrate[s], cavity, scarring) consistent with TB.
Normal (including abnormal not consistent w/TB)	Results showed no abnormalities consistent with TB. This category includes any other abnormalities that are not consistent with TB.
Not done	Used to indicate that CT scan or other chest imaging was not done in this case.
Unknown	Result of chest imaging is not known.

What if a patient has an abnormal chest imaging study, but the abnormality is only related to old, healed TB disease?

The "Abnormal (consistent with TB)" response option includes not only current active TB disease but also scarring and calcifications from old TB.

How should a patient with multiple differing test results from different locations (hospitals, clinics) be reported on the RVCT?

If possible, enter all test results. At a minimum, please record a result for chest x-ray and chest CT scan (even if the answer for either of these is "Not Done"). In addition, please record any result where the test result changes from "Not Consistent with TB" to "Consistent with TB".

Study type

Study type (select all that apply)	Description
CT Scan	Computed tomography, an advanced imaging technique using radiographs to display 3-dimensional images of thoracic structures with computer assistance.
MRI	Magnetic resonance imaging, an advanced imaging technique using strong magnetic fields to display 3-dimensional images of thoracic structures with computer assistance.
PET	Positron emission tomography, an advanced imaging technique that uses radioactive tracers to identify areas of higher chemical activity in the body.
Other	Select this option for imaging studies that do not fit into any of the above categories and specify imaging type.

Evidence of a cavity

Cavity (select one)	Description
Yes	The chest imaging study showed evidence of one or more cavities.
No	Results did not show evidence of one or more cavities.
Unknown	It is not known if results showed evidence of one or more cavities.

Evidence of Miliary TB

Miliary (select one)	Description
Yes	Results showed evidence of miliary disease (e.g., miliary TB, or
	miliary or bilateral micronodular pattern).
No	Results did not show evidence of miliary disease (e.g., miliary TB, or
	miliary or bilateral micronodular pattern).
Unknown	It is not known if results showed evidence of miliary disease (e.g., miliary TB, or miliary or bilateral micronodular pattern).

Miliary TB is a serious type of TB disease. It is a clinical or radiologic finding, rather than a site of disease. Miliary TB is the result of a TB infection eroding into the bloodstream and from there disseminating throughout the body to multiple organs. It appears on radiographs as a great number of small (1- to 2-mm), well-defined nodules that look like millet seeds scattered throughout the lungs, hence the name "miliary."

Site of TB disease (select all that apply)

If there is evidence that more than one organ or disease site is involved, select all sites affected by the TB disease process. Report all anatomic sites of disease considered by the clinician caring for this patient to be involved in the TB disease process; laboratory confirmation is not always possible for all sites of disease.

Option (select all that apply)	Description
Pulmonary	TB disease inside the lung structure
Pleural	TB disease in the pleural space outside the lungs (e.g., pleural effusion)
Lymphatic: cervical	TB disease in the cervical lymph nodes (e.g., scrofula)
Lymphatic:	TB disease in the intrathoracic lymph nodes (e.g., hilar, paratracheal,
intrathoracic	and mediastinal sites of disease)
Lymphatic: axillary	TB disease in the axillary lymph nodes
Lymphatic: other	TB disease in any other lymph nodes
Lymphatic: unknown	TB disease in the lymph nodes, site unknown
Laryngeal	TB disease in the larynx
Bone, joint and/or	TB disease in bones or joints (e.g., Pott's disease, spinal TB,
soft tissue	spondylitis)
Genitourinary	TB disease in the genitourinary system (except for the BCG strain of
	M. bovis, which should not be reported as TB)
Meningeal	TB disease that involves the meningeal space of brain or spinal cord
Peritoneal	TB disease that involves the peritoneum
Other (specify:)	
Site not stated	The anatomic site of disease is not known

The RVCT has no place to select **miliary TB** in Site of Disease. If the report of the initial chest radiograph or the initial chest CT scan indicates "miliary TB or a miliary or bilateral micronodular pattern," record this finding under Plain chest x-ray or CT scan or other chest imaging and enter "Pulmonary" as a Site of Disease.

Sputum culture conversion documented

Option (select one)	Description	Comment
Yes	Initial sputum specimen was	There should be no positive cultures
	culture-positive, followed by at	after the negative culture(s) and no
	least one negative sputum	other positive cultures within the same
	culture (not within initial set of	"set" of sputa (i.e., greater than one
	sputa).	consecutive specimen).
No	Initial sputum specimen was	Examples: all follow-up cultures were
	culture-positive, and no	positive, patient could not produce
	subsequent sputum specimens	sputum after therapy started, or no
	were culture negative.	follow-up sputum cultures were
		obtained.
Unknown	Results of all follow-up cultures	
	are not known, or it is not	
	known whether follow-up	
	cultures were done.	
Not applicable	No positive sputum cultures	Double check laboratory results
	were documented.	entered into the case record to confirm
		no positive sputum culture results have
		been entered by accident.

Primary Purpose: To monitor the rate of sputum culture conversion.

If Yes, enter the date specimen was collected for the FIRST consistently negative sputum culture. If No, select the one best reason for not documenting sputum culture conversion.

Are there rules about minimum number of hours apart, or whether sputum needs to be collected in the morning, to help us decide if a sputum result is valid?

The only requirement for this question is that the negative culture result cannot be part of a "same set of sputa" that also produced a positive culture result.

Please confer with your state mycobacteriology lab and TB medical consultant for local guidance. Typically, specimens should be collected at least 8 hours apart, with at least one being early morning (when the patient is more able to produce sputum).

Date isolate collected for FIRST consistently negative sputum culture

Date of collection for the first consistently negative sputum culture. Complete only for patients who had one or more positive sputum cultures and who subsequently had at least one documented negative culture. A follow-up specimen can be collected at any time after treatment initiation

There should be no positive cultures after this date. If a subsequent culture is positive after an initially documented sputum culture conversion, delete the originally documented date.

If the month and/or day is unknown, enter your best estimate or do the following:

- If the day is unknown, enter the first day of the known month as the date collected (e.g., if a specimen was collected in March 2020, enter 03/01/2020 as the date collected).
- If the month and day are unknown, enter the first day of the known year as the date collected (e.g., if a specimen was collected in 2020, enter 01/01/2020 as the date collected).

Reason for not documenting sputum culture conversion

Option (select one)	Description
No follow-up sputum	Repeat sputum collection was attempted (including induced
despite induction	sputum collection), but because of clinical improvement, patient
	was not able to produce sputani.
No follow-up sputum	Repeat sputum collection was attempted, but induced sputum
and no induction	collection was not attempted and patient was not able to
	produce sputum.
Died	Patient died before having an opportunity to submit sputum to
	document whether the sputum culture had converted.
Patient refused	Patient was lost to follow-up before having an opportunity to
	submit a sputum to document whether the sputum culture had
	converted.
Patient lost to follow-up	Patient refused to provide a sputum specimen for a repeat
	culture.
Other (specify)	A reason not included in the above choices (e.g., treatment failed
	or the patient moved outside the United States).
Unknown	It is not known why a repeat sputum culture was not obtained

Select the one best reason for not documenting sputum culture conversion.

Provide information on sputum culture conversion only for patients with initially positive sputum cultures. Sources for documentation of sputum culture conversion include patient medical records and laboratory reports.

This item should be completed once sputum culture conversion is documented. If the patient's sputum cultures later become positive again, the response to this item should be updated.

Treatment Question Package

*Date therapy started

Primary Purpose: To calculate program management indicators.

Enter the month, day, and year the patient began multidrug therapy for confirmed or possible TB disease. Patient history without medical documentation is not acceptable.

This may be one of several dates; ideally when the patient first ingested medication if documented in a medical record. Enter a date according to the following chart:



If the month and/or day is unknown, enter your best estimate or do the following:

- If the day is unknown, enter the first day of the known month as the date therapy started (e.g., if therapy was started in March 2020, enter 03/01/2020).
- If the month and day are unknown, enter the first day of the known year as the date therapy started (e.g., if therapy was started in 2020, enter 01/01/2020).

What if a patient started 2-drug treatment for LTBI/TB infection, but then had to switch over to a 4-drug regimen for active TB?

Enter the date the patient began taking treatment for suspected or verified TB disease (and not for LTBI).

**Anticipated treatment duration

This field is not a federal reporting requirement, but rather an important communication tool between the state TB team and LHJs. Especially for patients for whom a longer or unique treatment plan is appropriate, selecting an anticipated treatment duration allows state TB epidemiologist staff to target their data reporting completeness review appropriately and not unnecessarily inquire about treatment completion before it is expected. It is understood that this information may change and be updated over time as a TB patient progresses through their treatment process.

Initial drug regimen limited to RIPE/HRZE?

This field is included as a data entry time saver. If a TB patient will only be on a RIPE regimen, and you therefore select the checkbox for Yes, you will only need to complete drug regimen information for Isoniazid, Rifampin, Pyrazinamide, and Ethambutol. If you do not check this box, you will need to complete an answer selection for all drugs listed.

E/HRZE? (RIPE/HF	RZE is Isoniazid, Rifampin, Pyrazinamide and Ethambutol)
	Yes
~	* Isoniazid
~	* Rifampin
~	* Pyrazinamide
~	* Ethambutol
~	
~	-
~	
~	-
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~	
	E/HRZE? (RIPE/HI C (RIPE/HI

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*Initial drug regimen

Primary Purpose: To calculate program management indicators.

For each drug listed below, indicate whether it was used:

Option (select one)	Description
	Drug is known to be part of the initial regimen.
Yes	Yes indicates that the drug was initially prescribed for treatment of TB disease and was taken for at least one day within the first two weeks of therapy.
No	Drug is known to not be part of the initial regimen.
Unknown	It is not known if drug is part of the initial regimen.

Combination drugs

For combination drugs, select "Yes," for each drug that is a component of the combination drug

- Rifamate is a combination of isoniazid and rifampin
- Rifater is a combination of isoniazid, rifampin, and pyrazinamide

Other drugs

For Other, enter only anti-TB drugs. **Do not include pyridoxine, vitamin B6 in this field.**

What if a patient started 2-drug treatment for LTBI/TB infection, but then had to switch over to a 4-drug regimen for active TB?

Enter only the drugs used to treat active TB.

How should one complete this section if no treatment was initiated?

Indicate "No" for all drugs.
*If initial drug regimen NOT RIPE/HRZE, why not?

Primary Purpose: To calculate program management indicators.

This question should only be completed if the standard initial four-drug therapy (RIPE/HRZE, i.e., isoniazid, rifampin, pyrazinamide, and ethambutol) was not used for this patient.

Option (select one)	Description
Drug	There was a pharmacologic contraindication or interaction
contraindication/interaction	that prevented the use of RIPE/HRZE (combination therapy
	with isoniazid, rifampin, pyrazinamide, and ethambutol) in this patient
Drug susceptibility testing	The patient's drug susceptibility results were already known,
results already known	so a treatment regimen based on susceptibility results was
	used immediately.
Suspected drug resistance	Drug susceptibility testing results were not yet available, but
	the provider suspected drug resistance, (e.g., the patient was a
	contact of a drug-resistant TB case), so a different regimen was
	used.
Drug shortage	One or more RIPE/HRZE drugs could not be used because of
	national or local shortage of the drug(s).
Other (specify)	Other reason not covered in one of the provided categories.
Unknown	There is insufficient documentation to determine why a
	regimen other than standard first-line therapy was used.

What if a patient is on a new, CDC-recommended TB disease regimen option?

In this circumstance, select "Other (specify)" and indicate the details.

Drug regimen tracker (optional)

This section is optional and is not a federal or state reporting requirement. Some LHJ partners like to document additional details about start/stop of different drugs, particularly if a TB patient has their regimen change during the course of treatment. Completion of this section is up to the LHJ discretion/preference.

*Date therapy stopped

Primary Purpose: To monitor completion of therapy within a specified time.

Enter the month, day, and year the patient stopped taking medication for confirmed or possible TB disease. Patient history without medical documentation is not acceptable.

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 confirmed or possible TB disease. Although there may be interruptions in TB treatment, enter the final documented date on which the patient last ingested medication for confirmed or possible TB disease.

This may be one of several dates; ideally when the patient last ingested medication. However, if that date is not documented, enter a date according to the following chart:



Remember that recurrent TB is not countable as a new case of TB unless it is diagnosed at least 12 months after the last dose of treatment for the earlier case. If the patient had treatment interruptions or experienced relapse within 12 months and had to restart TB medications, use the last date treatment was ingested.

If the month and/or day is unknown, enter your best estimate or do the following:

- If the day is unknown, enter the first day of the known month as the date therapy stopped (e.g., if therapy was stopped in March 2020, enter 03/01/2020).
- If the month and day are unknown, enter the first day of the known year as the date therapy stopped (e.g., if therapy was stopped in 2020, enter 01/01/2020).

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*Reason therapy stopped or never started

Option (select one)	Description
Completed treatment	Patient completed the prescribed course of therapy per the medical record as recorded by the clinician caring for the patient.
Lost	Patient could not be located before the start or the completion of treatment (e.g., the patient moved to an unknown location, or the forwarding address is known but the patient was not found at that address). Code patients who move outside the United States and cannot be followed up as "Other."
Patient choice (uncooperative or refused)	Patient refused to start or complete therapy (e.g., stopped taking drugs). This option was previously "Uncooperative or Refused."
Adverse treatment event	Therapy was permanently stopped because of an adverse event due to anti-TB medications. Select this option only if the patient survived the adverse event.
	If the patient died because of an adverse TB treatment event, select Died as the reason therapy stopped and note that the death was TB-related in the sub questions for "Did the patient die".
Not TB	Completed diagnostic evaluation did not substantiate the diagnosis of TB (e.g., <i>M. avium</i> or <i>M. bovis</i> BCG was isolated from a clinical specimen).
Died	Patient was alive at diagnosis but died before the start or completion of treatment.
Dying	Treatment was stopped or never started by the clinician or at patient request because the patient's condition was terminal and death was imminent.
Other (specify)	Therapy was discontinued for a known reason not included in the above choices and is not Unknown (e.g., patient moved outside the United States).
Unknown	Reason that therapy was stopped is not known.

*Reason TB disease therapy extended >12 months (select all that apply)

Option (select all that apply)	Description
Inability to use rifampin (resistance, intolerance, etc.)	Rifampin (or another rifamycin such as rifabutin) could not be used to treat the patient (e.g., drug-resistant TB, rifampin intolerance), resulting in the treatment protocol lasting more than 12 months.
	This option includes any medication in the rifamycin family.
Adverse drug reaction	Patient had a significant adverse drug reaction or experienced an adverse treatment event from anti-TB medications (other than a rifamycin) that prolonged therapy.
Nonadherence	There were barriers to the patient's adherence to TB treatment (e.g. treatment interruption), resulting in extension of therapy beyond 12 months.
Failure	A culture tested positive 4 or more months after treatment began, resulting in prolonged therapy.
Clinically indicated other reasons	Clinical indications (other than adverse drug reactions) include central nervous system TB (e.g., meningitis), severe liver disease, or other criteria as specified by the clinician.
Other (specify)	Reason does not include any of the choices listed above. Specify the reason that therapy was extended.
Unknown	Reason is unknown.

Primary Purpose: To document reason for extended treatment and to calculate program indicators.

Sources for the reason(s) therapy was extended include patient medical records, patient interview, and health care provider interview.

Does inability to use rifampin include allergic reactions or discomfort so upsetting that the patient refuses to continue?

Please use the response option "Inability to use rifampin" (as well as any others that apply) if the clinicians caring for this patient document that the rifamycin medication is being discontinued because the medication is unable to be tolerated.

Was original treatment course altered due to drug resistance or adverse events?

This question and its sub questions are optional and are not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.

Option (select all that apply)	Description
DOT	Directly Observed Therapy (DOT), in person. Response applies if DOT was used for any doses for a patient.
EDOT	Electronic DOT (eDOT), via video call or other electronic method. Response applies if eDOT (e.g., video call, electronic medication bottle) was used to document adherence to the medication regimen for any doses.
Self-administered	Any doses of medication were taken by the patient not under DOT or eDOT (including any weekend doses).

*Treatment administration (select all that apply)

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 aide) or other reliable trained person (e.g., worker in a homeless shelter) of a patient's ingestion of medication. Delivering medication to a patient without visual confirmation of ingestion does not constitute DOT. However, electronic confirmation of ingestion of carefully selected patients (e.g., stable and compliant) constitutes electronic DOT.

How should the method of treatment administration be categorized for regimens given by DOT on weekdays and self-administered therapy on weekends?

This new RVCT item allows you to select all the options that apply without having to quantify the number of doses with each method. In the situation described, please mark any doses administered on the weekend or holidays as "self-administered."

*Was phenotypic/growth-based drug susceptibility (DST) testing done?

Primary Purpose: To identify TB cases with drug-resistant isolates using phenotypic/growthbased drug susceptibility testing methods.

Include initial result for all unique combinations of drug tested and specimen type as well as any subsequent tests where the result changed when new test results become available.

Option (select one)	Description
Yes	Growth-based drug susceptibility testing was performed.
No	Growth-based drug susceptibility testing was not performed
Unknown	It is unknown whether growth-based susceptibility testing was performed

Phenotypic/growth-based drug susceptibility testing is performed in tubes or on plates using liquid or solid medium.

Examples of terminology on reports may include:

- MGIT (Mycobacteria Growth Indicator Tube)
- mcg/mL (concentration of drug used in media)
- MIC (Minimum Inhibitory Concentration)
- Growth

See <u>Appendix C</u> for examples of phenotypic/growth-based lab results from various reporting laboratories.

Notes on different test types:

- **MGIT** Mycobacteria Growth Indicator Tube developed by Benton Dickinson (BD), uses liquid broth in tubes to grow MTB.
- Agar proportion Phenotypic DST using solid medium, can be in tubes or microplates, ex. 7H10, 7H11. PZA susceptibility cannot be tested using this method.
- VersaTREK & Sensititre Developed by Thermoscientific, growth-based testing using MIC. Both use liquid medium. VersaTRED is in tubes, Sensititre is in microplates (wells).
- MALDI-TOF mass spectrometry (phenotypic) method to ID MTB.
- **Broth** = liquid medium.

If Yes, enter additional details per specimen tested. After you select Yes, you will be prompted to enter a Specimen collection date. Once you have entered this, additional questions will appear. **Multiple results can be entered using the "Add New" link.**

* Was Phenotypic/Growth-Based Drug Su	Isceptibility Testing Done ²⁰⁰
Specimen collection date E	10/04/2022 Add New
Was only first-line DST done?	□ Yes
Specimen type	✓
Report date	MM/DD/YYYY
* Isoniazid	

Results for Phenotypic/growth-based DSTs are collapsible, and will display collapsed when returning to the record in the future. Expand or collapse results using the + and – boxes next to "Specimen collection date."

* Was Phenotypic/Growth-Based Drug S	susceptibility Testi	ing Done?	Yes	~
Specimen collection date 🗉 🛑	10/04/2022			
Specimen collection date 🗉 🛑	10/05/2022	Add New		
Was only first line DST done?				

Any specimens with **resistant results** reported will appear with a **red exclamation** next to the text that reads "Specimen collection date" when the results are collapsed.

Specimen collection date E	10/04/2022	
Specimen collection date .	10/05/2022	Add New
	0 (1.11) T	() D 011

Should we enter results for specimens that come back as contaminated, so no drug susceptibility testing was able to be performed?

You can enter "unknown" for the initial report of growth-based DST results. Then add new specimens for any subsequent tests where a DST result changed.

If a patient has multiple sites of infection (e.g. respiratory, lymphatic, etc.), should susceptibility results for all sites of infection be reported?

Please include all results if possible; do not just pick one site result to enter. At the very least, please show a DST result for all drugs tested and please show an additional result (and site of collection) for any result that changes from "susceptible" to "Resistant".

*Specimen collection date

Enter the month, day, and year the specimen was collected. If the month and/or day is unknown, enter your best estimate or do the following:

- If the day is unknown, enter the first day of the known month as the date collected (e.g., if a specimen was collected in March 2020, enter 03/01/2020 as the date collected).
- If the month and day are unknown, enter the first day of the known year as the date collected (e.g., if a specimen was collected in 2020, enter 01/01/2020 as the date collected).

*Was only first-line DST done?

This field is included as a data entry time saver for certain situations. If the DST lab report only includes results for Isoniazid, Rifampin, Pyrazinamide, Ethambutol, and Streptomycin, checking this box will shorten the list of drugs for which you need to enter DST results. If you do not check this box, you will need to enter a result for all drugs listed, even if the answer is "Not done."

lone? 🚺		
	Yes	
~	Chaoiman tuna	
MM/DD/YYYY	Specimen type	
~	Report date	MM/DD/YYYY
~	* Isoniazid	~
~	* Rifampin	~
~	* Pyrazinamide	~
· · · · · · · · · · · · · · · · · · ·	* Ethambutol	~
· · · · · · · · · · · · · · · · · · ·	* Streptomycin	~
×		
×		
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	Ione?	Ione? Yes MM/DD/YYYY MM/DD/YYYY Paport date Yational Yational<

*Specimen type

Select appropriate anatomic source site.

*Report date

Enter the month, day, and year the laboratory reported the initial set of results for this specimen. This date can be found on the laboratory report as the date the report is released or made available. In many instances, the result date and report dates are the same, if not, report the earliest date available.

If the month and/or day is unknown, enter your best estimate or do the following:

- If the day is unknown, enter the first day of the known month as the date reported (e.g., if a result was reported in March 2020, enter 03/01/2020 as the date reported).
- If the month and day are unknown, enter the first day of the known year as the date reported (e.g., if a result was reported in 2020, enter 01/01/2020 as the date reported).

As you enter DST results for each drug, a 'Date reported' field for each drug will appear and auto-populate with the value you just entered for the specimen overall. If results for a specific drug were released as an addendum on a different date, you can edit the 'Date reported' to reflect the date you received that particular result.

Report date	10/11/2022		
* Isoniazid	Susceptible 🗸	Date reported	10/11/2022
* Rifampin	Resistant 🗸	Date reported	10/11/2022
* Pyrazinamide	Susceptible 🗸	Date reported	10/13/2022
* Ethombutol			

*DST results

Select a DST result for each drug listed. If no DST testing was done on that drug, select "Not done"

Result options	Description	
Resistant	Any degree of resistance reported for drug	
Susceptible	Select only if completely susceptible	
Not done	DST testing was not done or reported for this drug with this specimen.	
Unknown	• It is not known whether the test was performed, or	
	 Results were not available or result is not known for a reason other than pending results. 	

*Was genotypic/molecular drug susceptibility testing done?

Primary Purpose: Provides information on test results for genetic mutations associated with drug resistance.

This field is optional at this time for LHJ staff.

Include initial result for each combination of gene and test type as well as any subsequent tests where the result changed when new test results become available.

Option (select one)	Description
Yes	Molecular drug susceptibility testing was performed.
No	Molecular drug susceptibility testing was NOT performed.
Unknown	It is not known if molecular drug susceptibility testing was performed.

Genotypic/molecular-based DST is performed by looking for specific mutations at certain locations on the bacterial genome (i.e. locus) that could be a marker for resistance to certain medications.

Examples of terminology/key words on reports may include:

MolecularGenome

- Pyrosequencing
- Sanger Sequencing Method

• Locus

HAIN

Mutation

- GeneXpert
- MDDR (Molecular Detection of Drug Resistance)

See <u>Appendix D</u> for examples of genotypic/molecular DST lab results from various reporting laboratories.

Notes on different test types and details:

- **Pyrosequencing** Molecular testing used for INH/RIF-related mutations at CDC, e.g. MDDR
- **DNA probe** Technique to identify a certain segment of MTB DNA, if on a PHL report this is a culture, other labs may use other types of probes that could be PCR/NAAT or culture.
- Sanger Sequencing Method Molecular testing (genotypic) for mutations that are related to other drugs aside from INH/RIF.
- Hsp65 targeted gene that is on all mycobacteria but is genetically variable between different species so a probe can differentiate one species from another.

If Yes, enter test and result details for each gene tested.

Item	Description	Comment
Gene name	Name of the gene associated with resistance to an anti-TB drug.	See <u>Appendix E</u> for details about each gene in the selection list.
Date collected	Month, day, and year the specimen was collected (e.g., 01/17/2020).	 Each test result should have a date collected. If the month and/or day is unknown, enter your best estimate or do the following: If the day is unknown, enter the first day of the known month as the date collected (e.g., if a specimen was collected in March 2020, enter 03/01/2020 as the date collected). If the month and day are unknown, enter the first day of the known year as the date collected in 2020, enter 01/01/2020 as the date collected).
Date reported	Month, day, and year (mm/dd/yyyy) the laboratory reported the result	 This date can be found on the laboratory report as the date the report is released or made available. If the month and/or day is unknown, enter your best estimate or do the following: If the day is unknown, enter the first day of the known month as the date reported (e.g., if a laboratory result was reported in March 2020, enter 03/01/2020 as the date reported). If the month and day are unknown, enter the first day of the known year as the date reported in March 2020, enter 03/01/2020 as the date reported).
Specimen type	Select appropriate anatomic source site.	

ltem	Description	Comment
Test result	Indicate if mutation was detected, not detected, or unknown.	
Nucleic acid change	For each gene mutation, indicate the nucleic acid (NA) change associated with the mutation as indicated on the laboratory report.	Nucleic acid changes appear only if a mutation has occurred and a sequencing test type was performed.
Amino acid change	For each gene mutation, indicate the amino acid (AA) change associated with the mutation as indicated on the laboratory report.	AA changes appear only if a mutation resulting in a substitution has occurred and a sequencing test type was performed.
Indel	Mark an answer if this information is recorded or noted on the lab report.	If a laboratory reports an insertion or a deletion but reports it as an "indel," mark "Indel (not otherwise specified)."
Test method	See below.	

Test method:

Test type (select one)	Description	Comment
Non-sequencing	 Non-sequencing methods can include: Realtime PCR Line-probe assay Xpert[®] MTB/RIF Xpert[®] MTB/RIF applies only to the rpoB gene associated with rifampin resistance). 	Non-sequencing methods do not usually have nucleic acid or amino acid changes reported on the laboratory report.
Sequencing	 Sequencing methods can include: Pyrosequencing Sanger sequencing Next Generation Sequencing (NGS) Targeted-Based Sequencing Targeted Sequencing Amplicon-Based Sequencing Whole Genome Sequencing (WGS) 	Sequencing methods will usually have nucleic acid or amino acid changes recorded on the laboratory report.
Unknown	The testing method was unknown or not indicated on the laboratory report	

See <u>Appendix F</u> for more detailed information about Genotypic/Molecular drug susceptibility testing.

Should "silent mutations" be reported?

Yes, silent mutation results should be reported. If you have questions about silent mutations, please don't hesitate to reach out to your DTBE Laboratory Branch consultant or the MDDR Service at CDC.

If a patient has multiple sites of infection (e.g. respiratory, lymphatic, etc.), should susceptibility results for all sites of infection be reported?

Please include all results if possible; do not just pick one site result to enter. At the very least, please show a DST result for all drugs tested and please show an additional result (and site of collection) for any result that changes from "susceptible" to "Resistant".

Was the patient treated as an MDR TB case (regardless of DST results)?

Primary Purpose: To determine whether a patient was treated as a multidrug-resistant (MDR) TB case. See <u>Appendix G</u> for more details about drug-resistant TB definitions.

This will include patients:

- Confirmed to have MDR TB through laboratory evidence (growth-based DST or molecular sequencing tests) of resistance to at least isoniazid and rifampin, or
- Presumed to have MDR TB, such as patients whom clinicians believe to have MDR TB despite lack of laboratory evidence (e.g., patients with a clinical diagnosis of TB who are known contacts to an MDR TB case), or
- With **XDR TB** or **pre-XDR TB**.



Do not mark this question as "Yes" if second-line TB drugs were used for reasons other than presumed or confirmed drug resistance (e.g., drug shortage, drug intolerance, interactions, adverse events).

Option (select one)	Description	Comment
Yes	The patient was treated as an MDR TB case at any point during therapy.	All cases believed by the clinician to have MDR TB should have "Yes" entered for this question. Sometimes TB cases are treated as if they were MDR TB, even if laboratory results are not available to confirm the MDR TB diagnosis (e.g., patients with a clinical diagnosis of TB who are a known contact to an MDR TB case, and thus presumed to also have TB).
No	The patient was not treated as an MDR TB case.	
Unknown	It is not known whether the patient was treated as an MDR TB case.	

History of treatment before current episode with second-line TB drugs for the treatment of TB disease (not LTBI)?

Primary Purpose: Case management and surveillance. Data are used to determine if the patient has been previously exposed to second-line TB drugs.

Option (select one)	Description
Yes	Patient was treated with second-line TB medications.
No	Patient has not been treated in the past with second-line TB medications.
Unknown	It is not known whether the patient was previously treated with secondline TB medications.

Often there is no documentation of the patient having been treated in the past if they were treated before arriving in a U.S. reporting area. When documentation is not available, self-report of treatment for a previous episode of MDR TB disease is acceptable. Do not enter a previous diagnosis of, or treatment course for, latent TB infection (LTBI).

Second line TB drugs include all drugs used to treat TB that is resistant to first-line TB drugs (e.g., capreomycin, ethionamide, cycloserine, ciprofloxacin, amikacin).

Date MDR TB therapy started for current episode

Primary Purpose: Programmatic function. Data are used for calculating time from TB diagnosis to start of MDR treatment regimen, overall duration of MDR treatment, and time from MDR treatment start date to culture conversion.

Date the patient first began a drug regimen containing at least 2 second-line drugs.

If the month and/or day is unknown, enter your best estimate or do the following:

- If the day is unknown, enter the first day of the known month as the date MDR treatment started (e.g., if MDR treatment was started in March 2020, enter 03/01/2020 as the date MDR treatment started).
- If the month and day are unknown, enter the first day of the known year as the date MDR treatment started (e.g., if treatment was started in 2020, enter 01/01/2020 as the date MDR treatment started.

Drugs ever used for MDR TB treatment

Primary Purpose: Programmatic function. Data are used for assessing medications that were used as part of a patient's MDR treatment regimen.

Select an option for each drug listed. Medications should be recorded as part of the regimen for the current episode beginning with the MDR TB treatment start date. Duration of therapy is a cumulative time period and does not have to be consecutively given. This accounts for treatment interruptions and temporary or short stoppages in treatment.

Option (select one)	Description
Not used	Drug is/was not part of the MDR TB treatment regimen.
	If a drug was recommended, but never prescribed or taken by the patient, this category should be marked.
<1 month	Drug is/was part of the MDR TB treatment regimen and was taken for less than one month.
≥1 month	Drug is/was part of the MDR TB treatment regimen and was taken for greater than or equal to one month.

What is the definition of <1 month?

You can consider <1 month to consist of 29 or fewer days taking that medication as part of the MDR TB therapy.

Why are INH and RIF listed as options under "Drugs ever used for MDR TB treatment?"

INH and RIF were included among the drugs that could have been used for MDR TB treatment because there are some limited situations in which they would be used, e.g., high-dose INH can be used in some MDR TB cases. If INH or RIF were used in an MDR TB treatment regimen. for whatever reason, the RVCT needs to be able to record that event.

Date injectable medication was stopped (if applicable)

Primary purpose: Programmatic function. Data will be used to determine the duration of injectable medication use in situations where injectables were administered and estimate the intensive phase in situations where applicable.

Date the patient ended the injectable medication (if applicable). If an injectable was started, stopped, and restarted, indicate the last day the injectable was stopped.

If the month and/or day is unknown, enter your best estimate or do the following:

- If the day is unknown, enter the first day of the known month as the date injectable stopped (e.g., if an injectable was stopped in March 2020, enter 03/01/2020 as the date injectable stopped).
- If the month and day are unknown, enter the first day of the known year as the date injectable stopped (e.g., if an injectable was stopped in 2020, enter 01/01/2020 as the date injectable stopped.

If patient did not receive any injectable medications, leave this field blank.

Was surgery performed to treat MDR TB?

Primary purpose: Case management and surveillance function. Data will be used to determine the number of patients needing surgery for MDR TB treatment.

Option (select one)	Description	Comment
Yes	Surgery was performed as part of MDR TB treatment for the current episode of MDR TB.	Biopsy done to diagnose MDR TB is not considered surgery to treat MDR TB. However, excisional biopsy for the treatment of extrapulmonary TB is considered surgical treatment for MDR TB.
Νο	Surgery was not done for the purpose of MDR TB treatment for the current episode of MDR TB.	

If Yes, indicate date the patient had surgery for MDR TB. If the month and/or day is unknown, enter your best estimate or do the following:

- If the day is unknown, enter the first day of the known month as the date of surgery (e.g., if surgery was performed in March 2020, enter 03/01/2020 as the date of surgery).
- If the month and day are unknown, enter the first day of the known year as the date of surgery (e.g., if surgery was performed in 2020, enter 01/01/2020 as the date of surgery.

Side effects

Primary purpose: Case management and surveillance function. Data will be used to determine the nature and number of patients experiencing side effects due to MDR TB treatment.

Side effects potentially related to medications is defined as <u>not existing</u> before MDR TB medication start, but having occurred during treatment.

Option (select one)	Description
Yes	Side effect reported. Side effects should have been reported by the patient or documented in the medical record.
	Side effect that <u>existed</u> before MDR TB medication start but exacerbated by MDR TB treatment leading to a MDR TB medication discontinuation should be recorded as "Yes."
No	Side effect not reported.
Unknown	It is unknown whether the side effect was reported.

If side effect reported, indicate when:

Option (select one)	Description
During	Patient reported side effect only during treatment, (i.e., the side effect
treatment	resolved when treatment was stopped).
At the end of	Patient reported report side effect only at the end of treatment, (i.e., after
treatment	the treatment was stopped).
Both	Patient reported side effect during treatment and at the end.

Side effect	Description
Depression	Prolonged feelings of sadness or dejection, or documentation of
	depression by provider.
Suicide attempt or ideation	Suicidal attempt or ideation (thoughts or attempt to hurt oneself).
Cardiac abnormalities	 QTc >500 ms (confirmed by repeat ECG or documented "prolonged QTc").
	 Clinically significant ventricular arrhythmia.
Hearing loss	 Subjective hearing loss or noticing the need to turn up the volume on phones or TVs
	 Requiring the needs for a hearing aid or intervention
	 Adults: If enrolled in Monitoring Program (on a 1, 2, 3, 4, 6 and 8 kHz audiogram): Threshold shift of 15-25 dB averaged at 3 contiguous test frequencies in at least one ear
	 Pediatric (on a 1, 2, 3, 4, 6 and 8 kHz audiogram): hearing loss sufficient to indicate therapeutic intervention, including hearing aids; threshold shift >20 dB at 3 kHz and above in at least one ear Speech-language related services indicated
Tinnitus	Subjective ringing, buzzing, roaring or clicking sounds in the ears.
Vestibular dysfunction	 Feeling that the world is revolving around the patient (objective vertigo) or the patient is revolving in space (subjective vertigo). Dizziness or imbalance
Perinheral neuronathy	 Dizziness of imbalance. Ecoling of tingling numbross, prossure, cold, and warmth that
	are experienced in the absence of a stimulus
	Usually limited to the extremities
Renal dysfunction	Change in baseline renal function or proteinuria
vision change/loss	Can involve one eye or both eyes
	Change of baseline of vision acuity or color vision
	 Optic nerve damage resulting in worsening vision or blindness not present at baseline
Liver toxicity	 Liver enzyme concentrations exceeding three times the upper limit of normal if associated with symptoms, or
	• Liver enzyme concentrations exceeding five times the upper limit of normal if the patient is asymptomatic
Myalgia	Muscle pain
Arthralgia	Joint pain. Reports of gout, tendonitis, or tendon rupture may also
	be marked here.
Other	Any additional side effects not included above.

Additional Information Question Package

*Contact investigation conducted for this case

Option (select one)	Description
Yes	Contact or source case investigation was conducted for this case. If TB disease or TB infection is identified via this contact investigation, remember to record the state case number for those records in the <u>epidemiologically-</u> <u>linked cases field</u> !
No	A contact investigation was not conducted for this case.
Unknown	It is not known if a contact investigation was conducted for this case.

This item should be answered for all cases, regardless of whether a contact investigation or source case investigation was warranted.

Contact investigations include location-based screenings (e.g., homeless shelter, workplace) after a TB case is identified at that location. This question should be answered "Yes" if a contact investigation was conducted that adequately identified contacts related to this case, even if the investigation was prompted by identification of a different case.

	 NTCA/CDC Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: <u>https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm</u>
	 Washington-specific recommendations for contact investigations can be found in the WA State TB Services and Standards Manual on our TB Partners SharePoint: <u>https://stateofwa.sharepoint.com/sites/DOH-</u> <u>tuberculosispartners/SitePages/TB-Manual.aspx</u>

When we do source case investigations for a child with TB disease, should we answer this question with "Yes" if this case led to our conducting a source case investigation?

Yes.

What if a patient was interviewed for a contact investigation, but did not want to provide names for anyone or stated they had not been anywhere outside the home?

This question should be answered "Yes" if a contact investigation was conducted that *adequately identified contacts*.

Per CDC, some things to consider for adequate contact investigations:

- A minimum of 2 interviews is recommended.
- Interviews should be as comprehensive as possible.
- Directly and indirectly identify contacts and transmission settings.
- Consider congregate settings for transmission, even if named contacts are not provided.
- Appropriately assess and classify contacts based upon risk.

See <u>TB Contact Investigation Guidance</u> for more details.

What if an adequate contact investigation was conducted, but the patient truly had no contacts identified?

Answer "Yes" for the question "Was a contact investigation conducted for this case," and then select "No" for the sub-question asking if contacts were identified.

For patients who are deceased when reported to public health, is it adequate to mark "Yes" for this question if contacts are elicited from a proxy interview of next of kin?

Yes, this is appropriate.

**Contact investigation start date

Enter the date the contact investigation was initiated.

**Were contacts identified?

This field is an important communication tool between the state TB team and LHJs. If a contact investigation was marked as having been done, but no TB contact records are connected to the case in WDRS, state TB epidemiologist staff may reach out to inquire further, unless the LHJ has already indicated that no contacts were identified.

*Please enter state case numbers for all known TB and LTBI cases epidemiologically linked to this case

Primary Purpose: To determine potential transmission links between cases.

Enter state case numbers for any known TB or LTBI records epidemiologically linked to this case. The state case number, or RVCT number, takes the following format:

4 digit year + state + nine-character string = state case number

TB Disease Example: 2022WA123456789

TB Infection Example: 2022WAINF123456

The nine-character string can contain letters or numbers and is assigned by the reporting area.

Additional state case numbers can be added using the "Add New" link:

Please enter state case numbers for all known TB and LTBI cases epidemiologically linked to this case 1 2022WA123456789 Add New

Epidemiologically linked cases might include any previous, concurrent, or subsequent cases to which this case was linked.

If epidemiologically linked cases are later identified, please update the RVCT record.

Epidemiologic link

For this variable, an "epidemiologic link" is defined as either a definite or probable link:

- **Definite**: patients <u>shared airspace</u> at the same location at the same time during one case's estimated infectious period.
- **Probable**: patients <u>shared airspace</u> at the same location during the same general time period, but investigator unable to document that they were there at the same time during one case's infectious period.

How do we enter state case numbers for LTBI/TB Infection records if another state doesn't have one available?

Please complete information to the best of your ability for any TB disease or LTBI in other persons that appears linked to this case (without regard to direction of the potential transmission). If the jurisdiction did not assign state case #s to the linked LTBI cases, please complete the report year and 2-letter state abbreviation.

Please note: all Washington TB infection records have a state case number generated as well. This can be located by navigating to the TB infection record, opening the Administrative Question Package, and locating the field "State infection number."

What is the expectation for the timeline to continue to report epi links?

At a minimum, any cases of TB disease or LTBI that are identified through this patient's contact investigation, or that are identified through the contact or source case investigation of another case should be listed.

Sometimes epidemiologic links are only ascertained after an unexpected matching genotype result, or a few years later when a contact not named during the earlier contact investigation develops TB disease. In such situations, where epi links are determined retrospectively, those RVCT records should be updated, *as resources permit*.

Does epi-linked include genotype links?

If there is no known epi-link between two cases, but there is a genotype match, you do NOT enter these as epi-links in this field. However, if the genotype match leads you to discover an epi-link that was previously not identified, then you would enter them as epilinks in this field.

What if you have two cases that are epi-linked but genotyping shows them to be unrelated, do you enter those in this field?

Yes. If there is an established epi-link between two cases, those would be entered in this field, even if transmission is unlikely based on genotyping information.

Type of insurance

This question is optional and is not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.

Health officer isolation order issued

This question is optional and is not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.

Quarantine station consultation?

This question is optional and is not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.

Overseas CXR available?

This question is optional and is not a federal or state reporting requirement. You may choose to complete this question for documentation purposes.

**LHJ close case

Select yes when the case record has reached an endpoint, has had all appropriate reporting data entered, and you would like it to leave your Workflows. By selecting 'Yes,' a Workflow message is initiated that alerts the state TB Program to review the case for closing.

**DOH close case

The state TB Program will determine if the case content is complete for CDC reporting. The program will reach out to the investigator if there are any further questions before the case can be closed. This field is read-only for LHJ users.

TB Contact Events - Contact Investigation Flowchart



Contacts Identified

<u>All</u> contacts identified in a TB disease case contact investigation need to be entered in WDRS.



- NTCA/CDC Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: <u>https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm</u>
- Washington-specific recommendations for contact investigations can be found in Chapter 11 of the WA State TB Services and Standards Manual on our TB Partners SharePoint: <u>https://stateofwa.sharepoint.com/sites/DOH-</u> <u>tuberculosispartners/SitePages/TB-Manual.aspx</u>

What if I identify a large number of contacts?

If you have a large contact investigation and need assistance with data entry, reach out to the WA DOH TB program at <u>tbservices@doh.wa.gov</u>. There are options available to make the data entry process easier in these situations.

No Contacts Identified

If an adequate contact investigation was conducted, and no contacts were identified, in the TB disease event answer "Yes" for the question "<u>Was a contact investigation conducted for this</u> <u>case</u>," and then select "No" for the sub-question asking if contacts were identified.

* Contact investigation conducted for this case	Yes 🗸
Contact investigation start date	MM/DD/YYYY
Contacts identified	No 🗸

Read more about these fields in the <u>TB Disease Question Packages</u> sections.

Create Linked Contact Events in WDRS

What if I created the wrong event type on accident? (creating a TB disease event when you meant to create a TB contact event, for example)

Please reach out to the <u>DOH TB Program</u> (<u>tbservices@doh.wa.gov</u>) for assistance. This is a common mistake and is easy to resolve when reported quickly.

To view, edit or add event linkages, go to the Event Summary screen of the source case/TB disease record. From the source case's Event Summary screen, click "View" adjacent to Linked Events/Contacts:

Ev	ent Summary	
	Basic Information	
	Event ID:	101557221
	Disease:	TB disease
	Person:	Tester Testerton (Other)
	Dates:	Create Date: 10/11/2022
	Type:	Interactive
	Investigation Status:	Active (Change to Closed)
	Linked Events/Contacts:	0 linked event(s)/contact(s (View)
	Attachments:	0 attachment(s) (Add)

Any existing TB-related events (e.g. cases, contacts, infection) already linked to the source case will be displayed in the Linked Events line list at the top of the screen.

Linked Events - Tester Testerton - TB disease						
Filter Linke Disease: (Apply Filt	ed Events ter Reset I	Filter				
Linked Eve	ents					
Event ID	Full Name	Status	Create Date	Disease	Event Date	
Displaying I	ink(s) 00					

This line list can also be filtered by type of linked event, by selecting the appropriate event type (i.e. TB contact, TB disease, TB infection) from the dropdown list for "Disease:." This line list can also be similarly filtered by "Status:" of the event (i.e. open, closed, deleted). Below this line list, a separate Link Events section allows you to either, (1) create a **new TB contact event** linked to the source case, (2) **link an existing contact event** to the source case, or (3) **link multiple existing contact events** to the source case. The default operation is "Create Linked Event." This can be changed as applicable.

Link Events				
Operation:	Create Linked Event	<u>·</u>		
Disease:	Create Linked Event			Select Person
	Link To Existing Event			
Link Type:	Link To Multiple Events		~	Reset
Relationship:		~		
-	1			

After navigating to the Linked Events/Contacts page for the source case, make the following selections to create a linked contact event:

• Click on "Select Person..." to search WDRS for the person identified as a contact.

Link Events		
Operation:	Create Linked Event 🗸	
Disease:	TB contact 🗸	Select Person
Link Type:	Contact 🗸	Reset
Relationship:	× V	

• Enter personal identifying information (e.g. first and last names, date of birth) into the "Search Criteria" that matches the person identified as a contact.

Search Party				
Search Criteria		Search Results		
Party ID:		Search Results		
Last Name:	Testerton	Full Name	Birth Date	Street Address
First Name:	Tester Jr	> Testerton, Tester Jr 🛛 🔌		
Birth Date: (Inexact)	MM/DD/YYYY	Showing 1 to 1 of 1 entr	es	F
Sex assigned at birth:	~			
City:		Select Cancel	Help	
State:	~			

When searching for a person in WDRS, it is important to avoid missing a match. If your search does not return any clear matches, make your search criteria less specific. Try using the wildcard function for your search (e.g. using Br* to return all names beginning with "Br") or search using Soundex which matches words phonetically (i.e. by pronounced sound). For more detailed information on how to search most effectively in WDRS, please refer to the <u>WDRS Reference Guide</u>.

When the person already exists in WDRS

If you are able to find the person in search results, click on the person name to highlight the correct row, and then click "Select" to auto-fill person information in the Link Events section.

Search Party					
Search Criteria		Search Results			
Party ID:		Search Results			
Last Name:	Testerton	Full Name	-	Birth Date	Street Address
First Name:	Tester Jr	> Testerton, Tester Jr	2		
Birth Date: (Inexact)	MM/DD/YYYY	Showing 1 to 1 of 1	entri	es	F
Sex assigned at birth:	~				
City:		Select Cancel		Help	
State:	~				



If the person already exists in WDRS, double check to make sure that they don't already have a contact event for this contact investigation. If they do, you might be creating a duplicate record.

Scroll to the bottom of the page and click "Save" to create a new, linked contact event.

When the person does not exist in WDRS

If the person identified as a contact does not already exist in WDRS (i.e. is not found in "Search Results"), proceed with creating a new linked contact event by filling out the details on the Link Events page.

• After selecting an existing person or entering their information (if they do not already exist in the system), specify the Link Type. When entering contact investigation records, we recommend selecting "Contact" for this field.

Link Events						
Operation:	Create Linked Event	~				
Disease:	TB contact				~	Select Person
Link Type:	Contact		~			Reset

• Specify the relationship that best describes the linkage.

Operation: Create L Disease: TB contact Link Type: Contact Relationship: Demographics First Name:* Parent	_inked Event 🗸 🗸	•		
Disease: TB contact Link Type: Contact Relationship: Demographics First Name:* Extende Parent				
Link Type: Contact Relationship: Demographics First Name:* Parent	act		~	Select Person
Relationship: Demographics First Name:* Parent		~		Reset
Demographics First Name:* Extende Parent	×	<u>×</u>		
Suffix: Child Suffix: Child Foster C Sibling Birth Date: Spouse MM/DD/YYYY Life Part Alternate Dem Daycare Co-work Care Giv Alias DOB alternate: Housem MM/DD/YYYY Self	ed Family in Child ther e/School/College ker ver	ie: Last Name:*		

 Provide any additional identifying information about the contact in the Demographics, Communication Information and Contact Information sections. Enter information exactly how you would when creating a new WDRS event. After entering identifying information, scroll to the bottom of the screen and click "Save."

What if I don't have the contact's full name and/or date of birth?

Ideally, we would have a full name and date of birth for every contact. This allows us to view history of TB exposure if the contact reemerges with TB infection or disease in the future. However, even if you don't have complete information for a TB contact, they still need to be entered in WDRS. This ensures that documentation of the contact investigation is complete. Using linked events in WDRS, we can determine the number of contacts identified for each case, the percent with TB infection, and if any contacts were determined to have TB disease.

Enter "Unknown" for first or last name if it is truly unknown.

Enter **"01/01/1900"** for DOB if it is truly unknown.

What if I don't have an address for a contact?

It is important to select a reporting address for contact records, as it populates the <u>accountable county field</u>, which in turn determines record access permissions. If you do not have an address for a contact, at least enter your county in the address section when creating the record so you can select the reporting address and populate accountable county.

The newly linked contact event will now display in the Linked Events line-list of the source case. The source case will also appear in the Linked Events line-list of the newly linked TB contact.

Linked Ev	ents - Tester Jr Te	sterton -	TB disease				
Filter Linked	Events						
Disease:					✓ State	atus:	~
Apply Filter	Reset Filter						
Linked Event	ts						
Event ID	Full Name	Status	Create Date	Disease	Event Date	Text1	Туре
101557141	Testerton, Tester Jr	Open	02/26/2023	TB contact	02/26/2023		Contact
Displaying link	k(s) 11						4

Contact Event Required Fields

All required fields are included in the TB Contact Wizard, which can be found in a dropdown on the Event Summary dashboard, below the Question Packages.

Question Packages	
Question Package	
Administrative	
Demographics	
Risk	
Diagnostics and Evaluation	
Treatment	
Additional Information	
View Question Package Wizar	rds View Wi
	TB Contact Wizard

Required fields are marked with an asterisk (*) and highlighted in yellow when they are blank, as displayed below for the disposition field.

		Disposition
* Disposition	~	

Required Fields in TB Contact Events:

\checkmark	Basic demographics ¹	~	Linking case number	\checkmark	Place exposed to TB
\checkmark	Accountable county ²	•	 Eligible for US citizenship Country of hirth 	\checkmark	Screening status ⁴
\checkmark	Contact investigation start	~		\checkmark	TST and IGRA results
	date	 ✓ History of TB disease ✓ History of TB infection 	✓ ✓	CXR results ⁵	
\checkmark	Date contact identified			Final disposition	
\checkmark	Date of last exposure ³	,	Thistory of TB Infection		

1. If known, first, last, date of birth2. Select reporting address3. Unless household contact is indicated4. Not initiated, Initiated but not completed, or Completed5. If TST or IGRA positive

More information on each required field is available in the <u>TB Contact Wizard</u> section.



The <u>TB Data Resources SharePoint</u> page has several quick tip documents for easy reference, including the <u>TB Contact Investigation Data</u> guide which outlines the required fields for contact events in WDRS.

Contact Screening

All exposed contacts identified in a TB contact investigation need to be screened for LTBI and active TB disease. This allows for prompt initiation of treatment which could prevent disease progression and future cases of active TB.

What if I am unable to get in touch with a contact for screening or they refuse?

ALL exposed contacts need to be entered into WDRS, regardless of final disposition. In this instance, you would enter any information that you have, and "lost to follow up" for final disposition. You can also add a note in the record about your attempts to get in contact and/or a refusal; this is optional but can help provide context for the record.

Disposition: Not Infected

To be fully evaluated and dispositioned as not infected, a contact needs two rounds of testing, with **at least one round of testing more than 8 weeks after the date of last exposure**. If a contact is determined to be not infected and all required fields are filled out, no further action is needed. Ensure all testing information is documented in WDRS.

Disposition: Infected

If a contact is determined to have TB infection, an additional TB infection event needs to be created and linked in WDRS.



The <u>TB Data Resources SharePoint</u> page has several quick tip documents for easy reference. See <u>WDRS Quick Tips: Linking Contact/Infection Events</u> for guidance on linking TB Contact and Infection events in WDRS in a quick, printable format for easy future reference.

Copy the contact to a new, linked infection event.

Whenever an existing TB event develops into another TB condition (in this instance a TB contact is diagnosed with TB infection), it is highly recommended to use a **copy** of the existing TB event to create a new event. Doing so will ensure data in the existing event is copied to the new TB event and does not need to be re-entered.

• To use a copy of a TB contact event to create a TB infection event, first return to the Event Summary screen of the TB contact event. Click "Copy Event."

Basic Information	101557141
Evenuid.	
Disease.	TB contact
Person:	Iester Jr Iesterton Birth Date: 01/01/2000 (23 yo Male)
Dates:	Create Date: 02/26/2023
Type:	Interactive
Investigation Status:	Active (Change to Closed)
Linked Events/Contacts:	0 linked event(s)/contact(s) (View)
Attachments:	0 attachment(s) (Add)
Notices:	Workflow Status (1)
	Event is in workflows [View List]
	General Notifications (1) Vital Status: Alive

• A new page will appear with a "Source Event" section at the top that displays basic information about the TB contact event, and then a "Target Event" section below.

Copy Event - Tester Jr Testerton - TB contact			
Source Event			
Event ID:	101557141		
Disease:	TB contact		
Dates:	Create Date: 02/26/2023		
Investigation Status:	Active		
Linked Events/Contacts:	2 linked event(s)/contact(s)		
Linked Exposure Sites:	0 linked exposure site(s)		
Attachments:	0 attachment(s)		
Name:	Tester Jr Testerton		
Sex assigned at birth:	Male		
Birth Date:	01/01/2000		
Social Security Number:			
Address:	WA		
County:	Spokane County		
Country:	USA		
		и	
Target Event			
Copy Mode:	Copy to new event 🗸		
Disease:	TB contact		
Status:	Open 🗸		
Notes:			

• Make the following selections in the "Target Event" section.

Target Event				
Copy Mode:	Copy to new event 🗸			
Disease:	TB infection			
Status:	Open 🗸			
Notes:				
Copy Question Packages:	Additional Information			
	Administrative			
	Demographics			
	Diagnostics and Evaluation			
	✓ Risk			
Copy Fields:	Copy attachments			
	Copy labs			
	Copy concerns (manual only)			
	Copy tasks			
	Copy case notes			
	Copy event links			
Link to Source as:	Disease Progression			
Save Cancel H	elp			

- Copy Mode: Leave the default "Copy to a new event"
- **Disease**: Select "TB infection" if diagnosed with TB infection
- Status: "Open"
- Copy Question Packages: Select the question packages you want copied to the new event. To ensure all question package data in the existing TB contact event is copied to the new TB infection event, select all question packages. Data will only be copied for fields that exist in both TB contact and TB infection records.
- Copy Fields: Select additional information to be copied to the new event.



Always include Copy event links in your selection to ensure any existing linkage(s) to other TB events are also copied over to this event. This will copy over the existing linkage to the corresponding TB Infection event.

- For Link to Source as, select "Disease Progression."
- o Click "Save."

• An Event Summary screen will appear for the new TB infection event created from a copy of the TB contact event. You can enter additional testing and treatment details into the infection record. Required fields are listed in the <u>TB Infection Events</u> section.

Event Summary					
Basic Information					
Event ID:	101557142				
Disease:	TB infection				
Person:	Tester Jr Testerton Birth Date: 01/01/2000 (23 yo Male)				
Dates:	Create Date: 02/26/2023				
Type:	Interactive				
Investigation Status:	Active (Change to Closed)				
Linked Events/Contacts:	2 linked event(s)/contact(s) (View)				
Attachments:	0 attachment(s) (Add)				
Notices:	Workflow Status (1) Event is in workflows [View List]				
	General Notifications (1) Vital Status: Alive				
Edit Event Properties	Copy Event				
Disposition: TB Disease

If a contact is determined to have TB disease, an additional TB disease event needs to be created and linked in WDRS.

Copy the contact to a new, linked disease event.

Whenever an existing TB event develops into another TB condition (in this instance a TB contact is diagnosed with TB disease), it is highly recommended to use a copy of the existing TB event to create a new event. Doing so will ensure data in the existing event is copied to the new TB event and does not need to be re-entered.

• To use a copy of a TB contact event to create a TB disease event, first return to the Event Summary screen of the TB contact event. Click "Copy Event."

event Summary	
Basic Information	
Event ID:	101557141
Disease:	TB contact
Person:	Tester Jr Testerton Birth Date: 01/01/2000 (23 yo Male)
Dates:	Create Date: 02/26/2023
Type:	Interactive
Investigation Status:	Active (Change to Closed)
Linked Events/Contacts:	0 linked event(s)/contact(s) (View)
Attachments:	0 attachment(s) (Add)
Notices:	Workflow Status (1) Event is in workflows [View List]
	General Notifications (1) Vital Status: Alive
Edit Event Properties	Copy Event

• A new page will appear with a "Source Event" section at the top that displays basic information about the TB contact event, and then a "Target Event" section below.

Copy Event - Tester Jr Testerton - TB contact			
Source Event	0 T		
Event ID:	101557141		
Disease:	TB contact		
Disease.	Create Date: 02/26/2023		
Investigation Status:	Active		
Linked Events/Contacts:	2 linked event(s)/contact(s)		
Linked Evens/contacts.	0 linked exposure site(s)		
Attachmonts	0 attachment(s)		
Namo:	Tester Ir Testerton		
Sev assigned at hirth:	Malo		
Birth Date:	01/01/2000		
Social Security Number:	01/01/2000		
Addrose:			
County:	Spokane County		
Country:			
Country.	USA		
Target Event			
Copy Mode:	Copy to new event 🗸		
Disease:	TB contact		
Status:	Open 🗸		
Notes:	2		

• Make the following selections in the "Target Event" section.

Target Event	
Copy Mode:	Copy to new event 🗸
Disease:	TB disease
Status:	Open 🗸
Notes:	
Copy Question Packages:	 Additional Information Administrative Demographics Diagnostics and Evaluation Risk
Copy Fields:	 Copy attachments Copy labs Copy concerns (manual only) Copy tasks Copy case notes Copy event links
Link to Source as:	Disease Progression
Save Cancel He	əlp

- **Copy Mode**: Leave the default "Copy to a new event"
- **Disease**: Select "TB disease" if diagnosed with active TB disease
- o Status: "Open"
- Copy Question Packages: Select the question packages you want copied to the new event. To ensure all question package data in the existing TB contact event is copied to the new TB infection event, select all question packages. Data will only be copied for fields that exist in both TB contact and TB infection records.
- Copy Fields: Select additional information to be copied to the new event.



Always include Copy event links in your selection to ensure any existing linkage(s) to other TB events are also copied over to this event. This will copy over the existing linkage to the corresponding TB Infection event.

- o For Link to Source as, select "Disease Progression."
- Click "Save."

 An Event Summary screen will appear for the new TB disease event created from a copy of the TB contact event. You can then enter additional testing and treatment details into the disease record. Required fields for TB disease events are listed in the <u>TB Disease</u> <u>Events</u> section.

Event Summary	
Basic Information	
Event ID:	101557362
Disease:	TB disease
Person:	Tester Jr Testerton Birth Date: 01/01/2000 (23 yo Male)
Dates:	Create Date: 09/08/2023
Type:	Interactive
Investigation Status:	Active (Change to Closed)
Linked Events/Contacts:	2 linked event(s)/contact(s) (View)
Attachments:	0 attachment(s) (Add)
Notices:	General Notifications (1) Vital Status: Alive
Edit Event Properties	Copy Event

Disposition: Prior or Coincidental TB

If a contact is determined to have prior or coincidental TB and does not need further treatment. This is a clinical decision made by a medical provider, including review of prior diagnosis and treatment documentation.

Disposition: Lost to Follow-Up

If a contact is unable to be reached for testing OR refuses testing.

Disposition: Unknown

This disposition is rarely used. Communicate with the DOH TB program (<u>tbservices@doh.wa.gov</u>) if you think this disposition is appropriate for a contact.

Closing a Contact Event

Once you are done entering data in a contact event in WDRS, select "Yes" for the <u>LHJ close case</u> field at the bottom of the <u>TB Contact Wizard</u> and the record will leave your workflows. This indicates that you are finished with the record and all data has been entered. The DOH TB program will reach out for any clarification or if there are any additional data points that are needed.

* LHJ close case	~
Comments	Yes

FAQs

Cross-Jurisdictional Contacts

Cross-jurisdictional contacts are contacts identified by one jurisdiction but screened by a different jurisdiction. This most frequently occurs when a contact resides in a different jurisdiction than the case.



Reference the <u>Cross Jurisdictional Contacts quick-guide</u> available on the <u>Data</u> <u>Resources SharePoint</u> page.



The LHJ that <u>identified</u> the contact is responsible for creating a contact record in WDRS, even if the contact lives in another jurisdiction.



The LHJ where the contact <u>resides</u> is responsible for screening the contact and entering all screening and clinical evaluation data into WDRS, unless the contact resides out of state.

If the contact lives in another Washington county:

- 1. The WDRS contact event is created by the LHJ that identifies the contact. Fill out as much information as possible, including demographics, address and phone information, and known epidemiologic linkages including the source case to which this person was exposed.
- The LHJ that created the event reaches out to the WA state TB Program (<u>tbservices@doh.wa.gov</u>) to share the event in WDRS with the LHJ where the contact lives.

- 3. The LHJ that created the event contacts the LHJ where the contact lives to notify that a contact has been identified in their jurisdiction.
- 4. The LHJ where the contact lives enters additional data directly into WDRS.
- 5. The LHJ where the contact resides will be the accountable county in WDRS, and they are responsible for entering screening and clinical evaluation data in WDRS.



If the contact lives outside of Washington State:

- 1. A WDRS contact event is created by the LHJ that identifies the contact. This LHJ is also responsible for completing an interjurisdictional notification and entering screening and clinical evaluation data received from the out of state jurisdiction into WDRS.
- 2. The LHJ that identifies the contact and enters the follow-up data in WDRS will be the accountable county in WDRS.

Linking Existing Contact Event(s) to the Source Case

If a contact event is not created through the recommended pathway (<u>Create Linked Contacts</u> <u>Events in WDRS</u>), the contact event will not be automatically linked to the corresponding TB disease event and a linkage will need to be made manually.

To view, edit or add event linkages, go to the Event Summary screen of the source case/TB disease record. From the source case's Event Summary screen, click "View" adjacent to Linked Events/Contacts:

vent Summary	
Basic Information	
Event ID:	101557221
Disease:	TB disease
Person:	Tester Testerton (Other)
Dates:	Create Date: 10/11/2022
Type:	Interactive
Investigation Status:	Active (Change to Closed)
Linked Events/Contacts:	0 linked event(s)/contact(s) (View)
Attachments:	0 attachment(s) (Add)

Any existing TB-related events (e.g. cases, contacts, infection) already linked to the source case will be displayed in the Linked Events line list at the top of the screen.

Linked Events - Tester Testerton - TB disease						
Filter Linked Events Disease:						
Apply Filter Reset Filter						
Linked Eve	ents					
Event ID	Full Name	Status	Create Date	Disease	Event Date	
Displaying link(s) 00						

This line list can also be filtered by type of linked event, by selecting the appropriate event type (i.e. TB contact, TB disease, TB infection) from the dropdown list for "Disease:." This line list can also be similarly filtered by "Status:" of the event (i.e. open, closed, deleted).

Below this line list, a separate Link Events section allows you to either, (1) create a **new TB contact event** linked to the source case, (2) **link an existing contact event** to the source case, or (3) **link multiple existing contact events** to the source case. The default operation is "Create Linked Event." This can be changed as applicable.

Link Events			
Operation:	Link To Existing Event 🗸		Select Event
Link Type:	Create Linked Event	~	Sciect Event
E	Link To Existing Event		Reset
Relationship:	Link To Multiple Events		

• The default choice for "Operation:" will be "Create Linked Event." If you have a single TB contact event to link, select "Link to Existing Event." If you have multiple TB contact events to link, select "Link to Multiple Events" to link them in one step.

• Specify the Link Type. When entering contact investigation records, we recommend selecting "Contact" for this field.

Link Events				
Operation:	Link To Ex	isting Event 🗸		Select Event
Link Type:	Contact		~	
Relationship:		~		Reset

• Specify the relationship that best describes the linkage. If linking to multiple events, you will only be able to select one relationship type.



• Click on "Select Event..." to search WDRS for TB contact event.

t Event
set

• Enter personal identifying information (e.g. first and last names, date of birth) into the "Search Criteria" that matches the TB contact event.

Search Party		
Search Criteria		Search Results
Party ID:		Search Results
Last Name:	Testerton	Full Name Birth Date Street Address
First Name:	Tester Jr	> Testerton, Tester Jr 🔹
Birth Date: (Inexact)	MM/DD/YYYY	Showing 1 to 1 of 1 entries
Sex assigned at birth:	~	
City:		Select Cancel Help
State:	~	

• Click on the person name to highlight the correct row, and then click "Select" to auto-fill person information in the Link Events section.

Search Party				
Search Criteria		Search Results		
Party ID:		Search Results		
Last Name:	Testerton	Full Name	Birth Date	Street Address
First Name:	Tester Jr	> Testerton, Tester Jr		
Birth Date: (Inexact)	MM/DD/YYYY	Showing 1 to 1 of 1 entr	ies	F
Sex assigned at birth:	~			
City:		Select Cancel	Help	
State:	~			

- If linking to multiple events, click on "Select Event..." as many times as necessary to populate a list of TB contact events to link. All of these linkages will share the same relationship type, so you can link each existing event individually if they require different relationship types.
- Click "Save" to add a linkage to the contact event(s).

The newly linked contact event will now display in the Linked Events line-list of the source case. The source case will also appear in the Linked Events line-list of the newly linked TB contact.

Linked Events - Tester Jr Testerton - TB disease								
Filter Linked Events Disease: ✓ Status: ✓ Apply Filter Reset Filter								
Linked Events	Full Name	Status	Create Data	Disease	Event Date	Toyt1	Type	
101557141	Testerton, Tester Jr	Open	02/26/2023	TB contact	02/26/2023	TEXLI	Contact	
Displaying link(s) 11							

TB Contact Wizard

As for TB disease events, the Event Summary screen includes an Event Data tab with a series of Question Packages to add information about the TB contact event record including: Administrative, Demographics, Risk, Diagnostics and Evaluation, Treatment, and Additional Information. Also, as for TB disease events, in each Question Package any question marked by an asterisk (*) indicates a required reporting field. Until each of these fields is complete, the status in each question package will remain "Incomplete."



Refer to this <u>Quick Guide</u> which outlines required fields for contact investigations in WDRS.

Unlike disease events, the DOH TB Program does not report line level contact data to CDC. Data are aggregated for CDC in alignment with <u>Aggregate Report for Tuberculosis Program</u> <u>Evaluation (ARPEs)</u> requirements.

All questions that are required for contact events are in the TB Contact Wizard. Compared to disease events, there are a lot fewer required fields.

A lot of questions in the TB Contact Wizard are not required but are available if you have the information and want to enter it. This could help save time later, if the contact is determined to have LTBI or TB Disease, and you copy over information from the contact event to a new event.

More details regarding specific fields in the TB Contact Wizard coming soon!

TB Infection Events

Infection Event Required Fields

All required fields are included in the LTBI Wizard.

Question Packages			
Question Package			
Administrative			
Demographics			
Risk			
Diagnostics and Evaluatio	n		
Treatment			
Additional Information			
View Question Package	Wizards	~	View V
		LTBI Wizard	

Required fields are marked with an asterisk (*) and highlighted in yellow when they are blank, as displayed below with a few demographics fields.

Demo	ographics
* Eligible for U.S. citizenship/nationality at birth (regardless of country of birth)	✓
* Country of birth	~

Required Fields in TB Infection Events:

✓	Basic demographics ¹	\checkmark	Primary reason evaluated	\checkmark	CXR results ³
\checkmark	Accountable county ²	\checkmark	History of TB disease	\checkmark	Treatment & start/stop
\checkmark	Eligible for US citizenship	\checkmark	History of TB infection	\checkmark	Reason therapy stopped
\checkmark	Country of birth	\checkmark	TST and IGRA results		or never started

1. If known, first, last, date of birth**2.** Select reporting address

 ${\bf 3}.$ Located in diagnostics and evaluation question package

More information on each required field is available in the LTBI Wizard section.

When TB Infection Progresses to TB Disease

Disease progression may be observed when you are conducting an initial WDRS person search prior to creating a new TB disease event, and that person matches to an earlier, existing TB infection event. In this scenario, a new WDRS TB disease event should be created from the existing TB infection event. Doing so will ensure that data existing in the TB infection record is retained in the new TB disease event.

The steps you take to record disease progression from TB infection to TB disease are similar in many ways to recording when a TB contact is diagnosed with TB infection or TB disease.

Start by using a copy of the existing TB infection event to create a new TB disease event.

Start from the search results screen, clicking once on the existing TB infection event you found corresponding to the person currently diagnosed with TB disease. Click "Select" to open to the Event Summary screen of the TB infection event selected.

Search Case							
Search Criteria			Search Results				
Туре:	Single Event 🗸		Search Results				
Event ID:			Event ID	Full Name	Birth Date	Status	Disease
Party ID:			>101557369 🕥	Testerton, Tester Jr		Open	TB infection
Disease:		~	101557367 🔬	Testerton, Tester Jr		Open	Other
Last Name:	Testerton						
First Name:	Tester Jr		Showing 1 to 2	of 2 entries			First Pr
Birth Date: (Inexact)	MM/DD/YYYY		Select	ate Decord for Derso	n Can	col	Help
Sex assigned at birth:	~			ate Necold IOI Feiso			Tieth

		Note
Event ID:	101557369	
Disease:	TB infection	
Person:	Tester Jr Testerton ()	
Dates:	Create Date: 12/23/2022	
Туре:	Interactive	
Investigation Status:	Active (Change to Closed)	
Linked Events/Contacts:	0 linked event(s)/contact(s) (View)	
Attachments:	0 attachment(s) (Add)	
Notices:	Concerns (2) Please fill in sex at birth information on Person screen. Please fill in the birth date information on Person Screen. General Notifications (1) Vital Status: Alive	

• Click "Copy Event" and scroll down to the "Target Event" section that appears.

Target Event	
Copy Mode:	Copy to new event V
Disease:	TB disease 🗸
Status:	Open 🗸
Notes:	
Copy Question Packages:	✓ Administrative
	Demographics
	✓ Risk
Copy Fields:	Copy attachments
	Copy labs
	Copy concerns (manual only)
	Copy tasks
	Copy case notes
	Copy event links
Link to Source as:	Disease Progression
Save Cancel He	elp

- Copy Mode: Leave the default "Copy to a new event"
- Disease: Select "TB disease" if diagnosed with active TB disease
- Status: "Open"
- Copy Question Packages: Select the question packages you want copied to the new event. To ensure all question package data in the existing TB contact event is copied to the new TB infection event, select all question packages. Data will only be copied for fields that exist in both TB contact and TB infection records.
- Copy Fields: Select additional information to be copied to the new event. Always include Copy event links in your selection to ensure any existing linkage(s) to other TB events are also copied over to this event. This will copy over the existing linkage to the corresponding TB disease event.
- For Link to Source as, select "Disease Progression."
- Click "Save."

Clicking "Save" will open to the Event Summary screen of the new TB disease event. From the Event Summary screen of the TB disease event created, clicking "View" adjacent to "Linked Events/Contacts" will show that the TB infection event is automatically added to the list of events linked to this TB disease event.

Linked Events - Tester Jr Testerton - TB disease									
Filter Linked Events									
Disease: Status: Status: 									
Linked Ever	nts Full Namo	Status	Croato Dato	Disoaso	Evont Dato	Toyt1	Туро		Polationship
101557369	Testerton, Tester Jr	Open	12/23/2022	TB infection	12/23/2022		Disease	Progression	telationship
Displaying li	Displaying link(s) 11 << First < Prev 1 / 1 Nex								

Similarly, this TB disease event is also added to the events linked to the initial TB infection event.

Linked Events - Tester Jr Testerton - TB infection								
Filter Linked Events								
Disease:							Status:	~
Apply Filt	er Reset Filter							
Linked Eve	nts							
Event ID	Full Name	Status	Create Date	Disease	Event Date	Text1	Type	Relationship
101557370	Testerton, Tester Jr	Open	12/23/2022	TB disease	12/23/2022		Disease Progression	
Displaying li	ink(s) 11						<< First <	Prev 1/1 Nex

LTBI Wizard

As for TB disease events, the Event Summary screen includes an Event Data tab with a series of Question Packages to add information about the TB infection event record including: Administrative, Demographics, Risk, Diagnostics and Evaluation, Treatment, and Additional Information. Also, as for TB disease events, in each Question Package any question marked by an asterisk (*) indicates a required reporting field. Until each of these fields is complete, the status in each question package will remain "Incomplete."



Unlike disease events, we do not report infection data directly to CDC. We report aggregate contact data and LTBI to CDC through an annual **Aggregate Report for Tuberculosis Program Evaluation (ARPEs)**.

All questions that are required for infection events are in the TB Infection Wizard. Compared to disease events, there are a lot fewer required fields.

A lot of questions in the TB Infection Wizard are not required but are available if you have the information and want to enter it. This could help save time later, if there is <u>disease progression</u> from TB infection to TB disease and you copy over information from the infection event to a new disease event.

More details regarding specific fields in the TB Infection Wizard coming soon!

Appendices

Appendix A: Case Verification Tool

WDRS TB Disease Case Verification Status Tool*

Outlined in this tool are the required fields needed in WDRS to meet the case verification categories described below. This tool uses the language from WDRS's data fields.

- The verification status for all newly created records defaults to 'Suspect'
- · Three different categories:
 - Lab diagnosis (verification status = Positive culture, Positive NAA, Positive smear)
 - Clinical Case Definition (verification status = Clinical case definition)
 - Provider diagnosis (verification status done by override function = Provider diagnosis)
- WDRS sections used to calculate case verification in the question packages <u>or</u> RVCT Wizard:
 - Administrative
 - Diagnostics and Evaluation <u>or</u> Diagnostic Testing
 - Treatment <u>or</u> Initial Drug Regimen

*This case verification status tool uses the National Tuberculosis Surveillance System's hierarchy of case verification criteria calculation

**Please consult with State TB Team if this override is needed.

Suspect

• All new records default to Suspect until criteria for other statuses are met or overwritten

Positive Culture

• Diagnostic & Evaluation - Sputum culture OR Culture of tissue and other body fluids = Positive

Positive NAA

• Diagnostic & Evaluation - Nucleic Acid Amplification test = Positive; Specimen type = Sputum or Other

Positive Smear Tissue

 Diagnostic & Evaluation - Sputum Smear OR Smear/Pathology/Cytology of Tissue and Other Body Fluids = <u>Positive</u>;

AND ALL Cultures = Not Done, Unknown, Indeterminate, Refused, Not Offered, or Test Done Result Unknown; AND ALL NAATS = Not Done, Unknown, Indeterminate, Refused, Not Offered, or Test Done Result Unknown;

Clinical Case Definition

• Diagnostic & Evaluation - Site of TB Disease is NOT Missing OR is NOT Site Not Stated; AND ALL Cultures = Negative, Not Done, Unknown, Indeterminate; Refused, Not Offered, or Test Done Result Unknown:

AND ALL NAATs = Negative, Not Done, Unknown, Indeterminate, Refused, Not Offered, or Test Done Result Unknown;

AND ANY TST or IGRA = <u>Positive</u>;

AND at least two drugs in Initial Drug Regimen are marked Yes;

AND <u>IF</u> Site of TB Disease = *Pulmonary, Pleural, or Lymphatic: Intrathoracic* with no extrapulmonary site included; THEN either:

ANY Plain chest x-ray = Abnormal (consistent with TB);

OR ANY CT scan or other chest imaging = Abnormal (consistent with TB)

Verified by Provider Diagnosis

- Administrative Verification Status of 'Suspect' overwritten with: Verified by Provider Diagnosis**
- Override status will change if criteria for another status is met

Not A Verified Case

- Treatment Reason Therapy Stopped or Never Started = Not TB; OR
- Administrative Suspect Case overwritten to Not a Verified Case

Appendix B: Patient Scenarios, How to Count, and Reporting Address

Patient Scenarios	How to Count	Reporting Address
Persons temporarily away from their	Count in the reporting area for the patient's usual residence.	Enter city, county, ZIP Code, and
usual residence (e.g., on vacation or		census tract of the patient's usual
a business trip), and who return to		residence.
their usual residence to complete TB		
treatment.		
Persons temporarily away from their	Count in the reporting area where the TB diagnostic evaluation was initiated.	Enter city, county, ZIP Code, and
usual residence (e.g., on vacation or		census tract of location where the
a business trip), and who remain in		patient was staying when the
the community that they were		diagnostic evaluation was initiated.
visiting to complete TB treatment.		
Persons without housing (e.g.,	Count in the reporting area where the TB diagnostic evaluation was initiated.	Enter city, county, ZIP Code, and
persons experiencing homelessness		census tract of location where the
or without a fixed residence).		patient was staying when the
		diagnostic evaluation was initiated.

Patient Scenarios	How to Count	Reporting Address
Persons with multiple residences.	Count in the reporting area where the patient lives most of the time, based on the length of the typical cycle between residences, subject to the following specific guidelines:	Enter city, county, ZIP Code, and census tract of the location where the patient stays in the reporting area that
	1. Commuter workers living away part of the week while working (on a weekly cycle) should be reported by the jurisdiction where they stay most of the week.	is counting the case.
	2. People who live in one state most of the year but who regularly spend part of the year in another state (e.g., snowbirds) can be said to have an annual cycle and should be reported by the jurisdiction of the residence where they live most of the year.	
	3. Children in joint custody should be reported by the jurisdiction of the residence where they live most of the time. If the time is equally divided, they are reported by the jurisdiction where they were staying at the time the TB diagnostic evaluation was initiated.	
	4. People who move between residences without any regular cycle should be reported by the jurisdiction of the residence where they live most of the time. If their time is equally divided, report based on where they were staying at the time the TB diagnostic evaluation was initiated.	
Students.	 College or boarding school students on a typical yearly academic cycle should be counted by the reporting area where they live most of the year. Intermittent or part-time students without a regular cycle for moving between parental and school residences should be counted by the reporting area where they were living at the time that diagnostic evaluation was initiated. 	Enter city, county, ZIP Code, and census tract of the location where the patient stays in the reporting area that is counting the case.
Foster children and wards of the state.	Count in the reporting area where the patient was living when TB diagnostic evaluation was initiated.	Enter city, county, and ZIP Code, and census tract where the patient was living when diagnostic evaluation was initiated.

Patient Scenarios	How to Count	Reporting Address
Uniformed service or merchant marine personnel.	 Uniformed service personnel residing in the United States should be counted by the reporting area for their usual residence, either on- or off-base (this is not necessarily the jurisdiction where the military member is registered to vote, pays taxes, etc.). 	Enter city, county, ZIP Code, and census tract of the location where the patient stays in the reporting area that is counting the case.
	2. Crews of uniformed service vessels with a U.S. homeport should be counted by the reporting area for their usual onshore residence if they report one (the place where they live and sleep most of the time when they are onshore); otherwise, they should be counted by the reporting area for their vessel's homeport.	
	3. Crews of U.S. flag merchant vessels engaged in inland waterway transportation should be counted by the reporting area for their usual onshore residence (the place where they live and sleep most of the time when they are onshore).	
	4. Crews of U.S. flag merchant vessels docked in a U.S. port or sailing from one U.S. port to another U.S. port should be counted at their usual onshore residence if they report one (the place where they live and sleep most of the time when they are onshore). If they have no onshore residence, count in the reporting area where the diagnostic evaluation was initiated.	

Patient Scenarios	How to Count	Reporting Address
Institutionalized persons.	1. Patients in general hospitals or wards at the time of symptom onset should be counted by reporting area for their usual residence (the place where they live and sleep most of the time when they are not hospitalized). Newborn babies who have not yet been discharged following delivery should be reported by the mother's usual residence.	Enter city, county, ZIP Code, and census tract of the location where the patient stays in the reporting area that is counting the case.
	2. In general, persons who are institutionalized for indefinite or longterm stays should be counted by the reporting area for the facility where they are staying at the time the diagnostic evaluation was initiated. Examples of such facilities include:	
	a. chronic or long-term disease hospitals; hospices; nursing or convalescent homes;	
	 b. inpatient drug/alcohol recovery facilities; homes, schools, hospitals, or wards for disabled persons 	
	c. federal and state prisons, jails, detention centers, and halfway houses;	
	d. orphanages or residential care facilities for children	
	3. Staff members living in hospitals, nursing homes, prisons, or other institutions should be counted by the reporting area for their usual residence (the place where they live and sleep most of the time); otherwise by the reporting area where the institution is located.	
Non-U.S. citizens (including, but not limited to, Immigrants, Refugees, Foreign Visitors (e.g., students, commercial representatives, and	1. Noncitizens who have established a household or are part of an established household in the United States, including those in the United States for work or study, should be counted by the reporting area for their usual residence in the United States.	Enter city, county, ZIP Code, and census tract of the location where the patient stays in the reporting area that is counting the case.
diplomatic personnel), and Border Crossers	2. Noncitizens who live on diplomatic compounds (e.g., embassies, consulates) should be counted by the reporting area where the diplomatic compound is located.	

Appendix C: Examples of Phenotypic/Growth-Based DST Lab Results

Sample Result from Florida Lab: Sensititre MIC Phenotypic DST Report

Test		Result	Reference Range Date Approved
	Rifabutin Interpretation	Resistant	Susceptible: ≤0.25
			Resistant: ≥0.5
	Ofloxacin Interpretation	Not Tested	Susceptible: ≤1
			Resistant: ≥2
	Ethionamide Interpretation	Not Tested	Susceptible: ≤1.2
			Resistant: ≥2.5
	Amikacin <mark> MIC</mark>	16 μg/mL	
	Amikacin Interpretation	No Interpretation	Susceptible: <2
		ouse in constant, and the second	Resistant: Breakpoint
			not established
	Moxifloxacin <mark>MIC</mark>	0.25 µg/mL	
	Moxifloxacin Interpretation	No Interpretation	Susceptible: ≤0.12
		3	Resistant: Breakpoint
			not established
	Para-Aminosalicylic Acid MIC	<0.5 µg/mL	
	Para-Aminosalicylic Acid Interpretation	Susceptible	Susceptible: ≤0.5
		ing an extension of a second	Resistant:Breakpoint
			not established
	Cycloserine MIC	4 µg/mL	
	Cycloserine Interpretation	Susceptible	Susceptible: ≤8.0
			Resistant: Breakpoint
			not established
	Capreomycin MIC	5 <mark>µg/mL</mark>	
	Capreomycin Interpretation	Susceptible	Susceptible: ≤5
	The second se	Construction of the construction of the co	Resistant: Breakpoint
	*		not established
	Levofloxacin MIC	0.5 μg/mL	
	Levofloxacin Interpretation	Susceptible	Susceptible; ≤0.5
		Contract of the second se	Resistant: Breakpoint
			not established
	Linezolid MIC	0.25 µg/mL	
	Linezolid Interpretation	Susceptible	Susceptible: ≤1.0:

Susceptible: ≤1.0; Resistant: Breakpoint

Sample Result from LabCorp: Liquid (Broth) Medium Phenotypic DST Report

aboratory Corporation of Am	nerica			Burlington,	NC 27215-3361		Pho	ne: 800-762-4	344
Specimen Number Patient ID 237-992-9220-0			Control Number	Account Num 9000099	ber Accour	nt Phone Number -436-8645	Route 00		
SAMPLE REP	Patien	nt Last Nam	le		LabCorp 2	Acco Test Mast	unt Address Cer		
Patient First N 182576	ame	3	Patient M	iddle Name	Test Acco	ount			
Patient SS#	I	Patient Pho	ne	Total Volume	3060 Sout	th Church	n Street		
Age (Y/M/D) 56/07/23	Date of Bir 01/01/	^{rth} 60	Sex M	Fasting	Burringeo	JII NC 2	/215		
	Patien	nt Address			SAMPLE REPO	Addition ORT	nal Information		
Date and Time Collect 08/24/16 00:	ted Date E 00 08/2	Entered	Date a	nd Time Reported	Physician Name	1	NPI	Physician	ID
Date and Time Collec 08/24/16 00: Mtb Suscepti	ted Date E 00 08/2 bility Bro	Entered 4/16 oth	Date a	nd Time Reported Tests (Physician Name Ordered	1	NPI	Physician	ID
Date and Time Collect 08/24/16 00: Mtb Suscepti	ted Date E 00 08/2 bility Br TESTS	Entered 24/16 oth	Date a	nd Time Reported Tests (RESULT	Physician Name Ordered FLAG	UNITS	NPI REFEREN	Physician CE INTERVAL	ID LAI
Date and Time Collect 08/24/16 00: Mtb Suscepti tb Suscept Organism I	ted Date E 00 08/2 bility Br TESTS 1b111ty D	entered 24/16 oth Broth	Date a	nd Time Reported Tests (RESULT	Physician Name Ordered FLAG Abnormal	UNITS	NPI REFEREN	Physician CE INTERVAL	ID LAI 01
Date and Time Collect 08/24/16 00: Mtb Suscepti tb Suscept Organism I Mycoba Streptomyco	ted Date E 00 08/2 bility Br TESTS ibility D D acterium	entered 24/16 oth Broth tube	Date a	RESULT	Physician Name Ordered FLAG Abnormal	UNITS	REFEREN	Physician CE INTERVAL	ID LAN 01
Date and Time Collect 08/24/16 00: Mtb Suscepti tb Suscept Organism I Mycoba Streptomyco Isoniazid	ted Date E 00 08/2 bility Br TESTS ibility D acterium in 1. ug/ 0.1 ug/m	entered 04/16 oth Broth tube (mL	Date a	RESULT Sis complex sceptible sceptible	Physician Name Ordered FLAG Abnormal	UNITS	NPI REFEREN SUS	Physician CE INTERVAL Ceptible	D LAI 01 01
Date and Time Collect 08/24/16 00: Mtb Suscepti tb Suscept Organism I Mycoba Streptomyc Isoniazid Rifampin 1	ted Date E 00 08/2 bility Br. TESTS ibility D acterium in 1 ug/n 0,1 ug/mL	entered (4/16) oth Broth tube 'mL	Date and 1 rculos Su Su Su	RESULT Sis complex sceptible sceptible sceptible	Physician Name Ordered FLAG Abnormal	UNITS	REFEREN SUS SUS SUS	Physician CE INTERVAL Ceptible Ceptible Ceptible	D LAP 01 01 01 01
Date and Time Collect 08/24/16 00: Mtb Suscepti tb Suscept Organism I Mycoba Streptomyc Isoniazid Rifampin 1 Ethambutol	ted Date E 00 08/2 Dility Br. TESTS ibility D acterium in 1 ug/n 0,1 ug/mL 5 ug/mL	entered (4/16) oth Broth tube (mL LL	Date a Date a 1 rculos Su Su Su Su Su Su	RESULT Sis complex sceptible sceptible sceptible sceptible	Physician Name Ordered FLAG Abnormal	UNITS	REFEREN SUS SUS SUS SUS SUS	Physician CE INTERVAL Ceptible Ceptible Ceptible Ceptible	ID LAR 01 01 01 01 01 01 01
Date and Time Collec 08/24/16 00: Mtb Suscepti Organism I Mycoba Streptomyc Isoniazid Rifampin 1 Ethambutol Pyrazinami Agar Probo	ted Date E 00 08/2 bility Br TESTS ibility D acterium in 1 ug/ 0.1 ug/mL 5 ug/mL 5 ug/mL de 100 u rtion Co	entered <u>44/16</u> oth Broth tube 'mL L L Jg/mL onfiru	Date a Date a su Su Su Su Su Su Su	RESULT Sis complex sceptible sceptible sceptible sceptible sceptible	Physician Name Ordered FLAG Abnormal	UNITS	REFEREN Sus Sus Sus Sus Sus	Physician CE INTERVAL Ceptible ceptible ceptible ceptible ceptible	ID LAF 01 01 01 01 01 01

Sample Result from WA Public Health Laboratory: MGIT Phenotypic DST Report

Microscopy Report		
10 D	Result	Performed by
AFB Smear	Positive	Lab Corp
Culture Report		
		Performed by
	Mycobacterium tuberculosis complex	Lab Corp
118) SIRE and PZA sensitivities pe	ending by: WAPHL	
Susceptibility Report - 1st Line	e of Drugs	
Drug (<mark>mcg/mL</mark>)	Result	Performed by
MGIT Pyrazinamide (PZA) 100	Sensitive	KMH
MGIT Streptomycin (SM) 1.0	Sensitive	KMH
MGIT Isoniazid (INH) 0.1	Sensitive	KMH
MGIT Rifampin (RIF) 1.0	Sensitive	KMH
MGIT Ethambutol (EMB) 5.0	Sensitive	KMH

Sample Result from CDC: Solid (Agar) Medium Phenotypic DST Report

MTBC Agar Proportion Susceptibility*	<u>% Resistant</u>	Interpretation
Isoniazid 0.2 <mark>µg/mL</mark>	0 %	Susceptible
Isoniazid 1.0 <mark>µg/mL</mark>	0 %	Susceptible
Isoniazid 5.0 µg/ml.	0 %	Susceptible
Rifampin 1.0 µg/mL	0 %	Susceptible
Ethambutol 5.0 µg/mL	0 %	Susceptible
Streptomycin 2.0 µg/mL	0 %	Susceptible
Streptomycin 10.0 µg/mL	0 %	Susceptible
Rifabutin 2.0 µg/mL	0 %	Susceptible
Ciprofloxacin 2.0 µg/mL	0 %	Susceptible
Kanamycin 5.0 µg/ml.	0 %	Susceptible
Ethionamide 10.0 µg/mL	0 %	Susceptible
Capreomycin 10.0 µg/mL	0 %	Susceptible
PAS 2.0 µg/mL	0 %	Susceptible
Ofloxacin 2.0 µg/mL	0%	Susceptible
Amikacin 4.0 µg/mL	0 %	Susceptible
Comments and Disclaimers + Susceptibility testing method: Indirect agar proportion, 7H10	medium. Resistance is defined as >1%	(growth on

drug-containing medium compared to drug-free medium).

Appendix D: Examples of Genotypic/Molecular DST Lab Results

Sample Result from CDC: Genotypic Complete Panel DST Report

Results for Molecular Detection of Drug Resistance (Complete Panel); Conventional Drug Susceptibility Test in progress.					
Drug	Locus *	Result	Interpretation		
Rifampin	гров	No mutation	Probably Rifampin susceptible. (97% of RMP-R isolates in our in-house evaluation of 550 clinical isolates have a mutation at this locus.)		
w.	InhA	No mutation			
Isoniazid	katG	Mutation: AGC>ACC: Ser315Thr	Isoniazid resistant, (100% of isolates in our in-house evaluation of 550 clinical isolates with this mutation are INH-R.)		
	fabG1	No mutation	-		
Ethambutol	embB	Mutation: ATG>GTG; Met306Val	Ethambutol resistant. (100% of isolates in our in-house evaluation of 550 clinical isolates with this mutation are EMB-R).		
Pyrazinamide	рлсА	Mutation: TAC>GAC; Tyr34Asp	Effect of this mutation on pyrazinamide resistance is unknown. Cannot rule out PZA resistance.		
	gyrA	No mutation	Cannot rule out fluoroquinolone resistance, (80% of EQ.R isolates in our in-house		
Fluoroquinolones	gyrß	No mutation	evaluation of 550 clinical isolates have a mutation at locus gyrA.)		
	rrs	No mutation	Cannot rule out resistance to injectable drugs (kanamycin, capreomycin, amikacin). (In our in-house evaluation of 550 clinical isolates;		
Second Line	eis	No mutation	 91% of AMK-R isolates have a mutation in the ris locus; 87% of KAN-R isolates have a mutation in either the ms locus or the eis locus 		
Injectables	tlyA	No mutation	 55% of CAP-R isolates have a mutation in either the ms locus or the tiyA locus.) 		

Sample Result from CDC: Genotypic MDDR INH-RIF DST Report

Drug	Locus *	Result	
	LUCUS		
Rifampin	фоВ	No mutation	Probably Rifampin susceptible. (97% of RMP-R isolates in our in-house evaluation of 550 clinical isolates have a mutation at this locus.)
	inhA	No mutation	
Isoniazid	katG	No mutation	Cannot rule out INH resistance. (86% of INH-R isolates in our in-house evaluation of 550 clinical isolates have a mutation in locus inhA or locus kat(3.)
	fabG1	No mutation	

*A negative result (e.g., no mutation) does not rule out contributory mutations present elsewhere in the genome.

NOTE: MDDR testing (Sanger sequencing, complete panel) will not be performed because mutations associated with RMP resistance were not detected. Contact laboratory if this testing is required for clinical reasons.

MDDR: Molecular Detection of Drug Resistance

INH: Isoniazid

RIF: Rifampin

Sample Result from Florida Lab: HAIN (MTBDRplus) Genotypic DST Report

Test		Result	Reference Range D
3145	HAIN Test GenoType MTBDRplus	rpoB point <mark>mutation</mark> detected katG point mutation detected	
		No inhA point mutation detected	
No	ote:The HAIN test is investigational. Not The clinical application of the HAIN for assistance with the Interpretation Consultation Network at 800-4TB-INF	t intended for diagnostic purposes, N results should be determined by the respo n of results of this test, please contact the T FO (800-482-4636).	onsible treating care provider B Physicians'

Appendix E: Anti-TB Drug Names and Genes Associated with Drug Resistance

Drug name	Gene name	Comments
Isoniazid (INH)	katG	
Isoniazid (INH) and ethionamide	inhA	<i>InhA</i> is associated with low level resistance to both isoniazid and ethionamide. Note that ethionamide has another gene associated with resistance, <i>ethA</i> (shown below).
Isoniazid (INH)	ahpC-oxyR	
Isoniazid (INH)	fabG1	Also known as <i>mabA</i> . Mutations associated with fabG1 (mabA) have also been reported for resistance to ethionamide.
Rifampin (RIF)	гроВ	Rifampin is among the drug group rifamycins. Rifamycins also include rifapentine and rifabutin. A mutation in the <i>rpoB</i> gene does not necessarily confer resistance to all rifamycin drugs.
Pyrazinamide (PZA)	pncA	
Ethambutol (EMB)	embB	
Second-line injectables	rrs	Second-line injectables include kanamycin (KAN), amikacin (AM), capreomycin (CAP). Note: <i>rrs</i> is also associated with streptomycin resistance. <i>rrs</i> is also known as 16S rRNA.
Kanamycin (KAN)	eis	
Capreomycin (CAP)	tlyA	
Fluoroquinolones	gyrA	Examples of fluoroquinolone drugs include moxifloxacin (MXF), ofloxacin (OFL), ciprofloxacin (CIP), and levofloxacin (LEV).
Fluoroquinolones	gyrB	Examples of fluoroquinolone drugs include moxifloxacin (MXF), ofloxacin (OFL), ciprofloxacin (CIP), and levofloxacin (LEV).
Ethionamide	ethA	
Streptomycin	rpsL, rrs	
Bedaquiline	atpE, rv0678, pepQ (rv2535c)	<i>pepQ</i> is also known as <i>rv2535c</i> . Mutations associated with <i>rv0678</i> can result in cross resistance with clofazimine.
Linezolid	23S rRNA, rpIC, rrI	rrl gene is also known as 23S.
Clofazimine	rv0678, pepQ, rv1979c	Mutations associated with <i>rv0678</i> can result in cross resistance with bedaquiline.
Delamanid	fbiA, fbiB, fbiC, ddn, fqd1	

Appendix F: Detailed Information about Genotypic/Molecular Drug Susceptibility Testing

Other Definitions:

There are other terms and items you may see on a laboratory report. Below are a few detailed definitions associated with mutations.

Single nucleotide polymorphism (SNP)

A change in a single nucleotide in the DNA sequence, an A, T, C, or G from what is commonly observed (i.e., wild type). Multiple point mutations can occur within the same locus.

Deletion

A mutation that can occur when a single nucleotide or set of nucleotides is removed from a DNA sequence. A deletion can be small (i.e., one to few nucleotides) or large (i.e., a whole segment of the chromosome) and the effect of the deletion on viability of the organism or antibiotic resistance will depend on the location of the deletion and how the deletion affects protein synthesis.

Insertion

A mutation that can occur when a single nucleotide or set of nucleotides is inserted within a DNA sequence. An insertion can be small (i.e., one to few nucleotides) or large (i.e., a whole segment of the chromosome).

Note: Insertions and deletions are often referred to as **indels**. Also, insertions and deletions can result in what is known as a frameshift mutation (also called frameshift change or FSC). Therefore, if "frameshift" or "FSC" is listed as the result on the laboratory report, mark the gene name, the result of mutation, and the test type.

Nucleic acid change

For each SNP, insert the nucleic acid change associated with the mutation as indicated on the laboratory report. Nucleic acid changes appear only if a mutation has occurred and a sequencing test type was performed.

Please insert the nucleic acid change in *abc>xyz* format, if included in the laboratory report. The *abc* is the 3- letter codon for the NA found in the naturally occurring bacterium, e.g. the nonresistant or sensitive (drug-susceptible) strain of *M. tuberculosis*. The *xyz* is the 3-letter codon for the nucleic acid found in the sample tested. Nucleic acid changes and amino acid changes are specific to the gene where the mutation occurs. A codon is three consecutive nucleotides (consisting of adenosine [A], thymidine [T], cytidine [C], or guanosine [G]) that enables the production of a specific amino acid. If the nucleic acid change is not provided in 3-

letter codon format, please enter the information as reflected in the laboratory report (e.g., c>z) or leave blank if not provided.

Certain genes, such as *inhA*, *ahpC-oxyR*, *rrs* and *eis* will typically only have nucleic acid changes (i.e., no amino acid change to report). Nucleic acid changes in this group of genes may appear differently and the location of the mutation on the genome will be added to the nucleic acid change, e.g., '*C*(-34)*G*' for *inhA*, '- 45 AT insertion' for *ahpC-oxyR*, 'A1410G' for *rrs*, or *G*(-10)A for *eis*.

If no mutation has occurred then no nucleic acid change should be listed on the laboratory report. The examples below show common mutations occurring in drug resistant TB with the nucleic acid and amino acid changes specific to the mutations occurring in the associated genes.

Examples:

Gene tested	Results	Nucleic acid change	Amino acid change
katG	Mutation detected	AGC>ACC	Ser315Thr
гроВ	Mutation detected	TCG>TTG	Ser531Leu
inhA	Mutation detected	C-15T*	Not applicable

* The position on the genome is -15. The nucleic acid change is from C [cytidine] to T [thymidine]

Amino acid change

Indicate the amino acid change associated with the mutation as indicated on the laboratory report. Amino acid changes appear only if a mutation resulting in a substitution has occurred and a sequencing test type was performed. Nucleic acid and amino acid changes do not usually appear on a laboratory report if the test type used was a non-sequencing method.

Amino acid changes are associated with mutations to genes *katG*, *rpoB*, *pncA*, *embB*, *tlyA*, *gyrA*, *gyrB*, *ethA* and *rpsL*. If a mutation has not occurred then the amino acid change, as well as a nucleic acid change, should not appear on the laboratory report. The genes *inhA* and *eis* are usually associated with only nucleic acid changes but some research has shown that amino acid changes can occur.

A common amino acid change found in drug resistant TB is the amino acid change for the gene associated with rifampin resistance, *rpoB*, Ser531Leu (or Ser450Leu depending on numbering system used). In this example, 531 refers to the location or position of the codon in the *rpoB* gene and Ser to Leu refers to the change in amino acid (serine to leucine).

The following explains the nomenclature used for reporting amino acid changes, using Ser531Leu as an example:

Ser531Leu

Ser is the abbreviation for serine, the amino acid found in wild-type *M. tuberculosis*.

531 refers to the location or position of the codon in the rifampin-resistant determining region (RRDR) of the *rpoB* gene where the mutation occurred.

Leu is the abbreviation for leucine, the amino acid substitution found in the resistant *M*. *tuberculosis*.

This amino acid change indicates there was a mutation in the RRDR of the rpoB gene at location **531** resulting in a change of the corresponding amino acid from **serine** to **leucine**.

Appendix G: Drug-Resistant TB Definitions

Background

In January 2021, the World Health Organization (WHO) made two updates to extensively drug-resistant tuberculosis (TB) definitions.

- 1. The extensively drug-resistant TB (**XDR-TB**) definition was **revised**.
- 2. Pre-XDR TB was formally defined for the first time.



Read more about these updates here: https://www.who.int/news/item/27-01-2021-who-announcesupdated-definitions-of-extensively-drug-resistant-tuberculosis

In January 2022, the CDC Division of TB Elimination (DTBE) adopted a new hybrid definition of pre-XDR and XDR-TB for U.S. TB surveillance purposes. Key points:

- 1. It would be **premature to eliminate second-line injectable drugs** (i.e., amikacin, kanamycin, and capreomycin) from the U.S. definitions of pre-XDR and XDR TB at this time.
- 2. Either the existing U.S. definitions or the WHO definitions may be used, with the exception that **documented resistance to isoniazid** (WHO definitions are inclusive of rifampin resistance only) would be a **requirement for all U.S. resistance classifications**.
- 3. **Bedaquiline and linezolid are added** to the list of drug classes that are considered when classifying cases into resistance groups.



Read more about these updates here: https://www.cdc.gov/tb/publications/letters/2022/surv-defxdr.html

WHO and CDC Drug-Resistant TB Definitions

WHO and CDC definitions of drug-resistant TB are provided here for reference:

Type of Drug- Resistant TB	WHO Definition	CDC Definition
MDR TB	Resistance of Mycobacterium tuberculosis strains to at least isoniazid and rifampicin , the cornerstone medicines for the treatment of TB. Rifampicin-resistant disease on its own requires similar clinical management as MDR-TB.	Caused by an organism that is resistant to at least isoniazid and rifampin .
Pre-XDR TB	TB caused by <i>Mycobacterium tuberculosis</i> (<i>M. tuberculosis</i>) strains that fulfil the definition of multidrug resistant and rifampicin-resistant TB (MDR/RR-TB) and which are also resistant to any fluoroquinolone .	Caused by an organism that is resistant to isoniazid , rifampin , and a fluroquinolone OR by an organism that is resistant to isoniazid, rifampin, and a second- line injectable (amikacin, capreomycin, and kanamycin).
XDR TB	TB caused by Mycobacterium tuberculosis (M. tuberculosis) strains that fulfil the definition of MDR/RR-TB and which are also resistant to any fluoroquinolone and at least one additional Group A drug (Group A drugs are the most potent group of drugs in the ranking of second-line medicines for the treatment of drug-resistant forms of TB using longer treatment regimens and comprise levofloxacin , moxifloxacin , bedaquiline and linezolid).	Caused by an organism that is resistant to isoniazid , rifampin , a fluroquinolone , and a second - line injectable (amikacin, capreomycin, and kanamycin) OR by an organism that is resistant to isoniazid, rifampin, a fluroquinolone, and bedaquiline or linezolid .

MDR TB = Multidrug-resistant tuberculosis

XDR TB = Extensively drug-resistant tuberculosis

Fluoroquinolones

- Levofloxacin
- Moxifloxacin
- Ciprofloxacin
- Ofloxacin

Second-line injectables

- Amikacin
- Capreomycin
- Kanamycin

Drug-Resistant TB Tool

The tool below is based on CDC guidelines for drug-resistant TB (for U.S. surveillance purposes), is current as of November 2022, and is superseded by any future or additional CDC, American Thoracic Society (ATS), or Infectious Diseases Society of America (IDSA) guidelines. See <u>https://www.cdc.gov/tb/publications/guidelines/mdr_tb.htm</u> for the most current CDC Drug-Resistant TB guidelines.

Resistance Classification	Isoniazid	Rifampin	Fluoroquinolone (at least one) • Levofloxacin • Moxifloxacin • Ciprofloxacin • Ofloxacin	Second-Line Injectable (at least one) • Amikacin • Capreomycin • Kanamycin	Bedaquiline	Linezolid
MDR-TB	•	•				
			•			
FIE-ADA IB*				•		
			•	•		
XDR TB*		•	•		•	
			•			

Drug Classes

*Each row indicates one combination of drug resistance that meets the respective definition

Appendix H: Glossary

Term	Definition
Acid-fast bacilli (AFB)	Microorganisms that when stained, retain color even after they have been washed in an acid solution; may be detected under a microscope in a stained smear.
Active case finding	Looking for undiagnosed cases by screening a population.
Adherence to treatment	Following the recommended course of treatment by taking all the prescribed medications for the entire length of time necessary.
Adverse effect	Negative side effect resulting from the use of a drug (for example, hepatitis, nausea, rash).
Bronchoscopy	A procedure used to obtain pulmonary secretions or lung tissue with an instrument called a bronchoscope.
Case management	A system in which a specific health department employee is assigned primary responsibility for the patient, systematic regular review of patient progress is conducted, and plans are made to address any barriers to adherence.
Case rate	The number of cases that occur during a certain time period, divided by the size of the population during that time period; the case rate is often expressed in terms of a population size of 100,000 persons.
Case reporting	Informing the state or local health department when a new possible or confirmed case (an occurrence) of TB disease has been diagnosed.
Cavity	A hollow space within the lung, visible on a chest radiograph or CT scan.
Census tract	Census tracts are small, relatively permanent statistical subdivisions of a county or statistically equivalent entity that can be updated by local participants prior to each decennial census as part of the Census Bureau's Participant Statistical Areas Program (PSAP). The primary purpose of census tracts is to provide a stable set of geographic units for the presentation of statistical data.

Term	Definition
Clinical evaluation	An evaluation done to find out whether a patient has symptoms of TB disease or is responding to treatment; also done to check for adverse reaction to TB medications.
Clinician	A physician, physician's assistant, or nurse/nurse practitioner
Concern	WDRS Term. Messages that appear on the Basic Information section of the Event Summary screen. These messages appear in red and are meant to notify you of an issue or concern regarding the event.
Congregate setting	A setting in which a group of usually unrelated persons reside in close physical proximity. These settings may include long-term care facilities, assisted living facilities, correctional facilities, or homeless shelters (see residential facilities).
Contact investigation	A procedure for interviewing a person who has TB disease to determine who may have been exposed to TB. People who have been exposed to a person with TB are located and tested for TB infection and TB disease, and treated if indicated.
Contacts	People exposed to someone with TB disease, generally including family members, roommates or housemates, close friends, coworkers, classmates, and others.
Country of birth	The country where a person was born.
Culture	To grow organisms in or on media (substances containing nutrients) so that they can be identified.
Daily regimen	A treatment schedule in which the patient takes a dose of each prescribed medication every day.
Diabetes mellitus	A disease in which the body's ability to produce or respond to the hormone insulin is impaired, resulting in abnormal metabolism of carbohydrates and elevated levels of glucose in the blood and urine. See detailed diagnostic criteria for diabetes elsewhere in this manual.
Diagnostic evaluation	An evaluation used to diagnose TB disease; includes a medical history, a chest radiograph, the collection of specimens for bacteriologic examination, and possibly a tuberculin skin test or an interferon-gamma release assay.
Term	Definition
------------------------------------	---
Directly observed therapy (DOT)	Where a designated health care worker watches the person with TB swallow each dose of the prescribed drugs.
Drug susceptibility test	A laboratory method for detecting drug-resistant microorganisms.
Drug-resistant TB	TB caused by organisms that are able to grow in the presence of a particular drug; TB that is resistant to at least one first-line antituberculosis drug.
End-stage renal disease (ESRD)	A condition when chronic kidney failure has progressed to the point where kidney function is less than 10% of normal; requires dialysis or transplantation; also known as stage 5 chronic kidney disease. The most common cause of ESRD in the United States is diabetes.
Epidemiologically linked	The patient has had contact with one or more persons who have/had TB disease or have been exposed to a point source of infection (i.e., a single source of infection, such as an event or location where one or more patients had a confirmed case of TB disease).
	Transmission of M. tuberculosis complex by the usual modes of transmission, e.g., aerosol, is plausible. A case may be considered epidemiologically linked to a laboratory-confirmed case if at least one case in the chain of transmission is laboratory confirmed.
Ethambutol (EMB)	A drug used to treat TB disease; may cause vision problems. Ethambutol should be used cautiously in children who are too young to be monitored for changes in their vision.
Extrapulmonary TB	TB disease that occurs in places other than the lungs, such as the lymph nodes, the pleura, the brain, the kidneys, or the bones; most types of extrapulmonary TB are not infectious.
First-line TB drugs	The initial drugs typically used for treating TB disease. Includes isoniazid (INH), rifampin (RIF), pyrazinamide (PZA), and ethambutol (EMB).

Term	Definition
GEOID	GEOID stands for Geographic Identifier. GEOIDs are numeric codes that uniquely identify all administrative/legal and statistical geographic areas for which the Census Bureau tabulates data. From Alaska, the largest state, to the smallest census block in New York City, every geographic area has a unique GEOID.
HIV	Human immunodeficiency virus, the virus that causes AIDS.
Immunosuppressive therapy	Therapy that suppresses or weakens the immune system.
Interferon-gamma (IFN-γ)	Protein that is normally produced by the body in response to infection.
Interferon-gamma release assay (IGRA)	A type of blood test that measures a person's immune reactivity to M. tuberculosis by measuring release of IFN-γ. In the U.S., QuantiFERON®- TB Gold, QuantiFERON®-TB Gold In-Tube, QuantiFERON®-TB Plus and T-SPOT®.TB are currently available IGRAs.
Isolate	A sample from a specimen that was identified as a certain organism such as M. tuberculosis complex
Isoniazid (INH)	A drug that is used for treating LTBI and one of the drugs used to treat TB disease; although relatively safe, it may cause hepatitis and other severe adverse reaction in some patients.
Latent TB infection (LTBI)	Refers to the condition when a person is infected with tubercle bacilli, but TB disease has not developed. Persons with LTBI do not have TB disease symptoms and they cannot spread TB to others. Persons with LTBI usually have a positive result to the Mantoux tuberculin skin test or an interferongamma release assay
LTBI treatment	Medication that is given to people who have latent TB infection to prevent them from developing TB disease.

Term	Definition
Mantoux tuberculin skin test (TST)	A method of testing for TB infection; a needle and syringe are used to inject 0.1 ml of 5 tuberculin units of liquid tuberculin between the layers of the skin (intradermally), usually on the forearm; the reaction to this test, sometimes a palpable swollen area (induration), is measured 48 to 72 hours after TST placement and is interpreted as positive or negative depending on the size of the induration in millimeters (mm) and the patient's risk factors for TB.
Miliary TB	Miliary TB is a serious type of tuberculosis infection. It is a histological or radiologic finding, rather than a site of disease. It appears on radiographs as a great number of small, well-defined nodules that look like millet seeds scattered throughout the lungs, hence the name "miliary."
Multidrug-resistant TB (MDR TB)	Resistant to at least the drugs isoniazid and rifampin; MDR TB is more difficult to treat than drug-susceptible TB.
Mycobacterium tuberculosis	One of the organisms causing TB in humans, and sometimes called the tubercle bacillus; belongs to a group of bacteria called mycobacteria.
Mycobacterium tuberculosis <i>complex</i>	A group of closely related mycobacteria that can cause TB (e.g., M. tuberculosis, M. bovis, M. africanum). Most TB in the United States is caused by M. tuberculosis.

Term	Definition
NEDSS/HL-7	National Electronic Disease Surveillance System (NEDSS)/Health Level 7 (HL-7)
Non-U.Sborn persons	Persons who are not eligible for U.S. citizenship at birth, regardless of the actual country of birth (formerly called "foreign-born").
Nucleic acid amplification (NAA)	A technique that amplifies (copies) DNA or RNA segments, in order to directly identify microorganisms in clinical specimens.
Possible TB case	A high index of suspicion for active TB (e.g., a known contact to an active TB case or to a person with signs or symptoms consistent with TB) who is currently under evaluation for TB disease. Also referred to as "Suspected" in some surveillance data systems.
Pre-XDR TB	Pre-extensively drug-resistant TB. The occurrence of TB in persons whose M. tuberculosis isolates are resistant to isoniazid, rifampin, and a fluroquinolone OR whose M. tuberculosis isolates are resistant to isoniazid, rifampin, and a second-line injectable (amikacin, capreomycin, and kanamycin).
Pulmonary TB	TB disease that occurs in the lungs, typically causing a cough and an abnormal chest radiograph. Pulmonary TB is usually infectious if untreated. Most TB cases reported in the United States are pulmonary TB.
Pyridoxine	Another name for vitamin B6; it is given to prevent peripheral neuropathy; should always be given to pregnant and breastfeeding women on isoniazid.
Question Packages	WDRS term. Sets of fields related to an event and related to a specific type of question where we collect our data (e.g. Administrative Question Package)

Term	Definition
Recurrence	A patient who has either a
	 Negative culture result while receiving TB treatment, but at some point after therapy is completed, either the culture result becomes positive for M. tuberculosis again or the patient has clinical or radiologic deterioration that is consistent with TB disease, or Negative smear and culture result (e.g., clinical case) at diagnosis and while receiving TB treatment, but at some point after therapy is completed, either the patient has a culture result that is positive for M. tuberculosis or has clinical or radiologic deterioration that is consistent with TB disease.
Rifamate	A combination of isoniazid (INH) and rifampin (RIF); used to treat TB disease or LTBI.
Rifater	A combination of isoniazid (INH), rifampin (RIF), and pyrazinamide (PZA); used to treat TB disease or LTBI.
Rifabutin	A drug used as a substitute for rifampin (RIF) in the treatment of TB disease and LTBI.
Rifampin (RIF)	A drug used to treat TB disease and LTBI.
Rifapentine	A drug used to treat TB disease and LTBI.
Second-line TB drugs	Drugs used to treat TB that is resistant to first-line TB drugs (e.g., capreomycin, ethionamide, cycloserine, ciprofloxacin, amikacin).
Smear	A specimen that has been smeared onto a glass slide, stained, washed in an acid solution, and then placed under the microscope for examination; used to detect acid-fast bacilli in a specimen.
Specimen	A sample collected from a person for testing.
Sputum	Phlegm from deep in the lungs, collected in a sterile container for processing and examination.
Susceptibility	An organism's ability to be killed by a particular drug.

Term	Definition
TB disease	An illness, caused by bacteria called Mycobacterium tuberculosis, in which tuberculosis (TB) bacteria are multiplying and attacking parts of the body, most commonly the lungs. A person with TB disease is capable of spreading the disease to others if the TB bacteria are active in the lungs or throat. The symptoms of TB disease include weakness, weight loss, fever, no appetite, chills, and sweating at night. Other symptoms may include a bad cough, pain in the chest, and coughing up blood.
Usual residence	In general, "usual residence" is defined as "the place where the person lives and sleeps most of the time, which is not necessarily the same as the person's voting residence, legal residence, or the place where they became infected with a reportable disease."
Wizards	WDRS term. Also called a "virtual question package." Allows the user to subset questions from multiple question packages to fill out easily and quickly. Questions answered in a wizard populate the corresponding fields in the question packages.
Workflows	WDRS term. A list of activities that need to be performed on records. Workflows are based on queries that retrieve event information that needs attention and organizes them for processing. Often workflow and queue are used interchangeably. Examples are: All open events and Events missing suspected exposure type.
XDR TB	Extensively drug-resistant TB. The occurrence of TB in persons whose M. tuberculosis isolates are resistant to isoniazid, rifampin, a fluroquinolone, and a second-line injectable (amikacin, capreomycin, and kanamycin) OR whose M. tuberculosis isolates are resistant to isoniazid, rifampin, a fluroquinolone, and bedaquiline or linezolid.

