9: Quality Assurance Cross-cutting Systems and Process: NTIP, TB GIMS and Cohort Review

Definitions

Term	Definition
Calculated variable	CDC-developed variables, calculated from existing information, to simplify certain algorithms.
Cohort	A group of TB patients managed over a specific period of time, usually 3 months.
Cohort review	A systematic review process for managing patients. TB cases in a specific cohort are reviewed for the patient's clinical status, the adequacy of the medication regimen, treatment adherence or completion, and the result of contact investigation.
Commercial surveillance software	A web-based surveillance system developed by a private company.
Country of birth (COB)	The country where a person was born. For a more detailed explanation see Report of Verified Case of Tuberculosis (RVCT): Self-Study Modules, RVCT item 12–Country of Birth http://www.cdc.gov/tb/programs/rvct/default.htm.
Country of origin	A calculated variable that combines the responses for RVCT item 12, Country of Birth, to determine U.S.-born or foreign-born status. The reason for this calculation is to obtain rates using the only available population estimates from the U.S. Census Bureau's American Community Survey.
Data completeness	A measure that indicates whether the information submitted contains the complete set of mandatory data items.

Term	Definition
Electronic Report of Verified Case of Tuberculosis (eRVCT)	A web-based surveillance system for reporting TB cases developed by CDC's DTBE and available to all reporting jurisdictions. The system is based on the RVCT form.
Genotype	A specific genetic pattern or strain that is detected by one or more of the genotyping techniques used for *M. tuberculosis*: spoligotyping, MIRU-VNTR analysis, or IS6110-based RFLP. National terminology for genotype is based on either spoligotype and 12-locus MIRU-VNTR (PCRType, e.g., PCR00002), or spoligotype and 24-locus MIRU-VNTR (GENType, e.g., G00011). GENType is routinely available for all culture-confirmed TB cases reported after April 2009.
Genotyping Accession Number	The tracking number assigned to each TB isolate received by a genotyping laboratory. Accession numbers are formatted as a 2-digit year, followed by either an L or RF depending on which genotyping lab assigned the number, and a unique 4-digit number that is assigned sequentially (e.g., 06L1058, 11RF0005, 12L3788). The California genotyping laboratory assigns L, and the Michigan laboratory assigns RF in their accession numbers.
Genotyping laboratories	The laboratories funded by CDC to provide TB genotyping services to state and local TB control programs. For 2004-2013, these laboratories are located at the Michigan Department of Community Health and the California Department of Health Services.
Indicators	Measures for assessing performance or progress of a program or activity.
Invalid, Missing and Unknown (MUNK)	RVCT variables that are either invalid, missing, or unknown.
Linking	The process of connecting a TB genotype result from a specific isolate to the corresponding surveillance record for the patient that was the source of that isolate. Linking in the context of genotyping is different from RVCT item 3, Linking State Case Number.
National Electronic Disease Surveillance System (NEDSS)	A web-based surveillance system with an infrastructure developed by CDC that uses specific Public Health Information Network (PHIN) and NEDSS messaging standards.
National TB Indicators Project (NTIP)	A monitoring system using standardized definitions, indicators, and calculations to track progress toward attaining national TB program objectives.
National TB Program Objectives	Objectives that reflect the national priorities for TB control in the United States.

Term	Definition
National Tuberculosis Surveillance System (NTSS)	The only national repository of TB surveillance data in the United States. NTSS receives data on TB cases from reporting jurisdictions' web-based systems through a standardized data collection form, the Report of Verified Case of Tuberculosis (RVCT).
NTSS reporting jurisdictions	All 50 U.S. states, the District of Columbia, New York City, American Samoa, the Federated States of Micronesia, Guam, the Republic of the Marshall Islands, the Commonwealth of the Northern Mariana Islands, Puerto Rico, the Republic of Palau, and the U.S. Virgin Islands.
Public Health Information Network (PHIN) code	A standardized code used by computer programmers to assign TB data to a specified RVCT variables. These variable codes are essential in transmitting data to CDC. Several data issues have been attributed to errors on data system programming involving PHIN codes. For example, if a code is incorrect, the data can disappear. If the data are all missing, check the PHIN Variable ID.
Report of Verified Case of Tuberculosis (RVCT)	The NTSS standardized data collection form. Data are collected by 60 reporting jurisdictions and submitted electronically to CDC. Data are used to monitor national TB trends, identify priority needs, and create the DTBE annual surveillance report, Reported Tuberculosis in the United States.
State Case Number	The official identification number for the case; commonly known as the RVCT number. If additional communication about a record is required between CDC and a reporting area, this number is used to identify the record.
Submitter number	A tracking number assigned to an isolate by a state public health laboratory. The format of the submitter number varies by state. Most state laboratories refer to this as an accession number; however, it is not the same number as a "genotyping accession number."
Tuberculosis Genotyping Information System (TB GIMS)	A secure web-based system designed to improve access, management, and application of genotyping data at the state and local level. As part of the NTSS, TB GIMS contains tools to detect and prioritize TB outbreaks.

Term	Definition
Tuberculosis Information Management System (TIMS)	TIMS was a Windows-based, client-server application that helped health departments and other facilities manage TB patients, conduct TB surveillance activities, and manage TB programs overall. TIMS replaced former DTBE software (SURVS-TB and TBDS) and provided for electronic transmission of TB surveillance data and program management reports. TIMS was replaced by web-based surveillance systems in 2009.
U.S.-born	A person born in 1 of the 50 states or the District of Columbia, or a person born outside the United States to at least one parent who was a U.S. citizen. For a more detailed explanation see Report of Verified Case of Tuberculosis (RVCT): Self-Study Modules, RVCT item 12 – Country of Birth http://www.cdc.gov/tb/programs/rvct/default.htm.

Overview of Quality Assurance Cross-cutting Systems and Process

Primary Purpose

This chapter provides several quality assurance (QA) cross-cutting systems that can be used to improve at least three of the five QA components (i.e., accuracy, completeness, and timeliness). In addition, a number of QA cross-cutting tools are described at the end of the chapter.

QA Cross-cutting Systems and Process

This chapter provides an overview of the following QA cross-cutting systems and process:

- The National Tuberculosis Indicators Project (NTIP) is used to track progress toward national TB program objectives.
- The Tuberculosis Genotyping System (TB GIMS) is designed to improve access, management, and application of genotyping data at the state and local level.
- Cohort Review is a systematic process being implemented by TB programs to manage TB patients.

National Tuberculosis Indicators Project (NTIP)

Primary Purpose

This section demonstrates how to use the National Tuberculosis Indicators Project (NTIP) to conduct QA for surveillance data. Readers will learn to assess surveillance data accuracy, completeness, and timeliness using NTIP reports and the Line List function.

Introduction

NTIP is a monitoring system for tracking the progress of U.S. tuberculosis (TB) control programs toward achieving national TB program objectives. The system was developed by the Division of Tuberculosis Elimination in collaboration with state and local TB programs.

NTIP contains a standardized indicator report for each objective to help programs describe their progress. Data used in NTIP are derived from data routinely reported to CDC through the National Tuberculosis Surveillance System (NTSS), the Aggregated Reports for Program Evaluation for Contacts (ARPE), and the Electronic Disease Notification (EDN) System. The reports are intended to help programs track progress across jurisdictions over time, prioritize program activities, and identify areas for improvement.

The national TB program objectives highlight key outcomes for TB control strategies in the United States – patient treatment, contact investigation, and evaluation of immigrants and refugees. Data for assessing indicators pertaining to patient treatment come from the Report of Verified Case of Tuberculosis (RVCT). Table 9.1 lists the national TB program objectives that use RVCT data to assess program progress toward objectives related to TB diagnosis and patient treatment.

Table 9.1
National TB Objectives Measured Using RVCT Data

National TB Objectives

• Completion of treatment
• TB case rates in the following populations:
  ○ U.S.-born persons
  ○ Foreign-born persons
  ○ U.S.-born non-Hispanic blacks
  ○ Children younger than 5 years of age
• Laboratory turnaround time
• Drug-susceptibility result
• Treatment initiation
• Sputum culture conversion
• Recommended initial therapy
• Universal genotyping
• Known HIV status
• Sputum culture reporting

The complete list of the National TB Program Objectives and Performance Targets for 2015 are available at http://www.cdc.gov/tb/programs/Evaluation/Indicators/ProgramObjectives.pdf.

Surveillance Data Quality and NTIP

The quality of surveillance data directly impacts the quality of data presented in NTIP reports. Because the data used to calculate indicators come directly from the data that programs have reported to CDC, reporting of inaccurate and incomplete surveillance data will result in inaccurate indicator data reported in NTIP. Similarly, delays in data reporting will be reflected in inaccurate reporting of indicators.

NTIP reports can be used to assess and monitor the following QA components of TB surveillance data:

- Data accuracy
- Data completeness
- Data timeliness

A number of factors at the program level have implications for the quality of TB surveillance data reported to CDC. Consequently, these factors affect the data reported in NTIP. Table 9.2 highlights common factors that affect the accuracy, completeness, and timeliness of surveillance data, and the impact of these factors on program performance portrayed in NTIP reports.

Table 9.2
Factors that Affect the Quality of Surveillance Data

Quality Assurance Components	Factors that Affect the Quality of Surveillance Data Reported to CDC	Impact on Program Performance in NTIP Reports
Data Accuracy	• Programming issue (e.g., incorrect Public Health Information Network [PHIN]code) • Data entry errors • Incorrect interpretation of variable definition	• Inaccurate portrayal of program performance
Data Completeness	• Data not being transmitted properly from state to CDC • Data not collected on the state RVCT form	• Inaccurate portrayal of program performance
Data Timeliness	• Data not being submitted or reported by local jurisdiction • Delay in case reporting by doctors to the health department • Delay in reporting to the state TB program official • Delay in data entry • Delay in data transmission by the state to CDC	• Delayed NTIP reports • The ability of program managers and policy makers to effectively use data for decision-making to guide development of TB programs.

RVCT Variables and NTIP

Approximately 60 of 300 RVCT variables (or 25 of 49 RVCT items) are used in NTIP. Cross-cutting Tool–5, RVCT Variables Used in NTIP highlights key components of NTIP and lists the RVCT variables used to calculate each of the NTIP indicators. The tool includes

- RVCT item numbers
- Variable descriptions
- Public Health Information Network code (or PHIN Code)
- NTIP Indicator Report

When NTIP Reports Are Available

NTIP is based on data that have been transmitted by NTSS reporting jurisdictions and successfully received by the Division of Tuberculosis Elimination. **NTIP is updated weekly, and reflects the most current data reported to CDC by NTSS reporting jurisdictions.**

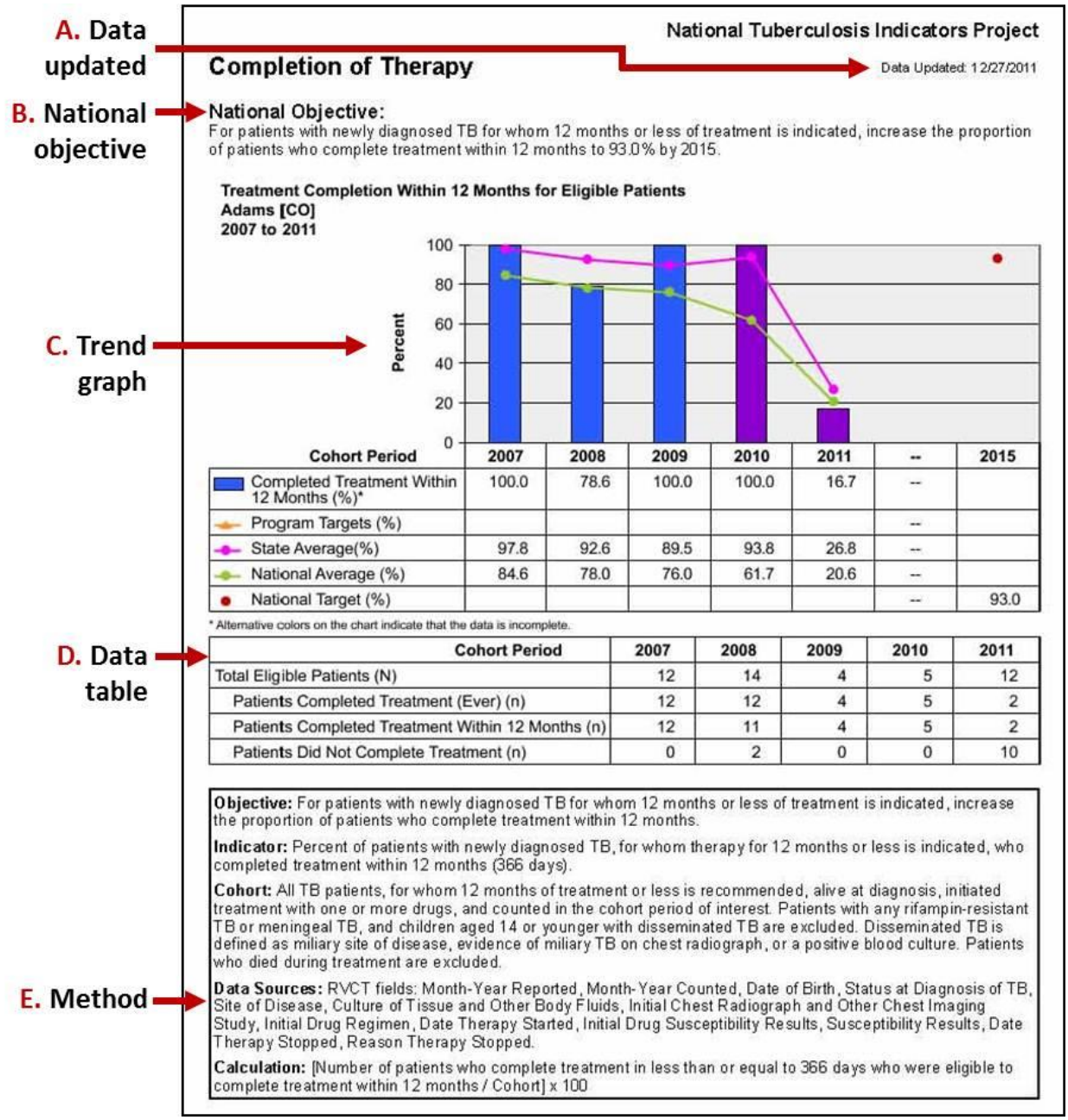
Examples of NTIP Reports

The trend graph on each indicator report provides clues on how accurate, complete, and current the surveillance data are at CDC.

Figure 9.1 provides a description of the following sections of the NTIP report:

A. **Data updated:** The date when data in the report were updated.
B. **National objective:** Statement of the national objective for indicator report.
C. **Trend graph:** Include
    - 5-year trend graph on the national objective along with national and state-level data for comparison
    - Reports can show data yearly or quarterly
    - The colored bars on the graphs provide visual clues for completeness of data
D. **Data table:** Provides raw data used to calculate the indicator.
E. **Method:** The section provides the definition of the indicator, the data sources from which data are derived, the inclusion and exclusion criteria for the cohort of cases, and the calculation for the indicator.

Figure 9.1
Sample NTIP Report



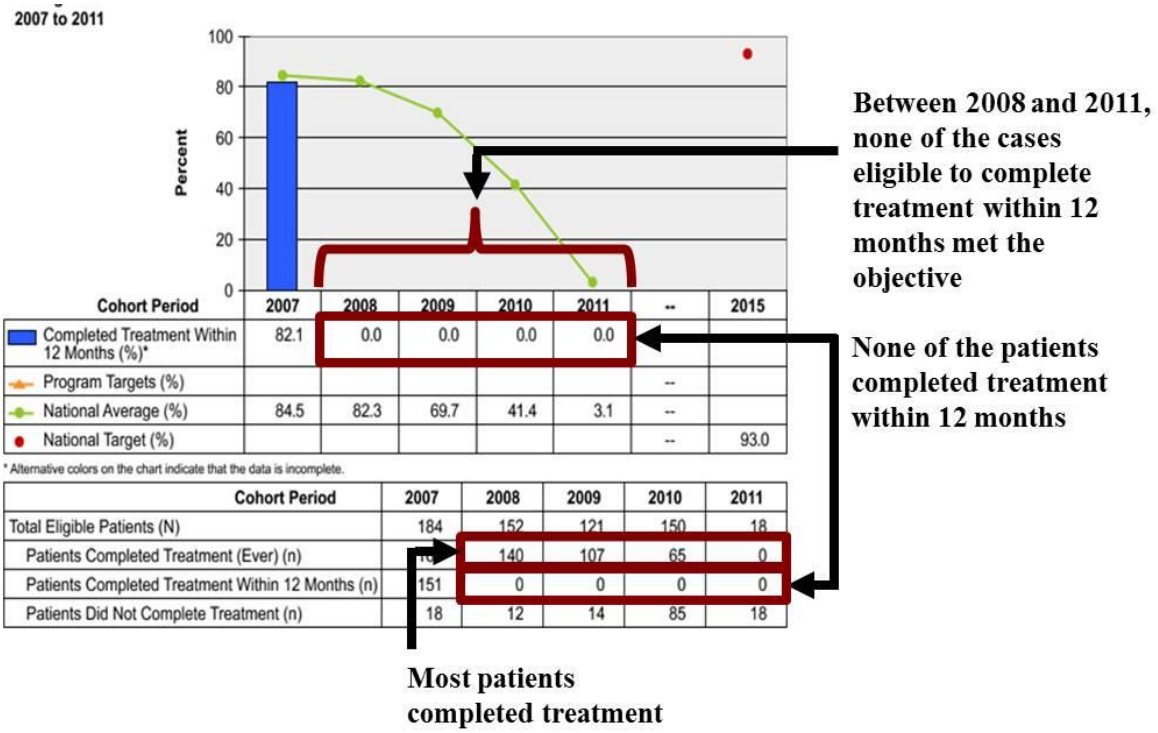
Assessing Surveillance Data Accuracy

Inaccurate surveillance data from the RVCT has a significant impact on NTIP indicators. **Inaccurate data in an RVCT variable leads to inaccurate indicator results.**

Example A

Figure 9.2 provides an example from the Completion of Therapy objective.

Figure 9.2
Example of NTIP Report with Inaccurate Data



Cohort Period	2007	2008	2009	2010	2011	--	2015
Completed Treatment Within 12 Months (%)*	82.1	0.0	0.0	0.0	0.0		
Program Targets (%)						--	
National Average (%)	84.5	82.3	69.7	41.4	3.1	--	
National Target (%)						--	93.0

* Alternative colors on the chart indicate that the data is incomplete.

Cohort Period	2007	2008	2009	2010	2011
Total Eligible Patients (N)	184	152	121	150	18
Patients Completed Treatment (Ever) (n)	[illegible]	140	107	65	0
Patients Completed Treatment Within 12 Months (n)	151	0	0	0	0
Patients Did Not Complete Treatment (n)	18	12	14	85	18

The graph shows:

- Between 2008 and 2011, none of the cases eligible to complete treatment within 12 months met the objective.
- Result is 0% treatment completion rate for this objective.
- Most of the patients have completed treatment.
- None of the patients completed treatment within 12 months.

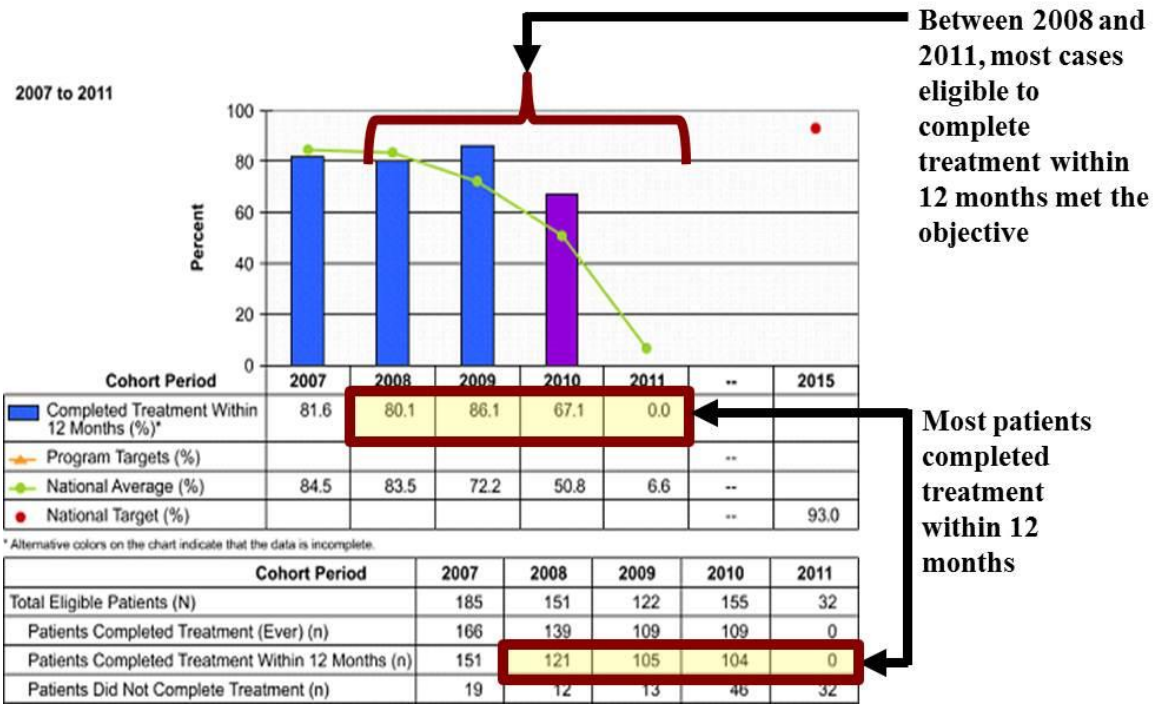
For the Completion of Therapy indicator, treatment **has to be completed within 366 days** for a case to meet this objective. The following two RVCT variables are used to calculate the treatment duration:

- **Date Therapy Started** (item 36)
- **Date Therapy Stopped** (item 43)

Missing data in one key variable such as **Date Therapy Stopped** can have a tremendous effect on the indicator result as shown in Figure 9.2 above. In this example, the PHIN code for the Date Therapy Stopped variable was incorrectly applied by the computer programmer, resulting in no data being transmitted to CDC for this variable.

Figure 9.3 shows the graph in Figure 9.2 after the missing variables are corrected.

Figure 9.3
Example of NTIP Report with Results of Data Corrected



Cohort Period	2007	2008	2009	2010	2011	--	2015
Completed Treatment Within 12 Months (%)*	81.6	80.1	86.1	67.1	0.0		
Program Targets (%)						--	
National Average (%)	84.5	83.5	72.2	50.8	6.6	--	
National Target (%)						--	93.0

* Alternative colors on the chart indicate that the data is incomplete.

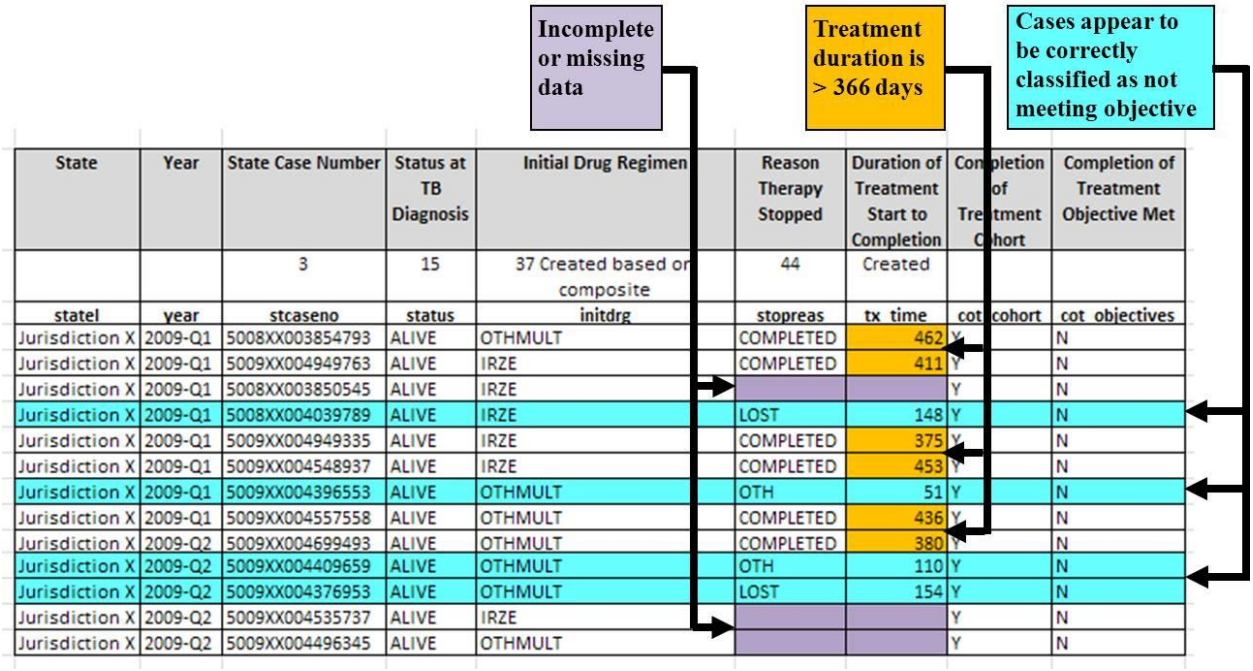
Cohort Period	2007	2008	2009	2010	2011
Total Eligible Patients (N)	185	151	122	155	32
Patients Completed Treatment (Ever) (n)	166	139	109	109	0
Patients Completed Treatment Within 12 Months (n)	151	121	105	104	0
Patients Did Not Complete Treatment (n)	19	12	13	46	32

Example B

Inaccuracies in surveillance data may not always be easily detected. Unlike the example provided in Figure 6.2, data may be incorrectly entered by program staff due to errors in data entry or misinterpretation of the variable definition. In this case, surveillance data are incorrect rather than incomplete or missing.

NTIP provides a Line List function that can be used to export line-listed data that were reflected in the aggregated NTIP report. The list can be used to validate the accuracy of data recorded at CDC. Inaccuracies in surveillance data in variables such as initial drug regimen, status at diagnosis, or date therapy started or completed can be assessed using the line-listed data provided in NTIP (Figure 9.4).

Figure 9.4
NTIP Line List



State	Year	State Case Number	Status at TB Diagnosis	Initial Drug Regimen	Reason Therapy Stopped	Duration of Treatment Start to Completion	Completion of Treatment Cohort	Completion of Treatment Objective Met
		3	15	37 Created based on composite	44	Created		
statel	year	stcaseno	status	initdrg	stopreas	tx_time	cot_cohort	cot_objectives
Jurisdiction X	2009-Q1	5008XX003854793	ALIVE	OTHMULT	COMPLETED	462	Y	N
Jurisdiction X	2009-Q1	5009XX004949763	ALIVE	IRZE	COMPLETED	411	Y	N
Jurisdiction X	2009-Q1	5008XX003850545	ALIVE	IRZE			Y	N
Jurisdiction X	2009-Q1	5008XX004039789	ALIVE	IRZE	LOST	148	Y	N
Jurisdiction X	2009-Q1	5009XX004949335	ALIVE	IRZE	COMPLETED	375	Y	N
Jurisdiction X	2009-Q1	5009XX004548937	ALIVE	IRZE	COMPLETED	453	Y	N
Jurisdiction X	2009-Q1	5009XX004396553	ALIVE	OTHMULT	OTH	51	Y	N
Jurisdiction X	2009-Q1	5009XX004557558	ALIVE	OTHMULT	COMPLETED	436	Y	N
Jurisdiction X	2009-Q2	5009XX004699493	ALIVE	OTHMULT	COMPLETED	380	Y	N
Jurisdiction X	2009-Q2	5009XX004409659	ALIVE	OTHMULT	OTH	110	Y	N
Jurisdiction X	2009-Q2	5009XX004376953	ALIVE	OTHMULT	LOST	154	Y	N
Jurisdiction X	2009-Q2	5009XX004535737	ALIVE	IRZE			Y	N
Jurisdiction X	2009-Q2	5009XX004496345	ALIVE	OTHMULT			Y	N

Instructions on how to export the line list and use Microsoft Excel's functions to examine the data can be found online in the NTIP Help/Resources section.

Assessing Surveillance Data Completeness

The trend graph in NTIP also provides clues on how complete and current the surveillance data are at CDC. The color of the bar graph provides a visual clue for how complete the surveillance data are for a particular cohort period as follows:

Blue bar = 90% completeness of the Date Therapy Stopped variable

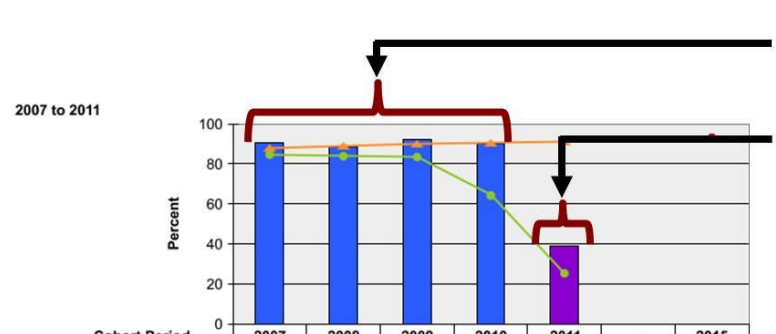
Purple bar = less than 90% completeness of the Date Therapy Stopped variable

In Figure 9.5, the color of the bar graph changes from purple to blue when the data are at least 90% complete.

In Completion of Treatment, the completeness of the variable **Date Therapy Stopped** is used to determine the completeness of the indicators. When the color of the graph turns blue, it signals that 90% of the data are complete for the reporting cohort period. The color notation can be used to assess how complete the treatment data are, and how reliable and accurate the indicator may be. When reviewing indicator reports, note the time period when the color of the bar graph remains purple. This provides an indication of the data quality for the time period. If the bar graph remained purple in a time period when most patients should have completed treatment, data quality is most likely poor.

In Figure 9.5, the data for 2011 are less than 90% complete (see purple bar). If you are reviewing this graph in 2014, when most of cases reported in 2011 should have completed treatment, the data quality is poor. However, if you are reviewing these data in 2011, when most of the patients are still on treatment, the purple bar on this graph shows what is expected.

Figure 9.5
Example of NTIP Yearly Report with Good Quality Data



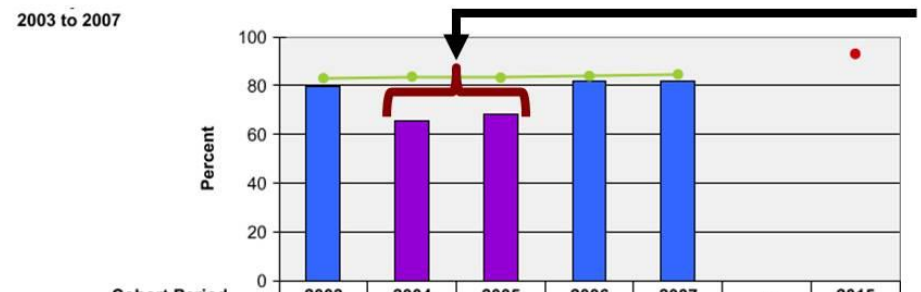
Cohort Period	2007	2008	2009	2010	2011	--	2015
Completed Treatment Within 12 Months (%)*	90.7	88.3	91.9	89.7	39.0	--	
Program Targets (%)	88.0	89.0	90.0	90.5	91.0	--	N/A
National Average (%)	84.6	83.7	83.3	64.1	25.2	--	
National Target (%)						--	93.0

* Alternative colors on the chart indicate that the data is incomplete.

Cohort Period	2007	2008	2009	2010	2011
Total Eligible Patients (N)	792	787	665	634	577
Patients Completed Treatment (Ever) (n)	765	751	641	586	276
Patients Completed Treatment Within 12 Months (n)	718	695	611	569	225
Patients Did Not Complete Treatment (n)	27	36	24	48	301

Figure 9.6 indicates that there are possible data quality concerns in 2004 and 2005. The purple color bars in 2004 and 2005 indicate that the **Date Therapy Stopped** (item 43) variable is less than 90% complete. While it is likely that this is due to patients that are still on treatment, the higher percentage of treatment completion rate and higher percentage of variable completeness for more recent cohorts (i.e., 2006 and 2007) indicate possible data quality concerns and reporting delays in 2004 and 2005.

Figure 9.6
Example of NTIP Yearly Report Indicating Possible Data Quality Issues



Cohort Period	2003	2004	2005	2006	2007	--	2015
Completed Treatment Within 12 Months (%)*	79.5	65.7	68.1	81.7	82.0	--	
Program Targets (%)						--	
National Average (%)	83.0	83.7	83.2	83.9	84.6	--	
National Target (%)						--	93.0

* Alternative colors on the chart indicate that the data is incomplete.

Cohort Period	2003	2004	2005	2006	2007
Total Eligible Patients (N)	288	280	270	295	245
Patients Completed Treatment (Ever) (n)	265	217	213	274	228
Patients Completed Treatment Within 12 Months (n)	229	184	184	241	201
Patients Did Not Complete Treatment (n)	23	63	57	21	17

Exercise 9.1: Identifying NTIP and MUNK Missing Data for Country of Origin

This exercise illustrates how to use an NTIP Report to identify invalid, missing or unknown data in the MUNK Report.

You are from the fictitious state of San Price. Your 2012 NTIP Report shows only 40% completion for Country of Origin for 2012 MUNK Report.

NTIP Report, 2012
Country of Origin

Variable	RVCT Fields	San Price 2012			Complete %
		(N)	Unknown Missing (n)	Complete (n)	
Date of Birth	**7**	**20**	**0**	**20**	**100%**
Race	**10**	**20**	**2**	**18**	**90%**
Country of Origin	**11**	**20**	**12**	**8**	**40%**

9.1	Use the 2012 MUNK Report below to help you identify cases with missing data. Note that **Country of Birth**, as well as **U.S.-born** status, is included when calculating **Country of Origin** for TB Case Rates. Circle the Row # on the left side of the report to indicate which case is missing data.

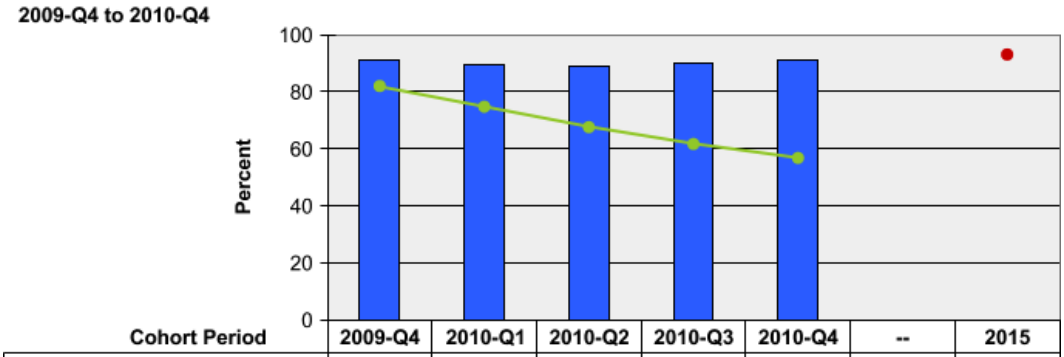
2012 MUNK Report

Row #	State_ Alpha_ Cd	Case_ Status	State_Case_ID	County_ Cd_Desc	Report_ Date	Count_ Date	Questions_Desc	Value	Value_ Desc
1	SP	Counted	2012SP201000001	Jackson	20120107	20120107	12-Country of Birth (v2)		
2	SP	Counted	2012SP201000002	Jefferson	20120106	20120106	13-Month-Year Arrived in US (V2)		
3	SP	Counted	2012SP201000002	Jefferson	20120106	20120106	19-Microscopic Exam		
4	SP	Counted	2012SP201000002	Jefferson	20120106	20120106	21-NAA Specimen Type or Anatomic Site		
5	SP	Counted	2012SP201000003	Cobb	20120114	20120114	12-Country of Birth (v2)		
6	SP	Counted	2012SP201000003	Cobb	20120114	20120114	43-Date Therapy Stopped		
7	SP	Counted	2012SP201000003	Cobb	20120114	20120114	44-Reason Therapy Stopped		
8	SP	Counted	2012SP201000007	Jackson	20120218	20120218	12-Country of Birth (v2)		
9	SP	Counted	2012SP201000013	Greene	20120326	20120326	12-U.S. Born		
10	SP	Counted	2012SP201000017	Stoddard	20120410	20120410	12-Country of Birth (v2)		
11	SP	Counted	2012SP201000017	Stoddard	20120410	20120410	44-Reason Therapy Stopped		
12	SP	Counted	2012SP201000019	Taney	20120415	20120415	12-Country of Birth (v2)		
13	SP	Counted	2012SP201000019	Taney	20120415	20120415	15-Status of TB Diagnosis		
14	SP	Counted	2012SP201000032		20120528	20120528	04-City		
15	SP	Counted	2012SP201000032		20120528	20120528	04-County		
16	SP	Counted	2012SP201000032		20120528	20120528	04-Zip Code		Null Zip Code
17	SP	Counted	2012SP201000032		20120528	20120528	12-Country of Birth (v2)		
18	SP	Counted	2012SP201000034	Calhoun	20120416	20120416	11-Race	2131-1	Other Race
19	SP	Counted	2012SP201000034	Calhoun	20120416	20120416	12-Country of Birth (v2)		
20	SP	Counted	2012SP201000040	Greene	20120626	20120626	12-Country of Birth (v2)		
21	SP	Counted	2012SP201000040	Greene	20120626	20120626	43-Date Therapy Stopped		
22	SP	Counted	2012SP201000045	Jackson	20120708	20120708	12-Country of Birth (v2)		
23	SP	Counted	2012SP201000045	Jackson	20120708	20120708	19-Microscopic Exam		
24	SP	Counted	2012SP201000064	Cobb	20120925	20120925	07-Previous TB	UNK	Unknown
25	SP	Counted	2012SP201000064	Cobb	20120925	20120925	11-Race	2131-1	Other Race
26	SP	Counted	2012SP201000064	Cobb	20120925	20120925	13-Month-Year Arrived in US (v2)		
27	SP	Counted	2012SP201000064	Cobb	20120925	20120925	19-Microscopic Exam		
28	SP	Counted	2012SP201000064	Cobb	20120925	20120925	21-NAA Specimen Type or Anatomic Site		
29	SP	Counted	2012SP201000064	Cobb	20120925	20120925	43-Date Therapy Stopped		
30	SP	Counted	2012SP201000064	Cobb	20120925	20120925	44-Reason Therapy Stopped		
31	SP	Counted	2012SP201000073	Calhoun	20121008	20121008	15-Status of TB Diagnosis		
32	SP	Counted	2012SP201000073	Calhoun	20121008	20121008	19-Microscopic Exam		
33	SP	Counted	2012SP201000073	Calhoun	20121008	20121008	21-NAA Specimen Type or Anatomic Site		
34	SP	Counted	2012SP201000078	Stark	20121029	20121029	12-Country of Birth (v2)		
35	SP	Counted	2012SP201000078	Stark	20121029	20121029	43-Date Therapy Stopped		
36	SP	Counted	2012SP201000082	Platte	20120803	20120803	12-Country of Birth (v2)		

Assessing Surveillance Data Timeliness

Monitoring the completeness and timeliness of surveillance data is similar to monitoring the progress of the jurisdictions with respect to the indicator. When looking at a jurisdiction that has kept its data collection and reporting up to date with its case management process, the cohort period in which most cases would have completed treatment would be five quarters prior to the current quarter (e.g., 4th quarter 2010 data would not be evaluated until January 2012). The blue bars in Figures 9.7 and 9.8 illustrate this point.

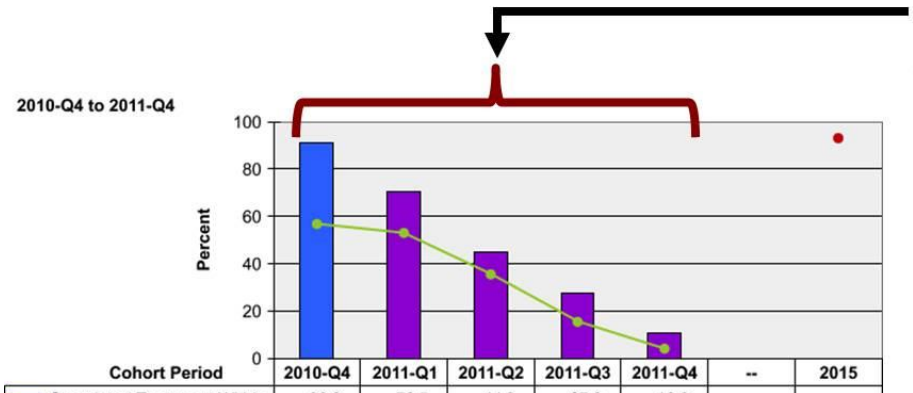
Figure 9.7
Example of a Quarterly NTIP Report of a Program with Timely Reporting



Cohort Period	2009-Q4	2010-Q1	2010-Q2	2010-Q3	2010-Q4	--	2015
Completed Treatment Within 12 Months (%)	90.8	89.3	89.0	90.1	90.8	--	
Program Targets (%)						--	N/A
National Average (%)	81.9	74.7	67.5	61.6	56.7	--	
National Target (%)						--	93.0

Cohort Period	2009-Q4	2010-Q1	2010-Q2	2010-Q3	2010-Q4
Total Eligible Patients (N)	163	168	164	172	130
Patients Completed Treatment (Ever) (n)	154	160	150	156	120
Patients Completed Treatment Within 12 Months (n)	148	150	146	155	118
Patients Did Not Complete Treatment (n)	9	8	14	16	10

Figure 9.8
Example of a Quarterly NTIP Report with Completed Cases



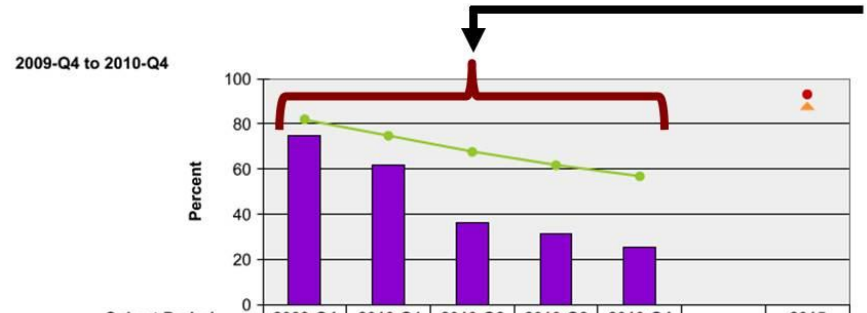
Cohort Period	2010-Q4	2011-Q1	2011-Q2	2011-Q3	2011-Q4	--	2015
Completed Treatment Within 12 Months (%)*	90.8	70.5	44.9	27.6	10.6	--	
Program Targets (%)						--	N/A
National Average (%)	56.7	52.9	35.4	15.3	4.0	--	
National Target (%)						--	93.0

* Alternative colors on the chart indicate that the data is incomplete.

Cohort Period	2010-Q4	2011-Q1	2011-Q2	2011-Q3	2011-Q4
Total Eligible Patients (N)	130	146	147	152	132
Patients Completed Treatment (Ever) (n)	120	121	87	48	20
Patients Completed Treatment Within 12 Months (n)	118	103	66	42	14
Patients Did Not Complete Treatment (n)	10	25	60	104	112

Figure 9.9 represents a program that has been transmitting data to CDC on a continuous basis as patients complete treatment. The curve in the quarterly indicator status reflects an increasing number of cases reported to have completed treatment within 12 months.

Figure 9.9
Example of Data Transmitted to CDC on a Regular Basis



Cohort Period	2009-Q4	2010-Q1	2010-Q2	2010-Q3	2010-Q4	--	2015
Completed Treatment Within 12 Months (%)*	74.6	61.5	36.4	31.0	25.3	--	
Program Targets (%)						--	88.0
National Average (%)	81.9	74.7	67.5	61.6	56.7	--	
National Target (%)						--	93.0

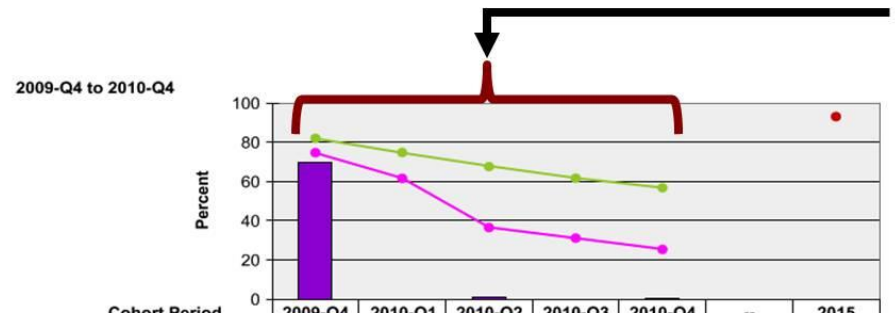
* Alternative colors on the chart indicate that the data is incomplete.

Cohort Period	2009-Q4	2010-Q1	2010-Q2	2010-Q3	2010-Q4
Total Eligible Patients (N)	712	387	500	522	700
Patients Completed Treatment (Ever) (n)	578	252	202	175	192
Patients Completed Treatment Within 12 Months (n)	531	238	182	162	177
Patients Did Not Complete Treatment (n)	134	135	298	347	508

This graph represents a TB program that regularly transmits data to CDC as patients complete treatment. The curve in the quarterly indicator report reflects a number of cases that are completing treatment as time goes by.

In contrast, Figure 9.10 represents a TB program that does not update or transmit data to CDC on a regular basis. As a result, a large amount of data may be missing. Delays in data reporting can be observed when comparing the program's status to the state or national averages.

Figure 9.10
Example of Data not Updated or Transmitted to CDC on a Regular Basis



Cohort Period	2009-Q4	2010-Q1	2010-Q2	2010-Q3	2010-Q4	--	2015
Completed Treatment Within 12 Months (%)*	69.9	0.0	0.7	0.0	0.3	--	
Program Targets (%)						--	N/A
State Average(%)	74.6	61.5	36.4	31.0	25.3	--	
National Average (%)	81.9	74.7	67.5	61.6	56.7	--	
National Target (%)						--	93.0

* Alternative colors on the chart indicate that the data is incomplete.

Cohort Period	2009-Q4	2010-Q1	2010-Q2	2010-Q3	2010-Q4
Total Eligible Patients (N)	286	54	144	123	311
Patients Completed Treatment (Ever) (n)	219	0	1	0	1
Patients Completed Treatment Within 12 Months (n)	200	0	1	0	1
Patients Did Not Complete Treatment (n)	67	54	143	123	310

This graph represents a TB program that does not update or transmit data on a regular basis. A large amount of data may be missing.

Where to Access NTIP Reports

NTIP can be accessed through the Secure Access Management System (SAMS). SAMS is a federal information technology system that gives authorized personnel secure, external access to non-public CDC applications. Request for access should be directed to the respective State TB System Administrator (contact information is listed below).

Additional Resources

- National Tuberculosis Indicators Project (NTIP) – Fact Sheet
  http://www.cdc.gov/tb/publications/factsheets/statistics/NTIP.pdf

- National Tuberculosis Indicators Project (NTIP): Frequently Asked Questions
  http://www.cdc.gov/tb/publications/factsheets/statistics/NTIPFAQs.htm

- National TB Program Objectives and Performance Targets for 2015
  http://www.cdc.gov/tb/programs/Evaluation/Indicators/ProgramObjectives.pdf

- Secure Access Management System (SAMS) portal
  https://sams.cdc.gov/

- Table 5. Tuberculosis Cases, Percentages, and Case Rates per 100,000 Population by Origin of Birth, United States, 1993-2011 in the Reported Tuberculosis in the United States, 2011
  http://www.cdc.gov/tb/statistics/reports/2011/table5.htm

Tuberculosis Genotyping Information Management System (TB GIMS)

Primary Purpose

This section describes how Tuberculosis Genotyping Information Management System (TB GIMS) can be used

- To improve the quality of RVCT data.
- As a tool for QA activities that enhances TB surveillance in the United States.

Application of Genotyping in TB Control Activities

TB genotyping is a laboratory process for examining the genetic pattern of *Mycobacterium tuberculosis* DNA in a TB case. TB genotyping can be used by TB programs to

- Detect specimen or isolate cross-contamination to identify false-positive TB cases.
- Distinguish between reactivation of an old infection with an old strain and recent infection with a new TB strain.
- Confirm known connections among cases.
- Identify previously unknown connections among cases.
- Rule out potential, but false, connections between cases, thereby saving resources.
- Detect outbreaks promptly.

TB GIMS

TB GIMS is a secure web-based system designed to improve the management and use of genotyping data in routine TB control activities. A primary purpose of TB GIMS is to conduct enhanced surveillance for TB outbreaks at the national, state, and local level. Even though local and state health departments may use local genotyping databases, TB GIMS is the primary way TB programs access and use genotyping data. Along with enhancing TB surveillance, TB GIMS can also be used by TB control programs to conduct QA activities on RVCT data.

Genotyping Data Management

TB genotype results must be linked to RVCT data before they can be used effectively by TB programs through TB GIMS. In order to support this linking, TB GIMS integrates data from two different sources: (Figure 9.11)

1. **Genotype results**
    - Are obtained from isolates from culture-confirmed TB cases; results are uploaded to TB GIMS by genotyping laboratories.
    - Are tracked by the **Genotyping Accession Number** (item 38), which is assigned by the genotyping laboratories.
    - Are available within 3 weeks of the isolate being received at the genotyping laboratories.

2. **Surveillance data**
    - Are obtained from RVCTs sent from states to NTSS.
    - Are tracked by the **State Case Number** (item 3).

Complete Patient Records in TB GIMS

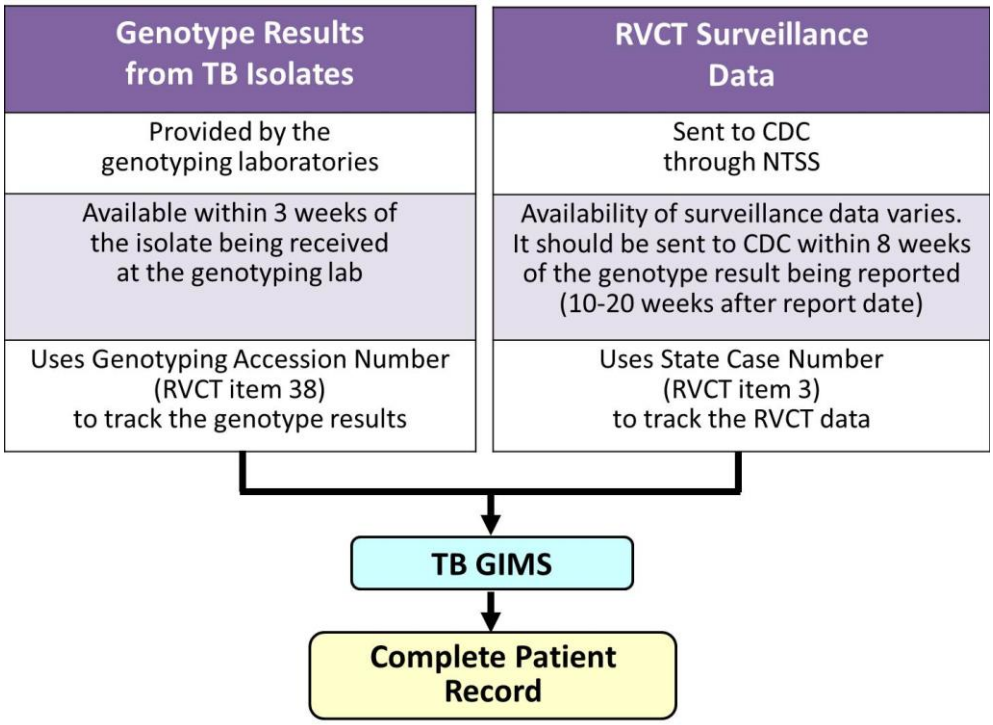
A complete patient record in TB GIMS is defined as a record that contains the genotype results connected (or linked) with the corresponding surveillance record.

Since genotype results are most useful when they can be reviewed in the context of information about case demographics, geography, and risk factors, TB programs need the information from these complete records to effectively apply genotyping in routine TB control activities. Additionally, TB outbreak detection methods are based on finding TB genotype clusters in specific geographic areas. Therefore, knowing the state, county, and zip code along with demographic and risk characteristics of the case from which the genotype result came is critical. This information is only available from the routinely collected surveillance data. Therefore, the more quickly the complete records are available, the more likely that TB programs can conduct timely surveillance activities and detect outbreaks promptly.

Creating a complete record requires two actions by states:

1. The RVCT must be sent to CDC.
2. Genotype results must be **linked** to the corresponding RVCT record for the TB case.

Figure 9.11
Genotyping Data Flow



Linking Genotype Results to Surveillance Record

There are two options for linking genotyping records to RVCT records

1. Within TB GIMS:
    - Linking within TB GIMS is managed by the TB GIMS Super User. The TB GIMS Super User is usually the genotyping coordinator for a state.
    - **State Case Numbers** that correspond to a G**enotyping Accession Number** are added to the genotype isolate record in TB GIMS. **State Case Numbers** can be entered into TB GIMS at any time, even before a genotype result is available.
    - For linking to occur, the TB GIMS Super User must have a list of **State Case Numbers** and patient names and dates of birth (DOB) for culture-confirmed cases. The Super User will compare this list with the list of patient names and DOB and **Genotyping Accession Numbers** for isolates submitted for genotyping; this information is obtained from the state TB laboratory. Matching these two lists is done outside of TB GIMS.
    - Super Users then enter the state case number associated with a specific **Genotyping Accession Number** into TB GIMS.

- Please note that under no circumstances should patient names and DOB be entered into TB GIMS.

- A valid **State Case Number** is 15 characters long in the following format: 4-digit Report Year (e.g., 2000) followed by 2-digit state acronym (e.g., CA) and a 9-digit tracking number assigned by the state (e.g., 123456789)
  - e.g., 2000CA123456789 is the correct format for a **State Case Number.**
  - e.g., 2012-XX-123456789 is an incorrectly entered **State Case Number**.

  Incorrectly formatted **State Case Numbers** entered into TB GIMS will not link to RVCT records.

2. Using **Genotyping Accession Number** (item 38) on the **Initial Drug Susceptibility Report (Follow Up Report-1)** (Figure 9.12)
   - Linking using Item 38 is managed by the state surveillance program, but requires coordination with the TB GIMS Super User/genotyping coordinator.
   - Item 38 is available on **Follow Up Report-1** and consists of two data entry fields
     - Isolates submitted for genotyping – Yes/No option
     - **Genotyping Accession Number** should be entered if the above is answered as a "Yes"; ensure that the number is entered in the correct format. The correct format for a **Genotyping Accession Number** is illustrated in Table 9.3.
     - Examples of valid accession numbers are: 11L3051, 10RF0016

Figure 9.12
RVCT Item 38
Genotyping Accession Number

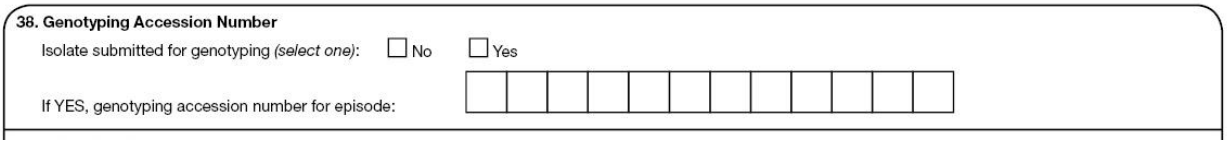


Table 9.3
Genotyping Accession Number Format

Sample Laboratories Performing Genotyping Service	Format for Genotyping Accession Number	Sample
California lab	**YY (the 2-digit year), followed by L and 4 digits**	**05L1234**
Michigan lab	**YY (the 2-digit year), followed by RF and 4 digits**	**06RF5678**
CDC lab	**YY (the 2-digit year), followed by a hyphen and 6 digits**	**06-012345**

- The TB GIMS Super User must have a list of **State Case Numbers** and patient names and DOB for culture confirmed cases. The Super User will compare this list with the list of patient names and DOB and **Genotyping Accession Numbers** for isolates submitted for genotyping; this information is obtained from the state TB laboratory.
- Super Users can then create a list of state case numbers and their associated **Genotyping Accession Numbers**. This list can then be given to the state surveillance program to enter into Item 38 on the RVCT.
- TB GIMS will automatically and routinely examine the **Genotyping Accession Numbers** entered into Item 38 on the RVCT and use this information to enter **State Case Numbers** for the corresponding genotype result in TB GIMS. This will only occur for genotype results with no **State Case Number** information entered. Therefore, if a genotype result already has a **State Case Number** entered, the system will **not** replace the information.
- States using this approach should still routinely check their linking to ensure that no errors have occurred.

TB control programs can use either or both of the above options for linking.

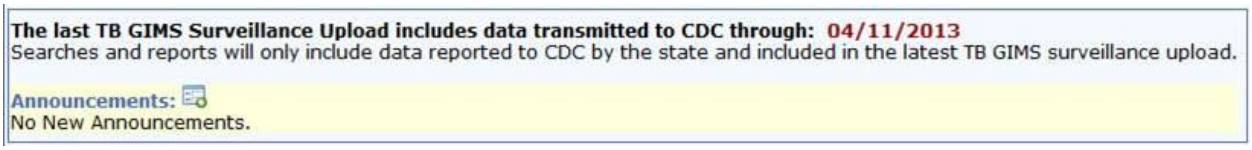
Regardless of which of the above options are used, linking should be performed <u>within 8 weeks</u> of receiving a genotype result.

Availability of Complete Records in TB GIMS

Availability of a complete record depends on coordination between the TB GIMS super users/genotype coordinators, the state TB laboratory, the surveillance coordinators, and CDC.

- Surveillance data in TB GIMS are refreshed weekly. The date of the most recent surveillance upload is located on the TB GIMS banner (Figure 9.13).

Figure 9.13
TB GIMS Banner



- Genotyping data uploaded from the genotyping labs are available immediately.
- **State Case Numbers** that are entered directly into TB GIMS by Super Users are available immediately. Linking using Item 38 from the RVCT is performed weekly. Since a complete record requires **both** genotyping **and** surveillance data, complete records will only appear in TB GIMS after linking has occurred and the RVCT has been sent to CDC. Since these steps may occur at different times, complete records may not appear immediately. The most efficient way to ensure that complete records are available in TB GIMS as soon as possible is to enter a **State Case Number** at the time an isolate is submitted for genotyping **and** submit the RVCT to CDC as soon as the case is known to be culture positive, even if other data are incomplete.

Using TB GIMS for Quality Assurance Activities

Genotyping data can be used to improve the quality of RVCT data. Case detection, data accuracy, completeness, timeliness, and data security are all potentially impacted by genotyping and TB GIMS. Surveillance coordinators should collaborate with TB GIMS Super Users/genotyping coordinators to implement the following QA activities.

Case Detection

Routine review of cases with genotype results in TB GIMS is a way to ensure that every culture-confirmed case has been reported to NTSS.

- Cases with genotype results in TB GIMS should be a subset of all culture-positive cases reported to the state.
    - At least annually, the TB GIMS Super User and surveillance coordinator should examine the list of patients for whom isolates have been sent for genotyping and ensure that each case has been reported to the state.
    - Additionally, the TB GIMS Super User should ensure that each isolate is linked to a **State Case Number** or is appropriately designated as not linkable within TB GIMS (i.e., is **not** a case, is a case from another state or country). Linking should occur within 8 weeks of receipt of a genotype result.
    - Isolates with genotype results that cannot be associated with a **State Case Number** may **not** have been reported to the state TB program. The information the laboratory has on the isolate may help the TB program identify the patient for further investigation.
- Genotyping data can also be used to help identify which cases may not be countable TB cases, such as cases with Bovis-BCG or nontuberculous Mycobacterium (NTM) infection. Even though BCG vaccination in the United States is very limited, BCG is used to treat patients with bladder cancer by injecting it into the bladder. The recovery of the BCG strain of M. bovis from urine should not be counted as TB because it is the result of the treatment and does **not** represent disease transmission. M. bovis-BCG isolates have the spoligotype 676773777777600 and have 12-locus MIRU-VNTR (MIRU Locus 04) with x, y or z in the second position. M. bovis-BCG isolates have one of three MIRU designations; 2x2324253322, 2y2324253322, 2z2324253322. These cases should **not** be counted as TB cases for surveillance purposes.
    - At least annually, TB GIMS Super Users should identify which cases may **not** meet the criteria for counting based on genotyping results and inform surveillance coordinators of these cases. The surveillance record for these cases can be changed to non-countable cases if that is appropriate.

Data Accuracy

TB GIMS can be used as a tool for checking the accuracy of surveillance records in NTSS.

- **Culture positivity**
    - All cases that have a genotype result should be listed as having a positive culture on the RVCT Item 18, **Sputum Culture** and Item 20, **Culture of Tissue and other Body Fluids**.
        - Within TB GIMS, the variable "Culture Status" should be listed as "Y" (Yes) in the line list of **TB GIMS Patient Results** since all cases with a genotype result must be culture positive.
    - TB GIMS Super User should review this variable at least quarterly. If a case in TB GIMS has a culture status listed as "N," they should coordinate with the surveillance coordinator to determine the following:
        - Whether the RVCT data on culture results are correct.
        - Whether the correct **State Case Number** has been linked to the correct genotype result.

- **Genotyping Accession Number (item 38)**
    - Surveillance coordinators should check at least quarterly that the accession number being entered in Item 38 is correctly formatted. Examples of incorrect accession numbers are presented in Table 9.4. The correct **Genotype Accession Numbers** may be obtained by coordinating with your state genotype coordinator/TB GIMS Super User.

Table 9.4
Valid and Invalid Accession Numbers

Valid Accession Numbers	**Invalid Accession Numbers**	
Correct Format • **2-digit year** • **RF** (Michigan lab) **or L** (California lab) • **4-digit number**	**Sample Number**	**Problem**
• 11L3051	• PCR03558	PCR Type designation
• 10RF0016	• 10-006-0232	Submitter number or state lab assigned ID
• 09L0207	• 09RF381MICH	Incorrect accession number format
	• TX_0056	State cluster name
	• 79211	GIMS ID

- If **State Case Number** (item 3) has a **Linking State Case Number** and the **Reason** code is "recurrence" or "previous diagnosis of TB," the accession numbers that correspond to current case of TB should be entered.

- **Surveillance variables in TB GIMS**
  TB control staff using genotyping information rely on accurate surveillance data in TB GIMS to assist with assessing and investigating TB genotype clusters. The staff also routinely collect data from contact investigations and other field work to help with investigating clusters. As a result, TB GIMS users may identify errors in RVCT data.

  TB GIMS users that suspect there is an error in a surveillance record should bring their concern to the surveillance coordinator and assist with investigating the issue.

  Example: A genotyping coordinator is investigating a TB cluster that has largely been seen in homeless persons. One of the cases in the genotype cluster is listed in TB GIMS as not being homeless; however, when the genotyping coordinator discusses the case with the contact investigator, they realize that the case has been homeless within the past year. The genotyping coordinator then contacts the surveillance coordinator to have the record corrected.

Exercise 9.2: Checking Data Accuracy

9.2	**Mr. Peanut Smith had TB in 2009 and was diagnosed with TB again in April 2012. If the program is linking records using TB GIMS, the Super User/genotyping coordinator should ensure that the State Case Number corresponds to the correct Genotype Accession Number. (i.e., ensure the accession number corresponding to the 2009 case is not from 2012 and vice versa.)** **What should be entered for Genotyping Accession Number (item 38) on Mr. Smith's RVCT?**
	Answer (provide an explanation):

Data Completeness

Complete RVCT data are important for effective use of TB genotyping data. Additionally, genotype cluster investigations can identify missing or incomplete data on the RVCT.

- **Genotyping Accession Number (item 38)**
  - Ideally, all culture-positive cases will have an isolate sent for genotyping. Surveillance coordinators can assist genotyping coordinators with this process by identifying culture-positive cases that do not have a **Genotyping Accession Number** entered into Item 38 on the RVCT.
  - At least quarterly, surveillance coordinators should generate a list of **State Case Numbers** and patient names for culture-positive cases without an accession number listed in RVCT Item 38.
  - By sharing this information with genotyping coordinators, additional cases for genotyping may be identified or the genotyping coordinator may be able to provide accession numbers for cases that have been genotyped already.

- **Linking State Case Number (item 3)**
  - Genotyping data can be used to help identify each case that should be listed as **Linking State Case Number**, because it is the same patient with a previous diagnosis of TB, is an epidemiologically linked patient, or is the same patient with a S**tate Case Number** from a different state.
    Note that this section refers to a different issue than the process needed to generate a complete record in TB GIMS, which is also referred to as linking,
  - **Reason Code 1: Recurrence or previous diagnosis of TB**

        - TB GIMS Super Users/genotyping coordinators may identify a case that had a previous diagnosis of TB through examining genotyping clusters. In this situation, the Super User should coordinate with the surveillance coordinator to ensure that the linking **State Case Number** for the TB case is entered into the RVCT.
    - **Reason Code 2: Epidemiologically linked case, source case, or contact with another case**
        - TB GIMS Super Users/genotyping coordinators frequently identify epidemiologic links among cases during cluster investigations. As per their state's process, genotyping coordinators should consider sharing this information with surveillance coordinators to ensure that **Linking State Case Numbers** for epidemiologically linked cases, source cases, or contacts are entered into the RVCT.
    - **Reason Code 3: Case transferred from another area**
        - Surveillance coordinators should routinely provide genotyping coordinators with a list of all culture-positive cases that have a linking state case number from another state. Genotyping coordinators will use this information to ensure that genotype results are assigned to the correct state and associated with the correct state case number. TB GIMS Super Users/genotyping coordinators should routinely share information about cases with "out of state" isolates with surveillance coordinators, so that any linking state case numbers can be completed on the RVCT.

Data Timeliness

Genotyping can only be used effectively for outbreak surveillance and other TB control activities if the isolates are linked to RVCT records with the valid S**tate Case Number** and the RVCT records sent to CDC promptly.

Since culture confirmation is the gold standard for verifying a case of TB disease, there is an extremely high likelihood that all culture-positive cases will ultimately be verified cases of TB. Minimizing delays in assigning **State Case Numbers** for culture-positive cases will allow genotyping coordinators to more effectively use TB genotyping data.

In order to facilitate timely availability of complete records in TB GIMS

- **Surveillance programs should**
    - **Promptly**
        - Assign a **State Case Number** to every culture-confirmed case of TB and share the **State Case Numbers** with genotyping coordinators.
        - Initiate an RVCT for every culture-confirmed case of TB.

- **At least quarterly**
  - Submit the RVCT to CDC.
  - Share a list of reported case names and DOB along with the **Genotyping Accession Numbers** and **State Case Numbers** with local programs.
    - TB GIMS does not contain any names to protect patient confidentiality. However, local users usually only have access to patient names, therefore they are not able to use genotyping data from TB GIMS without a way to connect **State Case Numbers** or **Genotyping Accession Numbers** to patient names.
- Genotyping coordinators should enter **State Case Numbers** into TB GIMS **as soon as they are available** from the surveillance program.
  - Ideally **State Case Numbers** should be entered into TB GIMS when isolates are first sent for genotyping. In order for this to occur, TB laboratory staff will need routine access to **State Case Numbers**.

Data Security and Confidentiality

Since surveillance data are available to TB GIMS users, users must comply with data sharing agreements and rules of behavior (see Table 9.5).

Table 9.5
Data Sharing Agreements and Rules of Behavior

Use of TB GIMS data from TB program jurisdictions outside your own state or local health jurisdictions for research purposes, public presentations, or release to outside parties (such as the media) must be approved in advance by the states that provided the data, as well as by CDC. This includes all reports and maps from TB GIMS, such as the national map and national distribution reports. Data from your own jurisdiction may be shared according to your local data use guidelines or regulations. CDC encourages the use of TB GIMS information to enhance public health activities for TB control purposes. Please comply with the data-sharing agreements and seek appropriate permission prior to sharing information.

Exercise 9.3-9.4: What Genotype Information Can and Can Not be Shared

9.3	**Lisa is investigating an outbreak that includes a genotype cluster. The genotype is also found in three other states. Who can she share reports and maps with from TB GIMS?**
	Answer (provide an explanation):

9.4	**Can Lisa present her recent updates and findings at an upcoming regional conference?**
	Answer (provide an explanation):

Additional Resources

- Best practices document: (http://www.cdc.gov/tb/publications/factsheets/statistics/Genotyping_BestPractices.pdf)
- Genotyping fact sheet: http://www.cdc.gov/tb/publications/factsheets/statistics/genotyping.htm
- TB GIMS fact sheet:

  http://www.cdc.gov/tb/publications/factsheets/statistics/gims.htm
- NTIP fact sheet:

  http://www.cdc.gov/tb/programs/Evaluation/Indicators/default.htm
- Annual TB genotyping report: (http://www.cdc.gov/tb/programs/genotyping/GenotypingReport.pdf)

Cohort Review and Quality Assurance for TB Surveillance Data

Primary Purpose

This section discusses how cohort review can be used to improve case detection, accuracy, completeness, and timeliness of surveillance data.

Cohort Review Process

Cohort review is a systematic process for reviewing the management of patients. A "cohort" is a group of TB patients managed over a specific period of time, usually 3 months. TB cases are reviewed for the patient's clinical status, the diagnosis, the adequacy of the treatment regimen, complications with the treatment process, and the patient's treatment adherence or completion. Depending on the program, the result of contact investigation may also be included for review.

Cohort review, in its simplified form, is when TB control staff at the local level meet to review the treatment outcomes of every patient listed in a chronological patient register. Reviewing these cases allows staff to detect potential problems in the way the case is being managed.

TB programs across the country have adopted a variety of approaches to conducting cohort reviews. Instructions on how to establish a cohort process for TB programs and a self-assessment checklist for the process can be found at the end of this section.

Cohort review includes three key components:

1. Preparation
2. Presentation
3. Follow-up

Each of these components presents opportunities for local program staff to:

- Clarify RVCT variable definitions.
- Review data submitted to the surveillance system.
- Validate surveillance data in the local TB registry and the national TB surveillance system with those recorded in the medical charts and patient record.

Table 9.6 provides a list of possible opportunities for TB programs to conduct QA of surveillance data during cohort review.

Table 9.6
Opportunities to Conduct QA for TB Surveillance Data during Cohort Review

Cohort Review Process	QA Component	Opportunity for QA During Cohort Review Process
Preparation	**Case Detection and Timeliness**	• Ensure all data are collected and entered into the registry and reported to the national surveillance system.
	Accuracy	• Review NTIP to ensure all data have been reported and recorded correctly at CDC. • Compare local data to NTIP. • Generate and review NTIP line list to identify any discrepancies. • Correct errors and resubmit data to state and CDC.
Presentation	**Accuracy**	• Verify data presented in the case presentation with those reported in NTIP reports and line list.
	Completeness	• Review case record to ensure completeness and consistency of RVCT data items.
Follow-up	**Completeness**	• Ensure follow-up of missing or unknown data.

Figure 9.14 provides a sample timeline for conducting QA of TB surveillance data during the cohort review process.

Figure 9.14
Sample Cohort Review QA Timeline

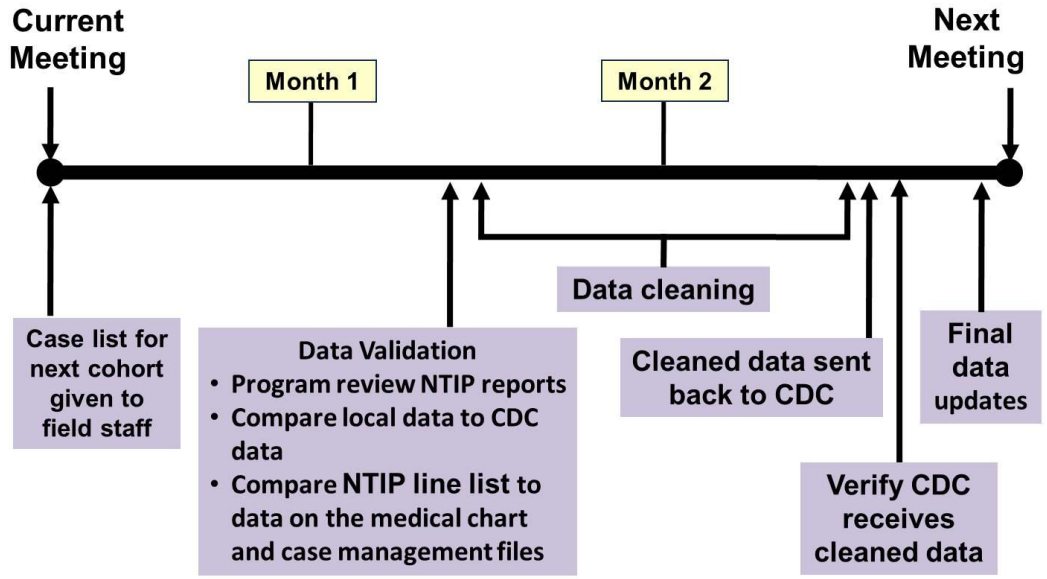


Table 9.7 provides suggestions for TB programs for conducting QA as part of the cohort review process.

Table 9.7
Suggestions for TB Program Cohort Review

• Integrate the QA process for TB surveillance data into routine TB program activities.
• Implement the cohort review process quarterly, by subregions.
• Mobilize case managers to conduct data QA process
• Use NTIP reports and line list to:
  ○ Validate CDC and local data.
  ○ Select cases for review and discuss.
  ○ Describe program performance.

Additional Information

CDC. Understanding the TB Cohort Review Process: An Instruction Guide. 2006. Division of Tuberculosis Elimination, NCHHSTP, CDC, Atlanta, GA. Available at

http://www.cdc.gov/tb/publications/guidestoolkits/cohort/default.htm

Quality Assurance Cross-cutting Tools

This section includes other cross-cutting tools that impact multiple QA components and/or related areas of QA for TB surveillance data (Table 9.8). Examples of the tools are located in Chapter 10: Toolkit for Quality Assurance. To view or download the tools, please visit: http://www.cdc.gov/tb/programs/rvct/default.htm.

Table 9.8
Quality Assurance Cross-cutting Tools

Tool #	Tool Name	Description and How to Use	Format	Source Contact
Cross-cutting–1	**TB Control Program Procedures for PHIMS: Data Entry and Quality Control Procedures : QA Protocol Example**	Four-phase process for entering Report of Verified Case of Tuberculosis (RVCT) data, conducting quality control, and ensuring timeliness in reporting.	Word 8 pages	Tuberculosis Control Program, Public Health–Seattle & King County
Cross-cutting–2	**TB Case/Suspect QA Review Form**	A checklist to use for reviewing TB cases/suspects.	Word 3 pages	Oregon TB Program
Cross-cutting–3	**TB Review and QA Schedule for TB Case/Suspects**	Quality assurance schedule for various reviews of TB cases/suspects.	Word 1 page	Oregon TB Program
Cross-cutting–4a	**2009 RVCT Trending Guidance**	An explanation of the transition between old and revised RVCT variables. Mapping shows the user exactly how the definitions of previous variables match up with the new ones.	Word 7 pages	CDC/DTBE

Tool #	Tool Name	Description and How to Use	Format	Source Contact
Cross-cutting–4b	**Mapping Old RVCT Data (1993-2008) to New RVCT Data (2009-present)**	A diagram that illustrates mapping the old RVCT data to the new RVCT data. The diagram illustrates the following three RVCT items: • Site of Disease (item 16) • X-ray (item 22A and 22B) • Type of Health Care Provider (item 46) It provides a visualization of the transition between old and revised RVCT variables. Mapping shows the user exactly how the definitions of previous variables match up with the new ones.	Word 3 pages	CDC/DTBE
Cross-cutting–5	**RVCT Variables Used in NTIP (Spread Sheet)**	List of the RVCT variables used in the NTIP indicator calculation.	PDF 3 pages	CDC/DTBE
Cross-cutting–6	**Cohort Review Preparation: Roles and Responsibilities by Time Due**	Guidance for planning and conducting a cohort review session. Includes preparation timeline and job responsibilities. Determines when participants need to be notified of scheduled events leading up to the cohort review session.	Word 3 pages	Washington State Department of Health Tuberculosis Program and the Tuberculosis Control Program, Public Health–Seattle & King County
Cross-cutting–7	**NTIP Decision Memo: Sputum Culture Conversion Documented**	DTBE's decision to exclude patients who moved out of the country from NTIP calculation RVCT item (41) Sputum Culture Conversion Documented.	PDF 4 pages	DTBE