1: Introduction to the Guide and Toolkit

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Background

Conducting tuberculosis (TB) surveillance is a core public health function. The on-going and systematic collection, analysis, interpretation, and dissemination of surveillance data allow TB programs to target resources and interventions that will provide the most impact in eliminating TB. These surveillance data are essential in describing morbidity and mortality, monitoring trends in TB incidence and prevalence, detecting potential outbreaks, and defining high-risk groups. In addition, TB data are needed to evaluate TB control programs, identify deficiencies, and allocate resources. In order to perform these important functions, it is essential that surveillance data be collected and reported in an accurate, complete, and timely manner.

National Tuberculosis Surveillance System (NTSS)

The National Tuberculosis Surveillance System (NTSS), located in the Division of Tuberculosis Elimination (DTBE), Centers for Disease Control and Prevention (CDC), is the national repository of TB surveillance data in the United States. CDC receives data on TB cases from reporting jurisdictions through a standardized data collection form, the Report of Verified Case of Tuberculosis (RVCT). NTSS currently has 60 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, Commonwealth of the Northern Mariana Islands, Puerto Rico, Republic of Palau, and U.S. Virgin Islands.

The RVCT is revised periodically as the epidemiology of TB in the United States changes. The most recent revision was implemented in 2009. As part of that revision, data collection and reporting transitioned into web-based systems. An interdisciplinary DTBE team collaborated with key national partners, state-based medical and health officers, and other local healthcare professionals to develop and launch a national training program on the new RVCT. Extensive reviews of training materials enabled partners to provide feedback for improvements on the instructions for each of the 49 RVCT items. The team also developed a participant manual that trainers used during facilitator-led trainings. The manual can be used for self-study or as a reference. A facilitator manual was developed and used during training-of-trainers courses to build RVCT training capacity throughout the reporting jurisdictions.

For more information about the RVCT and view or download the Report of Verified Case of Tuberculosis Self-Study Modules, please visit:
http://www.cdc.gov/tb/programs/rvct/default.htm.

Development of the Quality Assurance Process

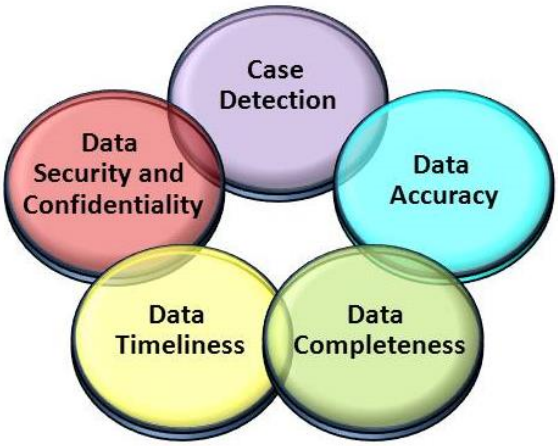
Quality assurance (QA) is a critical part of any successful surveillance system and is a continuous cycle of monitoring, evaluating, and improving data quality. Prior to 2009, jurisdictions depended on a single CDC-developed system for collection and reporting of TB data. This system provided a standard set of validations to jurisdictions for collecting and managing data. When state TB programs transitioned to web-based systems in 2009, there was a need for a standardized QA process that jurisdictions could adapt to their setting.

The logical follow-up to the RVCT trainings was to enhance the QA knowledge and skills of TB surveillance staff. Furthermore, the RVCT training participants expressed concerns regarding the lack of data validation of some state systems and some challenges with electronic data submission. DTBE staff began working individually with state public health partners to develop QA strategies.

DTBE understands the uniqueness of the NTSS data set and wants to ensure that data are collected as uniformly as possible across all jurisdictions, whether large or small. The RVCT QA training team, in collaboration with key partners, developed innovative strategies for providing standardized methodologies, skills, and tools to enhance the capacity for conducting QA. The team used the systematic health education approach to develop training materials and includes needs assessment, development, pilot testing, implementation, and outcome evaluation.

The QA process is based on the 2014 CDC Tuberculosis Elimination and Laboratory Cooperative Agreements (CoAg) and the results of a QA needs assessment conducted with 11 of the 60 reporting jurisdictions. The process includes five components (Figure 1.1). For more information, see Chapter 3: Overview of Quality Assurance Process.

Figure 1.1
Five Quality Assurance Components for TB Surveillance Data



Goal and Objectives

Goal

The goal for this manual is to help improve the quality of TB surveillance data by providing TB surveillance reporting jurisdictions with

- A standardized process for conducting QA, and
- Tools that can be used and adapted for conducting QA.

Objectives

After using this guide and toolkit, the user should be able to

- Describe the five components of the QA process,
- Access various tools that can be used to perform QA for TB surveillance data, and
- Describe what to include in a written QA protocol as required by the CoAg.

Target Audience

The target audience includes health care staff from state and local health departments, territories, and U.S.-affiliated Pacific Islands who

- Collect TB data from patients,
- Complete RVCT form,
- Enter data from RVCT into the surveillance system,
- Monitor accuracy of TB program data collection, and
- Analyze data from the RVCT.

About the Guide and Toolkit

The Guide

The guide includes a set of nine chapters and four appendices. A description of the chapters and appendices is included in Table 1.1.

Table 1.1
Description of Chapters and Appendices

Chapter	Title	Description
1	**Introduction to the Guide and Toolkit**	Background, goals and objectives, target audience, and how to use the guide and toolkit
2	**National Tuberculosis Surveillance System Data Flow**	Data flow structure from the jurisdictions to CDC
3	**Overview of the Quality Assurance (QA) Process**	Definition of QA, factors influencing data quality, cooperative agreement, QA component definitions, and tools
The five QA components that provide the main content of the manual		
4	**Case Detection**	Purpose, definitions, process, decline in TB investigation, and tools
5	**Data Accuracy**	Purpose, definitions, process, NTSS data validation, laboratory data accuracy, data validation pilot project, and tools
6	**Data Completeness**	Purpose, definitions, process, missing and unknown, data completeness, accuracy study, and tools

Chapter	Title	Description
7	**Data Timeliness**	Purpose, definitions, process, case count process, TB data report availability, and tools
8	**Data Security and Confidentiality**	Purpose, definitions, process, data security and confidentiality guidelines, and tools
9	**Quality Assurance Cross-cutting Systems and Process: NTIP, TB GIMS and Cohort Review**	Examples of systems and a process that can be used for improving at least three of the five QA components (i.e., accuracy, completeness, and timeliness). These include the National TB Indicators Project, the TB Genotyping Information Management System, and the cohort review process.
10	**Toolkit for Quality Assurance**	Examples of the tools that can be easily adapted for local use. Tools are grouped by chapter and content topic (e.g., Chapter 3: Overview of the Quality Assurance Process).
Appendix	**Title**	**Description**
A	**References**	List of all references used in the development of this guide
B	**Glossary**	Compilation of all the definitions provided in this guide
C	**Quality Assurance Process Slides**	Set of slides that describe the QA process
D	**Report of Verified Case of Tuberculosis (RVCT) Questions and Clarifications**	Compilation of questions and clarifications since the 2009 publication of the RVCT instructions. This document is updated periodically and is available at http://www.cdc.gov/tb/programs/rvct/default.htm.
E	**Answers to the Exercises**	Discussions of answers to exercises included in this guide

Chapter Sections

Most of the chapters include the sections described in Table 1.2.

Table 1.2
Chapter Sections

Section	Description
QA Process and Examples	• The QA process includes suggested procedures for conducting QA for each of the five components that are based on the requirements of the CoAg. • Some sections include examples that provide additional information, processes, and tools that are helpful when conducting QA.
Definitions	Definitions of terms are provided in some sections and in Appendix B: Glossary.
Primary Purpose	Each section includes a primary purpose that states the focus of the content and how it is applicable to QA of TB surveillance data.

Exercises	• Exercises are provided to help readers apply the content to similar situations.
	  ○ Types of exercises include
	  ▪ Study questions
	  ▪ Case studies
	  ○ Answer choices include
	  ▪ Multiple choice
	  ▪ Fill in the blank
	• When working through the exercises, readers should answer the questions first, and then check the answers against the key, located in Appendix E. Some of the difficult questions include explanations to help readers understand the correct answer.

Master List of Tools	• At the end of each chapter is the Master List of QA Tools that corresponds with that particular chapter (e.g., Chapter 3: Overview of the Quality Assurance Process). Some tools are referenced within the chapter to explain a particular process.

Master List of Tools

The Master List of Tools provides a brief description of each tool. The tools are grouped together by chapter. The list includes information described in Table 1.3.

Table 1.3
Master List of Tools

Section	Description
Name	Each tool has a name at the top of the page.
Tool Number	Each tool has a unique identifier located in the top right corner of the tool. The identifier includes the content topic and a number (e.g., QA Plan Tool-1, Case Detection Tool-1). Some tools are linked by functionality; these include a letter after the number (e.g., Accuracy Tool-1a, Accuracy Tool-1b).
Description and How to Use	A brief description includes the purpose of the tool and how to use it.
Format	The tools are in either Microsoft Word, Excel, PowerPoint, or Adobe Acrobat PDF format. Also included are the number of pages and the page size of the document (if it is other than 8 ½″ x 11″).
Source Contact	The source contact indicates the agency that developed the tool. Contact information for some of the sources is available on the last page of the complete Master List of QA Tools in Chapter 10: Toolkit for Quality Assurance.

The Toolkit

Staff from CDC and various jurisdictions developed approximately 50 QA tools that include tables, charts, graphs, processes, and templates. The tools are available in commonly used software so that they can be easily used or adapted to a jurisdiction's setting. Table 1.4 provides information about the tools.

Table 1.4
Information about the Tools

Item	Description
Examples of the Tools	• **Located in Chapter 10: Toolkit for Quality Assurance.** The Master List of Tools is organized by chapter (e.g., Chapter 3: Overview of QA Process) and followed by examples of each of the tools. For most examples, only the first page of the tool is shown, but the QA Plan Tools described in Chapter 3 include the entire document.
The Actual Tools	• **To view or download the tools, please visit:** www.cdc.gov/tb/programs/rvct/default.htm

Disclosure Statement

The "Quality Assurance for Tuberculosis Surveillance Data: A Guide and Toolkit" lists nonfederal resources in order to provide information and tools to consumers. These resources were developed by the authors and staff from various jurisdictions and are not endorsed by the Centers for Disease Control and Prevention, the Public Health Service, or the Department of Health and Human Services.

How to Access the Materials

To view or download the "Quality Assurance for Tuberculosis Surveillance Data: A Guide and Toolkit," please visit:
http://www.cdc.gov/tb/programs/rvct/default.htm.

Additional Information

For additional information about QA for Tuberculosis Surveillance Data, please contact the RVCT/QA Training Team at
rvctqualityassurance@cdc.gov.