

3: Overview of the Quality Assurance Process

Section	Page
Definitions	3-1
Introduction to the Quality Assurance Process	3-1
Written Quality Assurance Protocol Guide	3-4
Quality Assurance Plan Tools	3-5

Definitions

Term	Definition
Case Verification Criteria (VERCRIT)	An RVCT calculated variable used for verifying a TB case.
Data quality	The accuracy and completeness of the data recorded in the TB surveillance system.
Quality assurance	A continuous process to improve TB surveillance data that includes a continuous cycle of planning, doing, checking, and improving data quality.

Introduction to the Quality Assurance Process

Primary Purpose

This chapter provides an overview of the quality assurance (QA) process for TB surveillance data.

Quality Assurance

Quality assurance is a continuous process for improving TB surveillance data that includes a continuous cycle of planning, doing, checking, and improving data quality. Data quality is influenced by several factors, including

- Quality of TB screening and reporting of diagnostic test results (e.g., case detection activities),
- Clarity and preciseness of the definitions for each data element of the surveillance data collection forms (e.g., printed or electronic),
- Quality of training and supervision of staff who complete these forms, and
- Carefulness of staff in managing data.

Improvement of these factors results in better data quality. Table 3.1 provides a list of the benefits of QA of TB surveillance data.

Table 3.1
Benefits of Quality Assurance of TB Surveillance Data

Benefits
<ul style="list-style-type: none"> • Ensures that all TB patients are reported and their relevant data are collected and entered correctly into an electronic disease surveillance system. • Ensures that the data are congruent and reflect the true diagnostic, treatment, and other clinical patient information. • Captures the completeness of case reporting. • Ensures that data are accurate or valid, timely, complete, and relevant to program needs. • Ensures achievement of data management goals, including <ul style="list-style-type: none"> ○ Protecting the privacy and confidentiality of surveillance data, and ○ Monitoring the system to confirm that objectives are being met.

QA Components

QA for TB surveillance data is a continuous process of improving all five of the QA components (Table 3.2). The QA process focuses on these areas for surveillance activities. Specific details regarding the QA process for each of these areas are discussed in Chapters 4-9.

Table 3.2
QA Components

QA Components	Definition
Case Detection	Detection of one instance of a specific disease or exposure, e.g., TB. A front-line surveillance activity, it is typically accomplished as a by-product of routine medical or veterinary care, or laboratory work, or via an astute observer such as a health care worker.
Data Accuracy	The data submitted matches patient records maintained at the point of care. The recorded data in the surveillance system are consistent with what happens in a clinical encounter, whether or not it is clinically appropriate.
Data Completeness	A measure that indicates whether the information submitted contains the complete set of mandatory data items.
Data Timeliness	Prompt reporting of surveillance data to health authorities.
Data Security and Confidentiality	Data security is the protection of public health data and information systems to prevent unauthorized release of identifying information and accidental loss of data or damage to the systems. Data confidentiality is the protection of personally identifiable information collected by public health organizations.

Cooperative Agreements

The QA process is based on the surveillance section of the 2014 Tuberculosis Elimination and Laboratory Cooperative Agreements (CoAg). This is the portion of the agreement between DTBE and the 60 reporting jurisdictions describing required surveillance activities (Table 3.3).

A copy of the surveillance section of the 2014 CoAg is provided in QA Plan Tool–1 located in Chapter 10: Toolkit for Quality Assurance. Also, in QA Plan Tool–2, the CoAg requirements are organized into five QA components with potential data sources and activities.

Table 3.3
Summary of Surveillance Section of the
2014 CoAg Requirements

Note: The requirements are based on Fiscal Year 2014 CoAg and may need to be updated when the CoAg is updated. The CoAg is reformatted into the following table.

Summary of CoAg Requirements
<ul style="list-style-type: none"> • Incorporate quality assurance policies and procedures into surveillance activities to ensure <ul style="list-style-type: none"> ○ Case detection (finding, counting, and reporting all TB cases), ○ Data accuracy (accuracy of data abstracted from original patient records, of registry data, and of data entered onto the RVCT form and transmitted to CDC), ○ Data completeness, ○ Timeliness, and ○ Data security and confidentiality.
<ul style="list-style-type: none"> • Develop a written protocol for quality assurance (QA) for TB surveillance data. Describe how each of the QA components (case detection, data accuracy, data completeness, data timeliness, and data security and confidentiality) is being conducted.
<ul style="list-style-type: none"> • Develop and implement plans for improvement.

Written Quality Assurance Protocol Guide

The surveillance section of the CoAg also requires jurisdictions to provide a written QA protocol that incorporates QA policies and procedures into surveillance activities. The protocol facilitates development of a yearly summary of QA activities. CDC has created a template (QA Plan Tool-3) to help jurisdictions write the protocol. It correlates with the requirements in the CoAg, is organized by sections that represent the five components, and can be adapted for local use.

Quality Assurance Plan Tools

The QA Plan Tools are listed below (Table 3.4). **These tools are very important because they provide the basis for the QA process.**

Table 3.4
Quality Assurance Plan Tools

Note: QA Plan Tools 1-3 are based on the 2014 CoAg. These documents may need to be updated if the CoAg is updated. 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>.

Tool #	Tool Name	Description and How to Use	Format	Source Contact
QA Plan-1	CDC Tuberculosis Elimination and Laboratory Cooperative Agreements (CoAg) TB Surveillance Section	The TB surveillance section of the 2014 version of the CoAg document.	PDF 6 pages	CDC/DTBE
QA Plan-2	QA for TB Surveillance Data CoAg Requirements	A table that lists all of the CoAg requirements for TB surveillance and possible data sources and activities. This is based on the 2014 CoAg.	Word 9 pages	CDC/DTBE
QA Plan-3	Quality Assurance for TB Surveillance Data Written Quality Assurance Protocol - Guide	A guide to help jurisdictions write their own QA protocol based on the CoAg requirements.	Word 3 pages	CDC/DTBE
QA Plan-4	Case Verification Criteria (Vercrit) Calculation	An RVCT calculated variable algorithm used in counting a TB case.	PDF 4 pages	CDC/DTBE

