Appendix C: Quality Assurance Process Slides

Description

The "Quality Assurance for Tuberculosis Surveillance Data: A Guide and Toolkit" is accompanied by a PowerPoint slide set for use in presentations and training programs. Images of the slides are included in this appendix. The slide set can be accessed the following ways:

- Located on the companion CD-ROM in the QA Manual folder: Appendix C - Quality Assurance Process Slides
- Downloaded from www.cdc.gov/tb/programs/rvct/default.htm

Quality Assurance for TB Surveillance Data

Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Place Division name here

1

Goal and Purpose of Course

Goal

- Increase QA for TB surveillance data within the United States and its jurisdictions.

Purpose

- Enhance knowledge, skills, and processes required to perform QA for TB surveillance data.

2

Target Audience

Health care workers from state and local health departments, territories, and U.S.-affiliated Pacific Islands who

- Collect data from patients
- Complete RVCT form
- Enter data from RVCT into data system
- Monitor accuracy of TB program data collection
- Analyze data from RVCT

3

Objectives

After reading this manual you will be able to

- List the five components of the QA process
- Describe tools that can be used to perform QA
- Describe what to include in a QA written protocol as required by the Cooperative Agreement (CoAg)

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Chapter 1
Introduction to the QA Guide and Toolkit

5

Basis of QA Process

- QA process is based on the 2011 Tuberculosis Elimination and Laboratory Cooperative Agreement (CoAg)
- Results of a QA needs assessment conducted with 11 of the 60 reporting jurisdictions

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QA Guide and Toolkit

QA Manual
(Provides a standardized process for conducting QA)

Tool Kit
(Includes over 50 tools to use and adapt for conducting QA)

Download from DTBE RVCT website
http://www.cdc.gov/tb/programs/rvct/default.htm

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Sections of the Guide

	Chapter	Sections
	1	Introduction to the Guide and Toolkit
	2	National Tuberculosis Surveillance System Data Flow
	3	Overview of the Quality Assurance Process
5 QA Components	4	Case Detection
	5	Data Accuracy
	6	Data Completeness
	7	Data Timeliness
	8	Data Security and Confidentiality
	9	QA Cross-cutting Systems and Process (NTIP, TB GIMS, and Cohort Review)
	10	Toolkit for Quality Assurance

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Sections of the Guide (cont.)

Appendix	Section
A	References
B	Glossary
C	QA Process Slides
D	Report of Verified Case of Tuberculosis Questions and Clarifications
E	Answers to the Exercises

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Sections Within Each Component

- Definitions
- Primary Purpose
- QA Process (based on CoAg requirements)
- Examples and Related Topics
- Exercises
- List of QA Tools

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Chapter 2
TB Surveillance Systems Structure and Data Flow

11

Surveillance Systems Update

- NEDSS Base System (NBS)
- eRVCT
- State Developed System
- Commercial System

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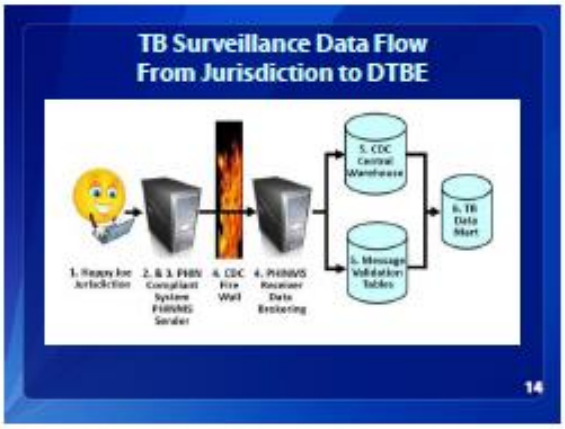
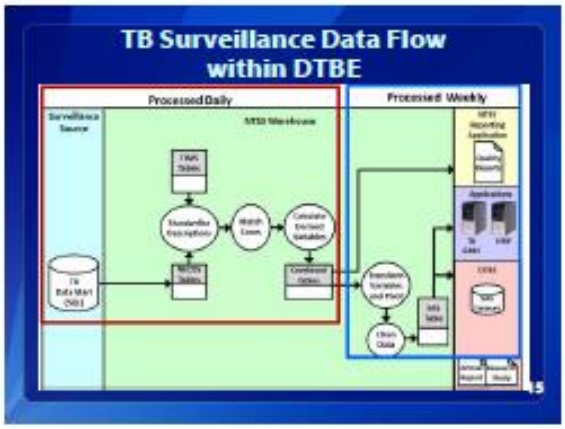
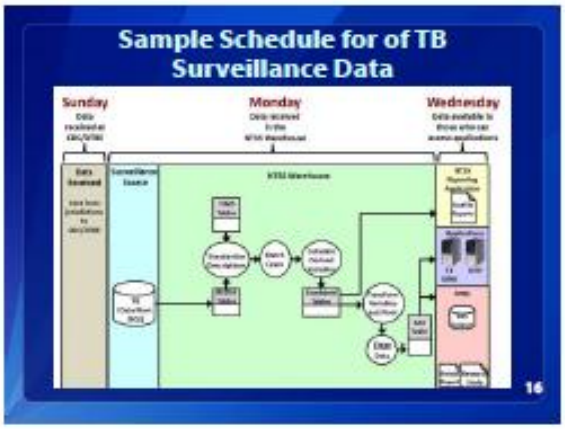
Tuberculosis Surveillance Systems in the United States, 2013
Transition Option Status
eRVCT Option - 7
NBS Option - 18
Commercial Option - 19
State-Developed Option - 16
Pacific Islands
Virgin Islands
13


TB Surveillance Data Flow From Jurisdiction to DTBE
1. Inquiry for Jurisdiction
2. & 3. PHIN Compliant System PHINMS Sender
4. CDC Fire Wall
4. PHINMS Receiver Data Brokering
5. CDC Central Warehouse
6. TB Data Mart
5. Message Validation Tables
14


TB Surveillance Data Flow within DTBE
Processed Daily
Processed Weekly
15


Sample Schedule for of TB Surveillance Data
Sunday
Monday
Wednesday
16


Typical Weekly TB Surveillance Data Availability Timeliness Tool – 5, Chapter 10
17


For More Information Contact
TB Applications Support
ntss@cdc.gov
678-460-7828 /
404-639-8444
18

Chapter 3
Quality Assurance for TB Surveillance Data

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Cooperative Agreement

CoAg

- Agreement between National TB Surveillance System reporting jurisdictions and DTBE
- Requirement: QA for TB surveillance data

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Cooperative Agreement (CoAg) Requirements for QA of TB Surveillance Data

CoAg QA Plan Tool – 1 Chapter 10	QA Requirements QA Plan Tool – 2 Chapter 10	Written Protocol QA Plan Tool – 3 Chapter 10
		

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QA Components and Process

Based on

- CoAg requirements for QA of TB surveillance data
- Needs Assessment

22

CoAg

Summary of Cooperative Agreement Requirements

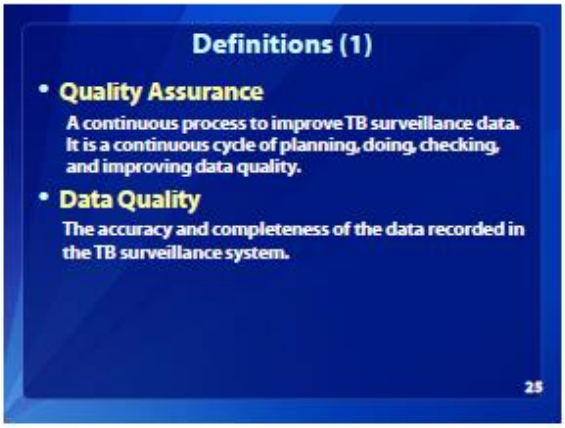
- Incorporate quality assurance policies and procedures into surveillance activities to ensure
  - Case detection
  - Data accuracy
  - Data completeness
  - Data timeliness
  - Data security and confidentiality
- Develop a written protocol for QA for case detection, data accuracy ,data completeness, data timeliness, and data security and confidentiality
- Develop and implement plans for improvement

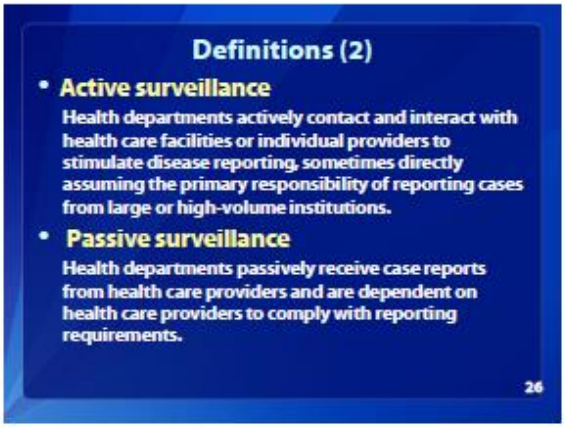
23

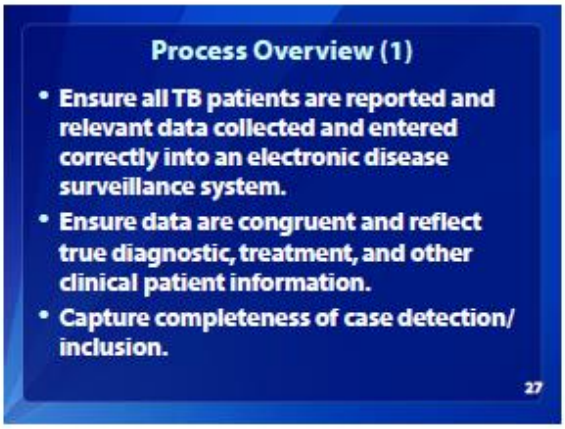
QA Components

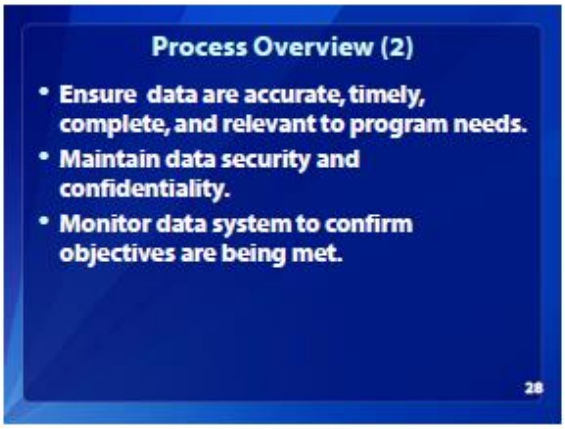
QA for TB surveillance data is a continuous process of improving all five QA components

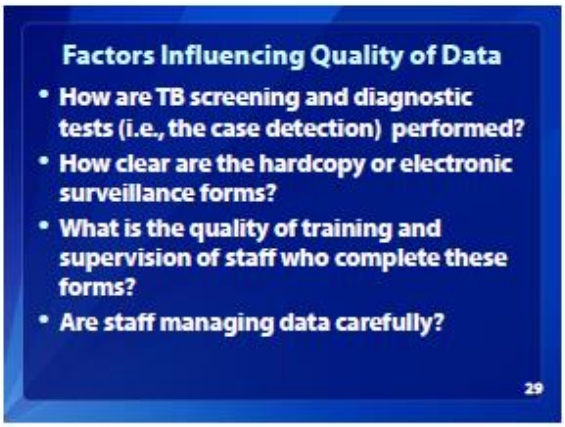
24

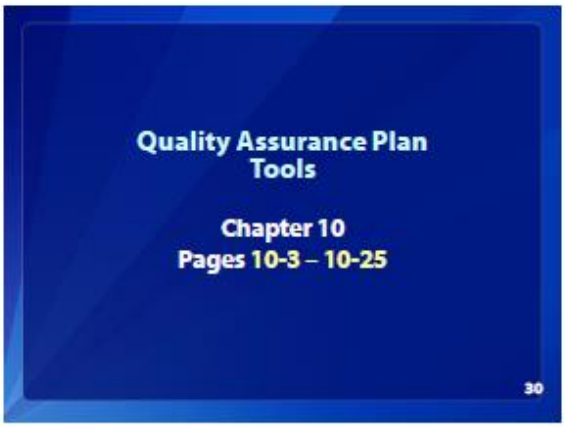

Definitions (1)
• Quality Assurance
A continuous process to improve TB surveillance data. It is a continuous cycle of planning, doing, checking, and improving data quality.
• Data Quality
The accuracy and completeness of the data recorded in the TB surveillance system.
25


Definitions (2)
• Active surveillance
Health departments actively contact and interact with health care facilities or individual providers to stimulate disease reporting, sometimes directly assuming the primary responsibility of reporting cases from large or high-volume institutions.
• Passive surveillance
Health departments passively receive case reports from health care providers and are dependent on health care providers to comply with reporting requirements.
26


Process Overview (1)
• Ensure all TB patients are reported and relevant data collected and entered correctly into an electronic disease surveillance system.
• Ensure data are congruent and reflect true diagnostic, treatment, and other clinical patient information.
• Capture completeness of case detection/ inclusion.
27


Process Overview (2)
• Ensure data are accurate, timely, complete, and relevant to program needs.
• Maintain data security and confidentiality.
• Monitor data system to confirm objectives are being met.
28


Factors Influencing Quality of Data
• How are TB screening and diagnostic tests (i.e., the case detection) performed?
• How clear are the hardcopy or electronic surveillance forms?
• What is the quality of training and supervision of staff who complete these forms?
• Are staff managing data carefully?
29


Quality Assurance Plan Tools
Chapter 10
Pages 10-3 – 10-25
30

Chapter 4
Case Detection

31

Case Detection

- **Definition**

  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 care
  - Veterinary care
  - Laboratory work
  - An astute observer
- **Purpose**

  To find all patients with TB diagnosis so that they are reported to NTSS.

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Case Detection Process

CoAg

A. Maintain a registry of TB cases
B. Establish liaisons with appropriate reporting sources to enhance QA of surveillance data
C. Develop and implement active case detection activities
D. Evaluate completeness of reporting of TB cases to the system

33

CoAg

A. Maintain a registry of TB cases (1)

- Contains at a minimum the elements to produce data for the RVCT.
- All local jurisdictions should also have at least a log, if not a registry, that contains key demographic and clinical information on each reported TB suspect.

34

CoAg

A. Maintain a registry of TB cases (2)

- Data on TB cases receiving diagnostic, treatment, or contact investigation services in the local jurisdiction, although not included in the annual morbidity total, should be included in the TB registry.

35

CoAg

B. Establish liaisons with appropriate reporting sources to enhance quality assurance of TB surveillance data (1)

- Enhance identification, reporting, and follow up of TB cases and suspects by establishing liaisons with appropriate reporting sources.
- Jurisdictions should provide a plan for case finding and how they will or have established appropriate liaisons.

36

CoAg

B. Establish liaisons with appropriate reporting sources to enhance QA of TB surveillance data (2)

- TB programs should provide periodic feedback and at minimum, an annual written report summarizing surveillance data to reporting sources.

37

CoAg

C. Develop and implement active case detection activities

- At a minimum, ongoing active laboratory surveillance should be conducted by on-site visits in all areas to ensure complete reporting of all TB cases and suspects with positive acid-fast bacilli (AFB) smears and cultures for *M.tuberculosis*.

38

CoAg

D. Evaluate the completeness of reporting of TB cases to the surveillance system (1)

- To find potentially unreported TB cases, at least every two years, identify and investigate at least one population based secondary data source by reviewing:
  - Statewide laboratory records
  - Pharmacy records
  - Hospital discharge data

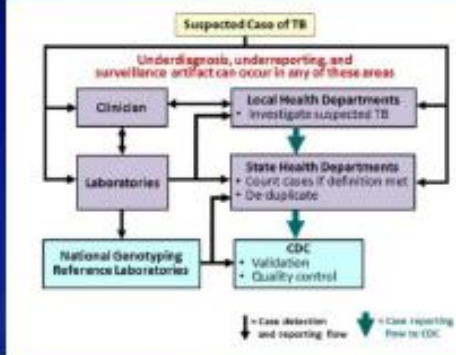
39

CoAg

D. Evaluate the completeness of reporting of TB cases to the surveillance system (2)

- Potential TB cases identified during the evaluation must be verified.
- Reasons for nonreporting of TB cases should be determined and a plan for improvement developed and implemented.

40



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Decrease in Reported Tuberculosis Lessons Learned (1)

- Surveillance artifact important to rule out
- Underdiagnosis very difficult to assess
  - Required chart reviews
  - No simple method to determine if TB patients did not seek care

42

Decrease in Reported Tuberculosis Lessons Learned (2)

- Laboratory data can be an objective measure of TB incidence
  - Caveat: good coverage, no changes in procedures
- Crossmatch of secondary TB data sources and surveillance data simple but follow-up of unmatched cases can be challenging

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Decrease in Reported Tuberculosis Conclusions

- Multiple factors contributed to 2009 decline in TB
  - Unlikely surveillance artifact or underreporting
  - Unable to rule out underdiagnosis due to TB patients failing to seek care
- Educating clinicians to maintain suspicion for TB important
  - Could see more advanced disease if patient delays in care
- Ongoing collection and analysis surveillance data necessary to continue to assess trends
  - Timeliness and quality of data key

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Case Detection Tools

Chapter 10
Pages 10-26 – 10-38

45

Chapter 5
Data Accuracy

46

Data Accuracy

- **Definition**
  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.
- **Purpose**
  To identify and correct errors in the surveillance data.

47

Accuracy Process

CoAg

A. Evaluate accuracy/validity of RVCT data

B. Assess knowledge, skills, and abilities of staff and provide training if needed

48

CoAg

A. Evaluate Accuracy/Validity of RVCT Data

- At least annually, compare:
  - RVCT data
  - Jurisdiction's TB registry data
  - Original data sources

49

CoAg

B. Assess Knowledge, Skills, and Abilities of Staff and Provide Training

- Assess knowledge, skills, and abilities of all existing personnel and new hires.
- Provide training and evaluation.

50

Data Accuracy Tools

Chapter 10
Pages 10-39 – 10-53

51

Chapter 6
Data Completeness

52

Data Completeness

- **Definition**
  A measure that indicates whether the information submitted contains the complete set of mandatory data items.
- **Purpose**
  To capture all relevant data on TB patients on the RVCT to support and improve the function of NTSS.

53

Completeness Process

CoAg

A. Maintain completeness for all RVCT variables

B. Match TB and AIDS registries

54

CoAg

A. Maintain completeness for all RVCT variables (1)

- Achieve 95% completeness of all RVCT variables.
- Achieve at least 95% reporting of HIV status of all newly reported TB cases.

55

CoAg

A. Maintain completeness for all RVCT variables (2)

- Report a valid genotype accession number for at least 85% of all reported culture-positive cases.

56

CoAg

B. Match TB and AIDS registries (1)

- Collaborate with HIV/AIDS program to conduct TB and AIDS registry matches, at least annually.
- Investigate and verify all TB cases reported to the HIV/AIDS program and not reported to the TB program.

57

CoAg

B. Match TB and AIDS registries (2)

- Assess reasons for incomplete HIV results on RVCT at least annually.
- Determine if patients were not tested for HIV or were tested but results not reported to TB program.
- Develop and implement plans for improvement in increasing HIV testing and reporting to TB program.

58

What's a MUNK?

Report of Invalid, Missing, and UNKnown TB surveillance data variables

59

How do we calculate the MUNK report?

- Missing and unknown responses for a specified list of variables
- MUNK includes current year's data and goes back 3 years
- Verified cases only
- Includes validation check

60

Where and when can you find your MUNK report?

- Where?
  - Secure FTP site
  - SAMS portal
    https://sams.cdc.gov/
  - NTSS application
    ntss@cdc.gov
- When?
  - Reports updated weekly
    - Refreshed every Monday

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Data Completeness Tools

Chapter 10
Pages 10-54 – 10-61

62

Chapter 7
Data Timeliness

63

Data Timeliness

- Definition
  - Prompt reporting of surveillance data to health authorities.
- Purpose
  - To ensure that data is available for TB program planning and appropriate distribution of resources.

64

Timeliness Process

CoAg

A. Report all newly diagnosed cases of TB to the CDC according to schedule
B. Submit complete RVCT reports according to schedule
C. Analyze TB surveillance data at least quarterly
D. Evaluate programmatic performance by using TB surveillance data at least annually

65

CoAg

A. Report all newly diagnosed cases of TB to CDC according to schedule

- Report all newly diagnosed cases of TB to the CDC according to a schedule agreed upon each year
  - Generally, monthly
  - At least, quarterly

66

CoAg

B. Submit complete RVCT reports according to schedule (1)

- RVCT Initial Case Reports monthly and at least quarterly.
- RVCT Follow Up 1 Report, for cases with positive culture, within 2 months after initial RVCT submitted or when drug susceptibility results available.

67

CoAg

B. Submit complete RVCT reports according to schedule (2)

- RVCT Follow Up 2 Report, for all cases alive at diagnosis, updated when data available, and completed when case closed.
- All Follow Up 2 Reports completed within two years of initial case reporting.

68

CoAg

C. Analyze TB surveillance data at least quarterly

- Analyze data to monitor trends, detect potential outbreaks, and define high-risk groups
- Produce and disseminate at least an annual report summarizing current data and trends.

69

CoAg

D. Evaluate programmatic performance by using TB surveillance data at least annually

- To determine extent to which program objectives are being met
- To assist in developing strategies for improvement.

70

Data Timeliness Tools

Chapter 10
Pages 10-62 – 10-70

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Chapter 8
Data Security and Confidentiality

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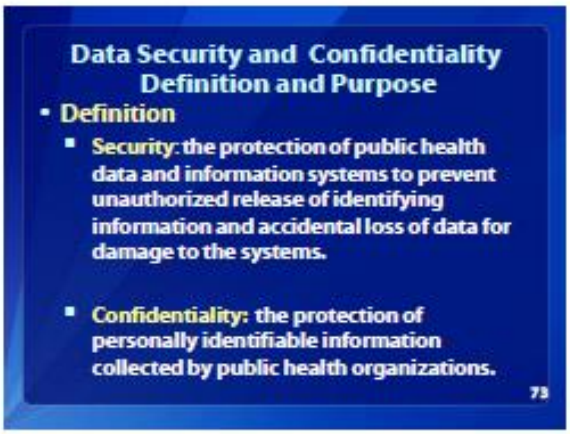
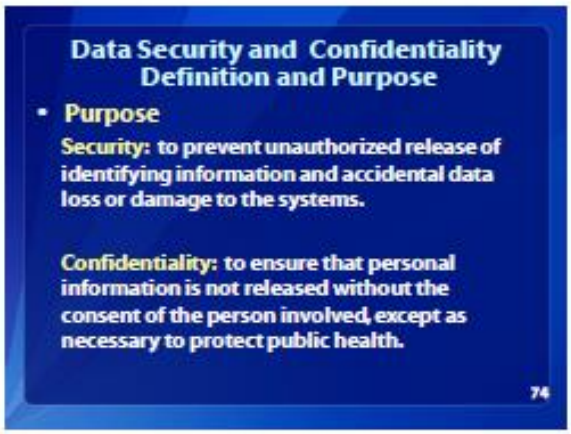
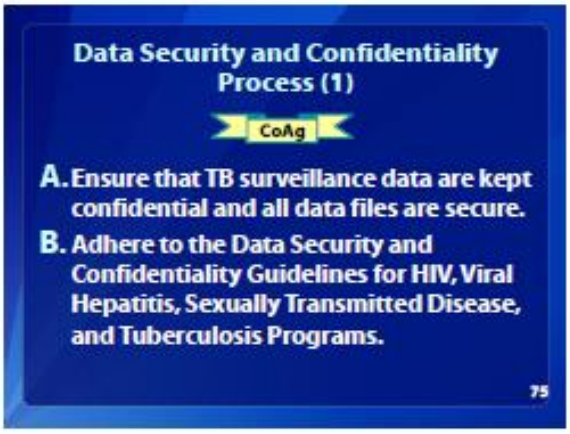
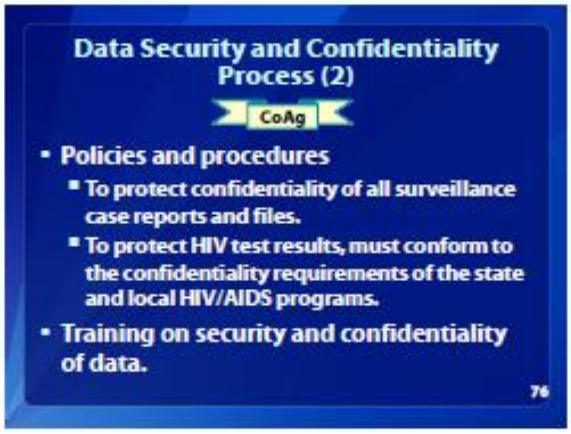

Data Security and Confidentiality Definition and Purpose
• Definition
▪ Security: the protection of public health data and information systems to prevent unauthorized release of identifying information and accidental loss of data for damage to the systems.
▪ Confidentiality: the protection of personally identifiable information collected by public health organizations.
73


Data Security and Confidentiality Definition and Purpose
• Purpose
Security: to prevent unauthorized release of identifying information and accidental data loss or damage to the systems.
Confidentiality: to ensure that personal information is not released without the consent of the person involved, except as necessary to protect public health.
74


Data Security and Confidentiality Process (1)
CoAg
A. Ensure that TB surveillance data are kept confidential and all data files are secure.
B. Adhere to the Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs.
75


Data Security and Confidentiality Process (2)
CoAg
• Policies and procedures
▪ To protect confidentiality of all surveillance case reports and files.
▪ To protect HIV test results, must conform to the confidentiality requirements of the state and local HIV/AIDS programs.
• Training on security and confidentiality of data.
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Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs
• Minimum Standards and Use to Facilitate Data Sharing and Use of Surveillance Data for Public Health Action
NEW
• Certification will be required annually
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Initial Assessments
• A baseline review of current policies and procedures to identify gaps and barriers.
• Follow a set of specified steps
78

Initial Assessment Steps (1)

1. Assess current policies and gather resources.
2. Assess physical security and define the secure area.
3. Assess electronic security, protections, and methods of data transfer and storage.
4. Assess current training needs.

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Initial Assessment Steps (2)

5. Identify key individuals and designate an overall responsible party/person (ORP)
6. Identify weaknesses and barriers to data sharing
7. Address non-traditional work environments
   - Teleworking
   - Field work
   - Remote work

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Data Security and Confidentiality Tools

Chapter 10
Pages 10-71 – 10-76

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NCHHSTP Data Security and Confidentiality Guidelines

http://www.cdc.gov/nchhstp/ProgramIntegration/docs/PCSIDataSecurityGuidelines.pdf

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Chapter 9 QA Cross-cutting Systems and Process (NTIP, TB GIMS, and Cohort Review)

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QA Cross-cutting Systems and Process

Examples of systems and a process that can be used for improving at least three of the five QA components .

- National Tuberculosis Indicator Project (NTIP)
- Tuberculosis Genotyping Information Management System (TB GIMS)
- Cohort Review

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Quality Assurance Cross-cutting Tools

Chapter 10
Pages 10-77 – 10-86

85

Chapter 10
Toolkit for Quality Assurance

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Toolkit

- Over 50 QA tools (e.g., tables, charts, graphs, processes, and templates)
- Available in commonly used word processing formats (e.g., Word, Excel, PowerPoint, or PDF)
- Can be used by and adapted to your setting
- Developed by staff from CDC and various jurisdictions

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Appendicies

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Appendices

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	QA Process Slides	Set of slides that describe the QA process

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Appendices

Appendix	Title	Description
D	Report of Verified Case of Tuberculosis Questions and Clarifications	Compilation of questions and clarifications since the 2009 publication of the RVCT instructions . 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 the guide

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Additional Information

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Summary of RVCT/QA Materials

http://www.cdc.gov/tb/programs/rvct/default.ht

RVCT

- 2 Manuals (for facilitators and participants)
- CD ROM
- Brochure
- Fact sheet
- Questions & Clarifications document
- Continuing Education Units

QA

- 1 Manual
- CD ROM (includes Toolkit)
- Fact sheet

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RVCT/QA Publications

RVCT

- J Public Health Management and Practice 2011; 17(5): 427–430. The National Tuberculosis Surveillance System training program to ensure accuracy of tuberculosis data
- TB Notes No. 3, 2009 DTBE's comprehensive and innovative training program on the revised RVCT

QA

- Tuberculosis Research and Treatment May 2012. Innovative-quality-assurance strategies for tuberculosis surveillance in the United States
- TB Notes No. 4, 2011 DTBE training course on quality assurance for tuberculosis surveillance data

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For More Information Contact

The RVCT/QA Training Team

rvctqualityassurance@cdc.gov

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