10: Toolkit for Quality Assurance

Description and Disclosure

Description

Staff from CDC and various jurisdictions developed over 50 quality assurance (QA) tools that include tables, charts, graphs, processes, and templates.

The tools are available in commonly used word processing formats such as Word, Excel, PowerPoint, or PDF. They may be used by and adapted to your setting. To view or download the tools, please see the QA Toolkit CD in the back of this manual or visit: http://www.cdc.gov/tb/programs/rvct/default.htm.

The tools are organized by chapter. Each chapter section begins with the master list of tools for that chapter, followed by examples of the tools. For most examples, only the first page of the tool is shown. This is because there are a lot of tools and some of them have multiple pages. However, the QA Plan Tools described in Chapter 3: Overview of QA Process, include the entire document because they are very important to the QA process and can be easily referenced while working through this manual. The images of the tools in this chapter are screen shots of the tools and may be a little fuzzy. For a clearer image see the actual tools on the CD or RVCT website listed above.

The Master List of Tools provides a brief description of each tool. The tools are organized by chapter and the list includes information described in the table below.

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 file format of the tool is listed as either Word, Excel, PowerPoint or PDF. Also included is the number of pages and the size of the size of the tool (if it is other than 8 ½" x 11").
Source Contact (for the tool)	The source contact indicates the agency that developed the tool. Contact information for some of the sources is available on the last page of this Chapter.

Disclosure

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.

Chapter 3: Quality Assurance Plan Tools

The QA Plan Tools includes a list of the tools followed by examples of the tools. **These tools are some of the most important tools in the toolkit because they provide the basis for the QA process.** The entire document for each of the tools is included because these are helpful to the jurisdictions for conducting QA.

Quality Assurance Plan Tools

Note: QA Plan Tools 1-3 are based on Fiscal Year 2014 CoAg and may need to be updated when the CoAg is updated.

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	**Quality Assurance 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

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention (CDC)
Tuberculosis Elimination and Laboratory
Cooperative Agreements

Announcement Type: Continuation – Type 2
Funding Opportunity Number: CDC-PS-10-1005 CONT14
Division of Tuberculosis Elimination (DTBE), NCHHSTP, OID, CDC
Catalog of Federal Domestic Assistance Number: 93.116

3. TB Surveillance/Reporting

- Enhance identification, reporting, and follow-up of TB cases and suspects by establishing liaisons with appropriate reporting sources such as hospitals, clinics (e.g., TB and HIV/AIDS clinics), laboratories performing tests for mycobacteria, selected physicians (e.g., pulmonary and infectious disease sub-specialists), correctional facilities, community and migrant health centers, pharmacies, and other public and private facilities providing care to populations with or at risk for TB. Jurisdictions should provide a plan for case finding and how they will or have established appropriate liaisons. Thereafter, TB programs should provide periodic feedback and at minimum, an annual written report summarizing surveillance data to reporting sources.

- Develop and implement active case detection activities to ensure complete and timely reporting of TB cases and suspects. At 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.tb*.

- Maintain a registry of TB cases that the jurisdiction will include in its morbidity total that contains at a minimum the elements to produce data for the national TB case report, the revised 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. 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.

- Report all newly diagnosed cases of TB to the CDC according to a schedule agreed upon each year, generally monthly, and at least quarterly. TB case data will be reported to CDC using the revised RVCT form via an electronic format that conforms to Public Health Information Network (PHIN) and/or National Electronic Disease Surveillance System (NEDSS) messaging standards. TB programs will maintain at least 95 percent reporting completeness for all variables existing on the pre-2009 RVCT. HIV status will be reported

for at least 95 percent of all newly reported TB cases age 25-44 years. A valid genotype accession number (generated by the CDC-sponsored genotyping laboratory) will be reported for at least 85 percent of all reported culture-positive cases. By 2013, TB programs will achieve 95% completeness of all variables in the revised RVCT.

- Submit complete RVCT reports, including Follow Up 1 (Initial Drug Susceptibility Report) and Follow Up 2 (Case Completion Report). The Initial Case Reports should be submitted generally monthly and at least quarterly. Follow Up 1 Report, which is only for TB cases with positive culture results, should be completed and submitted within 2 months after the initial RVCT was submitted, or when drug susceptibility results are available, whichever is later. The Follow Up 2 Report, which should be submitted for all cases in which the patient was alive at diagnosis, should have data entered as it becomes available, and it should be complete when the case is closed to supervision. All Follow Up 2 Reports should be completed within two years of initial case reporting.

- Assess the knowledge, skills and abilities of all existing personnel and new hires whose duties involve the collection and reporting of registry and RVCT data. Provide training and evaluation. Training will focus on accurate and timely completion of the revised RVCT and maintenance of data confidentiality. Within 6 months of implementation of the revised RVCT, all existing staff will be trained on revised RVCT data collection. New staff should be trained within 2 months of hire date.

- Incorporate quality assurance policies and procedures into surveillance activities to ensure completeness, timeliness and accuracy of data abstracted from original patient records, of registry data and of data entered onto the RVCT form and transmitted to CDC. Develop a written protocol for quality assurance to achieve data completeness, timeliness and accuracy. The protocol should be submitted to CDC in August 2010. At least annually evaluate the validity of RVCT data by comparing RVCT data and the jurisdiction's TB registry data to original data sources. Develop and implement plans for improvement.

- At least quarterly, analyze (e.g., quarterly) TB surveillance data to monitor trends, detect potential outbreaks, and define high-risk groups, and produce and disseminate at least an annual report summarizing current data and trends.

- At least annually evaluate programmatic performance by using TB surveillance data to assist in compiling supporting evidence to determine the extent to which program objectives are being met and also to assist in developing strategies for improvement. This objective can be met through NTIP reports.

- Ensure that TB surveillance data are kept confidentially and that all data files are secure. Policies and procedures must be in place to protect the confidentiality of all surveillance case

reports and files. Policies and procedures to protect HIV test results must conform to the confidentiality requirements of the state and local HIV/AIDS programs.

- Periodically (e.g., at least every two years) evaluate the completeness of reporting of TB cases to the surveillance system by identifying and investigating at least one population-based secondary data source (e.g., statewide laboratory record review, pharmacy review, hospital discharge data review) to find potentially unreported TB cases. Potential TB cases identified during the evaluation must be verified through review of medical records, physician interviews, or patient interviews. Reasons for non-reporting of TB cases should be determined and a plan for improvement developed and implemented.

- Collaborate with the HIV/AIDS program to conduct at least annual TB and AIDS registry matches to ensure completeness of reporting of HIV and TB co-infected patients to both surveillance systems. Investigate and verify all TB cases reported to the HIV/AIDS program and not reported to the TB program. Update the TB registry and reporting to CDC as needed.

- At least annually assess reasons for incomplete HIV results on the RVCT for each verified case of TB. Determine if patients were not tested for HIV or were tested but results not reported to the TB program. Develop and implement plans for improvement in increasing HIV testing and reporting to patients and TB programs.

Attachment 5

Additional Guidance to Clarify Data Necessary for TB Registry and Reporting Requirements for FY 2014 Interim Progress Report

All grantees, as part of Section I.3., Awardee Activities, A.(3), TB Surveillance/Reporting, will develop and implement surveillance activities to ensure complete, accurate, and timely reporting and counting of TB cases, and maintain a registry of verified TB cases. **Timeliness includes reporting all verified TB cases to CDC on a monthly or at least quarterly basis, particularly patients with multi-drug resistant TB who are reported and counted during that quarter.** In addition, the grantees should incorporate quality assurance of surveillance data (case detection, data accuracy, data completeness and data timeliness) routinely into their surveillance activities.

Reporting should include complete data on all data items in the Report of Verified Case of Tuberculosis (RVCT). All RVCT data items (listed below) should be filled out completely according to CDC instructions for the revised RVCT. (Reference: CDC. Report of Verified Case of Tuberculosis (RVCT) instruction manual. Atlanta, GA: US Department of Health and Human

Services, CDC; 2009. Available at http://ftp.cdc.gov/pub/software/tims/2009%20rvct%20documentation/rvct%20training%20materials/rvct%20instruction%20manual.pdf)

1. Date Reported
2. Date Submitted
3. Case Numbers
4. Reporting Address for Case Counting
5. Count status: 1) TB case, 2) Noncountable TB case: a. Verified case: Counted by another US area, b. Verified case: TB treatment initiated in another country, c. Verified case: Recurrent TB within 12 months after completion of therapy
6. Date Counted
7. Previous Diagnosis of TB Disease
8. Date of birth
9. Sex at Birth
10. Ethnicity
11. Race
12. Country of birth
13. Month-Year Arrived in U.S.
14. Pediatric TB Patients (less than15 years old)
15. Status at TB Diagnosis: If dead, enter date of death and whether TB was a cause of death.
16. Site of TB Disease
17. Sputum Smear: date collected
18. Sputum Culture: date collected and date result reported
19. Smear/Pathology/Cytology of Tissue and other Body Fluids: date collected, anatomic code, type of exam
20. Culture of Tissue and Other Body Fluids: date collected, anatomic code, type of exam, date result reported, reporting laboratory type
21. Nucleic Acid Amplification Test Result: date collected, date result reported, specimen type, reporting laboratory type
22. A. Initial Chest Radiograph, if abnormal: evidence of cavity or military TB; 22B. Initial Chest CT Scan or Other Chest Imaging Study, if abnormal: evidence of cavity or military TB
23. Tuberculin (Mantoux) Skin Test (TST) At Diagnosis, date TST placed, millimeters of induration
24. Interferon Gamma Release Assay for *Mycobacterium tuberculosis* at Diagnosis, date collected
25. Primary Reason Evaluated for TB Disease
26. HIV Status at Time of Diagnosis, if positive, enter State HIV/AIDS patient number and City/County HIV/AIDS patient number
27. Homeless Within Past Year
28. Resident of Correctional Facility at Time of Diagnosis, if YES, whether under custody of Immigration and Customs Enforcement
29. Resident of Long-Term Care Facility at Time of Diagnosis, if YES, select facility type
30. Primary Occupation Within Past Year
31. Injecting Drug Use Within Past year
32. Non-Injecting Drug Use Within Past Year

33. Excess Alcohol Use Within Past Year
34. Additional TB Risk Factors
35. Immigration Status at First Entry to the U.S.
36. Date Therapy Started
37. Initial Drug Regimen

Initial Drug Susceptibility Report, Follow Up Report- 1 (Complete this report only for cases with positive culture for *M. tuberculosis* complex. Complete and submit this report as soon as initial drug susceptibility results are available.)

38. Genotyping Accession Number
39. Initial Drug Susceptibility Testing, if YES, enter date first specimen collected on which initial drug susceptibility testing was done and specimen type
40. Initial Drug Susceptibility Results

Case Completion Report (Follow Up Report-2) (Complete this form for all patients who were alive at the time of TB diagnosis).

41. Sputum Culture Conversion Documented: if YES, enter date specimen collected for FIRST consistently negative sputum culture; if NO, enter reason for not documenting sputum culture conversion
42. Moved: if moved out of the U.S., whether transnational referral
43. Date Therapy Stopped
44. Reason Therapy Stopped or Never Started
45. Reason Therapy Extended more than12 Months
46. Type of Outpatient Health Care provider
47. Directly Observed Therapy (DOT), number of weeks of DOT
48. Final Drug Susceptibility Testing, if YES, enter FINAL date
49. Final Drug Susceptibility Results

If there are problems in completing all the data items in the RVCT and in sending quarterly reports to CDC, the grantee should:

1. Describe the problems.
2. Describe barriers in solving these problems.
3. Describe solutions or remedies.
4. Describe needs for training or other technical assistance.
5. Describe the differences between program data and those received by CDC and reflected in NTIP

HIV Status

Subheading number 3 (Surveillance/Reporting) of Awardee Activities of the Funding Opportunity Announcement describes HIV status reporting to include only patients between the ages of 25-44 years. However, HIV testing and status should be reported for all persons diagnosed with TB disease (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4813a2.htm)

Data Security and Confidentiality

Subheading number 3 (Surveillance/Reporting) of Awardee Activities of the Funding Opportunity Announcement ensures that TB surveillance data are kept confidentially and that all data files are secure. Awardees should adhere to the Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs. (http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf).

Quality Assurance for TB Surveillance Data

Subheading number 3 (Surveillance/Reporting) of Awardee Activities of the Funding Opportunity Announcement describes a written protocol for quality assurance (QA) for TB surveillance data. Awardees should report on how they are conducting each of the QA components (case detection, data accuracy, data completeness, data timeliness, and data security and confidentiality).

Quality Assurance for TB Surveillance Data
Cooperative Agreements (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 tables with an addition of possible data sources and activities.

Summary of CoAg Requirements
• Incorporate quality assurance policies and procedures into surveillance activities to ensure o Case detection (finding, counting, and reporting all TB cases) o 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) o Data completeness o Timeliness o Data security and confidentiality
• 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.
• Develop and implement plans for improvement.

Case Detection Requirements

CoAg Requirements	Description	Possible Data Sources and Activities
Maintain a registry of TB cases	**At a minimum, the registry of TB cases should contain** • The elements to produce data for the national TB case report, the revised RVCT.	Review TB database or log of all local jurisdictions.
	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**.	
	Include in the TB registry • Data on TB cases receiving diagnostic, treatment, or contact investigation services in the local jurisdiction, although not included in the annual morbidity total	
Establish liaisons with appropriate reporting sources to enhance quality assurance of TB surveillance data	**Enhance identification, reporting, and follow-up of TB cases and suspects by** • Establishing liaisons with appropriate reporting sources.	Contact: • Hospitals • Clinics (e.g., TB and HIV/AIDS clinics) • Laboratories performing tests for mycobacteria • Selected physicians (e.g., pulmonary and infectious disease subspecialists) • Correctional facilities • Community and migrant health centers • Pharmacies • Other public and private facilities providing care to populations with or at risk for TB.
	Provide a plan for • Case finding • How appropriate liaisons have been or will be established.	
	TB programs should provide • Periodic feedback • At a minimum, an annual written report summarizing surveillance data to reporting sources.	
Develop and implement active case detection activities	**At a minimum,** • Conduct ongoing active laboratory surveillance 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*.	Review laboratory reports.

CoAg Requirements	Description	Possible Data Sources and Activities
Evaluate the completeness of reporting of TB cases to the surveillance system	**Periodically (e.g., at least every two years)** • Evaluate the completeness of reporting of TB cases to the surveillance system by identifying and investigating **at least one population-based secondary data source** to find potentially unreported TB cases.	Conduct record reviews of secondary data sources such as • Statewide laboratory • Pharmacy • Hospital discharge data.
	Verify potential TB cases identified during the evaluation. • Determine reasons for nonreporting of TB cases. • Develop and implement a plan for improvement.	Investigate by • Medical record review • Physician interviews • Patient interviews.

Data Accuracy Requirements

CoAg Requirements	Description	Possible Data Sources and Activities
Evaluate accuracy or validity of RVCT data	**At least annually** • **Evaluate the accuracy or validity of RVCT data** by comparing RVCT data and the jurisdiction's TB registry data to original data sources.	Review and evaluate accuracy of • RVCT data collection forms • Patients' medical records • TB database.
Assess knowledge, skills, and abilities of staff and provide training if needed	**Assess the knowledge, skills, and abilities of** all existing personnel and new hires whose duties involve the collection and reporting of registry and RVCT data.	Determine staff competencies • Review personnel files. • Conduct staff interviews. • Observe and evaluate staff skills.
	Provide training and evaluation • Focus training on accurate and timely completion of the revised RVCT. • Train all existing staff on the revised RVCT data collection; new staff should be trained **within 2 months of hire date**.	Train staff as needed.

Data Completeness Requirements

CoAg Requirements	Description	Possible Data Sources and Activities
Maintain completeness for all RVCT variables	**Report TB case data to CDC using the** Revised RVCT form via an electronic format that conforms to • Public Health Information Network (PHIN). **and/or** • National Electronic Disease Surveillance System (NEDSS) messaging standards.	Complete and submit the RVCT form via an electronic format.
	Report the HIV status • For at least 95% of all newly reported TB cases.	Review HIV reports.
	Report a valid genotype accession number (generated by the CDC-sponsored genotyping laboratory) • For at least 85% of all reported culture-positive cases.	Complete genotyping reports via TB GIMS.
	Maintain at least 95% reporting completeness • For all variables existing on the pre-2009 RVCT.	Complete pre-2009 RVCT report.
	Achieve 95% completeness of all variables in the revised RVCT.	Complete post-2009 RVCT report.
Match TB and AIDS registries	**Collaborate with the HIV/AIDS program to conduct at least annually** • TB and AIDS registry matches to ensure completeness of reporting of HIV and TB coinfected patients to both surveillance systems.	Examine • TB database • HIV/AIDS registries
	Investigate and verify all TB cases reported to the HIV/AIDS program and not reported to the TB program. • Update the TB registry and report to CDC as needed.	
	At least annually • Assess reasons for incomplete HIV results on the RVCT for each verified case of TB.	

CoAg Requirements	Description	Possible Data Sources and Activities
	Determine whether patients • Were **not tested** for HIV, or • Were **tested but results not reported** to the TB program.	
	Develop and implement plans to improve • HIV testing • Reporting of HIV test results to patients and TB programs	

Data Timeliness Requirements

CoAg Requirements	Description	Possible Data Sources and Activities
Report all newly diagnosed cases of TB to CDC according to schedule.	**Report all newly diagnosed cases of TB to CDC** • According to a schedule agreed upon each year, generally monthly, and at least quarterly.	Submit RVCT reports.
Submit complete RVCT reports according to schedule.	**The RVCT Initial Case Reports should be** • Submitted generally monthly and at least quarterly.	Submit RVCT Initial Case Reports.
	Follow Up Report–1 should be • Completed only for TB cases with positive culture results • Completed and submitted within 2 months after the initial RVCT was submitted, or when drug susceptibility results are available, whichever is later.	Submit completed RVCT Follow Up Report–1 (Initial Drug Susceptibility Report).
	The Follow Up Report–2 should • Be submitted for all cases in which the patient was alive at diagnosis • Have data entered as they become available • Be completed when the case is closed. • Be completed within 2 years of initial case reporting. (Note: Completion of reports may be longer than 2 years for drug-resistant TB [MDR and XDR] cases.)	Submit completed RVCT Follow Up Report–2 (Case Completion Report).
Analyze TB surveillance data at least quarterly.	**At least quarterly, analyze TB surveillance data to** • Monitor trends • Detect potential outbreaks • Define high-risk groups • Produce and disseminate at least an annual report summarizing current data and trends.	Review surveillance database.

CoAg Requirements	Description	Possible Data Sources and Activities
Evaluate programmatic performance by using TB surveillance data at least annually.	**At least annually, evaluate programmatic performance by using TB surveillance data to** • Assist in compiling supporting evidence to determine the extent to which program objectives are being met • Assist in developing strategies for improvement.	Review NTIP reports.

Data Security and Confidentiality Requirements

CoAg Requirements	Description	Possible Data Sources and Activities
Ensure that TB surveillance data are kept confidentially and that all data files are secure. **Adhere to the Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs.**	**Policies and procedures must be in place to protect the confidentiality of all surveillance case reports and files.**	• Write data security and confidentiality policies and procedures of the TB program. • Review surveillance case reports and files.
	Policies and procedures to protect HIV test results, • Must conform to the confidentiality requirements of the state and local HIV/AIDS programs.	• Review confidentiality requirements of the state and local HIV/AIDS programs. • Develop data security and confidentiality policies and procedures to protect HIV test results. • Observe how staff comply with the policies and procedures.
	Provide training on security and confidentiality of data.	

QA Plan Tool - 3

Quality Assurance for TB Surveillance Data
Written Quality Assurance Protocol Guide
<TB Program's Name>
<Date>

Note: The protocol guide is based on 2014 CoAg and may need to be updated if the CoAg is updated.

Background
<Describe briefly your TB program's TB morbidity (e.g., patients' demographic and clinical information).>

Case Detection
<Describe your TB program's activities for each of the following:>

- **Maintain a registry of TB cases**.
  - What type of surveillance system does your program have?
  - How does your program include all TB suspects in the registry?
- **Establish liaisons with appropriate reporting sources to enhance quality assurance of TB surveillance data.**
  - How does your program establish liaisons with partners? [e.g. hospitals, clinics, laboratories, selected physicians, correctional facilities, community and migrant health centers, pharmacies, other public and private facilities (e.g., homeless shelters, drug treatment facilities, nursing homes)]
- **Develop and implement active case finding/detection activities.**
  - What steps must your program take to find all TB cases?
  - How does your program conduct ongoing active laboratory surveillance?
  - How does your program conduct site visits on a regular basis?
- **Evaluate the completeness of reporting of TB cases to the surveillance system.**
  - How does your program evaluate completeness of TB reporting by identifying and investigating at least one population-based secondary data source (e.g., statewide laboratory records, pharmacy, and hospital discharge data) at least every two years?
  - How are identified potential TB cases verified?

1

- How are reasons for non-reporting of TB cases determined and rectified?

Data Accuracy

<Describe your TB program's activities for each of the following:>

- **Evaluate accuracy/validity of RVCT data.**
  - How does your program compare the following?
    - RVCT data
    - Program TB registry
    - Original data sources (e.g., patient's medical records)
- **Assess knowledge, skills, and abilities of staff and provide training and evaluation.**
    - How does your program provide training on accurate and timely completion of RVCT items?
- Are all existing staff trained on the instructions for RVCT data collection and new staff trained within 2 months of hire?

Data Completeness

<Describe your TB program's activities for each of the following:>

- **Maintain completeness for all RVCT variables.**
  - How will your program achieve 95% completeness of all RVCT variables?
  - What are your program's plans to achieve at least 95% reporting of HIV status of all newly reported TB cases?
  - How about reporting of a valid genotype accession number for at least 85% of all reported culture-positive cases?
- **Match TB and AIDS registries.**
  - How does your program collaborate with the HIV/AIDS program to conduct at least annual TB and AIDS registry matches?
  - How are TB cases reported to the HIV?AIDS program and not reported to the TB program investigated and verified?
  - How are reasons for incomplete HIV results on the RVCT for each verified case of TB assessed and rectified?

Data Timeliness

<Describe your TB program's activities for each of the following:>

- **Report all newly diagnosed cases of TB to the CDC according to schedule.**
  - What timeline does your program use to report all newly diagnosed TB cases to CDC? Monthly? Quarterly?
- **Submit complete RVCT reports according to schedule.**
  - How are the RVCT Initial Case Reports submitted? Monthly? Quarterly?
  - How are the RVCT Follow Up 1 Reports (i.e., for TB cases with positive culture results) completed and submitted? Within 2 months after the initial RVCT was submitted, or when drug susceptibility results are available?
  - How are the RVCT Follow Up 2 Reports for all cases who were alive at diagnosis completed and submitted? Are these reports completed within 2 years of initial case reporting?
- **Analyze TB surveillance data at least quarterly**.
  - How are data analyzed to monitor trends, detect potential outbreaks define high-risk groups?
  - How does your program produce and disseminate an annual report summarizing current data and trends?
- **Evaluate programmatic performance by using TB surveillance data at least annually.**
  - How does your program use surveillance data to evaluate and improve programmatic performance?

Data Security and Confidentiality

<Describe your program's activities for each of the following:>

- **Ensure that TB surveillance data are kept confidentially and that all data files are secure.**

  Adhere to the Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs.
  - How are surveillance case reports and files protected and secured?
  - How are HIV test results protected? How do your program's policies and procedures conform to your state and local HIV/AIDS programs?
  - How does your program provide training on security and confidentiality of data?

Case Verification Criteria ("Vercrit") Calculation

Overview

The calculation of case verification is hierarchical. A record that satisfies the criteria for more than one Case Verification value will be assigned the value that appears first in the hierarchy. For example, a record that meets the criteria for both ***Positive Culture*** and ***Clinical Case Definition*** will be assigned a value of ***Positive Culture***.

Not a Verified Case appears twice in the hierarchy because there are two sets of criteria that will result in a Case Verification value of ***Not a Verified Case.*** They are:

1. **Reason Therapy Stopped or Never Started** is Not TB
2. ***Suspect Case*** is changed by the user to ***Not a Verified Case***

Suspect Case is the default Case Verification value assigned to all records created in the Surveillance module.

0 - Not a Verified Case

The record is assigned a ***0-Not a Verified Case*** case verification value if **Reason Therapy Stopped or Never Started** is Not TB.

1 - Positive Culture

The record is assigned a ***1-Positive Culture*** case verification value if either **Sputum Culture** or **Culture of Tissue and Other Body Fluids** is Positive.

1A - Positive NAA

The record is assigned a ***1A-Positive NAA*** case verification value if **Nucleic Acid Amplification Test Result** is Positive.

2 - Positive Smear/Tissue

The record is assigned a ***2-Positive Smear/Tissue*** case verification value if:

- **Sputum Smear** or **Smear/Pathology/Cytology of Tissue and Other Body Fluids** is Positive

  -AND-
- **Sputum Culture** and **Culture of Tissue and Other Body Fluids** are both either Not Done or Unknown

  -AND-
- **Nucleic Acid Amplification Test Result** is either Not Done, Unknown or Indeterminate

3 - Clinical Case Definition

The record is assigned a ***3-Clinical Case Definition*** case verification value if all the following are true:

- **Site of TB Disease** is not Missing or is not Site Not Stated .

- **Sputum Culture** and **Culture of Tissue and Other Body Fluids** are either Negative, Not Done, or Unknown
- **Nucleic Acid Amplification Test Result** is either Negative, Not Done, Unknown, or Indeterminate
- When **Site of TB Disease** is either Pulmonary, Pleural, or Lymphatic: Intrathoracic then either **Initial Chest Radiograph** or **Initial Chest CT Scan or Other Chest Imaging Study** is Abnormal,
- **Tuberculin (Mantoux) Skin Test at Diagnosis** or **Interferon Gamma Release Assay for *Mycobacterium tuberculosis* at Diagnosis** is Positive
- **Initial Drug Regimen** has at least two drugs marked Yes

If criteria to satisfy any of the previous case verifications are not met, the user has the option to overwrite the assigned case verification default value ***5-Suspect***, by selecting either ***4-Verified by Provider Diagnosis*** or ***0-Not a Verified Case***.

5 - Suspect

All new records are considered ***5-Suspect*** until they meet the criteria for another Case Verification value or are overwritten by the user as either ***4-Verified by Provider Diagnosis*** or ***0-Not a Verified Case***.

4 - Verified by Provider Diagnosis (Overwrites Suspect)

The user elects to overwrite case verification default value ***5-Suspect*** with ***4-Verified by Provider Diagnosis***.

0 - Not a Verified Case (Overwrites Suspect)

The user elects to overwrite the ***5-Suspect*** case verification default with ***0-Not a Verified Case***.

Technical Specification

If **TB154** (Case Verification) calculates to **'5 – Suspect'** and the user changes the value to **'0 - Not a Verified Case'** or **'4 - Verified by Provider'**, then **'5 – Suspect'** will not be included in the rule calculation and the user entered value should be maintained for **TB154** (Case Verification).

0 - Not a Verified Case

IF

[**TB177** (44. Reason Therapy Stopped or Never Started) = 'Not TB']

THEN

TB154 (Case Verification) = **'0 - Not a Verified Case'**

1 – Positive Culture

IF

[**TB109** (18. Sputum Culture:) = 'Positive'

OR

TB113 (20. Culture of Tissue and Other Body Fluids) = 'Positive']

THEN

TB154 (Case Verification) = **'1 – Positive Culture'**

1A – Positive NAA

IF

[**TB255** (21. Nucleic Acid Amplification Test Result) = 'Positive']

THEN

TB154 (Case Verification) = **'1A – Positive NAA'**

2 – Positive Smear/Tissue

IF

[**TB108** (17. Sputum Smear) = 'Positive'

OR

TB110 (19. Smear/Pathology/Cytology of Tissue and Other Body Fluids) = 'Positive']

AND

[**TB109** (18. Sputum Culture) = 'Not Done' or 'Unknown']

AND

[**TB113** (20. Culture of Tissue and Other Body Fluids) = 'Not Done' or 'Unknown']

AND

[**TB255** (21. Nucleic Acid Amplification Test Result) = 'Not Done', 'Unknown', or 'Indeterminate']

THEN

TB154 (Case Verification) = **'2 – Positive Smear/Tissue'**

3 – Clinical Case Definition

IF

[**TB205** (16. Site of TB Disease) DOES NOT = 'Site Not Stated' or BLANK]

AND

[**TB109** (18. Sputum Culture) = 'Negative', 'Not Done', or 'Unknown']

AND

[**TB113** (20. Culture of Tissue and Other Body Fluids) = 'Negative', 'Not Done', or 'Unknown ']

AND

[**TB255** (21. Nucleic Acid Amplification Test Result) = 'Negative', 'Not Done', 'Unknown', or 'Indeterminate']

AND

[IF **TB205** (16. Site of TB Disease) = 'Pulmonary', 'Pleural', or 'Lymphatic: Intrathoracic"

AND

[TB116 (22A. Initial Chest Radiograph) = 'Abnormal'

OR

TB245 (Initial Chest CT Scan or Other Chest Imaging Study) = 'Abnormal']]

AND

[**TB119** (23. Tuberculin (Mantoux) Skin Test at Diagnosis) = 'Positive'

OR

TB250 (24. Interferon Gamma Release Assay for *Mycobacterium tuberculosis* at Diagnosis = 'Positive']

AND

[**TB132 – TB146, TB260-TB262, TB264** (37. Initial Drug Regimen) = At Least Two Drugs = 'Yes']

THEN

TB154 (Case Verification) = **'3 – Clinical Case Definition'**

5- Suspect

ELSE

TB154 (Case Verification) = **'5 – Suspect'**

Chapter 4: Case Detection Tools

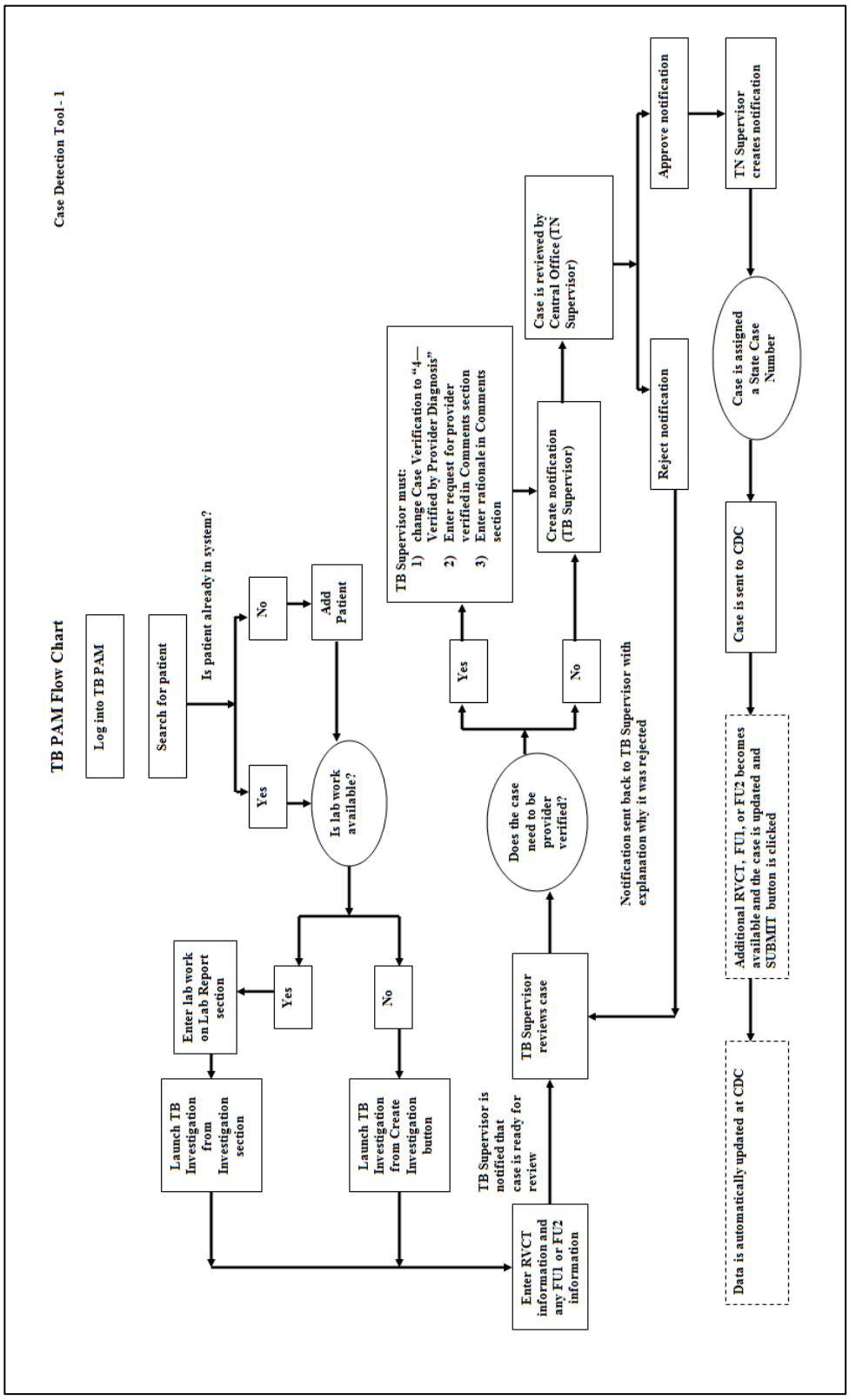
The Case Detection Tools include a list of the tools followed by examples of the first page of each tool.

Case Detection Tools

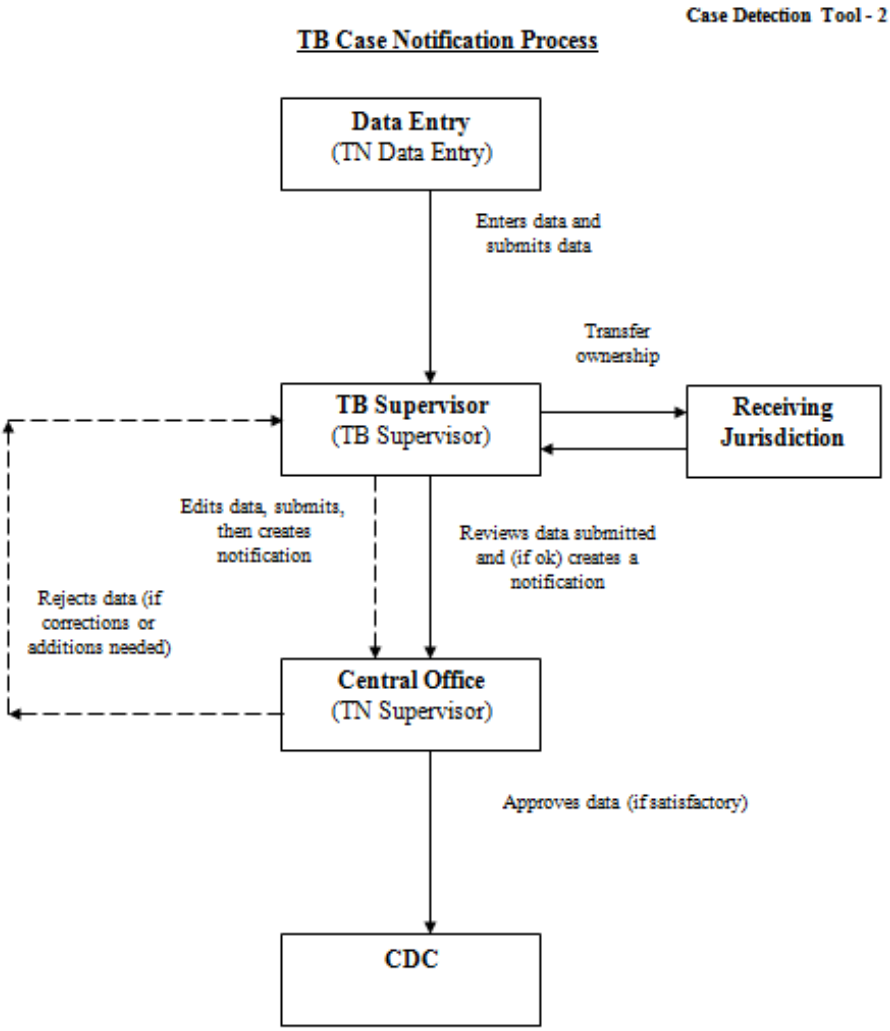
Tool #	Tool Name	Description and How to Use	Format	Source Contact
Case Detection–1	**TB PAM Flow Chart**	A flow chart to help search for patient records. It was created initially to emphasize the importance of always searching for a patient record within the TB Program Area Module (PAM) so that duplicate patient records are not created. This chart also outlines the process for creating "Provider Verified" cases, and also addresses approval and rejection of notification.	Word 1 page Legal size	Tennessee TB Elimination Program
Case Detection–2	**TB Case Notification Process**	A flow chart that shows the case notification process. Tennessee has a tiered process for TB case notification. The chart identifies each person's role (with a particular TB PAM access right) in the notification process, and what happens when a notification is rejected or approved. Within Tennessee, only TB Program Managers (nurses within the TB Program) create a notification, and it must be approved by the TB Program Central Office Epidemiologist before it is sent to CDC for case counting.	Word 1 page	Tennessee TB Elimination Program

Tool #	Tool Name	Description and How to Use	Format	Source Contact
Case Detection–3	**TB Suspects Weekly Report**	This report is generated weekly for all suspects reported in TB PAM, through Friday of the previous week. In Tennessee, suspects should be classified as a case or not a case within 56 days from the date of report. When the Date of Report is entered, a built-in feature calculates 56 days from that date. All suspects that are past due for classifying (over 56 days) require a follow-up from one of the Central Office Nurse Consultants.	Excel 1 page 11x17	Tennessee TB Elimination Program
Case Detection–4	**TB Case Verification and Treatment Status**	A table that indicates case verification and treatment status. This spreadsheet is used to monitor treatment progress with the goal of completing treatment within 12 months. There are built-in calculations for 3, 6, 9 and 12 months from treatment start that are populated when the Date Therapy Started is entered. Case Verification is included to help identify anticipated treatment length.	Excel 1 page Legal size	Tennessee TB Elimination Program
Case Detection–5	**Decline in Reported Tuberculosis Cases Survey**	Sample survey to investigate decline in reported TB cases.	Word 1 page	CDC/DTBE
Case Detection–6	**Investigation Process for Underreporting of TB for QA for TB Surveillance Data**	Table that provides a process for investigating underreporting of TB data.	Word 2 pages	CDC/DTBE
Case Detection–7	**Counted Tuberculosis Case Verification Report**	Form that provides counted TB case verification.	Word 1 page	Texas Department of State Health Services Epidemiology & Surveillance Branch

Tool #	Tool Name	Description and How to Use	Format	Source Contact
Case Detection–8a	**TB Case Closeout Letter**	Sample letter to accompany TB Case Close List (Tool 8b) and TB Case Closeout Form (Tool 8c).	Word 2 pages	California Tuberculosis Control Branch, California Department of Public Health
Case Detection–8b	**TB Case Close List**	List by jurisdiction indicating TB case closeout status.	Excel 1 page	California Tuberculosis Control Branch, California Department of Public Health
Case Detection–8c	**TB Case Closeout Form**	Form for confirmation and signature on closeout of TB cases	Word 1 page	California Tuberculosis Control Branch, California Department of Public Health


TB PAM Flow Chart
Case Detection Tool - 1
Log into TB PAM
Search for patient
Is patient already in system?
No
Add Patient
Yes
Is lab work available?
Yes
Enter lab work on Lab Report section
Launch TB Investigation from Investigation section
No
Launch TB Investigation from Create Investigation button
Enter RVCT information and any FU1 or FU2 information
TB Supervisor is notified that case is ready for review
TB Supervisor reviews case
Does the case need to be provider verified?
Yes
TB Supervisor must:
1) change Case Verification to "4—Verified by Provider Diagnosis"
2) Enter request for provider verified in Comments section
3) Enter rationale in Comments section
No
Create notification (TB Supervisor)
Case is reviewed by Central Office (TN Supervisor)
Approve notification
Reject notification
Notification sent back to TB Supervisor with explanation why it was rejected
TN Supervisor creates notification
Case is assigned a State Case Number
Case is sent to CDC
Additional RVCT, FU1, or FU2 becomes available and the case is updated and SUBMIT button is clicked
Data is automatically updated at CDC

Case Detection Tool - 2



TB Suspects Weekly Report

Case Detection Tool - 3

Date of Report	Date for Central Office Follow-up	Investigation Start Date	Jurisdiction Name	Patient County	Calculated Reported Age	Calculated Site of Disease	Skin Test at Diagnosis	Millimeters of Induration	Chest X-ray Results	Abnormal Chest X-ray Evidence of Cavity	Abnormal Chest X-ray Evidence of Miliary TB	Sputum Smear	Sputum Culture	Date Therapy Started	Investigator Last Name	Investigator First Name
10/8/10	12/3/10	10/8/10			65	Pulmonary	Negative	0	Abnormal	Yes	No	Positive	Unknown	10/11/10		
9/30/10	11/25/10	10/1/10			38	Extra Pulmonary	Positive	23	Normal			Unknown		10/1/10		
8/16/10	10/11/10	7/16/10			25	Pulmonary	Not Done		Unknown			Not Done	Not Done			
8/23/10	10/18/10	8/23/10			61	Pulmonary	Positive	20	Normal			Negative		8/25/10		
9/2/10	10/28/10	9/2/10			85	Pulmonary	Not Done		Normal			Not Done	Not Done			
9/8/10	11/3/10	9/8/10			29	Pulmonary	Not Done		Normal			Positive		9/8/10		
9/13/10	11/8/10	9/13/10			84	Pulmonary	Negative	0	Normal			Negative				
7/14/10	9/8/10	7/14/10			54	Pulmonary	Negative	0	Abnormal	No	No	Negative	Negative	7/14/10		
7/20/10	9/14/10	7/20/10			52	Extra Pulmonary	Positive	28				Negative		7/20/10		
9/2/10	10/28/10	9/2/10			52	Pulmonary	Negative	0	Abnormal	Yes	No	Negative	Unknown	9/2/10		
9/3/10	10/29/10	9/8/10			40	Extra Pulmonary						Not Done	Not Done			
9/7/10	11/2/10	9/7/10			79	Extra Pulmonary										
9/28/10	11/23/10	9/28/10			49	Pulmonary	Not Done		Unknown			Unknown	Unknown	9/26/10		
10/5/10	11/30/10	10/5/10			71	Pulmonary	Positive	10				Positive		10/4/10		
10/8/10	12/3/10	10/8/10			48	Pulmonary	Positive	17	Abnormal	No	No	Positive		10/8/10		
10/8/10	12/3/10	10/8/10			28	Both	Positive	20	Unknown			Unknown	Unknown	9/30/10		
10/18/10	12/13/10	10/18/10			70	Pulmonary			Unknown			Not Done	Not Done			
9/17/10	11/12/10	9/17/10			45	Pulmonary	Positive	15				Negative	Negative	9/14/10		
10/6/10	12/1/10	10/6/10			83	Pulmonary	Unknown		Unknown			Positive	Unknown	10/8/10		
8/18/10	10/13/10	8/19/10			37	Pulmonary	Positive	20	Unknown			Negative	Negative	8/18/10		
9/8/10	11/3/10	9/8/10			69	Unknown										
9/14/10	11/9/10	9/14/10			55	Unknown										
9/15/10	11/10/10	9/16/10			88	Pulmonary	Negative	0	Abnormal	Yes	No	Not Done	Not Done	9/15/10		
9/22/10	11/17/10	9/23/10			23	Both	Positive	15	Unknown			Negative	Unknown	9/22/10		
10/13/10	12/8/10	10/13/10			5	Pulmonary	Positive	15	Unknown			Unknown	Unknown	10/13/10		
10/14/10	12/9/10	10/14/10			64	Pulmonary						Negative				
10/18/10	12/13/10	10/18/10			61	Pulmonary	Positive	29	Unknown			Unknown	Unknown	10/15/10		
9/28/10	11/23/10	9/28/10			77	Pulmonary			Abnormal	No	No	Not Done				
10/4/10	11/29/10	10/4/10			84	Pulmonary	Negative	0	Normal			Positive		10/1/10		
9/8/10	11/3/10	9/8/10			59	Pulmonary	Positive	15	Normal			Negative	Unknown	9/8/10		
10/5/10	11/30/10	10/5/10			22	Extra Pulmonary	Positive	25	Normal			Negative		10/5/10		

1	Case Verification and Treatment Status													Case Detection Tool - 4		
2																
3																
4	Date Counted	Jurisdiction Name	Case Verification	Date Therapy Started	3-Month Interval	6-Month Interval	9-Month Interval	12-Month Interval	Date Therapy Stopped	Reason Therapy Stopped	Directly Observed Therapy	Number Weeks DOT	Investigation Status			
5	3/9/10		1 - Positive Culture	1/25/10	4/25/10	7/24/10	10/22/10	1/25/11	7/30/10	Completed Therapy	Yes, Total DOT	26	Closed			
6	4/19/10		1A - Positive NAA	4/12/10	7/11/10	10/9/10	1/7/11	4/12/11	10/15/10	Completed Therapy	Yes, Total DOT	26	Closed			
7	4/6/10		1 - Positive Culture	3/10/10	6/8/10	9/6/10	12/5/10	3/10/11					Open			
8	6/14/10		3 - Clinical Case Definition	6/7/10	9/5/10	12/4/10	3/4/11	6/7/11					Open			
9	7/9/10		1 - Positive Culture	7/8/10	10/6/10	1/4/11	4/4/11	7/8/11					Open			
10	9/16/10		1 - Positive Culture	7/17/10	10/15/10	1/13/11	4/13/11	7/17/11					Open			
11	9/28/10		1 - Positive Culture	8/26/10	11/24/10	2/22/11	5/23/11	8/26/11					Open			
12	3/3/10		1 - Positive Culture	1/25/10	4/25/10	7/24/10	10/22/10	1/25/11	8/13/10	Died	Yes, Total DOT	16	Closed			
13	2/26/10		1 - Positive Culture	2/22/10	5/23/10	8/21/10	11/19/10	2/22/11	3/13/10	Died	Yes, Total DOT	1	Closed			
14	3/19/10		1 - Positive Culture	3/18/10	6/16/10	9/14/10	12/13/10	3/18/11	9/23/10	Completed Therapy	Yes, Total DOT	26	Closed			
15	4/16/10		1A - Positive NAA	4/5/10	7/4/10	10/2/10	12/31/10	4/5/11	10/12/10	Completed Therapy	Yes, Total DOT	27	Closed			
16	4/23/10		1 - Positive Culture	4/23/10	7/22/10	10/20/10	1/18/11	4/23/11	10/25/10	Completed Therapy	Yes, Total DOT	26	Closed			
17	6/4/10		1 - Positive Culture	5/20/10	8/18/10	11/16/10	2/14/11	5/20/11	10/15/10	Died	Yes, Total DOT	21	Closed			
18	2/19/10		1 - Positive Culture	1/29/10	4/29/10	7/28/10	10/26/10	1/29/11					Open			
19	3/3/10		1 - Positive Culture	2/11/10	5/12/10	8/10/10	11/8/10	2/11/11					Open			
20	7/7/10		3 - Clinical Case Definition	4/12/10	7/11/10	10/9/10	1/7/11	4/12/11					Open			
21	5/7/10		1 - Positive Culture	4/25/10	7/24/10	10/22/10	1/20/11	4/25/11					Open			
22	5/19/10		1 - Positive Culture	5/8/10	8/6/10	11/4/10	2/2/11	5/8/11					Open			
23	8/6/10		3 - Clinical Case Definition	5/24/10	8/22/10	11/20/10	2/18/11	5/24/11					Open			
24	9/8/10		3 - Clinical Case Definition	7/9/10	10/7/10	1/5/11	4/5/11	7/9/11					Open			
25	9/16/10		1A - Positive NAA	9/1/10	11/30/10	2/28/11	5/29/11	9/1/11					Open			

Case Detection Tool - 5

Decline in Reported Tuberculosis Cases
<insert agency name> Survey

Dear County Health Department,

The <insert agency name> is investigating an unexpectedly large decline in reported TB cases in the state.

You assistance is greatly needed to verify the number of TB cases in your county or district in <insert year>. **Please complete the survey below and fax this sheet to the <insert agency name> at <insert fax number> with Attention: <insert staff name>, preferably by close of business <insert due date>.**

Regarding TB cases reported in your facility in <insert year>, please complete the following information:

District: _____ Unit: _____ County:_____

Survey Completed by: _____ Phone #: _____

District TB Controller: _____

Number of all TB cases (confirmed and suspected) reported to your county or district in <insert year>:_____

- Among these <insert year> cases, how many were **confirmed**: _____
    - Confirmed up to February 5, <insert year>: _____
    - Confirmed from February 5, <insert year> to today: _____
- Among these <insert year> cases, how many are still **suspects** as of today:_____
    - Of these suspects, how many were reported >90 days ago: _____

Investigation Process for Underreporting of TB for Quality Assurance for TB Surveillance Data

Case Detection

Within the Public Health System **Due to delays or disruptions in flow of TB surveillance information from the local level to the state, and from the state level to CDC.**
Interview TB staff to identify delays in reporting and counting, and changes in resources.
Compare counts of TB cases known to the county (or reporting district) versus cases known to state and CDC.
Review paper charts and lab data of suspect TB cases awaiting case verification.
Conduct system queries and analyses of all reported (i.e., suspect, verified, and counted) cases during the affected year to identify • Suspect cases still awaiting verification >90 days since first reported; • Cases awaiting to be counted; • The percentage and monthly trend of counted cases during the affected year; • Delays in counting (i.e., mean number of days between "record entry date" and "count entry date").
Develop and email surveys to the counties with >3 case decline for the affected year to identify discrepancies in the numbers of counted and suspect TB cases between county and state records. Verify survey results by phone.
Conduct site visits to local TB programs with the largest decline. At site visits, interview staff to understand changes and challenges in routine reporting practices. In addition, compare state and county numbers of counted and suspect cases, and review charts of suspected TB cases still awaiting verification or not entered in the system.

Counted Tuberculosis Case Verification Report

Case Detection Tool - 7

SSN: **RVCT State Case Number : _ _ _ _ - _ _ - 2011 _ _ _ _ _**

Name: ____ DOB: ____/____/____
Last First Middle

Date Reported: ______/______/_______

Date Submitted: ______/______/_______
(For State Use Only)

Date Counted: (DX AT S 3) ______/______/_______

MMWR Year: _______________

☐ New ☐ Recurrent (>365 days)
Status at DX: ☐ Dead ☐ Alive

Reporting County: _________________ **TB SA:** _______________

☐ **Resident of Correctional Facility at Time of Dx**

☐ **Resident of Long Term Care Facility at Time of Dx**

Other:

☐ **colonia resident** ☐ **displaced citizen** ☐ **shelter** ☐ **school dorm**

Binational Status: (A) (B) (C)

Linking State Case Number:

☐☐☐☐ ☐☐ ☐☐☐☐☐☐☐☐☐

☐☐☐☐ ☐☐ ☐☐☐☐☐☐☐☐☐

Criteria Met for "Published" Case Definition:

☐ **Lab Confirmed**
- ☐ + Culture ☐ + NAA
- ☐ + Smear/Cult not done ☐ + Pathology/Cytology

☐ **Clinical Case Definition**
- ☐ Positive TST/IGRA and abnormal CXR or signs/symptoms; at least 2 anti-TB meds

Site of Disease (select all that apply):

☐ Pulmonary / Laryngeal

☐ Meningeal

☐ Other extra-pulmonary site(s): ______________________

Criteria Met for Clinical Case by Provider Diagnosis:
(Belonging to a high population or medical risk group and at least one of the following)

- ☐ Not done or negative TST and considerable improvement on abnormal CXR (or)
- ☐ Considerable clinical improvement based on symptoms from onset after started on at least 2 anti-TB meds
- ☐ **Child recent contact to active case**
- ☐ Autopsy report
- ☐ TB Expert Consult

TB-340 Priority:

- ☐ **Sputum Smear + / Cavitary Chest x-ray**
- ☐ Sputum, Laryngeal or Pleural Culture +
- ☐ Pediatric Case
- ☐ DX at a Correctional Facility
- ☐ DX at a Long-term Care Facility
- ☐ Homeless Shelter

Drug Resistance: ☐ MDR ☐ Pre-XDR ☐ XDR String ☐ XDR ☐ RES

☐ Patient Relapsed and is considered infectious again:
Date new CI conducted: _____/_____/______

Communication Log

Date	To/From	Name	Change or Error

Case Closure

☐ Completed Therapy ☐ Lost ☐ Deceased ☐ **Refused** ☐ **Serious Adverse Drug Reaction** - Date of report: ____/_____/____

Months of Rx Recommended: ______ # Months of Rx Completed: ______ **Reason Rx Extended >12 mos:** ______________
Sputum Conversion Documented? Yes: ____/____/____ Reason could not convert: ______________________

☐ Moved out of State; IJT sent on: _____/______/______ Moved to other jurisdiction; ____form sent on: ______/_______/______
☐ Non-TB: Class 3 record resumed as class 5 (suspect); justification for misdiagnosis on file.

Case Detection Tool – 8a

<Insert date>

Dear TB Control Partners:

As part of the ongoing process of closing out the <insert year> case count, we are sending to all jurisdictions a preliminary TB CASE CLOSE LIST. This is in preparation for sending out a <insert year> TB CASE CLOSEOUT FORM to be signed by your TB Controller.

Because of the changes to the RVCT form in <insert year> we will be modifying the TB CLOSE OUT FORM to reflect the different case status now collected:

- Not a verified TB Case
- Count as a TB Case
- Verified Case: Counted by another US area
- Verified Case: TB treatment initiated in another country
- Verified Case: Recurrent TB w/in 12 months" after completion of therapy

Attached, please find your preliminary TB CASE CLOSE LIST in Excel format, which includes the following:

1. Not a verified TB Case
2. Total number of counted cases
3. Total number of verified cases counted by another US area
4. Total number of verified cases where TB treatment initiated in another country
5. Total number of verified cases that were recurrent TB w/in 12 months" after completion of therapy
6. Total number of MDR and XDR cases
7. Line listing of all your TB cases sorted by state case number. The listing includes the following:
    a. Count Status of each case
    b. State Case Number
    c. A field indicating MISSING RVCT if there is a skip in the State Case Number sequence
    d. Case Verification value
    e. MDR field that will denote a mdr case by the value "MDR CASE" in the cell
    f. XDR field that will denote a xdr case by the value "XDR CASE" in the cell
    g. IncidentID which is the unique identifier which should be included in all communications about a specific case
    h. NewStateCaseNo, which is used by the CDC for identifying cases
    i. Local Health Jurisidction to identify which jurisdictions worksheet is on the screen.

Jurisdictions are listed on separate worksheets within the workbook.

Please review your worksheet for the following purpose

a. Reconcile the totals for each Count Status with your record by reviewing the totals for each of the different Count Status categories in the first few rows of columns A and B in the worksheet
b. Review the line listing to confirm the number of MDR and XDR cases as indicated in columns F and G of the worksheet
c. Review the line listing to confirm the missing RVCT numbers as indicated in column. Please note the reason for the missing number such as: deleted.

1

<Insert Year> TB Case Close List

<Insert Jurisdiction>

Case Detection Tool – 8b

Incident I	RVCT Number	27-Jan-11	VERCRIT	Las	Firs	DOB	City	Count	Comments
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	4. Provider						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	1. Culture						This was xxxx, but now corrected.
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	4. Provider						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	4. Provider						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	3. Clinical						
		1Count as a TB Case	4. Provider						
NA		~~Not TB~~	~~Not TB~~						~~Never rec'd RVCT, only FIU2 indicating Not TB~~
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	4. Provider						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	3. Clinical						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	1. Culture						
		1Count as a TB Case	1. Culture						Changed RVCT# to xxxx, since ********** is supposed to be xxxx5.
	~~1235~~	~~Deleted~~	~~Deleted~~						~~Deleted RVCT. Please disregard pt is counted under ######~~

N=37

REDACT

Case Detection Tool – 8c

<insert year> TB Case Closeout Form

Please review the following information, and confirm that it is correct with your signature at the bottom of this page. Please contact the TB Registry <insert phone number> if any of this information is incorrect.

Local Health Jurisdiction: **<insert jurisdiction>**

Our records indicate that you have **<insert number>** counted TB case(s) for **<insert year>**

Highest state case number for **<insert year>**: **<insert highest state case number>**

MDR Cases in **<insert year>**: **<insert case numbers>**

Other (Non-countable) TB Cases: **<insert case numbers>**

Missing State Case Numbers

Please indicate the reason for missing numbers if not already listed.

State Case Number	Reason Why It Is Missing

If in agreement, please sign and return this document. Thank you.

Local Health Jurisdiction sign here: _____ Date: _____

TB Controller sign here: _____ Date: _____

Please fax back to TB Registry: <insert fax number>

Thank you!!!

Chapter 5: Data Accuracy Tools

The Data Accuracy Tools include a list of the tools followed by examples of the first page of each tool.

Chapter 5
Data Accuracy Tools

Tool #	Tool Name	Description and How to Use	Format	Source Contact
Accuracy–1a	**Data Accuracy Checklist for RVCT**	Checklist for reviewing RVCT data for accuracy.	Word 9 pages	CDC/DTBE
Accuracy–1b	**Data Accuracy Checklist CDC SAS Code**	SAS code corresponding to the Data Accuracy Checklist – Accuracy Tool - 1a; based on CDC RVCT variable names.	Word 7 pages	CDC/DTBE
Accuracy–1c	**CDC TB Surveillance RVCT Data Dictionary**	Data dictionary for interpreting the CDC RVCT variable names used in Data Accuracy Checklist CDC SAS Code – Accuracy Tool - 1b.	Excel 16 pages	CDC/DTBE
Accuracy–2	**Options for Prioritizing Medical Chart Reviews When Resources Are Limited**	Various options to help prioritize medical chart reviews when resources are limited.	Word 1 page	CDC/DTBE
Accuracy–3	**RVCT Surveillance Data Base Audit Form for Timeliness and Accuracy**	Checklist for checking the accuracy of RVCT.	Word 1 page	CDC (adapted from New Hampshire)

Tool #	Tool Name	Description and How to Use	Format	Source Contact
Accuracy–4	**Accuracy Checklist for Sputum Culture Conversion**	Table used to indicate number of days for culture conversion by jurisdiction. This applies to cases that are sputum culture-positive only. There are built-in features/tools that calculate the dates that are 30 and 60 days from treatment start (once the Date Therapy Started is entered). There is also a built-in calculation for the number of days to sputum culture conversion. This helps identify those patients who did not meet the NTIP objective of converting their sputum culture within 60 days of treatment initiation.	Excel 1 page	Tennessee TB Elimination Program
Accuracy–5	**Nucleic Acid Amplification (NAA) Tests**	Comparison of NAA tests.	Excel 1 page	CDC/DTBE
Accuracy–6	**Culture-Based (Phenotypic) Laboratory Tests for Drug Susceptibility Testing**	Comparison of culture-based (phenotypic) laboratory tests for drug susceptibility testing.	Excel 1 page	CDC/DTBE
Accuracy–7	**Molecular-Based Laboratory Tests for Detecting Mutations Associated with Drug Resistance**	Comparison of molecular-based laboratory tests for detecting mutations associated with drug resistance.	Excel 1 page	CDC/DTBE
Accuracy–8	**2009 RVCT Form with PHIN Variable IDs**	2009 RVCT Form with Public Health Information Network (PHIN) Variable IDs, by RVCT item number, to use as a reference for reporting codes.	PDF 6 pages	CDC/DTBE
Accuracy–9	**Comparison of Concordant and Discordant RVCT Items - Summary**	A list of RVCT variable items suggested for surveillance review.	Word 2 pages	CDC/DTBE

Tool #	Tool Name	Description and How to Use	Format	Source Contact
Accuracy–10	**Health Level 7 CDC Race and Ethnicity Code Set**	A comprehensive list of race and ethnic groups including tribes for HL7 coding.	PDF 38 pages	CDC

Accuracy Tool – 1a

Data Accuracy Checklist for Report of Verified Case of Tuberculosis (Inconsistent and Outlying Data Field Values) 4/17/2012

This document provides a checklist to determine the accuracy for items from the Report of Verified Case of Tuberculosis (RVCT).

Check the following for accuracy:

- Calculated variables
- Text fields
- Data response patterns
- Date fields (no future dates and no dates too far in the past; dates for certain events in wrong order resulting in negative time duration)

Examples for Checking Accuracy

This includes common errors to check for accuracy.

RVCT		Check for Accuracy
#	Item	
1	Report Date	Report date should be later than or equal to January 1st, 1990
3	Case Numbers	• State case number, city/county case number and linking state case number should equal 15 characters in length • If Linking State Case Numbers are entered then Linking Reason should also be entered
	City	If City Limits is entered then City should also be entered
7	Previous Diagnosis of TB Disease	• If Previous Year of TB has been entered then "Yes" should be checked for Previous Diagnosis of TB Disease • Year of previous diagnosis of TB should be a four digit text value
8	Date of Birth	Birth dates should be in the past (not future)
11	Race	• If Asian Extent or Asian Name is entered then Asian Race should be entered as "Y" • If Native Hawaiian Extent or Native Hawaiian Name is entered then Native Hawaiian Race should be entered as "Y"
9	Sex at Birth	Check for high rates of completion of demographic variables
10	Ethnicity	
11	Race and	
12	Country of Birth	
11	Race	Check for correct Country of Birth for Race of • Native Hawaiian or other Pacific Islander • American Indian or Alaska Native
12	Country of Birth	

1

Accuracy Tool – 1b

Data Accuracy Checklist CDC SAS Code

RVCT		CDC SAS Code
#	Item	
1	Report Date	If REPORTDATE le MDY(1,1,1990); If VERCOUNT = 'Y' and REPORTDATE = .;
3	Case Numbers	If LKREAS1 ne ' ' and LKCASE1YR = ' '; If LKREAS1 ne ' ' and LKCASE1ST = ' '; If LKREAS1 ne ' ' and LKCASE1ID = ' '; If LKREAS2 ne ' ' and LKCASE2YR = ' '; If LKREAS2 ne ' ' and LKCASE2ST = ' '; If LKREAS2 ne ' ' and LKCASE2ID = ' ';
4	Reporting Address for Case Counting	If CLIMITS ne ' ' and CITY = ' ';
7	Previous Diagnosis of TB Disease	If PREVYR ne ' ' and PREVTB ne 'Y';
8	Date of Birth	If DOB gt TODAY();
11	Race	If ASIAN ne 'Y' and (ASIANEXT ne ' ' or ASIANNME ne ' '); If NAHAW ne 'Y' and (NAHAWEXT ne ' ' or NAHAWNME ne ' ');
12	Country of Birth	If NATION = ' ' or CNTRYLN = ' '; If USBORN = 'N' and CNTRYLN = 'UNITED STATES'; If CNTRYLN = 'UNITED STATES' and ARRIVEUSDATE ne .;
13	Month-Year Arrived in U.S.	If USDATE gt TODAY();
14	Pediatric TB Patients (<15 years old)	If OUTUS ne 'Y' and (CNTRYLIVCD1 ne ' ' or CNTRYLIVCD2 ne ' ' or CNTRYLIVCD3 ne ' ');
15	Status at TB Diagnosis	If STATUS = 'DEAD' and TBCAUSE = ' '; If STATUS = 'ALIVE' and DEATHDATE ne .;
16	Site of TB Disease	If SITEANAT1 ne ' ' and SITEOTH = ' '; If SITEANAT2 ne ' ' and SITEOTH = ' '; If SITEANAT3 ne ' ' and SITEOTH = ' ';
17	Sputum Smear	If SPSMRCOL ne . and SPSMEAR not in ('POS','NEG');
18	Sputum Culture	If SPCULTCOL ne . and SPCULT not in ('POS','NEG'); If SPCULTLAB ne ' ' and SPCULT ne 'POS'; If SPCULTREP ne . and SPCULT ne 'POS'; If SPCULTREP ne . and SPCULTCOL = .;
19	Smear/Pathology/Cytology of Tissue and Other Body Fluids	If MICRCOL ne . and MICREXAM not in ('POS','NEG'); If MICRANA1 ne ' ' and MICREXAM not in ('POS','NEG'); If (MICRSMR ne ' ' or MICRPATH ne ' ') and MICREXAM not in ('POS','NEG');
20	Culture of Tissue and Other Body Fluids	If CULTCOL ne . and CULTOTHR not in ('POS','NEG'); If CULTREP ne . and CULTOTHR ne 'POS'; If CULTLAB ne ' ' and CULTOTHR ne 'POS'; If CULTANA1 ne ' ' and CULTOTHR not in ('POS','NEG'); If CULTREP ne . and CULTCOL = .;

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Accuracy Tool - 1c

CDC TB Surveillance RVCT Data Dictionary

Blue cells = new variables from the 2009 revised RVCT

Revised RVCT Form # and Name	Revised Var Name	Revised Code	Standardized Code Description
Reporting State	STATE	2-letter state code	2-letter state code
1. Date Reported	RPTDATE	MMDDYYYY	Month-day-year reported
2. Investigation Start Date (Date Submitted)	DATESUBM	MMDDYYYY	Month, day, and year submitted
3. Case Number	CCCASEYR	YYYY	Year the case is reported
	CCCASEST	2-letter state code	2-letter postal code of the state reporting this case.
	CCCASENO	case #	9 numbers/characters that are locally assigned to identify this RVCT.
	STCASEYR	YYYY	Year the case is reported
	STCASEST	2-letter state code	2-letter postal code of the state reporting this case.
	STCASENO	case #	9 numbers/characters that are locally assigned to identify this RVCT.
	LKCASE1YR	YYYY	Year the case is reported
	LKCASE1ST	2-letter state code	2-letter postal code of the state reporting this case.
	LKCASE1NO	case #	9 numbers/characters that are locally assigned to identify this RVCT.
	LKREAS1	1	Epidemiologically linked
		2	Recurrence or Previous diagnosis of TB
		3	Case transferred from another area
	LKCASE2YR	YYYY	Year the case is reported
	LKCASE2ST	2-letter state code	2-letter postal code of the state reporting this case.
	LKCASE2NO	case #	9 numbers/characters that are locally assigned to identify this RVCT.
	LKREAS2	1	Epidemiologically linked
		2	Recurrence or Previous diagnosis of TB
		3	Case transferred from another area
4. Reporting Address for Case Counting	CITY	City Name	City Name
	COUNTY	County Name	County Name
	COUNTYFIPS	County FIPS Code	3-digit FIPS code
	ZIPCODE	zip code	Zip code
	ZIPSUFFIX	zip code suffix	Zip code suffix
	CLIMITS	N	No
		UNK	Unknown
		Y	Yes
5. Count Status	VERCOUNT	Y	Count as a TB Case
	NONCNTREAS	US	Verified Case - Counted by another US area
		OOC	Verified Case - TB treatment initiated in another country
		REC	Verified Case - Recurrent TB within 12 months after completion of therapy
	NONSPEC	Specify	Specifies the country where the case is counted
6. Date Counted	CNTDATE	MMDDYYYY	Month-day-year counted

Options for Prioritizing Medical Chart Reviews When Resources Are Limited

Following are options that can help you prioritize medical chart reviews to compare with your surveillance system.

- **Review NTIP and MUNK reports to check for problematic RVCT Items and review and locate data for those RVCT items in the medical records**

- **Conduct a random sampling**
  - Review 10% - 30% (according to your needs) of medical charts in reporting areas that typically have problems with accuracy
  - Review medical charts for every 10 - 20 (according to your needs) cases

- **Conduct a convenience sampling**
  - Review charts that are convenient to access

- **Review RVCT items listed in NTIP objectives**

- **Conduct a thorough review in one (or more) reporting areas at a time so that over a period of several years all areas are reviewed**

Accuracy Tool - 3

RVCT Surveillance Data Base Audit Form for Timeliness and Accuracy

Audit Date: _____

Patient Name: _____ **Case Manager:** _____

Audit PHN: _____ **Data Base Auditor:** _____

For Timeliness: Check below whether or not the form was sent to the TB Program (TBP) within the designated timeframe. **Y=Yes N=No**

		Sent to TBP in Time	
RVCT Reports	**Timeframe**	**Y**	**N**
RVCT Initial Case Report (pages 1-3) to TBP	Within **30 days of completion.**		
Follow-up 1 Report (page 4) to TBP	Within **2 months after initial RVCT submitted or when drug susceptibility results are available** (whichever is later).		
Follow-up 2 Report (page 5-6) to TBP.	Within **30 days of discharge.**		

For Accuracy: Check below whether or not the RVCT items on the following three data sources were reviewed. Indicate if the RVCT items on the three data sources agree or not.

RVCT Pg #	RVCT Item #	Data Sources Reviewed?						RVCT, Chart, and Data Base Agree?		Comments
		RVCT Form		Paper Chart		Data Base				
		Y	N	Y	N	Y	N	Y	N	
1	5. Case Count									
1	16. Site of Disease									
2	17. Sputum Smear									
2	18. Sputum Culture									
3	26. HIV status at time of diagnosis									
3	36. Date therapy started									
3	37. Initial drug regimen									
Follow-up - 1 (pg 4)	38. Genotyping accession number									
Follow-up - 2 (pg 5-6)	41. Sputum culture conversion documented									
	47. DOT									

Accuracy Tool - 4

Accuracy Checklist for Sputum Culture Conversion

Jurisdiction Name	Date Therapy Started	30 Days from Treatment Start	60 Days from Treatment Start	Culture Conversion Documented	Date of First Consistently Negative Culture	# Days for Culture Conversion	Reason for not documenting conversion
	1/25/10	2/24/10	3/26/10	Yes	2/10/10	16	
	7/8/10	8/7/10	9/6/10	Yes	8/12/10	35	
	3/10/10	4/9/10	5/9/10	Yes	5/28/10	79	
	4/23/10	5/23/10	6/22/10	Yes	4/27/10	4	
	1/25/10	2/24/10	3/26/10	Yes	2/2/10	8	
	4/25/10	5/25/10	6/24/10	Yes	5/11/10	16	
	2/11/10	3/13/10	4/12/10	Yes	3/22/10	39	
	1/29/10	2/28/10	3/30/10	Yes	3/10/10	40	
	5/8/10	6/7/10	7/7/10	Yes	6/30/10	53	
	5/20/10	6/19/10	7/19/10	Yes	8/23/10	95	
	1/7/10	2/6/10	3/8/10	Yes	1/6/10	-1	
	6/3/10	7/3/10	8/2/10	Yes	6/23/10	20	
	5/13/10	6/12/10	7/12/10	Yes	6/30/10	48	
	7/22/10	8/21/10	9/20/10			-40381	
	7/9/10	8/8/10	9/7/10			-40368	
	5/21/10	6/20/10	7/20/10	Yes	5/25/10	4	
	6/8/10	7/8/10	8/7/10	Yes	6/20/10	12	
	7/28/10	8/27/10	9/26/10	Yes	8/11/10	14	
	6/1/10	7/1/10	7/31/10	Yes	6/22/10	21	
	7/29/10	8/28/10	9/27/10	Yes	8/22/10	24	
	6/18/10	7/18/10	8/17/10	Yes	7/13/10	25	
	1/14/10	2/13/10	3/15/10	Yes	2/12/10	29	
	1/7/10	2/6/10	3/8/10	Yes	2/10/10	34	
	1/28/10	2/27/10	3/29/10	Yes	3/3/10	34	
	2/25/10	3/27/10	4/26/10	Yes	4/25/10	59	
	4/21/10	5/21/10	6/20/10	Yes	6/24/10	64	
	8/25/10	9/24/10	10/24/10			-40415	
	8/12/10	9/11/10	10/11/10			-40402	
	6/25/10	7/25/10	8/24/10			-40354	
	5/7/10	6/6/10	7/6/10	No		-40305	Died
	5/25/10	6/24/10	7/24/10	Yes	4/24/10	-31	

Nucleic Acid Amplification Tests

Accuracy Tool - 5

	AccuProbe®	Amplified *Mycobacteria tuberculosis* (MTD®) Direct	Cepheid GeneXpert® MTB/RIF	GenoType MTBDRplus®	Laboratory Developed Test (LDT)
Company	**Gen-Probe, Inc**	**Gen-Probe, Inc**	**Cepheid**	**Hain Lifescience**	**Not Applicable**
Nucleic Acid Amplification?	**No**	**Yes**	**Yes**	**Yes**	**Yes**
Identification of MTBC from culture isolates	Yes	No	No	Not usually	Sometimes
Detection of MTBC in clinical specimens	No	Yes	Yes	Yes	Yes
Detection of mutations associated with drug resistance	No	No	RIF	RIF, INH	RIF, others depending on platform
Genes associated with drug resistance detected	None	None	*rpo* B	*kat* G, *inh* A, *rpo* B	*rpo* B, others depending on platform
Mechanism	No amplifcation; DNA probe hybridizes to a specific ribosomal RNA target.	Transcription Mediated Amplification (TMA) to amplify the ribosomal RNA target followed by DNA probe hybridization to detect the amplified target.	Real time polymerase chain reaction (PCR) and molecular beacon technology to simultaneously amplify and detect the rpoB gene.	Polymerase chain reaction (PCR) to amplify the genes followed by hybridization to specific probes on nitrocellulose strips (line probe assay).	Various methods including PCR, real time PCR, "molecular beacons," DNA sequencing.
FDA approved	Yes	Yes	Yes (cleared)	No	No
Turn-around time from specimen receipt in lab	Requires growth in culture	24-48 hrs	24-48 hrs	24-48 hrs	24-48 hrs
Common name	Probe, DNA probe	MTD, "Direct test," often mistakenly called "probe"	GeneXpert, Xpert	The "Hain test" Line Probe Assay (LPA)	"Home brew," molecular beacons, PCR
How reported: Examples					
Positive result		• **Detected** • **Positive** • **Positive for *M. tuberculosis* complex rRNA**	**MTB Detected; Rif Resistance Detected/ Rif Resistance Not Detected**	• **Point mutation detected**	
Negative result		• **Not Detected**	**MTB Not Detected**	• **No point mutation detected**	
RVCT item	18 - Sputum Culture	21 - Nucleic Acid Amplification (NAA) Test Result	21 - NAA	21 - NAA	21 - NAA

Culture-Based (Phenotypic) Laboratory Tests for Drug Susceptibility Testing

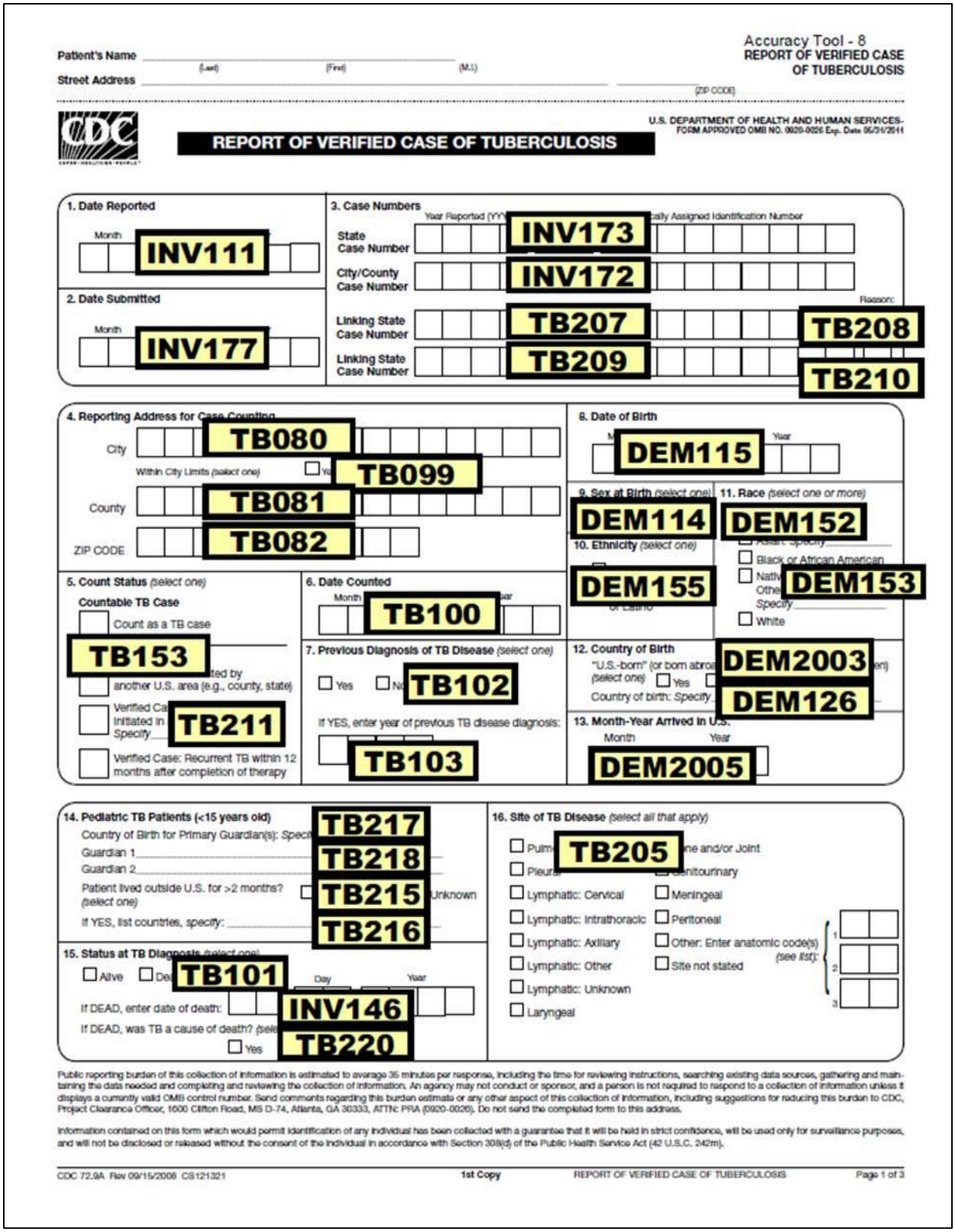
Characteristics	Method				
	Method	**MGIT 320 or 960**	**VersaTrek**	**Indirect Agar Proportion**	**Trek Sensititre**
Company	**Becton Dickinson**	**Becton Dickinson**	**Thermoscientific**	**Not Applicable**	**Thermoscientific**
Frequency of use for drug susceptiblility testing (DST)	No longer available (few labs using remaining stock)	Most common DST method in U.S. for first-line drugs	<10% of labs performing DST use this method	Used primarily by reference labs	Not commonly used
Media	Liquid broth	Liquid broth	Liquid broth	Solid	Liquid broth
Format	Tube	Tube	Tube	Petri plate	96-well microtitre plate
Results: • **Resistant** • **Susceptible or** • **Minimum Inhibitory Concentration (MIC)**	**Usually** • **Resistant** • **Susceptible** **(National Jewish reported MICs)**	**Usually** • **Resistant** • **Susceptible** **(very few labs might report MIC for some drugs)**	• **Resistant** • **Susceptible**	**Usually** • **Resistant** • **Susceptible**	**MIC** **(laboratory might provide interpretive criteria of Resistant or Susceptible)**
Drugs	Isoniazid (INH), Rifampin (RIF), Pyrazinamide (PZA), Ethambutol (EMB), Streptomycin (STR)	INH, RIF,PZA, EMB, STR (some labs might not test STR or PZA)	INH, RIF, PZA, EMB	Varies depending on lab but can include first-lines (except PZA) and second-line drugs	INH, RIF, EMB, STR, Rifabutin, Ethionamide, Amikacin, Kanamycin, Ofloxacin, Moxifloxacin, Cycloserine, Para-Amino Salicylic Acid
Concentrations tested	Generally one critical concentration for each drug with exception of INH (2 concentrations)	Generally one critical concentration for each drug with exception of INH (2 concentrations)	Generally one critical concentration for each drug with exception of INH (2 concentrations)	Generally one critical concentration for each drug with exception of INH and some second-line drugs (e.g., moxifloxacin)	6-8 different concentrations of each drug for determining MIC
FDA approved	**Yes**	**Yes**	**Yes**	**No** **(laboratory developed test)**	**No** **(research use only)**
Expected turn-around time (TAT)	Typically within 5 weeks of specimen receipt	Typically within 5 weeks of specimen receipt	Typically within 5 weeks of specimen receipt	Longer TAT than broth-based methods	Within 10-21 days of incubation
Common name	460	MGIT	Trek	Agar proportion	Sensititre
RVCT item*	40 -Initial DST results, 49 - Final DST results				Resistant or Susceptible**
RVCT result	Resistant, Susceptible, Unknown, or Not Done				Resistant or Susceptible**

* RVCT Definition for Drug Susceptibility Results: Record the results of initial (for initial DST result) drug susceptibility testing on the **first** specimen and on the **final** specimen (for final DST) on which drug susceptibility testing was performed. Report results from conventional DST only. Do **not** report rapid DST test results (molecular beacon, molecular line probe assays, or other molecular tests).

** Report resistant or susceptible according to the laboratory report. Do **not** report if reported as MIC only.

Molecular-Based Laboratory Tests for Detecting Mutations Associated with Drug Resistance

Characteristic	Method			
	GeneXpert® MTB/RIF	HAIN Genotype® MTBDRplus	Sanger Sequencing	Pyrosequencing
Company	**Cepheid**	**HAIN Lifescience**	**Not Applicable (N/A) (laboratory developed test)**	**N/A (laboratory developed test)**
Frequency of use	Platform widely available- broad use possible	Not common	Method for CDC MDDR service- Not commonly used- performed by small number of PHL	Method for CDC MDDR service- Not commonly used- performed by small number of PHL
Genetic loci	*rpoB* (for RIF)	*rpoB* (RIF), *katG* (INH), and *inhA* (INH)	Varies but can include *rpoB*, *inhA*, *katG*, *aphC*, *embB* (EMB), *pncA* (PZA), *gyrA* (FQ), and *rrs* (injectables)	Varies but can include *rpoB*, *inhA*, *katG*, *aphC*, *gyrA*, and *rrs*
Format	Semi-automated real-time PCR	Line probe assay	DNA sequencing	DNA sequencing
Results	• **Rif *resistance* detected** • **Confirmation of rifampin resistance pending** • **Rif resistance not detected**	• **Likely mutation detected** • **Mutation not detected for each locus**	**Can vary** • **Typically nucleotide sequence indicating mutation (with amino acid change if applicable)** • **Wild-type (no mutation)**	**Can vary** • **Typically nucleotide sequence indicating mutation (with amino acid change if applicable)** • **Wild-type (no mutation)**
FDA approved	**Yes**	**No**	**N/A (laboratory developed test)**	**N/A (laboratory developed test)**
Expected turn-around time from specimen receipt in laboratory	1-2 working days	1-2 working days (depends on how often performed in lab)	1-2 working days (depends on how often performed in lab)	1-2 working days (depends on how often performed in lab)
Common name	Cepheid, Xpert, MTB/RIF	HAIN, Heinz	MDDR, sequencing, Molecular DST	Pyro, sequencing
RVCT item	Not Collected			
RVCT result	Not Collected			


Patient's Name
(Last)
(First)
(M.I.)
Street Address
(ZIP CODE)
Accuracy Tool - 8
REPORT OF VERIFIED CASE OF TUBERCULOSIS
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FORM APPROVED OMB NO. 0920-0026 Exp. Date 05/31/2011
REPORT OF VERIFIED CASE OF TUBERCULOSIS
1. Date Reported
Month
INV111
2. Date Submitted
Month
INV177
3. Case Numbers
Year Reported (YY)
Locally Assigned Identification Number
State Case Number
INV173
City/County Case Number
INV172
Reason:
Linking State Case Number
TB207
TB208
Linking State Case Number
TB209
TB210
4. Reporting Address for Case Counting
City
TB080
Within City Limits (select one)
TB099
County
TB081
ZIP CODE
TB082
8. Date of Birth
Month
Year
DEM115
9. Sex at Birth (select one)
DEM114
11. Race (select one or more)
DEM152
10. Ethnicity (select one)
DEM155
Black or African American
DEM153
White
5. Count Status (select one)
Countable TB Case
Count as a TB case
TB153
another U.S. area (e.g., county, state)
Verified Case Initiated in
Specify
TB211
Verified Case: Recurrent TB within 12 months after completion of therapy
6. Date Counted
Month
Year
TB100
7. Previous Diagnosis of TB Disease (select one)
Yes
TB102
If YES, enter year of previous TB disease diagnosis:
TB103
12. Country of Birth
"U.S.-born" (or born abroad of U.S. parent(s)) (select one)
Yes
DEM2003
Country of birth: Specify
DEM126
13. Month-Year Arrived in U.S.
Month
Year
DEM2005
14. Pediatric TB Patients (<15 years old)
Country of Birth for Primary Guardian(s): Specify
TB217
Guardian 1
TB218
Guardian 2
Patient lived outside U.S. for >2 months? (select one)
TB215
Unknown
If YES, list countries, specify:
TB216
15. Status at TB Diagnosis (select one)
Alive
TB101
Day
Year
If DEAD, enter date of death:
INV146
If DEAD, was TB a cause of death? (select one)
Yes
TB220
16. Site of TB Disease (select all that apply)
TB205
Genitourinary
Lymphatic: Cervical
Meningeal
Lymphatic: Intrathoracic
Peritoneal
Lymphatic: Axillary
Other: Enter anatomic code(s) (see list):
Lymphatic: Other
Site not stated
Lymphatic: Unknown
Laryngeal
Public reporting burden of this collection of information is estimated to average 35 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-74, Atlanta, GA 30333, ATTN: PRA (0920-0026). Do not send the completed form to this address.
Information contained on this form which would permit identification of any individual has been collected with a guarantee that it will be held in strict confidence, will be used only for surveillance purposes, and will not be disclosed or released without the consent of the individual in accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m).
CDC 72.9A Rev 09/15/2008 CS121321
1st Copy
REPORT OF VERIFIED CASE OF TUBERCULOSIS
Page 1 of 3

Accuracy Tool – 9

Comparison of Concordant and Discordant RVCT Items - Summary

All 49 RVCT items are listed below. Compare your findings to what is entered into your state's surveillance system.

RVCT #	RVCT Item	# of Discordant Answers	RVCT Item-Level % Concordance	RVCT Item-Level % Discordance
1	Report Date			
2	Date Submitted			
3	Case Numbers			
4	Reporting Address for Case Counting			
5	Count Status			
6	Date Counted			
7	Previous Diagnosis of TB Disease			
8	Date of Birth			
9	Sex at Birth			
10	Ethnicity			
11	Race			
12	Country of Birth			
13	Month-Year Arrived in U.S.			
14	Pediatric TB Patients (<15 years old)			
15	Status at TB Diagnosis			
16	Site of TB Disease			
17	Sputum Smear			
18	Sputum Culture			
19	Smear/Pathology/Cytology of Tissue and Other Body Fluids			
20	Culture of Tissue and Other Body Fluids			
21	Nucleic Acid Amplification Test Result			
22 A	Initial Chest Radiograph			
22 B	Initial Chest CT Scan or Other Chest Imaging Study			
23	Tuberculin (Mantoux) Skin Test at Diagnosis			
24	Interferon Gamma Release Assay (IGRA) for *Mycobacterium Tuberculosis* at Diagnosis			
25	Primary Reason Evaluated for TB			
26	HIV Status at Time of Diagnosis			
27	Homeless within Past Year			
28	Resident of Correctional Facility at Time of Diagnosis			
29	Resident of Long-Term Care Facility at Time of Diagnosis			
30	Primary Occupation Within Past Year			
31	Injecting Drug Use Within Past Year			
32	Non-Injecting Drug Use Within Past Year			
33	Excess Alcohol Use Within Past Year			

CDC Race and Ethnicity Code Set - Version 1.0

TABLE 1 – Race Concepts and Codes

Unique Identifier	Hierarchical Code	Concept	Synonym	Date Added to Version	Date Removed from Version
1000-9	R	Race		March 31, 2000	
				March 31, 2000	
1002-5	R1	American Indian or Alaska Native		March 31, 2000	
				March 31, 2000	
1004-1	R1.01	American Indian		March 31, 2000	
				March 31, 2000	
1006-6	R1.01.001	Abenaki		March 31, 2000	
				March 31, 2000	
1008-2	R1.01.002	Algonquian		March 31, 2000	
				March 31, 2000	
1010-8	R1.01.003	Apache		March 31, 2000	
1011-6	R1.01.003.001	Chiricahua		March 31, 2000	
1012-4	R1.01.003.002	Fort Sill Apache		March 31, 2000	
1013-2	R1.01.003.003	Jicarilla Apache		March 31, 2000	
1014-0	R1.01.003.004	Lipan Apache		March 31, 2000	
1015-7	R1.01.003.005	Mescalero Apache		March 31, 2000	
1016-5	R1.01.003.006	Oklahoma Apache		March 31, 2000	
1017-3	R1.01.003.007	Payson Apache		March 31, 2000	
1018-1	R1.01.003.008	San Carlos Apache		March 31, 2000	
1019-9	R1.01.003.009	White Mountain Apache		March 31, 2000	
				March 31, 2000	
1021-5	R1.01.004	Arapaho		March 31, 2000	
1022-3	R1.01.004.001	Northern Arapaho		March 31, 2000	
1023-1	R1.01.004.002	Southern Arapaho		March 31, 2000	
1024-9	R1.01.004.003	Wind River Arapaho		March 31, 2000	
				March 31, 2000	
1026-4	R1.01.005	Arikara		March 31, 2000	

Chapter 6: Data Completeness Tools

The Data Completeness Tools include a list of the tools followed by examples of the first page of each tool.

Data Completeness Tools

Tool #	Tool Name	Description and How to Use	Format	Source Contact
Completeness–1	**Source List for Locating RVCT Data**	Document used to locate information (i.e., location on medical chart, laboratory report) for each item on the RVCT	Word 2 pages	Adapted from Tuberculosis Control Program, Public Health–Seattle & King County
Completeness–2	**Treatment Outcome Status**	Table used to indicate therapy status by 12-month interval. This spreadsheet is used to monitor treatment progress with the goal of completing treatment within 12 months. There are built-in calculations for 3, 6, 9, and 12 months from treatment start that are populated when the Date Therapy Started is entered. This tool targets the NTIP objective of treatment completion within 12 months.	Excel 1 page	Tennessee TB Elimination Program
Completeness–3	**Culture and Drug Susceptibility Status**	Table that indicates culture and drug susceptibility status by jurisdiction. This report shows the susceptibility results for isoniazid, rifampin, pyrazinamide, and ethambutol. It shows those cases that are multi drug-resistant and also those who have an unknown or blank susceptibility report. It is for all culture-positive TB cases. The tool targets the National TB Indicators Project (NTIP) objective of drug susceptibility reporting.	Excel 1 page	Tennessee TB Elimination Program

Tool #	Tool Name	Description and How to Use	Format	Source Contact
Completeness–4	**TB PAM Process: Initiation of RVCT through Case Closure**	Flow chart that shows the TB PAM process (initiation of RVCT through case closure). This chart was created for Tennessee's use with TB PAM, from initiating the RVCT to closing the case. This flow chart also identifies the responsible person(s) for the various steps.	Word 1 page Legal size	Tennessee TB Elimination Program
Completeness–5	**Data Abstraction Instructions**	Detailed procedures for RVCT quality control queries	Word 4 pages	Tuberculosis Control Program, Public Health–Seattle & King County
Completeness–6	**Explanation of Invalid, Missing, and Unknown Variables**	A description of invalid, missing, and unknown variables in the MUNK report.	Excel 14 pages Over-sized (fit all columns on one page)	CDC/DTBE

Completeness Tool - 1

Source List for Locating RVCT Data

RVCT		Source for the Data
#	Item	
1	Report Date	
2	Date Submitted	
3	Case Numbers	
4	Reporting Address for Case Counting	
5	Count Status	
6	Date Counted	
7	Previous Diagnosis of TB Disease	
8	Date of Birth	
9	Sex at Birth	
10	Ethnicity	
11	Race	
12	Country of Birth	
13	Month-Year Arrived in U.S.	
14	Pediatric TB Patients (<15 years old)	
15	Status at TB Diagnosis	
16	Site of TB Disease	
17	Sputum Smear	
18	Sputum Culture	
19	Smear/Pathology/Cytology of Tissue and Other Body Fluids	
20	Culture of Tissue and Other Body Fluids	
21	Nucleic Acid Amplification Test Result	
22A	Initial Chest Radiograph	
22B	Initial Chest CT Scan or Other Chest Imaging Study	
23	Tuberculin (Mantoux) Skin Test at Diagnosis	
24	Interferon Gamma Release Assay (IGRA) for *Mycobacterium Tuberculosis* at Diagnosis	
26	HIV Status at Time of Diagnosis	
27	Homeless within Past Year	
28	Resident of Correctional Facility at Time of Diagnosis	

Treatment Outcome Status

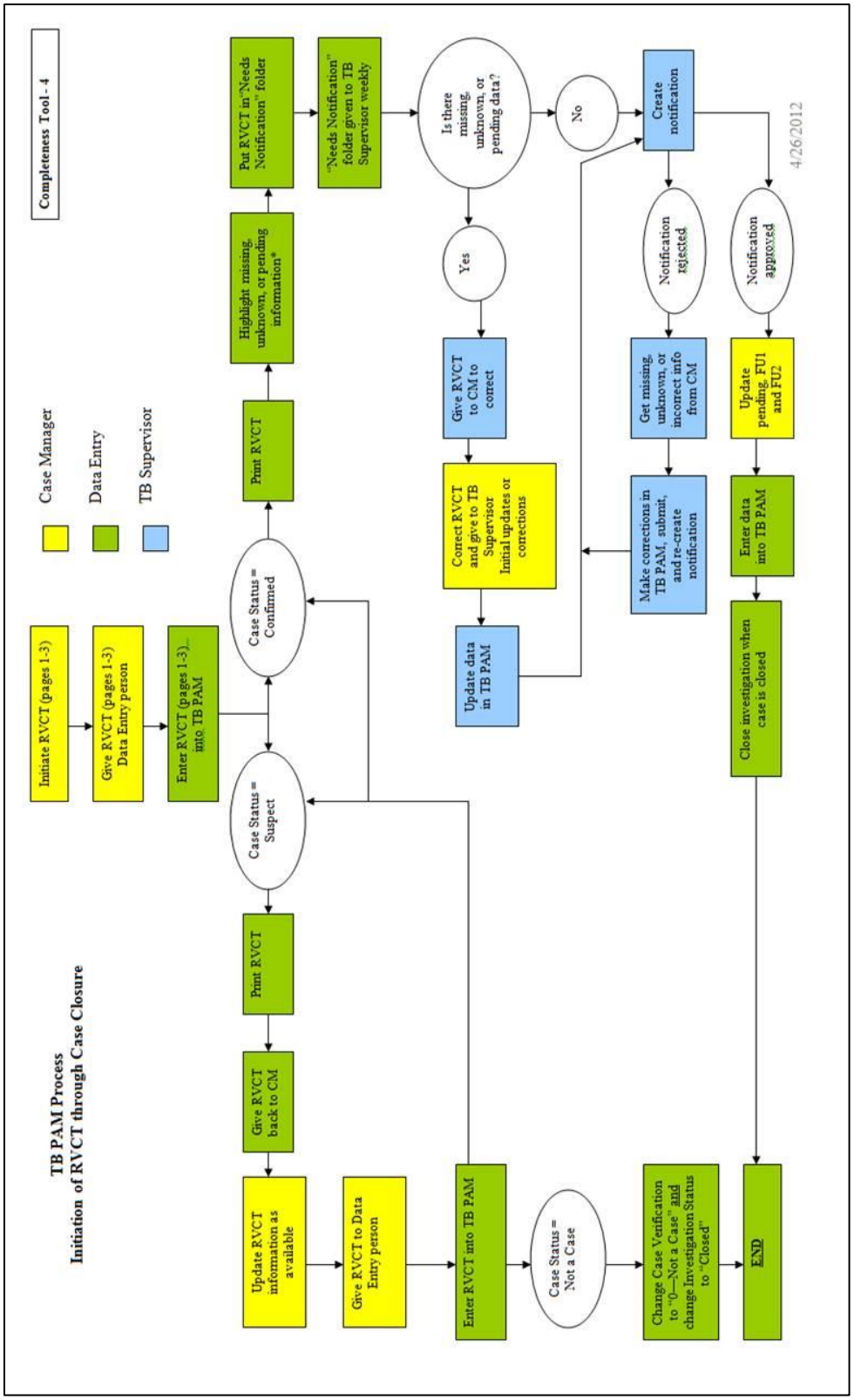
Completeness Tool - 2

Date Counted	Jurisdiction Name	Case Verification	Date Therapy Started	3 Month Interval	6 Month Interval	9 Month Interval	12 Month Interval	Date Therapy Stopped	Reason Therapy Stopped	Directly Observed Therapy	Number Weeks DOT	Investigation Status
3/9/10		1 - Positive Culture	1/25/10	4/25/10	7/24/10	10/22/10	1/25/11	7/30/10	Completed Therapy	Yes, Total DOT	26	Closed
4/19/10		1A - Positive NAA	4/12/10	7/11/10	10/9/10	1/7/11	4/12/11	10/15/10	Completed Therapy	Yes, Totally Directly Observed	26	Closed
4/6/10		1 - Positive Culture	3/10/10	6/8/10	9/6/10	12/5/10	3/10/11					Open
6/14/10		3 - Clinical Case Definition	6/7/10	9/5/10	12/4/10	3/4/11	6/7/11					Open
7/9/10		1 - Positive Culture	7/8/10	10/6/10	1/4/11	4/4/11	7/8/11					Open
9/16/10		1 - Positive Culture	7/17/10	10/15/10	1/13/11	4/13/11	7/17/11					Open
9/28/10		1 - Positive Culture	8/26/10	11/24/10	2/22/11	5/23/11	8/26/11					Open
3/3/10		1 - Positive Culture	1/25/10	4/25/10	7/24/10	10/22/10	1/25/11	8/13/10	Died	Yes, Total DOT	16	Closed
2/26/10		1 - Positive Culture	2/22/10	5/23/10	8/21/10	11/19/10	2/22/11	3/13/10	Died	Yes, Total DOT	1	Closed
3/19/10		1 - Positive Culture	3/18/10	6/16/10	9/14/10	12/13/10	3/18/11	9/23/10	Completed Therapy	Yes, Total DOT	26	Closed
4/16/10		1A - Positive NAA	4/5/10	7/4/10	10/2/10	12/31/10	4/5/11	10/12/10	Completed Therapy	Yes, Total DOT	27	Closed
4/23/10		1 - Positive Culture	4/23/10	7/22/10	10/20/10	1/18/11	4/23/11	10/25/10	Completed Therapy	Yes, Total DOT	26	Closed
6/4/10		1 - Positive Culture	5/20/10	8/18/10	11/16/10	2/14/11	5/20/11	10/15/10	Died	Yes, Total DOT	21	Closed
2/19/10		1 - Positive Culture	1/29/10	4/29/10	7/28/10	10/26/10	1/29/11					Open
3/3/10		1 - Positive Culture	2/11/10	5/12/10	8/10/10	11/8/10	2/11/11					Open
7/7/10		3 - Clinical Case Definition	4/12/10	7/11/10	10/9/10	1/7/11	4/12/11					Open
5/7/10		1 - Positive Culture	4/25/10	7/24/10	10/22/10	1/20/11	4/25/11					Open
5/19/10		1 - Positive Culture	5/8/10	8/6/10	11/4/10	2/2/11	5/8/11					Open
8/6/10		3 - Clinical Case Definition	5/24/10	8/22/10	11/20/10	2/18/11	5/24/11					Open
9/8/10		3 - Clinical Case Definition	7/9/10	10/7/10	1/5/11	4/5/11	7/9/11					Open
9/16/10		1A - Positive NAA	9/1/10	11/30/10	2/28/11	5/29/11	9/1/11					Open
9/8/10		1A - Positive NAA	9/7/10	12/6/10	3/6/11	6/4/11	9/7/11					Open
9/27/10		1 - Positive Culture	9/16/10	12/15/10	3/15/11	6/13/11	9/16/11					Open
9/27/10		1 - Positive Culture	9/16/10	12/15/10	3/15/11	6/13/11	9/16/11					Open
3/5/10		1 - Positive Culture	1/7/10	4/7/10	7/6/10	10/4/10	1/7/11	7/23/10	Completed Therapy	Yes, Total DOT	26	Closed
6/4/10		1 - Positive Culture	3/22/10	6/20/10	9/18/10	12/17/10	3/22/11	9/16/10	Completed Therapy	Yes, Total DOT	25	Closed
6/4/10		1 - Positive Culture	5/13/10	8/11/10	11/9/10	2/7/11	5/13/11					Open
6/17/10		1 - Positive Culture	6/3/10	9/1/10	11/30/10	2/28/11	6/3/11					Open

Culture and Drug Susceptibility Status

Completeness Tool - 3

Jurisdiction Name	Sputum Culture Date Result Reported	Drug Susceptibility Testing Done	Culture of Tissue Date Result Reported	Isoniazid Initial Susceptibility	Rifampin Initial Susceptibility	Pyrazinamide Initial Susceptibility	Ethambutol Initial Susceptibility
	3/8/10	Yes	3/8/10	Susceptible	Susceptible	Susceptible	Susceptible
	4/6/10	Yes		Susceptible	Susceptible	Susceptible	Susceptible
	7/23/10	Yes		Susceptible	Susceptible	Susceptible	Susceptible
	9/14/10	Yes	9/16/10	Susceptible	Susceptible	Unknown	Susceptible
			9/20/10				
	3/1/10	Yes	3/1/10	Susceptible	Susceptible	Susceptible	Susceptible
	2/19/10	Yes	2/11/10	Susceptible	Susceptible	Susceptible	Susceptible
	3/17/10	Yes		Susceptible	Susceptible	Susceptible	Susceptible
		Yes	2/22/10	Susceptible	Susceptible	Susceptible	Susceptible
	5/5/10	Yes	3/17/10	Susceptible	Susceptible	Susceptible	Susceptible
	4/22/10	Yes		Susceptible	Susceptible	Susceptible	Susceptible
	6/10/10	Yes	5/6/10	Susceptible	Susceptible	Susceptible	Susceptible
	6/10/10	Yes		Susceptible	Susceptible	Susceptible	Susceptible
	9/9/10	Yes		Susceptible	Susceptible	Susceptible	Susceptible
			9/17/10				
			9/16/10				
	2/2/10	Yes		Susceptible	Susceptible	Susceptible	Susceptible
	5/5/10	Yes	5/5/10	Susceptible	Susceptible	Susceptible	Susceptible
	5/20/10	Yes		Susceptible	Susceptible	Susceptible	Susceptible
	6/2/10	Yes		Susceptible	Susceptible	Susceptible	Susceptible
	8/9/10	Yes		Resistant	Resistant	Resistant	Resistant
	2/8/10	Yes		Not Done	Susceptible	Susceptible	Susceptible
		Yes	4/9/10	Resistant	Susceptible	Susceptible	Susceptible
	6/4/10	Yes		Resistant	Susceptible	Susceptible	Susceptible
	1/19/10	Yes		Susceptible	Susceptible	Susceptible	Susceptible
	2/10/10	Yes		Susceptible	Susceptible	Susceptible	Susceptible
	3/30/10	Yes	3/5/10	Susceptible	Susceptible	Susceptible	Susceptible
	3/3/10	Yes	2/23/10	Susceptible	Susceptible	Susceptible	Susceptible
	3/17/10	Yes		Susceptible	Susceptible	Susceptible	Susceptible
		Yes	4/20/10	Susceptible	Susceptible	Susceptible	Susceptible
	6/28/10	Yes		Susceptible	Susceptible	Susceptible	Susceptible
	6/4/10	Yes		Susceptible	Susceptible	Susceptible	Susceptible
	8/3/10	Yes	8/12/10	Susceptible	Susceptible	Susceptible	Susceptible
	6/3/10	Yes	7/6/10	Susceptible	Susceptible	Susceptible	Susceptible


Completeness Tool - 4
TB PAM Process
Initiation of RVCT through Case Closure
Case Manager
Data Entry
TB Supervisor
Initiate RVCT (pages 1-3)
Give RVCT (pages 1-3) Data Entry person
Enter RVCT (pages 1-3) into TB PAM
Case Status = Confirmed
Case Status = Suspect
Print RVCT
Highlight missing, unknown, or pending information*
Put RVCT in "Needs Notification" folder
"Needs Notification" folder given to TB Supervisor weekly
Is there missing, unknown, or pending data?
Yes
No
Give RVCT to CM to correct
Correct RVCT and give to TB Supervisor Initial updates or corrections
Update data in TB PAM
Create notification
Notification rejected
Notification approved
Get missing, unknown, or incorrect info from CM
Make corrections in TB PAM, submit, and re-create notification
Update pending, FU1 and FU2
Enter data into TB PAM
Close investigation when case is closed
Print RVCT
Give RVCT back to CM
Update RVCT information as available
Give RVCT to Data Entry person
Enter RVCT into TB PAM
Case Status = Not a Case
Change Case Verification to "0—Not a Case" and change Investigation Status to "Closed"
END
4/26/2012

TB Control Program
Data Abstraction Instructions

Completeness Tool - 5

Policy and Procedure Title:	**Data Abstraction Instructions**
Category:	
Final Review & Approval By:	
Effective Date:	

Approval Authority **Date**

This document shall be reviewed ____ months following implementation. If necessary, a second review will occur after another ____ months. Following the review, the procedure will be reviewed and/or updated annually as noted below.

Review Date	Revision Date	Signature

1

Explanation of Invalid, Missing, and Unknown (MUNK) Variables

Completeness Tool - 6

NEW MUNK	RVCT Question #	RVCT Question Description	Message Version v1 = TIMS v2 = NEDSS	All Years 2006 - Current Year	All Years to Follow Up Report 2006-2010	New RVCT Follow Up Report 2009 - 2010	New RVCT 2009 - Current Year	Verified Case	Patient Alive at Diagnosis	Patient is Culture Positive	Missing	Unknown	Invalid	Comment
	Q01	Date Reported	v1 & v2	✓				✓			✓			Date Reported or Date Reported String
	Q03	State Case ID	v1 & v2	✓							✓		✓	Invalid length (Not equal 15 characters) or duplicate state case ID's
*	Q03	Linking Case 1 Number	v2				✓	✓			✓		✓	Linking Case 1 Number is populated and the case contains an Invalid length (Not equal 15 characters).
*	Q03	Linking Case 2 Number	v2				✓	✓			✓		✓	Linking Case 2 Number is populated and the case contains an Invalid length (Not equal 15 characters).
*	Q03	Linking Case 1 Reason	v2				✓	✓			✓		✓	Must have a Linking Case 1 Number populated and have a valid code.
*	Q03	Linking Case 2 Reason	v2				✓	✓			✓		✓	Must have a Linking Case 2 Number populated and have a valid code.
	Q04	Zip Code	v1 & v2	✓				✓			✓		✓	Invalid length (Not equal to 5 or 10 characters)
	Q04	County	v1 & v2	✓				✓			✓			
	Q04	City	v1 & v2	✓				✓			✓		✓	Either Reporting City or Alternate Reporting City is missing and valid check for numeric code only.
	Q05	Count Status	v2	✓				✓			✓			
	Q06	Date Counted	v1 & v2	✓				✓			✓			Either Count Date or Count Date String is missing and Count Status = Count as a TB Case.
	Q07	Previous TB	v1 & v2	✓				✓			✓		✓	Not a valid code Yes or No
	Q07	Previous TB Year	v1 & v2	✓				✓			✓			Patient had Previous Diagnosis (Dx) of TB.
	Q08	Date of Birth	v1 & v2	✓				✓			✓			
	Q09	Sex	v1 & v2	✓				✓			✓		✓	Must be a (M)ale or (F)emale in current sex or birth sex.
	Q10	Ethnicity	v1 & v2	✓				✓			✓		✓	Invalid code
	Q11	Race	v1 & v2	✓				✓			✓		✓	Invalid code
	Q12	U.S. Born	v1 & v2	✓				✓			✓		✓	Not equal to Yes or No.

Chapter 7: Data Timeliness Tools

The Data Timeliness Tools include a list of the tools followed by examples of the first page of each tool.

Data Timeliness Tools

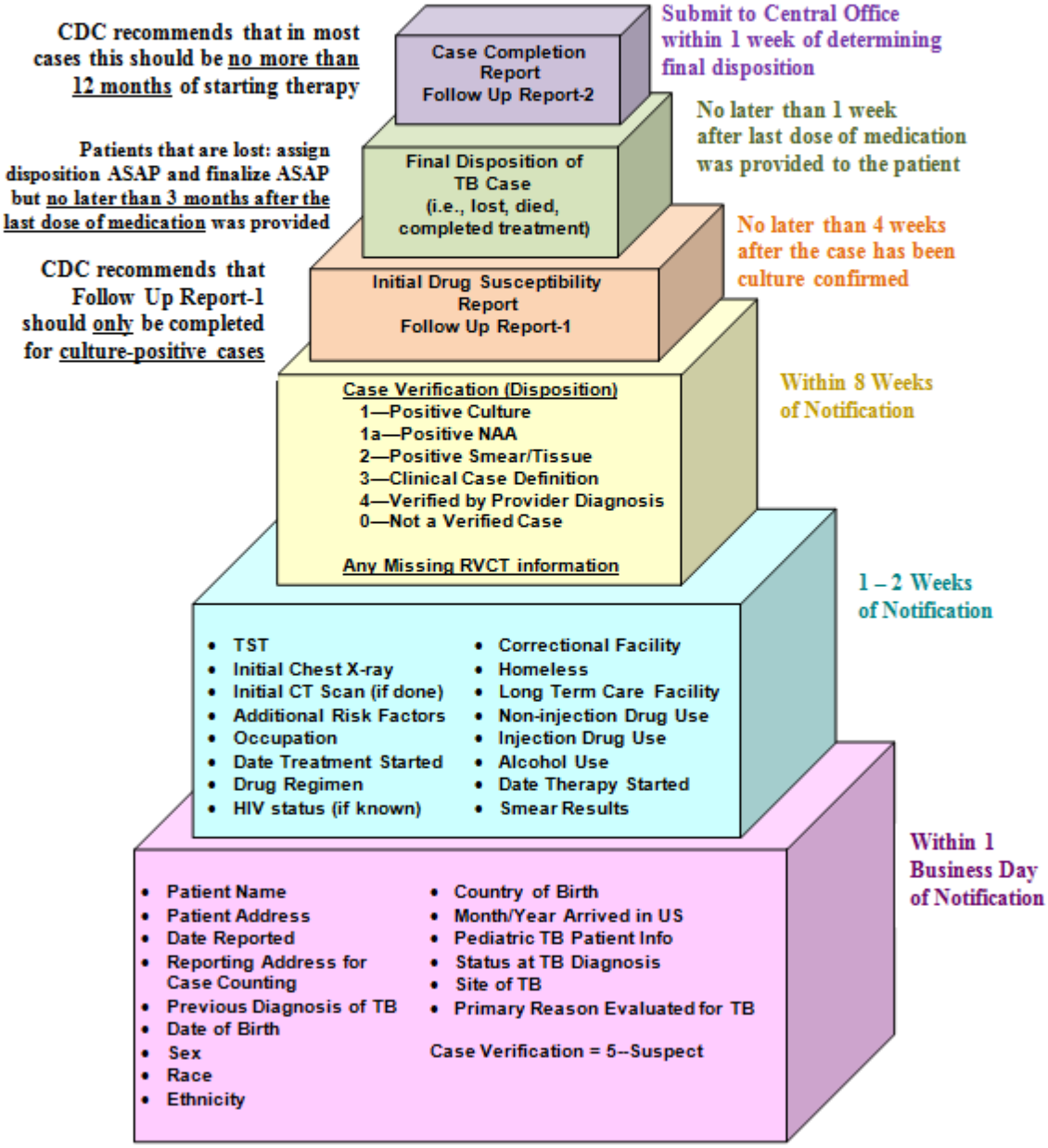
Tool #	Tool Name	Description and How to Use	Format	Source Contact
Timeliness–1a	**Building a TB Case: Schedule for Entering Information for a TB Suspect into the RVCT**	Timeline diagram that indicates when RVCT variables should be entered. This example is based on Tennessee policies. This helps field staff know when information should be available and when the State Central Office expects it to be entered. The time frames should be based on your jurisdictional policies and procedures.	Word 1 page	Tennessee TB Elimination Program
Timeliness–1b	**Time Schedule for Entering RVCT Data**	Timeline table similar to Timeliness Tool-1a. It is in a table format rather than the graphic of the building blocks. The time frames should be based on your jurisdictional policies and procedures.	Word 3 pages	CDC/DTBE adapted from Tennessee TB Elimination Program
Timeliness–2	**Quarterly Case Summary – Timeliness Data**	Document that summarizes timeliness measures and objectives for a cohort of TB patients. Pre-defined case outcome objectives are provided for that particular set of TB patients.	Excel 2 pages	Washington State Department of Health Tuberculosis Program
Timeliness–3	**Timeliness Data Dictionary**	Description of the data used to calculate timeliness measures for analysis. These measures are used to determine completion of state objectives.	Word 1 page	CDC/DTBE Adapted from Washington State Department of Health Tuberculosis Program

Tool #	Tool Name	Description and How to Use	Format	Source Contact
Timeliness–4	**Timeline for Reporting Annual TB Surveillance Data to CDC**	Timeline for reporting TB cases and final TB data transmissions to CDC	Jpg 1 page	CDC/DTBE
Timeliness–5	**Typical Weekly CDC TB Surveillance Data Availability Chart**	Typical weekly data availability by day of the week	PDF 1 page	CDC/DTBE
Timeliness–6	**Verbal Case Count and Provisional TB Data Transmitted**	Spreadsheet to determine the discrepancies between the Verbal and Provisional Case Counts.	Excel 1 page	CDC/DTBE

Timeliness Tool – 1a

Building a TB Case
Schedule for Entering Information for a TB Suspect into the RVCT

Note: Most time intervals should be based on your jurisdictional policies and procedures.



Timeliness Tool – 1b

Time Schedule for Entering Data into the RVCT

Note: Most time intervals should be based on your jurisdictional policies and procedures.

Time to Complete Entering Data	RVCT Item	Comments
Within ___ days of notification	1 – Patient name 2 – Patient address 3 – Date Reported 4 – Reporting Address for Case Counting 5 – Count Status 6 – Date Counted 7 – Previous Diagnosis of TB Disease 8 – Date of Birth 9 – Sex at Birth 10 – Ethnicity 11 – Race 12 – Country of Birth 13 – Month-Year Arrived in U.S. 14 – Pediatric TB Patients (<15 years old) 15 – Status at TB Diagnosis 16 – Site of TB Disease	

1

QUARTERLY CASE SUMMARY - Timeliness Data					
					Timeliness Tool - 2
Cases Counted: <Location>					
n = 0 cases					
OUTCOME MEASURES	Smear +	Smear - Culture +	Pediatric[1]	Other[2]	Total
	(n =)	(n =)	(n =)	(n =)	(n =)
Index of Completion as of Feb. 2004	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
Including cases likely to complete	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
Excluding MDR resistant cases	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
DOT usage as of Feb. 2004	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
Died + Reported at Death	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
Lost to Follow-up[3]	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
Refused to Continue Treatment	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
Treatment Not Completed w/in 12 mos[4]	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
HIV Non-Screening[5]	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
Treatment Interruptions					
Medical/Adverse Reactions	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
Patient Adherence Reasons	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
Provider Reasons	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
Timeliness: MTD Test	-	-	-	-	-
MTD (Mean Days)	0.00	-	-	-	-
(Median)	0	-	-	-	-
Timeliness: Lab Sputum Collection	-	-	-	-	-
(Mean Days)	0.00	0.00	0.00	0.00	0.00
(Median)	0	0	0	0	0
Timeliness: Meds Starting[6] (n=)	-	-	-	-	-
Smear +:	-	-	-	-	-
(Mean Days)	0.00	-	-	-	-
(Median)	0	-	-	-	-
Cavitary CXR:	-	-	-	-	-
(Mean Days)	0.00	-	-	-	-
(Median)	0	-	-	-	-
Timeliness Reporting: LHJ-DOH	-	-	-	-	-
(Mean Days)	0.00	-	-	-	-
(Median)	0	-	-	-	-
Timeliness Reporting: HCP-LHJ (n=)	-	-	-	-	-
Smear +:	-	-	-	-	-
(Mean Days)	0.00	-	-	-	-
(Median)	0	-	-	-	-
Cavitary CXR:	-	-	-	-	-
(Mean Days)	0.00	-	-	-	-
(Median)	0	-	-	-	-
Timeliness Reporting: Lab-LHJ	-	-	-	-	-

Timeliness Data Dictionary

Timeliness: Amplified *Mycobacterium tuberculosis* (MTD) Test: Of the smear negative, culture positive cases that received MTD testing, the average number of days between the date sputum was collected and the date they started TB medication.

Timeliness: No MTD Test: Of the smear negative, culture positive cases that did not receive an MTD test, the average number of days between the date sputum was collected and the date they started TB medication. Use this calculation as a comparison to those cases that were MTD tested.

Timeliness: Lab Sputum Collection: The average number of days between the date sputum was collected and the date it was received at the lab.

Timeliness: Culture: The average number of days between the date a culture was received at the lab and the date the result was reported.

Timeliness: Meds Starting: The average number of days between the date of the sputum smear + result and the date they started TB medication. *(Includes only smear + cases)*

Timeliness Reporting: LHJ - DOH: The average number of days between the date of the sputum smear + result and the date the LHJ (Local Health Jurisdiction) reports the case to DOH (State Department of Health). *(Includes only smear + cases.)*

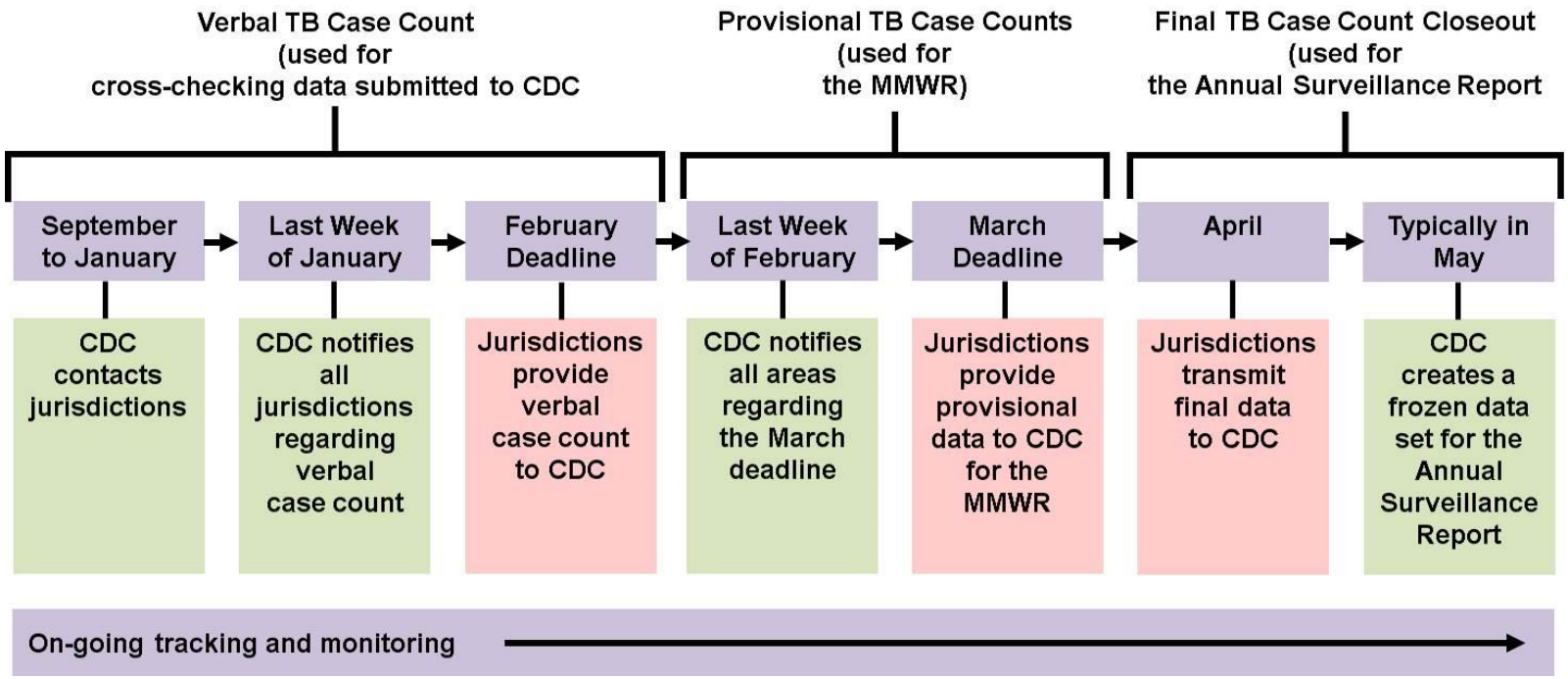
Timeliness Reporting: HCP-LHJ: The average number of days between the date of the sputum smear + result and the date the HCP (Health Care Provider) reports the case to the LHJ (Local Health Jurisdiction). *(Includes only smear + cases)*

Timeliness Reporting: Lab-LHJ: The average number of days between the date of the sputum smear + result and the date that the lab reports this information to the LHJ (Local Health Jurisdiction). *(Includes only smear + cases)*

Timeliness: Susceptibility: The average number of days between the date of the first MTB culture positive result and the date that the lab (local or state lab) reports the results to the LHJ (Local Health Jurisdiction). *(Includes all culture positive cases)*

Timeline for Reporting Annual TB Surveillance Data to CDC

Timeliness Tool –4



Typical Weekly CDC TB Surveillance Data Availability Chart

Day	Activities	Data Available
MONDAY	• Collect data received through SUNDAY • Process data through warehouse • Analyze and QA data • Create SAS table • Push data to Staging for NTIP, NTSS, TB GIMS	WEDNESDAY of current week
TUESDAY	• Collect data received through MONDAY (data received on TUESDAY will be available on WEDNESDAY of the next week) • Process data through warehouse • Analyze and QA data	WEDNESDAY of the next week
WEDNESDAY	• Applications pick up data from Staging • New data available in NTIP, NTSS, TB GIMS • Collect data received through TUESDAY • Process data through warehouse • Analyze and QA data	WEDNESDAY of the next week
THURSDAY	• Collect data received through WEDNESDAY • Process data through warehouse • Analyze and QA data	WEDNESDAY of the next week
FRIDAY	• Collect data received through THURSDAY • Process data through warehouse • Analyze and QA data	WEDNESDAY of the next week

<Date> Verbal Case Count and Provisional TB Data Transmitted

Timeliness Tool - 6

Jurisdiction's	Jurisdictions' Verbal Case Count	Date	Jurisdicstion's <Date> Case Counts	<Date> % Jurisdiction's Verbal Case Counts	Date Provisional Data Transmitted	Comments

#	Summary of Jurisdictions Reporting
	Jurisdictions
	Jurisdictions' Report Verbal Case Count
	Jurisdictions' Provisional Verbal Case Count Matches Data Transmission
	Jurisdictions' Report Date for Provisional Data Transmission
	* Jurisdictions' Revise Case Count

Chapter 8: Data Security and Confidentiality Tools

The Data Security and Confidentiality Tools include a list of the tools followed by examples of the first page of each tool.

Data Security and Confidentiality Tools

Tool #	Tool Name	Description and How to Use	Format	Source Contact
Data Security and Confidentiality –1	**Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, STD and TB Programs – Standards**	A list of the minimum standards required for data sharing and use of surveillance data for public health action	Word 3 pages	CDC/ NCHHSTP
Data Security and Confidentiality –2	**Data Security and Confidentiality Initial Assessment**	Guidelines on how to initially assess the TB program's data security and confidentiality policies and procedures	Word 3 pages	CDC/ NCHHSTP
Data Security and Confidentiality –3	**Data Security and Confidentiality Periodic Assessment Checklist**	Checklist for conducting ongoing assessment of TB program compliance with the data security and confidentiality guidelines	Word 12 pages	CDC/ NCHHSTP
Data Security and Confidentiality –4	**Data Security and Confidentiality Guidelines Frequently Asked Questions**	Questions and answers to clarify issues regarding the Data Security and Confidentiality Guidelines	Word 5 pages	CDC/ NCHHSTP
Data Security and Confidentiality –5	**Data Security and QA Checklist**	Checklist for data security and QA activities	Word 1 page	California Tuberculosis Control Branch, California Department of Public Health

Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, STD, and TB Programs

Standards to Facilitate Data Sharing and Use of Surveillance Data for Public Health Action

1.0 PROGRAM POLICIES AND RESPONSIBILITIES

1.1 Develop written policies and procedures on data security and confidentiality; review policies and procedures at least annually; revise them as needed; and ensure their review by and accessibility to all staff members having authorized access to confidential individual-level data.

1.2 Designate a person or persons to act as the overall responsible party (ORP) for the security of public health data your program collects or maintains, and ensure that the ORP is named in any policy documents related to data security.

1.3 Ensure that data security policies define the roles and access levels of all persons with authorized access to confidential public health data and the procedures for accessing data securely.

1.4 Ensure that data security policies require ongoing reviews of evolving technologies and include a computer back-up or disaster recovery plan.

1.5 Ensure that any breach of data security protocol, regardless of whether personal information was released, is reported to the ORP and investigated immediately. Any breach that results in the release of personally identifiable information (PII) to unauthorized persons should be reported to the ORP, to CDC, and, if warranted to law enforcement agencies.

1.6 Ensure that staff members with access to identifiable public health data attend data security and confidentiality training annually.

1.7 Require all newly hired staff members to sign a confidentiality agreement before being given access to identifiable information; require all staff members to re-sign their confidentiality agreements annually.

1.8 Ensure that all persons who have authorized access to confidential public health data take responsibility for 1) implementing the program's data security policies and procedures, 2) protecting the security of any device in their possession on which PII are stored, and 3) reporting suspected security breaches.

1.9 Certify annually that all data security standards have been met.

2.0 DATA COLLECTION AND USE

2.1 Clearly specify the purpose for which the data will be collected.

2.2 Collect and use the minimum information needed to conduct specified public health activities and achieve the stated public health purpose.

2.3 Collect personally identifiable data only when necessary; use nonidentifiable data whenever possible.

2.4 Ensure that data that are collected and/or used for public health research are done in accordance with stipulations in Common Rule, Title 45, Part 46 of the Code of Federal Regulations, which includes obtaining both institutional review board (IRB) approval for any proposed federally funded research and informed consent of individuals directly contacted for further participation.

DATA SECURITY AND CONFIDENTIALITY INITIAL ASSESSMENT

This checklist can be used to guide the initial assessment of a program's compliance with the Standards for Data Security and Confidentiality. This will be particularly useful for state and local public health programs that currently lack data security and confidentiality policies and procedures.

As indicated previously in this document, the initial assessment should be conducted by a team led by the ORP(s). The team should include:

Program managers, directors, or equivalent leaders from participating programs

Other representatives of participating programs

Staff members with technical expertise in data security

IT staff

The initial assessment should include the following steps:

- Identify key individuals and designate an ORP
- Review current security-related materials (e.g., written policies and procedures)
- Review relevant state and local laws that might affect data security and confidentiality policies
- Identify any policies or procedures that are either barriers to information sharing or sources of data security weaknesses
- Consult standard operating procedures (SOPs) from other programs that might be useful sources of ideas or suggestions for procedural changes
- Review any history of data security breaches or near-breaches, and associated lessons learned
- Assess physical security and define the secure area
- Assess electronic security protections and methods of data transfer and storage
- Assess factors related to security of information in the field, as appropriate
- Assess training needs

Data Security and Confidentiality Periodic Assessment Checklist

This checklist can be used to guide the periodic assessment of a program's compliance with the Standards for Data Security and Confidentiality.

For the answer to be "yes" to a question with multiple parts, all boxes must be checked. For each "No" response, provide additional information describing how the program intends to achieve compliance with that standard.

Name of Program being assessed _____

Name of person assessing the program _____

1.0 PROGRAM POLICIES AND RESPONSIBILITIES

STANDARD 1.1

In your program, how are staff members who are authorized to access HIV/VH/STD/TB information or data made aware of their data confidentiality and security responsibilities?

_____

_____

Are the following points addressed in your policies and agreements?

☐	Yes	☐	No	Are staff provided training on security policies and procedures and where to find resources?
☐	Yes	☐	No	Does the program have written data security and confidentiality policies and procedures?
☐	Yes	☐	No	Are written policies and procedures reviewed at least annually and revised as needed?
☐	Yes	☐	No	Are data security policies readily accessible to all staff members who have access to confidential, individual-level data? Where are the policies located? _____

Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action

Frequently Asked Questions

1. Why are these not titled "Guidelines for Sharing Data"? Why don't they have the word "sharing" in the title?

These guidelines provide standards for security and confidentiality for data in all programs funded by the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP). Sharing is facilitated when the lack of protection is no longer a barrier for programs that conform to these guidelines. Data sharing standards are included as part of these guidelines, however, this document does not specify details of how, what, or when data should be shared.

2. Do these replace the HIV Security and Confidentiality Guidelines?

Yes. These replace the *Technical Guidance for HIV/AIDS Surveillance Programs, Volume III: Security and Confidentiality Guidelines* and establish formal security and confidentiality guidelines for HIV, viral hepatitis, STD, and TB programs funded through NCHHSTP.

3. How do these fit with the Partner Services Security and Confidentiality Guidelines?

These replace the data security and confidentiality guidelines contained in Appendix D, "Guiding Principles and Standards for Record Keeping and Data Collection, Management, and Security for Partner Services Programs for HIV Infection, Syphilis, Gonorrhea, and Chlamydial Infection" of the *Recommendations for Partner Services Programs for HIV Infection, Syphilis, Gonorrhea, and Chlamydial Infection*.

4. Do these guidelines apply to CDC-funded prevention activities?

Yes. All programs funded by NCHHSTP will be required to implement these guidelines for personally identifiable or potentially personally identifiable information. Beginning in 2012, adhering to the Guidelines is being incorporated into all core funding announcements. Surveillance programs, prevention programs, and programs who receive surveillance or program data are within the scope of these Guidelines.

Data Security and Confidentiality Tool - 5

Data Security and Quality Assurance Checklist

#	Procedures	Yes	No	If no, indicate the plan for improvement
1.	Is the TB Program patient management database on a secure server located within a locked room at the TB Clinic?			
2.	Is secure password protection maintained for the TB Program patient management database?			
3.	Have modifications that are needed for surveillance and patient management activities been made to the TB Program patient management system?			
4.	Is the system backup of the TB Program patient management database performed nightly?			
5.	Are the TB registry data secure and confidentiality of all surveillance case reports, HIV test results, and other patient files maintained in accordance with local and state guidelines?			
6.	Are QA protocols created for monthly and annual monitoring of data validity?			
7.	Are the data-collection, data-entry, and QA protocols easily accessible to all staff?			
8.	Is periodic training conducted to ensure staff are up to date with QA protocols?			
9.	Are existing QA reports reviewed and queries created in the TB Program patient management system to produce line lists of records with missing or incorrect information?			
10.	Does the program comply with HIPAA regulations?			

Chapter 9: Quality Assurance Cross-Cutting Tools

The QA Cross-cutting Tools include a list of the tools followed by examples of the first page of each tool.

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

TB Control Program
Procedures for PHIMS Data Entry and Quality Control Procedures

<QA Protocol Example>

Policy and Procedure Title:	**PHIMS Data Entry and Quality Control**
Category:	
Final Review & Approval By:	**Leadership Group**
Effective Date:	

Approval Authority **Date**

This procedure shall be reviewed three months following implementation. If necessary, a second review will occur after another three months. Following the review, the procedure will be reviewed and/or updated annually as noted below.

Review Date	Revision Date	Signature

Cross-cutting Tool - 2

TB Case/Suspect QA Review Form

New Case Review *Case Name:* *Date:*

Data reporting: Required elements (present or not)

Date of Birth	☐ Yes	☐ No	**Sputum Smear**	☐ Yes	☐ No	☐ NA
Race	☐ Yes	☐ No	**Sputum Culture**	☐ Yes	☐ No	☐ NA
Country of Origin	☐ Yes	☐ No	**Cx Tissue/Other**	☐ Yes	☐ No	☐ NA
Mo-Yr Arrived in U.S.	☐ Yes	☐ No	**NAAT Result**	☐ Yes	☐ No	☐ NA
Status at Diagnosis of TB	☐ Yes	☐ No	**Chest X-ray**	☐ Yes	☐ No	
Previous Diagnosis of TB	☐ Yes	☐ No	**TST at Diagnosis**	☐ Yes	☐ No	
Major Site of Disease	☐ Yes	☐ No	**Treatment Start Date**	☐ Yes	☐ No	

Treatment initiation: Is patient sputum-smear positive? ☐ Yes ☐ No ☐ NA

Initial sputum collection date: _____ Tx initiation date: _____
(should be <7 days from collection to tx initiation)

Recommended initial therapy: Was standard 4-drug regimen started? ☐ Yes ☐ No

If no, why? List regimen: _____

HIV Status: ☐ Test date/result recorded ☐ Test done, result pending ☐ No test done

If no test done, why? _____

Sputum culture report: For all pulmonary/pleural/laryngeal cases

Has sputum been collected? ☐ Yes ☐ No ☐ NA

If no, why not? _____

Contact investigation: Is contact investigation needed? ☐ Yes ☐ No

Has CI been started? ☐ Yes ☐ No If no, why not? _____

1

TB Review and QA Schedule for TB Case/Suspects

Weekly TB Case/Suspect Review:

- New cases/suspects are reviewed at weekly case meetings
- New cases checked for overall completion; f/u with LHD as necessary
- Clinical case review for counting/not counting at weekly case meetings

Monthly TB Case/Suspect Review:

- Review all cases/suspects at 2 month mark
    - Cases: Check for complete information, appropriate treatment/clinical decisions
    - Suspects: Decide if they are cases, are not cases, or are still being evaluated.

Monthly TB Case Data Review:

- Check case data for missing info (common: HIV, date of entry, risks, etc) based on Orpheus data exports

Monthly Lab/Genotyping Review:

- Check that all culture + cases have had specimens sent to OSPHL for susceptibility testing
- Check that all culture + cases have had specimens sent to CA lab for genotyping

Monthly Program Review:

- NAAT evaluation – identify and f/u with counties about how NAAT results did or did not affect clinical decisions and contact investigations

2009 RVCT Trending Guidance

The newly revised RVCT form (OMB approval through 2011) contains several changes compared to items on the expired RVCT (OMB approval through 2008). A workgroup was formed to address how these changes should be incorporated into trend analysis for common analyses of surveillance data..

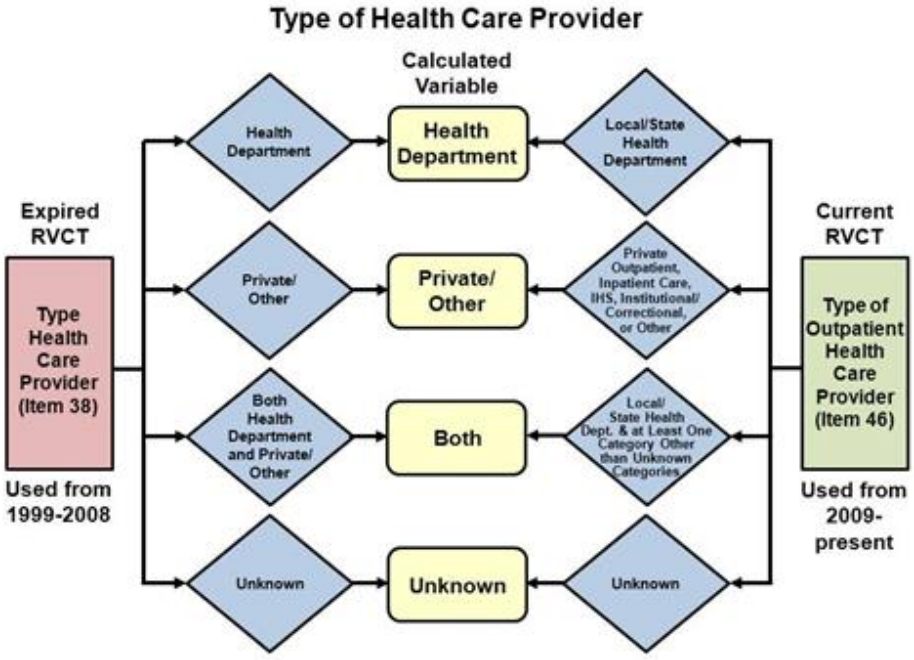
The following is a list of some trending issues identified. The list is not exhaustive; not all changes to the RVCT are addressed. For detailed instructions on changes to the RVCT, refer to: CDC. *Report of Verified Case of Tuberculosis (RVCT) Instruction Manual.* Atlanta, GA: U.S. Department of Health and Human Services, CDC, June 2009.

Sites of Disease:

Expired Item	Revised Item	Impact	Trend Guidance
Major Site of Disease (Item 15) captured one primary site of disease. If Miliary was selected, no other sites could be chosen under Additional Site of Disease. Additional Site of Disease (Item 16) captured multiple sites, provided that no site matched Item 15.	Miliary is no longer collected on Item 16 and is now collected in Initial Chest Radiograph (Item 22A) and Initial Chest CT Scan or Other Chest Imaging Study (Item 22B) for abnormal radiograph or imagining results only. Site of TB Disease (Item 16): Two anatomic codes were extracted from Other and are now listed individually: Lymphatic: Axillary, and Laryngeal.	Impact on the trend of interest, site of disease, is unknown. From 1993 to 2008, miliary was selected as a major site 3465 times (1.4%). Miliary was selected as an additional site 1123 times (0.4%). Of the 4957 cases of miliary disease, 647 (13.1%) occurred where the patient had a normal chest radiograph.	Creation of a new miliary yes/no variable to indicate miliary disease from 1993 through the present. This variable will be populated with miliary site of disease from the expired RVCT (Item 15 or Item 16) and miliary sub-response within abnormal chest radiograph or imaging study on the revised RVCT (Items 22A/B). Expired Item or Revised Item → Miliary Disease • Miliary Major Site of Disease Item 15 or Miliary Additional Site of Disease Item 16 or Evidence of miliary TB Yes in Item 22A/B → yes • All other sites excluding Miliary (Item 15 or Item 16) or Evidence of miliary TB No in Item 22A/B → no • Site Not Stated or Missing Item 15 or Unknown or Missing Item 22A/B → unknown • Normal in Item 22A/B → no The calculated miliary variable will assist in trending site of disease as pulmonary, extrapulmonary, or both. Miliary disease is considered both pulmonary and extrapulmonary.

Mapping Old RVCT Data (1993-2008) to New RVCT Data (2009-present)

These are visual examples of three of the calculated RVCT variables mentioned in Cross-cutting Tool-4a 2009 RVCT Trending Guidance.



Calculated variable means the value is assigned based on the contents of one or more RVCT variables.

RVCT Variables Used in NTIP (Spread Sheet)

Cross-cutting Tool - 5

RVCT Item #	Variable Description	PHIN Variable ID	NTIP Indicator Report									
			COT	Rate	DST	HIV	TX INIT	RIT	LAB TAT	SP CULT	CULT COV	GENO
01	Date Reported	INV111	D/L	N/L	L	S/L	L	L	L	D/L	L	L
03	State Case Number	INV173	L	L	L	L	L	L	L	L	L	L
03	City/County Case Number	INV172	F/L	L	F/L	F/L	F/L	F/L	F/L	F/L	F/L	F/L
03	Reporting State	NOT116	F/L	F/L	F/L	F/L	F/L	F/L	F/L	F/L	F/L	F/L
04	Reporting Address City	TB080	F	F	F	F	F	F	F	F	F	F
04	Inside City Limits	TB099	F	F	F	F	F	F	F	F	F	F
04	Reporting Address County	TB081	F	F	F	F	F	F	F	F	F	F
05	Count Status	TB153	F/L	F/L	F/L	F/L	F/L	F/L	F/L	F/L	F/L	F/L
05	Case Verification	TB154	F	F	F	F	F	F	F	F	F	F
06	Date Counted	TB100	F/L	F/L	F/L	F/L	F/L	F/L	F/L	F/L	F/L	F/L
08	Date of Birth	DEM115	D	N		S				D		
10	Ethnicity	DEM155		N/L								
11	Race Category	DEM152		N/L								
12	Country of Birth: US Born	DEM2003		N/L								
12	Country of Birth Specify	DEM126		N/L								
15	Status at Diagnosis of TB	TB101	N/D/L	L	L	L	D/L	D/L	D/L	D/L	D/L	L
16	Site of Disease	TB205	F/D	F	F	F	F	F	F/D/L	F/D/L	F	F
17	Sputum Smear	TB108	F	F	F	F	F/D/L	F	F	F	F/S	F
17	Sputum Smear Date Collected	TB221					N					
18	Sputum Culture	TB109	F/D	F	F/D/L	F	F	F	F/D/N/C/L	F/N/L	F/D/L	F/D/L
18	Sputum Culture Date Collected	TB223							C			
18	Sputum Culture Date Result Reported	TB225							C			
18	Sputum Culture Reporting Laboratory Type	TB227							S			
19	Smear/path/Cyt of Tissue and Other Body Fluids	TB110	F	F	F	F	F	F	F	F	F	F
20	Culture of Tissue and Other Body Fluids	TB113	F/D	F	F/D/L	F	F	F	F/D/C/L	F	F	F/D/L
20	Culture Anatomic Site	TB114	D						D			
20	Culture of Tissue Date Collected	TB231							C			
20	Culture of Tissue Date Result Reported	TB233							C			

Cohort Review Preparation:
Roles and Responsibilities by Time Due

Timeline	Job Role	Responsibility
12 weeks prior	**Admin**	Organizes room and AV equipment
6 weeks prior	**Epidemiologist**	1) Identifies cohort period, pulls data, and ensures that NTIP and cohort measures are up-to-date 2) Provides list of cases to Nurse Case Managers for Mock cohort 3) Runs case, contact and NTIP reports and analyses 4) Fixes data issues 5) Follow-up with leads if particular issues were identified at last cohort
	Nursing Supervisor/Lead Nurse	Provides list of needed case charts to Admin
	Admin	Pulls needed case charts for nurse case managers/DRDS
5 weeks prior	**Epidemiologist**	1) Prepares list of issues/challenges/success along with potential cases and gives to nursing supervisor for distribution 2) Provides new clean list once to Nurse case managers once feedback has been received 3) Updates RVCTS, NTIP data 4) Reviews Cohort/NTIP issues identified with management team
	Nursing Supervisor/Lead Nurse	Identifies those cases that may be of interest for discussion at cohort (based on Epi list)
	Nurse Case Manager	Prepares cases of interest for cohort review. Addresses indicators.
4 weeks prior	**Epidemiologist**	Prepares cohort review presentation list based on PHIMS data
	DIS	Prepares cohort review presentation list contact investigation updates
	CDC	Provides updated NTIP summaries; RVCT #'s for those cases not meeting indicators

1

Cross-cutting Tool-7

TO: Director, DTBE
FROM: Chair, NTIP Workgroup
DATE: July 15, 2013

SUBJECT: NTIP Decision Memo. Sputum culture conversion documented within 60 days of treatment initiation to be sustained.

Through: Chief, SEOIB, DTBE

Background
Monitoring culture conversion at 2 months is essential for assessing treatment progress and evaluating the effectiveness of the treatment regimen. According to the American Thoracic Society/CDC's guidelines on the treatment of tuberculosis, approximately 80% of patients with pan-susceptible pulmonary TB will have converted to culture-negative after 2 months of treatment. Closer monitoring of patient to ensure adherence, and extending treatment to a minimum of 9 months may be warranted for treatment success if conversion did not take place within 60 days of treatment initiation.

The national objective encourages programs to strive for increasing the proportion of culture-positive patients with culture conversion within 60 days of initiating treatment. Since becoming one of the national objectives, local TB programs have worked on this indicator, bringing the national average from 47.2% in 2008 to 56.4% in 2010.

A positive-culture result in the initial sputum specimen is the basis for assessing conversion. Sputum culture conversion is defined as two consecutive negative cultures with no positive culture thereafter. The guidelines recommend that sputum specimens be obtained at a minimum of monthly intervals until two consecutive specimens are culture-negative. The RVCT defines the date of conversion as the specimen collection date for the first consistently negative culture at least one week after the last positive culture, suggesting specimen collections at least 7 days apart.

NTIP users proposed the following changes to this indicator:

1. Remove the objective for attaining culture conversion within 60 days, and focus on the documentation of sputum culture conversion alone (i.e. culture conversion ever). Or change the objective of 60 days to 65, 70, or 75 days.
2. Revise the RVCT instruction on the "Sputum Culture Conversion" variable stipulating that the first consistently negative culture should be a least 7 days after the last positive culture (i.e., allow follow-up cultures to be obtained at shorter intervals).
3. Exclude patients with cavitary disease from the indicator cohort.
4. Exclude patients who moved out of the country from the indicator cohort.

Source Contact List for QA Tools

The list below includes contact information for some of the tools.

Source Contact List for Tools

Program	Phone
CDC/Division of Tuberculosis Elimination (DTBE) rvctqualityassurance@cdc.gov	404-639-5312 or 404-639-8401
California Tuberculosis Control Branch, California Department of Public Health	510-620-3055
Oregon TB Program	971-673-0174
Tennessee TB Elimination Program	615-741-5818
Texas Department of State Health Services Epidemiology & Surveillance Branch	512-776-3577
Tuberculosis Control Program, Public Health—Seattle & King County	206-744-4579
Washington State Department of Health Tuberculosis Program	360-236-3423