**QA Plan Tool - 2**

**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.

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| **Summary of CoAg Requirements** |
| * Incorporate quality assurance policies and procedures into surveillance activities to ensure
* Case detection (finding, counting, and reporting all TB cases)
* Data accuracy (accuracy of data abstracted from original patient records, of registry data, and of data entered onto the RVCT form and transmitted to CDC)
* Data completeness
* Timeliness
* 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. |
| **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 ofsecondary 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.
 |
| **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. |
| **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.** |