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
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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).