# Health Department Use and Application of CDC Drug Resistant TB Laboratory Services

OSTLTS Generic Information Collection Request
OMB No. 0920-0879

## Supporting Statement – Section A

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# Section A – Justification

## 1. Circumstances Making the Collection of Information Necessary

**Background**

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS Survey Center (OSC) – OMB No. 0920-0879. The respondent universe for this data collection aligns with that of the OSC. Data will be collected from public health officials in 60 U.S. health department jurisdictions acting in their official capacities. These jurisdictions include 50 states, 9 major U.S. Cities, and the District of Columbia. This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241).

TB Control Programs have a mission of carrying out programs to prevent, control, and eventually eliminate TB. The roles and responsibilities of these programs are complex and must be carried out at national, state, and local levels. The state and local public health departments have the primary responsibilities for preventing and controlling TB. TB patients often receive care in a variety of settings, including public and private sectors, which must report all TB cases to the health department in that jurisdiction. Regardless if a patient is being cared for in a public or private setting, state and local health departments must coordinate with the healthcare providers and facilities to ensure prevention and control strategies are being met. TB Control programs must work closely with laboratories to ensure the rapid delivery of specimens or isolates to the state or local public health laboratories for prompt reporting of AFB smear results, culture results, and drug-susceptibility test results to the clinician and health department.

In the United States, primary, multidrug resistant (MDR) TB, defined as TB that is resistant to at least the two most effective first-line drugs, rifampin (RMP) and isoniazid (INH), accounted for 1.3% of the total number of cases in 2011. Extensively drug resistant (XDR) TB, defined as TB resistant to at least RMP, INH, a fluoroquinolone and one of the three injectables (i.e., amikacin, kanamycin, capreomycin), remains relatively low in the United States with a total of 12 cases reported from 2008 to 2011, 6 of these being reported in 2011 (**See Attachment A**).

Rapid and reliable diagnosis of MDR TB is essential to the prevention of ongoing transmission and the appropriate selection of anti-TB drugs for effective treatment. Conventional phenotypic drug susceptibility testing (DST) methods like the agar proportion method and the liquid culture method (e.g. MGIT system) are considered the "gold standard" for DST in TB. These methods are based on timely indirect methods that depend on primary culture. Because *Mycobacterium tuberculosis* has a slow growth rate, isolation from clinical specimens may take 2-6 weeks followed by another 2-6 weeks before DST results are available. In some situations, conventional DST is not even feasible (e.g. when isolate is non-viable or fails to grow in conventional media).

In September of 2009, CDC rolled out the MDDR service to rapidly identify drug resistance in isolates and clinical specimens (2012 inclusion) containing M. tuberculosis complex. The implementation of this Clinical Laboratory Improvement Amendments (CLIA) compliant service by

the Laboratory Branch within the Division of TB Elimination was in response to an Advisory Council for the Elimination of TB (ACET) recommendation to CDC to provide rapid DST in the United States (**See Attachment B**). MDDR uses polymerase chain reaction (PCR) for amplification of targeted genes and conventional DNA sequencing to detect mutations associated with resistance to four first-line drugs, RMP, INH, pyrazinamide and ethambutol and the most effective second-line drugs, the fluoroquinolones and injectables. Conventional DST, the agar proportion method and MGIT for pyrazinamide is also done on all samples received for MDDR. The service is available to all U.S. Public Health TB programs and samples may be submitted by public health laboratories if they meet at least one of the submission criteria. Samples must receive approval prior to sending to CDC for testing. Submission criteria include samples from patients whom have a high-risk for RMP resistance, have known RMP resistance, TB cases with high public impact (e.g. a daycare worker or nurse), or have adverse reactions to current drug regimen, or from samples which failed to grow in conventional DST medium. Other situations may be considered on a case by case basis. From September 2009 to May 2013, 1,274 samples have been received for MDDR testing from all states except Wyoming.

An assessment of the impact of MDDR results on public health interventions is needed. The information being collected is specific to CDC MDDR testing service. Since this service is new and unique, there are no other data collection systems available for evaluation of this service. An assessment of the service from a laboratory perspective (i.e. soliciting information from public health laboratory directors) was completed in January, 2012, using the OSTLTS Gen-IC mechanism, but no assessment measuring the impact on TB control programs (i.e. soliciting information from TB Controllers) has been done. An assessment from the perspective of the TB control programs are necessary to understand how the molecular results from this CDC clinical laboratory service might be used for public health interventions and to identify service improvements to better serve state and local TB Control Programs.

**Privacy Impact Assessment**

Overview of the Data Collection System – The data collection system consists of a web-based questionnaire (**see Attachment C –Data Collection Instrument: MS Word version and Attachment D– Data Collection Instrument: Online version**) designed to assess TB controllers from 60 state and local U.S. jurisdictions that receive awards through the CDC TB Elimination Cooperative Agreement regarding the use of the MDDR service and use of results from service on public health interventions for TB control . The data collection instrument will be administered as a web-based assessment using Adobe® FormsCentral. An email with an HTML link will be sent to the TB Controllers. The email will also contain instructions for completing and submitting the assessment.

Based on an internal pilot test, the average time to complete is 10 minutes, with a range of 6-15 minutes, including time spent on instructions. The pilot study was completed by three subject matter experts. An email with instructions and the html link to the assessment was sent. Participants were asked to record the amount of time to complete and note any technical errors or difficulties.

Items of Information to be Collected – The assessment consists of 20 questions including multiple choice questions, for which respondents will be informed to select either one or all responses that apply, and questions that will use a rating scale for responses. The data collection instrument uses skip patterns, therefore, some participants may not see all 20 questions based on their answers to specific questions. Some selections are formatted for open-ended responses and text field boxes will be included. The assessment will collect information on the following:

a. factors that trigger state and local TB Control Programs to request their partner public health laboratories to refer samples for MDDR testing
b. who primarily initiates the requests to submit a sample for MDDR testing
c. if TB controllers are involved in the process for requesting MDDR testing.
d. ability of TB Controllers to understand and interpret results from the MDDR testing service
e. what sources TB Controllers consult to better understand the results
f. how the results are utilized by TB Controllers for public health interventions
g. actions taken by TB Controllers if discordance is noted between molecular results and conventional results performed at CDC or their public health laboratory.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age –No website content will be directed at children.

**2. Purpose and Use of the Information Collection**

To gain a better understanding of the how the results from the MDDR testing service impact the work of the TB Control Program, a qualitative assessment to be sent to TB Controllers to assess the use and application of MDDR service.

Lessons learned could aid in clarifying laboratory reporting language and focus training and educational efforts to improve understanding of the MDDR service and molecular results. It is important to ensure there is an understanding of these types of molecular results among laboratorians, TB control programs, and clinicians to ensure prompt and adequate treatment and prevent ongoing transmission of MDR TB. This assessment is necessary to gain a program perspective and to identify service improvements to better serve state and local TB Control Programs.

Privacy Impact Assessment

CDC will not receive any personally identifiable information. Information will be collected electronically and all data will be input into secure data bases.

**3. Use of Improved Information Technology and Burden Reduction**

Data collection will be conducted by using a web-based instrument, using Adobe® FormsCentral. Web tools reduce respondent burden by enabling easy access and completion at a convenient time and location. The online tool will consist of easy-to-read response selections or embedded text boxes. Skip logics will be programmed into the tool to direct respondents to appropriate questions. Screen shots of are shown in Attachment D. The instrument was designed to collect the minimum information necessary for the purposes of this project. (i.e., limited to 20 questions).

**4. Efforts to Identify Duplication and Use of Similar Information**

The information being collected is specific to CDC MDDR testing service. Since this service is new and unique, there are no other data collection systems available for evaluation of this service. An assessment of the service from a laboratory perspective (i.e. soliciting information from public health laboratory directors) was completed in January, 2012, under the OSTLTS Gen-IC mechanism, but no assessment measuring the impact on TB control programs (i.e. soliciting information from TB Controllers) has been done. In addition, a review of the literature reveals few qualitative evaluations or outcomes (i.e. assessments that describe the impact on a TB Control Program or the clinical impact) of molecular diagnostic services for drug resistance detection.

**5. Impact on Small Businesses or Other Small Entities**

No small businesses will be involved in this data collection.

**6. Consequences of Collecting the Information Less Frequently**

This request is for a one time data collection. There are no legal obstacles to reduce the burden. The consequences for not collecting this information would be:

- Failure to improve reporting of MDDR test results by not identifying whether results from the MDDR service are being interpreted correctly by TB Controllers.
- Failure to assess the impact of MDDR test results on TB Control Programs.
- Negative patient outcomes if TB Controllers do not accurately report results to health care providers, such as:
    - Exposure to inadequate treatment, selecting for amplified drug resistance, thus making treatment even more difficult and more costly.
    - Furthering the spread of drug resistance TB in the community.
    - Deterioration of patient's health, thus narrowing the window for effective treatment, especially in patients infected with HIV.

**7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

**8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS Survey Center (OSC) – OMB No. 0920-0879. This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS Survey Center (OSC) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on October 22, 2010, Vol. 75, No. 204; pp. 65353-54. Two comments were received from the Association of State and Territorial Health Officials (ASTHO), and the National Association of County and City Health Officials (NACCHO).

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

**9. Explanation of Any Payment or Gift to Respondents**

CDC will not provide payments or gifts to respondents.

**10. Assurance of Confidentiality Provided to Respondents**

The Privacy Act does not apply to this data collection. Employees of state and local public health agencies will be speaking from their official roles and will not be asked, nor will they provide individually identifiable information. This data collection is not research involving human subjects.

**11. Justification for Sensitive Questions**

No information will be collected that are of personal or sensitive nature.

**12. Estimates of Annualized Burden Hours and Costs**

The estimate for burden hours is based on a pilot test of the instrument by 3 of public health professionals. In the pilot test, the average time to complete including time for reviewing instructions, gathering needed information and completing the assessment, was approximately 10 minutes. Based on these results, the estimated time range for actual respondents to complete the is 10-15 minutes. For the purposes of estimating burden hours, the upper limit of this range (i.e., 15 minutes) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations – medical and health services managers in state government (http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf). Based on DOL data, an average hourly wage of $57.11 is estimated for all 60 respondents. Table A-12 shows estimated burden and cost information.

**Table A-12:** Estimated Annualized Burden Hours and Costs to Respondents

| Type of Respondent | No. of Respondents | No. of Responses per Respondent | Average Burden per Response (in hours) | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|---|---|---|
| State and Local TB Controllers | 60 | 1 | 15/60 | 15 | $57.11 | $856.65 |
| **TOTALS** | **60** | **1** | | **15** | | **$856.65** |

**13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers**
There will be no direct costs to the respondents.

**14. Annualized Cost to the Government**
There are no equipment or overhead costs. Contractors are not being used to support this data collection. The only cost to the federal government would be the salary of CDC staff supporting the data collection activities and associated tasks. The lead staff from the LB for this project consists of a Microbiologist and Team Leader from the Laboratory Capacity and a Public Health Advisor from the Field Service and Evaluation Branch. The lead staff will collect the data; code, enter, and prepare the data for analysis; conduct data analyses and prepare the evaluation report. Hourly rates of $25.34 for GS-9 (step 3), $51.81 for GS-14 (step 3) and $52.86 for GS-13 were used to estimate staff costs. The estimated cost to the federal government is $19,676.16. Table A-14 describes how this cost estimate was calculated.

**Table A-14:** Estimated Annualized Cost to the Federal Government

| Staff (FTE) | Average Hours per Collection | Average Hourly Rate | Average Cost |
|---|---|---|---|
| **Microbiologist (GS-9)** Instrument development, pilot testing, OMB package preparation, data collection, data coding and entry, quality control, data analysis, report preparation | 300 | $25.34 | $7602.00 |
| **Microbiologist (GS-14), Team lead, Laboratory Capacity Team** Instrument development, pilot testing, OMB package preparation, report preparation | 130 | $51.81 | $6735.30 |
| **Microbiologist (GS-13)** Instrument development, OMB package preparation | 100 | $52.86 | $5286.00 |
| **Public Health Advisor (GS-13)** Instrument development, communications with respondent universe, data analysis | 10 | $52.86 | $52.86 |
| **Estimated Total Cost of Information Collection** | | | **$19,676.16** |

**15. Explanation for Program Changes or Adjustments**
This is a new data collection.

**16. Plans for Tabulation and Publication and Project Time Schedule**

Results of this data collection will be prepared for publication in a peer-reviewed journal. Concurrently, CDC lead staff will externally communicate results to Health Officials representing PHL.

Project Time Schedule

- ✓ Design questionnaire.....(COMPLETE)
- ✓ Develop protocol, instructions, and analysis plan.....(COMPLETE)
- ✓ Pilot test questionnaire.....(COMPLETE)
- ✓ Prepare OMB package.....(COMPLETE)
- ✓ Submit OMB package.....(COMPLETE)
- ❑ OMB approval.....(TBD)
- ❑ Conduct assessment.....(open 2 weeks)
- ❑ Collect, code, enter, quality control, and analyze data.....(2 days)
- ❑ Prepare report.....(1 week)
- ❑ Disseminate results/reports.....(6 weeks)

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

We are requesting no exemption.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

## LIST OF ATTACHMENTS – Section A

Note: Attachments are included as separate files as instructed.

**Attachment A. Reported Tuberculosis in the United States, 2011**

**Attachment B. Report of Expert Consultations on Rapid Molecular Testing to Detect Drug-Resistant Tuberculosis in the United States**

**Attachment C. Data Collection Instrument- MS Word version**

**Attachment D. Data Collection Instrument-Online (PDF) version**