# Evaluation of a CDC Service Provided to Public Health Laboratories to Rapidly Identify Multidrug-Resistant Isolates of TB

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 State and local public health laboratory directors and their designees acting in their official capacities.

In response to the Advisory Committee for the Elimination of Tuberculosis (ACET) resolution, CDC convened an expert panel of consultants (see **Attachment A**) "to examine the current status of rapid drug resistance testing in the United States, published evidence, and current guidelines and to provide guidance and make recommendations to CDC for developing a system to provide access to rapid drug-susceptibility testing to all TB Control programs in the United States". The expert panel recommended that procedures for rapidly detecting and reporting discrepancies between the results of molecular and conventional testing must be developed and implemented. Subsequently, in November 2010, ACET unanimously approved a motion stating that "DTBE collect outcome data for all patients whose specimens are submitted to the MDDR service." To implement ACET recommendations, it is necessary to periodically perform evaluation of the MDDR testing service in order to measure discordance among molecular and conventional drug susceptibility testing performed at CDC and at the local level, to analyze how MDDR results are interpreted and used by healthcare providers, and to collect information regarding patient outcomes. The MDDR testing service must be analyzed to ensure that it is providing the intended impact by rapidly identifying drug resistance and providing easy to interpret results to stakeholders for initiation of treatment.

The Laboratory Branch (LB) in the Division of Tuberculosis Elimination (DTBE) requests approval for a new sub-collection information package under the approved generic ICR that supports quick evaluation of program impact. The LB offers a service for the molecular detection drug resistance (MDDR) to rapidly identify multidrug-resistant isolates of *Mycobacterium tuberculosis* Complex (MTBC). This service utilizes DNA sequencing for detection of mutations most frequently associated with rifampin and isoniazid drug resistance. Additional testing is conducted to identify mutations associated with resistance to the most effective second-line drugs; fluroquinolones, amikacin, kanamycin, and capreomycin. The critical contribution of MDDR tests for TB treatment and control is earlier detection of resistance: they can reliably detect mutations associated with drug resistance in 1 to 2 days. Not only does this reduce the time to detect rifampin resistance, this also reduces the time from TB diagnosis to the start of treatment. The reduction in the infectious period after diagnosis should have a large impact on public health measures to stop the spread of drug-resistant TB.

Information for this collection will be provided by public health laboratories (PHL) funded by DTBE cooperative agreements who submit isolates of MTBC to CDC for molecular

detection of drug resistance (MDDR). Results are reported back to a laboratory contact and, if requested, to TB control or the health care provider.

This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (see **Attachment B**).

**Privacy Impact Assessment**

Overview of the Data Collection System – The data collection system consists of a survey instrument (see **Attachments C & D**) designed to elicit information from Public Health Laboratory Directors or their designees regarding their perceptions and utilization of the MDDR service and results for isolates submitted by PHL to the MDDR testing service. A separate word version of the data collection instrument (see **Attachments E)** will be sent to PHL for each isolate submitted. In addition, a link to a web version of the data collection instrument (see **Attachment F**) will be sent to potential respondents. The data collection instrument is designed to collect information on local testing for drug susceptibility in order to measure discordance with MDDR results from CDC. Both the survey and data collection instruments will be distributed using Snap® Surveys software by emailing potential respondents a link to the survey instrument and a link to a data collection instrument for each isolate. The email will contain instructions for completing the instruments online. Respondents will also be given the choice of filling in Word versions of the instruments that can be returned by either email or fax. The survey was piloted by nine randomly-selected Public Health Laboratory Directors from PHL who had previously submitted isolates to the MDDR testing service. Feedback from this group was used to refine questions as needed and establish the estimated time required to complete the survey.

Items of Information to be Collected – The survey consists of 19 questions with multiple responses for selection. Respondents will be informed to select either one or multiple responses that apply. Some selections are formatted for open-ended responses. The survey will collect information on the following:

a. How Public Health Laboratory Directors or their designees first received information on the MDDR service offered by CDC.
b. who initiates requests for MDDR testing
c. satisfaction of Public Health Laboratory Directors or their designees with turnaround time for receiving results from the MDDR testing service
d. reasons Public Health Laboratory Directors or their designees may delay reporting results from CDC to health care providers
e. how Public Health Laboratory Directors or their designees report MDDR results from CDC to health care providers
f. how Public Health Laboratory Directors or their designees compare MDDR results from CDC with their own local testing

g. discordance between MDDR results from CDC and local test results identified by Public Health Laboratory Directors or their designees
h. actions initiated by Public Health Laboratory Directors or their designees when they have identified discordance between MDDR results from CDC and local test results
i. decisions by Public Health Laboratory Directors or their designees to perform further testing when MDDR results from CDC are the first results available
j. difficulty Public Health Laboratory Directors or their designees have interpreting and discussing MDDR results from CDC
k. where Public Health Laboratory Directors or their designees sought additional help if they experienced difficulty interpreting results

The data collection instrument will be used to collect the following information on each isolate submitted by PHL to the MDDR service at CDC for testing:

a. whether drug susceptibility testing was performed for the isolate locally
b. methods used to perform drug susceptibility testing
c. whether the isolate was referred to another laboratory other than CDC for further testing
d. drug susceptibility results for each isolate from local testing

No individually identifiable information is being collected.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age – This information collection does not involve websites or website content directed at children less than 13 years of age.

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

The survey instrument will be used to determine if either Public Health Laboratory Directors or their designees experience difficulty interpreting MDDR results from CDC and what steps they take before these results are reported to health care providers. Information from the survey will also be used to measure customer satisfaction with the MDDR service and to determine where respondents first learned of the availability of the MDDR service. These assessments will enable the LB to measure how effectively they are providing clear and understandable results to their target audience. In addition, by asking respondents for information on customer satisfaction and how they learned of the MDDR service, the LB can gauge the effectiveness of service delivery. Collectively, results from the survey are vital to an effective process where the LB can identify areas for program improvement.

The data collection instrument will be used to obtain local DST results for measuring discordance with MDDR results from CDC. To implement ACET recommendations, it is necessary to measure discordance among molecular and conventional drug susceptibility

testing performed at CDC and at the local level since these discrepancies can directly affect treatment decisions by health care providers and patient outcomes.

Privacy Impact Assessment

Information will be collected electronically. CDC will not receive any personally identifiable information. The Laboratory Branch will provide submitter specimen identifier and CDC specimen identification numbers to PHL to facilitate the information collection. Respondents are participating in their official capacity as health officials in state (or District) departments of health.

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

Data collection will be conducted by using a web-based survey, using Snap® Surveys software. Web surveys reduce respondent burden by enabling easy access and completion at a convenient time and location. The online survey will consist of either easy-to-read response selections or embedded text boxes. Skip patterns will be programmed into the survey to direct respondents to appropriate questions. Screen shots of the web-based survey are shown in **Attachment D.** Respondents will also be given the choice of filling in Word versions of the instruments that can be returned by either email or fax. The survey was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 19 survey questions).

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

The information being collected is specific to the CDC MDDR testing service. Since this service is new and unique, there are no other data collection systems available for evaluation of this service. In addition, a review of the literature did not reveal any similar efforts to measure discordant results for drug susceptibility testing of isolates of MTBC.

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

No small businesses will be involved in this data collection.

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

The purpose of this request is determine if either Public Health Laboratory Directors or their designees experience difficulty interpreting MDDR results from CDC and to identify discordant results for drug susceptibility testing performed at CDC and at the local level. 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 either Public Health Laboratory Directors or their designees
- Negative patient outcomes if Public Health Laboratory Directors or their designees do not accurately report results to health care providers

There are no legal obstacles to reduce the burden.

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.

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. 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 sensitive information will be collected.

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

    The estimate for burden hours is based on a pilot test of both the survey and data collection instruments by nine randomly-selected Public Health Laboratory Directors or their designees from PHL who had previously submitted isolates to the MDDR testing service.

    In the pilot test, the average time to complete the survey including time for reviewing instructions, gathering needed information and completing the survey, was approximately 10 minutes. Based on these results, the estimated time range for actual respondents to

complete the survey is 10-15 minutes. For the purposes of estimating burden hours, the upper limit of this range (i.e., 15 minutes) is used for completion of the survey.

The estimated time to complete a data collection instrument for collecting local DST each isolate submitted to the MDDR testing service was approximately 5 minutes. Based on these results, the estimated time range for actual respondents to complete a data collection instrument for each isolate submitted to the MDDR testing service was 5-10 minutes. For purposes of estimating burden hours, the upper limit of this range (i.e., 10 minutes) is used for completion of a data collection instrument.

Survey and data collection instruments will be sent to 43 Public Health Laboratory Directors or their designees representing PHL (see **Attachment G**). The number of data collection instruments that each potential respondent will receive range from 1 to 29 based on the number of isolates submitted by each PHL to the MDDR testing service. An average of 7 data collection instruments per PHL will be used for calculation of burden hours. 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 43 respondents. Table A-12 shows estimated burden and cost information for each Public Health Laboratory Director or their designee to complete the MDDR survey and data collection instruments.

**Table A-12:** Estimated Annualized Burden Hours and Costs to Respondents – MDDR Survey and Data Collection Instruments

| Type of Respondent | Instrument | No. of Respondents | No. of Responses per Respondent | Average Burden per Response (in hours) | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|---|---|---|---|
| Public Health Laboratory Directors or their designees | Survey | 43 | 1 | 15/60 | 11 | $57.11 | $628.21 |
| Public Health Laboratory Directors or their designees | Data Collection Form | 43 | 7 | 10/60 | 50 | $57.11 | $2,885.50 |
| **TOTALS** | | **43** | **8** | | **61** | | **$3,513.71** |

**13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers**

There will be no direct costs to the respondents other than their time to participate in each survey.

**14. Annualized Cost to the Federal 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 Leaders from the Laboratory Capacity and Reference Teams. 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 $43.70 for GS-13 (step 3), $51.81 for GS-14 (step 3) and $72.37 for GS-15(step 10) were used to estimate staff costs. The estimated cost to the federal government is $18,248.80. 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-13)**<br>Instrument development, pilot testing, OMB package preparation, data collection, data coding and entry, quality control, data analysis, report preparation | 780 hours | $50.69 | $39,538.20 |
| **Microbiologist (GS-14), Team lead, Laboratory Capacity Team**<br>Instrument development, pilot testing, OMB package preparation, report preparation | 130 hours | $51.81 | $6735.30 |
| **Research Microbiologist (GS-15)**<br>Consultation, instrument development, and report preparation consultation. | 52 hours | $72.37 | $3763.24 |
| **Estimated Total Cost of Information Collection** | | | **$50,036.74** |

**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 survey questionnaire.....(COMPLETE)
- ✓ Develop survey protocol, instructions, and analysis plan.....(COMPLETE)
- ✓ Pilot test survey questionnaire.....(COMPLETE)
- ✓ Prepare OMB package.....(COMPLETE)
- ✓ Submit OMB package.....(COMPLETE)
- ❑ OMB approval.....(TBD)
- ❑ Conduct survey.....(Survey open 4 weeks)
- ❑ Completion of Data Collection Forms……..(4 weeks)
- ❑ Collect, code, enter, quality control, and analyze data.....(2 weeks)
- ❑ Prepare report.....(2 weeks)
- ❑ Disseminate results/reports.....(Date TBD)

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

CDC does not request exemption from display of the OMB expiration date.

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

There are no exceptions to the certification.

## LIST OF ATTACHMENTS – Section A

Note: Attachments are included as separate files as instructed.

A. **Report of Expert Consultations on Rapid Molecular Testing to Detect Drug-Resistant Tuberculosis in the United States**
B. **Authorizing Law**
C. **Survey Instrument-Word version**
D. **Survey Instrument-Web shot**
E. **Data Collection Instrument-Word version**
F. **Data Collection Instrument-Web shot**
G. **Public Health Laboratories and Isolates of *Mycobacterium tuberculosis* Complex submitted to the MDDR Testing Service**