Public Health Laboratory Testing for Emerging Antibiotic Resistance and Fungal Threats

Request for OMB approval of an Existing Collection in Use without an OMB Control Number

12/9/2019

Supporting Statement B

Contact:
Nancy Khalil, J.D.
MS H16-5
Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, Georgia 30329-4027
Phone: (770) 488-2070
Email: kuj2@cdc.gov

Table of Contents

1. Respondent Universe and Sampling Methods

State and local antibiotic resistance laboratory testing will be implemented in jurisdictional public health laboratories. The respondent universe currently includes all fifty states, four large cities, and Puerto Rico. This approach shows that the sites are located nationwide as a whole.

CDC recommends that isolates be collected from acute care hospitals at a minimum. If possible, isolate collection should be extended to other healthcare facilities where antimicrobial resistance can be a problem (e.g., long-term care facilities) due to high-risk facilities and/or patient populations. CDC also recommends screening patients to identify potential transmission of carbapenemase producing organisms. The number of specimens collected will depend upon the prevalence of resistance in the jurisdiction, the reporting and isolate submission laws in the jurisdiction, and the volume capabilities of the jurisdictional public health laboratory.

2. Procedures for the Collection of Information

Participating public health laboratories will work with healthcare facilities and clinical labs in their jurisdiction to submit isolates of *Candida* and targeted carbapenem-resistant organisms for testing. Some states require reporting of carbapenem-resistant *Enterobacteriaceae* (CRE), carbapenem-resistant *Pseudomonas aeruginosa* (CRPA), carbapenem-resistant *Acinetobacter baumannii* (CRAB) (Attachment 4) and/or *Candida* spp., including *C. auris* (Attachment 6). State and local CRE/CRPA/CRAB/*Candida* laboratory capacity is supported by the CDC's Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) funding instrument, with up to 55 awards (Attachment 5, "G2, Tiers 1 and 2", page 142).

Clinical facilities will send requested/required clinical specimens to their local public health laboratory for detection and characterization of novel and emerging resistance threats. The public health laboratory testing results for bacterial isolates will be reported back to the submitter within 2 working days of testing for isolates and one working day of testing for screening swabs. Testing results for *Candida* identification will be reported back to the submitter within 1 working day. Results will be reported to CDC at least monthly. If targeted AR threats that require immediate public health action are detected, the public health laboratory will alert the jurisdictional public health department and CDC within 1 working day to facilitate containment and prevention activities.

Participating state and local public health laboratories will use Forms 1, 2, 3, and 4 (Attachments 3a, 3b, 3c, 3d) to report data on bacterial specimens to CDC. Forms 5, 6, and 7 (Attachment 3e, 3f, 3g) will be used for report *Candida* identification data to CDC. All forms will be used in accordance with the following requirements and procedures:

1. Annually, participating laboratories will submit a summary report describing bacterial specimen testing and response methods and volume (Attachment 3a: Summary of Testing Methods). These reports can be submitted by email to ARLN_DHQP@cdc.gov. These measures are to be used by the Program Office (DHQP) to determine the ability of the laboratory to confirm and characterize AR organisms and their overall capacity to support state HAI/AR prevention programs.

2. Annually, participating laboratories will provide an Evaluation and Performance Measurement Report (Attachment 3b) on bacterial specimen testing to CDC via email to HAIAR@cdc.gov. Data will be used to indicate progress made toward program objectives and challenges encountered. Required performance measures for the project period are listed below:
    - Characterization of the clinical laboratory network in jurisdiction;
    - Median and range (in days) from receipt of isolates to communication of final mechanism testing and antibiotic susceptibility testing (AST) results to submitting laboratory;
    - For results identified as a defined "alert" by CDC:
        a. Median and range (in days) to communicate test results with alert values to CDC and HAI/AR program of originating jurisdiction;
    - Number of laboratory personnel trained to proficiency in performing all tests in their AR Lab Network test directory;
    - Proportion of isolates tested, and number of isolates tested by genera;
    - Number of isolates transported upon request to CDC;
    - Frequency and content of laboratory testing report or summaries shared with the HAI/AR program
    - For laboratories performing whole genome sequencing (WGS):
        a. Proportion of healthcare associated organism isolates tested by WGS that passed quality control in accordance with CDC testing protocols;
    - Proportion of colonization swabs tested with results returned to submitter, in accordance with timeline per CDC guidance;
    - Proportion of isolates tested for expanded drug susceptibility with results returned to submitter, in accordance with timeline per CDC guidance.

3. Annually, laboratories participating in *Candida* identification will provide an Evaluation and Performance Measurement Report (Attachment 3e) to CDC via email to ARLN@cdc.gov. Data will be used to indicate progress made toward program objectives and challenges encountered. Required performance measures for the project period are listed below:
    - Proportion of isolates tested;
    - Number of isolates tested by genera.

4. Participating laboratories will report all testing results to CDC (Attachment 3c and Attachment 3f, if applicable), requested at least monthly, by CSV or Health Level 7 (HL7) using an online web-portal transmission, or by REDCap for *Candida* identification. This information will be used to (1) provide data for state and local infection prevention programs, (2) identify new types of antibiotic resistant organisms, (3) identify new resistance mechanisms in targeted organisms, (4) describe the spread of targeted resistance mechanisms, and (5) identify geographical distribution of antibiotic resistance or other epidemiological trends. Participating laboratories will utilize secure public health messaging protocols to transfer results data to CDC and submitting facilities and clinical laboratories. For messaging to CDC, these messaging protocols will be based in Association of Public Health Laboratories (APHL) Informatics Messaging Services (AIMS) platform. The AIMS platform is a secure environment that provides shared services to assist public health laboratories in the transport, validation and routing of electronic data. AIMS is transitioning to the use of HL7 messaging for data to be transmitted in real-time, allowing more frequent reporting or results while simultaneously lessening burden on public health laboratories.

5. For those resistant organisms and resistance mechanisms that pose an immediate threat to patient safety and require rapid infection control, facility assessments, and/or additional diagnostics, an immediate communication to the local healthcare-associated infection program in the jurisdictional public health department and CDC is needed. The "AR Lab Network Alerts" encompass targeted AR threats that include new and rare plasmid-mediated ("jumping") carbapenemase genes, *C. auris* isolates, isolates resistant to key drugs or all drugs tested, and detection of human reservoirs for transmission. These alerts must be sent within 1 working day of detection. Participating laboratories will utilize REDCap and email to communicate these findings. The elements of these messages will include the unique public health laboratory specimen ID and a summary of its testing results to date.

The information obtained from AR Lab Network testing will be recorded in such a manner that human subjects cannot be identified directly or through specimen identifiers. No identifying information, such as names, birthdays and addresses, will be recorded in the data reported to CDC.

Data from all forms arriving at CDC will be logged, edited if necessary, and entered into secure folders or databases for processing and analysis. Related CDC personnel will visit or communicate with each site as needed to resolve data or reporting issues that may arise.

3. Methods to maximize Response Rates and Deal with No Response

Response to data collection requests is required as part of participation in the AR Laboratory Network. CDC only collects the minimum information necessary for the purpose of communicating isolate and case characteristics that will facilitate detection and response to resistance threats. The CDC program offices (Division of Healthcare Quality Promotion and Division of Foodborne, Waterborne, and Environmental Diseases) will contact member laboratories to offer assistance with submitting data or to resolve issues with no response.

Site visits and frequent communication between the CDC program office and individuals responsible for reporting data will contribute to higher response rates and reporting compliance. In order to maximize response rates, all information will be reported electronically to CDC.

4. Tests of Procedures or Methods to be undertaken

All laboratory testing should be implemented in accordance with current Clinical and Laboratory Standards Institute (CLSI) standards and in compliance with Clinical Laboratory Improvement Amendments (CLIA) regulations. Therefore, each participating laboratory is required to validate and adhere to standard protocols for all testing.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

CDC does not require the respondents (healthcare facilities, clinical laboratories, and participating jurisdictional public health laboratories) to perform statistical analysis.

CDC subject matter experts (SMEs) from the Division of Healthcare Quality Promotion (DHQP) or the Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) will collect and compile data, offer assistance with statistical needs, analyze the state and local AR laboratory testing data, and share summaries of these analyses with AR Lab Network stakeholders.

Specifically, data collection, management and analysis will be planned and performed by:
Clinical and Environmental Microbiology Branch
DHQP/NCEZID, Centers for Disease Control and Prevention
1600 Clifton Road, N.E.
Atlanta, Georgia 30333
Work Email: ARLN_DHQP@cdc.gov

Mycotics Diseases Branch
DFWED/NCEZID, Centers for Disease Control and Prevention
1600 Clifton Road, N.E.
Atlanta, Georgia 30333
Work Email: ARLN@cdc.gov