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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
[30Day-20-19AYV]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Public Health Laboratory Testing for Emerging Antibiotic Resistance and Fungal Threats to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on July 5th, 2019 to obtain comments from the public and affected agencies. CDC received one comment from the public. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of

the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Public Health Laboratory Testing for Emerging Antibiotic Resistance and Fungal Threats - Existing Collection in Use without an OMB Control Number - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This state and local laboratory testing capacity study is being implemented by the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC) in response to the Executive Order 13676 of September 18, 2014, the National Strategy of September 2014 and to implement sub-objective 2.1.1 of the National Action Plan of March 2015 for Combating Antibiotic Resistant Bacteria. Data collected throughout this network is also authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241).

The Antibiotic Resistance Laboratory Network (AR Lab Network) is made up of jurisdictional public health laboratories (i.e. all fifty states, four large cities, and Puerto Rico). These public health laboratories will be equipped to detect and characterize isolates of carbapenem-resistant Enterobacteriaceae (CRE), carbapenem-resistant *Pseudomonas aeruginosa* (CRPA), and carbapenem-resistant *Acinetobacter baumannii* (CRAB), as well as

carbapenemase-positive organisms (CPOs) from colonization screening swabs. These resistant bacteria are becoming more and more prevalent, particularly in healthcare settings, and are typically identified in clinical laboratories, but characterization is often limited. The laboratory testing will allow for additional testing and characterization, including use of gold-standard methods. Isolate characterization includes organism identification, antimicrobial susceptibility testing (AST) to confirm carbapenem resistance and determine susceptibility to new drugs of therapeutic and epidemiological importance, a phenotypic method to detect carbapenemase enzyme production, and molecular testing to identify the resistance mechanism(s). Screening swabs will undergo molecular testing to identify whether carbapenemase-producing organisms are present.

Results from this laboratory testing will be used to (1) identify targets for infection control, (2) detect new types of resistance, (3) characterize geographical distribution of resistance, (4) determine whether resistance mechanisms are spreading among organisms, people, and facilities, and (5) provide data that informs state and local public health surveillance and prevention activities and priorities.

Additionally, some jurisdictions will participate in reference identification of *Candida* spp. to aid in these pursuits using matrix-assisted laser desorption ionization/time-of-flight

(MALDI-TOF) mass spectrometry or deoxyribonucleic acid (DNA) based sequencing.

CDC's AR Lab Network supports nationwide lab capacity to rapidly detect antibiotic resistance and inform local public health responses to prevent spread and protect people. It closes the gap between local capabilities and the data needed to combat antibiotic resistance by providing comprehensive lab capacity and infrastructure for detecting antibiotic-resistant pathogens (germs), cutting-edge technology, like DNA sequencing, and rapid sharing of actionable data to drive infection control responses and help treat infections. This infrastructure allows the public health community to rapidly detect emerging antibiotic-resistant threats in healthcare and the community, mount a comprehensive local response, and better understand these deadly threats to quickly contain them.

Funded state and local public health laboratories will provide the following information to the Program Office at CDC - Division of Healthcare Quality Promotion (DHQP):

1. Annually, participating laboratories will submit a summary report describing testing methods and volume. These reports will 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 each laboratory to confirm and characterize targeted AR organisms and their overall

capacity to support state healthcare-associated infection (HAI)/AR prevention programs.

2. Annually, participating laboratories will provide Evaluation and Performance Measurement Report to CDC via email to HAIAR@cdc.gov. Data will be used to indicate progress made toward program objectives and challenges encountered.
3. Participating laboratories will report all testing results to CDC, at least monthly, by CSV or Health Level 7 (HL7) using an online web-portal transmission. 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 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 of results while simultaneously lessening burden on public health laboratories.

4. Detection of targeted 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, isolates resistant to all drugs tested, and detection of human reservoirs for transmission. These alerts must be sent within one working day of detection. Participating laboratories will utilize REDCap 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.

Sites participating in *Candida* identification testing will also provide the following to the Mycotics Program Office at CDC - Division of Foodborne, Waterborne, and Environmental Diseases (DFWED):

1. Annually, participating laboratories will provide an Evaluation and Performance Measurement Report to CDC via email to ARLN@cdc.gov. Data will be used to indicate progress made toward program objectives and challenges encountered.
2. Participating laboratories will report all testing results to CDC, requested at least monthly, by REDCap or Health Level 7 (HL7) using an online web-portal transmission. This information will be used to (1) identify and track antifungal resistance and emerging fungal pathogens, and (2) aid public health departments and healthcare facilities in rapidly responding to fungal public health threats and outbreaks. Participating laboratories will utilize secure public health messaging protocols to transfer results data to CDC, submitting facilities and clinical laboratories. For messaging to CDC, these messaging protocols will be based in REDCap or the AIMS platform. The REDCap and AIMS platforms are secure environments that provide 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 of results while simultaneously lessening burden on public health laboratories.

3. For those resistant organisms 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 *C. auris*, which is rapidly emerging in healthcare settings. These alerts must be sent within one working day of detection.

Participating laboratories will utilize REDCap and/or email to ARLN_alert@cdc.gov to communicate these findings. The elements of these messages will include the unique public health laboratory specimen ID and a summary of specimen testing results to date.

The estimated annualized burden hours were determined as follows. There are 55 public health laboratories within this framework. A "respondent" refers to a single participating testing public health laboratory. A "response" is defined as the data collection/processing associated with an individual specimen from an individual patient.

The average burden per response for the Annual Summary of testing methods was evaluated to be approximately six minutes.

The average burden per response for the Annual Evaluation and Performance Measurement Report was evaluated to be 4 hours

per report.

Based on previous laboratory experience in analyzing carbapenem-resistant isolates and specimens, the estimated time for each participating public health laboratory for Monthly Testing Results Report is four hours per response. Because of the need to add more data collection points as new drugs are developed, new susceptibility testing methods are made available, new resistance mechanisms emerge, and new pathogens are prioritized as threats, the Monthly Data Report includes some placeholder elements in expectation of evolving needs. For *Candida* identification, elements to include are fairly minimal (specimen ID, submitting laboratory ID, etc.) and the estimated time for each participating laboratory for the *Candida* Monthly Data Report is two hours.

The use of ARLN Alerts encompass targeted AR threats that include new and rare plasmid-mediated ("jumping") carbapenemase genes, isolates that are non-susceptible to all drugs tested, and detection of novel resistance mechanisms. These alerts must be sent within one working day of detection. The elements of these messages include the unique public health laboratory specimen ID and a summary of specimen testing results generated to date. With the conversion to HL7 messaging of these data will be transmitted in real-time, thus eliminating the need to send alerts. Until that time, REDCap will be utilized to communicate

alerts. CDC estimates that public health laboratories send an average of 34 ARLN Alerts per lab each year, with an estimated burden per response of 0.1 hours. The estimated burden of response for *Candida* identification is also 0.1 hours, though far fewer alerts are reported yearly (estimated to be approximately 700 total per year including all 55 jurisdictions, averaging to 13 per each jurisdiction).

The total estimated annualized burden across all AR Lab Network labs and activities for DHQP is 4555 hours. Public Health laboratories receive federal funds through CDC's Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) mechanism to participate in this project.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Public Health Laboratories	Annual Report of Testing Methods	55	1	6/60

Public Health Laboratories	Annual Evaluation and Performance Measurement Report	55	1	4
Public Health Laboratories	Monthly Testing Results Reports	55	12	4
Public Health Laboratories	ARLN Alerts	55	34	6/60
Public Health Laboratories	Annual Evaluation and Performance Measurement Report (<i>Candida</i> identification)	55	1	2
Public Health	Monthly Testing Results Reports	55	12	2

Laboratories	- <i>Candida</i> identification			
Public Health Laboratories	AR Lab Network Alerts - <i>Candida auris</i>	55	13	6/60

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