Public Health Laboratory Testing for Emerging Antibiotic Resistance and Fungal Threats

Revision of a Currently Approved Collection

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Supporting Statement B

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1. Respondent Universe and Sampling Methods

The respondent universe for antimicrobial resistance laboratory testing currently includes jurisdictional public health laboratories from fifty states, five large cities, Guam, and Puerto Rico.

Samples from patients with traditionally healthcare-associated pathogens (e.g., CRE, CRAB, CRPA, *Candida* spp.), community pathogens of concern (e.g., *Streptococcus pneumoniae, Haemophilus influenzae*, and *Neisseria gonorrhoeae*) are shipped from clinical laboratories and healthcare facilities to public health laboratories in the AR Lab Network for testing. Results from public health laboratory testing will be reported back to the submitters, to public health infection prevention programs, and to CDC.

CDC recommends that isolates be collected from acute care hospitals and STD clinics 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 traditionally healthcare-associated pathogens (e.g., carbapenemase-producing organisms, *Candida auris*). 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, Neisseria gonorrhoeae* and targeted carbapenem-resistant organisms for testing.

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. For *N. gonorrhoeae*, antimicrobial susceptibility testing results will be reported to the submitter in 7-10 days, and 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.

Funded state and local public health laboratories will provide the following information, using the indicated forms, to the Program Office at CDC - Division of Healthcare Quality Promotion (DHQP) about traditionally healthcare-associated bacterial pathogens, which include carbapenemase-producing organisms (CPOs) (i.e., CRE, CRAB, CRPA). These data will be collected in accordance to the descriptions below:

1. Annually, participating laboratories will submit a report summarizing testing methods and volume (Attachment 3a). These reports will be submitted via REDCap. These measures are to

be used by the Program Office (DHQP) to determine the ability of each laboratory to confirm and characterize carbapenemase-producing organisms and their overall capacity to support state healthcare-associated infection (HAI)/AR prevention programs.

2. Annually, participating laboratories will report on a set of Evaluation and Performance Measures (PMs) (Attachments 2a, 2b, 2d, 2f, 2q, 2s, 2t). Data will be entered into a data management platform that our ELC Partnering Office will determine (e.g., REDCap or CAMP). Data will be used to indicate progress made towards program objectives and challenges encountered.

3. Participating laboratories will report all testing results to CDC (Attachment 3b), 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 antimicrobial resistant organisms, (3) identify new resistance mechanisms in targeted organisms, (4) describe the spread of targeted resistance mechanisms, and (5) identify geographical distribution of antimicrobial resistance or other epidemiological trends. 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 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. For those resistant organisms and 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 for CPOs" serve this purpose of providing a platform of communicating important laboratory generated results with "those who need to know". 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 (Attachment 3c).

Funded state and local public health laboratories will provide the following information, using the indicated forms, to the Mycotics Program Office at CDC - Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) about traditionally healthcare-associated fungal pathogens, e.g., *Candida* spps. These data will be collected in accordance to the descriptions below:

1. Annually, participating laboratories will report on a set of Evaluation and Performance Measures (PMs) (Attachments 2b, 2c, 2e, 2p). Data will be entered into a data management platform that our ELC Partnering Office will determine (e.g., REDCap or Cooperative Agreement Management Platform [CAMP]). Data will be used to indicate progress made towards program objectives and challenges encountered.

2. Participating laboratories will report all *Candida* spp. testing results (e.g., organism identification, antifungal susceptibility testing, whole genome sequencing [WGS], colonization screening) to CDC (Attachments 3d and 3e), 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, (2) aid public health departments and healthcare facilities in rapidly responding to fungal public health threats and outbreaks, (3) support outbreak investigations (i.e., helping to identify new introductions and ongoing or undetected transmission), and (4) to monitor circulating clades and strains. 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 (in case of HL7). 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 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 (Attachment 3d).

4. Regional laboratories that perform testing for *Aspergillus fumigatus* report data to CDC using real-time HL7 transmission. This testing is provided as a service for clinicians since antifungal susceptibility testing for this pathogen is not widely available in the United States. Data collected are used to inform what is known about resistance in the United States. Although azole-resistant *A. fumigatus* currently appears to be uncommon in the United States, resistance has been increasingly detected in Europe and is associated with worse outcomes compared with azole-sensitive *A. fumigatus;* thus, ongoing monitoring in the United States remains a public health priority.

Funded state and local public health laboratories will provide the following information, using the indicated forms, to the Sexually Transmitted Disease (STD) Laboratory Reference and Research Branch (SLRRB) at CDC - Division of STD Prevention (DSTDP) on the detection and characterization *Neisseria gonorrhoeae.* These data will be collected in accordance to the descriptions below:

1. Annually, participating laboratories will provide an Evaluation and Performance Measure Report (Attachments 2h,2i, and 2u). Data will be used to indicate progress made toward program objectives and challenges encountered.

2. Participating laboratories will notify CDC DTSDP of any isolate(s) identified to demonstrate an "alert" minimal inhibitory concentration (MIC) as defined by SLRRB within one working day. Laboratories will utilize REDCap or email 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 (Attachment 3f).

3. Participating laboratories will report all testing results to CDC (Attachment 3f and 3g), requested at least monthly, by email, REDCap, or Health Level 7 (HL7) using an online web-portal transmission. This information will be used to support 1) national treatment recommendations, 2) local health departments determine distribution and use of STD prevention services and resources, guide prevention planning, and communicate best treatment practices to health care providers, and 3) aid public health departments and healthcare facilities in timely responding to antibiotic resistant gonorrhea. 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 currently supports CSV and HL7 but are working towards full HL7 implementation, allowing more frequent reporting of results while simultaneously lessening burden on public health laboratories.

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, Division of Foodborne, Waterborne, and Environmental Diseases, and Division of STD Prevention) 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), Division of Foodborne, Waterborne, and Environmental Diseases (DFWED), or Division of STD Prevention (DSTDP) 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:
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