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Peter Davies, BVSc, PhD
Co-Chair
Working Group on One Health Surveillance
Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

Elizabeth Jungman, JD, MPH
Co-Chair
Working Group on One Health Surveillance
Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

Dear Dr. Davies and Ms. Jungman:

Thank you for soliciting comments from the Infectious Diseases Society of America (IDSAs) to help inform your working group's discussions on the challenges faced in gathering and sharing antibiotic resistance (AR) data. As you know, IDSAs has long asserted that collecting and making publicly available data regarding antibiotic use and resistance patterns is critical to help guide and evaluate efforts to combat resistance. We are pleased to offer comments and recommendations regarding how best to organize a national public health network responsive to the need for identifying resistance as well as the development and utilization of specimen repositories in order to support measures to combat resistance. We hope this letter will be part of an ongoing dialogue between IDSAs and the Advisory Council, and we urge you to contact us at any time when we may be of assistance to your efforts.

1. How best to organize a national public health network responsive to the need for identifying antimicrobial resistance such that it has clinical relevance to the larger US healthcare system?

A comprehensive, coordinated approach to the collection of antibiotic use and resistance data is a critical component of our nation's broader efforts to combat resistance. Our surveillance system should be able identify new resistance as well as measure the burden of disease due to resistant pathogens and the proportion of priority pathogens that are resistant to first-line, second-line and last resort antibiotics. While this question is focused on identifying resistance, it is equally critical to collect and report data on antibiotic use given the impact of use on resistance.

Utilizing Public Health Infrastructure

To begin, IDSAs recommends utilizing and building upon existing public health infrastructure and reporting mechanisms and tools such as the Centers for Disease

Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) Antibiotic Use and Resistance (AUR) module. IDSA strongly supports the goal in the National Action Plan for Combating Antibiotic Resistant Bacteria (CARB) of 95% of Medicare-eligible hospitals and Department of Defense (DoD) and Veteran's Affairs (VA) health care facilities reporting data through the NHSN AUR module. We are encouraged by the \$3 million funding increase provided to NHSN for Fiscal Year (FY) 2016 and hope it will be useful in achieving this goal. Further, we urge the Advisory Council to recommend that the goal for using the NHSN AUR module be strengthened to include other types of healthcare facilities, particularly those associated with high rates of antibiotic use or resistance, including long term care facilities, dialysis centers and outpatient facilities. While many of the most highly resistant infections occur or are treated in hospitals, any approach to successfully combat resistance must include surveillance across the continuum of care.

CDC's Emerging Infections Program (EIP) is another existing resource that should be leveraged for this effort. This program is well suited to conduct population based surveillance critical for establishing incidence rates to determine the overall disease burden attributable to multidrug resistant infections and their resistance profiles. It should be noted that the EIP's work is very labor and resource intensive, and start-up time is needed to add a new pathogen to the EIP's surveillance capabilities. We are extremely encouraged that CDC's AR Solutions Initiative plans to double the number of EIP sites to expand tracking and that Congress is providing new funding for this effort for FY 2016. Geographic differences in antimicrobial resistance pose another potential limitation, making it critical that EIP surveillance efforts be well supplemented with activities that can provide more granular geographic and demographic data.

IDSA is extremely pleased that Congress is providing CDC with new funding in FY 2016 to establish a network of regional AR labs, which we believe will be helpful to further characterize isolates with concerning resistance patterns, to identify and evaluate new genetic mechanisms of resistance, and to assist in cluster or outbreak response by comparing strains. Also, it would be useful for this laboratory network to be able to characterize genetic mechanisms of resistance for highly resistant organisms such as carbapenem-resistant Enterobacteriaceae (CRE) for which there may be multiple genetic mechanisms that confer the phenotype. This would allow for a picture of the prevalence of *Klebsiella pneumoniae* Carbapenemase (KPC), New Delhi metallo-beta-lactamase (NDM), OXA-48-like Carbapenemases, and other variants and their spread in the US. These laboratories could also be activated to look for additional resistance genes that have been identified in other parts of the world, such as MCR-1 that was recently discovered in China and later found in other Asian countries and Europe. Lastly, laboratories in the new network will need to connect with state health departments, facilities, and clinicians.

Role of Health Care Facilities and ID Clinicians

While existing and soon-to-be developed public health infrastructure and tools will be critical components of the broader surveillance and data collection efforts, the public health system cannot accomplish these goals alone. Healthcare facilities and infectious diseases (ID) physicians and researchers will be necessary partners to provide content expertise, including epidemiology and knowledge of transmission and practical infection control in facilities.

Further, it must be recognized that resistance rates are typically highest in major medical centers that care for the most complex patients (including transplant patients and other immune-compromised patients) and in cancer hospitals. Therefore, major cancer, transplant, and other academic and other tertiary medical centers, as well as extended care facilities serving these centers, must be involved in surveillance efforts. While reporting data to NHSN is critical, IDSA also recommends that surveillance be done in at least a representative sampling of some high risk facilities or sentinel sites for more subtle changes such as increases in minimum inhibitory concentration (MIC) below the definition of resistance. Such data are often the first sign of a significant problem. The Advisory Council should recommend new federal funding to carry out this type of surveillance targeted to major hospitals in regions already known for being on the forefront of prior resistance emergence.

Surveillance and New Diagnostic Trends

The increasing use of non-culture based diagnostic tests adds some complexity to surveillance. IDSA has long championed the use of next generation diagnostic tests in order to provide the most rapid results in a point-of-care setting for maximum impact on treatment decisions and patient outcomes. However, it is challenging to do surveillance for some resistant pathogens (such as *Neisseria gonorrhoea*) for which the diagnosis is now typically made without culture and antimicrobial susceptibility testing. Non-culture based methods are becoming more popular for other pathogens as well, which likely means so there will soon be less susceptibility testing for *Campylobacter*, *Shigella*, *Salmonella* and others. As we move towards more non-culture based methods for more pathogens, we will need to figure out a way to keep an eye on new resistance mechanisms, such as possibly calling for culturing in cases of treatment failure or utilizing public health laboratories or the regional AR laboratories to culture an appropriate sample of specimens across facilities and geographic settings. We urge the Advisory Council to further consider how to address the surveillance challenges brought about by advances in diagnostic technologies and associated changes in diagnostic practices.

Public Availability of Data and Public Engagement

As we enhance our surveillance capabilities, it is critical that clinically relevant data be made available in real time and that data be regularly publicly reported. On the first point, Illinois and Chicago successfully utilize a multidrug resistant organism registry to immediately inform infection preventionists about patients with CRE. This rapid communication is critical for halting the spread of CRE within a facility or community and is a strong example of the many ways in which the public health system can support local communities. We urge the Advisory Council to consider mechanisms for implementing such best practices in additional states and communities. It is also important to disseminate data on a regular and timely basis to the clinical community and the public. This will help inform everyone about new and ongoing problems and the impact of ongoing efforts, and help build support at all levels of the community for combating resistance.

To further enhance participation of patients, consumers, families and community members, IDSA encourages the Advisory Council to recommend strengthening public awareness

campaigns about appropriate antibiotic use and antibiotic resistance. We have always supported CDC's Get Smart program, but recognize that its reach must be significantly expanded. We have appreciated recent studies unveiled during Get Smart Week that highlight state and regional differences in antibiotic resistance and use metrics, and recommend that more of these types of activities be undertaken to help identify best practices, drive improvement in areas of greatest need, and empower caregivers and patients with knowledge about appropriate antibiotic use and resistance.

Research on Best Practices

Once again, IDSA is delighted to see a strong commitment from the federal government to improving surveillance and data collection regarding antibiotic use and resistance. Our last point on this topic is that we must invest in research and evaluation to determine best practices for surveillance that keep pace with increasing patient and public health needs, emerging threats and technological capabilities, as well as research on how to translate surveillance into action that changes clinical practice to improve patient care and safety.

- 1. From a clinical infectious disease standpoint, please comment on the development and utilization of specimen repositories (U.S. government (USG) and external to the USG) beyond "typical" research-based initiatives in order to support measures intended to control the development and spread of antimicrobial resistant strains within communities and our healthcare institutions.**

IDSA agrees that specimen repositories are extremely useful efforts to combat resistance, including to help support the development of urgently needed new diagnostic tests and to support surveillance activities and efforts to control the development and spread of resistance. Repositories are needed to ensure that routine laboratories can access samples for quality control purposes. Specimens in repositories must be regularly updated to be sure that all known resistance genes are available.

Repositories maintained by CDC or state or local public health departments can be helpful for reportable or unusual ID cases. However, these repositories are often under resourced and, as a result, may be unable to meet the short timeframes necessary to impact clinical decision-making. While clinicians are independently seeking out private laboratories for this type of service, such an approach is obviously fraught with gaps. It would be very helpful to have reliable, federally supported repositories that would be able to take clinical isolates for testing, banking, and assessment of resistance patterns. It also would be helpful to receive information from these repositories about patients in the context of other patients and trends in the area. IDSA expects that many ID physicians would be willing to participate and donate small numbers of isolates to such repositories if they could in return receive information that would impact infection control and treatment.

In addition to supporting specific initiatives aimed at controlling the development and spread of resistant strains, specimen repositories can be particularly useful for diagnostic research and development (R&D). Accessing specimens, particularly for more rare pathogens, is currently a

key barrier in diagnostic development. Often the cost of accessing specimens may be prohibitive, particularly for smaller companies, or accessing needed specimens may simply not be possible or feasible. A repository that makes needed specimens easily and affordably available to researchers and diagnostics companies would be extremely valuable in stimulating diagnostic R&D.

IDSA recommends that the Advisory Council consider ways to build upon existing initiatives in this area. For example, the National Institute of Allergy and Infectious Disease (NIAID) funded Antibacterial Resistance Leadership Group (ARLG) established a [Virtual Biorepository \(VB\) Catalogue](#)¹, a web-based system that provides researchers with unique access to clinically well-characterized bacteria for the development of diagnostic tests and other research. The bacteria are already being collected through other ARLG research projects and are housed at multiple locations. This approach requires significantly less resources than traditional physically centralized biorepositories. Researchers are able to search the virtual biorepository catalogue to locate the samples they need. Additional funding for this project could allow for it to be expanded to include additional institutions, pathogens, and uses.

The more recently launched AR Isolate Bank, managed by the CDC and the Food and Drug Administration (FDA), stores and makes available microbial pathogens with well-characterized resistance profiles, primarily to support the development of new diagnostic tests and antibiotics. With appropriate support, the capacity and utility of this resource could be expanded upon to meet some of the additional needs described above.

Any expanded efforts regarding specimen repositories must include more regionally representative collections for surveillance and research purposes. The Advisory Council could consider drawing upon CDC's Active Bacterial Core (ABC) Surveillance system as one potential way for obtaining a broader array of geographically diverse specimens for federally supported repositories.

Once again, IDSA thank you for requesting our input on these important topics and we look forward to future opportunities to work with the Advisory Council. Should you have any questions, please contact Amanda Jezek, IDSA Vice President for Public Policy and Government Relations, at 703-740-4790 / ajezek@idsociety.org.

Sincerely,



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President, IDSA

¹ <https://arlg.org/laboratory-center-strain-access>