

13-SI-01

**Committee:** Surveillance

**Title:** Recommendations for strengthening public health surveillance of antimicrobial resistance in the United States

## I. Statement of the Problem:

### A. Background

The availability of effective antimicrobial agents for treatment of life-threatening infections was once taken for granted, but now clinicians are encountering infections caused by bacterial, mycobacterial, and fungal pathogens that are resistant to most, and sometimes all, available therapeutic agents. These pathogens are the focus of the Position Statement's call to action. Few drugs are in the developmental pipeline, and for many of the drugs that are developed, we can expect the emergence of resistance unless changes are implemented in how antimicrobial agents are used. Because of these factors, there is an increasing need to prevent the misuse of antimicrobial agents as well as the transmission of resistant pathogens. Prevention efforts are highly dependent upon accurate knowledge of where and when antimicrobial resistance occurs. Antimicrobial resistance was first recognized in the healthcare setting (e.g., penicillin-resistance in *Staphylococcus aureus*). Today, transmission of antimicrobial resistant pathogens also occurs in the community (e.g., methicillin-resistant *Staphylococcus aureus* [MRSA] skin infections in child daycare settings, foodborne infections from resistant bacteria transmitted through the food chain). In addition to this expansion of resistant pathogens to new populations or settings, resistance is emerging in an increasing number of pathogens. Significant resistance problems have been identified in nearly all species of pathogenic bacteria. Resistant fungal pathogens were reported soon after the development of new antifungal therapeutics. Although resistant tuberculosis is a limited threat in the United States, it is a significant problem abroad and importation is a continuous concern. Expansion of antimicrobial resistance problems to new pathogens, new populations, and new settings creates challenges for control and prevention.

Surveillance for antimicrobial resistance provides vital data on the emergence and spread of resistant pathogens. Early detection of resistance at the local and state level is important for studying the factors responsible for the emergence as well as preventing spread. We must identify and track antimicrobial resistance before we are fully able to construct control and prevention strategies. A standardized and comprehensive national system is needed; otherwise safety can only be assured in a few locations. Without a comprehensive antimicrobial resistance surveillance system in the United States patient and consumer safety cannot be assured. Preservation of the usefulness of antimicrobial agents requires a multi-pronged and comprehensive approach that includes judicious use, the support of new agent research, innovative new treatment options, healthcare quality improvement, program evaluation and surveillance.

A particularly important opportunity to prevent transmission occurs when patients who are infected or colonized with resistant pathogens are transferred from one healthcare facility to another. Unless the infection or colonization is identified, dissemination of antimicrobial resistance from one facility to another can occur. Another occurs when a highly resistant pathogen emerges in an animal population and is transferred to humans through food. To effectively recognize and respond to resistance problems, local, state, and national public health laboratories need sufficient staff and resources to provide molecular epidemiology information, confirmatory testing, and training for clinical laboratories. Clinical laboratories need to develop and maintain testing competencies, report data about pathogens and resistance patterns that are of public health concern, and exchange information with healthcare facilities and other clinical laboratories in their region that enable rapid identification, prevention, and control of resistance transmission among healthcare facilities. Antimicrobial resistance data are needed at the national level for setting priorities, developing national strategies, coordinating prevention and control efforts, and evaluating effectiveness of countermeasures. When new resistance emerges, awareness and action are needed at all jurisdictional levels for appropriate prevention

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measures, such as infection control in healthcare settings, mitigation of use of agents in animals, and identifying or developing laboratory methods for accurate detection of resistance.

### **B. New solutions are needed for comprehensive surveillance**

At present, surveillance for antimicrobial resistance is inadequate to contend with the rapidly evolving problem of resistance. New solutions are needed that build upon the strengths of existing infrastructure and provide more timely, comprehensive, and broadly applicable data about current and emerging antimicrobial resistance problems. Improved laboratory diagnostic tests and additional training for laboratories on detection of resistant pathogens are high priorities. Evaluation and dissemination of effective surveillance programs is imperative. Actions that strengthen public health surveillance of antimicrobial resistance should complement efforts aimed at improving clinical decision making about antimicrobial use and clinical performance benchmarking. A comprehensive surveillance strategy should provide timely, accurate and standardized data in the following four categories:

1. Early detection of new antimicrobial resistance
2. Monitoring the spread of antimicrobial resistance over time
3. Measuring the burden of infection, identifying at-risk populations, and evaluating interventions
4. Microbiological characterization of resistant pathogens

Presented below are descriptions of the data needed in each category, how these data are currently obtained, and an assessment of data gaps.

**1. Early detection of new antimicrobial resistance** – Routine antimicrobial testing typically occurs in healthcare laboratories and involves the collection of a specimen from a patient, culture of the pathogenic bacterium or fungus from that specimen using traditional microbiologic methods, and susceptibility testing of the resulting pure bacterial or fungal isolate. Pathogens with unusual or previously unrecognized resistance are usually sent to a reference laboratory, either at the State Health Department or CDC, for confirmation of results and characterization of resistance mechanisms. New or emerging resistance is typically detected in this fashion and if testing is available in local or state public health laboratories, rapid analysis and early detection are feasible. Alternatively new resistance may be detected by sentinel surveillance systems (i.e., isolate-based surveillance in which random isolates of a pathogen are collected and characterized for antimicrobial resistance). For example, enteric pathogens such as *Shigella* and *Salmonella* are not always tested for antimicrobial resistance in the healthcare laboratory, but the National Antimicrobial Monitoring System (NARMS) is in place to ensure that representative isolates are sent to a CDC reference laboratory for antimicrobial resistance testing. Both methods of detecting new resistance, reference laboratory services and sentinel surveillance programs like NARMS, have resulted in the identification of significant antimicrobial resistance threats. However, important resistance can be missed if it is not recognized as novel or important at the healthcare laboratory or if it is infrequent, and sentinel surveillance is not broad enough or sensitive enough to detect it. The primary laboratory techniques used to identify microorganisms in clinical specimens are changing. Although not yet widely available many of the newer techniques are genetic or antigen based and therefore do not produce a pure culture isolate for antimicrobial susceptibility testing. These culture-independent diagnostic tests (CIDTs) have many implications for antimicrobial resistance testing and reporting. If CIDTs reduce or replace the use of traditional culture-based methods, strategies will be needed to ensure that isolates are available for more comprehensive testing for antimicrobial resistance.

**2. Monitoring the dissemination of antimicrobial resistance over time** – Antimicrobial resistance often emerges in a limited geographic region and then disseminates. Understanding this dynamic is important for focusing control and prevention efforts. Current mechanisms to map and track dissemination are limited. A success story is the national requirement for public health reporting of vancomycin-resistant *S.*

*aureus* (VRSA). This requirement has resulted in the identification of 13 VRSA cases in the United States since 2000, with most of the cases occurring in limited geographical areas. Since VRSA cases are infrequent, identified at the rate of a case every one to two years, mandated public reporting has been very effective for tracking resistance and for developing prevention strategies. Rarely do resistance problems emerge this slowly. In contrast, carbapenem-resistant *Enterobacteriaceae* (CRE) was first identified in North Carolina in 1998. By 2001, outbreaks were identified in several locations including New York City. In 2012, CRE cases have been identified in nearly every state and in several cities CRE has become endemic in healthcare institutions. CRE infections are resistant to nearly all available antimicrobials. If CRE dissemination is not slowed, it will likely spread from healthcare into community settings as has occurred with cephalosporin-resistant *E. coli* and MRSA. Widespread colonization of people by resistant organisms in the community is of grave concern as this will provide a nearly inexhaustible supply of resistant pathogens into healthcare settings. For this reason it is essential that antimicrobial resistant threats such as CRE be identified early and tracked for geographical dissemination over time so that appropriate prevention interventions can be put in place. Sometimes resistance emerges in many locations during the same timeframe. For example, penta-resistant *Salmonella* serotype Typhimurium emerged in cattle and humans in Europe in the early 1990s. NARMS surveillance did not yet exist in the United States, so clinicians and public health officials were unaware of this emerging pathogen. By the time representative surveillance was available in 1996, 35 percent of the Typhimurium isolates from humans were resistant to the 5 drugs associated with the resistance in Europe.

### **3. Measuring the burden of infection, identifying at-risk populations, and evaluating interventions –**

Surveillance for antimicrobial resistant organisms should enable enumeration of the extent of the problem, provide sufficient clinical and demographic information to characterize the affected populations, and serve as a means for systematically and comparably evaluating programs designed to prevent or control resistance. Identifying populations at greatest risk for antimicrobial resistant organisms is necessary to allocate resources, focus interventions, and evaluate the effectiveness of countermeasures. Adherence to sound surveillance practice means assuring that data are collected in a planned and rigorous manner, with close attention to accepted standards, analyzed systematically, and disseminated to those who need to know. Examples of existing surveillance systems include the Active Bacterial Core surveillance (ABCs) system and the Healthcare-Associated Infections Community Interface (HAIC) project (<http://www.cdc.gov/hai/eip/>), which are conducted via the Emerging Infection Program (EIP) network. Data can also be collected through linkage of population-based surveillance programs like the Foodborne Diseases Active Surveillance System (FoodNet, which is conducted via the EIP network) with a sentinel laboratory surveillance program like NARMS. Population-based surveillance can provide estimates of disease that can be used to track national goals, and some case-based surveillance systems provide detailed demographic and clinical features of infected patients. However, case-based surveillance is resource intensive and as a result is limited in the number of resistance problems that can be monitored and the number of sites where surveillance is conducted. Programs such as ABCs, HAIC, and FoodNet should be complemented by surveillance for antimicrobial resistance across a broader or more wide-scaled range of communities and key pathogens. Broad surveillance for antimicrobial resistance is desirable, but this requires collecting less information about individual cases of resistance. However, the information would allow for more directed and strategic use of population- or case-based surveillance.

### **4. Microbiological characterization of resistant pathogens –**

The collection of resistant isolates is often an important part of an antimicrobial resistance surveillance system. Collecting isolates enables laboratory characterization of the antimicrobial resistance profile, associated resistance mechanisms, and features of the isolates' molecular epidemiology. This type of information is necessary for developing new diagnostic tests to detect resistance, making recommendations for detecting resistance, and developing effective vaccines and new antimicrobial drugs. Further characterization of resistance mechanisms and other pertinent molecular "fingerprints" can also improve understanding of resistance in the context of local, national, and international transmission patterns of the pathogen in question and related pathogens. CDC conducts multiple surveillance programs which include isolate collection, for example ABCs, HAIC, the Gonococcal Isolate Surveillance Project (GISP), and NARMS. Most of these programs are in the EIP network or the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) program and all of

them are individually designed to collect isolates in the most efficient manner possible since this is a resource-intensive activity. Similarly, broad surveillance of antimicrobial resistance could complement existing isolate-based surveillance efforts by facilitating targeted collection of isolates with novel resistance when it is identified, thereby making the overall surveillance for resistance more representative.

### **C. Antimicrobial resistance surveillance at the local, state, and federal levels**

Broad agreement exists among most state and local health departments that they should identify, monitor, and respond to antimicrobial resistance problems, both in their own jurisdictions and, through collaborative arrangements, in larger geographic regions in which their jurisdictions are located. Although consensus has been achieved on the importance of antimicrobial resistance surveillance for public health purposes, further work is needed to clarify the roles, responsibilities, and returns on investment expected for health departments and laboratories. State and local health departments and public health laboratories vary widely in their resources for collecting and analyzing antimicrobial resistance data and test isolates that lead to actions in response to antimicrobial resistance problems that are identified or confirmed. A “one size fits all” approach to designing, developing, and maintaining state and local surveillance systems is unlikely to be successful. An alternative approach, with better prospects for success, is one that takes into account resource differentials across state- and local- health departments, near- and longer- term priorities for antimicrobial resistance surveillance, the role of federal surveillance systems and support, and the practical value at the state and local levels of step-wise development that seeks to accomplish basic and advanced objectives in sequence but takes both into account in strategic planning and implementation.

Some national surveillance programs that address antimicrobial resistance were developed to meet a primary public health objective other than antimicrobial resistance surveillance, and although they have evolved to meet some needs for antimicrobial resistance data, gaps persist. For example, the ABCs system (<http://www.cdc.gov/abcs/index.html>) in the EIP network (<http://www.cdc.gov/ncezid/dpei/eip/index.html>) was designed to measure the burden of community-acquired invasive bacterial infections that typically manifest as sepsis and meningitis. It has become a critical program for tracking antimicrobial resistance in *Streptococcus pneumoniae* and for monitoring the impact of new vaccines on the burden of resistant *S. pneumoniae* infections. Similarly, a primary purpose of the National Healthcare Safety Network (NHSN) was to track healthcare-associated infections, but it also has been the primary source of antimicrobial resistance data for pathogens causing these infections. With the dissemination of antimicrobial resistance to new pathogens and new populations, current surveillance for antimicrobial resistance is insufficient. For example, infections caused by cephalosporin-resistant *Escherichia coli* used to be limited to healthcare-associated infections and were monitored in NHSN. However, these resistant bacteria have emerged as an important cause of urinary tract infection outside of the healthcare setting. Patients with these infections represent a significant new reservoir for further dissemination of multi-drug resistant pathogens. An EIP-based surveillance program is in development to detect and track this evolving antimicrobial resistance threat, but effective management of a program such as this requires high-level national coordination and significant state-based resources. Although NARMS was developed to conduct surveillance for antimicrobial resistance, it gathers only basic demographic data about patients. Data about hospitalization and death is available only for the very small proportion of isolates that are also available in the FoodNet surveillance system.

### **D. Electronic laboratory reporting (ELR) and antimicrobial resistance surveillance**

In concept, at least, electronic laboratory reporting (ELR) has great potential to help strengthen antimicrobial resistance surveillance because it can provide timely antimicrobial resistance data that can be used by state and local health departments to identify new and rapidly evolving antimicrobial resistance problems. Depending on the extent of geographic coverage, ELR also can enable more comprehensive and ongoing analyses of the public health burden of antimicrobial resistance within and across jurisdictions. However, state and local health departments’ capacities for antimicrobial resistance surveillance often are limited by shortcomings in the available data or by shortages in staff and resources needed for in-depth analysis of antimicrobial resistance data or even maintenance of a basic surveillance program that targets known problems. Large national and regional laboratories have developed capacity to produce ELR messages, but the content of those messages often includes laboratory results that lack key information or the content is not

expressed in a machine-processable form. If ELR messages contain unstructured, non-standard expressions of microbiology results, further work is needed on the receiving side to process and standardize the data. Further, many smaller laboratories do not yet have the capacity to produce ELR messages. Implementation of ELR has been uneven across public health jurisdictions in the U.S., and even where ELR has been deployed, uncertainties about sufficient staff and resources delay full implementation and jeopardize maintenance of ELR programs. Staff is needed for outreach to laboratories, training, technical support, and analysis and use of the ELR data. To insure interoperability between sending and receiving systems, laboratories must comply with prevailing standards for expressing, formatting, and conveying microbiology results data. Receiving systems, in turn, must maintain their technical capacity for receiving ELR messages and their workforce capacity for analyzing and using the data they receive.

ELR-based surveillance for antimicrobial resistance must include sufficient patient information to meet the needs of various programs and users. All surveillance programs need to describe basic patient information such as age, sex, and specimen source. In addition, programs that monitor the spread of resistant healthcare-associated infections need to know the patient location within a healthcare facility when the infection occurred. Programs that monitor the burden of antimicrobial resistant community-associated infections need to know at least the patient's county of residence and preferably more discrete geographic information. Local, state, and national public health agencies that respond to outbreaks of resistant infections need sufficient patient identifiers to be able to link one laboratory result to a patient's healthcare record, including other laboratory results.

An ideal ELR-based antimicrobial resistance surveillance system should allow uniform acquisition and communication of the types of antimicrobial susceptibility data that are currently available, and should also easily accommodate other types of data obtained from the culture-independent methods that will complement or replace traditional culture-based methods. Leveraging existing ELR programs, and implementing them where they have yet to be initiated, represent important opportunities to enhance near real-time antimicrobial resistance reporting for the same reasons that ELR has had a positive impact on infectious disease reporting.

#### **E. Improvements in ELR are not enough to strengthen antimicrobial resistance surveillance**

Strengthening antimicrobial resistance surveillance requires more than improving ELR. Additional needs must be met. These include the availability of accurate methods for antimicrobial susceptibility testing in laboratories, standardized interpretive criteria or breakpoints for reporting susceptibility testing results, and standard terminology for reporting of ELR messages. Antimicrobial susceptibility testing methods need ongoing verification and updating when new resistance emerges and it is important that these systems can implement revised breakpoints in timely manner. To the extent possible, new and revised breakpoints must be harmonized among regulators and standard setting organizations rapidly so that laboratories and laboratory equipment manufacturers have standard criteria for identifying and reporting resistance. Accurate laboratory methods and standardized breakpoints are necessary for the collection of high-quality, consistent data. Once these data are generated, they need to be transmitted using standard terminology.

Laboratory information management systems (LIMS) used to acquire, store, and transmit diagnostic microbiology results are the primary source systems for reporting antimicrobial resistance data to public health agencies. However, the ways in which LIMS are used in clinical practice, in particular the suppression of some antimicrobial susceptibility test results for cost reasons or to prevent agent overuse that could drive resistance, often exerts an adverse impact on antimicrobial resistance reporting to public health surveillance systems and infection control programs. Strategies and rules are needed to assure that the supply of antimicrobial resistance data to public health surveillance systems is not impeded by suppression of some test results that may be withheld from clinical end users.

The test methods that form the basis for surveillance of disease and antimicrobial resistance are changing, and unless a method is devised to link data from traditional culture-based methods with data from newer test methods, information central to the prevention and control of disease and antimicrobial resistance could be lost. For decades, bacterial, mycobacterial, and fungal infections have been diagnosed by traditional

microbiological culture followed by antimicrobial susceptibility testing of the microorganism responsible for the infection. Capturing and maintaining isolates of the microorganisms that cause infections are imperative because, as diseases and diagnostic tests change, isolate collections are the key resource for understanding how new laboratory tests perform, how a new variant of a disease differs from that previously seen, and whether patients' infections are likely to respond successfully to treatment with a new drug. CIDTs detect features such as DNA sequences of specific microorganisms. These newer tests can be used directly on patient samples, and do not require traditional culture of the microorganism. CIDTs often yield results that are much faster and more sensitive than traditional culture-based tests, a factor that provides a huge benefit for individual patient management. However, there are two important challenges associated with CIDTs that need to be addressed. First, widespread adoption of CIDTs by clinical and public health laboratories could end the supply of isolates and current types of data that are central to clinical and public health communication and decision-making. Scientists and those who develop electronic systems to manage laboratory data must find ways to anchor results from new CIDTs to data from traditional culture-based tests so that CIDTs build on what we already understand from decades of using traditional culture-based tests. Culture-based tests will need to be performed along with CIDTs for the foreseeable future so that we fully understand the meaning of various CIDT results (such as presence of DNA sequences that might predict antimicrobial resistance) in the context of what we already know about the biology and epidemiology of a disease (e.g., the actual antimicrobial resistance the microorganism shows in a traditional culture-based antimicrobial susceptibility test). Many different CIDTs are being developed, which could complicate standardization of reporting. The second challenge is that CIDTs are not currently capable of detecting novel antimicrobial resistance. This is because CIDTs are developed to measure features (such as DNA sequences) responsible for biological functions that have already been identified by traditional culture-based tests (e.g. a traditional antimicrobial susceptibility test). Some degree of traditional culture-based testing will need to be performed long-term to inform CIDT development as novel mechanisms of antimicrobial resistance emerge.

CIDTs are already used widely to diagnose gonorrhea infections and, although there is effective isolate-based surveillance for gonorrhea in sentinel sites, it is difficult to know the scope or trends of cephalosporin- resistant gonorrhea infections beyond the cities included in the sentinel surveillance. Many clinical laboratories no longer maintain expertise in the culture-based methods needed to isolate the bacterium that causes gonorrhea, and since the CIDTs available for detecting gonorrhea do not detect antimicrobial resistance, clinical laboratories have no way to assess if a given patient's infection is resistant or not. Outside the sentinel surveillance areas, resistance would only be recognized clinically, when a patient's infection persists or worsens despite treatment with antimicrobials.

#### **F. Concerted action is needed to improve antimicrobial resistance surveillance**

Strengthening public health surveillance of antimicrobial resistance will require a concerted effort by CDC, CSTE, and individual state and local health departments coupled with active participation by other organizations that have major roles in delivering or using those data for analysis and action. Strategic objectives include (1) better defining and coordinating the responsibilities of surveillance systems at all jurisdictional levels for early detection and ongoing monitoring of antimicrobial resistance problems, (2) establishing strategies and rules for safeguarding against suppression of antimicrobial susceptibility test results when those results are delivered from LIMS to public health surveillance systems, (3) assuring that ELR serves the dual purpose needs of communicable disease and antimicrobial resistance reporting at the local, state, and national levels, (4) enabling antimicrobial resistance surveillance systems to take full advantage of a shared technical infrastructure on the sending side for microbiology results reporting while preserving and enhancing their capacity to meet additional jurisdictional- or program-specific needs that go beyond ELR messages, (5) identifying and coordinating a response to the challenges and opportunities that multiple antimicrobial resistance surveillance systems face as a result of changes in diagnostic microbiology technology and practices, (6) taking full advantage of public-private partnerships and policy levers that can be applied to further streamline and standardize the delivery of antimicrobial resistance data to public health surveillance systems, and (7) recommending models for communicating antimicrobial resistance data to healthcare practitioners, policymakers, and the public in actionable forms to promote and inform antimicrobial resistance prevention programs.



Achieving these strategic objectives and others needed to strengthen public health surveillance of antimicrobial resistance calls for a national initiative that is catalyzed and coordinated by CDC and CSTE.

## **II. Statement of the desired action(s) to be taken:**

In federal fiscal year 2014, CDC should provide resources and staff to support a three-year project in which CDC program and CSTE representatives serving on a antimicrobial resistance surveillance task force would commit time and effort to identifying, developing, and putting into practice scientific, technical, and policy solutions needed to strengthen surveillance. Representation and input from other government agencies and private sector organizations, including commercial laboratories, will be needed to assure a broad base of support, wide adoption of task force recommendations, and the best outcomes.

## **III. Public health impact:**

A successful response to the challenges and opportunities that multiple antimicrobial resistance surveillance systems are encountering will yield benefits for analysis and action at all jurisdictional levels and across all categorical disease programs. More timely detection of new problems, more comprehensive coverage of temporal and geographic trends, and improved capacity to measure public health burden and characterize the microbiology of resistant pathogens are achievable through a concerted effort. No single system can meet all needs, but a singularly well-organized initiative will help assure that scarce resources are focused on cross-cutting priorities and support systems that are optimally integrated and operating as efficiently and effectively as possible.

## **IV. References**

## **V. Coordination**

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