



July 23, 2019

The Honorable Robert Casey
Committee on Health, Education, Labor, and Pensions
United States Senate
393 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Johnny Isakson
Committee on Health, Education, Labor, and Pension
United States Senate
131 Russell Senate Office Building
Washington, DC 20510

Re: Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act (S. 1712)

Dear Senators Casey and Isakson:

AdvaMedDx commends and supports your commitment to addressing the growing public health threat of antimicrobial resistance as demonstrated by your leadership on the DISARM Act. As reported by the Centers for Disease Control and Prevention, antimicrobial resistance is the third leading cause of death in the United States. Antimicrobial resistance threatens our ability to effectively treat infectious diseases and safely manage medical procedures such as major surgery and cancer chemotherapy. Antimicrobial resistance also drives up healthcare costs and threatens medical innovation.

Antibiotic stewardship programs (ASP) in hospital settings have been demonstrated to play a pivotal role in ensuring appropriate antibiotic use and improving patient outcomes. We were especially pleased that the DISARM Act recognizes the critical importance of antimicrobial stewardship in hospitals by requiring for eligibility for additional payments under the Act that hospitals have, “an antimicrobial stewardship program that aligns with the Core Elements of Hospital Antibiotic Stewardship Programs of the Centers for Disease Control and Prevention or the Antimicrobial Stewardship Standard set by the Joint Commission.” Such requirements in all hospitals will slow the development of resistance.

AdvaMedDx, a division of the Advanced Medical Technology Association (or AdvaMed), represents the world’s leading manufacturers of medical diagnostic tests, including those that are front line tools in the fight against antimicrobial resistance. Diagnostic tests are a critical component in any strategy to address the threat of antimicrobial resistance – especially in ASPs. These innovative tests can be used to identify, monitor, and track resistance, and inform judicious ordering of antibiotics. Proper utilization of diagnostic tests can improve patient care by reducing the use of unnecessary antibiotics while ensuring targeted use of appropriate antibiotics. Furthermore, while diagnostic tests inform patient management decisions, they also may influence institutional infection control protocols.

The DISARM Act aims to strengthen the antimicrobial research and development pipeline to ensure that patients who are infected with drug-resistant infections have access to new, effective treatments. Diagnostic tests are critical to preserving the efficacy of new antimicrobial drugs. Such tests help to preclude the overuse and misuse of antibiotics that leads to resistance and poor patient outcomes. The proper utilization of diagnostic tests to adequately safeguard newly developed antimicrobials is paramount given the continual challenges posed in the development and commercialization of these new treatments.

There are opportunities to augment the existing CDC Core Elements and Joint Commission Standards to more appropriately emphasize the role and importance of the laboratory and point of care diagnostic testing in antimicrobial stewardship. AdvaMedDx, led by its members' medical experts with clinical backgrounds and knowledge of hospital operations, has developed a set of diagnostics stewardship recommendations that would bolster antimicrobial stewardship programs through meaningful integration of laboratory expertise and diagnostics tests in delivery of patient care.

We encourage you to consider incorporating stronger diagnostic stewardship elements to bolster the antimicrobial stewardship program requirements outlined in the DISARM Act, and support efforts to strengthen stewardship requirements across public and private healthcare programs to help achieve the ultimate goals of the DISARM Act.

AdvaMedDx's diagnostic stewardship recommendations include:

1. **Ensuring a laboratory director is made part of ASP leadership.** Given the prominent and critical role of a hospital laboratory in an ASP, laboratory leadership and accountability are necessary for the success and sustainability of an ASP.
2. **Measuring and shortening the duration between sample and test result availability for more timely use of test results to guide patient care, including through point of care tests that can bring testing closer to the patient.** Time matters a great deal to patients who are sick and are initially presented with non-specific but potentially severe symptoms. Complicated work flows can lead to significant delays in delivery of test results to treating clinicians as well as delays in leveraging results in patient care. Measuring critical time frames and reporting average time frames back to ASP leaders can help incentivize hospital-specific efficiencies in work flow. Furthermore, tying these data to patient outcomes could be a powerful tool that can lead to improved patient care and outcomes.
3. **Maximizing use of clinical decision support systems that incorporate evidence-based diagnostic testing.** A major key to operationalizing several of these recommendations is the successful implementation of data analysis solutions. Laboratory and clinical electronic data can be leveraged to identify, measure, and report key data points. Data analysis solutions are essential in enabling information capture and sharing in line with clinical workflow.
4. **Generating consumable and concise reports on test results to foster confidence among clinicians in how best to understand and leverage test results.** Laboratory reports, such as susceptibility results, should be presented in a manner that is consumable by the average treating physician, independent of

specialized training in infectious diseases, to enable informed antibiotic treatment decisions and avoid delays.

Attached to this letter is AdvaMedDx's complete set of recommendations.

As the legislative process advances, AdvaMedDx and our members offer our assistance and resources should you need additional information regarding the development and utility of diagnostic tests.

Thank you for your leadership on this critically important issue. We look forward to working with you in this fight against antibiotic resistance.

Sincerely,



Susan Van Meter
Executive Director
AdvaMedDx

Enclosure: AdvaMedDx Inpatient Hospital Diagnostic Stewardship Recommendations to Bolster Antimicrobial Stewardship Programs



July 23, 2019

AdvaMedDx Inpatient Hospital Diagnostic Stewardship Recommendations to Bolster Antimicrobial Stewardship Programs

AdvaMedDx, which operates as a division of the Advanced Medical Technology Association (or AdvaMed), represents the world's leading manufacturers of medical diagnostic tests, including those that are front line tools in the fight against antimicrobial resistance. Diagnostic tests are a critical component in any strategy to address the threat of antimicrobial resistance. These innovative tests can be used to identify, monitor, and track resistance, and inform judicious ordering of antibiotics. Proper utilization of diagnostic tests can improve patient care by reducing the use of unnecessary antibiotics while ensuring targeted use of appropriate antibiotics. Furthermore, diagnostic tests not only inform patient management decisions but may influence institutional infection control protocols.

In the inpatient hospital setting, antibiotic stewardship programs (ASP) serve a pivotal role in ensuring appropriate antibiotic use and improving patient outcomes. ASPs can optimize the treatment of infections and reduce adverse events associated with antibiotic use. Importantly, the Centers for Disease Control and Prevention's (CDC) Antimicrobial Stewardship Core Elements and the Joint Commission's Antimicrobial Stewardship standards are guiding hospitals in establishing ASPs to address the misuse of antibiotics.

AdvaMedDx believes there are opportunities to augment the existing CDC Core Elements and Joint Commission Standard to more appropriately emphasize the role and importance of the laboratory and point of care diagnostic testing in antimicrobial stewardship. AdvaMedDx, led by its members' medical experts with clinical backgrounds and knowledge of hospital operations, has developed a set of diagnostics stewardship recommendations that would bolster antimicrobial stewardship programs through meaningful integration of laboratory expertise and diagnostics tests in delivery of patient care. Those recommendations are summarized below:

I. Elevate the role of laboratory director, or equivalent, from “support,” to a co-leadership position of a hospital's ASP, alongside an infectious disease physician and pharmacist, to ensure that the core functions and expertise required of an ASP are adequately represented and accountable at the highest level.

Given the prominent and critical role of a hospital laboratory in an ASP, laboratory leadership and accountability are necessary for the success and sustainability of an ASP. The CDC Core Elements acknowledges the role of diagnostic testing in ASPs, labeling these laboratory elements as key support functions. AdvaMedDx believes that diagnostic testing and laboratory leadership play a central role in ASPs and the CoE program criteria should be modified to reflect an elevated positioning of laboratory leaders.

The value of including a laboratory leader as a co-leader of the ASP cannot be understated. Ordering physicians and pharmacists alone may not be aware of the full suite of testing options that are available, nor how to leverage the results of diagnostics tests. Hospital laboratories and their professional staff perform the diagnostic testing, analyze the data, and return the results to the treating medical team. Laboratory leadership is essential in educating hospital senior leaders leading ASPs on the latest developments in infectious disease diagnostic testing, as well as in conducting, guiding, and planning for the surveillance, detection, and prevention of infectious organisms, reporting of emerging pathogens, and tracking of antibiotic use and resistance trends in the hospital and community setting. In addition to technical expertise, priority should be given to including a laboratory



director or equivalent who has a broad view of hospital finance and is able to appreciate the value of diagnostic tests over episodes of patient care and across the patient population as an ASP co-leader.

Further, ASP leaders should prioritize ensuring nurse managers and quality officer are empowered as critical partners in stewardship. Finally, ASP leaders should embrace deliberate and ongoing stewardship education of clinical and non-clinical staff, including infection control experts, who all play key roles in operationalizing an ASPs.

II. Improve efficiencies in clinical work flow and leverage diagnostic test results to improve patient health and health care by measuring and reducing four critical time frames.

- a. Four time frames should be measured: 1) the time from when a clinician orders a test to when the laboratory receives the order and specimen; 2) from when a test is ordered to when the test is performed; 3) from when the test is complete to when it is made available in the electronic health record (EHR); and 4) from when the results are accessible to the treating physician to when he/she leverages the results in clinical decision-making.**

Time matters a great deal to patients who are sick and are initially presented with non-specific but potentially severe symptoms. Traditional susceptibility testing assays require 18-24 hours of incubation, but rapid diagnostic tests are becoming increasingly available that may provide results in under 24 hours. However, complicated work flows can lead to significant delays in delivery of test results to treating clinicians as well as delays in leveraging results in patient care. Measuring critical time frames and reporting average time frames back to ASP leaders can help incentivize hospital-specific efficiencies in work flow.

AdvaMedDx strongly recommends applying measures at four key laboratory and clinical workflow phases to narrow the time gap: 1) the time from when a clinician orders a test to when the laboratory receives the order and specimen, 2) from when a test is ordered to when the test is performed, 3) from when the test is complete to when it is made available in the EHR; and 4) from when the results are accessible to the treating physician to when he/she leverages the results in clinical decision-making.

- b. The four critical time frames should be reported back to ASP program leadership and participants. Tying these data to patient outcomes could be a powerful tool in generating workflow efficiencies that can lead to improved patient care and outcomes.**

We encourage hospitals provide the timeframe data back to ASP leadership and participants so that it can be considered in the oversight of their ASP. As data is collected, it should be tied to patient outcomes, summarized, and reviewed by ASP participants routinely. This could serve as affirmation for ASPs that are performing efficiently and as a signal for others that improvements may be needed. A similar mechanism for individual clinician feedback on adherence to ASP clinical guidelines could also be constructive in influencing positive change in antibiotic ordering practices. Proactive sharing of these data, at both an institutional and individual clinician level, could serve as a powerful tool to allow clinicians to examine their performance compared to their peers, making the necessary changes to achieve the ASP objectives.

Key to operationalizing this recommendation, and others in this letter, is the successful implementation of data analysis solutions that include laboratory modules and clinical decision support tools. Laboratory and clinical electronic data can be leveraged to identify, measure, and report the above-mentioned timeframes.



III. Clinical thought leaders should investigate how, when, and to whom preliminary test results can inform clinical decision-making.

This recommendation seeks to bring the hospital laboratory staff and functions closer to patient care and patient outcomes. Laboratorians, by nature of their work, are resolute in attaining correct and validated data prior to reporting. While accuracy is paramount in providing the highest standard of patient care, we encourage medical policy leaders to contemplate how preliminary results might provide directional insight into patient care that treating clinicians should consider from an antimicrobial stewardship perspective. We urge professional societies, such as the Infectious Disease Society of America (IDSA) to develop standards for circumstances where incremental information from the laboratories can be made available to the treating clinicians to inform treatment decisions earlier.

As with the previous recommendation, data analysis solutions are essential in enabling information capture and sharing in line with clinical workflow.

IV. AdvaMedDx encourages the standardization of ASP laboratory reports in a manner that is easily consumable and actionable by treating physicians – regardless of their medical specialty or background, while leveraging EHR clinical decision support tools in developing informed antibiotic order sets that require use of diagnostic tests and test results, as appropriate.

Testing data and results from the laboratory must be reported back to the treating physician(s) in a format that can be interpreted and is actionable. Although access to laboratory leadership and expertise is critical to achieve appropriate patient management in ASPs, this expertise may not always be available. Laboratory reports, such as susceptibility results, should be presented in a manner that is consumable by the average treating physician, independent of specialized training in infectious diseases, to enable informed antibiotic treatment decisions and avoid delays.

Furthermore, standardized and consumable reports can assist non-infectious disease physicians in interpreting test results, providing confidence in making clinical decisions based on those results. Building sustained clinical trust and confidence in diagnostic results to make patient treatment decisions, such as antibiotic de-escalation, has been observed to be a challenge. A fundamental prerequisite for an ASP to be successful is a clinician's comfort and willingness to act upon diagnostic results. One contributing factor may be that many treating physicians do not possess the infectious disease expertise to either interpret the test results and/or make an informed decision based on the test results. Better integration of laboratory expertise with treating physicians in ASPs, via standardized, actionable reports, could alleviate part of the problem.

EHR clinical decision support tools would naturally prove critical companion tools to the standardized and actionable laboratory reports. The optimization of EHR clinical decision support could help ensure that antibiotic order sets require use of diagnostic tests and test results, where appropriate.

We believe these recommendations will support ongoing ASP efforts to achieve cultural change in clinical acceptance of diagnostics test results, particularly when those results show antibiotic de-escalation would be the best course of action for patients. Higher trust and confidence in diagnostic testing in ASPs will help correct practice patterns and improve clinical decision-making.