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Leveraging Diagnostic Stewardship to Advance Appropriate Diagnostic Use

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Executive Summary

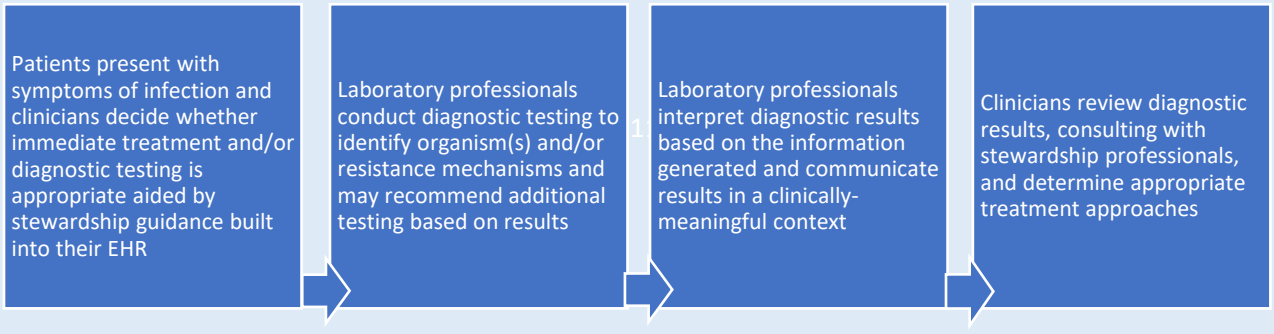
This brief emphasizes the importance of incorporating diagnostic stewardship into existing antimicrobial stewardship programs and discusses strategies that federal policymakers, hospital systems, and other stakeholders can adopt to support diagnostic stewardship. Additionally, this brief offers strategies to advance diagnostic stewardship within health system policies and practices, incentivize diagnostic stewardship through coverage and payments, advance guidelines for diagnostic stewardship, support research to improve diagnostic stewardship, and strengthen the role and influence of public health authorities.

Introduction

Bacterial diagnostics offer methods to detect and identify bacterial infections in the body, and advances in bacterial diagnostic technologies improve the ability for clinicians and laboratories to characterize and treat bacterial infections. When incorporated into an antimicrobial stewardship program (ASP), diagnostic stewardship enhances efforts to mitigate the emergence of antibiotic resistance and preserve the effectiveness of existing antibiotics.[1,2] Effective diagnostic stewardship helps ensure that clinical and laboratory professionals select appropriate bacterial diagnostics, correctly interpret their results, reduce errors, and accurately diagnose and treat their patients. These factors are expected to improve patient outcomes, mitigate antibiotic, and potentially reduce overall health care costs.[3] When antibiotic resistant infections occur, effective diagnostic stewardship supports their timely identification and enables clinicians to optimize antibiotic therapy, thereby preventing the spread of antibiotic resistant bacteria both within health care facilities and among the broader community Furthermore, when antibiotic resistant infections are prevented from spreading, bacteria with genetic elements that confer antibiotic resistance cannot reproduce and the effectiveness of existing antibiotics is preserved.[4,5]

Diagnostic stewardship engages clinicians and laboratory professionals involved in ordering, performing, and interpreting bacterial diagnostics toward optimal diagnosis and directed therapy. This process is described in the following illustration:

FIGURE 1: Dianostic Stewardship in the Clinical Process



Because there are several opportunities for error and inefficiency throughout this process, clinical and laboratory professionals must act carefully to ensure the utility and reliability of bacterial diagnostics. For certain sensitive bacterial diagnostics, laboratory professionals may benefit from additional clinical education to mitigate the incidence of false positives that inappropriately encourage antibiotic therapy (for example, cases of bacterial colonization versus true bacterial infection).

This brief recommends strategies that federal policymakers, health systems, hospitals, and other organizations can adopt to leverage diagnostic stewardship and advance appropriate diagnostic use to support antimicrobial stewardship. A range of bacterial diagnostics exist, and clinicians, payers, and patients can benefit from strategies that optimize bacterial diagnostics' utility and value. Stakeholders should implement these strategies in a manner that anticipates operational and socio-behavioral factors that can positively or negatively influence the clinical impact of bacterial diagnostics.

Increased Diagnostic Stewardship in Antimicrobial Stewardship Programs

Federal agencies and professional organizations have recommended incorporating diagnostic stewardship into ASPs.[2,3,10] Despite the prevalence of health system and hospital-based ASPs, the Center for Disease Control (CDC) findings describe how ongoing and substantial deviations from antibiotic prescribing guidelines and clinical approaches to treatment can vary when clinical guidelines and evidence to inform optimal diagnostic use and antibiotic treatment strategies are lacking.[7–9] These circumstances underscore an opportunity for diagnostic stewardship to enhance the impact of ASPs and improve adherence to antibiotic prescribing guidelines (see Box 1).

BOX 1: Bacterial Diagnostics in Antimicrobial Stewardship

Optimizing the use of bacterial diagnostics improves antimicrobial stewardship by enabling clinical teams to:

- Distinguish between viral and bacterial infections to avoid inappropriate antibiotic use.
- Identify infectious bacteria with both high sensitivity and specificity to guide treatment selection.
- Determine antibiotic susceptibilities that help determine optimal antibiotic therapy.
- Consider antibiotic resistance genes, markers, or virulence factors that help determine optimal antibiotic therapy.
- Measure biomarkers as indicators of host response to infection or high-risk conditions.
- Participate in clinical studies to evaluate new antibiotics therapeutic strategies.

In The Core Elements of Hospital Antibiotic Stewardship Programs: 2019, the CDC encourages hospital system leadership to integrate antimicrobial stewardship activities into other quality improvement and patient safety efforts, such as sepsis management and diagnostic stewardship. Additionally, the agency recommends incorporating frontline staff such as nurses into antimicrobial stewardship to help optimize hospital systems' diagnostic stewardship. The CDC specifically notes that microbiology laboratory staff can help create guidelines for diagnostic stewardship that ensure the proper use of tests and reporting of results, including potential implementation of rapid diagnostic tests and up-to-date interpretive criteria for antibacterial susceptibility tests.[10] Relatedly, the Infectious Diseases Society of America (IDSA) has discussed the need to motivate, incentivize, or require health care facilities to invest in diagnostic stewardship, to focus on optimizing high-volume diagnostic tests, and to incorporate the perspectives of clinicians, ASP staff, informaticians, and clinical laboratory staff in

diagnostic stewardship. Additionally, the IDSA has highlighted how health systems should focus on training and workforce development because staffing is often limited for ASPs.[1] The Society for Healthcare Epidemiology of America (SHEA) notes that bacterial diagnostics have historically been the sole responsibility of microbiology laboratories, but a better clinical understanding of diagnostic test results has the potential to influence antimicrobial utilization and therefore should be incorporated into broader ASPs. The SHEA describes a diagnostic pathway that guides diagnostic stewardship and notes that stewardship methods will vary by setting because testing needs likewise vary among different populations.[3]

To fulfill these recommendations, successful ASPs require adequate funding and support for leadership and staff.[11] Enhancing the impact of bacterial diagnostics within ASPs requires a multidisciplinary approach involving clinicians, laboratory experts, health information technology professionals, and hospital administrators. Unfortunately, shortages of clinical and laboratory professionals have made it difficult for some health systems to establish ASPs with dedicated leadership and staff, optimize their utilization of bacterial diagnostics, and adopt newer bacterial diagnostics. Regardless, health systems that ensure these key stakeholders can work together to design, improve, and sustain an ASP that incorporates diagnostic stewardship are more likely to benefit from bacterial diagnostics (Box 2 described examples of such systems).

Health systems ought to ensure that experts within the microbiology laboratory are fully invested in supporting both antimicrobial and diagnostic stewardship. Involving the microbiology laboratory in leading health system ASPs is critical to elevating the role and impact of diagnostic stewardship (example described in Box 2). Because interpreting bacterial diagnostics and treating infections can be complicated, clinical microbiologists can support ASPs and diagnostic stewardship by leading clinical education and guidance development on bacterial diagnostic ordering and interpretation. Beyond supporting continuing medical education, clinical microbiologists and laboratory professionals can contribute to ASPs by helping to design interventions that ensure that health systems' policies and health information technology (like electronic ordering and reporting systems) encourage appropriate bacterial diagnostic testing and interpretation. Similarly, when health system leaders consider new bacterial diagnostics for adoption, clinical microbiologists and laboratory professionals ought to be able to design and implement guidance and address concerns and questions about their appropriate use and anticipated benefits, for both clinicians and hospital administrators.

BOX 2: Successful Use of Diagnostic Stewardship in Health Systems

The Cleveland Clinic created a Laboratory Stewardship Committee, which consists of clinicians, pathologists, administrators, and caregivers that focuses on optimizing test utilization within the health system to provide better patient care and reduce costs associated with laboratory testing. Their efforts have led to significant savings in test-related costs and improved patient outcomes since 2011.[12–14]

The Mayo Clinic established a COVID-19 Diagnostic Stewardship Task Force with the primary goal to evaluate effective ways to allocate and deploy testing resources related to COVID-19. The task force identified key strategies which included predictive test utilization modeling, consensus-based testing guidance, and a real-time practice group which helped to optimize testing resource allocation, create consensus-based guidelines, implement real-time adaptability, improve patient outcomes, and reduce healthcare costs. They also work to assess the use of broad spectrum antibacterial agents for COVID-19 patients to determine effects on patient outcomes and to ensure proper antimicrobial stewardship.[15–17]

Finally, ASPs ought to incorporate strategies to mitigate clinically inappropriate or low-yield bacterial diagnostic utilization. Diagnostic stewardship involves both encouraging the appropriate use of

bacterial diagnostics and mitigating their use when inappropriate. Experts noted that there are circumstances when bacterial diagnostics are unnecessary or unlikely to provide actionable clinical information (and may even provide misleading information, such as when the pre-test probability is low). For example, spontaneous testing for *C. difficile* may occur in patients whose symptoms do not point to infection, leading to inappropriate antibiotic treatment in patients who are colonized but not infected with *C. difficile*.[18] Similarly, diagnostic testing for asymptomatic bacteriuria is generally unnecessary and frequently leads to inappropriate antibiotic treatment.[19] Accordingly, ASPs that focus on incorporating diagnostic stewardship can positively influence the selection and interpretation of bacterial diagnostics.

Enabling Diagnostic Stewardship Through Health Care Coverage and Payments

Without clear evidence of cost-savings or improved clinical outcomes, clinicians and payers are hesitant to adopt and pay for new bacterial diagnostics.[20] Experts who were interviewed shared that large private payers consider the cost of new diagnostic technologies and health technology assessments that include economic data, while smaller private payers rely less on their own technology assessments and instead consider how assessments conducted by other payers apply to their own beneficiaries. Payers ought to join the dialogue and support claims-based research to help identify infections that are treated with the aid of bacterial diagnostics and whether bacterial diagnostic use is associated with fewer complications and readmissions, improved outcomes, or lower long-term costs.

Major payers like the Centers for Medicare & Medicaid Services (CMS) can support diagnostic stewardship by optimizing the reimbursement system to support appropriate diagnostic adoption and utilization. While inpatient versus outpatient reimbursement for bacterial diagnostic utilization varies, the current reimbursement paradigm was designed for simpler, traditional bacterial diagnostics and has not been redesigned to account for newer technologies that may cost more. Moreover, in 2018, 2019, and 2020, the CMS reduced reimbursement for most diagnostic tests by 10 percent.[21] Accordingly, experts who were interviewed noted that when newer bacterial diagnostics are clinically warranted, insufficient coverage may prevent clinicians from ordering them to avoid burdening patients and health systems with excess costs.

Approaches like the CMS New Technology Add-On Payment (NTAP) program help subsidize the cost of newer bacterial diagnostic technologies but may not meaningfully support new bacterial diagnostic adoption and stewardship. Accordingly, a reimbursement paradigm that requires appropriate diagnostic testing as a condition of coverage for antibiotic therapy—a "companion therapeutic" approach versus a "companion diagnostic" approach—can encourage clinicians to practice diagnostic stewardship, direct antibiotic prescribing, and address existing reimbursement-related financial disincentives.[20] Such an approach might also assuage concerns that insufficient reimbursement for bacterial diagnostics limits directed antibiotic therapy and contributes to inappropriate antibiotic prescribing and increased antibiotic resistance.[21]

Guidelines and Governance for Diagnostic Stewardship

Federal agencies and professional societies ought to continue encouraging diagnostic stewardship through guidance and guidelines. The CDC has already taken steps to highlight the importance and role of diagnostic stewardship in the context of broader antimicrobial stewardship and can continue to support ASP leaders through the Core Elements, efforts to address healthcare-associated infections, and Clinical Laboratory Advisory Committee public workshops.[22–24] Other influential stakeholders like the CMS and the Joint Commission can consider additional strategies to incorporate

diagnostic stewardship into their standards and guidelines, such as their ASP guidelines and Standards of Excellence in Health Care. When new clinical evidence becomes available, professional societies ought to support the development of specific guidance regarding newer, rapid bacterial diagnostics, multiplex bacterial diagnostics, and point-of-care (POC) diagnostics. Such guidance can assist ASP leaders working to advance diagnostic stewardship, and agency supported toolkits, webinars, and online education can supplement guidance. Experts acknowledge that producing rigorous clinical evidence can be challenging and that there is limited clinical evidence to demonstrate the impact of diagnostic stewardship on more holistic measures such as patient outcomes and health care costs. Accordingly, in lieu of full updated clinical guidelines, health care systems that have successfully integrated diagnostic stewardship into their ASPs can disseminate best practices through journal articles, professional societies, and webinars.

Health care systems can help establish governance structures and follow best practices when implementing diagnostic stewardship or adopting new bacterial diagnostics. When introducing new diagnostic stewardship practices or bacterial diagnostics, health systems' leadership ought to make available the necessary resources and clinical expertise to implement and continuously improve diagnostic stewardship practices. Implementing and continuously improving diagnostic stewardship practices or the adoption of new bacterial diagnostics often involves accounting for new costs, resource requirements, information technology needs, and clinical education to facilitate practice change (Box 3).

BOX 3: Health care system leadership can consider the following policies and practices informed by experts to help health successfully integrate diagnostic stewardship into ASPs.

Consider the full cost and time to incorporate diagnostic stewardship into the health system.	• Conduct forward thinking evaluations to demonstrate diagnostic impact when considering new diagnostic tools. • Consider the medical necessity of high-cost diagnostics within the system. • Avoid implementing budget reductions within microbiology labs before understanding the impact of budget reductions on ASPs.
Ensure antimicrobial stewardship teams are multidisciplinary so they can effectively consider the potential impact of new or updated interventions.	• ASP leaders ought to have appropriate clinical experience and an adequate understanding of quality improvement, regulatory requirements, and the laboratory and ordering process.
Integrate testing guidance into diagnostic ordering at the health system level with approaches like clinician decision support systems (CDSS) based interventions that direct clinicians towards appropriate diagnostic use.	• Integrate diagnostic tests into clinical and health information technology (HIT) systems in a manner that limits disruption to existing clinical workflows. • Avoid creating conditions for 'alert fatigue' in EHR systems and focus strategies to encourage the appropriate use of diagnostic tests particularly on high volume tests like urine cultures.
Engage information technology professionals when implementing diagnostic technologies and to help ASPs track the impact of the new or updated interventions.	
Emphasize that communication is important for successful integration and utilization of new diagnostic tools.	• Distribute information that is tailored to the appropriate audience and educate clinical staff on the strengths and weaknesses of new or updated diagnostic technologies.
Enable ASPs to champion new diagnostics technologies and their stewardship.	• ASPs should address misperceptions about diagnostic costs or questions about diagnostics that create inappropriate hesitancy among clinicians.
Incorporate diagnostic stewardship practices into smaller health system sites and satellite facilities that rely on the clinical laboratories of larger centralized systems and consider how to mitigate diagnostics delays.	• Coordinate system-wide stewardship meetings to align stewardship practices even when capacity and technology differs among facilities.
Assess and support the feasibility and effectiveness of new diagnostic stewardship interventions based on system resources, workflow, work preferences, and potential burden on clinicians.	• Ensure department leadership and frontline staff are "bought-in" regarding new diagnostic stewardship policies. • Implement clinical protocols that ensure the diagnostics' results are acted upon in a timely manner. • Develop internal guidance for common high-volume tests such as blood cultures, urine cultures, respiratory cultures, and C. difficile testing.[3] • Consider the most appropriate manner to influence diagnostic testing choices and consider unintended consequences of diagnostic stewardship interventions.

Supporting Research to Advance Diagnostic Stewardship

After decades of work to create and implement ASPs, understanding and optimizing diagnostic stewardship remains a challenge.[25] The lack of outcome measures that characterize bacterial diagnostic effectiveness and safety complicate the development of evidence-based guidance for bacterial diagnostics.[26] Notably, clinical utility studies are often not feasible until a bacterial diagnostic has been cleared and marketed for two to four years owing to limited early adoption. Additional barriers impacting research toward clinical outcome measures include the cost and complexity of multicenter studies, difficulties collecting data, compliance with protocols, and difficulties enrolling target populations.[25] To improve diagnostic stewards, policymakers can support research networks or partnerships such as the Antibiotic Resistance Leadership Group (ARLG) that seek to overcome these barriers and disseminate actionable evidence-based guidance for bacterial diagnostics.

BOX 4: Barriers that limit research to advance diagnostic stewardship:

- Limited interventions and outcome measures that demonstrate the appropriateness and clinical value of bacterial diagnostics.
- Limited ability to understand how much variation in clinical care is attributable to additional clinical information from bacterial diagnostics.
- Limited resources among bacterial diagnostic developers to support extensive post-market evidence development.

Stewardship and Cost Savings

Policymakers and professional societies can continue to support research that generates evidence of clinical cost-effectiveness and improved clinical outcomes. This research can support appropriate reimbursement, benefiting clinicians, health care systems, and health care insurers because effective diagnostic stewardship is expected to improve cost-effectiveness by (1) mitigating unnecessary diagnostics testing, and (2) directing antibiotic therapy toward more effective treatments that reduce adverse outcomes—and in the inpatient setting—reduce length of stay.[3,27] Accordingly, diagnostic test developers typically allocate more resources toward developing evidence for payers than toward developing evidence for regulatory approval because securing reimbursement from payers is crucial for the commercial success of a diagnostic test.[20] There are currently no consensus guidelines on how best to conduct economic evaluations of diagnostic tests. Additional data demonstrating the cost-effectiveness of bacterial diagnostics would benefit efforts to ensure reimbursement supports effective diagnostic stewardship and the adoption of newer technologies such as rapid bacterial diagnostics and multiplex panels.

Public Health and Bacterial Diagnostic Stewardship

AMR is one of the greatest threats to global public health, and there is an imperative for public health authorities to ensure that programs to combat AMR are robust and incorporate the stewardship of both antibiotics and diagnostics.[28] Accordingly, policymakers ought to support the development and stewardship of bacterial diagnostics to prepare for future public health emergencies. This approach is necessary because bacterial diagnostics become the primary means of controlling bacterial outbreaks when medical countermeasures are unavailable or ineffective (and remain important when medical countermeasures are in limited supply and must be thoughtfully allocated). Policymakers will recall that

during the first months of the COVID-19 pandemic, limited access to effective diagnostics crippled the initial public health response.

Furthermore, because hospitals do not routinely allocate resources to conducting diagnostic testing for public health purposes, policymakers must consider how to ensure hospitals are prepared to quickly deploy bacterial diagnostics and report their results to public health authorities. Supporting the ongoing development and adoption of platform technologies—such as those that enable rapid testing based on multiplex polymerase chain reaction (PCR) and culture-independent methods—may represent a practical approach. These diagnostic technologies and their appropriate stewardship can enhance routine health care and hospital readiness for health emergencies. Relatedly, because the population health value attributable to bacterial diagnostics that mitigate the transmission of infections and antibiotic resistant bacteria is unclear, stakeholders can pursue better estimates of this value to justify additional funding for diagnostic technologies that enhance population health and public health preparedness.

To fully leverage newer bacterial diagnostic technologies, hospitals and public health authorities need support establishing and sustaining effective data sharing mechanisms and a well-trained workforce. Clinical laboratories equipped with bacterial diagnostics that can rapidly detect and characterize antibiotic resistant bacteria are well positioned to support the mission of public health authorities, including their activities related to disease surveillance, confirmatory and genomic testing, and case investigation. Unfortunately, mechanisms for sharing data from bacterial diagnostics that generate detailed information (such as antibiotic susceptibility) with public health authorities are not widely implemented. Efforts to better integrate health care and public health are underway, and enhanced testing capabilities and burden-free reporting mechanisms that support bi-directional data exchange (such as NC's Trusted Exchange Framework and Common Agreement) can help build the value case for expanding newer bacterial diagnostic technologies among hospitals and health systems. To sustain and fully benefit from this integration, both health systems and public health authorities will require clinical microbiologists, epidemiologists, and laboratory professionals, who can be difficult to train and hire without targeted incentives.

Conclusion

There is clear and growing evidence of the benefits of diagnostic stewardship and the importance of incorporating diagnostic stewardship into existing ASPs. Federal policymakers, health system leaders, professional societies, and payers can all help ensure that diagnostic stewardship is successfully incorporated into existing ASPs by implementing new health system policies and practices, incentivizing diagnostic stewardship through coverage and payments, advancing guidelines for diagnostic stewardship, supporting research to improve diagnostic stewardship, and strengthening the role and influence of public health authorities.

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Acknowledgments
This project was supported by the Wellcome Trust. The opinions and conclusions expressed or implied are those of the authors and do not necessarily represent the official views of, nor an endorsement, by the Wellcome Trust.

The authors would like to acknowledge **Dr. Marianne Hamilton Lopez**, Senior Research Director of Biomedical Innovation at Duke-Margolis for kindly contributing to the review of this issue brief.

The authors thank the following individuals who graciously shared their perspectives with Duke-Margolis, including:

- **Arjun Srinivasan, MD:** Deputy Director for Program Improvement, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention. Captain (retired), United States Public Health Service
- **Bert Lopansri, MD**: Chief, Division of Infectious Diseases at Intermountain Medical Center, Associate Professor (Clinical) in Internal Medicine at the University of Utah.
- **Eddie Stenehjem, MD**: Executive Vice Chair of the Department of Medicine at the University of Colorado.
- **John A. Jernigan, MD, MS**: Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention
- **L. Clifford McDonald, MD**: Associate Director for Science in the Division of Healthcare Quality Promotion (DHQP) at Centers for Disease Control and Prevention
- **Lauri Hicks, DO**: Director for the Office of Antibiotic Stewardship in the Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention
- **Linoj Samuel, Ph.D., D(ABMM)**: Division Head for Clinical Microbiology at Henry Ford Health, Clinical and Public Health Microbiology Committee Vice-Chair at American society of Microbiology
- **Michael Craig, MPP**: Director of the Antimicrobial Resistance Coordination and Strategy Unit (ARX) at Centers for Disease Control and Prevention
- **Sara Cosgrove, MD**: Director, Johns Hopkins Hospital Department of Antimicrobial Stewardship Program; Professor of Medicine in the Division of Infectious Disease at Johns Hopkins University School of Medicine.
- **Sarah Kabbani, MD**: Deputy Director, Office of Antibiotic Stewardship, Centers for Disease Control and Prevention
- **Stefanie Bumpus McBride, PhD**: Associate Director for Policy & Partnerships, Antimicrobial Resistance Coordination & Strategy Unit, Centers for Disease Control and Prevention
- **Susan Van Meter, MA**: President of the American Clinical Laboratory Association (ACLA).
- **Robin Patel, MD**: Elizabeth P. and Robert E. Allen Professor of Individualized Medicine, Professor of Microbiology and Medicine, and Chair of the Division of Clinical Microbiology at the Mayo Clinic.
- **Vance Fowler, MD**: Florence McAlister Distinguished Professor of Medicine at Duke University.

The viewpoints expressed in this issue brief are solely those of the authors and do not necessarily reflect the viewpoints of the individuals listed above, nor the viewpoints of their affiliated organizations. The affiliations of the individuals listed above reflect their positions at the time they shared their perspectives with Duke-Margolis.