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February 26, 2013

Helen Burstin, MD, MPH  
Senior Vice President, Performance Measures  
National Quality Forum  
601 Thirteenth St, NW, Suite 500 North  
Washington, DC 20005  
Submitted electronically: hburstin@qualityforum.org

Re: Antimicrobial Stewardship Measure Concepts

Dear Dr. Burstin,

The Infectious Diseases Society of America (IDSA) and the Society for Healthcare Epidemiology of America (SHEA) are writing to engage the National Quality Forum (NQF) in a discussion of the critical gaps that exist in the area of antimicrobial stewardship promotion and to seek the NQF's guidance on how best to proceed with quality measure development. Our organizations share a common interest with the NQF related to antimicrobial use, including appropriate care, antimicrobial stewardship, and management of antimicrobial resistance.

In recent years, IDSA and SHEA, in collaboration with other relevant stakeholders, such as the Centers for Disease Control and Prevention (CDC), have developed training and educational content, policy statements, and clinical practice guidelines to promote and enhance stewardship activities among a diverse group of healthcare professionals. We also have embarked on preliminary work to define quality measure concepts addressing antimicrobial stewardship that may serve as a foundation for guiding policy at the federal and local levels. While we believe these measure concepts address a critical gap in care and comprehensively support the nation's goal of safer, more effective and more efficient care, they do not necessarily have the evidence base needed to receive endorsement under the NQF's current Consensus Development Process (CDP). Before making further investments in this effort, we would greatly appreciate the opportunity to discuss with the NQF challenges with respect to insufficient data we currently face, potential strategies to overcome them, and to what extent forthcoming modifications to the NQF's CDP may accommodate unique situations such as ours.

## **The Problem**

Antimicrobial stewardship is the judicious use of antimicrobials to achieve the best clinical outcomes while minimizing adverse events, limiting factors that lead to antimicrobial resistance, and reducing excessive costs attributable to suboptimal antimicrobial use. As such, it is in alignment with the National Quality Strategy's three-part aim of better care, affordable care, and healthy people in healthy communities. It is a clinical topic that has significance across the continuum of care and relies heavily on multi-disciplinary and collaborative approaches to care, which are high priorities for both the public and private sector. It also coincides with the Department of Health and Human Services' Action Plan to Prevent Healthcare-Associated Infections.

Ample data exist from both inpatient and outpatient settings demonstrating that antibiotics are often prescribed sub-optimally or inappropriately. Antibiotics are misused in a variety of different ways. They are often administered when they are not needed, continued when they are no longer necessary, or prescribed at the wrong dose. Broad-spectrum agents may be used unnecessarily against bacteria that are very susceptible or the wrong antibiotic may be given to treat a particular infection.

Antibiotic overuse, in particular, leads to resistance among patients and resistance leads to adverse outcomes, including mortality. Over the past 30 years, we have seen bacteria that are extremely resistant to traditional treatments or resistant to multiple drugs spread widely among patients in healthcare settings. In some cases these pathogens have been pan-resistant, meaning that they are resistant to all available antibiotics. The unique nature of antibiotics, in which the use of the drugs in one patient can impact the effectiveness of the drug in a different patient, make antibiotic overuse a serious patient safety issue and public health threat. In fact, the World Health Organization has characterized antibiotic resistance as "a crisis that has been building up over decades, so that today common and life-threatening infections are becoming difficult or even impossible to treat."<sup>1</sup> Resistant infections not only result in increased morbidity and mortality, but increased economic burdens. For example, studies have shown that antibiotic-resistant infections are associated with longer lengths of stay and increased mortality, both in the hospital and in ICUs. Combined with a dramatic drop in the development and approval of new antibacterial agents over the last decade and a rapidly dwindling antimicrobial armamentarium, it is becoming increasingly difficult to treat infectious diseases.

Fortunately, improvements in antibiotic use have been shown to be associated with improvements in patient outcomes, including reductions in *C. difficile* infections, reductions in antibiotic resistance, and increases in infection cure rates. More appropriate antibiotic use is also associated with cost-savings, making antibiotic stewardship a win-win intervention.

## **Potential Solutions**

Despite ample evidence regarding the impact of inappropriate antibiotic use and the outcomes associated with better management of antibiotic use, there is less concrete evidence regarding the most effective strategies for reaching that goal. Furthermore, even where well documented interventions exist to improve antimicrobial use, their adoption has been limited.

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<sup>1</sup> [The evolving threat of antimicrobial resistance](#) - Options for action, The World Health Organization

Through a range of publications, IDSA and SHEA have supported a multi-faceted approach to improving antibiotic use in the U.S. For example, in 1997, we published “Guidelines for the Prevention of Antimicrobial Resistance in Hospitals,”<sup>2</sup> and in 2007, “Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship.”<sup>3</sup> This latter document discusses the development of multidisciplinary teams in acute care settings to review and improve antimicrobial use and improve patient care and calls for processes to measure and monitor antimicrobial use at the institutional level for internal benchmarking.

IDSA also published a 2011 policy paper titled “Combating Antimicrobial Resistance: Policy Recommendations to Save Lives,” which calls for the adoption of antimicrobial stewardship programs in all U.S. healthcare facilities, better research to define optimal elements of antimicrobial stewardship programs in different settings, expanded educational efforts on antimicrobial stewardship, novel mechanisms to prevent the over-prescription of newly approved antibacterial agents, and the development of new antibacterial therapies, vaccines, and rapid, point-of-care diagnostic tests that would enable appropriate care, including the avoidance of antibacterial agents for viral etiologies.

Most recently, in 2012, IDSA, SHEA, and the Pediatric Infectious Diseases Society (PIDS), issued a “Policy Statement on Antimicrobial Stewardship.”<sup>4</sup> This statement identified significant knowledge gaps in our understanding of antimicrobial resistance and interventions, as well as in our ability to measure associated impacts and clinical outcomes in these areas. Some of the action it called for is as follows:

- The development of standardized data collection tools to facilitate measurement and interpretation of antimicrobial use data in both the inpatient and outpatient settings. Accurate and readily available data to track and benchmark antimicrobial use is currently lacking in the U.S.
- The development of clear, well-defined, and validated process and outcome measures that may be utilized to assess the clinical impact of stewardship efforts across care settings.
- Patient-centered outcomes research to determine the most effective and cost-efficient deployment of antimicrobial stewardship interventions in different healthcare settings. To date, research in this area has been plagued by poor study design issues and an absence of standardized definitions.
- Alternative markers of success. While it is critical to understand the impact of antimicrobial stewardship on epidemic and endemic resistance rates both within and between healthcare institutions, there is also a need for validated surrogate markers of success. Such measures may include, but are not limited to, rates of *C. difficile* infection, time to administration of appropriate therapy, adverse drug reactions or interactions

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<sup>2</sup> Shlaes DM, Gerding DN, John JF Jr, et al. Society for Healthcare Epidemiology of America and Infectious Diseases Society of America Joint Committee on the Prevention of Antimicrobial Resistance: guidelines for the prevention of antimicrobial resistance in hospitals. *Clin Infect Dis* 1997;25:584–599.

<sup>3</sup> Dellit TH, Owens RC, McGowan JE Jr, et al. Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America guidelines for developing an institutional program to enhance antimicrobial stewardship. *Clin Infect Dis* 2007;44:159–177.

<sup>4</sup> <http://www.jstor.org/stable/10.1086/665010>

related to antimicrobial therapy, drugs administered to patients with documented allergies, multidrug regimens with redundant antimicrobial spectra, regimens that are either inadequate or excessive, and duration of intensive care and overall hospitalization for patients treated.

### **Draft Measure Concepts for Consideration**

In February 2011, a multi-stakeholder group consisting of IDSA, SHEA, CDC, and other leaders met to explore opportunities to collaborate on quality measure development. The group subsequently arrived at a set of draft quality measure concepts aimed at inpatient antimicrobial use. Up to 30% of antimicrobial use in hospitals is either unnecessary or inappropriate and while well documented interventions exist to improve antimicrobial use in hospitals, their adoption has been limited.<sup>5 6 7 8</sup> The Inpatient Antimicrobial Use measure concepts developed by this group include:

- **Ensuring that antibiotic orders have an indication.** Antibiotics are often continued unnecessarily in hospitals because clinicians do not have information indicating why the antibiotics were started initially or for how long they were to be continued. This challenge is compounded in today's healthcare system where primary responsibility for patient care is frequently transitioned from one clinician to another.
- **Ensuring that processes are in place to prompt clinicians to review a selected course of antibiotic therapy within 72 hours of initiation.** Antibiotics are generally started before a patient's full clinical picture is known. When additional information is available, including microbiology, radiographic and clinical information, antibiotic therapy should be reassessed to determine if an antibiotic is still warranted or the prescribed antibiotic is the best one.
- **Ensuring that processes are in place to review selected episodes of blood culture growth to ensure that the patient is receiving optimal antimicrobial therapy.** Blood culture growth presents an important opportunity to ensure the most appropriate therapy and to stop therapy that is no longer needed.
- **Not treating asymptomatic bacteriuria**

Despite this initial work, the group was hesitant to move forward with further development of these measures (e.g., submission to NQF) since many of the concepts do not have adequate implementation data to support their value and use. However, subsequent conversations with CMS eventually gave rise to the inclusion of several of these measures in a patient safety pilot aimed at testing revised surveys for assessing hospital compliance with specific Conditions of Participation (CoPs). The following antibiotic stewardship concepts are currently being tested as

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<sup>5</sup> Cosgrove SE, Seo SK, Bolon MK, et al. Evaluation of post-prescription review and feedback as a method of promoting rational antimicrobial use: a multicenter intervention. *Infect Control Hosp Epidemiol* 2012; 33:374-80.

<sup>6</sup> Hecker MT, Aron DC, Patel NP, et al. Unnecessary use of antimicrobials in hospitalized patients: current patterns of misuse with an emphasis on the antianaerobic spectrum of activity. *Arch Intern Med* 2003; 163:972-978.

<sup>7</sup> Arnold FW, McDonald LC, Smith RS, et al. Improving antimicrobial use in the hospital setting by providing usage feedback to prescribing physicians. *Infect Control Hosp Epidemiol* 2006; 27:378-382.

<sup>8</sup> Camins BC, King MD, Wells JB, et al. Impact of an antimicrobial utilization program on antimicrobial use at a large teaching hospital: a randomized controlled trial. *Infect Control Hosp Epidemiol* 2009; 30:931-938.

part of an expanded list of items that must be assessed during on-site surveys to determine compliance with the Infection Control Condition of Participation:

- C.3.a Facility has a multidisciplinary process in place to review antimicrobial utilization, local susceptibility patterns, and antimicrobial agents in the formulary *and* there is evidence that the process is followed.
- C.3.b Systems are in place to prompt clinicians to use appropriate antimicrobial agents (e.g., computerized physician order entry, comments in microbiology susceptibility reports, notifications from clinical pharmacist, formulary restrictions, evidenced based guidelines and recommendations).
- C.3.c Antibiotic orders include an indication for use.
- C.3.d There is a mechanism in place to prompt clinicians to review antibiotic courses of therapy after 72 hours of treatment.
- C.3.e The facility has a system in place to identify patients currently receiving intravenous antibiotics who might be eligible to receive oral antibiotic treatment.

We are hopeful that this pilot will yield useful data on the utility and implementation of these measure concepts. More information about it is available at:

<http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-12-32.pdf>

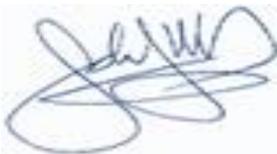
### **Next Steps**

The IDSA and SHEA thank the NQF for taking the time to consider this important issue. We value the NQF's guidance and insight, and would greatly appreciate the opportunity to have a follow-up discussion with you to determine whether formal quality measure development is the best path forward for achieving our goals. To further discuss this issue, please contact Andres Rodriguez, IDSA Senior Program Officer for Practice & Payment Policy at 703-299-5146 or [arodriguez@idsociety.org](mailto:arodriguez@idsociety.org)).

Sincerely,



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President, IDSA



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