THE SOCIETY FOR HEALTHCARE EPIDEMIOLOGY OF AMERICA

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Emergence of the Superbug: Antimicrobial Resistance in the United States

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Chairman Kennedy, Ranking Member Enzi and Members of the Senate Health, Education, Labor and Pensions Committee, thank you for inviting The Society for Healthcare Epidemiology of America (SHEA) to present our views on the challenges of healthcare-associated infections in light of the emergence of antibiotic-resistant infections. I am Patrick J. Brennan, President of SHEA and Chief Medical Officer of the University of Pennsylvania Health System. I am also a Fellow of the Infectious Diseases Society of America (IDSA). SHEA and IDSA are sister organizations, many of whose members overlap. Our societies have mutual interests in the prevention and elimination of healthcare associated infections and in the development of better tools, including antimicrobial agents to combat these infections.

SHEA was organized to foster the development and application of the science of infection prevention and control and healthcare epidemiology through research and education in such areas as surveillance, risk reduction, device and procedure management, and epidemiologic investigation. I would like to be clear from the outset that our testimony is provided strictly for the good of the public's health and the patients we treat. We are not here on behalf of any other interest or industry and our advocacy is not financed in any way by industry.

SHEA and its members are committed to implementing evidence-based strategies to prevent healthcare-associated infections. SHEA members have scientific expertise in evaluating potential strategies for eliminating preventable HAIs. We collaborate with a wide range of infection prevention and infectious disease societies, specialty medical societies in other fields, quality improvement organizations, and patient safety organizations in order to identify and disseminate best practice evidence. Our principal partners in the private sector have been sister societies such as IDSA and the Association of Professionals in Infection Control and Epidemiology (APIC). The Centers for Disease Control and Prevention (CDC), its Division of Healthcare Quality Promotion (DHQP) and the federal Healthcare Infection Practices Advisory Committee (HICPAC), and the Council of State and Territorial Epidemiologists (CSTE) have been invaluable federal partners in the development of guidelines for the prevention and control of HAIs and in their support of translational research designed to bring evidence-based practices to patient care.

Healthcare-Associated Infections

Healthcare-associated infections (HAIs) are diseases caused by microbes, primarily bacteria, viruses, and fungi and their toxins that occur during the delivery of healthcare and were not present or incubating in the patient at the time of entry into the healthcare system. They are often related to the delivery of healthcare itself. Four diseases represent the most common HAIs. They are: 1) infections of the urinary tract; 2) pneumonia resulting from the aspiration of the contents of the mouth, throat, or stomach; 3) infections at the site of a recent surgical procedure; 4) infections involving the bloodstream that are usually related to the use of an intravenous catheter. Oftentimes these infections are related to the use of a medical device, such as a urinary bladder catheter or a ventilator to support respiration. Such devices when used appropriately are necessary to support patients through their recovery from illness. However, devices represent double edge swords whose beneficial effects must be weighed against the risks of infection they pose through proper or improper placement and maintenance and unnecessary use.

As healthcare is delivered more frequently outside the hospital, in clinics, outpatient surgical and oncology centers, extended care facilities, and in private homes, the line between community-acquired and healthcare-associated infection has become blurred, and prevention of HAIs becomes even more challenging. Reducing preventable HAIs is a complex challenge that requires multiple interventions. No single intervention is a sufficient solution. Combinations of strategies, or bundles of activity, such as appropriate hand hygiene during patient care and careful placement maintenance and removal of supportive medical devices, is essential. Isolation practices are often necessary once infection occurs and must be carefully followed.

Accurate measurement of the occurrence of HAIs and the impact of preventive strategies is important. Measurement of infection rates and the public disclosure of rates can be useful in part because it allows hospitals to have a frame of reference for their performance. It enables patients, purchasers and payors to hold hospitals accountable, and creates the opportunity for dialogue between patients and providers on these issues. Transparency enables providers to better understand the successes and failures that others have had in process improvement related to HAIs and to adopt strategies that have been found to be effective in other facilities treating similar patient populations. The process of collecting and disclosing HAI rates must be balanced with the likelihood that the data collected can lead to actionable information and performance improvement. If data are collected that are not actionable, scarce hospital resources will be diverted to meaningless activities from more valuable interventions.

Antibiotic resistance complicates the management of HAIs. Since the discovery of antibiotics, it has been recognized that microbes possess the ability to resist the killing and inhibitory effects of these drugs. While most germs possess their own native resistance to one or more antibiotics, germs causing infection in healthcare settings have become more resistant to our commonly available antibiotics (e.g. methicillin-resistant *Staphyloccus aureus* or “MRSA” infections) thereby limiting our therapeutic options. Compounding the problem of antibiotic resistance is the overuse of antibiotics in humans and animals and the limited availability of alternate antibiotic choices when resistance arises. In some situations we have we moved beyond second and third line drug choices to the need to re-introduce into common practice antimicrobial agents that had been relegated to the pharmacy shelf decades ago because of their toxic side effects. Now, as our therapeutic options have been limited by resistance it has been necessary to re-introduce such drugs into practice. I have had the experience in my career of seeing a patient die of a drug-resistant infection when he developed a rare but serious allergic reaction to the only available, effective drug to treat his infection. We were left without therapeutic alternatives.

Hospitals must have flexibility in their choice of prevention strategies. There has been a growing interest in legislative mandates for action against specific germs. We believe such mandates are unfounded and potentially hazardous. Hospitals develop their own microbial ecology and patterns of infection and as a result must tailor their prevention strategies to their experience. MRSA is a good example of this. This is an extremely important pathogen and one that has had a serious impact on the life and career of one our panelists, former-Washington Redskin Brandon Noble, as well as many patients. While this is a virulent and important germ, many mistakenly believe is the only significant cause of HAIs in the United States. In fact, MRSA constitutes approximately 8% of HAIs in the United States. While we have begun to make progress against MRSA, the incidence of which has fallen by more than 50% in the past 10 years in hospital

medical/surgical intensive care units, much more work remains to be done. Although there are promising options to treat MRSA, the antibiotic pipeline for other types of infections is more limited. Mandates for all hospitals to specifically address MRSA may divert activity away from the increasing resistance in gram-negative infections. Decisions as to appropriate resource allocation can only be made by local risk assessment processes. Appropriate institutional oversight ("stewardship") of antibiotic use is an important aspect of the prevention of some HAIs and may impact the subsequent development of drug resistant pathogens in healthcare settings.

Increasing levels of bacterial resistance are being identified against some classes of antibiotics. Through an analysis done by the Infectious Diseases Society of America, it is apparent that the antibiotic pipeline is in decline and is not strong enough to meet the challenges that we face. Antibiotic research development is an important resource that must be restored. The drugs in development will not be able to address the growing number of antimicrobial resistant infections in the various healthcare settings. In particular, there are no drugs in the pipeline to address many gram-negative bacteria. It will first be necessary to understand what measures are needed to ensure the development of new antibiotics. Congress should commission such a study.

The extent to which HAIs are preventable and the number of lives that can be saved remains a matter of debate. What is not debatable is that we should attempt to prevent every infection and save every life possible through the application of the best evidence to practice. SHEA recently provided Congress with a white paper (See Appendix) with a range of estimates for the number of infections that can be prevented and the potential number of lives saved. Those estimates did not conclude that all infections are preventable at this time. There are significant limitations to the available information from which the estimates are derived but the elimination of HAIs remains an aspirational goal.

Protecting the health of our patients and preventing HAIs in the settings where healthcare is delivered in the United States will require a multi-faceted approach that includes identification and widespread adoption of evidence-based best practices. Where evidence does not exist, uniformity in practice should be adopted and studied to determine effectiveness. Failed practices should be discarded and successes widely disseminated. Prevention and control of HAIs also will require better tools in the form of new and novel antimicrobial agents, better knowledge of strategies to effect implementation and adherence to proven prevention methods, and accountability for performance.

What federal action is most needed with regard to HAIs?

SHEA supports the conclusions of the recent GAO report on coordination among Health and Human Services Agencies related to HAI prevention. We believe that coordinated action among CDC, CMS and AHRQ is critical. CDC and its Division of Healthcare Quality Promotion should function as the lead agency in surveillance and prevention activities related to HAIs at the federal level because of its historic and successful role in this area. CDC has had an enviable track record of prevention and its development and management of the foremost surveillance system of its kind, the National Healthcare Safety Network (NHSN) has created a national resource that many states have now mandated as their public reporting tool. Furthermore, guidelines developed by the federal Healthcare Infection Control Practices Advisory Committee are widely regarded

as the standards for the field. Coordinated activity among the agencies can lead to better informed public policy and payment reform.

SHEA urges enhanced support for CDC and its sister agencies including the Agency for Health Care Research and Quality (AHRQ), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH) to further the goals of prevention and control of HAIs, and the establishment of a robust pipeline of effective, new antimicrobial agents for treatment and the coordination of efforts to improve the health of our citizens.

SHEA believes that federal action would have the greatest impact on HAI infection prevention and anti-microbial resistance by supporting and strengthening the infrastructure currently in place to implement evidence-based interventions. Important actions include:

- Protect and improve resources for implementation of programs that standardize measurement of appropriate HAI outcomes and performance measures. Our most valuable resource in this regard is the CDC National Healthcare Safety Network (NHSN). The current administration budget proposes to reduce the source of most NHSN resources at a time when many states consider NHSN the best option for implementing standardized reporting of HAI data. NHSN has now been adopted by 17 states and more than 25% of all US hospitals for the surveillance and reporting of HAIs. It is an enormously important national resource and effective funding and support is essential.
- Enactment of the Strategies to Address Antimicrobial Resistance (STAAR) Act to reauthorize the Interagency Antimicrobial Resistance Task Force, improve coordination and accountability of HHS and HHS agencies to combat antimicrobial resistance; improve upon and further strengthen existing surveillance efforts; create a joint blueprint for antimicrobial research; collect comparable and reliable data to allow government to better assess the antimicrobial resistance problem including how antibiotic use in humans and animals triggers the development of resistance; and establish demonstration projects to encourage more appropriate use of existing antibiotics.
- Congress should support the development of the next generation of experts in this field. Designate grants to state and local health departments, and private organizations to support specialized education and training is essential to ensure that adequately trained personnel are available to meet the growing needs throughout the United States.
- Support standards and HAI preventive measures that assure availability of local expertise in infection prevention in every state and locality and in every healthcare facility. Such standards might set a minimum number of infection control professionals and healthcare epidemiologists based on size and acuity level of a facility and/or population of a state.
- Create demonstration projects to test the real world effectiveness of various implementation strategies for evidence-based interventions to prevent infections.
- Support states' efforts to create appropriate statutes to ensure optimal HAI prevention activities and, in some cases, public reporting standards that fit their own HAI challenges.
- Ensure that unintended consequences of well-intended mandates such as public reporting of HAIs (for example, avoidance of surgery on patients thought to be at higher risk of infection, or inappropriate antimicrobial treatment of asymptomatic patients where such treatment is not indicated) are considered prior to adoption of surveillance or reporting requirements.

- Address the prevention of HAIs broadly (rather than focusing on specific organisms) to ensure that healthcare institutions can adequately allocate resources to HAIs of highest priority to local needs. As an example, SHEA endorses the emphasis the Joint Commission places on conducting a risk assessment in order to target preventive efforts effectively. We believe that this strategy allows healthcare facilities to use local information to develop and implement optimal and individualized prevention plans designed to reduce healthcare-associated infections that are identified as local problems. Goals should be written in such a way to allow hospitals the flexibility to identify and target their own safety threats within the domains that are considered critical, and healthcare facilities should be expected to be able to justify their infection prevention program based on local risk assessments.
- Allow flexibility for healthcare facilities to select locally appropriate interventions from among "evidence-based practices" in creating a prevention program that is effective. This flexibility recognizes the influence of local conditions on the control of healthcare-associated infections, and allows rapid modification of strategies as new knowledge is gained.

Thank you. I will be happy to answer any questions.