DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion

Healthcare Infection Control Practices Advisory Committee

July 14-15, 2016
Atlanta, Georgia

Record of the Proceedings

Meeting Agenda

Healthcare Infection Control Practices Advisory Committee
July 14-15, 2016
Centers for Disease Control and Prevention
Tom Harkin Global Communications Center (Building 19, Auditorium 3)
1600 Clifton Road NE, Atlanta, GA

Thursday, November 5, 2016

Time	Topic	Purpose	Presider/Presenter
9:00	Welcome and Introductions	Information	Daniel Diekema (HICPAC Co-Chair) Deborah Yokoe (HICPAC Co-Chair) Jeff Hageman (DFO, HICPAC; CDC)
9:15	CDC Updates: Division of Healthcare Quality Promotion (DHQP)	Information	Denise Cardo (DHQP)
9:45	NHSN Updates	Information	Barry Rhodes (DHQP)
10:30	**Break**		
10:45	NHSN Updates cont'd • Rebaseline Update • *C. difficile* testing	Information Discussion	Margaret Dudeck (DHQP) L. Clifford McDonald (DHQP)
11:15	Guideline Updates	Information Discussion	Katy Irwin (DHQP) David Kuhar (DHQP)
12:00	**Lunch**		
1:30	DHQP Stewardship Updates	Information Discussion	Arjun Srinivasan (DHQP) Lauri Hicks (DHQP)
2:15	Update on HICPAC Workgroup Antimicrobial Stewardship Principles for Treatment Guidelines	Information Discussion Vote	Michael Tapper (HICPAC)
2:45	Update on Heater Cooler	Information Discussion	Daniel Diekema (HICPAC)
3:25	**Break**		
3:40	Challenges in Guideline Development	Information Discussion	Michael Bell (DHQP)
4:15	Public Comment		
4:30	Liaison/*ex officio* reports		
5:00	**Adjourn**		

Friday, July 15, 2016

Time	Topic	Purpose	Presider/Presenter
9:00	Welcome and Roll Call	Information	Dan Diekema (HICPAC Co-Chair) Deborah Yokoe (HICPAC Co-Chair) Jeff Hageman (DFO, HICPAC; CDC)
9:10	Update on Zika	Information	Christine Olson (CDC)
9:25	Update on HICPAC Reprocessing Workgroup	Information Discussion	Vickie Brown (HICPAC) Lisa Maragakis (HICPAC)
10:30	**Break**		
10:45	Emerging Resistance Updates	Information Discussion	Snigdha Vallabhaneni (CDC) Alison Laufer Halpin (CDC)
11:15	Public Comment		
11:30	Summary and Work Plan		
12:00	**Adjourn**		

List of Participants

July 14, 2016

HICPAC Members
Dr. Daniel Diekema, Co-Chair
Dr. Deborah Yokoe, Co-Chair
Dr. Hilary Babcock
Ms. Vickie Brown
Dr. Sheri Chernetsky Tejedor
Ms. Loretta Fauerbach
Dr. Michael Howell
Dr. W. Charles Huskins
Ms. Lynn Janssen
Dr. Lisa Maragakis
Dr. Selwyn Rogers
Dr. Thomas Talbot
Dr. Michael Tapper

***Ex Officio* Members**
Ms. Elizabeth Claverie-Williams, Food and Drug Administration
Dr. David Henderson, National Institutes of Health
Dr. Melissa Miller, Agency for Healthcare Research and Quality
Dr. Gary Roselle, Veteran's Administration
Dr. Daniel Schwartz, Centers for Medicare and Medicaid Services
Ms. Judy Trawick, Health Resources and Service Administration

Liaison Representatives
Dr. Elaine Dekker (America's Essential Hospitals (AEH))
Dr. Mark Russi (American College of Occupational and Environmental Medicine (ACOEM))
Dr. Elizabeth Wick (American College of Surgeons (ACS))
Ms. Amber Wood (Association of periOperative Registered Nursed (AORN))
Ms. Michael Anne Preas (Association of Professionals of Infection Control and Epidemiology (APIC))
Dr. Valerie Haley (Association of State and Territorial Health Officials (ASTHO))
Ms. Marion Kainer (Council of State and Territorial Epidemiologists (CSTE))
Ms. Lisa McGiffert (Consumers Union (CU))
Ms. Linda Spaulding (DNV Healthcare)
Dr. Stephen Weber (Infectious Diseases Society of America (IDSA))
Dr. Jennifer Gutowski (National Association of County and City Health Officials (NACCHO))
Ms. Kathleen Dunn (Public Health Agency of Canada (PHAC))
Ms. Lori Harmon (Society for Critical Care Medicine (SCCM))
Dr. Mark Rupp (Society for Healthcare Epidemiology of America (SHEA)
Dr. Jennifer Meddings (Society of Hospital Medicine (SHM))
Dr. Robert Sawyer (Surgical Infection Society (SIS))
Ms. Kathryn Spates (The Joint Commission)

CDC Representatives
Ms. Jessica Adam, CDC/DHQP
Ms. Mosunmola Adeyemi, CDC/ DHQP
Ms. Denise Albina, CDC/ DHQP
Ms. Zuleika Aponte-Torres, CDC/ DHQP
Dr. Matt Arduino, CDC/ DHQP
Dr. Michael Bell, CDC/ DHQP
Mr. Isaac Benowitz, CDC/DHQP
Ms. Melissa Brower, CDC/ DHQP
Dr. Denise Cardo, CDC/DHQP
Ms. Nicole Coffin, CDC/ DHQP
Ms. Mahnaz Dasti, CDC/ DHQP
Ms. Maggie Dudeck, CDC/ DHQP
Mr. Jonathan Edwards, CDC/ DHQP
Dr. Ryan Fagan, CDC/ DHQP
Ms. Pam Greene, CDC/ DHQP
Dr. Bill Greim, CDC/ DHQP
Ms. Stephanie Gumbis, CDC/ DHQP
Mr. Jeff Hageman, CDC/ DHQP
Dr. Allison Laufer Halpin, CDC/ DHQP
Ms. Charalynn Harris, CDC/ DHQP
Dr. Rita Helfand, CDC/NCEZID
Ms. Tara Henning, CDC/ DHQP
Ms. Rosa Hererra, CDC/ DHQP
Dr. Lauri Hicks, CDC/ DHQP
Dr. Kathleen Irwin, CDC/ DHQP
Dr. Brendan Jackson, CDC/ NCEZID/ DFWED/ MDB
Dr. John Jernigan, CDC/DHQP
Ms. Michele Junger, CDC/ DOH
Dr. Rima Khabbaz, CDC/ OID
Ms. Laura King, CDC/ DHQP

Dr. David Kuhar, CDC/ DHQP
Dr. Preeta Kutty, CDC/ DHPQ
Dr. Jason Lake, CDC/ DHQP
Mr. Kent Lemoine, CDC/ DHQP
Mr. Joseph Lutgring, CDC/ DHQP
Dr. Meghan Lyman, CDC/ DHQP
Dr. Cliff MacDonald, CDC/ DHQP
Dr. Shelley Magill, CDC/ DHQP
Ms. Barbara McMullan, CDC/ DHQP
Ms. Kerri Moran, CDC/DHQP
Ms. Elizabeth Mothershed, CDC/ DHQP
Ms. Heather Moulton-Meissner
Ms. Lyn Nguyen, CDC/ DHQP
Ms. Erin O'Leary, CDC/ DHQP
Ms. Amibola Ogundimu, CDC/DHQP
Ms. Amanda Overholt, CDC/ DHQP
Ms. Danielle Palms, CDC/ DHQP
Dr. Joe Perz, CDC/ DHQP
Ms. Ruby Phelps, CDC/ DHQP
Dr. Daniel Pollock, CDC/ DHQP
Mr. Paul Prabasaj, CDC/ DHQP
Ms. Jan Ratterreee, CDC/ DHQP
Dr. Sujan Reddy, CDC/ DHQP
Dr. Barry Rhodes, CDC/DHQP
Ms. Kristin Roberts, CDC/ DHQP
Ms. Laura Rose, CDC/ DHQP
Dr. Issac See, CDC/ DHQP
Ms. Kathy Seiber, CDC/ DHQP
Dr. Rachel Slayton, CDC/ DHQP
Ms. Henrietta Smith, CDC/ DHQP
Dr. Arjun Srinivasan, CDC/ DHQP
Ms. Erin Stone, CDC/ DHQP
Dr. Nimalie Stone, CDC/ DHQP
Ms. Abbigail Tumpey, CDC/ DHQP
Dr. Snigdha Vallabhaneni, CDC/ NCEZID/ DFWED/ MDB
Ms. Katharina van Santin, CDC/ DHQP
Ms. Ellen Wan, CDC/DHQP
Dr. J. Todd Weber, CDC/ DHQP
Ms. Victoria Wright, CDC/ DHQP
Ms. Shuai Zheng, CDC/DHQP

Members of the Public
Mr. Nick Austerman, Bard Medical
Ms. Lynne Batshon, Society for Healthcare Epidemiology
Ms. Nicole Bryan, CSTE
Mr. Frank Canonica, Pentax Medical
Dr. Russ Castioni, 3M
Ms. Pamela Falk, Northside Hospital
Mr. Hudson Garrett, PDI
Ms. Amna Handley, GA Pacific
Ms. Linda Homan, Ecolab
Ms. Jessica Kilcarne, Ethicon
Ms. Mary Kundus, 3M
Ms. Rachel Long, BD
Ms. Deborah Nelson, Reuters
Ms. Renee Odehnal, Ethicon
Ms. Erin O'Malley, America's Essential Hospitals
Ms. Silvia Quevedo, Association of Professionals in Infection Control
Ms. Maria Rodriguez, Xenex
Ms. Lisa Tomlinson, APIC
Mr. Tim Waitkus, Bard Medical
Ms. Cindy Winfrey, Pentax

July 15, 2016

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Ms. Uzma Ansari, CDC/ DHQP
Dr. Matt Arduino, CDC/ DHQP
Dr. Michael Bell, CDC/ DHQP
Mr. Isaac Benowitz, CDC/DHQP
Ms. Melissa Brower, CDC/ DHQP
Dr. Denise Cardo, CDC/DHQP
Ms. Nicole Coffin, CDC/ DHQP
Dr. Matthew Crist, CDC/ DHQP
Dr. Jonathan Daniels, CDC/ DHQP
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Dr. Cliff MacDonald, CDC/ DHQP
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Ms. Kerri Moran, CDC/DHQP
Dr. Judith Noble-Wang, CDC/ DHQP
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Dr. Lynne Sehulster, CDC/ DHQP
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Executive Summary

The US Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on July 14-15, 2016, in Atlanta, Georgia. The Designated Federal Official (DFO) and Chair confirmed the presence of a quorum of HICPAC voting members and *ex officio* members.

The meeting was called to order at 9:06 a.m. on July 14, 2016. Dr. Denise Cardo provided updates from DHQP, including the division's response to outbreaks and threats; approach to communication; plans to fund state and local Healthcare Associated Infection-Antibiotic Resistance (HAI-AR) programs; and other funding opportunities. Dr. Barry Rhodes explained technical aspects of the National Healthcare Safety Network (NHSN) and provided an overview of the network's future direction. Ms. Margaret Dudeck updated HICPAC on the re-baseline process for NHSN HAI data. Dr. Cliff McDonald shared questions and challenges related to the impact of laboratory testing on the *Clostridium difficile* infection (CDI) standardized infection ratio (SIR) in NHSN. Dr. Lauri Hicks described recent progress in DHQP's stewardship activities, including program expansion for implementation of the Core Elements of Antibiotic Stewardship Programs. Dr. Arjun Srinivasan provided an update on the Antibiotic Use (AU) option of NHSN. Dr. Michael Tapper shared progress from the HICPAC Working Group on Antimicrobial Stewardship Principles for Treatment Guidelines. Dr. Daniel Diekema presented updates and progress since the March 2016 HICPAC meeting on the *Mycobacterium (M) chimaera* outbreak linked to heater-cooler units. Dr. Kathleen Irwin presented an overview of DHQP's plans to update the draft Guideline on Infection Prevention in Neonatal Intensive Care Units (NICUs). Dr. David Kuhar apprised HICPAC about plans to update the 1998 Guideline for Infection Prevention in Healthcare Personnel. Mr. Jeff Hageman and Dr. Michael Bell led HICPAC in a discussion of challenges associated with guideline production at CDC. HICPAC liaison representatives and *ex officio* members provided written and oral reports.

HICPAC stood in recess from 5:18 p.m. on July 14 until 9:05 a.m. on July 15. Dr. Christine Olson presented HICPAC with an update on Zika virus. Ms. Vickie Brown presented an update on the activities of the Endoscope Reprocessing Workgroup. HICPAC discussed and voted unanimously to approve with minor edits the Essential Elements of a Reprocessing Program for Flexible Endoscopes. HICPAC discussed and voted unanimously to approve the Antimicrobial Stewardship Principles for Treatment Guidelines presented by Dr. Charles Huskins, with some suggested edits. Dr. Snigdha Vallabhaneni updated HICPAC on the globally-emerging multidrug-resistant yeast *Candida auris (C. auris*). Dr. Alison Laufer Halpin presented on the plasmid-mediated colistin resistance (*mcr*-1) gene. Public comment was offered by Ms. Mary Kundus of 3M Medical.

HICPAC stood in recess at 11:29 a.m. on July 15, 2016.

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National Center for Emerging and Zoonotic Diseases
Division of Healthcare Quality Promotion

Healthcare Infection Control Practices Advisory Committee (HICPAC)

July 14-15, 2016
Atlanta, Georgia

Minutes of the Meeting

The Division of Healthcare Quality Promotion (DHQP), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) the Centers for Disease Control and Prevention (CDC), United States Department of Health and Human Services (HHS) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on July 14 and 15, 2016 at the Tom Harkin Global Communications Center at the Centers for Disease Control and Prevention, 1600 Clifton Road NE, Atlanta, Georgia.

Thursday, July 14, 2016

Welcome and Introductions

Jeff Hageman
Division of Healthcare Quality and Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
Designated Federal Official, Healthcare Infection Control Practices Advisory Committee

Mr. Jeff Hageman called the meeting to order at 9:05 a.m. and welcomed HICPAC members, *ex officio* members, and liaison representatives. He conducted a roll call. A quorum was present. HICPAC members disclosed the following conflicts of interest:

- Dr. Daniel Diekema has received research funding from bioMérieux.
- Dr. Lisa Maragakis receives research funding from Clorox and Versus, Inc.
- Ms. Lynn Janssen's spouse works for a biotech company, Dynavax, which develops immunology products, including vaccines.
- Dr. W. Charles Huskins has served as an advisory board member for Genentech. He has received supplies and equipment for research from GOJO.
- Dr. Thomas Talbot's spouse receives funding for vaccine research from Sanofi Pasteur, MedImmune, Gilead Sciences, and Novartis.

CDC Updates: Division of Healthcare Quality Promotion (DHQP)

Denise Cardo, MD
Director, Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Dr. Denise Cardo greeted HICPAC and explained that moving forward, DHQP updates will include information about the division's scientific work, as well as updates on the division's strategic plans. This will help HICPAC provide advice on the division's directions and will help HICPAC liaison representatives to determine how their organizations can help advance the division's work. The updates will focus on the following areas:

- Outbreaks and Responses
- State and Local Programs: Prevention
- Data Systems
- Innovation and Research

DHQP is actively responding to new and ongoing outbreaks. The responses include emerging threats and resistance, as well as outbreaks in outpatient settings and in settings with high-risk patients related to a lack of adherence to infection control practices. There is a multi-state outbreak related to contaminated medical products and unsafe compounding practices. DHQP relies on state health departments, hospitals, healthcare epidemiologists, and other partners to invite the division to respond. For emerging resistance in healthcare settings, one case is enough for DHQP to respond. Some responses require containment-focused approaches with aggressive prevention and screening strategies. The division is working proactively in these cases. The National Strategy for Combating Antibiotic-Resistant Bacteria (CARB) is the federal plan focused on combating emerging resistance and DHQP is working with domestic and global partners to respond to emerging resistance. This work is not the responsibility of CDC alone.

DHQP is also taking a proactive approach to communication. For instance, as soon as there is potential for a contaminated product, information will be shared in an effort to prevent additional cases. Partners must take part in this communication and inform hospitals, look for additional cases, and look for gaps in infection control practices. CDC counts on its partners to embrace the concept of acting proactively and early in the process to protect patients, at times even before an association is proven.

DHQP works closely with the US Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS). These partnerships are critical in outbreak investigations in enforcing action and penalties if safe practices are not enacted. The paradigm of response to outbreaks and to emergent resistance is changing. During the last HICPAC meeting, division updates included plans for federal funding CDC has received to combat antibiotic resistance. One of the topics was state and local Healthcare Associated Infection-Antibiotic Resistance (HAI-AR) programs. The next time HICPAC meets, Dr. Cardo hopes to be able to show each state's funding and plan, as well as the division's strategy to work with each state to monitor and prevent infections. All states will receive funding for HAI-AR programs and, there will be at least one person to coordinate that program. Also, all states will receive some support for Carbapenem-resistant *Enterobacteriaceae* (CRE) testing, including identifying mechanisms of resistance. Approximately 25 states will receive support for prevention programs, which will address device-related infections and present a coordinated approach to

prevent CRE, *Clostridium difficile* (*C. diff*), and other multidrug-resistant organisms (MDROs). There has been a misperception that the main focus of AR is stewardship. Stewardship is one strategy to combat antibiotic resistance, but progress on combating AR continues to be measured based on prevention of infections and prevention of transmission of infections in addition to improved use. Several states also receive funds for stewardship activities in both inpatient and outpatient settings. While some states have received these funds in the past, the new funds represent an opportunity to expand and work more aggressively. States receiving funds for the first time will utilize these funds to begin activities.

DHQP funds 11 CDC Prevention Epicenters, which is a research program that includes collaboration with leading researchers at academic institutions. The HAI aspect of the Emerging Infections Program (EIP) is also funded by DHQP. Some state and local health departments will receive Epidemiological and Laboratory Capacity (ELC) funds to expand core capacities to prevent HAIs, to improve CRE detection, and for their EIP to monitor pathogens and focus on prevention. DHQP is visiting these states to learn how the Epicenters collaborate with the EIPs and the ELCs. These visits are intended to explore and demonstrate how collaboration across groups can lead to prevention impact.

The division is engaged in a number of innovative approaches. The Prevention Epicenters focus on best approaches for preventing infections in healthcare facilities. Safe Healthcare, Epidemiology, and Prevention Research Development (SHEPheRD) is a funding mechanism that allows CDC to work with healthcare systems, academic centers, and other groups on a variety of research domains. New domain areas include nursing homes and healthcare information technology. Ebola funds have allowed for an expanded number of Epicenters to assess approaches to prevent transmission of infections, including how transmission is occurring, effectiveness of personal protective equipment (PPE), environmental factors, and environmental source control.

Legacy Epicenters were also recently funded, and a press conference was held at the Chicago Epicenter. Their emphasis is on multi-center projects in a range of areas. The primary focus remains on prevention, even as new areas are explored, such as the microbiome. The Epicenters, SHEPheRD recipients, and some local health departments are pursuing projects with a coordinated approach to *C. diff*, CRE, and other MDROs. For example, in Chicago, the health department is working with the Epicenter to show that this approach will prevent infections and to identify the factors that are critical for success.

For the first time, DHQP is providing direct assistance to some state and local health departments. A full-time CDC employee will work with the health department to help expand upon local HAI/AR prevention efforts.
The fiscal year (FY) 2016 Broad Agency Announcement (BAA) contains a number of broad research priorities. While the categories are broad for the first announcement, the opportunities will be more specific in the future. More than 100 letters of intent were received, which is a good sign that the community recognizes these questions are important and is interested in finding ways to move forward.

One of the main topics announced in the BAA is microbiome assessment to address AR. This category includes natural history, as well as understanding of microbiome disruption and the importance of the microbiome in the transmission of infection. The category also includes the importance of antibiotic use in the microbiome. Other areas of focus include:

- Understanding and prevention of antibiotic-resistant organism transmission and emergence.

- Understanding the role of the environment in pathogen transmission, measuring the environment, and considering innovative ways to prevent those transmissions.
- Enhanced understanding of medication safety threats.
- Evaluating the capacity for tracking and preventing antibiotic-resistance threats in non-acute care settings is another aspect of the BAA.

The President's Advisory Committee for CARB extended questions regarding the environment, and the management of waste, and sewage. There are opportunities to improve understanding and to develop strategies to address the role of the larger environment in new resistance or transmission of resistance.

Dr. Cardo noted that the HICPAC meeting agenda included presentations and discussion regarding emerging resistance and about the National Healthcare Safety Network (NHSN), particularly its future work, for the re-baseline and *C. diff*. As soon as the BAA is finalized, HICPAC will be updated regarding the funded proposals and how the pieces will be assembled to make a difference. HICPAC members and liaisons play a role in DHQP's work, particularly in sharing observations regarding how CDC can better work with partners. Many more challenges lie ahead regarding resistance, "because the more you look, the more you find." HICPAC is an important part of containing and preventing infections.

Discussion Points

HICPAC commented on the exciting and broad range of activities in the portfolio being led by DHQP.

Dr. Michael Bell commented that the BAA is a research funding mechanism that the entire agency can use to address broad areas of work.

CSTE asked about the AR Laboratory Network. Dr. Cardo said that approximately seven regional laboratories, in a combination of public health and academic centers, will be funded to provide support to the response. The support will depend upon the pathogen. For instance, if there is an outbreak or new resistant mechanism in a specific facility and screening is recommended, these laboratories can provide that screening as well as additional capacity. In addition to providing additional capacity to respond to emerging threats, regional laboratories can provide training, support, and additional capabilities to state public health laboratories.

There was discussion regarding the interaction between DHQP and the National Institute of Allergy and Infectious Diseases (NIAID). The AR Leadership Group is also charged with research studies to address resistance, and there are potential interactions between DHQP's work and that group's charge.

Dr. Cardo answered that DHQP works with NIH, as well as the other federal agencies and the CARB plan helps to ensure that their work is not duplicative. This approach represents a new way for the agencies to collaborate. Some recent examples include, working with the US Department of Defense (DoD) in sharing emerging resistance isolates and communicating early allowed for movement forward together. DHQP has also been working with NIH and, Dr. Cliff McDonald, who leads much of the Division's work on the microbiome, works with several NIH groups. Recently, a joint meeting was convened with the Agency for Healthcare Research and Quality (AHRQ) to assess research gaps and that will allow for coordination of research funding

NHSN Updates

NHSN Overview and Future Direction: NHSN2

Barry Rhodes, PhD
Technical Lead, National Healthcare Safety Network
Surveillance Branch
Division of Healthcare Quality and Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Dr. Barry Rhodes explained technical aspects of NHSN and provided an overview of the network's future direction. NHSN has approximately 36,000 active users representing more than 14,000 facilities. Approximately 25% of the facilities report data electronically via clinical document architecture (CDA) messages. Tremendous strides have been made toward electronic messaging, but there is more to do. NHSN supports national-level public health surveillance, state reporting mandates, and CMS reimbursement programs.

NHSN is a centralized information technology (IT) infrastructure; that is, all data are reported to a single database located at CDC. Most data are entered manually into web pages, which are hosted from a single site at CDC. The network supports CDA, a Health Level (HL) 7 standard format for sending data. Data are received through two mechanisms. A user has access to the CDAs that have been created by an electronic health record (EHR) vendor or infection control software vendor and can manually upload the information. Data can be received through a protocol called DIRECT, in which an electronic healthcare system can create CDAs and send them directly to CDC without manual intervention. Increasingly more facilities want to utilize this method, as it reduces user burden significantly. Data are available to partners for analysis within the application or in useful downloaded formats. For large groups or states, the data are not available immediately.

NHSN is nearly 11 years old and has been, by all accounts, a tremendous success. Expectations for its expansion, functionality, and coverage continue to grow. There are new areas for surveillance and coverage is expanding to new areas, such as long-term care facilities and nursing homes. NHSN was designed and developed in 2003 and went live in 2005. Technology has changed tremendously since then. NHSN is "like a split-level ranch house that has been remodeled into a skyscraper." It was initially designed for 300 teaching hospitals, all of which volunteered to enter data. Elements of the network have been rebuilt over its 11-year history, but its foundational design principle has not changed. As a system is modified, it becomes more complex. Software development seeks to manage that complexity. It is a testament to CDC's developers and testing teams that NHSN functions as well as it does.

A technical redesign of NHSN will incorporate several new elements:

- Responsive design to support the use of smartphones, tablets, and laptops, as well as to be easily compatible across browsers and devices;
- Leveraging of cloud computing: CMS reporting occurs on a quarterly basis, leading to spikes in user load four times per year. A cloud environment can address those differing levels of usability with elasticity, adding more servers when they are needed and removing them when they are not needed;
- Horizontal scaling to add functionality and vertically to add more users;
- Simplified user experience, streamlining the look and feel of the application to make it as responsive as possible
- Move to electronic data submission of pre-existing health data when possible, extracting information from an EHR system or infection control system without burdening users;
- Implementation of several initiatives are underway at CDC to consider common platforms and shared services across the agency; NHSN can lead CDC, in some ways, to broaden the "stovepipe" surveillance systems into a more common, sharable system; and
- Better data provisioning to the people who need it, when they need it.

A redesign of NHSN presents opportunities to think in new ways and to incorporate certain design principles. NHSN receives data primarily from three data sources:

- Pre-existing electronic data that are extracted from a system: newer definitions in NHSN, such as ventilator-associated events (VAEs), have taken advantage of this pre-existing data extraction.

- Electronically augmented manual data entry: many software vendors recreate the NHSN screens in their applications so that users can pre-populate some information in NHSN and then verify it. The systems then create CDA messages and send them to NHSN.

- Manual data entry, in which infection preventionists enter data directly into the NHSN application.

The highest priority is on pre-existing data, which requires little intervention and places less burden on users.

Other design principles for consideration include stable core reporting paired with a more nimble investigative study capability. NHSN is very large and it is not very nimble; that is, if a new field is added to a definition, the information needs to be coded at CDC and shared with EHR vendors, which then code it into their systems. The change is incorporated into the NHSN schedule and then must be implemented at facilities, which also takes time and can have financial implications. There are ways to build a system with two pieces to include a stable core and a responsive mechanism for making changes. An open Application Programming Interface (API) will open NHSN to a broader spectrum of users. The data may not be patient-level initially, but vendors need access to many elements of NHSN, and that access is currently cumbersome. For example, location mapping tables may be needed by an EHR vendor. Currently, users must manually download the location mapping table so that vendors can upload it into their system in order to create reports. It would be easier for vendors to access the tables directly from NHSN. Infrastructure should respond to user load spikes. On a day-to-day basis, much of the infrastructure is not needed. A newer system will have the elasticity to respond. Migration of existing definitions to use pre-existing electronic healthcare data, and away from subjective determinations. Current definitions do not lend themselves to the use of pre-existing electronic data. For instance, subjective determinations are needed for certain central line-associated bloodstream infections (CLABSIs) and surgical site infections (SSIs). It is a significant undertaking to rethink those definitions, but moving toward a truly electronic system will require their evolution.

Early thinking about redesigning NHSN proposes a next generation, NHSN2. HICPAC can be helpful in gathering high-level requirements of the system, as the design is less about technology and more about how the network functions. Technology translates ideas into systems and behaviors—the design is those ideas. Another early step is defining a set of CDC-wide services and platforms that NHSN2 requires and currently supports and how NHSN2 will integrate into the broader spectrum of CDC's surveillance systems as well as state systems so that they can be leveraged and work together. Electronic Laboratory Reporting (ELR) is an example of this idea, as Laboratory Identified (LabID) reporting and antimicrobial resistance (AMR) reporting are very similar and do not necessarily need completely separate systems. The systems have different requirements and different needs, however, and should fit together. Initial conversation are underway within CDC and elsewhere to understand how the different systems can work together, even given their different timing requirements and other attributes. Rethinking NHSN is not necessarily focused on changing the elements of the system that are good and necessary, but on expanding and extending its capabilities to address current and future needs.

The proposed first phase of an NHSN redesign is an agreed-upon vision. This vision should be developed with CDC, its partners, HICPAC, and other stakeholders to consider the strategic and tactical levels. The vision will include goals, objectives, milestones, deliverables, and a migration plan in three areas: 1) Technical; 2) Scientific, particularly regarding the evolution of definitions; and 3) Policy, such as how to share data with state and local entities and the implications of common ELR and NHSN reporting. While a move to NHSN2 is necessary, the current state of NHSN is not dire. CDC can continue to make significant and incremental improvements to the application so that NHSN continues to evolve. These changes become increasingly difficult and introduce potential bugs in the absence of a rational design that aligns with current technologies. Even so, NHSN is stable and sound and will be for some time.

Discussion Points

HICPAC thanked Dr. Rhodes and his team for their work. End users appreciate the work and the usability and features of NHSN that help to prevent infections and to save lives.

Dr. Bell noted that many HICPAC members are long-term experts in the content of NHSN. The application is complex and is directly tied to reimbursement of hospitals and other healthcare settings. If the system has a glitch that prevents a user from inputting information on time, then there could be delays in payment. There is a great deal of pressure on Dr. Rhodes's group to ensure that the system is working all of the time and particularly during last-minute surges. Additionally, users require a great deal of support, especially when they join NHSN. When 14,000 nursing homes join the network, they bring many new individuals to be trained and supported. Dr. Rhodes's group also must work with IT vendors, sharing data elements and methodologies. All of this work takes place in the context of a moving field. When NHSN was first designed, there were no issues such as antibiotic use (AU), AR, CRE, and related concerns. The demands for the system have increased as these issues have emerged.

NHSN will need to transition to NHSN2 soon, as each new investment in the current system will be larger and yield less. The reporting platforms used by newer, specialty societies could be instructive since they are tackling similar issues.

HICPAC asked whether Dr. Rhodes is working with HL7 and the new Fast Healthcare Interoperability Resources (FHIR) standards to ensure that there are not large gaps in terms of vocabulary and standardization. Dr. Rhodes answered that DHQP is working with these standards in mind. FHIR is a 21st Century version of an interoperability standard through HL7. His group is currently examining FHIR for lower-security level functionalities within NHSN, such as vocabulary. DHQP is providing value sets and organism codes, for instance, to partners through a FHIR interface. Experiences at this level will inform the reporting of patient-level information. They are receiving advice from HL7 experts at every step.

Users and societies likely will not be comfortable with many elements being available through an automated pull. An approval mechanism will be needed. A mechanism is in place now, but it is somewhat tedious and requires too much manual work. The next design of NHSN could have approvals built in so that data could still be shared in an automated fashion. The case can be made that the time, and effort spent by organizations in inputting data and receiving reports will represent a significant return on investment with a new design. Infection preventionists at facilities should be engaged in infection prevention work rather than data wrangling.

HICPAC asked about a strategy regarding the reporting interface and visualization; that is, what is the business intelligence layer on top of the data to make it more helpful for users so that they want to interact with the data and use it?

Dr. Rhodes said that there are several ideas regarding how to present the information in a digestible format. Using Statistical Analysis System (SAS) for data analytics and to provide reporting mechanisms is somewhat arcane. In the future, NHSN will evolve to a dashboard-like look and feel so that reports are available at a glance. Much of the network's business logic is now written in prose and could be converted into a format that is machine-readable and that can be shared with others. This approach will be especially helpful for vendors that reproduce NHSN screens in their systems.

HICPAC commented on reticence to moving toward electronic definitions where the definitions are currently subjective. Work was done across the Epicenters on the CLABSI definition so that it could be made electronic. LabID was created to collect electronic data so that individuals did not have to make decisions. HICPAC asked about plans to adopt electronic definitions now rather than waiting for NHSN2 so that the new definitions are not perceived as threatening.

Dr. Rhodes said that there is a tremendous amount of work associated with migrating to those definitions. The definitions do not appear to be mature enough to be required, but discussions are ongoing about what they might look like, particularly regarding probabilistic CLABSI or healthcare-associated bloodstream infection (BSI). He hoped that NHSN could offer support of small studies of new definitions in order to build trust.

Dr. Cardo added that many of the improvements in NHSN will be used in the future. The investments are prioritized. The definition development process is moving toward electronic definitions. Infections need to be prevented in all hospitals, and their work should keep that in mind as they improve current definitions. When HICPAC provides input to definitions, it is important to consider not only how the infection prevention and control field works now, but also how it will work in the future. The focus is always on what is best for the patient. DHQP is aware of the burden that surveillance can place on infection preventionists. It is important to make time to utilize tools to use data for action to prevent infections, using information to conceive of different ways to work. The Antimicrobial Use and Resistance (AUR) module of NHSN is all electronic and represents a step forward in a long process of improvement in collecting data that can be used for prevention. In creating definitions that use electronic data, it is important to focus on how best to prevent infections. The definitions also are used for payment. Ultimately, many factors combine to make an impact. Keeping HICPAC informed means that HICPAC can help with solutions as well as engagement. She encouraged HICPAC not to think about a switch to NHSN2 as much as a process for moving toward a new infrastructure for NHSN2.

The Association of Professionals of Infection Control and Epidemiology (APIC) commented that infection preventionists are looking for the EHR and third-party data mining systems to “speak the same language” and to have interfaces that do not require a great deal of IT support and that feed directly to CDC. Standardized language would be helpful. There is a dependence upon third-party vendors or supplemental measures to provide data to NHSN, which requires financial and IT resources from hospitals. Because there is pushback against this approach, it would be helpful to pressure the industry to make the process standardized and simple, allowing infection preventionists more time to do their important work.

The Council of State and Territorial Epidemiologists (CSTE) thanked Dr. Rhodes and DHQP for providing the infrastructure for NHSN. State health departments appreciate being able to use the data for action. The principles of the proposed redesign are spot on. It would be helpful to create a process by which stakeholders and constituents can provide input into the redesign. Regarding the priority of using electronic data immediately, the groups that are using third-party or black-box software are seeing mistakes in the data that have implications for calculation; for example, hospital-onset methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia or *C. diff*. infection. Particular problems are associated with dates. The date of admission is not always clear for an observation-status patient and in terms of the location of attribution. Even in the simplest extraction of data, there are significant problems. It is important that validation occurs, given the serious implications.

The evolution of NHSN is important, but it also is important to consider the needs of critical access hospitals and hospitals that do not have resources. These facilities are likely to fall further behind without an infusion of capital, making problems worse over time.

HICPAC shared concerns regarding the process for creating electronic data definitions, particularly LabID. The chart review validation for *C. diff* LabID showed that only 50% of the patients had signs and symptoms of *C. diff* disease. To prevent the LabID events, half of the work is in infection prevention and the other half is in clinician ordering and testing behaviors. Clinical documentation and coding are important elements as well. Without resources to conduct chart review to understand what the data represent, facilities could be frustrated as they try to prevent events that are not real events. More information is needed so that strategies align with what the data represent. There are risks associated with eroding infection preventionists' credibility as well. If an infection preventionist comes to a unit with a line list of patients who do not have the disease that is being measured, then their messages will not be heard. Infection preventionists can give input on improving the usability of the NHSN interface so that lists can be retrieved. Transparency about the algorithms also would be welcome, especially regarding exclusions and the reasoning behind them.

Dr. Cardo said that it is important for DHQP to understand whether these problems are associated with system definitions, bad practice, or both. In *C. diff*, the problem is not with LabID, but with testing ordered by clinicians. In the future, it is important to educate clinicians regarding when to order a test.

Dr. Rhodes agreed that validation is key. DHQP is interested in understanding how to scale validation because it is so intense. The division is working with the US Department of Veterans Affairs (VA) with a set of synthetic data sets to exercise an external system to extract this information and to learn whether data are extracted properly. This exercise is not a complete validation process because of lingering "garbage in, garbage out" problems. Electronic data has issues itself in areas such as admission dates and transfer dates. There are ways to conduct validation that scale more broadly than manual chart reviews. He urged HICPAC to think through these approaches and to share them.

HICPAC agreed that moving to a more modern platform is the right thing to do for NHSN. Further, the most important design principle is that infection control practitioners should not be the interface between two electronic systems. This approach is a waste of human talent. Building a platform to enable large-scale experimentation regarding definitional issues in the future is an important concept. Problems such as SSI are subjective, but in the future, deep learning may be applied to them, so the platform should build in this possibility. Equity across sites must be considered as the work moves forward, because disparities could worsen. Many EHR and other data systems have logistical problems that create challenges beyond surveillance issues.

HICPAC commended DHQP for the thoughtful planning for moving NHSN forward. When moving to more electronic platforms, some use common language and can "talk to each other," which frees infection preventionists for other work. It also is important to understand that the process requires expansion of IT resources at the same time, however. Putting resources into IT personnel who can work with electronic data is appropriate so that infection preventionists can concentrate on their infection prevention work; however, the change represents a shift in resources from one department to another. NHSN began as a means for helping facilities understand their performance compared to their peers and to help drive change. In the process of redesigning NHSN, DHQP is encouraged to think broadly about what the goal is for NHSN. Is

the goal still to build a deep understanding of a facility and to use information to drive action, or is it to provide actionable data to CMS for reimbursement? Within the goal, the electronic reporting and electronic data element capture should incorporate what the definition changes mean. There is a perception that an electronic measure will increase buy-in from providers, which was not the case with VAE. There are differences between clinical and surveillance definitions, but it is important to recognize that as definitional changes are made to improve electronic capabilities, focus remains on understanding and explanations. DHQP is encouraged to consider opportunities to include data elements that will improve risk stratification models and risk understanding, helping facilities focus on their best opportunities for progress.

Dr. Cardo agreed that NHSN's focus is on data that can be used for prevention. Data can be helpful to make a difference at the facility level, and it can be used at the state and federal levels to make a difference as well. The entire field has changed. NHSN is not just a "boutique" system. Future updates to HICPAC can illustrate how much NHSN has changed over its history. DHQP knows the limitations and hopes for HICPAC's help in finding solutions that are scientifically correct and to move the field forward.

It would be helpful to build competence into state HAI programs regarding how to help hospitals that want to use CDA. State health departments work with contractors for this work, but public health needs the competence. Infection preventionists should not be IT professionals, but they should speak the language at some level in order to understand what they are asking for. The current disconnect has probably impeded progress.

Dr. Rhodes agreed and said that DHQP is talking to the Public Health Informatics Institute (PHII) about building competencies for CDA creation and working with hospitals.

America's Essential Hospitals (AEH) agreed with the sentiments that had been expressed regarding the needs of hospitals. It is important to remember that a facility's size does not necessarily translate to the financial resources available for IT programs and support. In many facilities of various sizes, the IT department could be one or two people. Initial funding to start an electronic program does not always attend to long-term arrangements, updates, and improvements to the system that was developed with outside financial assistance. Infection preventionists struggle with changes in epidemiological surveillance definitions and differences between those definitions and clinical definitions. Data can be pulled electronically, but there should still be an "eyes on" approach.

Regarding NHSN2, systems that extract data for third-party payers, CMS, or insurance companies should ensure that the data are extracted appropriately so that reports are not posted with erroneous data. Currently, there are not sufficient checks and balances, and other systems may not understand the data. Electronic definitions will not be perfect, but they can be a best estimate so that the data can indicate trends. As the transition to NHSN2 approaches, there should be education, dialogue, and training with physicians to build understanding of why the work is done, why it is valid, and why the results do not always align with clinical data.

Dr. Rhodes thanked HICPAC for the comments, which represent a starting point for a strategic plan.

Update on the NHSN Rebaseline of HAI Data

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Ms. Margaret Dudeck updated HICPAC on the re-baseline process for NHSN HAI data. The baseline uses a static time period of NHSN data to calculate standardized infection ratios (SIRs) and to measure progress toward prevention goals. The purpose of the re-baseline is to use 2015 NHSN data to produce updated risk models and new models for future measurement of progress toward HIA prevention goals.

The scope of the re-baseline extends beyond analyzing data and generating new risk models. The re-baseline will also introduce a new measure, the standardized utilization ratio (SUR). The implementation aspect of the re-baseline includes implementing the new risk models into the NHSN application for use by hospitals and other external partners, as well as implementing the new models into files that are submitted to CMS for the Quality Reporting Program and for CDC's internal metrics. The education aspect of the re-baseline has been introduced over the past year. As the SIRs are implemented, education and communication efforts will expand.

Publication of models is planned, as well as the development of a predicted rate calculator. The risk models will allow SIRs to be available for use on a regular basis for comparison to national data. DHQP understands the importance of having national-level rates available for device-associated infections and for other issues, such as SSI rates that use the same risk factors and models. The predicted rate calculator will be a publicly-available tool that will ask for the type of HAI, the type of setting, and the set of risk factors that are applicable to that setting and HAI type. The tool will then produce a predicted rate using 2015 national data. Users can compare their own rates under the same set of factors to the predicted rate.

The risk adjustment methods and models will vary from the original baselines. DHQP is using this opportunity to assess and reassess all of the available factors that are applicable to the settings and HAIs that are being analyzed. Most notably, in device-associated infections, the models are moving away from using national pooled mean rates for the calculation of SIRs. Instead, the new approach will utilize risk models for that calculation, allowing for the re-categorization of location and consideration of other factors, such as medical school affiliations and potentially bed sizes of hospitals.

The re-baseline will analyze data for acute care hospitals separately from critical access hospitals, long-term acute care hospitals (LTACHs), and inpatient rehabilitation facilities (IRFs). The re-baseline will assess each HAI separately. The mucosal barrier injury (MBI) data will be taken out of CLABSI data and analyzed on its own. The SURs will be analyzed for each device for which data are collected. Multiple SSI models are planned. This new work equates to 190 new models that will be developed and implemented in NHSN.

The bulk of the new models are SSI models, as data are analyzed for each operative procedure category, and there are different categories of models. For instance, the "All SSI" model will

include all of the SSIs that can be reported. Other new models include the "Complex admission/readmission (A/R)" model and the "Complex 30-day" model, which is used for CMS reporting. The "all" and "complex A/R" models will be split by adults and pediatrics, and among the pediatrics, there is potential to split among two levels of age groups: 0-2 years and greater than 18 years. LabID models will be available for LTACHs and IRFs. VAE models are planned as well. The exact number of new models is shifting as the analysis phase of work nears. Some of the models may be intercept-only, due to the low number of infections reported at the national level. There also is the potential for expansion among the pediatric SSI group.

All of the new models that are related to the CMS Quality Reporting programs will be used from CMS data submissions, beginning with the data from the first quarter of 2016, which are due on August 15, 2016. Between now and then, DHQP will develop and validate all models using a bootstrap validation. The division will prepare, test, and verify the CMS Quality Reporting files before the data are submitted to CMS on behalf of all the facilities for which the data apply. In the fall and winter of 2016, DHQP will develop all of the new reports within the NHSN application. The planned release date is winter 2016-2017. Education and communication will continue, as it is important to provide education and communication before the models are implemented, using quick reference guides, newsletters, and re-baseline Webinars that will be available prior to the final implementation. Continuing education will be offered for the webinars.

Discussion Points

HICPAC asked when the data that have been run with the new models will be submitted to CMS and when the data will be made public. Ms. Dudeck said that CDC submits the data on the first business day after August 15, 2016. Prior to a CMS Quality Reporting data deadline, CDC produces multiple preliminary files. The new models will be implemented, tested, and verified within these preliminary files. When it is time to send and share the models, they will be accurate and high-quality. She was not aware of the timeline for CMS to post the data publicly on Hospital Compare.

California is one of the states that reports vancomycin-resistant *Enterococcus faecium* (VRE) BSIs. A model might be developed for them, perhaps with the assistance of state epidemiology staff. California generates a report stratified by hospital type rates, which is not satisfying. Ms. Dudeck answered that such a model could be considered after completion of this phase of the re-baseline.

If possible, it would be valuable to have a pediatric-specific CLABSI model. There is a large collaborative of children's hospitals, Solutions for Patient Safety, that have had specific issues related to CLABSI in 2015, and this information would be helpful for them.

Ms. Dudeck said that one of DHQP's approaches in analyzing the data is to consider the facility type for each HAI type, determining whether the status of pediatric hospital is a significant factor. For the device-associated infections, mainly CLABSI and catheter-associated urinary tract infection (CAUTI), the individual CDC location type is analyzed as well, which has an indication for pediatric units within the hospital. The pediatric hospitals are rolled into the acute care hospital model, but in some instances, there will be a risk factor of pediatric, either hospital or location, in the model so that those data will be adjusted for separately.

CSTE asked whether the 2015 data will be resubmitted to CDC using the new risk adjustment, or whether only 2016 data will be used.

Ms. Dudeck answered that the SIRs from 2015 data reported to NHSN will be recalculated using the 2015 models and resubmitted to CMS for the purpose of future hospital value-based purchasing program years. This resubmission will apply only to acute care hospitals, not LTACHs and IRFs.

In terms of education, there has been a great deal of focus on the infection control community. It is extremely important to extend broad education to the non-infection control community, especially Chief Executive Officers (CEOs), Chief Medical Officers (CMOs), and Chief Operating Officers (COOs). These officers know about NHSN because of value-based purchasing, and it will be confusing to understand changes in the SIR due to changes in NHSN. Medical leadership and administrative organizations will be important partners in communication. The re-baselining is extremely important. The risk modeling and risk adjustment are also important. This element of the public reporting data is still behind. For instance, comparable facilities to one hospital comprise only 3.5% of the pool of facilities in NHSN, making it challenging to find benchmarks and to assess other factors which cannot be controlled, such as immunosuppression, that make comparisons difficult. A more equitable concrete plan for risk adjustment would be welcome. Hospital administrations look at NHSN numbers in their efforts to reduce events, but it is frustrating when it appears that they have reached a floor. The ability of NHSN to have different benchmarking pools will be helpful as well. A user could link to a certain peer group for comparison and to set goals.

HICPAC asked if the updated complex 30-day models for colon surgery (COLO) and abdominal hysterectomy (HYST), which generate data that are submitted to committee will include additional risk variables. Ms. Dudeck answered that the new models will expand beyond age and American Society of Anesthesiologists (ASA) score.

Various groups, including surgical groups, have discussed that the current risk adjustment is minimal. The planned expansion is laudable.

Regarding the frequency of re-baselining, Ms. Dudeck said that DHQP has not defined how often re-baselining will occur, but the HAI Action Plan draft goals are set through 2020. She did not anticipate re-baselining more frequently than every five years.

SIS asked whether the modeling techniques will incorporate machine learning or other methodologies that will allow for more frequent re-baselining and avoid older notions regarding having limited numbers of variables in complicated situations. There is discontent with collecting two or three variables to predict SSI, when data are collected on hundreds of variables and could be reanalyzed using more modern techniques.

Ms. Dudeck said that the main modeling methods used are negative binomial regression or logistic regression.

Consumers Union (CU) asked about plans to educate the public on the new baselines. The public is often uninformed about what SIRs mean. It might be helpful to specify that the previous baseline allows for a snapshot of what happens at a hospital, and the re-baseline is a reset before moving forward. If CDC and NHSN are thinking about presenting data to the public in different ways, then stratification by type of hospital would be a beneficial presentation, perhaps as part of an annual report, so that the public is trained in how to understand the hospital comparisons.

Ms. Dudeck answered that CDC will discuss public education, potentially as part of the next HAI Progress Report.

It would be valuable to have a more dynamic SIR. It is difficult for hospitals to use the SIR for internal quality improvement when it is not updated frequently. The re-baselining will require a great deal of education and may add to the confusion. In using data for improvement on a local level, it would be interesting to understand the barriers to a more dynamic SIR.

In using the SIR for daily improvement, some hospitals drill down to the unit level and work with smaller groups within larger entities. Often, the denominator is not large enough to generate an SIR. The facility then creates its own institutional dashboards that represent data in a different way. Predictive models or other tools could be used to communicate.

Ms. Dudeck said that one of the items under consideration is lowering the threshold for the requirement of calculating the SIR. The SIRs currently are not calculated if the predicted number is less than 1. DHQP has conducted some preliminary analysis of data using the original baselines and has found that the threshold could be lowered to 0.2; however, the analysis should be conducted with the new baselines to determine what that threshold may be.

At the lower end of the threshold for inclusion, there is potential to allow small hospitals with low expected values into the larger pool. This shift increases the need for facilities to select appropriate benchmarking pools. With this pool selection, in theory, a facility also could select a time period for comparison, which would mitigate shocking changes that occur with delayed re-benchmarking.

Regarding the re-baselining, HICPAC asked whether it is expected that a substantial number of facilities will move from outlier status to average, or whether the outlier population might change. Ms. Dudeck answered that it is expected that some facilities may shift closer to 1 in the new baseline, particularly with the 2015 and 2016 SIRs. New SIRs have not yet been generated, but that work will begin in the next few days as the files are prepared. DHQP is interested in learning how some hospitals will shift.

The process should be transparent. Facilities with reported performance changes, when the actual performance has not changed, will need guidance and communication strategies with the update. These issues are complicated.

NHSN Intersection with *Clostridium difficile* Infection (CDI) Lab Testing

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Dr. Cliff McDonald shared with HICPAC questions related to the impact of laboratory testing on the CDI SIR in NHSN. Concern has been expressed by members of the Infectious Diseases Society of America (IDSA) and others regarding the risk adjustment used to calculate the SIR and that it does not control adequately for major categories of diagnostic sensitivity. There is a perceived penalty associated with using the nucleic acid amplification test (NAAT) polymerase chain reaction (PCR) and the possibility of driving practice toward using less-sensitive enzyme immunoassays (EIAs).

The goals of risk adjustment in NHSN, currently and historically, are generally to remove variability in measured rates due to factors outside the control of the facility and to reach a higher degree of fairness in accountability and equality, focusing prevention by making measures more responsive to actual prevention of the outcome of interest.

Laboratory diagnosis of CDI has evolved over the years. In 1980, Koch's postulates were fulfilled for *C. diff* as a cause of pseudomembranous colitis using cell cytotoxin neutralization assay (CCNA). In the 80s and 90s, early attempts at developing EIAs failed. Eventually, the attempts succeeded and EIAs were used in the 90s. It was determined that some toxin A-negative, B-positive strains were missed by EIAs, but the major toxins were then incorporated into the EIAs. By 2003, less than 5% of hospitals in the US used CCNA. In the 2000s, there were increasing rates of morbidity and mortality, likely related to the hypervirulent strain. In 2009, the first commercial PCR NAAT was approved. Throughout that period, there were anecdotal cases of people being EIA-negative and having *C. diff*, and there was a practice of "testing times three" because of the perceived insensitivity of EIAs. There are pros and cons associated with EIAs versus molecular tests. The high negative predictive value of the NAAT led to its acceptance. By the first quarter of 2014, 43% of NHSN facilities used NAAT. The numbers have increased further since then. Approximately 80% of all patient days in 2015 were under surveillance using NAAT.

There was a change in the clinical definition of "significant diarrhea" during this time, and the average length of stay has shortened. These changes have put pressure on shortening the duration of symptoms before a test is ordered. Additionally, the hypervirulent strains and deaths and the drive to reduce rates are important factors. The clinical definition of significant diarrhea" in 1980 was "six unformed stools over 48 hours." By 2010, the IDSA / Society for Healthcare Epidemiology of America (SHEA) Guideline shortened the definition to "three unformed stools over a 24-hour period. Often in practice, one unformed stool would be taken as a sign of diarrhea." In one study, it was noted that 30% to 40% of patients for whom a *C. diff* test was ordered had had a laxative in the last 24 hours. In this sense, "practice" refers to the use of tests in the patient population, which is crucial to remember.

In considering current EIAs, the gold standard is the toxigenic culture; that is, culturing the stool for *C. diff* and proving that it is a toxin-producing strain. The sensitivity to toxigenic culture of EIAs in recently-published review ranged from 42% to 82%, with a pooled result of 67%. Using toxigenic culture as a standard for NAAT, the sensitivity of NAAT ranges from 90% to 100%, with a non-weighted average among nine studies of 96.6%. The step-up across the pool of literature, which is utilized for FDA submission and package inserts, is approximately 50%, but the studies were conducted in different patient populations. When NAATs were first introduced, there was a 43% to 67% step-up in CDI incidence. These statistics represent longitudinal step-ups from a switch to EIA and NAAT, comparing the surveyed rates of *C. diff*. Some facilities saw as much as a doubling of rate. There is evidence of distribution and not a straightforward result.

The current modeling is based on 2010-2011 data and on 850 hospitals reporting from only a few states. The re-baselining of NHSN will be important for these models, as over 4000 hospitals now report *C. diff* to NHSN. At the time, 46% of the facilities utilized NAAT, and 47% EIA. A number of factors contributed to the model:

The model can be downloaded so that facilities can generate their expected number of events.

The diagnosis of *C. diff* has led to some turmoil in the field. There are many positive aspects to using NAAT. It has a high negative predictive value, which can be helpful clinically. However, there is concern regarding over-diagnosis. A paper from Planche, et al titled "Cytotoxin Negative, Toxigenic Culture Positive Patients Have Outcomes Similar to Negative/Negative Patients" addressed this issue. EIA has a sensitivity similar to cytotoxin, so EIA-negative, toxigenic culture positive patients are expected to have outcomes similar to negative/negative patients. The outcomes included mortality and lengths of stay.

A more recent paper from Polage, et al used NAAT versus EIA in the same patients. Only the EIA results were reported clinically. Patients who were NAAT positive but EIA negative had outcomes that were more similar to patients who were negative/negative. Differences in outcomes were seen only among patients who were EIA positive. This study included the outcome of duration and resolution of diarrhea by test group. The toxigenic-negative, PCR-positive patients did not have a positive result reported, so they could have received empiric treatment. However, it is more likely that they were not treated and their duration of diarrhea was similar to patients who were negative/negative. Another paper by Longtin, et al suggests the same results. The real association with outcomes was duration of diarrhea, mortality, and length of stay, which were associated with toxin positivity, not NAAT positivity.

In 2015, approximately 80% of patient-days in NHSN are under the surveillance of NAAT. Approximately 20% of those are under a diagnostic algorithm that uses another test, glutamate dehydrogenase (GDH), a highly sensitive but nonspecific test, as a screening test:

GDH-positive results lead to additional testing for toxins. The final sensitivity is close to NAAT alone. Some argue that GDH is not as sensitive as NAAT, but it is within 10 percentage points. NAAT is the final arbiter. If it is assumed that all EIA positives are NAAT positives, this algorithm provides insight into what a *C. diff* rate might be if a facility used EIA versus NAAT.

Dr. Diekema's facility applied this algorithm to calculate CDI rates based upon EIA versus NAAT. Because there is a step-up in the community onset, if a SIR will be calculated using one method or another, the prevalence of community-onset *C. diff* also will change. There is concern that by this measure, the risk adjustment model does not bring SIRs together in a way that an individual hospital would like to see. The difference in step-up between community-onset versus hospital-onset is noteworthy.

Why, if the same diagnostic is being used, is the model performing differently with regard to surveyed number of cases in different populations? It may not be appropriate to "hold NHSN to the fire" to necessarily pinpoint facilities' SIR regardless of the tests used, as there may be a distribution of step-ups. There are asymptomatic carriers, and the number of these carriers exceeds the number of CDI cases. Both numbers increase with ongoing healthcare exposures. Further, there are many different rates, and the prevalence of asymptomatic carriage varies: does the ratio of asymptomatic carriage to CDI also vary? The "jury is still out" about NAAT and its use; however, it is clear that the use of any test depends upon the population in which it is used.

Dr. McDonald presented the following questions for HICPAC to consider:

- What are the factors that might contribute to variation in the "step-up" in measured/ observed CDI between EIA and NAAT?
- What should define "success" in adjusting for test type in NHSN?

- Is parallel testing in an individual facility/population leading to the same or similar SIR an appropriate benchmark for defining "success?" Re-baselining will help with this issue; new models are likely to help now, but the situation may change in future years, depending upon changes in testing. If a facility's SIR does not "line up" based on the model, it does not necessarily mean that the model is not good. Distribution is an important factor.
- How tolerant/intolerant should we be of NHSN measurement driving clinical practice, in this case choice of diagnostic test used by a facility?
- Could the perceived inadequacy of test type risk adjustment really be a signal that a hospital should abandon clinical use of NAAT due to a high colonization/infection ratio in their tested population? Or, should they fix that tested population and work on test stewardship? This conversation also applies to CAUTI and increased interest in diagnostic stewardship.
- What risk adjustment methods are both feasible in NHSN and achieve the greatest equanimity?

DHQP is conducting a small survey in Prevention Epicenter hospitals, using the algorithm to learn how the data vary. Testing intensity may play a role as well, and this survey also will collect positivity rates. As testing intensity increases, prevalence in the tested population likely will decrease. As prevalence in the tested population decreases, there may be differences in the colonization/infection ratio as well.

Discussion Points

HICPAC asked about testing these models in non-acute settings. For instance, patients often stay in LTACHs for long periods of time and are on chronic antibiotics. Information often is not available regarding where patients came from, and some of the "community onset" could be related to LTACH or chronic care facilities.

HICPAC thanked Dr. McDonald for the presentation on the challenges and controversies associated with *C. diff* testing. The prevalence of *C. diff* carriage is likely to vary substantially among different patient populations, which could impact the results of NAAT testing. Improving risk stratification and the CDI metrics could address this issue. For example, a hospital with a large population of oncology patients who are constantly exposed to chemotherapy and antibiotics and whose microbiomes are disrupted may see a higher CDI carriage rate, which could impact NAAT results.

Dr. McDonald agreed and commented on the challenges of burden, feasibility, and granularity. The CDI laboratory tests are facility-wide in NHSN. The numerator is reported by location, but the denominator is facility-wide.

Even with its major limitations, this metric is transmitted to CMS and used to determine reimbursement level. HICPAC asked if there is enough data to provide guidance to CMS to rethink using this metric.

Dr. McDonald said that at least 15,000 people per year die of CDI, and billions of dollars in excess costs are incurred. He suggested that if NAAT is not working for a facility, the population being tested and/or diagnostic stewardship could be improved. They should not overlook the possibility that improving this metric might align well with improving care of the patient population. Further, the 2014-2015 model that was based on 2010-2011 data is probably not performing as well as the newer models with the re-baselining. Perhaps the concerns with these

measures can be addressed by rethinking testing practice. In England, the guideline is that a toxin test is the arbiter for clinical decision-making and for reporting, but the carrier status of patients who are colonized is also considered. DHQP is investigating to learn how often the carriers transmit CDI as well.

Diagnostic test stewardship can work in concert with *C. diff* prevention activities. Patients experience real outcomes when they are tested and receive a positive result and treatment, which results in a longer hospital stay in isolation. Clinicians are reacting to positive *C. diff* tests as if they are indicators of real disease, which has consequences for the institution in this NHSN metric and for individual patients. Cost is an important element as well. Other groups also are interested in the colonization questions regarding whether active surveillance should be conducted and whether colonized patients should be placed in isolation. While efforts are underway to decrease inappropriate testing for patients who do not have signs and symptoms of CDI, some clinicians are intent on increasing testing. This tension is difficult, and the publicly-reported metrics add penalties to the problem.

Adverse effects of unnecessary treatment of patients with positive C. difficile PCR results who may not have clinical infection have not been articulated well, for example unnecessary urine cultures that show some colonization and lead to a course of antibiotics. In this case, the typical treatment of oral vancomycin is tremendously disruptive to the microbiome. Patients will be better served by better understanding of adverse effects. It may be that the ordering of unnecessary tests is doing more damage than is realized.

IDSA appreciated the balance of considering diagnostic stewardship as well as test performance, and inquired about the proliferation of multiplex gastrointestinal (GI) panels which might include *C. diff*, salmonella, et cetera. Clinicians hope to order tests judiciously, but some of the available assays do not permit selectivity.

Dr. McDonald expressed concern about this issue, which introduces the possibility for a great deal of complexity. These concerns should be articulated.

IDSA suggested that considerations of the potential for misinterpretation of results should be brought to bear at the institutional and organizational levels. The entities marketing these assays can make an economic case for applying them in the laboratory. Absent acknowledgement of the potential concerns, there is a risk of further proliferation.

Regarding the issue of colonization, there could be an infection control case for testing and potentially isolating a patient with active diarrhea from another cause who has the potential to spread toxigenic *C. diff*, versus a patient with colonization with formed stool. There is more nuance to the issue of patients with diarrhea with strains who may not be infected, but could lead to spread.

These situations represent a “perfect storm.” Patients are in and out of the hospital quickly, so a great deal of disease presents after discharge. Unless patients return to the hospital, there is not an easy way to conduct post-discharge surveillance. Patients may experience symptoms and return to a private physician or clinic in a local community, and they are not captured. He wondered how to get a full picture of *C. diff* given these challenges.

Dr. McDonald said that the Emerging Infections Program (EIP) has established that post-discharge *C. diff* is sizable. He agreed that rates are not captured in a manner that will allow for individual facilities to react.

The question of tolerance or intolerance to NHSN measurement driving clinical practice should not be a question of whether measurement drives practice, but should acknowledge that decades of evidence overwhelmingly indicates that public reporting and payment will drive diagnostic test use and other practices. Rather than being tolerant or intolerant, there should be efforts to assess the consequences.

Dr. Diekema thanked Dr. McDonald and noted that the issue is difficult and does not present a simple solution. He pointed out that the United Kingdom (UK) approach to public reporting incorporates language to describe and differentiate among "carriers" and those who are EIA toxin positive. An approach to hospitals that utilize an algorithmic approach with a varying step-up is to allow them to report either as a PCR or an EIA facility. Hospitals that choose to conduct screening, if they are using the algorithm, would be able to report their EIA and not be concerned about the additional PCR positives contributing to an elevated SIR. This approach does not obviate the need for better adjustment by method for the centers that utilize PCR alone, which is still a substantial proportion of centers.

With no additional questions or comments, Dr. Yokoe noted that the next topic on the agenda, Guideline Updates, would be moved to the afternoon.

DHQP Stewardship Updates

CAPT Lauri Hicks, DO
Division of Healthcare Quality and Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Dr. Lauri Hicks shared with HICPAC recent progress in DHQP's stewardship activities. Get Smart About Antibiotics Week, will be November 14-20, 2016. During that week, DHQP engages a number of different types of stakeholders across the spectrum of healthcare. They also pair with animal health partners at CDC to share messages about antibiotic resistance and appropriate antibiotic use. Get Smart About Antibiotics Week has evolved into a global effort. In 2015, the World Health Organization (WHO) launched World Antibiotic Awareness Day, which coincided with Get Smart. CDC has worked with the European Union (EU) to coordinate events with the EU's Antibiotic Awareness Day, November 18. There was a 50% increase in partner engagement in 2015, attributable to the White House Forum focused on antibiotic stewardship in June 2015 and engagement with partners from the forum. The annual Twitter chat will be help on November 18, 2016.

CDC's Core Elements for Antibiotic Stewardship Programs in Hospitals were published in March 2014, followed by a document focused on nursing homes in September 2015. The launch of the Core Elements was successful. DHQP is working with partners to implement the Core Elements. A new set of Core Elements for outpatient settings will be released in November 2016 to coincide with Get Smart Week.

A survey was conducted in 2015 assessing 2014 participation in the Core Elements. At that time, 39% of US acute care hospitals reported having antibiotic stewardship programs incorporating all seven CDC Core Elements for Hospital Antibiotic Stewardship Programs. Data from 2015 suggest that this number has increased. There is a great deal of variability from one state to another in terms of the percent of hospitals that are meeting the Core Elements. The highest state, California, reports 59%. Not surprisingly, smaller hospitals have more difficulty

implementing the Core Elements. Of hospitals with fewer than 50 beds, 25% are implementing all Core Elements compared to 55% of hospitals with more than 200 beds. DHQP is working on ways to help smaller facilities move forward.

A number of partners, especially Anthem and Blue Cross/Blue Shield (BCBS), are promoting Core Elements and stewardship incentives. Starting in 2016, Anthem added compliance with the CDC Core Elements to its Quality-In-Sights® Hospital Incentive Program (Q-HIP®). This addition represents one of the first times that a private payer has tied antibiotic stewardship to any financial incentive. DHQP is working with Anthem regarding opportunities to introduce antibiotic stewardship into outpatient settings as well. The Leapfrog Group is adding questions based on the CDC Core Elements to their annual survey. This survey means a great deal to hospital leadership and administration. Administrators want their hospitals to be "Grand Champions," and incorporation of stewardship into those rankings will incentivize adoption of the Core Elements. Work is ongoing with the National Quality Forum (NQF), with the release of a Playbook in May 2016. The Playbook, based on the CDC Core Elements for Hospital Antibiotic Stewardship Programs, has had tremendous uptake and has been downloaded thousands of times. It is a "how-to" guide for implementing the Core Elements, providing examples, addressing barriers, and advising the engagement of leadership. The Playbook also includes a section on measurement in stewardship, which is a useful tool. DHQP is interested in pursuing this approach for other healthcare settings.

DHQP is expanding its horizons for implementation of the Core Elements. Health systems are being funded to implement the Core Elements across all settings using the SHEPheRD funding mechanism. One acute care project, one long-term care project, and one outpatient project will be funded in the near future. These projects will increase understanding of how best to implement the Core Elements and of their impact on antibiotic use in different facility types. The work will also provide an opportunity to refine the Core Elements if necessary.

State health departments are an integral partner in dissemination of antibiotic stewardship strategies and in capturing the data needed for antibiotic use measurement. Support is expanding for state health departments in HAI prevention activities and in stewardship. This expanding support will occur as both an increase in the amount of funding and in the number of participating states. Work is also expanding with a number of important partners. The Society for Hospital Medicine (SHM) launched "Fight the Resistance" campaign. DHQP will meet with the American Nurses Association (ANA) to determine ways to engage nurses in stewardship. This work will begin with acute care and will expand to all settings.
Recent meetings with members of the critical care community have explored opportunities to improve antibiotic use in intensive care units, especially regarding sepsis care. The balance and integration of improving antibiotic stewardship with improving sepsis is an important issue. DHQP has partnered with The Pew Charitable Trusts in acute care and outpatient settings to measure antibiotic use and understand how to implement stewardship activities in these settings. This work will expand to engage retail and urgent care clinics, with a first meeting planned for September 2016, and long-term care facilities.

Data for action is extremely important to improve the targeting of efforts not only to reduce unnecessary antibiotic use, but also to identify specific targets for conditions for which selection can be improved. For example, a UTI is one of the number-one reasons for a patient receiving a fluoroquinolone in an outpatient setting. However, it is not the first-line recommended therapy.

The National Action Plan for CARB includes significant expected outcomes for antibiotic stewardship, including the establishment of antibiotic stewardship programs in all acute care

hospitals and improved antibiotic stewardship across all healthcare settings by 2020; and the reduction of inappropriate antibiotic use by 50% in outpatient settings, and by 20% in inpatient settings by 2020. The challenge is to determine how much antibiotic use in these settings is inappropriate. An analysis of data that were collected before the National Action Plan was released indicates that on average, 842 prescriptions are dispensed per 1000 patients in outpatient settings. The data are consistent from one year to the next. That dispensation is enough for every five out of six people to receive an antibiotic, with 263 million prescriptions dispensed annually in the US. These data were gathered from IMS Health Xponent and represent sales data from community pharmacies. The data do not allow for an analysis of appropriateness, as there are no indications or diagnoses associated with the prescriptions.

The US uses a great deal of outpatient antibiotics, compared to other countries. There is also significant geographic variability in antibiotic prescribing within the US. States within the Appalachian region, for instance, prescribe nearly twice as many antibiotics as the Pacific Northwest. Much of the unnecessary use is in response to respiratory conditions. However, it is not known what fraction of all antibiotic use in the outpatient setting is unnecessary.

Fleming-Dutra, et al published a recent study in the *Journal of the American Medical Association* (*JAMA*) to establish the prevalence of inappropriate antibiotic prescriptions among US ambulatory care visits, in collaboration with the Pew Charitable Trusts. The study was accompanied by a lay report from Pew to describe the findings for an audience of the general public. The study used data from the National Ambulatory Medical Care Survey (NAMCS) and the National Hospital Ambulatory Medical Care Survey (NHAMCS), which are nationally-representative surveys incorporating a sample of visits to non-federal employed office-based physicians and sample of visits to emergency and outpatient departments in non-institutional, general and short-stay hospitals. Visits from 2010 and 2011 were included, as they were the most recent data available at the time. It is not expected that the data have changed dramatically since then. The data sources include demographics, diagnoses, and medications, which allow for an assessment of appropriateness.

The analysis of the data sets showed that 12.6% of visits led to antibiotic prescriptions, equating to approximately 154 million antibiotic prescriptions annually in physician offices, emergency departments (EDs), and hospital outpatient departments. The datasets do not include urgent care clinics, retail health clinics, telemedicine, dental clinics, and other settings; however, this analysis represents a good start. Regarding the age distribution, the under-2 years of age population has the highest antibiotic prescribing rate, with over 1200 prescriptions per 1000 persons. The rates drop in subsequent age groups and increase again in older adult populations. The IMS Health data source allows for the analysis of state-by-state antibiotic prescribing and regional variations. These data also indicate higher prescribing rates in the South and Appalachian regions compared to the West.

In the outpatient setting, 44% of antibiotics prescribed are for diagnoses of acute respiratory conditions, with sinusitis representing 11% of all antibiotics prescribed in these settings, followed by otitis media and pharyngitis. Many conditions are included on this list that do not warrant antibiotic use at all: bronchitis, bronchiolitis, upper respiratory infections (URIs), asthma and allergy, influenza, and pneumonia.

In terms of the process for establishing targets for antibiotic use, in situations in which antibiotics are almost always necessary (pneumonia and UTI), no reduction is recommended. In situations in which antibiotics are not necessary (viral URIs, bronchitis, and influenza), it is recommended that no antibiotics are prescribed. In situations in which a patient has a syndrome for which

antibiotics are sometimes necessary, the target was based upon bacterial prevalence and regional variation in prescribing, using the lowest-prescribing region as the reference. This approach was applied to pharyngitis, suppurative otitis media, and sinusitis.

DHQP approached this task with a conservative mindset and a desire not to overestimate. It is likely that the numbers could be higher. The target of a 15% reduction was set for other conditions. DHQP concluded that at least 30% of all antibiotics prescribed in physicians' offices, EDs, and outpatient facilities, as well as hospital-affiliated outpatient departments were unnecessary. This conclusion helps to set targets. The 2020 goal is to reduce inappropriate outpatient antibiotic use by 50%. A 15% reduction in the 30% unnecessary prescriptions equates to 47 million unnecessary antibiotic prescriptions per year.

There are challenges associated with performing similar analysis in acute care and nursing home settings, as the available data for these settings are not as granular as the data available through NAMCS and NHAMCS. Pew and CDC met with a working group to understand the best way to monitor national progress toward the goal of reducing inappropriate hospital prescribing by 20% by 2020. A point prevalence survey was determined to be the best approach in the immediate time frame.

EIP sites have completed data collection for the repeat of the antibiotic use point prevalence survey, called the QuadRx study. Data collection was completed in 2014 and will be repeated in 2016. The data are being analyzed and will provide a descriptive overview of frequency, selection, and indications for antibiotic prescribing for hospitalized patients. The analysis will focus on four situations:

- Appropriate prescribing for pneumonia
- Appropriate prescribing for UTIs
- Vancomycin
- Quinolones

Similar work is being conducted in nursing home settings. A pilot point prevalence survey of antibiotic use in nursing homes has been completed, and the full survey is underway.

CAPT Arjun Srinivasan, MD
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Dr. Arjun Srinivasan provided HICPAC with an update on the AU option of NHSN. Enrollment continues to grow slowly, with 140 facilities reporting at least one month of data. Thirty states are represented. The facilities reporting are slightly larger hospitals than the national average size of facility, but some small hospitals are reporting data as well. Slightly more than half of the facilities are teaching hospitals, and much of the submission is occurring as part of networks or health systems. The facilities are either using vendor systems, reporting into the AU option through an EHR vendor, or are sending data via a direct interface with the AU option.

DHQP is working to grow enrollment in the AU option. More growth is needed in order to conduct benchmarking for AU. Through the SHEPheRD mechanism, funding was provided last year to the Duke Antimicrobial Stewardship Outreach Network, and they are working to bring the approximately 30 hospitals that they work with into the system. BD/CareFusion also

received funding. That group has an interface with the AU option and a group of hospitals to bring in.

Some health systems committed to enrolling their hospitals in NHSN after the White House Forum. The Hospital Corporation of America (HCA) and Ascension Healthcare are working actively with CDC's NHSN team to bring their facilities into the AU option. Enrollment is expected to grow tremendously.

Requests for Proposals (RFPs) were released and are now being reviewed to take next steps in better understanding how to use Standardized Antibiotic Administration Ratio (SAAR) data to improve antibiotic use. SAAR is a new measure, and it is important to understand how to use it, how and where it is useful for quality improvement and benchmarking, and where it may need to be adjusted. The successful candidates under this RFP either already have or will enroll a large group of hospitals in NHSN and will use the CDC Core Elements to implement or enhance stewardship programs. The work will evaluate the impact of their stewardship intervention on the SAAR data, which will build understanding of whether SAAR measures change if hospitals implement, or implement more effectively, the Core Elements. If the measures change, it will be encouraging to know that they change when appropriate processes are implemented. The projects also will address changes in the SAAR measures if the Core Elements are implemented in different ways and determine the approaches that are most effective when measured by the SAAR. The projects also will determine whether some Core Elements or implementation strategies are more effective than others.

Significant changes are on the horizon for antibiotic stewardship. The Joint Commission has taken the lead by issuing a final accreditation standard that will require all healthcare settings, beginning with hospitals, to implement stewardship programs. The standard was released in the Summer of 2016 and takes effect in early 2017. Approximately 80% of all acute care hospitals are Joint Commission accredited and, therefore, will have to have stewardship programs. The Joint Commission standard has synergy with the CDC Core Elements.

CMS issued a proposed rule for hospital conditions of participation in June 2016. It will require hospitals to have an antibiotic stewardship program. The conditions are out for comment through mid-August 2016. These programs will work closely with infection control, but will be distinct from the infection control programs. CMS also has signaled interest in the SAAR measure, recently asking for public comment on the potential of including the SAAR measure in future iterations of the Inpatient Prospective Payment System. The comments will be helpful, as there are many unanswered questions associated with taking the next step.

DHQP is interested in ensuring that stewardship does not become another "stovepipe" mentality, in which the stewardship team works independently and out of connection with other hospital teams. The recent CMS measure on sepsis is an example of this situation. The stewardship team should be involved with the selection of antibiotics for sepsis. In some facilities, there was strong collaboration that included the stewardship team in developing the protocols for sepsis management. In other facilities, those connections were not made, and different guidelines were created. Stewardship efforts should take advantage of efficiencies and processes that exist in hospitals to ensure that quality improvement cuts across the entire facility.

Discussion Points

The National Association of County and City Health Officials (NACCHO) encouraged local and state involvement with the projects, particularly in long-term care.

Dr. Hicks agreed and said that a number of city and county health departments will be funded as part of the expansion. In every instance, DHQP asks state partners about implementation and engagement, and whether the local health department is involved. Decision-making is different in different states. Often, local health departments act independently of the state health department. DHQP has encouraged states to connect with local health departments and identify the departments that are interested in identifying their local partners for stewardship work. Much of this work is grassroots since individual providers, clinics, and facilities need to be reached in order to make progress.

The VA commented that the highest rates of antibiotic prescription were among the age groups of less than 10 years and greater than 65 years. The younger age groups have other sources and pressures that may lead to more antibiotic prescription. For instance, children may not be allowed to return to daycare or school unless they are on antibiotics. If the rest of the data are stratified by age, it might allow for a laser-like focus on the group where the greatest progress can be made.

Dr. Hicks agreed and emphasized the important concept of identifying targets for stewardship; not only target populations, but also target conditions and target drugs. There have been improvements in prescribing for pediatric populations, where the same progress has not been made in older adults. Further, there are many complications associated with antibiotic use for CDIs in those populations. DHQP is interested in identifying the quickly and easily achievable goals in the adult population. For example, bronchitis is a condition for which 80% of adults receive an antibiotic, and antibiotics are not recommended for these patients. No groups can be ignored and DHQP will continue to engage pediatricians and family practitioners, who prescribe more antibiotics than any other provider group in the US. Some data suggest that family practitioners treat children the same way they treat adults, and there is room for progress in changing their prescribing behaviors. She agreed that it is important to identify specific targets for stewardship interventions.

Regarding how to ensure that stewardship and sepsis programs come together, HICPAC suggested adding an element to the CDC Guideline and asking the question on the NHSN annual survey. The data are not perfect, as they depend upon who answers the survey, but facilities are realizing that multiple people within a hospital need to answer the question. Just asking the question is educational.

Regarding targets, HICPAC encouraged DHQP to consider azithromycin because of its interface with respiratory tract infections. It is used frequently in children, the highest prevalence group. It is also tied to macrolide resistance, Group A *Streptococcus*, and pneumococci, which are easily measurable targets.

Dr. Hicks said that DHQP is particularly interested in macrolides as well as fluoroquinolones. These two drug classes often are selected as the agent for treatment, even though the recommended agent is amoxicillin or amoxicillin clavulanate. In particular, a macrolide for acute otitis media or pharyngitis is an inferior treatment. Efforts should focus on appropriate use of these drugs for conditions that warrant antibiotic use. Conditions that do not warrant antibiotic use often lead to treatment with these drugs as well.

Azithromycin is an anti-inflammatory agent, so it is used and under-dosed not only for its antimicrobial properties. Dr. Hicks said that discussion is ongoing regarding how to address the anti-inflammatory effect of azithromycin. There are many unintended consequences associated with use of these drugs, in particular with macrolides for anti-inflammatory purposes, that they should not be considered as first-line responses for anti-inflammatory reasons.

HICPAC asked whether it is possible for the data to separate treatment of secondary infections, especially in patients aged 65 and older, from acute treatment. Dr. Hicks replied that the data are somewhat limited in this regard because they include some information regarding whether the prescription represents an acute visit, but little information regarding whether it could represent a follow-up visit.

These details would be helpful to cull from the data. Dr. Hicks agreed and said that DHQP is considering other sources that might allow for following individual patients longitudinally, as opposed to the survey data.

Dr. Cardo reinforced that the initial approach was to decrease inappropriate and unnecessary antibiotic use. The work has evolved to examine age groups, syndromes, and drugs. The messages for older adults will be different from messages for young children. Further, the messages may be different for specific antibiotics. Even if there are not overall changes in use, there may be changes in specific combinations of age, syndrome, and antibiotics.

Dr. Srinivasan said that one of the limitations of the SAAR is that it is risk-adjusted on facility-level characteristics and cannot be adjusted for how many patients have infections in a facility, or for severity of illness. DHQP is working with groups that have access to more granular, patient-level data who are also using SAAR to do correlations to learn about patient-level characteristics might be added to the SAAR in the future. For example, how much better are the data if they include International Classification of Diseases (ICD)-10 codes, or if the data include how many patients have immunosuppressive conditions? DHQP is working with Kaiser in this area, and the VA is also looking at correlations between the SAAR measure and appropriate use.

CU thanked Drs. Hicks and Srinivasan for the work in this area; however, the work is not occurring fast enough. The desire to move slowly and carefully are understood, but DHQP is encouraged to move as quickly as possible on this major issue for the US and the world. It would be beneficial if CDC supported stronger language for mandates to require reporting and to require results so that these stewardship programs yield positive outcomes in the near-term. CU inquired about plans for releasing specific information to practitioners and hospital staff about the use of specific drugs, such as when the drugs are necessary and appropriate and appropriate dosage levels. There is a great deal of ignorance in these areas, and healthcare personnel seek guidance and specifics. The overuse of fluoroquinolones, for instance, is a terrible problem that should be specifically communicated.

Dr. Hicks said that DHQP has been talking about creating a list of “never events” and crafting recommendations for specific situations, such as syndromes and drug combinations that should not happen. However, there are some caveats such as in cases of patients with allergies. There are ways to message around these exceptions, listing situations in which a specific drug should not be used, or situations in which antibiotics should not be used at all.

CU would be happy to help communicate this information to consumers.

Dr. Cardo added that a recent study examined visits to the ED as a result of adverse events due to medication.

Dr. Hicks said that the most frequent reason a child goes to an ED is for an adverse drug event. This message should be shared with the general public and with providers. The concept of adverse events associated with outpatient antibiotic use is underappreciated and will be highlighted in communications over the next year.

The recent multi-society critical care conference on stewardship, sponsored by the Society of Critical Care Medicine (SCCM), had an anticipated result of a formal statement on how to implement stewardship in intensive care settings. The conversation was productive. The sepsis guidelines from 2012 include a Category 1B recommendation for daily assessment for de-escalation and a formal statement recommending collaboration with antimicrobial stewardship programs, where they exist. The language in the guidelines is strong, but real-world implementation is challenging.

The committee that creates in-service training exams for the American Board of Internal Medicine (ABIM) and the American College of Physicians (ACP) met recently, and the questions for infectious disease did not include a question directed at the issue of antimicrobial stewardship, choice of antibiotics, limitations of antibiotics, et cetera. It is important that training is done appropriately. Older practitioners may be reluctant to change their work patterns. There should be determined efforts to ensure that these issues are included in training curricula, perhaps through professional associations for medical schools, nursing schools, and physician assistant (PA) schools. SHM has engaged in this area. Program directors in internal medicine and residents are focused on the boards. If this information is included in the boards and stewardship is mandated in training not only for internal medicine, but also for pediatrics, surgery, and other specialties, a generation of healthcare professionals can be trained regarding the appropriate caution needed when choosing and prescribing an antibiotic. Regarding patient allergies, it is important to encourage thorough history-taking for allergy history in inpatient as well as outpatient scenarios. Regarding changing practices, FDA will be a major partner. FDA's recent notices regarding azithromycin and quinolone garnered a great deal of attention.

Dr. Hicks agreed and said that DHQP has developed a medical school curriculum, but its uptake has not been strong. Help is welcome to determine how best to integrate these educational components into the different stages of training for healthcare personnel. Work is ongoing with the American Academy of Pediatrics (AAP) to incorporate modules into Maintenance of Certification. AAP has developed a new module related to appropriate antibiotic use. It would be ideal to incorporate these concepts earlier in training than the Maintenance of Certification phase.

HICPAC was impressed with DHQP's efforts to collect data, improve the collection of data, analyze the data, and move forward with action simultaneously. These issues are important and are moving with an urgent timeline. She commented on other pressures that affect antibiotic prescribing. The decision-making and education of individual prescribers is important, but many other aspects of public and patient education regarding expectations and requests are also important. The use and impact of patient satisfaction data for outpatient and inpatient providers should also be considered. Insurance company perspectives also are important. Some companies require the administration of antibiotics in order to cover hospital stays. These factors will affect the data and the ability of providers to make improvements in data in complex situations with such external pressures.

Dr. Hicks said that patient expectations and ratings represent major challenges that do not yet have strong solutions. DHQP encourages providers to address patient expectations at the time of the office visit. For example, a provider could post a poster in examination rooms demonstrating the commitment to prescribe appropriately. This simple intervention helps patient understanding and alleviates pressure on the provider. The challenge associated with patient satisfaction scores is significant.

Update on HICPAC Working Group: Antimicrobial Stewardship Principles for Treatment Guidelines

Michael Tapper, MD
HICPAC Member
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Dr. Tapper shared with HICPAC progress from the Working Group on Antimicrobial Stewardship Principles for Treatment Guidelines. The Working Group was formed after discussion during the November 2015 HICPAC meeting. The group is charged with developing points to consider regarding antibiotic stewardship for antibiotic guidelines. The points are not intended to be antibiotic stewardship guidelines per se; rather, they are meant to serve as a guideline for groups such as SHM and other organizations that write guideline for their members. The points will serve as a reminder to these groups to include stewardship principles as they craft their recommendations for the use of antimicrobials for specific populations. The group has met by teleconference and email. Input from the March 2016 HICPAC meeting was incorporated into the draft document.

The document introduction includes:

- Problem of antimicrobial resistance
- Importance of antibiotic stewardship
- Importance of guidelines for a variety of societies and guidelines for defining antibiotic use; however, most of these statements do not routinely incorporate statements about antibiotic stewardship that are important in the control of antibiotic utilization, such as how to choose an antibiotic, which antibiotic to choose, and principles of increasing or tapering antibiotics

Points for consideration in guideline development include:

<u>Principles of Testing</u>

- Cultures with susceptibility testing and rapid diagnostic tests, when indicated, should be sent promptly to identify specific infections and facilitate the use of narrow-spectrum antibiotics, preferably monotherapy or, at most, dual therapy, when possible.
- Diagnostic tests should be used wisely to avoid unnecessary antibiotic therapy. Cultures done without appropriate indication can cause unintended consequences. For instance, a urine culture, rapid strep test, or *C. diff* testing should not be performed unless the patient has clinical signs and symptoms of infection and meets the criteria for testing.

<u>Principles of Treatment</u>

- While prompt, broad-spectrum antibiotics are needed for serious infections, including sepsis, the likelihood of an infection requiring antibiotics should be reconsidered after

cultures and diagnostic tests are available. De-escalation of the antibiotic regimen and/or culture-directed therapy once a pathogen is identified should be used.
- Use of the most narrow-spectrum agent can assist in preserving the activity of broader-spectrum agents for resistant organisms when needed.
- If there are situations where the risk of prescribing an antibiotic may exceed the benefit, potential adverse events should be noted in the guideline so that providers may opt not to prescribe an antibiotic, or to choose a recommended agent that has a lower potential for adverse events.

The CDC Core Elements are the lead reference for the document, and additional guidelines are for long-term care and outpatient care are considered. The Working Group recognizes that some of the guidelines cited in the draft document have since been updated, such as the statement from the Joint Commission. Other standards are forthcoming and will be incorporated into the final product from the group.

Dr. Tapper presented the following questions for HICPAC to consider:

- Will HICPAC Liaison Organizations ensure these principles are incorporated into guidelines moving forward? If not, why?
- Will HICPAC Liaison Organizations help promote these principles? If not, why?
- Will HICPAC Liaison Organizations assist in identifying the most critical societies and disseminate the finalized document to them?

Discussion Points

Regarding the Principles of Testing, HICPAC suggested adding a specific statement related to whether antibiotics should be used. The statement could read “encourage the use of rapid diagnostic tests, biomarkers, and decision rules that have good performance characteristics to differentiate bacterial versus non-bacterial infection in order to determine whether antibiotics are needed or not.” Additional statements can relate to narrowing or tailoring antibiotics. The document could state “whether molecular testing to identify specific resistance genes or novel, non-culture-based assays of susceptibilities may be used to target therapy to susceptible or resistant organisms.” Procalcitonin is an example of a rapid test, but if biomarkers are available, they should be used. The specific aspects of a particular infection could be left to the society writing the guideline, depending on whether an appropriate biomarker is available.

Regarding the Principles of Treatment, HICPAC noted that the first two points have de-escalation components, but the document may need to emphasize de-escalation as a separate point, perhaps mentioning daily reassessment and other techniques, such as stop orders.

Dr. Tapper noted that the comments focused on acute care inpatient hospitals. The CDC Core Elements focus on acute care, but the Working Group document is intended to cross a variety of settings and should be worded carefully.

The point on rapid diagnostics will need to be wordsmithed, but it raises an important point about stewardship. The concepts of “appropriate use” and “inappropriate use” are dynamic as diagnostics improve. If hospitals are being rewarded and punished based on certain measures, these diagnostics will not all be adopted simultaneously by every hospital. Some diagnostics will be resource-intensive. There will be a period of evolution toward improved stewardship in which appropriate use in one institution may be inappropriate use in another institution that has access to rapid molecular diagnostics.

Dr. Cardo clarified that the document is intended for professional organizations that are writing guidelines, so the recommendation could be that the guideline includes the importance of ruling out a bacterial infection.

An important emphasis in the Principles of Testing will be that specimens should be handled appropriately, including collection, storage, and transport. These issues are important for UTI and other infections. If the test is ordered, it should be performed correctly. The Joint Commission has announced a new Medication Management (MM) standard, MM.09.01.01, effective January 1, 2017. It can be added as a reference to this strong work, which will help others.

Dr. Yokoe clarified that Dr. Huskins had circulated his suggested revisions to the Working Group. Group Chair Dr. Jan Patterson emailed her support of the suggestions.

HICPAC asked about how the document can be operationalized; that is, how organizations will incorporate the suggestions into their guideline processes. Some of the items might lend themselves to a statement proposing language for a guideline. Others can serve as guidance when treatment recommendations are created.

HICPAC suggested recommending that guidelines include a specific section on antimicrobial stewardship.

Dr. Tapper said that while many organizations have guidelines, certain critical guidelines, such as the Red Book, should be targeted for stewardship principles to be incorporated. Penicillin allergies are an important area for HICPAC liaisons to consider, particularly regarding how to encourage the taking of better and more accurate histories in the outpatient setting.

The Surgical Infection Society (SIS) is interested in supporting stewardship extensively. SIS is finishing the latest Intra-Abdominal Infection Management Guidelines. In providing advice to organizations writing guidelines, HICPAC could be bolder and specifically state certain issues that should be addressed. For example, the document does not mention source control, which should be addressed in any guideline regarding treatment. The document also could address minimal duration, optimum dose, and the need to stop antibiotics when cultures or other tests are negative.

IDSA enthusiastically supports stewardship. The challenge is associated with implementation. If the expectations are too detailed and prescriptive, there could be pushback from other societies. The document should balance meaningful suggestions and compromise.

The American College of Occupational and Environmental Medicine (ACOEM) noted that much of the antibiotic prescription for their constituents is pro forma. To the extent that occupational medicine physicians are increasingly engaged in primary care activities within employer clinics, this guidance is one that ACOEM would want to embrace.

SHM is investing a great deal of resources into antimicrobial stewardship programs. Implementation is critical. The document does not note whether stewardship principles are consistent among different healthcare settings. Particularly among the ED, primary care, and inpatient settings, consistency of message is important. The care recommendations need to be explained to patients.

Antimicrobial resistance is an important area for Public Health Agency of Canada (PHAC). PHAC is working with provinces and territories to make improvements and agrees with the principles of operationalizing antimicrobial resistance. There are wide differences among protocols that are utilized in the larger teaching hospitals, such as those pertaining to automatic stops, renewals, and reminders. There also are differences between providers such as family practitioners and long-term care, and in the movement of patients setting to setting.

The VA does not write guidelines. The VA focuses on operational implementation. The VA has a specific stewardship program that addresses de-escalation and other issues, providing examples for facilities to apply. This series allows hospitals not to reinvent each program. Not all of the VA's 150 hospitals have high-level infectious disease or high-level infection control, so they need assistance. The VA's first implementation system was a business plan for working with hospital administration.

SCCM has 21 guidelines currently in process. Two of the guidelines, the Adult Guideline which is in revision and a Pediatric Guideline which is slated for release in 2018, address source identification and antibiotic stewardship. There are opportunities to address these issues in the other guidelines.

The American College of Surgeons (ACS) does not write guidelines per se, but ACS is invested in training and education. There is opportunity to enhance the elements of antimicrobial stewardship in the national training and educational curricula.

The Association of periOperative Registered Nurses (AORN) does not generate treatment guidelines, but is supportive of antimicrobial stewardship programs. There is potential to incorporate the perioperative nurse into the surgical process in collaboration with surgeons and anesthesia providers.

CU agreed that there are questions regarding how the document will translate to those who will use the recommendations from day to day. More details may address these concerns. The information is important, and the people on the front line need to understand it.

HICPAC clarified that the document is intended for societies and other groups that write guidelines that are used by front-line providers. The document will encourage the writers of guidelines to incorporate these principles when they write treatment guidelines.

DNV Healthcare has a certification program for hospitals, Managing Infection Risk, which has a significant component of antibiotic stewardship. The HICPAC guidelines will help them move in the correct directions. The new hospital accreditation standards are expected to reflect more intense antibiotic stewardship, which has been required since 2012.

There was discussion regarding the review, approval, and release process for making this document available. The sooner this document can be shared, the more helpful it will be.

Mr. Hageman said that when HICPAC approves the final document, it will be formatted and shared on the HICPAC website. HICPAC work products that are developed by the committee are released directly on the HICPAC website. They require no CDC clearance, as these products represent the advice and recommendations of the committee. Guidelines and CDC documents that have HICPAC input and public comment have a different process.

Other societies that write treatment guidelines are not represented as HICPAC liaisons. It was suggested that HICPAC send these recommendations to these societies with a cover letter, asking that the societies share the document with their guideline committees.

Dr. Tapper said that the document was not intended to be limited to HICPAC liaisons, but was meant to be disseminated more widely.

Dr. Hicks said that DHQP has created a list of organizations that develop guidelines. The list can be shared with HICPAC and serve as an initial list for outreach.

CSTE pointed out that this document also could serve as a foundation for required teaching in medical schools for infectious disease doctors, and also for potential dissemination to individual hospitals as they create their own internal facility guidelines. The document could be expressed in a manner to help facilities implement it immediately, giving it a life beyond guideline development societies.

Dr. Huskins offered to incorporate HICPAC's comments into a draft of the document and circulate it to the Working Group for input and consensus. It could then be considered for a full HICPAC vote.

Dr. Tapper said that while the document was written with the audience of groups that write antibiotic guidelines in mind, it will be publicly available. HICPAC can decide other uses for it.

Update: *Mycobacterium (M) chimaera* and Heater-Cooler Units

Daniel J. Diekema, MD
HICPAC Co-Chair

Dr. Diekema shared updates and progress since the March 2016 HICPAC meeting on the *M. chimaera* outbreak linked to heater-cooler units. Several presentations have been made at different venues to increase awareness, including at meetings of the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), SHEA, and American Society for Microbiology (ASM). The journal *Eurosurveillance* published on the German outbreak investigation and its findings. CDC published helpful case-finding guidance. A new FDA alert was released regarding the specific unit that has been implicated in the *M. chimaera* cases. The FDA Circulatory Devices Panel met on June 2-3, 2016. There was an FDA/SHEA/IDSA conference call regarding how to share information and increase awareness among infectious disease physicians and infection prevention programs. The first US case series was published in *Open Forum Infectious Diseases* on three patients who had been referred to the Mayo Clinic in Rochester, New York with disseminated *M. chimaera* infection.

The ECCMID presentation included the first public presentation of whole genome sequencing (WGS) data from this outbreak. The data demonstrate the relatedness of *M. chimaera* isolates from multiple different hospitals in the Netherlands during their nationwide outbreak. These outbreak isolates are separated by no more than 10 single nucleotide polymorphisms (SNPs). Epidemiologically unrelated isolates of *M. chimaera* are separated by hundreds and thousands of SNPs. Clearly, these isolates are epidemiologically linked, providing strong evidence that they had a common source.

The German outbreak investigation provided some insight to a potential point source. The investigation included sampling water from new heater-cooler units directly from the

manufacturing sites as well as from the pump assembly area at the manufacturing sites. The units are filled to test them prior to shipping. *M. chimaera* was grown from these samples, suggested in the preliminary molecular typing data that these units may have arrived at their destination already contaminated with environmental *M. chimaera*.

The CDC Case Finding Guidance will be useful going forward. It includes three major categories of information:

- Laboratory assessment looking for sterile site or invasive isolates of nontuberculous *Mycobacterium* (NTM). In many laboratories, it will only be identified as *Mycobacterium* avium complex; the species-level identification requires a send-out test for most laboratories.

- Clinical assessment of the most common clinical syndromes that have been found to be associated with this outbreak:

    - Prosthetic valve endocarditis (PVE) or graft infection
    - Sternal wound infection
    - Mediastinitis
    - Mycobacteremia
    - Disseminated infection
    - History of exposure to a heater-cooler unit during, in most cases, a cardiopulmonary bypass procedure

- Additional considerations about strategies to improve detection, including considering within an institution the extent to which provider and patient notification is needed if and when cases are detected

A thorough investigation was conducted by public health authorities in Pennsylvania, with state and local entities, as well as CDC personnel. The case-controlled study included 10 cases of invasive *M. chimaera* disease, and controls had no positive cultures for NTM after cardiothoracic surgery. The study confirmed the link to heater-cooler units, with odds ratios of almost 6 for exposure to a heater-cooler unit, and an odds ratio of over 16 for extended exposure, and molecular typing that linked the patient and environment isolates.

FDA issued an alert on June 1, 2016, that recognized the findings of the *Eurosurveillance* study suggesting this direct link between *M. chimaera* cases and a single model of heater-cooler unit: Mycobacterium chimaera Infections Associated with Sorin Group Deutschland GmbH Stöckert 3T Heater-Cooler System: FDA Safety Communication. The alert gives instructions for healthcare providers who are in institutions where this unit is used, primarily addressing issues of provider notification and maintenance/ operation of the heater-cooler units

The FDA Circulatory Devices Panel met June 2-3, 2016 and had a wide-ranging discussion. The panel advised FDA on several issues:

- Detecting and mitigating contamination, including the cultures that should be done, the cleaning that is indicated, and when units should be returned to the manufacturer for deeper cleaning
- Patient and provider notification instructions, which prioritized provider notification over patient notification

- Initial steps in an investigation when an infection is detected, the look back window for cases of approximately five years, the recommendation to make invasive NTM a reportable disease
- Device considerations for reducing the risk of exposure and disease, such as redirecting exhaust from the units outside the operating room (OR) and how the units could be designed in the future so as not to generate bio-aerosols in an environment that needs to be sterile

Questions for HICPAC include:

How can we better find current cases?

- Improve clinician awareness, such as among professional societies
- Should additional national provider and patient notifications be considered?
- Are there specific triggers at the institutional or public health levels? For instance, many patients are diagnosed with sarcoidosis because they have disseminated granulomatous inflammatory process; is there a way to search registries or databases for patients who carry that diagnosis and have had exposure to cardiopulmonary bypass?

How can we better manage identified cases?

- This clinical syndrome is new to many providers, and its attributable mortality seems to be well over 50% and rising. More clinical information regarding management and outcome will help guide clinicians' and patients' decision-making

How can we better prevent additional cases?

- The best prevention approach is to completely separate the exhaust air from implicated heater-cooler units from OR air, but that approach represents a major engineering challenge, as the implicated unit is responsible for 60%-70% of the market.
- Recall of these units is not a realistic proposition if cardiac surgery is to continue.
- Long-term engineering solutions should be considered, as well as the question of whether any device that contains water and a fan on the same unit should ever be in an OR environment.

Discussion Points

Anytime a point source is identified and the data are compelling enough to inspire concern in this case, a recall should be discussed even if it is not an immediate solution. There is a point in time past which the problem may have been addressed with the units, so models manufactured before a certain date could have an action plan for replacement, culturing them, or taking other action. The units could not all be replaced overnight, but within a span of time.

Dr. Diekema said that the advice from the panel was given to the FDA, and it is not clear what action might be taken.

Regarding finding cases, HICPAC suggested that the recommendation to culture could be escalated. Some institutions were not sure how to proceed regarding culturing.

FDA did not offer a comment on the issue. The review of the minutes and outcome of the FDA Circulatory Devices Panel, at which Dr. Diekema was present, is ongoing. From the FDA's perspective, recall is a post-market issue.

The most important interim measure is to address the exhaust from the heater-cooler units in the OR and what can be done today to reduce risk. Stopping use of the machine would be ideal, but directing the exhaust out of the OR is likely to help.
Regarding the definition of "invasive" in this clinical setting, Dr. Diekema said that the main clinical syndrome identified in a majority of cases in this outbreak was positive blood cultures or other positive sterile site cultures, such as biopsy of bone marrow. Some cases have indicated more localized sternal wound infection. The invasive bloodstream involvement is almost exclusive to patients with vascular grafts and prosthetic valves in place.

HICPAC asked, if a formal recall is not possible, whether there is a formal mechanism similar to the approach applied to endoscopes asking the manufacturer of a specific device for a redesign. FDA replied that there is such a mechanism. All recommendations regarding redesign of devices are pre-market, and FDA is working with companies regarding those recommendations.

APIC observed that the manufacturer and FDA have given a great deal of instruction to institutions using the devices regarding culturing and follow-up. Guidance regarding situations in which device are culture-negative, but suspect cases are detected, would be welcome. Extraction from the environment is difficult, and not all devices will yield a positive culture.

Dr. Diekema did not believe that the FDA ultimately will recommend routine cultures for *Mycobacteria*. Some devices can be culture positive one month and culture negative the next. The negative predictive value of culture is poor, and only two or three laboratories in the country can do the testing reliably. The manufacturer recommends culturing, but a negative culture is falsely reassuring, which is why the FDA communication is worded as it is, to recommend provider notification and the development of a surveillance system to identify cases if the devices are used at all within an institution.

APIC said that the issue speaks to the point regarding recalling the devices in general if they were manufactured within the timeframe of the devices that are contaminated. APIC, Joint Commission, and others have considered moving exhaust outside the OR. There are many barriers associated with this approach, such as breaches in the one- and two-hour firewall barriers, disruptions in airflow, and safety concerns. These factors should be considered in providing guidance regarding moving ventilation outside the OR.

Dr. Diekema agreed. His institution only operates the units outside the OR, but that approach is not possible in every hospital.

APIC suggested that it would be helpful to provide guidance to facilities regarding how they might be able to accomplish that.

Regarding communication, there remains a struggle to share information about these patients to the providers who need to know about the problem. Has there has been focused communication to rheumatologists, perhaps through the American College of Rheumatology (ACR)? Communication involvement with cardiothoracic surgeons could be important. Surgeons can be helpful motivators for redesign issues and other barriers that may seem to be insurmountable. Risk communication to surgeons can communicate risk and threats to outcomes for their patients, and they are likely to be invested and concerned. What about the impact of a recall or similar approach regarding cost-sharing and responsibility for replacement of devices? In these situations, manufacturers may receive bad publicity, but they benefit financially when institutions purchase new devices.

HICPAC asked about the value of the September 2014 date, which is cited as the time when the manufacturer made changes to the process; however, there may be cases associated with devices that were built later than September 2014 and the date may not be fully reassuring.

Dr. Diekema assumed that September 2014 was the date when the manufacturer began to filter the water used to fill the devices and to dry the units prior to shipping. A comment was made at SHEA to the effect that cases had been detected in units manufactured after that date. This situation is unusual and complex in a number of ways. The ability to coordinate an outbreak investigation across multiple countries speaks to the need for advanced molecular capability that can be quickly coordinated not just across the US in the event of a nationwide outbreak, but across the world in the case of a global outbreak.

AORN has expressed several concerns about removing heater-cooler units from the OR, maintaining the room pressurization of positive pressure, and the air exchanges of temperature and humidity, which can be challenging. The built environment in the OR is difficult and complex. AORN works closely with engineering organizations such as American Society for Healthcare Engineering (ASHE) and American Society of Heating, Refrigerating, and Air-Conditioning Engineers (AHRAE) to meet their guidance regarding how to proceed, as they are the experts in this area. There is a need to stop transmission immediately and there is risk to patient safety. The risk-benefit analysis includes questions such as whether a facility has the capacity and layout to make changes. This equipment should not be placed in a sterile supply room, for instance. Additional guidance is needed, perhaps regarding a tiered approach based on whether infections have been detected or are serious. AORN is concerned about solving one problem, but causing another.

Dr. Bell said that in one sense, if surgery cannot be done safely, it should not be done. It may be inconvenient to move walls, change air handling, or take other steps, but the infection prevention field should be ready to insist that the issue should be addressed, recognizing cost, inconvenience, and the opportunity cost of providing surgery to people who need it urgently. As a group and a community, there is an obligation to “throw down a gauntlet” to the field, to the healthcare system, and to industry ensure that the work is done right. When the problems could not be identified effectively, it was understandable not to take strong steps. Had this infection been a more routine organism than *M. chimaera*, it may not have been attributed to the heater-cooler unit. Given the exhaust from these machines in the OR, it would not be surprising to learn that other organisms are aerosolized and deposited in places they do not belong.

Regarding finding cases and increasing clinician awareness, CSTE asked about the possibility of a Clinician Outreach and Communication Activity (COCA) call. These calls reach a large audience. There is concern about family practitioners who may not be connected to the hospital system where patients are seen and who may be treating these patients without recognizing the problem.

Dr. Diekema said that a Webinar will be held in the third week of August 2016, but he agreed that a COCA call is a good idea and perhaps should already have been done.

Facilities resist the idea of moving heater-cooler units out of the OR unless they have identified cases. There are staffing considerations with moving the units outside the room, unless there is a remote way to control the machine or a means for venting the exhaust outside. A statement from HICPAC, CDC, FDA, or another entity strongly making the case to move these units outside the OR is needed.

Dr. Diekema clarified that in his institution, the units are operated outside the OR entirely. The facility has addressed issues regarding maintaining positive pressure and air exchanges. They are continuously monitored in the OR. The units are operated with a remote device.

HICPAC commented on non-infectious risks associated with a device that takes all of the blood out of the body and circulates it. The longer the lines become, the larger the temperature change and the more difficulty in controlling the electrolytes. If thousands of facilities move the devices, there may be an increase in the aggregate harm done to patients. This problem is complicated because of the number of reasons listed by AORN in addition to the fact that the machinery itself is complicated. This problem is due to a failure of device design with a lack of microbiological safety. The burden has now been put onto facilities to mitigate the problem in a way that is dangerous for patients and expensive for facilities.

Dr. Diekema clarified that the cardiopulmonary bypass machine remains in the OR and the heater-cooler water circuits only, which never come into contact with a patient's blood, are outside the room. Many countries are struggling with these issues. The units have been moved out of the OR in The Netherlands, but not in Germany or Switzerland.

This problem is not the first that has arisen regarding water, machinery, air, and heat. In approving new devices, "forewarned is forearmed." Devices of this nature have the potential for high infection control risk. Even if FDA does not issue a recall or additional warning, there could be potential changes in FDA's approval process to heighten the responsibility of manufacturers of these devices. Hospitals bear the responsibility and cost associated with replacing machines with faulty designs that allow contamination.

FDA said that in the past, devices such as these were reviewed in various FDA divisions. The Center is organized according to specialty areas, with the Divisions of Cardiology, Obstetrics/Gynecology (OB/GYN, which includes gastrointestinal; Ear, Nose, and Throat (ENT), and others. Infection Control is in a separate division. The other divisions focused on design, function, and engineering. Even though "safety" is written into the definition, infection control was not included in the safety review. There are a number of predicates on the market that did not have infection control oversight, and now history is catching up. The Center is working to train engineers to recognize when they need to consult the Infection Control Division in the course of approval of certain devices. Her division is actively working with the Cardiology group regarding the heater-cooler units, helping them with an infection control plan to include cleaning and reprocessing and recommendations regarding the exhaust system, which should not be near the sterile field. FDA is working to evaluate devices that are on the market, and is working with its own engineers to recognize that devices that were once considered low-risk really are not.

Anytime there is new construction in a healthcare facility, an infection control risk assessment (ICRA) must be conducted. FDA may need a similar rule so that before a device is approved, there should be an assessment of the potential for infection control risk.

The situation is intolerable, as patients are put at risk and there is a struggle to "put Band-Aids on this problem." The temporary solutions are probably inadequate. However, it is not clear where to "throw down the gauntlet."

Dr. Bell said that the solutions should come from a community discussion that incorporates groups and interests beyond infectious disease control professionals. Individuals who are on

boards of hospitals and healthcare systems or who manage facilities should be involved. An across-the-board decision should be made regarding how to prioritize certain safety elements, recognizing pragmatic limitations associated with timing, process, and other concerns. In almost every instance, there is a nearly-endless list of reasons why changes cannot be made; however, the ultimate goals are to remove the problems, prevent them in the future, and hold industry accountable to develop safe products.

APIC asked about patients who have had these procedures who may not feel well and do not know why. Is patient notification limited to patients with known infections, or is there consideration to alerting all patients that have had a patient with that device so that they are on alert for signs and symptoms? This approach would be the most proactive.

Dr. Diekema said that most, but not all, institutions with cases linked to devices at their facilities have made patient notifications. The FDA Panel did not recommend a national patient notification of all patients who have been exposed to this make and model of heater-cooler unit.

When DNV Healthcare talks to clients about the Managing Risk Certification, risk assessments are raised as a constant concern. Hospitals do not feel comfortable conducting good risk assessments. DNV has recommended that facilities consider, when a piece of equipment will be purchased, asking the vendor to conduct a risk assessment on it to determine infection risks and how to mitigate them. This approach puts the onus on the manufacturer, and the facility can double-check the results of the risk assessment.

AORN agreed that all stakeholders should be at the table for these discussions, including cardiac surgeons, perfusionists, anesthesia providers, and engineers.

CU encouraged HICPAC to include patient notification in any recommendations or statements. Patients have a right to know that they may have been exposed.

Guideline Updates

Neonatal Intensive Care Unit (NICU) Infection Prevention Guideline Update

Kathleen Irwin, MD, MPH
Lead, Guideline Team
Division of Healthcare Quality and Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Dr. Kathleen Irwin presented HICPAC with an overview on DHQP's plans to update the 2013 draft Guideline on Infection Prevention in NICUs. This guideline underwent the CDC guideline development process. It was cleared by CDC and was ready to be posted in the *Federal Register* to solicit public comment; however, CDC decided to delay public comment on the draft to add reports published after 2011 because of concerns that the literature review was out of date. The guideline development process was then paused due to staff transitions and public health emergencies in which key staff were detailed to other activities.

The Core Writing Group will include national subject matter experts as well as CDC staff. After the draft is updated, expert review will be sought from the co-authors and reviewers of the 2013 draft as well as HICPAC members, HICPAC liaison representatives, and other experts. The partner organizations include:

- AAP
- SHEA
- APIC
- Vermont Oxford Network (VON)
- National Association of Neonatal Nurses (NANN)

The Guideline will address the same topics covered in the 2013 draft:

- CLABSI
- Respiratory Infections
- MRSA
- *C. diff*

Key Question: Central CLABSI

- What are the most effective strategies to prevent CLABSI in the NICU?

Key Questions: Respiratory Infections

- What are the most effective methods of prevention and control of respiratory illnesses in the NICU, including respiratory syncytial virus (RSV), pertussis, and varicella zoster virus (VZV)?
- Should transmission-based precautions be modified for patients in isolettes?
- What is the most effective diagnostic approach to identifying respiratory pathogen outbreaks in the NICU?

Key Questions: MRSA

- What are the risk factors, both modifiable and non-modifiable, for MRSA colonization and infection in NICU patients?
- What are the most effective strategies to screen for MRSA colonization in NICU patients?
- What are the most effective measures to prevent hospital-acquired infection or colonization with MRSA?

Key Questions: *C. diff*

- What are the most effective strategies for *C. diff* testing in NICU patients?
- When should testing for *C. diff* be performed in NICU patients?
- What is the significance of a positive *C. diff* test in a NICU patient?

The databases and sources will remain the same as the 2013 draft Guideline. The writing group will search for original sources and systematic reviews between January 2012 and June 2016, and the same inclusion and exclusion criteria will be applied to the articles as were applied in the earlier draft. The data sources include:

- MEDLINE
- Excerpta Medica (EMBASE)
- Health Literature – Cumulative Index to Nursing and Allied Health Literature (CINAHL)
- Cochrane Library
- National Guideline Clearinghouse
- National Institute for Health and Care Excellence Guidelines (UK)
- Scottish Intercollegiate Guidelines Network

- Infection Prevention Websites: CDC, SHEA, IDSA, APIC, AAP

The initial search of the four topics found that up to 2000 articles and guidelines may be relevant, but the past search found that approximately 80% of the articles and guidelines were excluded from the literature review. Nevertheless, the writing group, will still be a number of resources to review and evaluate.

The next steps of the development process are as follows:

July - September 2016
- Collect declarations of interest from Core Writing Group members
- Search post-2011 literature and apply inclusion criteria
- Compile and appraise evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) method, which was also used in the 2013 draft

October - December 2016
- Determine if new evidence warrants revising the recommendations. (The 2013 draft includes several “no recommendations” and “weak recommendations” because of sparse evidence; those recommendations, in particular, will be evaluated to determine whether new evidence changes those appraisals.)
- Revise draft with updated information
- Seek HICPAC input and start the CDC clearance process

Winter/Spring 2017
- Complete CDC clearance
- Seek public comment and revise as needed

Summer 2017
- Revise and publish on the CDC website

Questions for HICPAC to consider include:

- Questions about the update process
- Are you aware of relevant studies or guidelines that are very recently published and may not yet be indexed in electronic databases, or studies or guidelines in the pipeline that might be helpful in the review?

Discussion Points

HICPAC discussed the possibility of making CDC Guidelines “living” documents, perhaps updating and posting a section at a time. Dr. Irwin replied that when the NICU Guideline is updated with the interval literature search for all four topics, the updated document can serve as a baseline for segmental updates on individual topics as the evidence expands.

Mr. Hageman thanked Dr. Huskins and Ms. Fauerbach, who agreed to join the Core Writing Group. He added that Dr. Alexis Elward, who was the lead when she was a member of HICPAC, is remaining engaged in this effort.

Update on Guideline for Infection Prevention in Healthcare Personnel

David T. Kuhar, MD
Medical Officer
Division of Healthcare Quality and Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Dr. David Kuhar updated HICPAC on plans to update the 1998 Guideline for Infection Prevention in Healthcare Personnel. The 1998 Guideline provided recommendations for reducing the transmission of infections among healthcare personnel and patients. It was different from the Guideline for Isolation Precautions, as it was aimed at occupational health providers working in healthcare facilities, primarily hospital settings. It focused on infections known to be transmitted in healthcare settings and among personnel and patients and provided recommendations on strategies to prevent transmission that involve the occupational health service, such as:

- Immunizations
- Education about isolation precautions
- Managing ill and exposed personnel, with an emphasis on post-exposure prophylaxis (PEP) and work restrictions, if necessary

The first section of the 1998 Guideline includes discussion on the infrastructure needed to provide infection prevention services to healthcare personnel. It identified the objectives of an occupational health service, such as managing ill or exposed healthcare personnel, and provided the critical elements or infrastructure pieces that an occupational health service needs to deliver needed services, such as coordinating with other departments like infection prevention services, providing medical evaluations, and others. The second section of the Guideline provided in-depth discussion on selected infections transmitted among healthcare personnel and patients, such as MRSA, measles, or pertussis. For each disease, the Guideline typically addressed the epidemiology in healthcare, immunization if available for that pathogen, and management of ill or exposed personnel, including PEP and duty restrictions. The third section of the guideline addressed special populations who might have unique infection prevention service needs, such as pregnant healthcare personnel.

The scope of the Guideline, content, and primary audience for the update will be similar to the 1998 Guideline, as the user community indicated that it was very useful. DHQP plans to modernize delivery of the Guideline to the user community, publishing it as a “living” guideline on CDC’s website. The update will have an electronic format with the sequential online publication of complete sections rather than an all-at-once publication of a single product. The update process will involve HICPAC input as well as public comment for each of the sections as they are updated. The update will have some revised organization for individual sections, as well as expansion of scope to address healthcare settings beyond hospitals. DHQP is also revising the list of pathogens to be addressed, although most are likely to be carried forward from the 1998 Guideline as they are still relevant.

Currently, the update is planned to have at least two sections. The first section will address the necessary infrastructure and practices for providing infection prevention services to personnel, as in the 1998 Guideline. This section will be published ahead of other sections. The second section will provide information on the prevention of selected diseases that may be transmitted among personnel and patients. Special healthcare personnel populations who may require more

individualized considerations will either be addressed as part of each pathogen section, or in a separate Section 3.

The writing group for Section 1 was reconvened in November 2015. It addresses the objectives for an occupational health service for providing infection prevention services and includes a revised list of infrastructure elements for occupational health services to provide those services to healthcare personnel. Revisions to the elements include adding a section on Leadership and Management and Risk Assessment in the Healthcare Facility. The outline of Section 1 is:

- Introduction
- Methods for Developing the Recommendations
- Infection Prevention Objectives for Occupational Health Service
- Elements of Occupational Health Services for Infection Prevention
    - Leadership & Management
    - Interdisciplinary Collaboration and Communication
    - Risk Assessment in the Healthcare Facility
    - Medical Evaluations (preplacement, periodic, and episodic; health counseling)
    - Health and Safety Education and Training
    - Immunization Programs
    - Management of Potentially Infectious Exposures and Illnesses
    - Management of Healthcare Personnel Records and Information

Regarding the evidence base for Section 1, a systematic literature identified approximately 310 articles related to the objectives, infrastructure, and elements for occupational health services for infection prevention. The review also identified 30 related guidelines and 25 government and non-government websites for review. Section 1 recommendations will not use GRADE to evaluate the data; rather, they will refer to current existing guidelines and regulatory requirements or standards. Additionally, recommendations indicated as “good practice” recommendations will be included. These recommendations can be based on scientific evidence, core infection prevention practices, program experience, and expert opinion.

The systematic literature review is complete, and the writing group has been meeting every two weeks to review subsections of Section 1, such as a the section on managing personnel records and information, or health and safety education and training, to refine each section. The draft is still being refined, but it will be shared for HICPAC review when it is complete. Simultaneous work is ongoing on Section 2, which will begin with an introduction to include a general review of isolation precautions with reference to updated guidance on the topic. The section will focus on selected pathogens that can be transmitted among personnel and patients. There are likely to be modifications to the list of pathogens, but most of them were addressed in the 1998 Guideline.

A few individual pathogens will be updated at a time. Pathogens will be selected for update based upon several considerations, such as having high priority information in need of more urgent update. Pathogen selection also will be based upon logical clusters, such updating measles, mumps, and rubella at the same time due to the vaccine cluster. Practical considerations will also apply, such as efficiency in generating an update. MRSA will be updated first. Not only are there topic specific issues in need of update, but also the update process can inform the literature search and update processes for all subsequent pathogens.

Each pathogen subsection will have a similar outline. As in the 1998 Guideline, the section will to briefly discuss the epidemiology of the pathogen, transmissions that have occurred among personnel and patients, its general clinical manifestations, and its incubation period as it is directly relevant to duty restrictions. The section will link to recommended isolation precautions or vaccination recommendations, if available. Some pathogens, such as tuberculosis (TB), will have recommended screening among healthcare personnel, and the Guideline will link to that information.

Management of ill or exposed personnel is a primary service provided by occupational health services. The Guideline will focus on post-exposure management, making work restrictions recommendations clear, and on return-to-work issues. DHQP is aware that the role of occupational health services is not to lead outbreak or epidemiologic investigations; however, occupational health services has a role in this work, such as testing healthcare personnel. The writing group is discussing ways to address this role.

Some topics may not require a full systematic literature review. A credible source or the CDC website may provide information, for instance, regarding rates of pathogen colonization among healthcare personnel or the general US population. In addition, the writing group will identify important or critical questions for each pathogen that are not addressed by federal guidance and will conduct a systematic literature review for those questions. A system for determining the strengths of recommendations is under discussion.

HICPAC's input is sought regarding important questions for the update to MRSA. Exact wording of the questions is being discussed. Additional sub-questions may be generated, based on the answers to some of the questions that are posed and how to implement those answers.

<u>MRSA Colonization</u>

- Absent a MRSA outbreak epidemiologically linked to healthcare personnel, should healthcare personnel be routinely screened for MRSA because of evidence that they transmit infection to patients or other personnel?
- How should colonized healthcare personnel be managed?
- Should they be decolonized? If so, how is successful decolonization defined?
- What duty or patient care restrictions should be in place, and what should be their type and duration?

<u>Managing infected healthcare personnel</u>

- What types of MRSA infections among healthcare personnel warrant duty restrictions?
    - Should healthcare personnel with skin and soft tissue MRSA infections that can be fully contained under a dressing be restricted from patient care duties?
    - Does this apply to all anatomic sites; that is, should a lesion on a person's hand be treated differently from a lesion on his or her leg?
- What criteria should be used for determining when duty restrictions are no longer needed?

<u>The role of Occupational Health Services in outbreaks involving healthcare personnel</u>

- While not leading the investigations, Occupational Health Services are involved in the assessment, testing, counseling, and management of healthcare personnel.
- What questions might be relevant in this topic area?
- Should healthcare personnel who are epidemiologically linked to MRSA outbreaks be subject to work or duty restrictions? Be decolonized? If they should be decolonized, should there be work or duty restrictions, and for what duration?

The timeline for the MRSA Section is:

July - September 2016
- Finalize important questions, inclusion criteria, search terms
- Conduct literature search (January 1999 – June 2016)

October - December 2016
- Revise pathogen draft with updated information
- Seek HICPAC input

The following questions were presented for HICPAC's consideration:

- Are there additional important questions regarding MRSA that should be addressed?
- Are there questions presented that should not be addressed?

Discussion Points

HICPAC agreed with the content presented but suggested a different order. The Guideline should begin with the infected healthcare worker, because regardless of whether a link or transmission is established, the infected healthcare worker should be the focus. The next area of focus could be an outbreak situation. There is good data available to support recommendations in this area. Colonization might be left to the end of the recommendation, as there is little, if any, good evidence related to screening healthcare workers in the absence of an outbreak. In an outbreak, an infected healthcare worker might be identified at the time of screening. The narrative flows more logically in this order, beginning with an approach to treatment in a healthcare worker, addressing whether to treat the infection, to conduct decolonization in addition, and other questions. The approach is different from treating MRSA in a patient who is not a healthcare worker, as some decolonization is likely, which may or may not be the case in a patient who is not a healthcare worker.

Dr. Kuhar said that treatment is given if a person is infected. Decolonization is another question.

HICPAC agreed that there should be effective treatment. The next question focuses on the when, and to what extent, also to decolonize. If so, then with what? Should there be a culture to verify the decolonization? Is a healthcare worker removed from work in the meantime? What if the decolonization is not successful? If these questions are addressed initially, the subsequent sections can build on them.

HICPAC suggested considering methicillin-susceptible *Staphylococcus aureus* (MSSA) in addition to MRSA. Both are screened preoperatively and have the same implications, although it is easy to focus only on MRSA.

Dr. Kuhar agreed and indicated that both MSSA and MRSA will be addressed.

CSTE suggested considering whether healthcare workers might be treated differently based on the patient population with whom they work. For instance, NICUs are different from burn units, which are different from general medical wards.

Presenting different approaches by different patient populations may be problematic. Some hospitals include oncology patients on general medical wards, for instance. Parsing out low-risk versus high-risk populations is complicated.

CSTE suggested that the Guideline explicitly state this point, as some facilities treat patient populations differently. A statement that all patients should be treated the same with an accompanying rationale will be helpful.

This issue arises in particular for healthcare personnel who work in the NICU, where different follow-up or documentation of clearance may be required. General medical wards include a range of immunocompromised patients, and it may not be possible to identify a "low-risk" area of a hospital. However, the issue is worth considering for NICU personnel if literature is available to address the question.

Challenges in Guideline Development

Jeff Hageman
Division of Healthcare Quality and Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Mr. Hageman said that the SSI Guideline has completed the CDC clearance process. He thanked Erin Stone, who has ensured that the Guideline has progressed. The next step is to put the Guideline in the appropriate format for posting on the CDC website. DHQP is working with a subset of the co-authors to disseminate it with companion pieces in the peer-reviewed literature. HICPAC will be informed when there is confirmation of publication in a journal.

Currently, CDC guidelines for healthcare infection control purposes are located on different websites with different portals of entry. Many guidelines currently are on the HICPAC website, but other guidelines for healthcare infection control, such as dialysis settings, are in other locations and did not have HICPAC involvement at the time that they were developed. Other guidelines may reside on pathogen-specific sites, such as the influenza site. Dr. Irwin and her team are working to coalesce that information onto a site that is dedicated to healthcare infection and control, which can link to other content sites. The launch of the website is anticipated in the coming months

Michael Bell, MD
Division of Healthcare Quality and Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Dr. Bell addressed guideline production at CDC. The needs and functions of guidelines have changed dramatically in the last 20 years. The form and process for creating guidelines is changing as well. The guidelines of the past looked like textbooks. Guidelines were expected to teach about a condition or situation, as well as to provide guidance regarding how to address it. The guidelines could be hundreds of pages long, with hundreds of references. Users took on faith that the references supported the recommendations within the document. This approach is difficult to maintain, or even support. The move to a GRADE approach, which has challenges and limitations, was inspired by a desire to substantiate recommendations with specific, powerful information. This approach is a sea change from the early days of guidelines.

The question now regards how to maintain the focus on a selected question in guidelines. The old system of spending two or three years on a document is not sustainable. The lead authors of guidelines are not available in perpetuity. A more systematic, sustainable approach is needed. DHQP now has an in-house Guideline Group, which is charged with leading the production and maintenance of guidelines. This group focuses on a range of elements, including consistency of style, evidence review and analysis, and methodology. A robust methodology that can be brought to bear and that is functional and effective for DHQP is an important part of this work.

The organization of information is an important consideration. Focus remains on discrete, document-like projects, albeit presented as a smaller series of questions. At the same time, there is a "warehouse" of several hundred recommendations. Some of them have been captured in the Core Practices document, as no evidence review will be conducted to change them, and they are standards that will persist. Regarding review of the rest of the guidelines, conducting the review based on one guideline versus another may not be the best approach. The temptation will be to revise the entire guideline. DHQP is making an exception with the occupational health document, as it is different. However, most prevention recommendations can be clustered by relation and relevance. They can be reviewed systematically to determine elements that are urgently in need of consideration that might be revisited, but do not likely have evidence to change them, and according to other criteria. At any moment, a recommendation could rise to the top of the list with new evidence or new urgency for review. On the whole, the work should integrate into a workflow that is ongoing, tenable, and transparent.

Dr. Irwin and her colleagues are in the process of gathering the recommendations and assembling them into a spreadsheet for evaluation. A first step could be to review the recommendations and name the ones that need to be updated, based on expert opinion. The old documents will remain available in an archive. Many recommendations may incorporate pop-up overlays to illustrate the old recommendation, the date of the update, and the rationale for the change. There are many opportunities to use technology to make CDC's guidelines more active in practice.

It is clear that there are differences between HICPAC recommendations for products and for practices. A potential document could explore those ways in which a recommendation related to a product is different from a recommendation related to a practice. Another point to consider is the reality of bundled practices, which did not exist when the Isolation Guideline was originally drafted. Actions, practices, and products are now bundled. When a new element shows evidence promise but perhaps not in the context of a bundle, there should be a means and rationale for thinking through potential trade-offs, disassembling a bundle, or adding to a bundle.

The grading of recommendations from the mid-1990s is still being used. The entire community is accustomed to the language labeling recommendations; however, mapping to the old categories is increasingly awkward. Now may be the time to think about re-labeling the categories. There may be an opportunity to change the language that is used for guidelines to reflect a sense of evidence of effectiveness and appropriateness. Language can be crafted to convey nuances, to say what HICPAC wants to say, and that is useful to users who implement the document. HICPAC might consider taking on the task of re-thinking the categorization of recommendations and the language that can accompany it.

Discussion Points

Assemblage of the guidelines presents an opportunity to review their publication dates. HICPAC has discussed such a review to determine which guidelines should be updated and when. Some of the guidelines are quite old.

HICPAC asked for an update on the Core Practices Document. Mr. Hageman said that the set of Core Practices also will be folded into the new website.

HICPAC supported the idea of creating templated language so that recommendations do not need to be wordsmithed each time, for each strength of recommendation. This approach will ensure consistency among the guidelines so that recommendations that are "must do" or are "optional" are stated in the same way. The approach also will save time in discussion and in the approval process.

HICPAC asked if changing from the current categorization might permit expert opinion.

Dr. Bell said that one of the goals of this work is to move away from documents that contain many questions with the answer, "no recommendation currently can be made." There is opportunity to include expert opinion. One of the inherent values of a group such as HICPAC is the opportunity to glean thoughts from leaders in the field. These opinions could be captured in a different manner, such as with a text box in the narrative, which is useful to users. He hoped to hear from users in infection prevention as well as from clinicians and healthcare system leadership who need to link recommendations to priority-setting and resource management.

HICPAC appreciated the start of this conversation, and supported the idea of writing a document since transparency regarding the issues and HICPAC's thoughts is important. The process of committing ideas to paper will help clarify thinking. Similar discussions have taken place in writing and creating the paradigm used by the Compendium. The bundle is an important concept. Core practices that need to be included in a best practices bundle will help inform research and how the research will be judged for inclusion in guidelines.

CSTE commented on a WHO document on Interim Treatment Guidance for H5N1 when there was essentially no evidence available. The document can serve as a model for how to integrate expert opinion. It described the experts' thoughts and value sets, as well as the benefits and harms that they discerned. The document conveyed why the experts arrived at particular opinions, and the accumulated additional evidence indicated the future direction. There is precedent, therefore, for including expert opinion in a transparent manner.

HICPAC appreciated Dr. Bell's comments, which reflect frustrations that many have felt with the process by which guidelines are developed, including weighting of the evidence. However, they should not "throw the baby out with the bathwater." CDC guidelines have enormous global and domestic power. Different people and different groups everywhere look to CDC. If the format and presence of guidelines are changed dramatically, there could be losses. The current categorization is somewhat arbitrary, and the comments regarding "no recommendation" are related to the lack of well-executed randomized controlled trials (RCTs) in the discipline of infection control. The need for guidance and recommendations always will be present. CDC has released interim guidance and recommendations in different areas. The interim documents are typically generated by CDC staff, but there is a place for HICPAC to contribute expert opinion.

HICPAC agreed with the idea of incorporating expert opinion and with the idea of specifying a process for it. Ad hoc experts could be convened to provide opinions on a given topic. A document could represent two points of view as a means for representing the potential diversity

of opinion without being constrained by the need to create a single recommendation that is wordsmithed to the point that it is no longer helpful.

AEH commented that CDC has done a wonderful job writing guidelines. Many infection preventionists do not have a standard text for use in training, so CDC guidelines are used to help new infection preventionists understand the reasons for their work. The core source document is valuable to delve into the supporting research. HICPAC could adopt a combination approach, using a core document with a strong background perspective, and updates as needed based on new literature and research.

Public Comment

Dr. Yokoe called for public comment at 4:55 p.m. Hearing none, she noted that there would be another opportunity for public comment during the second day of the meeting.

Liaison / Ex Officio Reports

National Institutes of Health (NIH): NIH had one of the early reports of very resistant yeast, which was sent to CDC.

AHRQ: AHRQ continues to support research and implementation projects to combat antibiotic resistance in three domains:

- Promoting antibiotic stewardship
- Preventing transmission of resistant bacteria
- Preventing HAIs in the first place

These projects take place in acute care hospitals, long-term care settings, and ambulatory care settings.

AHRQ recently completed field testing of its implementation guide for antibiotic stewardship in nursing homes. The guide is based on tools from previous AHRQ-supported studies. Data from the field testing are being analyzed. Wide dissemination of the guide is anticipated in late 2016. AHRQ and CDC held a successful conference of experts and stakeholders on June 6, 2016 to identify knowledge gaps in research areas of antibiotic-resistance. Since the last HICPAC meeting, AHRQ has released two Request for Task Order Proposals for the Comprehensive Unit-based Safety Program (CUSP) for Antibiotic Stewardship. The first five-year project is aimed at adapting CUSP for implementation of Antibiotic Stewardship in 250 acute care hospitals, 250 long-term care facilities, and 250 ambulatory care settings. AHRQ hopes to make an award in September 2016. The second project focuses on adapting CUSP for enhanced recovery after surgery (ERAS), a constellation of preoperative, intra-operative, and postoperative practices to decrease complications and accelerate recovery. This five-year project aims for implementation in 750 hospitals nationwide, focusing on a variety of surgeries. This award is also anticipated by September 2016. Other AHRQ Safety Programs include the program for Intensive Care Units (ICUs) with Persistently Elevated Rates of CLABSI/CAUTI, for Mechanically Ventilated Patients, for Ambulatory Surgery, and for Long-Term Care Prevention of CAUTI and Other HAIs.

CMS: No report.

VA: Work on disease prevention and stewardship continues at the VA.

PHAC: A new Canadian government was elected in the fall of 2015, and the priorities for the Health Minister are filtering to PHAC. Immunization is a significant issue. Other important issues include TB, emerging infections, global health issues, and preparedness and response. Antimicrobial resistance is also a priority. Sexually transmitted, bloodborne infections; hepatitis C; and resistant organizations are also high on the agenda. PHAC has ongoing discussions and dialogue with CDC regarding guideline development and sharing methodologies. The two agencies have cross-populated some working groups, such as the Endoscope Reprocessing Working Group. PHAC looks for opportunities to collaborate and share expertise wherever possible. Canada's national surveillance system for HAIs is in place. A new surveillance system is being developed for antimicrobial resistance, which brings together existing animal and human surveillance systems. PHAC is completing two large projects, one on managing healthcare workers who have been infected with bloodborne pathogens, and one on updated guidance for tattooing, piercing, branding, personal services, and body modification. The endoscope and heater-cooler unit issues have triggered interest in Canada, and PHAC has been flooded with requests for information. Canada's regulatory authority, Health Canada, has reached out to FDA, as clinicians are seeking advice. CRE is another significant issue for PHAC, and an upcoming guideline will address dialysis.

SHM: SHM has developed an antimicrobial stewardship program that will launch later in 2016. It is a mentored implementation program. SHM is developing an implementation guide and will begin recruiting later in 2016. SHM leadership is involved in several of the state-based and national collaboratives funded by AHRQ and CDC for the antimicrobial stewardship issues and prevention of CAUTI, CLABSI, *C. diff*, and MRSA. SHM will participate in CDC's Get Smart! campaign in November 2016 with its campaign "Fight the Resistance." The campaign is collecting case studies from clinicians and patients related to its recommendations. Patient stories are often the strongest motivators.

ACOEM: ACOEM has published a number of guidance documents in recent months. ACOEM is also finishing the third edition of the guidance document for occupational health services in medical centers. ACOEM and the American Association of Occupational Health Nurses (AAOHN) have published joint guidance for employers on the impact of marijuana in the workplace.

SHEA: SHEA held a successful spring 2016 meeting in Atlanta, Georgia. An antimicrobial stewardship training course was introduced at that meeting, as well as a mentorship program. SHEA is working with its partners on the fall meeting, which will be held in New Orleans, Louisiana, in October 2016. SHEA is developing a series of podcasts related to stewardship. Expert guidance documents have been created concerning duration of contact precautions, infection prevention in the anesthesia work area, and initiation of antibiotics in long-term care. Regarding public policy and advocacy, SHEA has been strongly advocating for funding for various public health agencies and has been communicating information about the contaminated heater-cooler units to the membership. SHEA is also promoting antimicrobial stewardship. The Research Committee has been busy, having released a series of papers on methodology. A number of additional projects are in the queue, including legal issues in stewardship. A full list of activities is provided in the written liaison report.

IDSA: The liaison report includes full information regarding IDSA's issues. IDSA continues to engage in antimicrobial resistance and the promotion of stewardship. In the legislative arena, IDSA briefs policymakers on the importance of the range from research and development of new drugs, to stewardship and surveillance, as well as the importance of animal and human

health and promoting an expert infectious disease workforce. IDSA has done a great deal of work on the Conditions of Participation regarding stewardship. In what is good timing, in addition to the stewardship work that was completed in partnership with SHEA, a joint product from the American Thoracic Society (ATS) and IDSA has been released: a hospital-acquired and ventilator-associated pneumonia guidelines, which not only promotes a shorter course of therapy, but also highlights the importance of institutional antibiograms and unit-specific antibiograms. This model could be advanced going forward. IDSA released a position statement on antimicrobial stewardships via telehealth, which is an important complement, especially given issues about workforce.

SIS: The major theme of the Spring 2016 SIS meeting was the microbiome and how it is altered by stress, surgery, and other important conditions. SIS has launched a new e-journal for surgical infections case reports. SIS continues to work on guidelines. The most recent edition of the Intra-Abdominal Infection Management Guideline should be published in early 2017. SIS works with CDC regarding how best to partner in several areas, including developing a curriculum for surgeons who are involved in infectious disease matters; for example, teaching surgeons about antibiotic stewardship.

SCCM: SCCM added to the liaison report a thank-you to CDC for the strong partnership regarding sepsis. They are working together and with other organizations on upcoming webcasts and other activities.

ACS: ACS is continuing efforts to streamline and bring together its different registries onto a single platform to ease hospital participation. The registries incorporate elements of HAIs in their outcomes. The annual ACS National Quality Improvement Program® (NSQIP®) conference will be held in July, 2016 in San Diego, California with an expected attendance of approximately 1500.

AORN: AORN has completed its hand hygiene guideline. It will be published electronically in September 2016 and in print in 2017. The updated guideline does not include significant changes. The largest change is associated with nail lengths, which are now in alignment with recent studies showing that the maximum nail length should be two millimeters rather than .25 inch. AORN has aligned with the SHEA Compendium Guidelines, as well as with CDC and WHO guidelines. The feedback on the guideline has been positive. This summer, the AORN guideline for humidity ranges and smoke safety will be posted for public comment. This guideline is new. AORN has been working on surgical smoke safety, communication information and awareness. AORN launched the Globe Clear Award, a program in which hospitals that have implemented smoke evacuation and good practices for preventing smoke exposure in the OR can be recognized for their efforts and the level that they have achieved in working toward best practices. The AORN conference will be held in Boston, Massachusetts in April 2017. The deadline for poster abstracts is in September 2016, and posters on SSI and heater-cooler units would be welcome. This information is important for perioperative nurses and does not always reach the bedside.

CU: CU has submitted numerous comments CMS and the CARB committee on antibiotic resistant issues. CU recommended that the CARB committee consider recommending that CMS use its payment policies to change the way that antibiotics are prescribed, for example, requiring Medicare prescriptions to include the indication; making Medicare data about prescriptions available to CMS, which could make it available to researchers, for use for free; requiring hospitals to use rapid diagnostic testing and reimbursing them for that. CU continues to push for requiring hospitals to report their antibiotic use to NHSN. CU worked on legislation in

Missouri that passed this year, with some changes from the initial iterations, that includes a requirement that hospitals in the state report using the AUR module of NHSN. This requirement is contingent on Stage 3 Meaningful Use regulations becoming effective. It does not make the information public, which is a concern, but it could lead to additional information for NHSN to use in determining baselines. CU is advocating for more conversations and sharing of information between the different parts of health department, such as the surveillance and the enforcement elements, so that there is increased collaboration. The surveillance groups can only be invited to work with hospitals, and there are ways that licensure could stipulate a plan of action in which hospitals will have to work with surveillance to improve. *Consumer Reports* has been publishing ratings of hip and knee replacements in California in collaboration with the Insurance Department there, looking at complication rates, infections, and costs. Work also has been ongoing regarding C-section rates.

DNV Healthcare: DNV is currently revising the Managing Infection Risk (MIR) standards as well as hospital accreditation standards to update to the CMS Rules of Participation. DNV is also working with its research and innovation group in Norway regarding bringing a safety culture to its clients.

AEH: In addition to the liaison report, AEH continues to support, publish, and promote awareness for ongoing work in standard practice, outbreak response, and related issues.

Joint Commission: On July 1, 2016, the Joint Commission announced its new Antimicrobial Stewardship Standard for critical access hospitals and nursing care centers. The standard becomes effective January 1, 2017. The Joint Commission is working with CDC to develop standards for the ambulatory surgery setting.

NACCHO: NACCHO has continued a multi-year HAI demonstration site project at three local health departments. This year, the project has focused on stewardship. In March 2016, NACCHO launched the Lessons in Infection Control Initiative with 11 local health department demonstration sites. This project supports local health departments in improving healthcare and community infection control practices. CDC's support is appreciated in this effort. In April 2016, NACCHO co-hosted a learning session on integrating preparedness and infectious disease prevention and control at the Preparedness Summit with the Association of State and Territorial Health Officials (ASTHO). Scholarships were awarded in May, 2016 to support 35 local health department staff in obtaining their certification in infection control. In July 2016, NACCHO completed development of an HAI guidance document for local health departments to engage in HAI prevention activities. That document was based on the demonstration sites that are conducting HAI work. The document is in the process of being posted online. NACCHO position statements responded to the Notice of Request for Information by the Presidential Advisory Committee on CARB, urging healthcare departments to actively engage with their local health departments to share information and identify ways to collaborate.

APIC: In addition to the liaison report, APIC has announced its first class of Fellows for 2016. This advanced designation program recognizes APIC members with the status of Fellow of the Association for Professionals in Infection Control and Epidemiology (FAPIC). This status is a distinction of honor for infection preventionists who are not only advanced practitioners of infection prevention practice, but also leaders in the field. APIC is excited about the class of 200 individuals. The APIC annual conference was a great success and APIC thanked CDC for contributing to 21 sessions at the conference.

ASTHO: ASTHO launched a web-based toolkit to support health departments in accessing EHRs for outbreak investigations. The Council for Outbreak Response: Healthcare-Associated Infections and Antibiotic-Resistant Pathogens (CORHA), co-chaired by ASTHO and CSTE, seeks to improve practices and policies for detection, investigation, control, and prevention of HAI and AR outbreaks and emerging infection disease threats across the healthcare continuum. CORHA is working on initial implementation plans.

CSTE: CORHA is a major activity for CSTE. In addition, the core planning group of the Antimicrobial Resistance Surveillance Task Force is meeting approximately one to two hours per week via conference calls. The meetings are focused on specific issues, including defining the challenges of ELR and NHSN reporting for CRE; addressing the selective reporting of susceptibility data; and describing the roles, responsibilities, and core capacities needed at the federal, state, and local levels. The CSTE annual conference was held in Anchorage, Alaska. The major position statement of relevance to HICPAC related to inter-facility communication to prevent and control HAIs and antimicrobial-resistant pathogens across healthcare settings. CSTE will engage partners in providing guidance.

Adjourn

Dr. Diekema thanked HICPAC for the day's discussion. HICPAC stood in recess at 5:18 p.m.

Friday, July 15, 2016

The second day of the HICPAC meeting was called to order at 9:05 a.m. on Friday, July 15, 2016.

Welcome and Roll Call

Mr. Hageman offered some housekeeping notes and conducted a roll call of HICPAC members, *ex officio* members, and liaison representatives. A quorum was present.

Dr. Diekema welcomed the group and noted an addition to the agenda that HICPAC would vote to approve the Antimicrobial Stewardship Principles for Treatment Guidelines, which had been edited.

Zika Virus Update

Christine Olson, MD, MPH, CAPT, USPHS
Centers for Disease Control and Prevention

Dr. Christine Olson presented HICPAC with an update on Zika virus. Zika virus is a single-stranded RNA virus in the genus *Flavivirus*, family *Flaviviridae*. It is closely related to dengue, yellow fever, Japanese encephalitis, and West Nile viruses. Zika virus is transmitted to humans primarily by two *Aedes* species mosquitoes, which are aggressive daytime biters that live in and around households, lay eggs in domestic water-holding containers, and also can transmit dengue and Chikungunya viruses. Zika virus transmission has also been documented through:

- Intrauterine and perinatal transmission
- Sexual transmission
- Laboratory exposure
- Blood transfusion

Before 2015, Zika outbreaks occurred in areas of Africa, Southeast Asia, and the Pacific Islands. Currently, outbreaks are occurring in many countries and territories in the Americas and worldwide, including Puerto Rico, American Samoa, and the US Virgin Islands. Zika has not yet been spread by mosquitoes in the continental US; however, Zika virus has been associated with returning travelers. In addition, a few non-travelers have contracted Zika through sex with infected travelers.

CDC is not able to predict how much Zika virus will spread in the continental US. Many areas in the US have the type of mosquitoes that can become infected with and spread Zika virus. Recent outbreaks in the continental US of Chikungunya and dengue, which are spread by the same type of mosquito, have been relatively small and limited to a small area.

Pregnant women can be infected with Zika through the bite of an infected mosquito or through sex with an infected partner. If a woman is infected with Zika around the time of conception, the risk to the fetus is currently unknown; however, given what is known about other viral infections, infections around the time of conception potentially can lead to infections in the fetus. If a woman is infected during pregnancy, Zika virus can be passed to her fetus during pregnancy or around the time of birth.

Mounting epidemiologic, clinical, laboratory, and pathologic evidence suggests a link between congenital Zika virus infection and birth defects, such as microcephaly and brain abnormalities. Recently, CDC conducted a systematic evaluation of the evidence and concluded that a causal relationship does exist between prenatal Zika virus infection and microcephaly and other serious brain abnormalities.

It is known that Zika can cause microcephaly, a severe birth defect that is a sign of a problem with brain development. Microcephaly is a condition in which a baby's head is much smaller than expected. During pregnancy, a baby's head grows because the baby's brain grows. Microcephaly can occur because a baby's brain has not developed properly during pregnancy, or has stopped growing after birth. There have been numerous reported brain abnormalities with congenital Zika virus infection, including:

- Decreased total brain tissue
- Calcium deposits in the brain
- Excess fluid in the brain cavities

In addition to microcephaly, other problems that have been detected in pregnancies and among fetuses and infants infected with Zika virus before birth include miscarriage, stillbirth, absent or poorly-developed brain structures, defects of the eye, hearing deficits, and impaired growth. While the evidence supports a causal link with microcephaly and other severe fetal brain defects, many questions still remain.

To learn more about Zika virus, CDC is collecting data for action. In collaboration with state, tribal, local, and territorial (STLT) health departments, CDC established the US Zika Pregnancy Registry. CDC is working to collect information about pregnant women with laboratory evidence of possible Zika virus during pregnancy in the US, and their infants. CDC helped develop a similar system in Puerto Rico, the Zika Active Pregnancy Surveillance System. CDC has established enhanced surveillance of pregnant women with Zika in Colombia.

Zika virus infection during pregnancy has been linked to adverse outcomes. Despite these observations, little is known about the risks of Zika virus infection during pregnancy. CDC has established the US Zika Pregnancy Registry to monitor pregnancies and infant outcomes to learn more about the timing, absolute risk, and spectrum of outcomes associated with Zika virus infection during pregnancy to help inform clinical guidance and to direct public health action. The registry is a supplemental surveillance effort that is coordinated by CDC and is dependent on the voluntary collaboration of clinicians and STLT health departments.

The registry includes:

- Pregnant women in the US with laboratory evidence of Zika virus infection; that is, positive or equivocal test results, regardless of whether they have symptoms
- Periconceptionally, prenatally, or perinatally exposed infants born to these women
- Infants with laboratory evidence of congenital Zika virus infection, positive or equivocal test results regardless of symptoms, and their mothers

The registry can be supported by sharing awareness about it and by offering assistance to health departments as they follow up with women and infants who are part of the registry.

As of June 30, 2016, CDC has worked with STLT health departments to identify 320 pregnant women with any laboratory evidence of possible Zika virus infection, with or without symptoms, in the US and the District of Columbia (DC), and 303 pregnant women in the US territories, including Puerto Rico, US Virgin Islands, and American Samoa. These numbers are updated and posted on the website every Thursday.

Starting on June 16, 2016, CDC began reporting poor outcomes of pregnancies with laboratory evidence of possible Zika virus infection for the US states and DC. As of June 30, 2016, there were 320 pregnant women reported to the US Zika Pregnancy Registry; seven live-born infants with birth defects; and five pregnancy losses with associated birth defects.

CDC has created tools for healthcare providers and health departments to use to implement current guidance for caring for pregnant women with possible Zika virus exposure. CDC has also created tools for pregnant women who are living in or traveling to areas with active Zika virus transmission. The tools are free and available on the website: CDC Zika Update. This work represents the work of many people and collaborators.

Discussion Points

HICPAC asked about updates regarding transfusion safety or solid tissue transplant safety with respect to Zika virus.

Dr. Olson answered that a few months ago, FDA posted information on transfusion, products associated with in vitro fertilization, and related topics. FDA took a cautious approach, as more is learned very day about Zika. She was not aware of updates on blood transfusion. Cases of blood transfusion-related Zika have been documented in Brazil.

Dr. Rita Helfand noted that CDC and FDA are working with state and local health departments and companies that can conduct NAAT testing of blood in areas that are at high risk for Zika. Some areas are opting to wait to test until they have local transmission, but these efforts are ongoing actively to minimize risk.

SHEA asked about updated estimates of the incidence of infection associated with pregnancy. Estimates are as low as 1% or 2%, and as high as 20% or 30%, seemingly based on the trimester of pregnancy when a woman is infected.

Dr. Olson said that because there are so many unknowns about Zika, new information is emerging every day. There are reported ranges of infections, transmission, and birth defects associated with infection. Those numbers cannot be narrowed more than what has been published in the literature. Part of the purpose of the pregnancy registry is to collect systematic information to better assess risk. The ranges depend on the study.

HICPAC asked about official surveillance for the neurologic complications for Guillain-Barré syndrome (GBS), or whether the surveillance would rely on reports from clinicians.

Dr. Olson answered that CDC is offering support and assistance in the areas more heavily affected by Zika that have ongoing studies. Such studies cannot be conducted in the US, but if that situation changes, CDC will follow GBS here.

CSTE commented that at the recent CSTE, Zika was made nationally notifiable and the case definitions will be posted. When a disease or condition is reportable, providers and laboratories report to the state health department. When a disease or condition is nationally notifiable, the information is sent to CDC. There are now formal case definitions and specific data elements for both infected and asymptomatic in pregnancy and congenital disease. This issue was the topic of a long discussion at the CSTE annual conference. The position statements are being formalized and should be available on the CSTE and CDC websites soon. CSTE also has discussed potential risk factors associated with tissue and organ transplantation and blood donation and a potential time period to identify transmission from those modes.

The CDC representative at the CSTE meeting gave a presentation that did not provide specific statistics, but acknowledged models for transmission in other countries where Zika has been reported previously, particularly in some of the southern Pacific Islands where there were large outbreaks. The area of most concern now is Puerto Rico. The FDA guidelines that are in place call for self-exclusion for a period of six months for persons who have been in a Zika-infected area.

SHEA asked about plans if local transmission is observed in US localities.

NACCHO added that local health departments send vector control to people's homes and ask them to stay indoors in the period when they can be infectious in order to prevent local spread. This approach is similar to the approach for Chikungunya.

ACEOM commented on joint CDC / Occupational Safety and Health Administration (OSHA) guidance that was issued in April 2016 on protecting workers from Zika exposures. There is also guidance for pregnant women. It was not clear whether guidance has been released for healthcare workers sustaining a needle stick, particularly pregnant workers, from a Zika patient. The protocol would be somewhat intuitive, but what are the plans to address that specific circumstance?

Dr. Olson answered that the question has been discussed, but specific guidance has not been issued. An article in the *Morbidity and Mortality Weekly Report* (*MMWR*) addressed infection control practices, but the next step should be what to do when there is a breach in infection

control. CDC is relying on standard approaches to infection control and follow-up but would be interested in collecting information on those types of breaches.

Mr. Hageman added that CDC has emphasized that the focus should not only be on the Zika potential. If there is a needle stick, the worker should be assessed via normal processes for other bloodborne pathogens as well. Issues should be addressed on a case-by-case basis in consultation with public health.

APIC asked whether an uptick in Zika is expected after the Olympics, with travelers returning to the US from Brazil.

Dr. Olson said that the issue has been receiving a great deal of attention understandably. An *MMWR* was published on this topic by NCEZID's Division of Global Migration and Quarantine (DGMQ). In relative terms, the amount of expected travel related to the Olympics and Zika-affected areas is small.

HICPAC appreciated the update and asked how the committee can be of assistance.

Mr. Hageman said that HICPAC liaison organizations can help to disseminate information to their members, especially regarding clinical areas. DHQP will circulate information as it becomes available.

Dr. Bell asked about the kind of work being done to learn about the persistence of Zika virus in various tissues.

Dr. Olson answered that the body fluids of greatest concern are those that pose the risk of transmission, outside of organ transplantation. The greater risk appears to be transmission through semen and saliva. There are clearly documented cases of sexual transmission of Zika. There is intense interest in this area, as well as in how long the virus may be persistent in people who are not pregnant and pregnant women. Investigation is active in this area, which has potential for recommendations to minimize transmission. She was not certain about plans to delineate risk associated with organ transplantation, which is more challenging. Ongoing investigations are focusing on blood, semen, urine, and stool in countries with high rates of Zika transmission and an adequate patient base to conduct the studies. Information has been shared about the pregnancy registry, but the registry will be only as good as its participation rates. If HICPAC members have the opportunity to convey information about the registry, those efforts will be appreciated.

NIH commented that vaccines for *Flaviviruses* have not been successful historically and asked whether the potential is better for a vaccine for Zika.

Dr. Olson said that work on vaccine development is ongoing. With the attention and funding that has been received, the Zika work is probably farther along than with some other vaccines. It is important to note that vaccines rely on uptake for success, and there are other issues when vaccinating the public.

CMS has regulations for transplant programs and organ procurement organizations. In recent months, CMS has asked the Health Resources and Services Administration (HRSA) and the Advisory Committee on Blood Tissue Safety Availability about what recommendations should be. The lead is not likely to be FDA for solid organ transplant. Will CDC take responsibility for recommendations for transplantation? There is concern in this area from many organizations.

Mr. Hageman said that the next HICPAC meeting could include an update on blood and organ issues.

Update on HICPAC Endoscope Reprocessing Workgroup

Vickie Brown, MPH, RN, CIC
HICPAC Member
Co-chair, HICPAC Endoscopy Reprocessing Workgroup

Ms. Vickie Brown provided HICPAC with an update on the activities of the Endoscopy Reprocessing Workgroup. There have been a number of outbreaks of bacterial infection associated with improperly reprocessed endoscopes. The devices themselves are highly complex, and the cleaning and reprocessing steps are technical, with many potential risks for error. Therefore, HICPAC formed an Endoscopy Reprocessing Workgroup, which provided its first update to HICPAC at the March 2016 meeting. The goal of the workgroup is that healthcare facilities should have a reliable, high-quality system for endoscope reprocessing which minimizes infection risks. The workgroup charge was to:

- Identify the elements necessary to achieve this goal, including risk assessment tools, training and competencies, measurement, management.
- Deliver these draft elements and recommendations to HICPAC for deliberation and input to produce recommendations from HICPAC to CDC.

The workgroup has been active, with membership representing a range of areas of expertise as well as professional organizations, federal agencies, and CDC. The workgroup activities have included:

- Biweekly conference calls to identify gaps and priorities
- Conceptualizing the final product of the workgroup
- Refining the Essential Elements of Flexible Endoscope Reprocessing document
- Creating and refining Toolkit Document examples that can be provided to users

Upon advice gathered from HICPAC during the March 2016 meeting, the workgroup made some adjustments to the draft document. The basic steps of reprocessing were added to the beginning of the document to serve as a baseline, beginning with pre-cleaning immediately after the use of an endoscope to the final steps of storage and documentation. Other changes include:

<u>Administrative</u>

- Accountability: Ensuring that the essential elements are followed and ensuring that endoscopes are reprocessed according to manufacturer's Instructions for Use (IFU)
- Policies: Address the use of "loaner" endoscopes that are not owned by healthcare facility; hold management accountable for assessment and reprocessing prior to use of "loaner" scopes

<u>Management</u>

- Ensure that reprocessing policies are in place and regularly updated to include competency for each type of endoscope used in facility, as there can be variability in the steps for reprocessing different scopes and models

- Certification for those who reprocess flexible endoscopes is encouraged, but does not negate ongoing competency assessment of those individuals
- Regarding water and rinse water, professional society guidelines recommending more stringent water quality standards can be considered

Documentation
- Users of flexible endoscopes also should include the steps and results of any investigation of potential critical events

Physical Setting
- Provide dedicated space for manufacturer IFU binders and safety data information, or enable access to a computer

Training and Competencies
- Post visual education aids and Standard Operating Procedures (SOPs)
- Certification does not mitigate the need for orientation, ongoing education and training, and competency assessments

Quality Assurance
Comprehensive gap analysis should include:
- Verification of staff competencies
- Sufficient reprocessing personnel for all contingencies
- Manufacturer IFU are available and followed
- Adequate physical space
- Heating, Ventilating, and Air Conditioning (HVAC) parameters are monitored and controlled
- Documentation is maintained
- If an Automated Endoscope Reprocessor (AER) is used, assess for documentation verifying the compatibility of the endoscope and the endoscope component's use with the AER

Disinfection / Sterilization Failure
- If there is suspicion or concern related to a sterilization or high-level disinfection failure, convene a multidisciplinary review of each event to determine corrective steps and need for patient notification
- Team use of available resources to assist in breach evaluation and guide the evaluation
- Notify FDA through MedWatch if persistent bacterial contamination is suspected

Unresolved Issues include:
- Supplemental measures that organizations may opt to use after high-level disinfection of an endoscope, such as culturing of the device or ethylene oxide (EtO) sterilization for endoscopic retrograde cholangiopancreatography (ERCP) scopes
- Endoscope storage interval: the length of time for which an endoscope can remain stored between each use is not determined
- Endoscope storage space: what is the ideal type of storage cabinet to protect endoscopes after they have been reprocessed?
- Replacement of endoscopes: the interval is not well-known regarding how often a scope should be replaced and what its life might be

Sample documents for the Reprocessing Toolkit may include:

- Gap analysis (annually)
- Audit tool (monthly or quarterly)
- Inventory template (annually)
- Competency verification checklist (upon hire and at least annually)
- Policy template (reviewed at least every three years)

Questions for HICPAC are:

- Is the Essential Elements document missing any important points?
- Are there elements in the document that require further refinement?
- Should water quality for the final post high level disinfection rinse in manual flexible endoscope reprocessing be described as tap, filtered, or sterile or a combination of all three?
- Are there areas the document should highlight where additional research/data are needed?
- Are any sample documents missing from the toolkit?
- Are any of the toolkit sample documents missing any important points?

Discussion Points

Question One: Is the Essential Elements document missing any important points?

VA commented that the document might emphasize the posting of SOPs.

Question Two: Are there elements in the document that require further refinement?

Regarding the unresolved issue of supplemental measures, HICPAC suggested providing examples, such as culturing. As worded, the document is slightly vague.

The document is excellent. Within the Quality Assurance section, under "comprehensive gap analysis" and "periodic audit," the document does not provide suggested intervals or frequencies. The toolkit provides general suggestions, but if the intervals are agreed-upon, they might be included in the text.

Dr. Bell observed that the document includes a great deal of information regarding current systems and processes, and advice regarding managing that challenging system. He wondered about the possibility of adding examples of what the future might look like based on expert opinion, such as managing a number of different scope models, turnover and reducing staff turnover, and other issues.

Ms. Brown said that the working group hoped that the document would help mitigate the current, challenging situation. The group can consider discussion of the future as well.

HICPAC wondered about adding a "risk mitigation" section of considerations for steps that a facility might take beyond technical aspects.

Dr. Bell clarified that the document could address a theoretical description of an endoscope reprocessing system that is as good as possible and as un-burdensome as possible. With a vision of a "halcyon future," the field can take small steps toward it.

Envisioning a better future is important and could be addressed in a supplemental document. There is time urgency to releasing this document to minimize the challenges of the current situation. HICPAC can work collaboratively with FDA to provide guidance to industry. This document includes a great deal of information to help a range of institutions, including smaller ones that may not have a great deal of infection control oversight or input. The document was created in collaboration with a number of professional organizations and should move as quickly as possible.

Ms. Brown agreed with the idea of writing a supplement so that the Essential Elements document can move forward. An ideal endoscope reprocessing program will standardize its scopes and perhaps utilize scopes that are single-use and disposable, eliminating reprocessing entirely.

Dr. Bell observed that the draft document focuses on the best ways to manage the existing, available technology and processes. HICPAC has an opportunity to send a message regarding targets to industry that is developing the next generation of models.

CU said that the document might provide additional guidance regarding patient notification or requirements for physicians using the devices to acknowledge understanding of the danger that patients are subjected to when these devices are used. Patients should be advised prior to using the scopes that have had problems, and after exposure. The document's references to leadership, management, and responsibility are somewhat vague. The document refers to the need for a policy to be in place. CU suggested that a facility should designate a person who is responsible for all of the elements of the policies and for ensuring that the policies are implemented. The only reference to microbiological culturing or similar approaches to double-check whether the cleaning was successful is on Page 6 of the document, referring to duodenoscopes. Other kinds of scopes have had other contamination issues and may need to be specified.

Ms. Brown said that the document is structured to show various levels of responsibility: administrative responsibilities, which have ultimate oversight for providing personnel and financial support an effective program; and management responsibilities. Patient notification is included in the section on addressing a suspected or known breach in reprocessing. There should be patient disclosure when there is the possibility of disease transmission associated with a procedure with an endoscope.

Mr. Hageman clarified that the charge to the workgroup focused on the reprocessing process, recognizing that there are other areas of consideration.

AEH said that the document is excellent, and suggested specifically addressing a risk assessment based on an individual facility and the types of scopes that are used, which vary widely. A great deal of attention has been focused on duodenoscopes alone. The document does not refer, other than in an inventory, to determining a facility's level of risk and whether all measures apply with the same level of intensity.

The workgroup can revisit that language. Their intention was to emphasize the concept of risk assessment, with the inventory serving as its foundation. The scope of the document is specifically flexible endoscopes.

AEH said that a gap analysis is a good starting point for a risk assessment, but when facilities begin to collect information, the process depends on the people conducting it. It is helpful to

establish a risk assessment process, including the volume of patients, patient turnover, how many different scope procedures are performed, the types of procedures that are performed, patient population mix, and other factors. Facilities may need help shaping their risk assessment processes, as infection preventionists may not have direct knowledge of the different types of scope procedures.

Ms. Brown said that the workgroup might rethink the "inventory tool." The document is structured to ask risk assessment-like questions, such as the number and type of procedures and how scopes are reprocessed.

HICPAC suggested referring to the inventory tool in the parts of the document that refer to risk assessment.

Question Three: Should water quality for the final post high-level disinfection rinse in manual flexible endoscope reprocessing be described as tap water, filtered water, sterile water, or a combination of all three?

Ms. Brown said that there are different recommendations regarding rinse water from a variety of organizations. The workgroup asks for input from HICPAC and the liaison organizations regarding moving beyond an existing CDC recommendation for rinsing a flexible endoscope beyond using tap or filtered water followed by an alcohol rinse.

HICPAC pointed to the current wording in the document on page 3, "at a minimum, water use for reprocessing of endoscopes meets the specifications that are recommended by the device and reprocessing equipment manufacturers." A sub-bullet states, "professional society guidelines that recommend more stringent water specifications can be considered" and references are provided.

AEH asked what FDA requires for approval. If recommendations defer to manufacturer IFU and if the onus for detecting problems is at the right level, the focus should be on pre-release of devices. If the manufacturers and the FDA approval process is not trusted, then problems are created for facilities.

HICPAC discussed whether there is confidence that the manufacturer recommendations are adequate.

AEH asked whether, given situations such as the problems with endoscope reprocessing and with contaminated heater-cooler units, FDA can ask endoscope manufacturers to verify that their IFU are effective in light of new knowledge, and whether FDA can re-certify the devices.

FDA said that this work is ongoing with manufacturers. When devices are reviewed by the Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices, manufacturers are required to conduct testing on all of the IFU. The scope manufacturers may say that their product can be reprocessed in a certain AER, but the manufacturer of a certain AER, sterilizer, or disinfectant may not have tested that product. In-house, the FDA groups that work on the reprocessors and on the endoscopes to ensure that the scope device manufacturers must validate their processes. The scope manufacturers are validating their scopes in AERs, and AER manufacturers are testing scopes. A web page is updated monthly as the AER companies validate a particular load. The page lists for users which scopes can adequately be reprocessed: Information about AERs and FDA's Evaluation.

In this process, alcohol is used as a drying agent, not a disinfecting agent. There was concern about the varying levels of microbial contamination of potable water. New York City water, for instance, has a high concentration of atypical *Mycobacteria*. Public works activity in an area does not necessarily reflect the quality of the water that comes from a facility's faucet. There is variation depending on the age of the facility, the cleanliness of the pipes, the age and location of the tank water storage facility, and other factors. The workgroup did not make a specific recommendation regarding the type of water to be used for a rinse. When there is not a validation of the overall microbial content of the water supply, the issue may need to be revisited. HICPAC suggested asking the facility to conduct periodic sampling of the water supply coming into the endoscopy unit to be aware of the level of the microbial contamination, which changes over time.

AEH agreed that it is critical to know about water quality control in a facility and its area. The document could refer to "filtered water only," but that statement raises questions about how to filter.

AORN's guideline for flexible endoscopes recommends critical or sterile water, as evidence was found that utility water can contain microorganisms and endotoxins that can be deposited into the scope during the final rinse. There have been outbreaks of endoscopy-related infections and pseudo-infections related to flushing with rinse water. These data and a desire not to introduce more organisms into a scope were part of AORN's rationale for the recommendation.

HICPAC commented on some inconsistency in the treatment of contamination risk. There is risk associated with objects, such as the edge of a cabinet.

Ms. Brown said that the document emphasizes following manufacturer IFU. If an element of the document reaches beyond the IFU, then the wording will need to be constructed carefully to avoid confusion.

HICPAC suggested changing the document to indicate that more stringent professional societies "should be considered," as opposed to "can be considered." This wording would encourage facilities to make evaluations based on their scope of practice.

FDA is retesting and reconfirming their IFU. The document could state that "water used for reprocessing of endoscopes should meet the specifications recommended by the device and reprocessing equipment manufacturers as confirmed by" the website maintained by FDA. In the absence of that confirmation, then facilities "should use filtered or sterile water." The FDA website would be helpful to include in the document.

The existing wording successfully navigates some of the complexities of the issue. Making recommendations that are not in agreement with FDA and that make implementation more difficult are problematic, and there should be a compelling level of evidence to support such recommendations. Further, when state departments of health validate facilities on behalf of Conditions of Participation, facilities may not have the ability to go against manufacturer IFU for reprocessing and handling of endoscopes.

Regarding water sampling, APIC said that guidance will be needed regarding thresholds, such as whether more stringent requirements than potable drinking water standards are expected, and what those requirements might look like.

Dr. Maragakis thanked HICPAC for the comments. The workgroup discussed this issue extensively. She heard general support for this kind of approach, perhaps with some stronger wording and additional rationale so that the recommendations and language are more transparent, indicating that this issue is dynamic and there is a lack of evidence in many areas.

Dr. Diekema said that due to the sense of urgency, HICPAC can approve the document with the suggested edits. The document can be posted as a "living" document to incorporate additions and changes over time.

The AORN guideline includes evidence in its rationale and discussion.

SHM suggested that the document mention the water issue specifically when referring to guidelines from professional societies.

Question Four: Are there areas the document should highlight where additional research/data are needed?

There was agreement that additional research and data are needed regarding water in reprocessing.

HICPAC suggested that the document specifically state that improvements to the devices themselves are needed. In addition to more data and information, better devices are needed. Dr. Yokoe said that there is an intent to add a section describing a "future vision for scopes," as recommended by Dr. Bell. With that consideration and the opportunities described by Dr. Diekema for additional editing and additions when the document is posted, she moved for approval of the draft document.

Vote: Essential Elements of a Reprocessing Program for Flexible Endoscopes

Dr. Yokoe moved to approve the draft document, with the consideration of plans to add a section on "future vision" and with the minor edits proposed during HICPAC's discussion. Dr. Babcock seconded the motion. The motion carried unanimously, with no abstentions. The disposition of the vote was as follows:

13 Favored:	Diekema, Yokoe, Brown, Maragakis, Fauerbach, Janssen, Huskins, Talbot, Tapper, Babcock, Rogers, Tejedor, and Howell
0 Opposed:	None
0 Abstained:	None

Mr. Hageman said that when the edits are made and submitted, the document will be posted directly to the HICPAC website. HICPAC can consider reconvening the workgroup to discuss additional supplements or sections on "future directions." Groups that participated on the workgroup are encouraged to think about how the elements in the document can be translated to their membership. He thanked Ms. Brown, Dr. Maragakis, and Ms. Stone for moving this large, active workgroup forward.

CMS has had a long interest in the issue of cleaning and disinfecting scopes and offered thanks to HICPAC for taking the issue on, and for including CMS representatives on the workgroup. CMS's view on this issue has shifted. In the past, the agency has been somewhat reactive to the issue, with questions about cleaning and disinfection of scopes on the Hospital Infection

Control Worksheet. As outbreaks occurred, CMS conducted complaint investigations. CMS is now more proactive on the issue. CMS released a survey and short letter in 2015 instructing surveyors, upon entry to a facility, to ask whether the facility performs endoscopy. If so, the surveyor must observe the scope reprocessing. It is hoped that this approach is preventing some outbreaks and identifying facilities that have problems. The approach may seem punitive to facilities, but they are not terminated if they are not disinfecting their scopes properly. Facilities are given the opportunity to ameliorate their problems so that they are not transmitting infections during procedures. CMS is hosting a Webinar for surveyors on what to look for in the cleaning and disinfection of scopes. CMS works closely with accrediting organizations that may look more closely than the minimum health and safety standards associated with the Conditions of Participation. Regarding the issue of patient notification, CMS released a survey insert memo to inform surveyors that if there are serious injections safety breaches, the state health department must be notified to determine whether patient notification is warranted. Surveyors do not make that determination. CMS is considering updating that memo to include endoscopy, perhaps not to mandate notification, but to state that health departments should be notified in the event of serious breaches of cleaning and disinfection of scopes.

Mr. Hageman noted that CMS and FDA participation in the workgroup was an important part of the process.

Ms. Brown clarified that the workgroup would develop the proposed toolkit.

Discussion and Vote: Principles for Antimicrobial Stewardship for Guideline Development

Dr. Huskins highlighted changes in the draft document, based on HICPAC discussion.

Principles of Testing

2) Rapid diagnostic tests, biomarkers, and decision rules that have acceptable performance characteristics to differentiate bacterial versus non-bacterial infection should be used to avoid use of antibiotic therapy.

3) Bacterial cultures with susceptibility testing should be sent promptly and handled and processed appropriately to identify specific bacteria causing infection and facilitate use of narrow-spectrum antibiotics whenever possible.

4) When available and appropriate for the infection and the bacterial isolate, molecular testing to identify specific resistance genes (e.g., *mec* in *Staphylococcus*, *van* in *Enterococcus*) or novel non-culture based phenotypic assays of susceptibility may be used to target antibiotic therapy toward susceptible or resistant isolates.

Principles of Treatment

1) When appropriate for the infection, source control should be accomplished early in the course of treatment.
2) Recommendations for initial empiric antimicrobial therapy choices should balance treatment efficacy, severity of illness (i.e., sepsis), and the potential for adverse events including the development of antimicrobial resistance. Use of narrow-spectrum agents may be appropriate in many situations and can assist in preserving the activity of broader-spectrum agents for resistant organisms when needed.

3) Recommendations for optimal dosing of antimicrobials should be based on efficacy studies and pharmacokinetic and pharmacodynamics principles.
4) Recommendations for the minimum effective duration of antibiotic therapy should be provided.
5) Recommendations for de-escalation of initial empiric antibiotic therapy should be provided, including

- Using the results of bacterial cultures and diagnostic tests to discontinue or narrow unnecessarily broad-spectrum antibiotic therapy;
- Using other stewardship tools, such as consultation with an antimicrobial stewardship team and/or infectious diseases specialist, daily review of antibiotic therapy, and automatic stop orders after an adequate treatment duration.

6) Potential adverse events related to antibiotic treatment should be noted in the guideline so that providers may opt not to prescribe an antibiotic, or to choose a recommended agent that has a lower potential for adverse events.

Discussion Points

Regarding the third bullet point under "Principles of Testing," CSTE suggested including language about the collection of the specimen.

The phrasing "collected, handled, and processed appropriately and sent promptly" was suggested.

Concern was expressed about the second bullet point about biomarkers. Some institutions have utilized procalcitonin diagnostically to make the decision either to give or not to give antibiotics, or to stop antibiotics. The term "acceptable," which is somewhat vague, is potentially problematic; "clinically validated" markers was suggested.

Dr. Huskins suggested that the society writing group for a particular guideline should assess the data and determine whether it is acceptable or not.

HICPAC encouraged the document to be intentional about its use of "antibiotic," "antimicrobial," and "antibacterial," especially when discussing testing for other pathogens. Dr. Huskins said that the intent was to use "antibiotic" specifically. The group will ensure that the document is consistent. It was agreed that "antibiotic" is the preferred term.

Regarding the Principles of Treatment, "source control" is increasingly used to refer to more than one thing. A parenthetical example, such as abscess drainage, could be added to make sure the term is clear.

Dr. Huskins said that HICPAC suggested making the document more specific in terms of instructions for implementation. Dr. Srinivasan provided some recommendations on this front:

> "Professional societies should incorporate the principles of testing and treatment directly into the recommendations included in their guidelines by creating a hierarchy of treatment recommendations with "first choice" antibiotics representing those that both optimize effective treatment and minimize adverse consequences, including the development of antimicrobial resistance. In addition, guidelines should consider presenting advantages and disadvantages of treatment choices with respect to efficacy and adverse consequences, including antimicrobial resistance, either in the text or a table."

This paragraph is in response to the Pneumonia Guideline, which may have several recommendations, all of which address efficacy, but for which there may be reasons to prefer some over others because of issues associated with adverse consequences, including the development of antimicrobial resistance.

CSTE supported the statement, because there is a hierarchy. Australia has used that approach.

Dr. Huskins said that the language is intended to convey that agents "at the top of the list" should represent those that optimize effective treatment and minimize adverse consequences.

Vote: Principles for Antimicrobial Stewardship for Guideline Development

Dr. Diekema moved to approve the draft document with the minor edits suggested. Dr. Rogers seconded the motion. The motion carried unanimously with no opposition or abstentions. The disposition of the vote was as follows:

13 Favored:	Diekema, Yokoe, Brown, Maragakis, Fauerbach, Janssen, Huskins, Talbot, Tapper, Babcock, Rogers, Tejedor, and Howell
0 Opposed:	None
0 Abstained:	None

Mr. Hageman said that when the final version of the document is received, it will be posted on the HICPAC website. It will be shared with a number of organizations, and DHQP will continue to engage participants who were involved in its development. HICPAC liaisons with suggestions on reaching their groups, specifically their guideline development groups, were asked to share them.

Emerging Resistance Updates

***Candida auris*: A Globally Emerging Multidrug-Resistant (MDR) Yeast**

Snigdha Vallabhaneni MD, MPH
Medical Epidemiologist
Mycotic Diseases Branch
Centers for Disease Control and Prevention

Dr. Snigdha Vallabhaneni updated HICPAC on the globally-emerging multidrug-resistant yeast *Candida auris (C. auris*). *C. auris* was first reported in Japan in 2009. It was identified in an isolate of a patient's external ear infection. There were additional reports from South Korea in 2009 indicating ear infections caused by this novel, new *Candida* species. The isolates were from 2004 and 2006, giving the impression of a superficial ear infection. There were quick reports of invasive BSIs with *C. auris* in 2011 from South Korea in isolates dating to 1996, the first known *C. auris* in the world. Reports of *C. auris* began snowballing, with reports from India in 2011, with 12 BSIs from a hospital in New Delhi, followed by a 2015 report of ICU-associated candidemia in 19 ICUs in India. Today, approximately 5% of candidemias in India are from *C. auris*.

C. auris can cause invasive infections, predominantly fungemia. It is MDR, which is particularly concerning given that it is 93% resistant to fluconazole, 54% resistant to voriconazole, 35%

resistant to amphotericin B, 7% resistant to echinocandins, and 4% resistant to all three of the major antifungal drug classes (azoles, amphotericin B, and echinocandins).

C. auris requires molecular methods to distinguish it from other *Candida* species. It cannot be distinguished using normal biochemical methods. Phenotypically, it is similar to *Candida haemulonii*, and it belongs with *haemulonii* in the antifungal resistant clade with *Candida krusei*, *Candida lusitaniae*, and *Candida pseudohaemulonii*. *Candida albicans*, one of the most common types of *Candidas*, is far from them in the clade.

Between 2009 and 2015, additional countries reported the presence of *C. auris* (South Africa, Kuwait, Pakistan, Venezuela, and Colombia). CDC was able to collect isolates from some of these countries to conduct WGS to understand the emergence of this new organism. Was it spreading from place to place, or independently emerging? WGS suggests simultaneous and independent emergence of this organism in these countries. The isolates from India and Pakistan are highly clonal, differing only by 0 – 22 SNPs. Thousands of SNPs differ among the isolates from South Africa, Japan, and Venezuela, suggesting that the organism is clonal in each region, but different in different regions.

Collecting case report information from patients showed that the patients are of all age ranges, as with other candidemia. *C. auris* demonstrates similar risk factors to other *Candida* species, including diabetes, antibiotic use, recent surgery, and the presence of a central venous catheter (CVC). *C. auris* seems to emerge in conjunction with other *Candida* species. Many patients with *C. auris* were diagnosed while they were on antifungal treatment, typically fluconazole, for another indication. The median time from admission to infection was 17 days in the data collected by CDC, which suggests that *C. auris* is probably a nosocomial infection. Mortality is 60%, which is similar or slightly higher than mortality from other candidemia in these settings, which is generally higher than the US. Notably, 100% mortality was reported among NICU infants in Venezuela.

Concern was elevated upon discovery of an outbreak in the UK in 2015. The outbreak affected an adult critical care unit with 40 patients either colonized or infected with *C. auris*, with approximately 20% with invasive infections. This outbreak was extremely difficult to control despite intensive infection control efforts, including regular patient screening, environmental decontamination, and temporary ward closure. This ICU had never seen Candidemia before this outbreak started. CDC is working with the UK to understand how their isolates are related to the isolates collected from other parts of the world. This outbreak is concerning because of the UK's stringent infection control practices, as opposed to the practices in other parts of the world where *C. auris* had been detected.

C. auris is concerning for a number of reasons. The organism is MDR, and some isolates are resistant to all three major antifungal classes. It can be misidentified, usually as other *Candida* species or *Saccharomyces*, usually when using biochemical methods. Molecular methods such as matrix assisted laser desorption/ionization and time of flight spectrometer (MALDI-TOF) can identify *C. auris*, but not all MALDI-TOP manufacturers include *C. auris* in their databases. *C. auris* has caused outbreaks in healthcare settings. Unlike other *Candida* species, which are thought to be endogenous, it seems to colonize healthcare environments. It has been cultured off of surfaces in patient rooms and poses major infection control challenges.

CDC surveyed the EIP Candidemia Surveillance Program, which includes over 7000 Candida isolates that have been collected over the last eight years. No *C. auris* was detected, but the CDC library represents a small proportion of the total Candidemia cases that occur in the US

each year. CDC issued a Clinical Alert to healthcare facilities in June 2016 summarizing what is known about *C. auris* and asking that hospitals and microbiology laboratories report it to state health departments and CDC. The alert addresses challenges with identification as well as infection control.

Since the alert, there have been reports of two 2016 cases of *C. auris* in the US. Both appear to be single cases that are not associated with an outbreak in the hospital. The US isolates are only resistant to fluconazole and are susceptible to other antifungals; however, there is concern that the organism can develop resistance rapidly. Both case-patients had severe underlying conditions and have died. It is not clear whether they died of *C. auris* or another cause.

CDC has coordinated efforts with other countries. Public Health England also released an alert to clinicians about *C. auris*. PHAC also sent an alert recently. CDC recommends that all *C. auris* infections be reported to state and local health departments and that standard and contact precautions should be used. Patients should be placed in single rooms with daily and terminal cleans to reduce environmental burden of the organism with US Environmental Protection Agency (EPA) registered disinfectants. The UK guidelines recommend screening patients at risk for Candidemia. CDC is not recommending that screening at this point in the US, but the situation is in the early stages of learning about the organism and how it behaves.

CDC is conducting domestic case-finding through the clinical alert. It will be highlighted in the SHEA newsletter and through other avenues. EIP surveillance and the antibiotic resistance laboratory network are other information sources. A plan for outbreak response has been developed, if an outbreak occurs in the US. CDC also is working with EPA and FDA to understand what works for disinfection, since the UK experience showed that there was difficulty in disinfecting the environment. CDC is partnering with international collaborators to answer the many unanswered questions about *C. auris*:

- Why is this species emerging now?
  - Has it been here all along and we just misidentified it?
  - Why is it emerging in so many places simultaneously?
- What are risk factors for this infection?
- Why do some infections lead to outbreaks, while others are sporadic cases?
- How do we control the spread of this infection?

Discussion Points

Dr. Vallabhaneni confirmed that *C. auris* grows in routine bacterial *Candida* blood culture media.

HICPAC asked about any association in the reported cases related to the use of fluconazole prophylaxis, particularly in the neonatal population.

Dr. Vallabhaneni answered that minimal clinical information has been gathered from countries with these cases. Many of the cases had been treated with an antifungal, most commonly fluconazole, even when *C. auris* was isolated. It is not known whether the fluconazole was for prophylaxis. Only three NICU infants are in the collected data.

HICPAC asked whether the high mortality rate is due to the fact the patients are not put on effective antifungal therapy due to resistance, or whether the rate is related to the pathogenicity of the *Candida*.

Dr. Vallabhaneni replied that the mortality rate is due to a combination of those factors, as well as the lower level of care that is available in many of the countries where there have been *C. auris* outbreaks, particularly in Venezuela, where many hospitals do not have electricity. A lack of availability of Candins is also probably a factor.

Regarding the UK outbreak, HICPAC asked if an initial patient may have come from India, Pakistan, or another place where the organism appears to be more endemic.

Dr. Vallabhaneni said that the first UK case was not from any of the countries with a reported *C. auris* case. The case was a UK citizen of Caucasian origin who did not travel to those countries. In the US cases, there is no evidence of travel to those countries. WGS will be conducted on the US isolates to understand how they are related to the isolates from the rest of the world.

HICPAC asked about studies of the environmental links associated with *C. auris*, such as on how long it stays in the environment, resistance to cleaning, longer exposure time, or related issues.

Dr. Vallabhaneni answered that preliminary studies in this area have been conducted in the UK. It appears that the organism lasts in the environment for a long time, but specific details are not available. *C. auris* seems to be resistant to typical cleaning techniques, as the UK ICU struggled to eliminate it in the environment, despite terminal cleaning approaches. CDC is working with EPA to determine the best disinfectants to use.

Dr. Cardo said that DHQP will bring cases such as *C. auris* to HICPAC even when all of the answers are not known. One case, even in another country, is an alert. This situation is an example of how CDC is not only managing outbreaks, but also responding to potential cases. She encouraged HICPAC and liaison representatives and their facilities, states, and organizations to collaborate with CDC on this issue.

NIH sent one of the isolates to the CDC. The patient at NIH was a local resident, not a traveler, who had been hospitalized in multiple hospitals before coming to NIH. The patient had a hematologic malignancy and was treated with effective antifungals. NIH conducts all of its fungal identification by MALDI, so the diagnosis was made quickly and appropriate therapy was begun. Several sets of blood cultures were negative. The patient's chemotherapy failed, and the patient was sent to hospice, where he died of his underlying disease. NIH asked if *C. auris* seeks moist environments and withstands desiccation.

Dr. Vallabhaneni answered that *C. auris* appears to withstand desiccation. It is not clear about its preference for moist versus dry environments. If there is another active case, these issues can be studied. CDC is ready to respond if a case is reported. The cases that have been reported in the US occurred some months ago, so it was not possible to conduct environmental sampling. They hope to travel to other cases with active cases in order to learn more.

Many clinical microbiology laboratories are struggling to determine how to identify these cases, especially since some MALDI-TOF manufacturers do not include *C. auris* in their libraries. HICPAC asked if CDC is working with vendors that provide these diagnostic tests and what guidance might be provided to clinical microbiology laboratories.

Dr. Vallabhaneni said that CDC has been working with the two main manufacturers of MALDI-TOF. The Bruker MALDI-TOF includes *C. auris* in its database, but the bioMérieux. device does

not. BioMérieux plans to include *C. auris* in its next update, but it is not clear when that update will occur.

NIH's microbiology laboratory is sophisticated with respect to fungal identification and has created its own library of fungal isolates. The laboratory would be happy to provide assistance. In the laboratory, Dr. Anna Lau has worked extensively with this fungal library. Dr. Vallabhaneni added that CDC is accepting any isolates that are not discernible with routine laboratory practices.

The laboratories that use Bruker MALDIs need to conduct their own internal validation before they begin using it for different organisms and organism groups. Many users of MALDI still do not use it for yeast and mold, so there may be a gap, even among MALDI users.

SHM said that *Candida* is often seen on urine specimens, and it is often not further speciated. SHM asked if there should be concern and whether further speciation should be requested.

Dr. Vallabhaneni answered that a substantial number of the cases in Pakistan were urinary tract isolates. It is possible that *C. auris* could occur in urine.

Emerging Resistance Updates: Plasmid-mediated colistin resistance (*mcr*-1 gene)

LCDR Alison Laufer Halpin, PhD
Lead, Metagenomics and Molecular Biology Team
Clinical and Environmental Laboratory Branch
Division of Healthcare Quality and Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Dr. Alison Laufer Halpin presented on the plasmid-mediated colistin resistance (*mcr*-1) gene. The first description of *mcr*-1 was reported in November 2015 in food animals, food, and humans in China. With the publication of this description, many groups began performing reviews of their isolate collections. The reviews revealed that the *mcr*-1 gene has gone undetected since at least the 1980s. It has been found in a variety of bacterial species, including *Escherichia coli* (*E. coli*), *Klebsiella pneumoniae*, Salmonella, and Shigella. It was found on multiple plasmid types.

The review showed that *mcr*-1 has been found on almost every continent. It has been isolated from a variety of sources, including:

- Food animals such as chickens, pigs, and turkeys
- Environment, including river water
- Food, including meat and one case of a vegetable
- Ill patients
- Asymptomatically colonized individuals

In May 2016, DoD reported *E. coli* containing the *mcr*-1 gene isolated from a Pennsylvania resident. CDC is working in collaboration with DoD and state and local health departments to respond. The response includes using established screening approaches to identify asymptomatically colonized individuals, such as household contacts and healthcare providers. No positives were identified from that screening activity. In addition, in collaboration with the Enteric Disease Laboratory at CDC and the CDC Bioinformatics Core, next generation

sequencing technology was used to sequence the isolate to learn more about the antibiotic resistant genes that are present and about the plasmid that it resides on. Additional reports of isolates harboring the *mcr*-1 gene include a New York resident from whom the isolate was collected in 2015, as well as two porcine *E. coli* isolates carrying the *mcr*-1 gene.

When the paper detailing the China isolate was released, the DHQP Clinical and Environmental Microbiology Branch incorporated the described conventional PCR assay for detecting the *mcr*-1 gene. Subsequently, Maria Karlsson designed a TaqMan® probe-based real-time PCR (RT-PCR) assay to detect the *mcr*-1 gene. Real-time is often preferable to conventional PCR for a variety of reasons, including the absence of a requirement for post-PCR processing. RT-PCR is more precise than conventional PCR, adding confidence to the ability to detect. RT-PCR is quantitative; that is, an increase in fluorescence is proportional to an increase in the amplicon, or the target gene of interest.

The assay was optimized by Jonathan Daniels. It has extremely high efficiency at 98%. "Acceptable" efficiency is between 90% to 110%. The primers and probe for the PCR test are appropriately detecting the gene of interest. The assay was validated using a set of 25 isolates, including four *mcr*-1 positive isolates, and it is currently under review for Clinical Laboratory Improvement Amendments (CLIA) approval.

Using this assay, CDC screened its surveillance and reference collections for the *mcr*-1 gene, as it has potentially gone undetected since the 1980s. Thus far, the surveillance collections have been screened back to 2011, and the reference collection has been screened back to January 2015. Any isolate with a colistin minimum inhibitory concentration (MIC) greater than or equal to 4 has been tested. All isolates have been negative to date. Other mechanisms can confer resistance to colistin. A negative result for *mcr*-1 does not mean that there is not another mechanism causing the colistin resistance in these isolates.

DHQP has been working to increase capacity to use and leverage next generation sequencing technologies. The entire WGS collections from surveillance, outbreak, special studies, and reference collections were screened for the *mcr*-1 nucleotide sequence. Tom de Man and Adrian Lawsin screened 735 isolates for which sequence data are available, including 690 Enterobacteriaceae. They looked for perfect matches with the described *mcr*-1 gene, and the screen also lowered the threshold to 10% identity, indicating a more distant relative. No matches were found through this method.

In July 2016, a report from Belgium indicated identification of the *mcr*-2 gene from pig and cow isolates. The *Eurosurveillance* paper compares the *mcr*-1 and *mcr*-2 nucleotide sequences. There is only 76% identity by the nucleotide sequence. The protein structure shows 80% identity, depicted in the following graphic:

Because the differences are spread throughout the entire gene, it is not clear how the *mcr*-1 assay will perform. A new assay may need to be developed for *mcr*-2. Those isolates are not currently available, but DHQP hopes to acquire *mcr*-2 isolates to use and test. In the meantime, because the sequence has been published, DHQP can repeat the same analysis that was conducted with the *mcr*-1 gene in the WGS collection. At this point, no matching isolates have been identified.

Discussion Points

Dr. Bell asked for a sense of the denominator; that is, the number of individuals screened for carriage after the Pennsylvania case who were negative, and the other retrospective figures.

Dr. Halpin answered that 265 surveillance isolates were examined, and the reference collection was screened as well. Fifteen isolates have been received this year, and they all were screened and were negative. A large number of contacts, approximately 100, were screened in Pennsylvania.

CSTE asked when the real-time PCR might be shared with state public health laboratories. Dr. Halpin said that the real-time assay is undergoing validation and should be approved soon.

CU understood that it is still unknown how the Pennsylvania patient acquired the *mcr*-1 gene. The gene is resistant to polymixins, which are used in antibacterial ointment. She asked about an evaluation of the possibilities of this relationship.

Dr. Halpin did not know of plans for an evaluation. Antibiotic ointment contains polymixin B, and colistin is resistant to polymixin E, so they are different, although there is some cross-reactivity.

Dr. Bell said that places in the world use significant amounts of polymixin in agriculture and the environment. There is no evidence that the small quantities used in topical ointments are impactful. There is reason to think, in terms of sheer amount of exposure, that they would not be as impactful, especially with regard to the gut flora.

Dr. Bell commented that the new *Candida* species is different from other yeasts in terms of environmental durability, and the UK is working to understand its resistance and response to environmental cleaning responses. CDC also is working on these issues and, in parallel, is examining conjugation efficiency to learn how easily this plasmid moves from species to species. A question also is related to the transformative efficiency of naked DNA, which is not as fragile as RNA. Perhaps they should consider uptake of DNA by organisms in the environment. These organisms are not the inherently competent organisms, such as *Streptococcus*.

Dr. Diekema noted that these presentations clearly illustrated the challenges associated with improving laboratory detection of emerging pathogens, and reinforced the importance of having front-line clinical microbiology laboratories with the capacity to detect some of these things. Both issues highlighted in the presentations could not be detected by most clinical laboratories.

Public Comment

Dr. Diekema called for public comment at 11:26 a.m. The following comments were offered:

Mary Kundus, RN, BSN, MPH, CIC
Professional Relations and Medical Education
3M Medical

Ms. Kundus is a previous infection preventionist. Her division specializes in sterilization and monitoring processes for quality assurance. Regarding the utility of the endoscope reprocessing document, she commented that HICPAC might consider the addition of methods for cleaning verification. Even when workers do the best they can with cleaning and visual inspection, it is sometimes not enough. The addition of adenosine triphosphate (ATP) protein to help accentuate the visual inspection could be helpful. A great deal of work has been done by

Ofstead & Associates in the area of cleaning and challenges when all of the steps are followed, but contamination and bioburden remains.

Dr. Maragakis thanked Ms. Kundus for highlighting the issue, which the workgroup has discussed and will take into consideration. It is similar to many issues for which there are limited data. The document will be a “living” and “evolving” document.

Summary and Work Plan

Dr. Diekema described the robust HICPAC work plan, which includes the following:

- Ongoing work on the NICU Guideline
- Ongoing work on the Healthcare Personnel Guideline
- Consideration of important issues related to guideline development expressed by Dr. Bell, particularly regarding prioritizing guidelines for updating and development. HICPAC will move forward to begin this process and to revisit issues associated with how to proceed with guideline development.

Dr. Diekema thanked HICPAC and the liaison representatives for their contributions to the productive meeting.

With no additional comments or questions posed, the meeting adjourned at 11:29 a.m.

Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the July 14-15, 2016 meeting of the Healthcare Infection Control Practices Advisory Committee, CDC are accurate and complete.

_____
Date

_____
Daniel Diekema, MD, & Deborah Yokoe, MD, MPH
Co-Chairs, Healthcare Infection Control
Practices Advisory Committee, CDC

Attachment #1: Acronyms Used in this Document

Acronym	Expansion
A/R	Admission/Readmission
AAOHN	American Association of Occupational Health Nurses
AAP	American Academy of Pediatrics
ABIM	American Board of Internal Medicine
ACOEM	American College of Occupational and Environmental Medicine
ACP	American College of Physicians
ACR	American College of Rheumatology
ACS	American College of Surgeons
ADA	Americans with Disabilities Act
AEH	America's Essential Hospitals
AER	Automated Endoscope Reprocessor
AHRQ	Agency for Healthcare Research and Quality
AMR	Antimicrobial Resistance
ANA	American Nurses Association
AORN	Association of periOperative Registered Nurses
API	Application Programming Interface
APIC	Association of Professionals of Infection Control and Epidemiology
AR	Antibiotic Resistance
ASA	American Society of Anesthesiologists
ASHE	American Society for Healthcare Engineering
ASHRAE	American Society of Heating, Refrigerating, and Air-Conditioning Engineers
ASM	American Society for Microbiology
ASTHO	Association of State and Territorial Health Officials
ATP	Adenosine Triphosphate
ATS	American Thoracic Society
AU	Antibiotic Use
AUR	Antimicrobial Use and Resistance
BAA	Broad Agency Announcement
BCBS	Blue Cross/Blue Shield
BSI	Bloodstream Infection
C. auris	*Candida auris*
C. diff.	*Clostridium difficile*
CARB	(National Strategy/Action Plan for) Combating Antibiotic-Resistant Bacteria
CAUTI	Catheter-Associated Urinary Tract Infection
CCNA	Cell Cytotoxin Neutralization Assay
CDA	Clinical Document Architecture
CDC	Centers for Disease Control and Prevention
CDI	*Clostridium difficile* Infection
CEO	Chief Executive Officer
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CLABSI	Central Line-Associated Bloodstream Infection
CLIA	Clinical Laboratory Improvement Amendments
CMO	Chief Medical Officer
CMS	Centers for Medicare and Medicaid Services
COCA	Clinician Outreach and Communication Activity
COLO	Colon Surgery (NHSN code)

Acronym	Expansion
COO	Chief Operating Officer
CORHA	Council for Outbreak Response: Healthcare-Associated Infections and Antibiotic-Resistant Pathogens
CRE	Carbapenem-Resistant *Enterobacteriaceae*
CSTE	Council of State and Territorial Epidemiologists
CU	Consumers Union
CUSP	Comprehensive Unit-based Safety Program
CVC	Central Venous Catheter
DC	District of Columbia
DFO	Designated Federal Official
DGMQ	Division of Global Migration and Quarantine
DHQP	Division of Healthcare Quality Promotion
DoD	(United States) Department of Defense
E. coli	*Escherichia coli*
ECCMID	European Congress of Clinical Microbiology and Infectious Diseases
ED	Emergency Department
EHR	Electronic Health Record
EIA	Enzyme Immunoassay
EIP	Emerging Infections Program
ELC	Epidemiology and Laboratory Capacity
ELR	Electronic Laboratory Reporting
ENT	Ear, Nose, and Throat
EPA	(United States) Environmental Protection Agency
ERAS	Enhanced Recovery After Surgery
ERCP	Endoscopic retrograde cholangiopancreatography
EtO	Ethylene Oxide
EU	European Union
FAPIC	Fellow of the Association for Professionals in Infection Control and Epidemiology
FDA	(United States) Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
FY	Fiscal Year
GBS	Guillain-Barré Syndrome
GDH	Glutamate Dehydrogenase
GI	Gastrointestinal
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HAI	Healthcare-Associated Infection
HCA	Hospital Corporation of America
HHS	(United States Department of) Health and Human Services
HICPAC	Healthcare Infection Control Practices Advisory Committee
HIT	Health Information Technology
HL	Health Level
HRSA	Health Resources and Services Administration
HVAC	Heating, Ventilating, and Air Conditioning
HYST	Abdominal Hysterectomy (NHSN code)
ICD	International Classification of Diseases
ICRA	Infection Control Risk Assessment
ICU	Intensive Care Unit

Acronym	Expansion
IDSA	Infectious Diseases Society of America
IFU	Instructions for Use
IRF	Inpatient Rehabilitation Facility
IT	Information Technology
JAMA	*Journal of the American Medical Association*
LabID	Laboratory Identified
LTACH	Long-Term Acute Care Hospital
M. chimaera	*Mycobacterium chimaera*
MALDI-TOF	Matrix Assisted Laser Desorption/Ionization – Time of Flight (Spectrometer)
MBI	Mucosal Barrier Injury
mcr	Plasmid-Mediated Colistin Resistance
MDR	Multidrug-Resistant
MDRO	Multidrug-Resistant Organism
MIC	Minimum Inhibitory Concentration
MIR	Managing Infection Risk
MM	Medication Management
MMWR	*Morbidity and Mortality Weekly Report*
MRSA	Methicillin-resistant *Staphylococcus aureus*
MSSA	Methicillin-Susceptible *Staphylococcus aureus*
NAAT	Nucleic Acid Amplification Test
NACCHO	National Association of County and City Health Officials
NAMCS	National Ambulatory Medical Care Survey
NANN	National Association of Neonatal Nurses
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NHAMCS	National Hospital Ambulatory Medical Care Survey
NHSN	National Healthcare Safety Network
NIAID	National Institute of Allergy and Infectious Diseases
NICU	Neonatal Intensive Care Unit
NIH	National Institutes of Health
NQF	National Quality Forum
NSQIP®	National Quality Improvement Program®
NTM	Nontuberculous *Mycobacterium*
OB/GYN	Obstetrics/Gynecology
OR	Operating Room
OSHA	Occupational Safety and Health Administration
PA	Physician Assistant
PCR	Polymerase Chain Reaction
PEP	Post-Exposure Prophylaxis
PHAC	Public Health Agency of Canada
PHII	Public Health Informatics Institute
PPE	Personal Protective Equipment
PVE	Prosthetic Valve Endocarditis
Q-HIP®	Quality-In-Sights® Hospital Incentive Program
RCT	Randomized Controlled Trial
RFP	Request for Proposals
RSV	Respiratory Syncytial Virus
SAAR	Standardized Antibiotic Administration Ratio
SAS	Statistical Analysis System

Acronym	Expansion
SCCM	Society of Critical Care Medicine
SHEA	Society for Healthcare Epidemiology of America
SHEPheRD	Safe Healthcare, Epidemiology, and Prevention Research Development
SHM	Society of Hospital Medicine
SIR	Standardized Infection Ratio
SIS	Surgical Infection Society
SNP	Single Nucleotide Polymorphism
SOP	Standard Operating Practice/Procedure
SSI	Surgical Site Infection
STLT	State, Tribal, Local, and Territorial (Health Departments)
SUR	Standardized Utilization Ratio
TB	Tuberculosis
UK	United Kingdom
URI	Upper Respiratory Infection
UTI	Urinary Tract Infection
VA	(United States Department of) Veterans Affairs
VAE	Ventilator-Associated Event
VON	Vermont Oxford Network
VRE	Vancomycin-Resistant *Enterococcus faecium*
VZV	Varicella Zoster Virus
WGS	Whole Genome Sequencing
WHO	World Health Organization

Attachment #2: Liaison and *Ex Officio* Reports

Liaison Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: July 14-15, 2016
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Liaison name: Mark Russi, MD, MPH
Organization represented: American College of Occupational and Environmental Medicine

Interim activities and updates:
ACOEM annual meeting took place in Chicago, April 9-13, 2016. Forthcoming newly revised ACOEM guidance document addressing medical center occupational health was presented, along with several lectures addressing subject areas in which practice changes have occurred since the previous edition. Presentations over the five-day period covered a broad array of topics in the general field of occupational and environmental medicine.
Guidelines and Guidance: Please include both in-progress and planned in the coming year. If you have a different format (e.g., information on a website) you don't have to list them here but could just include the link to the website.
• ACOEM and AAOHN (American Association of Occupational Health Nurses) published in the April issue of JOEM joint guidance for employers on the impact of marijuana in the workplace. • ACOEM published in the March issue of JOEM a guidance statement addressing employee wellness programs and the EEOC regulations. • ACOEM published in the same issue of JOEM a guidance statement on reproductive hazards in the workplace. • New release of the ACOEM Medical Center Occupational Health Guidance Document is expected before year's end.
Position statements:
A position statement addressing lead exposure in the general environment and workplace, calling for more stringent standards, is in final stages of review.
Legislation:
Members of Congress have requested that the U.S. DOL reinstitute oversight of State Workers' Compensation programs. ACOEM has formally offered to be of assistance during the process.
Campaigns and related activities:
Press activities:
Publications:
As above.
Other items of note:

Liaison Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: July 14-15, 2016
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Liaison name: Elaine Dekker, BSN, CIC
Organization represented: America's Essential Hospitals

Interim activities and updates:
Guidelines and Guidance: Please include both in-progress and planned in the coming year. If you have a different format (e.g., information on a website) you don't have to list them here but could just include the link to the website.
• NQF's Playbook for Antibiotic Stewardship – supported and publicized to our members; this is an important area of interest as America's Essential Hospitals plans to submit comments to CMS on proposed Conditions of Participation which include requirements that hospitals develop a formal antibiotic stewardship program.
Position statements:
Legislation:
Campaigns and related activities:
America's Essential Hospitals continues to be a partner organization in the U.S. Stakeholder Forum on Antimicrobial Resistance (S-FAR), convened by the Infectious Diseases Society of America (ISDA), to support the principles that antimicrobial resistance (AR) is an urgent problem and to work with stakeholders from all industries to help inform policy and create awareness.
Press activities:
• **Cluster Outbreak (*B. cepacia* infection)** – America's Essential Hospitals used social media and other communication through its website to bring awareness of suspected outbreak of *B. cepacia* infection. • **Vital Signs (June)** – America's Essential Hospitals called our members' attention to CDC's publication in June which featured important information and data on the rise of Legionnaires disease.
Publications:
• **Zika** – America's Essential Hospitals continues to maintain its online Zika resource page for its member hospitals and others with an interest in this emerging health crisis. This resource page is updated regularly with new information, including materials provided by the CDC related to clinicians, infants, pregnant women, and travel. Essential hospitals provide a significant volume of public health and emergency preparedness services and stand ready to support the nation's response to Zika.
Other items of note:

Ex-Officio Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: July 14-15, 2016
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Ex-officio name: Melissa A. Miller, MD, MS
Organization represented: Agency for Healthcare Research and Quality

Interim Activities and updates:

National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB)

- AHRQ continues to support research and implementation projects to develop improved methods and tools to combat antibiotic resistance in three domains: 1. Promoting antibiotic stewardship; 2. Preventing transmission of resistant bacteria; and 3. Preventing healthcare-associated infections in the first place. These projects are combating antibiotic resistance in multiple healthcare settings: acute care hospitals, long-term care, and ambulatory care.
- AHRQ completed field testing of its implementation guide for antibiotic stewardship in nursing homes. The guide is based on tools from four previous AHRQ-supported studies of stewardship in nursing homes. Data from the field testing are being analyzed. Wide dissemination of the guide is anticipated toward the end of CY 2016.
- AHRQ and CDC held a conference of experts and stakeholders on June 6 to identify knowledge gaps for prevention of antibiotic-resistant healthcare-associated infections and identify potential interventions for development, field testing, and eventual widespread implementation.
- On June 14, AHRQ, CDC, CMS, and OASH met with HHS leadership to discuss progress on the Agency Priority Goal effort to accelerate the implementation of antibiotic stewardship programs in hospitals.
- Finally, AHRQ released a Request for Task Order Proposals for The Comprehensive Unit-based Safety Program (CUSP) for Antibiotic Stewardship. This will be a 5-year project aimed at adapting CUSP for implementation of Antibiotic Stewardship in 250 acute care hospitals, 250 long-term care facilities, and 250 ambulatory care settings (i.e. clinics, physician's offices, and urgent care centers). We anticipate that the project will significantly increase antibiotic stewardship in these settings. This will be a collaborative effort, incorporating CDC Core Elements of Antibiotic Stewardship, coordination with CMS, and possible participation by VA and DoD. The Task Order will be awarded by September 2016.

AHRQ Safety Program for Enhanced Recovery After Surgery

- AHRQ released a Request for Task Order Proposals for CUSP for enhanced recovery after surgery (ERAS). The project aims to use an adaptation of CUSP to improve patient outcomes by increasing the implementation of ERAS practices in hospitals. ERAS is a constellation of preoperative, intra-operative, and postoperative practices that can decrease complications (e.g., total complications including surgical site infections) and accelerate recovery. This 5-year project aims for implementation in 750 hospitals nationwide, focusing on a variety of surgeries in a phased approach. Task Order award is anticipated by September 2016.

AHRQ Safety Program for ICUs with Persistently Elevated Rates of CLABSI/CAUTI

- Initiated in September 2015, this 2.5 year project aims to reduce central-line associated bloodstream infections (CLABSI) and catheter-associated urinary tract infections (CAUTI) in intensive care units with persistently elevated rates of these infections. This is a follow-up to AHRQ's nationwide projects of CUSP for CAUTI and CUSP for CLABSI. Implementation strategies tailored to this group are being developed, including a modified set of CUSP training resources.

Thus far, 191 ICUs have been recruited and are participating.

AHRQ Safety Program for Mechanically Ventilated Patients

- This 3-year project aims to apply CUSP to increase the safety of mechanically ventilated patients by reducing ventilator-associated complications (including ventilator-associated pneumonia) through promoting use of a set of evidence-based practices in these patients. The project has recruited 255 units in 200 hospitals across 34 states, Puerto Rico, and Saudi Arabia and will reach completion in September 2016.

AHRQ Safety Program for Ambulatory Surgery

- This 4-year project aims to apply CUSP to improve safety and reduce complications including surgical site infections in ambulatory surgery centers and has recruited 662 centers in 46 states including one cohort specifically focused on endoscopy centers. Two issues that have been addressed for the endoscopy cohort are adequacy of scope cleaning and safety of sedation/anesthesia. This project will reach completion in September 2016.

AHRQ Safety Program for Long-Term Care: Preventing CAUTI and Other HAIs

- This 3-year project aims to apply CUSP to reduce catheter-associated urinary tract infections (CAUTI) and other HAIs in long term care facilities by adapting CUSP to this setting and by promoting broad implementation through State-based or regional consortia/collaborative efforts. More than 500 long-term care facilities across the United States are participating. The project will also reach completion in September 2016.

Position statements:

Legislation:

Campaigns and related activities:

Press activities:

Publications:

- Fletcher, K. E., Tyszka, J. T., Harrod, M., Fowler, K. E., Saint, S., & Krein, S. L. (2016). Qualitative validation of the CAUTI Guide to Patient Safety assessment tool. Am J Infect Control. doi:10.1016/j.ajic.2016.03.051
- Roghmann, M. C., Lydecker, A., Mody, L., Mullins, C. D., & Onukwugha, E. (2016). Strategies to Prevent MRSA Transmission in Community-Based Nursing Homes: A Cost Analysis. Infect Control Hosp Epidemiol, 1-5. doi:10.1017/ice.2016.96
- Saint, S., Greene, M. T., Krein, S. L., Rogers, M. A., Ratz, D., Fowler, K. E., . . . Fakih, M. G. (2016). A Program to Prevent Catheter-Associated Urinary Tract Infection in Acute Care. N Engl J Med, 374(22), 2111-2119. doi:10.1056/NEJMoa1504906

Other items of note:

Liaison Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: July 14-15, 2016
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Liaison name: Amber Wood
Organization represented: AORN

Interim activities and updates:
Hot Topics • Go Clear Award (recognizes health care facilities committed to a surgical smoke-free environment for their perioperative team and patients) Upcoming Events • AORN Global Surgical Conference & Expo 2017, April 1-5, Boston   o Poster abstract submission deadline: September 30, 2016 • Guideline Implementation Workshops, Sept-Nov 2016, multiple dates and cities
Guidelines and Guidance: Please include both in-progress and planned in the coming year. If you have a different format (e.g., information on a website) you don't have to list them here but could just include the link to the website.
• AORN guidelines are available in print and through electronic access (e-subscription and e-book). Information on how to obtain can be found on the AORN website. • The 2016 Guidelines for Perioperative Practice include 5 new evidence-rated guidelines: Radiation Safety, Retained Surgical Items, Hypothermia, Moderate Sedation/Analgesia, and Flexible Endoscopes • Guidelines completed for 2017: Information Management, Hand Hygiene, Energy Devices • Guidelines in development for 2017: Environment of Care Part 2 (Humidity), Smoke Safety, Minimally Invasive Surgery, and Positioning
Position statements:
Available at the AORN Website
Legislation:
The AORN legislative priorities for 2016 are RN as circulator, preserving and protecting the Perioperative Registered Nurse's scope of practice, supporting workplace safety and patient safety initiatives, and advancing positive health care improvements.
Campaigns and related activities:
Sharps Safety Campaign
Press activities:
Recent AORN press releases can be accessed at the AORN Website.
Publications:
2016 Guidelines for Perioperative Practice, AORN Journal, 2016 Perioperative Job Descriptions and Competency Evaluation, Perioperative Policies and Procedures, & Ambulatory Surgery Center Resources
Other items of note:

Liaison Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: July 14-15, 2016
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Liaison name: Michael Anne Preas
Organization represented: Association for Professionals in Infection Control and Epidemiology, Inc. (APIC)

Interim activities and updates:
• APIC Announces the 2016 Fellows. The Advanced Designation Program recognizes exemplary APIC members with status as a Fellow of the Association for Professionals in Infection Control and Epidemiology (FAPIC). Fellow of APIC status is a distinction of honor for infection preventionists who are not only advanced practitioners of infection prevention practice, but also leaders within the field. • The APIC Annual Conference was a huge success. The CDC presented 21 sessions at the APIC Annual Conference in Charlotte including a pre-conference workshop. Planning for APIC 2017 conference in Portland June 14-16 is well underway. For more information click - Portland 2017.
Guidelines and Guidance: Please include both in-progress and planned in the coming year. If you have a different format (e.g., information on a website) you don't have to list them here but could just include the link to the website.
N/A
Position statements:
N/A
Legislation and regulatory activities:
• Joined SHEA in submitting testimony to House/Senate Labor-HHS Appropriations subcommittees. • APIC Public Policy Committee lobby day on Capitol Hill in support of funding priorities. • Submitted comments to FDA on draft guidance for industry on enforcement policy for investigational new drug requirements for fecal microbiota for transplantation. • Submitted comments to OSHA on PPE information collection request. • Submitted comments to FDA on reclassification of blood lancets proposed rule. • Submitted comments to FDA on request for information on medical device reprocessing. • Submitted comments to FDA on guidance for industry on donor screening recommendations to reduce Zika transmission. • Submitted comments to FDA on proposed rule to ban powdered gloves. • Submitted comments to CMS on Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Payment System (IPPS/LTCH) proposed rule. • Submitted comments to CMS on Inpatient Rehabilitation Facilities Prospective Payment System proposed rule. • Submitted comments to CMS on Skilled Nursing Facilities Prospective Payment System proposed rule. • Submitted comments to CMS on Merit-Based Incentive Payment System proposed rule.
Campaigns and related activities:
• Developed campaign ideas for International Infection Prevention Week (October 16-22, 2016) around theme of "Breaking the chain of infection" • Activities to include: o Twitter chat (tentative dates: October 19 or October 20) around the "Break the Chain of

Infection" theme
- Thunderclap campaign (date TBD)
- Educational webinar for healthcare professionals (TBD)
- "Break the Chain of Infection" infographics
- "Do's and Don'ts of Glove Use" infographic
- Online infection prevention pledges for both consumers and healthcare professionals
- Social media memes
- Podcasts
- Engaging, fun quizzes
- New web pages on Infection Prevention and You

Press activities:

- Issued 9 press releases (4 scientific, 5 awards) in connection with APIC's Annual Conference in Charlotte, NC. Media relations and social media activity combined yielded more than 257 million impressions through 148 original articles, 3,880 Tweets and 39 Facebook posts.
- APIC Annual Conference news was covered by major media outlets including CNN, ABC News, NBC News, Glamour, HealthDay, Medscape, CIDRAP, and the Charlotte Observer.
- Additional major media coverage for APIC resulted from APIC president Susan Dolan's interviews with the Wall Street Journal and Kaiser Health News about banning flowers in patient rooms and contaminated medications, respectively. Susan Dolan was also interviewed by the Milwaukee Journal-Sentinel about the Elizabethkingia outbreak.
- APIC issued a media statement in support of the CDC *Vital Signs* message to "Protect every patient every time from antibiotic-resistant infections."
- Blog posts submitted by APIC members Angela Vassallo and Debra Johnson were published on the CDC Safe Healthcare Blog on May 6 and May 19, respectively.
- Press releases were issued on the following AJIC articles:
  - "Using medical student observers of infection prevention, hand hygiene, and injection safety in outpatient settings: A cross-sectional survey," by Deborah Thompson et al.

Publications:

- The following Consumer Alerts have been published since March 1, 2016: "Norovirus—a.k.a. the vomiting bug;" "Is strep causing that sore throat;" "Meningococcal disease: What it is and how to prevent it;" "Clean your hands often;" and "Diabetes, infections, and you."

Other items of note:

N/A

Liaison Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: July 14-15, 2016
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Liaison name: Valerie Haley, PhD (attending on behalf of Emily Lutterloh, MD, MPH)
Organization represented: Association of State and Territorial Health Officials (ASTHO)

Interim activities and updates:
• ASTHO is working in collaboration with CDC to develop tools and collect best practices for state HAI prevention. • ASTHO launched a web-based toolkit to support health departments in accessing electronic health records for healthcare-associated outbreak investigation. The toolkit is based on an assessment of experiences and tools from twelve states, and is available at: • ASTHO is also supporting state health agency HAI/AR programs as they conduct Ebola and infection control assessments through federal ELC supplemental funding. The objectives of this project are to: 1) facilitate coordination and implementation of Ebola-related activities for effective and sustainable HAI programs; and 2) accelerate capacity building around healthcare infection control assessment and outbreak response. Key activities include: o Conducting site visits in 3 states to understand the impact of Ebola/ELC funding on the state's HAI/AR program efforts, and how that impact might be optimized in the future. Site visits were completed in Colorado, Kentucky, and Oregon in February/March 2016. o Convening state teams meetings to explore lessons learned regarding ELC supplemental funding activities. The meetings were held in 2 locations to maximize participation. Participants included state HAI coordinators and public health and healthcare partners. A meeting report and summary documents are under development. o Assembling an HAI outbreak council, called the Council for Outbreak Response: Healthcare-Associated Infections and Antibiotic-Resistant Pathogens (CORHA). The Council is co-chaired by ASTHO and CSTE and seeks to improve practices and policies for detection, investigation, control and prevention of HAI/AR outbreaks and emerging infectious disease threats across the healthcare continuum. The council met in December 2015 and June 2016 to identify a central challenge, strategic priorities and objectives, and develop initial implementation plans. o Launched The Healthcare and Infection Control Gateway to share infection control and outbreak information, tools and resources. o Developing and testing public health communications tools designed to facilitate discussion of health-care associated infections for a variety of audiences.
Guidelines and Guidance: Please include both in-progress and planned in the coming year. If you have a different format (e.g., information on a website) you don't have to list them here but could just include the link to the website.
Position statements:
Legislation:
Ongoing: Real-time state HAI legislative tracking is available on ASTHO's website.

Campaigns and related activities:
Ongoing: ASTHO provides information to health officials on pertinent HAI issues through conference calls (All S/THO Call) and the *State Public Health Weekly* newsletter.
Press activities:
Publications:
ASTHO's HAI Publications are available online.
Other items of note:

Liaison Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: July 14-15, 2016
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Liaison name: Marion Kainer
Organization represented: Council of State and Territorial Epidemiologists (CSTE)

Interim activities and updates:
2016 annual conference was held in Anchorage, Alaska, June 19-23. Many of the presentations/ posters are available on the mobile app.
Guidelines and Guidance: Please include both in-progress and planned in the coming year. If you have a different format (e.g., information on a website) you don't have to list them here but could just include the link to the website.
• The core group members of the CDC-CSTE Antimicrobial Resistance Surveillance Taskforce (v 2.0) in response to CSTE PS 13-SI-01: "Recommendations for strengthening public health surveillance of antimicrobial resistance in the United States" continues to meet regularly since December 2015. It has been on a fact finding mission, with regular 2-3 hour conference calls per week. Core planning group members include Gus Birkhead, CSTE consultant (former deputy state epidemiologist, NY State), Dan Pollock (CDC/DHQP, Wes Kennemore (consultant), Dawn Sievert (consultant), Michael Iademarco (CDC/CSELS), Jeff Engel (CSTE) and Marion Kainer (TN DOH). The core planning group presented an update at the CSTE annual conference. It is tackling specific issues: 1) defining challenges of ELR and NHSN reporting for CRE, 2) addressing selective reporting of antibiotic susceptibility data; 3) describing the roles, responsibilities and core capacities needed at the federal, state and local levels. The core planning group will engage addition SMES and other groups as appropriate (e.g., CLIAC for selective reporting, CSTE subcommittee for ELR/HL7). It will designate taskforce members and convene an in-person meeting in Winter/Spring 2016-7. The goal will be to have a strategic roadmap that will identify roles, responsibilities, capacities; gaps and resource needs; as well as prioritization of issues and an implementation timeline. Under consideration is a "3-legged stool" for AR surveillance: isolate submission, NHSN and ELR reporting. • The Council for Outbreak Response: Healthcare Associated Infections and Antibiotic Resistant Pathogens (CORHA) met in June 2016. A one-pager describing the mission, vision, membership can be found online. The Council is co-chaired by CSTE and ASTHO; CDC, NACHO, APIC and SHEA are members of the Council and participated in the in-person meeting in June.

Position statements :
Position statements that were passed by CSTE membership at the annual meeting in June 2016 include: • 16-ID-09 Interfacility Communication to Prevent and Control Healthcare Associated Infections and Antimicrobial Resistant Pathogens across Healthcare Settings • 16-ID-01 Zika Virus Disease and Congenital Zika Virus Infection Interim Case Definition and Addition to the Nationally Notifiable Diseases List • 16-SI02 Electronic Case Reporting (eCR) • 16-SI-03 Veterans Health Administration Reporting of Diseases, Conditions, and Outbreaks to Local and State Public Health Authorities Position statements are currently being formatted. They shortly will be sent to agencies for response and information and will be available online.
Legislation:
Campaigns and related activities:
Press activities:
Publications:
Other items of note:

Liaison Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: July 2016
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Liaison name: Lisa McGiffert
Organization represented: Consumers Union (CU)/Consumer Reports

Interim activities and updates:
Guidelines and Guidance: Please include both in-progress and planned in the coming year. If you have a different format (e.g., information on a website) you don't have to list them here but could just include the link to the website.
n/a
Position statements:
CU submitted comments to the Council on Combating Antibiotic Resistant Bacteria in response to several questions they posed. We recommended that CMS use its payment policies to move forward with desired changes in use of antibiotics such as requiring prescriptions to include the indication for the antibiotic; require hospitals to use rapid diagnostic testing for determining the organism causing an infection when available and make CMS reimbursement rates higher if the hospital gives the appropriate antibiotic within certain timeframe; make antibiotic prescription information available to CMS and for CMS to make that data (de-identified) available to the public for analysis and to assess progress. In response to the CMS/IPPS request for comments, CU supported the use of NHSN Antimicrobial Use Measure (NQF #2720) in the Hospital Inpatient Quality Reporting program; we think that the measure will need to be refined after NHSN collected more data from hospitals to establish a baseline.
Legislation:
MO CRE as reportable condition; mandates hospitals and ASCs to create antibiotic stewardship programs; mandates hospitals to report to NHSN using the Antimicrobial Use and Resistance (AUR) when Stage 3 meaningful use regulations are effective; hospital specific information is not public except may be released on a case by case basis to protect people during a public health emergency. If this becomes effective it could help CDC get more data to determine baselines for the AUR measure but we are concerned that the limitations will delay implementation and hide results from the public unless the law is changed again.
Campaigns and related activities:
CU and other patient safety advocates are pushing for more collaboration within state health departments between epidemiologic experts collecting and reporting on HAIs and regulatory oversight staff in responding to prevention of hospital-acquired infections. We propose in CA and at above referenced consumer meeting that information be shared in real time to bring more accountability and response in prevention of HAIs. A recent LA Times article (May 2016) highlights the need to have more cross referencing of data: State found lapses in infection control at UCLA and Cedars-Sinai
Press activities:
Publications:
Complications from hip & knee replacements: CR analyzed data from LA hospitals for rates of infection, readmission rates, and complication rates, and found it can make a big difference which hospital you go to. Part of a collaboration with the California Department of Insurance, which includes an online tool to help you check out hospitals. California Healthcare Compare

CR Rating Center national hospital C-section rates and a social media work in highlighting the poorest performers. Your Biggest C-Section Risk May Be Your Hospital Continued coverage online and in other CR publications on antibiotic resistance.
Other items of note:
CU and a group of patient safety advocates attended a May CDC meeting on antibiotic resistance and sepsis during which we discussed consumer focused issues with CDC experts.

Liaison Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: July 2016
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Liaison name: Linda L. Spaulding
Organization represented: DNVGL Healthcare

Interim activities and updates:
DNVGL Healthcare is now offering a hospital infection prevention certification program called Managing Infection Risk (MIR).
Guidelines and Guidance: Please include both in-progress and planned in the coming year. If you have a different format (e.g., information on a website) you don't have to list them here but could just include the link to the website.
To learn more go to DNV Healthcare look under healthcare for the program.
Position statements:
MIR Certification follows a path very similar to hospital accreditation. A team of MIR surveyors will visit the hospital. The DNVGL surveyors apply a comprehensive 18-point standard, with each element representing known trigger points for infection risk. The result: Hospitals will know where their defenses are strong and where their vulnerabilities exist. Most importantly, hospitals can pinpoint the gaps in their cross-function and interdepartment workflows. That's knowledge that can immediately improve the hospitals processes and help save lives.
Legislation:
CMS is proposing a rule that prohibits discrimination, reduces hospital-acquired conditions, and promotes antibiotic stewardship in Hospitals. In line with this we will also be revising our accreditation requirements to incorporate more of what we are calling for in MIR to now be more of a standard related to compliance with the CMS Conditions of Participations.
Campaigns and related activities:
We are working to correlated the Hospital Acquired Condition scores and how the culture of the hospital impacts this. We know that with our MIR program is about engage so many others outside of the Infection Preventionist and we are also tying this in some respects to the Modern Safety Culture assessments we are working together with our Research & Innovation Group in Norway.
Press activities:
none
Publications:
MIR Standards
Other items of note:

Liaison Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: July 14-15
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Liaison name: Stephen Weber, MD
Organization represented: Infectious Diseases Society of America

Interim activities and updates:

- **IDSA Continues to Drive Legislative Progress on Antimicrobial Resistance**. IDSA and the Pew Charitable Trusts hosted a June 9 congressional briefing. The briefing publicized the UK AMR Review's final report, which echoed key IDSA recommendations for incentivizing antibiotic and diagnostics research and development (R&D); strengthening stewardship, surveillance and data collection in human and animal health; and investing in the ID workforce.
- The Presidential Advisory Council on Combating Antibiotic Resistant Bacteria (PACCARB) held a June 21-22 meeting to discuss incentives for antibiotics, diagnostics, vaccines and other therapeutics, as well as antibiotic resistance in agriculture and environmental health. **IDSA submitted comments to PACCARB and the Administration**.
- **IDSA is preparing comprehensive feedback regarding the Antibiotic Stewardship Condition of Participation for Hospitals Participating in Medicare**. IDSA is committed to rigorous expectations regarding the leadership, structure and performance of antibiotic stewardship programs to protect patients.

Guidelines and Guidance: Please include both in-progress and planned in the coming year. If you have a different format (e.g., information on a website) you don't have to list them here but could just include the link to the website.

Guidelines in development related to infection prevention and antimicrobial stewardship:

1. *Clostridium difficile* (Update) - *Joint w/SHEA*
2. Hospital-acquired, ventilator-acquired pneumonia (Update) - *Joint w/ATS*
3. IV Catheter Management (Update)
4. Outpatient Parenteral Anti-Infective Therapy (OPAT) - (Update)
5. Vancomycin - (Update) *Joint w/ASHP/SIDP/PIDS*

Published

1. Implementing an Antibiotic Stewardship Program (CID. 2016; 62: 1-27) – *Joint w/ SHEA*

Link to other guidelines on the IDSA website.

Position statements:

Antimicrobial Stewardship Programs via Telehealth. IDSA has updated its position statement on the use of telehealth and telemedicine in the practice of infectious diseases to include the use of telehealth technologies to administer and participate in antimicrobial stewardship programs (ASPs).

Legislation:

- **IDSA Engages House Subcommittee Ahead of Hearing on Antibiotic Resistance.** IDSA urges support for implementation of the National Action Plan for Combating Antibiotic-Resistance Bacteria, placing particular emphasis on antibiotic stewardship, incentives to spur R&D, ID workforce challenges, and the need for increased funding for federal AR programs.
- **IDSA Provides Testimony to House and Senate Spending Panels on 2017 Budget.** The statement largely focused on federal efforts to combat the Zika virus and antimicrobial resistance.

Campaigns and related activities:
Key areas of IDSA focus related to infection prevention and control remain: 1. New antibiotic development (10 x '20 initiative) 2. Antimicrobial resistance and stewardship 3. Infection prevention and control
Press activities:
Selected news releases: 1. New Antibiotic Stewardship Guidelines Focus on Practical Advice for Implementation (4/14/16) 2. IDSA Names Christopher D. Busky, CAE, as the Society's New CEO (4/18/16)
Publications:
Selected publications from IDSA journals • *A study in CID suggests seasonal flu vaccination during pregnancy may guard against stillbirth:* Regan, et al. Pregnancy and the Incidence of Stillbirth: Population-Based Retrospective Cohort Study. Clin Infect Dis. 2016; 62: 1221-1227.
Other items of note:

Liaison Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: July 14 – 15, 2016
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Liaison name: Jennifer Gutowski, Philadelphia Department of Public Health
Organization represented: National Association of County and City Health Officials (NACCHO)

Interim activities and updates:

- October 2014 – present: Activated a modified incident command structure to support local health departments and CDC in preparing for and responding to Ebola
  - An in-progress review meeting was held in August 2015 to reflect and assess the national public health response to-date, identify steps to ensure a strong and effective transition and recovery process, and determine ways to improve preparedness and response efforts, including crossover applications to other infectious disease threats
  - Partners included CDC and ASTHO and invitees included federal, state, and local representatives, as well as partner organizations
  - A report is currently being finalized by NACCHO and ASTHO to outline recommendations identified at the in-progress review meeting and key stakeholder interviews
- July 2015 – present: Started new fiscal year of multiyear HAI demonstration site project. The current project year focuses on local health departments' antibiotic stewardship efforts; the three funded demonstration sites and their general activities are:
  - Florida Department of Health in Orange County – Orlando, FL: Launched a partnership with the state's Department of Health to collaborate on HAI prevention efforts and increase local capacity to respond to active outbreaks; documenting work in decreasing unnecessary antibiotic use through urine specimen collection and prescribing practice
  - DuPage County Health Department – Wheaton, IL: Engaging long-term care facilities and acute care hospitals to improve their understanding of local needs and approaches to the prevention of HAIs and MDROs; also facilitating quarterly educational sessions, disseminating relevant reference materials, and distributing customized "Get Smart About Antibiotics" posters to facilitate communication among staff and with residents, visitors, and family members
  - Philadelphia Department of Public Health – Philadelphia, PA: Established a region-wide antimicrobial stewardship collaborative that includes acute care hospitals, long-term care facilities, non-profit organizations, and government agencies; offering an educational webinar series on antimicrobial stewardship
- March 2016 – present: Launched Lessons in INfection Control (LINC) Initiative demonstration sites
  - With support from the Centers for Disease Control and Prevention (CDC), 11 LINC Initiative award recipients will test new approaches to prepare for and respond to Ebola, healthcare-associated infections, and other emerging infectious diseases
  - The LINC Initiative supports local health departments in improving healthcare and community infection control practices by working with hospitals, long-term care facilities, and other healthcare settings to identify and address needs and opportunities
- April 2016: Attended the ASTHO meeting on HAI Programs: Enhancing Healthcare Infection Control Assessment & Response in Atlanta
- April 2016: Submitted a proposal to the Foundation for the Public's Health to build upon activities already undertaken by NACCHO to expand local health department capacity to address HAIs
  - Proposed funding would contribute directly to expanding capacity and capability of local

health department staff to address infection control through supporting training and certification in infection control

- April 2016: Co-hosted a learning session on Integrating Preparedness and Infectious Disease Prevention and Control at the Preparedness Summit with ASTHO
  - The session featured lessons learned from infectious disease outbreaks and the need for increased coordination of infection prevention and control with preparedness efforts
  - The session shared findings from a stakeholder review of the Ebola response and explore successful approaches to strengthen preparedness and response to emerging infections
- May 2016: Attended Trust for America's Health (TFAH) briefing on the state of America's readiness for infectious disease outbreaks
  - The briefing follows TFAH's report, *Outbreaks: Protecting Americans from Infectious Diseases*, which found that America still has major gaps in preparing for new infectious disease threats like Zika, MERS-CoV and drug-resistant superbugs, as well as resurging illnesses like whooping cough and tuberculosis
  - The briefing aimed to inform policymakers and partners on steps the nation can take to prevent and respond to infectious disease outbreaks
- May 2016: Awarded scholarships to support 35 local health department staff in obtaining certification in infection control
  - Scholarship recipients were reimbursed up to $2,500 for exam fees and study materials (including books and/or training courses)
  - Scholarship recipients will be expected to provide feedback on the certification process and demonstrated impact of certification to NACCHO to inform future project activities supporting local health departments in infection prevention and control
- May 2016: Attended the ASTHO meeting on HAI Programs: Enhancing Healthcare Infection Control Assessment & Response in Salt Lake City
- June 2016: Attended the two-day Council for Outbreak Response: Healthcare-Associated Infections and Antibiotic-Resistant Pathogens (CORHA) meeting in Atlanta hosted by CDC, ASTHO, and CSTE
  - One NACCHO representative and two local health department representatives from Los Angeles County Department of Public Health and Barren River District Health Department attended
- June 2016: Hosted a roundtable session at the CSTE Annual Conference on Local Health Department Roles and Activities to Improve Infection Control, Preparedness, and Response to Infectious Disease Threats
  - The session featured local health departments' experiences and lessons learned through the LINC Initiative and similar opportunities to address Ebola, HAIs, and other infectious diseases
- June 2016: Participated in IDSA S-FAR meeting on Patient Engagement and "Faces of Antimicrobial Resistance" Project launch
  - The project aims to assemble a collection of stories from firsthand accounts of the impact of AMR infections on individuals and their families
  - IDSA shared their vision for the project, collected feedback, and facilitated a discussion about other opportunities to increase patient engagement on antimicrobial resistance activities
- Ongoing: Participated in the following meetings, conference calls, and committees related to (1) obtaining updates on HAIs, injection safety, antimicrobial resistance, and infection control; and (2) determining how NACCHO can support national efforts to address related issues
  - Safe Injection Practices Coalition partner calls
  - CSTE HAI Standards Committee calls
- Ongoing: Participated in conference calls with ASTHO and CSTE to discuss HAI and Ebola and

Other Infection Control activities • Ongoing: Shared HAI prevention and infection control news and resources via NACCHO's regular communication channels
Guidelines and Guidance: Please include both in-progress and planned in the coming year. If you have a different format (e.g., information on a website) you don't have to list them here but could just include the link to the website.
• July 2016: Developed an HAI guidance document for local health departments to engage in HAI prevention activities – it is based on experiences and input from the local health departments participating in NACCHO's HAI prevention demonstration project, corresponding state health departments, and a DHQP representative o The guidance document is in the process of being posted online, so a link will be provided in the next meeting's update
Position statements:
• June 2016: Responded to the Notice of Request for Information by the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria o The letter urges healthcare organizations to actively engage with their local health departments to share information and identify the ways in which they can collaboratively improve infection prevent, decrease unnecessary use of antibiotics, and reduce the spread of antibiotic resistance o Participants shared infection control resources, experiences in compiling inventories of healthcare facilities and implementing tabletop exercises, and explored persisting gaps that stakeholders can address to improve infection control
Legislation:
N/A
Campaigns and related activities:
N/A
Press activities:
• May 2016: Published a press release and a blog post about the launch of the LINC Initiative demonstration sites
Publications:
N/A
Other items of note:
N/A

Ex-Officio Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: July 14, 2016
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Ex-officio name: David K. Henderson, M.D.
Organization represented: National Institutes of Health

Interim Activities and updates:
1. NIH has continued to communicate with DHHS and other federal Agencies about interventions related to Ebola. Over the past six months, we have also modified our containment facility. We have improved our communications strategies (higher resolution closed circuit television with expanded room coverage), improved the flow for solid waste, and improved shower facilities for staff. Dr. Palmore and her colleagues published a case report describing a severe case of meningoencephalitis in one of the Ebola patients for whom we provided care. She also was a collaborator in a study designed to evaluate the administration of post-exposure immunoprophylaxis to patients who had sustained occupational exposures to Ebola and was also a participant in the Working Group of the U.S.–European Clinical Network on Clinical Management of Ebola Virus Disease Patients in the U.S. and Europe. 2. Work is continuing to evaluate the transmission of Vancomycin-resistant *Enterococcus faecium* (VRE) in our hospital environment using whole-genome sequencing and detailed epidemiological information; a manuscript describing a cohort study of 350 patients who were found to have either VRE colonization or infection is in preparation. 3. In addition, studies of carbapenemase producing organisms (CPO) transmission are also continuing, including studies detecting the KPC gene in non-Enterobacteriaceae (both Aeromonas and *Pseudomonas aeruginosa*), studies assessing the dynamics of plasmid behavior in patients who have long-term colonization with CPOs. A manuscript evaluating healthcare workers for carriage of CPOs and other MDROs has been submitted for publication. 4. In terms of interesting/challenging clinical issues, the Clinical Center detected one instance of *Candida auris* fungemia. The patient survived, though the bloodstream infection broke through antifungal therapy to which it was determined to be susceptible *in vitro.* The isolate was sent to CDC.
Position statements:
Legislation:
Campaigns and related activities:
Press activities:
Publications:
1. Hughes H, Conlan S, Lau A, Dekker J, Michelin A, Youn J-H, Henderson DK, Frank KM, Segre JA, Palmore TN. Detection and whole genome sequencing of carbapenemase-producing *Aeromonas hydrophila* isolated from routine perirectal surveillance culture. *J Clin Microbiol*. 2016; 54(4):1167-70. 2. Hughes H, Henderson DK. Post-exposure prophylaxis after Hepatitis C occupational exposure in the interferon-free era. *Curr Opin Infect Dis* 2016 29(4):373-80.

3. Conlan S, Park M, Deming C, Thomas PJ, Young AC, Coleman H, Sison C; NISC Comparative Sequencing Program, Weingarten RA, Lau AF, Dekker JP, Palmore TN, Frank KM, Segre JA. Plasmid Dynamics in KPC-Positive *Klebsiella pneumoniae* during long-term patient colonization. M Bio. 2016 Jun 28;7(3): e00742-16.
4. Wong KK, Davey RT Jr, Hewlett AL, Kraft CS, Mehta AK, Mulligan MJ, Beck A, Dorman W, Kratochvil CJ, Lai L, Palmore TN, Rogers S, Smith PW, Suffredini AF, Wolcott M, Ströher U, Uyeki TM. Use of Postexposure Prophylaxis After Occupational Exposure to Zaire ebolavirus. Clin Infect Dis. 2016 Apr 26. pii: ciw256. [Epub ahead of print]
5. Chertow DS, Nath A, Suffredini AF, Danner RL, Reich DS, Bishop RJ, Childs RW, Arai AE, Palmore TN, Lane HC, Fauci AS, Davey RT. Severe Meningoencephalitis in a Case of Ebola Virus Disease: A Case Report. Ann Intern Med. 2016 Apr 5. doi: 10.7326/M15-3066. [Epub ahead of print]
6. Chertow DS, Palmore TN, Masur H. After the 2014-2015 Ebola Outbreak: Are We Ready If It Happens Again? Crit Care Med. 2016 Mar;44(3):457-9. doi: 10.1097
7. Dotson GA; NISC Comparative Sequencing Program, Dekker JP, Palmore TN, Segre JA, Conlan S. Draft Genome Sequence of a *Klebsiella pneumoniae* Carbapenemase-Positive Sequence Type 111 *Pseudomonas aeruginosa* Strain. Genome Announc. 2016 Feb 11;4(1). pii: e01663-15. doi: 10.1128/genomeA.01663-15.
8. Beekmann SE, Palmore TN, Polgreen PM, Bennett JE. Adequacy of Duodenoscope Reprocessing Methods as Reported by Infectious Disease Physicians. Infect Control Hosp Epidemiol. 2016 Feb;37(2):226-8. doi: 10.1017/ice.2015.256. Epub 2015 Oct 27
9. Munoz-Price LS, Banach DB, Bearman G, Gould JM, Leekha S, Morgan DJ, Palmore TN, Rupp ME, Weber DJ, Wiemken TL. Isolation precautions for visitors. Infect Control Hosp Epidemiol. 2015 Jul;36(7):747-58. doi: 10.1017/ice.2015.67. Epub 2015 Apr 10.
10. Uyeki TM, Mehta AK, Davey RT Jr, Liddell AM, Wolf T, Vetter P, Schmiedel S, Grünewald T, Jacobs M, Arribas JR, Evans L, Hewlett AL, Brantsaeter AB, Ippolito G, Rapp C, Hoepelman AI, Gutman J; Working Group of the U.S.–European Clinical Network on Clinical Management of Ebola Virus Disease Patients in the U.S. and Europe. Clinical Management of Ebola Virus Disease in the United States and Europe. N Engl J Med. 2016 Feb 18;374(7):636-46

Liaison Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: July 14/15 2016
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Liaison name: Craig M. Coopersmith (Jason M. Kane, MD filling in for Dr. Coopersmith)
Organization represented: Society of Critical Care Medicine

Interim activities and updates:
1. The Surviving Sepsis Campaign has named co-chairs and co vice-chairs for the pediatric sepsis guideline to begin development. For SCCM, Dr. N. Kissoon and Dr. S. Weiss respectively and for ESICM Dr. P. Tissieres and Dr. M. Peters respectively. The first meeting of the group will take place in October at the ESICM meeting in Milan. 2. SCCM is working with IDSA and ACEP to provide input to the Centers for Medicare and Medicaid on the antimicrobial table within the SEP 1 sepsis measure set. 3. The SCCM will partner with the CDC to offer two webcasts in September on sepsis for clinicians. Topics are being finalized. 4. SCCM provided input, editing and recording of several online learning modules to assist with compliance of care bundles related to CAUTI and CLABSI in ICUS. Additional modules are being finalized this month in collaboration with AHA HRET.
Guidelines and Guidance: Please include both in-progress and planned in the coming year. If you have a different format (e.g., information on a website) you don't have to list them here but could just include the link to the website.
1. Guideline for Adult ICU Admission, Discharge and Triage (pub 8/2016). 2. Guidelines for Admission and Discharge for the PICU and Levels of Care (in development) 3. Pediatric Pain, Agitation and Delirium in the ICU (in development) 4. Guidelines for Stress Ulcer Prophylaxis in Adult Critically Ill Patients (pub 12/2016) 5. Medication Use Safety (in review and journal submission cycle) 6. Clinical practice guidelines for sustained neuromuscular blockade in the adult critically ill patient (pub 11/2016) 7. Clinical practice guideline: Red blood cell transfusion in adult trauma and critical care (revision) 8. Clinical Parameters for Hemodynamic Support of Newborn and Pediatric Septic Shock (submitted to journal) 9. Recommendations for the Diagnosis and Management of Corticosteroid Insufficiency in Critically Ill Adults Patients: Consensus Statements for International Task force by the ACCM (in revision) 10. Guidelines for evaluation of new fever in critically ill adult patients: 2008 update from the American College of Critical Care Medicine and the Infectious Diseases Society of America (in revision) 11. Clinical practice guidelines for support of the family in the patient-centered intensive care unit: American College of Critical Care Medicine Task Force (being submitted to journal) 12. Surviving Sepsis Campaign Adult – (nearing journal submission) 13. Clinical Practice Guidelines for the Management of Pain, Agitation, and Delirium in Adult Patients in the Intensive Care Unit - Early Mobility and Sleep (in revision) 14. Guidelines for the appropriate use of bedside general and cardiac ultrasonography by the intensivist in the evaluation of critically ill patients—Part II: cardiac ultrasonography (on SCCM website) 15. Management of critically ill patients with liver disease (in development) 16. Defining Potentially Inappropriate Treatment: A Policy Statement from the SCCM Ethics

Committee (pending journal publication)

17. Recommendations for the Diagnosis and Management of Corticosteroid Insufficiency in Critically Ill Adults Patients: Consensus Statements for International Task force by the ACCM – Revision 2013
18. Pediatric and Neonatal Analgesia and Sedation in the ICU (Peds Sedation)
19. Joint Guideline ATS/ESICM/SCCM Mechanical Ventilation Adult ARDS (nearing completion comment period)
20. Pediatric Surviving Sepsis Campaign (new starting)

Position statements:

Legislation:

SCCM does not support this function within the organizational scope of work.

Campaigns and related activities:

SCCM continues to lead and support the Surviving Sepsis Campaign and ICU Liberation Campaign.

Press activities:

Publications:

Critical Care Medicine

- *Metabolite Profiles in Sepsis: Developing Prognostic Tools Based on the Type of Infection*. Neugebauer, Sophie MSc; Giamarellos-Bourboulis, Evangelos J. MD; Pelekanou, Aimilia MD; Marioli, Androniki MD; Baziaka, Fotini MD; Tsangaris, Iraklis MD; Bauer, Michael MD; Kiehntopf, Michael MD April 2016.
- *Time for a Randomized Controlled Trial to Investigate Optimal Time to Antibiotics for Patients With Sepsis*. Alam, Nadia MD; Nanayakkara, Prabath W. B. MD, PhD, FRCP April 2016
- *Evaluating the Impact of Antibiotic Exposures as Time-Dependent Variables on the Acquisition of Carbapenem-Resistant Acinetobacter baumannii*. Munoz-Price, L. Silvia MD, PhD; Rosa, Rossana MD; Castro, Jose G. MD; Laowansiri, Panthipa MD; Latibeaudiere, Rachel DO; Namias, Nicholas MD; Tarima, Sergey PhD May 2016
  The Role of Aerolized Colistin in the Treatment of Hospital-Acquired Pneumonia: Experience of Multicenter From Turkey Korkmaz Ekren, Pervin; Toreyin, Nur; Sayiner, Abdullah; 44(5):e304, May 2016.

Pediatric Critical Care Medicine

- *Ventilator-Associated Respiratory Infections: Choosing Between Scylla and Charybdis** 17(4):361-363, April 2016.
- *Does the Site of Sampling and Type of Diagnostic Test for Viruses Matter in Suspected Acute Severe Viral Respiratory Infection?** Mathew, Joseph L.; Singhi, Sunit 17(4):359-361, April 2016.
- *Temporal Trends of Respiratory Syncytial Virus-Associated Hospital and ICU Admissions Across the United States.* Gupta, Punkaj; Beam, Brandon W.; Rettiganti, Mallikarjuna
- *Getting to "Zero" on Central-Line Infections in the PICU** Wheeler, Derek S. 17(7):692-693, July 2016.
- *The Association of Central-Line–Associated Bloodstream Infections With Central-Line Utilization Rate and Maintenance Bundle Compliance Among Types of PICUs** Affolter, Jeremy T.; Huskins, W. Charles; Moss, Michele; 17(7):591-597, July 2016.

Other items of note:

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)

Centers for Disease Control and Prevention

Meeting Date: July 14, 2016
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Liaison name: Mark Rupp, MD
Organization represented: Society for Healthcare Epidemiology of America

Interim activities and updates:

SHEA Spring 2016: Science Guiding Prevention

Under the leadership of Co-Chairs, Drs. Tom Talbot and Silvia Munoz-Price, the SHEA Spring 2016 conference was held on May 18 – 21st in Atlanta, GA with a record number of attendees; 881.
SHEA 2016 highlights include:

- Focused scientific abstracts related to healthcare epidemiology, surveillance, implementation science and patient safety, and prevention strategies
- Poster and oral abstract awards for diverse professional fields related to healthcare epidemiology for all career levels
- Cutting-edge healthcare-associated infection prevention and antibiotic stewardship education PLUS sessions on multi-disciplinary and integrated approaches involving implementation science and prevention across the healthcare continuum
- Three Training Courses
  - SHEA/CDC Training Certificate Course in Healthcare Epidemiology
  - SHEA/CDC/AMDA Infection Prevention in Post-Acute and Long Term Care Certificate Course
  - SHEA Antibiotic Stewardship Training Course *(**New for 2016**)*
    - Pharmacy Credit will be available for this course
- Nursing credit will be available for the entire conference
- Launch of the SHEA Mentorship Program *(**New for 2016**)*
- The Women in Epi Networking Evening Event
- 2nd Annual SHEA Education & Research Foundation Dinner

SHEA Spring 2017

Planning for SHEA 2017 has begun with our new Co-Chairs, Drs. Matthew Linam and Belinda Ostrowsky. This conference will be held in St. Louis, MO on March 29-31, 2017.

IDWeek 2016

Arjun Srinivasan, MD alongside the Vice Chair, Hilary Babcock, MD and SHEA committee representatives: Keith Kaye, MD, Louise Dembry, MD, Kavita Trivedi, MD and Ebbing Lautenbach, MD identified the sessions for Category N & S (2 additional IDWeek Planning Committee members) for IDWeek 2016. These categories will be represented with 1 Pre-Meeting Workshop, 7 MTPs, 2 Interactive Sessions, 11 Symposiums and 2 Mini Symposiums. Daniel Sexton, MD was selected for the SHEA Lectureship.

Primer on Healthcare Epidemiology, Infection Control and Antimicrobial Stewardship

SHEA launched its Online Primer on June 1, 2015. This online educational course offers any Infectious Diseases practitioner or Fellow an opportunity to learn the basics of healthcare epidemiology, infection prevention and antimicrobial stewardship. Written by experts from adult and pediatric healthcare epidemiology, case-based information is presented in a dynamic and interactive learning environment intended to highlight the role of the healthcare epidemiologist. With 12 modules and topics varying from pathogen transmission, outbreak management in the healthcare setting, approach to control of bioterrorism agents, advanced occupational health management,

implementing antimicrobial stewardship and the prevention and management of multidrug resistant organisms including *Clostridium difficile*, surgical site infections and device-associated infections, to name a few, this has been very well received by Fellows and Physicians in the field. 4 CME credits are available for this course. This is a product of the membership of the Society of Healthcare Epidemiology of America and is endorsed by the Infectious Diseases Society of America (IDSA) and Pediatric Infectious Diseases Society (PIDS).

- In mid-February, SHEA added MOC Points for this online course.
- To date: 392 Fellows/Allied Healthcare Professionals & 96 Physicians have taken this course. 21 Physicians have claimed MOC since February.

Podcast on Stewardship

In July, SHEA will begin developing 4 podcasts on Antibiotic Stewardship under the leadership of Dr. Waleed Javaid and other volunteer members from the Education and Stewardship Committee.

Guidelines and Guidance: Please include both in-progress and planned in the coming year. If you have a different format (e.g., information on a website) you don't have to list them here but could just include the link to the website.

Under goals of sustaining development and dissemination of expert guidelines addressing healthcare-associated infections and of championing effective stewardship:

The Guidelines Committee (GLC) is currently engaged in the following projects:

- Expert Guidance: Duration of Contact Precautions (Chairs Drs. Banach and Bearman)
  - Background being written
- Expert Guidance: Infection Prevention Practices in the Anesthesia Work Area (Chair Dr. Munoz-Price)
  - PICO-style questions and search terms being finalized
- Expert Guidance: Initiation of Antibiotics in Long-Term Care (Chair Dr. Christopher Crnich)
  - PICO-style questions and search terms being finalized
  - Document being written in two phases: non-localizing conditions and syndromes

Commitments over the next three years:

- Literature review update: Guideline on Management of Healthcare Workers Infected with HIV, HBV, HCV
- Companion to HICPAC NICU Guideline
- Infection Prevention in LTC, 2 Expert Guidance Documents (update to 2008 SHEA/APIC guideline)
- Sterilization and Disinfection, 3 Compendium chapters (update to 2008 CDC guideline)

Recent guidelines comments:

- IDSA Infectious Diarrhea
- ASGE Reprocessing Endoscopes
- AORN Hand Hygiene
- IDSA HAP/VAP

Legislation/Regulation:

SHEA collaborates with multiple organizations and multiple coalitions to advocate for public health funding. As of May, the following activities have been accomplished:

- Coalition for Health Funding-led sign on letter in support of top-line budget allocation for Labor-HHS Appropriations
- CDC Coalition-led sign on letter in support of public health funding to the House and Senate.

- IDSA-led sign on letter to the House and Senate in support of public health funding, with an emphasis on programs for combatting antibiotic resistance.
- Coalition for Health Funding-led sign on letter expressing concern about projected cuts to the top-line budget allocation for Labor-HHS Appropriations.
- Friends of AHRQ-led sign on letters to the House and Senate in support of the President's FY2017 funding request for AHRQ.
- S-FAR Hill Day to support public health funding; SHEA led a group of advocates for the event.
- SHEA-led joint Outside Witness Testimony submitted jointly with APIC to the House and Senate for funding requests of public health programs.
- APIC-led sign on letter in support of funding for the CDC's NHSN to the House and Senate.
- March of Dimes-led coalition sign on letter in support of an emergency supplemental funding bill in response to the pending U.S. Zika virus crisis.

Contaminated Heater-Cooler Units

SHEA is working with FDA, CDC and other stakeholders to explore ways to improve awareness of heater-cooler units contaminated with M. chimaera. Specifically, we are looking for ways to encourage hospital surgical departments to conduct retrospective reviews of patients who may have been exposed to contaminated units during surgical procedures. SHEA continues to explore a policy initiative in support of additional funding for FDA to improve surveillance of medical devices that could potentially expose patients to infections due to inherent design flaws.

Medicare Condition of Participation – Antibiotic Stewardship, Infection Control

SHEA is preparing comments in response to CMS' proposed revision the hospital and critical access hospitals' Medicare Conditions for Participation. Of particular interest are the revisions to the existing infection control condition of participation and the proposed new section on antibiotic stewardship programs. SHEA is working collaboratively with a number of stakeholders to ensure our message of support for these proposed changes are aligned.

FY 2017 IPPS Proposed Rule: About the NHSN Antimicrobial Use Module Provision

SHEA's Public Policy and Government Affairs and Antimicrobial Stewardship Committees to CMS' request for public feedback on a proposal to include hospitals' antibiotic prescribing data in the CMS Hospital Inpatient Quality Reporting (IQR) Program published in the April 27 *Federal Register,* FY 2017 Inpatient Prospective Payment System (IPPS) and related policies. Of particular interest to SHEA is whether CMS should require hospitals to submit their antimicrobial use information to the agency through CDC's National Healthcare Safety Network (NHSN) Antimicrobial Use module. In comments SHEA expressed support for a future mandate, but provided recommendations on what programmatic changes needed to be made before requiring stakeholders to report:

1. CMS must ensure readiness and reliability of electronic health record systems, and must do so through stakeholder and vendor engagement;
2. The data and measure must be properly risk adjusted so that some hospitals are not unfairly penalized because of their patient populations;
3. There must be sufficient time to transition between pay-for-reporting to pay-for-performance.

President's Request for Information on Combating Antibiotic Resistant Bacteria

The Presidential Advisory Council on Combating Antibiotic Resistant Bacteria (PACCARB) solicited public comment on efforts and strategies to combat antibiotic-resistance as part of the National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB) initiative. The Advisory Council posed 5 key questions regarding antibiotic stewardship and infection prevention and control in both humans and animals, domestically and globally. SHEA submitted comments aligned with its commitment to the CARB initiative.

SHEA Convening LTPAC Stakeholders

SHEA's board of directors has commissioned a task force to evaluate how SHEA's programmatic

domains incorporate issues unique to the long-term post-acute care setting. The task force will also make recommendations on how best to address long-term post-acute care issues in each domain.

Expansion of the SHEA Grassroots Network

SHEA's Grassroots Network now includes 120 advocates. To date there have been three calls to action. A dedicated online community will be rolled out in the coming weeks.

Campaigns and related activities:

SHEA Awards

Press activities:

Below is a list of press releases that SHEA has released in the past few months. To read the complete text of any of the releases, visit the SHEA website.

- Central Line Infection Prevention Bundles Reduce Number of Deadly Infections in Newborns - June 13, 2016
- New Legionella Toolkit Puts Patients First - June 07, 2016
- New Antibiotic Stewardship Guidelines Focus On Practical Advice For Implementation - April 15, 2016
- Six-Step Hand-Washing Technique Found Most Effective for Reducing Bacteria - April 08, 2016
- SHEA Applauds Recommendations of Presidential Advisory Council on Combatting Antibiotic-Resistant Bacteria - March 31, 2016
- SHEA Announces Newest Delegation of the International Ambassador Program - March 28, 2016
- Effective Antibiotic Controls Needed to Combat Growing Threat of Antibiotic-Resistant Bacteria - March 03, 2016
- Antibiotic Stewardship Practices Widely Implemented in VA Healthcare System - February 24, 2016

SHEA continues to collaborate with Medscape submitting expert commentaries and contributing select articles from Infection Control and Hospital Epidemiology.

SHEA also has an active and growing social media presence which you can follow:
LinkedIn – The Society for Healthcare Epidemiology Group
Twitter: @SHEA_Epi
Facebook: www.facebook.com/SHEAPreventingHAIs

Publications:

SHEA Website

The SHEA Website needed to be updated with a recent upgrade to our membership database. All of the links on the page and SHEA member logins have changed. Visit the SHEA Website to reset your password. Anyone can email kweinshel@shea-online.org if they need assistance updating links they may have referencing the SHEA site.

SHEA Spotlight

The SHEA Spotlight is our weekly advertising supported newsletter that is outsourced to Multiview. We continue to see ad growth that is not related to Journal advertising and our open rate continues to stay strong. If you are interested in subscribing, please contact kweinshel@shea-online.org.

Other items of note:

Research

SHEA Annual Epi Project Competition Review

SHEA's Research Committee is on track to reintroduce the annual Epi Project Competition, which will be presented at the 2017 SHEA Spring Conference. The competition is held each year at the SHEA Spring Conference and invites ID fellows to submit research proposals. The proposals are judged by a panel of SHEA members and the winning submitter receives an award of up to $20,000.

Methodologies Paper Series
The Research Committee published a series of manuscripts on practical approaches to research focused on infection prevention, healthcare epidemiology, and antibiotic stewardship subjects. The purpose of the series is to educate the infection prevention community on research methodology as it relates to healthcare epidemiology research projects. The series are a succinct, quick reference for state-of-the-art research methods in the field.

SHEA Research Network (SRN)
Top responding institutions for the SRN have been recognized as "SRN Elite" and "SRN Active."
Open projects:

- SHEA Expert Guidance: Duration of Contact Precautions in Acute Care Settings

In queue:

- Legal Issues in Antibiotic Stewardship

Recently completed:

- Activities of the World Health Organization (WHO) against antimicrobial resistance (AMR)
- Evaluating current infection prevention practices in the cardiac electrophysiology laboratory
- Knowledge and information sharing for emerging infectious diseases 2015 SHEA Epi Project: Evaluating Current Practices to Optimize Surface Disinfection
- Hand Hygiene Irritation (industry funded)
- Antimicrobial Stewardship in SRN Hospitals
- Defining Healthcare-Acquired Influenza (NOSOFlu)

Liaison Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: July 14-15, 2016
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Liaison name: Jennifer Meddings
Organization represented: Society of Hospital Medicine

Interim activities and updates:
The Society of Hospital Medicine (SHM) has developed an antimicrobial stewardship mentored implementation program that will launch late this year. As part of the program, SHM is developing an implementation guide. SHM will begin recruitment for this program by the end of the calendar year.
Guidelines and Guidance: Please include both in-progress and planned in the coming year. If you have a different format (e.g., information on a website) you don't have to list them here but could just include the link to the website.
Position statements:
Legislation:
Campaigns and related activities:
SHM will participate in the CDC's Get Smart Campaign in November with our "Fight the Resistance" campaign.
Press activities:
SHM continues to support antimicrobial stewardship through its Fight the Resistance campaign and resources, and still collecting case studies related to the recommendations/campaign.
Publications:
Other items of note:

Liaison Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: July 14-15, 2016
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Liaison name: Robert G. Sawyer, MD
Organization represented: Surgical Infection Society (SIS). Website: www.sisna.org

Interim activities and updates:

- The annual Surgical Infection Society meeting took place from May 19-21 in Palm Beach, FL. 48 oral presentations and 44 poster presentations were given, as well as several focused symposia. A major theme of the meeting was the microbiome and its relationship to surgical diseases. The keynote Altemeier lecture was given by Professor Jack Gilbert from the University of Chicago, entitled "The Microbiome in Surgery." The searchable program can be found online.
- A new electronic journal *Surgical Infections: Case Reports* has been launched by Mary Ann Liebert as a companion journal to *Surgical Infections*, the official journal of the SIS.

Guidelines and Guidance: Please include both in-progress and planned in the coming year. If you have a different format (e.g., information on a website) you don't have to list them here but could just include the link to the website.

Guidelines in process

The members of the Guidelines and Therapeutics Committee are conducting the following systematic reviews:

1. Antibiotics for facial trauma
   a. December 2015: manuscript submitted to *Surgical Infections*
2. Revision of 2010 Guidelines for the management of intra-abdominal infections
   a. August 2015 Review literature
   b. November 2015 Complete analysis
   c. March 2016 Submit manuscript
   d. July 2016 Manuscript under review
3. Guidelines for the management of acute appendicitis
   a. May 2016 Review literature
   b. August 2016 Complete analysis
   c. November 2016 Submit manuscript
4. Guidelines for the management of the open abdomen
   a. Spring 2016 Review literature
   b. Summer 2016 Complete analysis
   c. Fall 2016 Submit manuscript
5. Guidelines for the management of necrotizing soft tissue infections
   a. April 2016 Review literature
   b. July 2016 Complete analysis
   c. October 2016 Submit manuscript

Position statements:

Legislation:

Campaigns and related activities:

Press activities:

Recent Publications:

Reviews

Antimicrobial Bowel Preparation for Elective Colon Surgery Full Access
Donald E. Fry
Surgical Infections. May 2016, 17(3): 269-274.

Antimicrobial Formulation and Delivery in the Prevention of Surgical Site Infection Full Access
Patrick B. O'Neal, Kamal M.F. Itani
Surgical Infections. May 2016, 17(3): 275-285.

Biology and Metabolism of Sepsis: Innate Immunity, Bioenergetics, and Autophagy Full Access
Anthony J. Lewis, Timothy R. Billiar, Matthew R. Rosengart
Surgical Infections. May 2016, 17(3): 286-293.

Beyond Blood Culture and Gram Stain Analysis: A Review of Molecular Techniques for the Early Detection of Bacteremia in Surgical Patients Full Access
Michelle H. Scerbo, Heidi B. Kaplan, Anahita Dua, Douglas B. Litwin, Catherine G. Ambrose, Laura J. Moore, COL Clinton K. Murray, Charles E. Wade, John B. Holcomb
Surgical Infections. May 2016, 17(3): 294-302.

The Significance and Challenges of Monocyte Impairment: For the Ill Patient and the Surgeon Full Access
Norman Galbraith, Samuel Walker, Susan Galandiuk, Sarah Gardner, Hiram C. Polk Jr.
Surgical Infections. May 2016, 17(3): 303-312.

Other items of note:

As previously noted, the SIS and CDC with the help of multiple personnel associated with HICPAC (Mike Bell, Jeff Hageman, Dan Pollock, and Joe Sharma) continue to work together to work on a possible joint venture centered on the development of an appropriate curriculum/training paradigm for hospital quality officers who need to be well-versed in the field of surgery-related HAIs. Part of this effort is the definition of the role of remote image capture in the diagnosis of surgical site infections in a cost efficient manner. This group will be meeting 7/14/16 for further discussions.

Liaison Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: July 14th and July 15th, 2016
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Liaison name: Kathryn Spates
Organization represented: The Joint Commission

Interim activities and updates:
• On July 1, 2016, The Joint Commission announced a new Antimicrobial Stewardship Standard for hospitals, critical access hospitals, and nursing care centers. The standard becomes effective January 1, 2017. • The Joint Commission is working with CDC to develop antimicrobial stewardship standard for ambulatory settings. • HICPAC Endoscope Workgroup Meetings (bi-monthly and on-going): Workgroup activities include the development of an *Essential Elements with Toolkit document* (specific to endoscopes) to be presented to HICPAC.
Guidelines and Guidance: Please include both in-progress and planned in the coming year. If you have a different format (e.g., information on a website) you don't have to list them here but could just include the link to the website.
Position statements:
Legislation:
Campaigns and related activities:
Participated in National Quality Forum's Antibiotic Stewardship in Acute Care Practical Playbook launch and follow-up meetings.
Press activities:
Publications:
New Antimicrobial Stewardship Standard was published in The Joint Commission's Perspectives July customer newsletter.
Other items of note: