

**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
March 31, 2016
Atlanta, Georgia

Record of the Proceedings

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Meeting Agenda

Healthcare Infection Control Practices Advisory Committee

March 31, 2016

Centers for Disease Control and Prevention

Tom Harkin Global Communications Center (Building 19, Auditorium 3)

1600 Clifton Road NE, Atlanta, GA

Thursday, March 31, 2016

Time	Topic	Purpose	Presider/Presenter
9:00	Welcome and Introductions	Information	Dan Diekema (HICPAC Co-Chair) Deborah Yokoe (HICPAC Co-Chair) Jeff Hageman (HICPAC DFO)
9:15	CDC Updates: Division of Healthcare Quality Promotion (DHQP)	Information	Denise Cardo (DHQP, CDC)
9:45	FDA Device Updates: Flexible Endoscopes and Heater Coolers	Information Discussion	Suzanne Schwartz (FDA) Catherine Wentz (FDA)
10:35	Break		
10:55	Update on HICPAC Workgroup: Endoscope Reprocessing	Information Discussion	Lisa Maragakis (HICPAC)
11:45	Device Considerations	Information Discussion	Michael Bell (DHQP, CDC) Shannon Keckler (DHQP, CDC)
12:30	Lunch		
1:45	FDA PPE Update: Gowns	Information	Terrell Cunningham (FDA)
2:00	Update on HICPAC Workgroup: Antimicrobial Stewardship Principles for Treatment Guidelines	Information Discussion	Jan Patterson (HICPAC)
2:50	Chlorhexidine-Impregnated Dressing Recommendation Update	Information Discussion	Erin Stone (DHQP, CDC) Tom Talbot (HICPAC)
3:40	Break		
4:00	Update on the Draft Guideline for Infection Prevention in Healthcare Personnel	Information Discussion	David Kuhar (DHQP, CDC) Katy Irwin (DHQP, CDC)
5:00	Public Comment		
5:15	Liaison/ <i>ex officio</i> reports		
5:30	Summary and Work Plan		
6:00	Adjourn		

List of Participants

March 31, 2016

HICPAC Members

Dr. Daniel Diekema, Co-Chair
Dr. Deborah Yokoe, Co-Chair
Dr. Hilary Babcock
Ms. Vickie Brown
Ms. Loretta Fauerbach
Dr. Michael Howell
Dr. W. Charles Huskins
Ms. Lynn Janssen
Dr. Lisa Maragakis
Dr. Jan Patterson
Dr. Tom Talbot

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

Mr. Michael McElroy (America's Essential Hospitals (AEH))
Dr. Elizabeth Wick (American College of Surgeons (ACS))
Ms. Amber Wood (Association of periOperative Registered Nurses (AORN))
Ms. Michael Anne Preas (Association of Professionals of Infection Control and Epidemiology (APIC))
Dr. Emily Lutterloh (Association of State and Territorial Health Officials (ASTHO))
Ms. Marion Kainer (Council of State and Territorial Epidemiologists (CSTE))
Dr. Stephen Weber (Infectious Diseases Society of America (IDSA))
Dr. Sarah Matthews (National Association of County and City Health Officials (NACCHO))
Ms. Laurie O'Neil (Public Health Agency of Canada (PHAC))
Dr. Craig Coopersmith (Society for Critical Care Medicine (SCCM))
Dr. Mark Rupp (Society for Healthcare Epidemiology of America (SHEA))

Dr. Vineet Chopra (Society of Hospital Medicine (SHM))
Dr. Robert Sawyer (Surgical Infection Society (SIS))
Ms. Margaret VanAmringe (The Joint Commission)

FDA Representatives

Mr. Terrell Cunningham, FDA/ CDRH
Dr. Catherine Gaylord, FDA
Ms. Julia Marders, FDA/ CDRH
Ms. Elaine Mayhall, FDA/ CDRH
Dr. Kapil Panguluri, FDA/ CDRH
Dr. Suzanne Schwartz, FDA/ CDRM

CDC Representatives

Ms. Jessica Adam, CDC/ DHQP
Ms. Denise Albina, CDC/ DHQP
Ms. Kathy Allen-Bridson, CDC/ DHQP
Dr. Matt Arduino, CDC/ DHQP
Ms. Sonya Arundar, CDC/ DHQP
Dr. Michael Bell, CDC/ DHQP
Ms. Ruth Bellflower, CDC/ DHQP
Ms. Kathy Bruss, CDC/ DHQP
Ms. Katy Capers, CDC/ DHQP
Dr. Denise Cardo, CDC/DHQP
Dr. Matthew Crist, CDC/ DHQP
Dr. Bryan Christiansen, CDC/ DHQP
Ms. Noline Collins, CDC/ DHQP
Ms. Katelyn Coutts, CDC/ DHQP
Ms. Mahnaz Dasti, CDC/ DHQP
Dr. Chad Dowell, CDC/NIOSH
Dr. Ryan Fagan, CDC/ DHQP
Dr. Scott Fridkin, CDC/ DHQP
Ms. Nancy Gallagher, CDC/DHQP
Ms. Janet Glowicz, CDC/ DHQP
Dr. Carolyn Gould, CDC/ DHQP
Ms. Pam Greene, CDC/ DHQP
Dr. Nicole Gualandi, CDC/ DHQP
Mr. Taylor Guffey, CDC/ DHQP
Ms. Stephanie Gumbis, CDC/ DHQP
Mr. Jeff Hageman, CDC/ DHQP
Dr. Lauri Hicks, CDC/ DHQP
Dr. Kathleen Irwin, CDC/ DHQP
Mr. Brendan Jackson, CDC/ NCEZID/ DFWED/ MDB
Dr. John Jernigan, CDC/ DHQP
Dr. Mary Shannon Keckler, CDC/ DHQP
Dr. David Kuhar, CDC/ DHQP
Dr. Jason Lake, CDC/ DHQP
Dr. Brandi Limbago, CDC/ DHQP
Dr. Meghan Lyman, CDC/ DHQP
Dr. Cliff MacDonald, CDC/ DHQP

Dr. Rajal Mody, CDC/ NCEZID/ DFWED/ MDB
Ms. Shunte Moon, CDC/ DHQP
Ms. Kerri Moran, CDC/ DHQP
Ms. Heather Moulton-Meissner, CDC/ DHQP
Dr. Duc Nguyen, CDC/ DHQP
Dr. Judith Noble-Wang, CDC/ DHQP
Ms. Amibola Ogundimu, CDC/ DHQP
Ms. Amanda Overholt, CDC/ DHQP
Ms. Danielle Palms, CDC/ DHQP
Ms. Kaeanne Parris, CDC/ DHQP
Dr. Priti Patel, CDC/ DHQP
Dr. Kiran Perkins, CDC/ DHQP
Dr. Joe Perz, CDC/ DHQP
Ms. Ruby Phelps, CDC/ DHQP
Dr. Daniel Pollock, CDC/ DHQP
Ms. Jan Ratterreee, CDC/ DHQP
Ms. Meredith Reagan, CDC/ DHQP
Ms. Cathy Rebmann, CDC/ DHQP
Dr. Sujun Reddy, CDC/ DHQP
Ms. Kristin Roberts, CDC/ DHQP
Ms. Georgeanne Ryan, CDC/ DHQP
Dr. Melissa Schaefer, CDC/ DHQP
Dr. Issac See, CDC/ DHQP
Dr. Lynne Sehulster, CDC/ DHQP
Ms. Kathy Sieber, CDC/ DHQP
Dr. Arjun Srinivasan, CDC/ DHQP
Ms. Erin Stone, CDC/ DHQP
Dr. Nicola Thompson, CDC/ DHQP
Ms. Abbigail Tumpsey, CDC/ DHQP
Dr. Snigdha Vallabhaneni, CDC/ NCEZID/
DFWED/ MDB
Ms. Wendy Vance, CDC/ DHQP
Ms. Ellen Wan, CDC/ DHQP
Dr. J. Todd Weber, CDC/ DHQP
Dr. Carrie Whitworth, CDC/ DHQP
Ms. Sarah Wiley, CDC/ OID
Ms. Sarah Yi, CDC/ DHQP

Members of the Public

Dr. Jim Arbogast, Gojo
Ms. Kay Argroves, American Association of
Nurse Anesthetists
Mr. Nick Austerman, Bard Medical
Mr. Steve Brash, HCA Hospitals, Richmond.
Ms. Nicole Bryan, CSTE
Dr. Russ Castioni, 3M
Ms. Kendra Cox, Cambridge Communications,
Training, & Assessments
Ms. Pamela Falk, Northside Hospital
Mr. Hudson Garrett, PDI
Ms. Maryellen Guinan, America's Essential
Hospitals
Ms. Amna Handley, GA Pacific
Ms. Lori Harmon, Society of Critical Care
Medicine
Ms. Linda Homan, Ecolab
Ms. Eve Humphries, Society of Healthcare
Epidemiologists of America
Dr. Jesse Jacob, Emory University
Mr. Robert Jones, Goldshield/ Energy and
Environmental
Dr. Jason Kane, Society of Critical Care
Medicine
MS. Rachel Long, BD
Dr. Peter Nichol, Medline Industries, Inc.
Ms. Renee Odehnal, Ethicon
Mr. Pat Parks, 3M
Ms. Silvia Quevedo, Association of
Professionals in Infection Control
Ms. Maria Rodriguez, Xenex
Dr. Michelle Stevens, 3M
Ms. Rachel Stricof, Council of State and
Territorial Epidemiologists
Ms. Lisa Tomlinson, APIC
Ms. Kathy Warye, Infection Prevention Partners

Executive Summary

The Division of Healthcare Quality Promotion (DHQP), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC), US Department of Health and Human Services (HHS) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on March 31, 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 9:07 a.m. on March 31, 2016. Dr. Denise Cardo provided updates from DHQP, particularly focusing on antimicrobial resistance (AMR). Dr. Suzanne Schwartz and Ms. Catherine Wentz, US Food and Drug Administration (FDA), shared updates on FDA's ongoing efforts regarding the public health concern of Nontuberculous *Mycobacterium* (NTM) infections associated with heater-cooler devices and efforts pertaining to duodenoscope reprocessing and instructions. HICPAC member Dr. Lisa Maragakis led a discussion on the progress of the HICPAC workgroup on Endoscope Reprocessing, which is drafting and revising an Essential Elements document to provide assistance to institutions that have endoscope reprocessing programs. Drs. Michael Bell and M. Shannon Keckler presented outlines for documents to describe device considerations for healthcare facility purchasing departments. Mr. Terrell Cunningham, FDA, briefed HICPAC on the current status of FDA's review and regulation of surgical/isolation gowns. HICPAC member Dr. Jan Patterson presented the progress of the HICPAC Antibiotic Stewardship Workgroup on antibiotic guidelines. Ms. Erin Stone and Dr. Tom Talbot, HICPAC member, presented updated data and an updated draft recommendation regarding Chlorhexidine Gluconate-Impregnated (CGI) Dressings for Intravascular Catheter Exit Sites. Drs. David Kuhar and Kathleen Irwin described progress on an update to the 1998 *Guideline for Infection Control in Healthcare Personnel*. There was a public comment period. HICPAC *ex officio* members and liaison representatives provided written and verbal updates.

HICPAC stood in recess at 5:23 p.m. on March 31, 2016. The next HICPAC meeting will be held on July 14-15, 2016, in Atlanta, Georgia.

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

Healthcare Infection Control Practices Advisory Committee (HICPAC)

March 31, 2016
Atlanta, Georgia

DRAFT Minutes of the Meeting

The Division of Healthcare Quality Promotion (DHQP), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC), US Department of Health and Human Services (HHS) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on March 31, 2016, at the Tom Harkin Global Communications Center at the Centers for Disease Control and Prevention, 1600 Clifton Road NE, Atlanta, Georgia.

Thursday, March 31, 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 9:07 a.m. He welcomed HICPAC members, *ex officio* members, and liaison representatives. He noted the following changes to HICPAC membership:

- Dr. Michael Howell, the former HICPAC liaison representative from the Society of Critical Care Medicine (SCCM), has rotated onto HICPAC as a member.
- Ms. Loretta Fauerbach is a new HICPAC member.
- Dr. Deborah Yokoe is serving as co-chair of HICPAC with Dr. Daniel Diekema.
- Mr. Hageman conducted a roll call. A quorum was present. HICPAC members disclosed the following conflicts of interest:
 - Dr. Diekema has received research funding from bioMérieux.
 - Dr. Jan Patterson's spouse conducted research in fungal disease and has served as a consultant to, or conducted research with, Merck, Astellas Pharma, and Toyama Chemical Company.
 - Dr. W. Charles Huskins has received research support from GOJO Industries and has served as an advisory board member for Genentech.
 - Dr. Thomas Talbot's spouse is a vaccine researcher who has received funding from Sanofi Pasteur, MedImmune, Gilead Sciences, and Novartis.
 - Dr. Lisa Maragakis receives research funding from Clorox/UltraViolet Devices, Inc. (UVDI) for studies of ultraviolet (UV) light.

- Ms. Lynn Janssen's spouse works for a biotech company developing vaccines and immunologics.

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 welcomed HICPAC and provided updates on CDC's plans regarding antimicrobial resistance (AMR) and the funds allocated for CDC in the fiscal year (FY) 2016 budget related to antibiotic resistance (AR). The budget initiative is an example of how evidence can lead to policy, and then to a budget initiative with opportunities to expand programs that are already being implemented.

Vital Signs is a monthly publication with CDC's *Morbidity and Mortality Weekly Report (MMWR)*. Each of CDC's "Winnable Battles" is featured in an issue of *Vital Signs* in a specific month. Healthcare-associated infections (HAIs), which include AMR, were featured in March. DHQP uses the *Vital Signs* mechanism to make a case for infection prevention and for the importance of engaging a range of different groups in making a difference in the problem of HAIs.

- The first *Vital Signs* on HAIs focused on successes in preventing central line-associated bloodstream infection (CLABSI) and on the lives that were saved. The issue also called for more action to continue to work on prevention.
- The next issue highlighted *Clostridium difficile (C. diff)* infections and their relation not only to infection control but also to antibiotic use.
- The topic of the third *Vital Signs* was emergence of carbapenem-resistant *Enterobacteriaceae (CRE)*, an issue that was well-known to experts but may not have been perceived by the broader healthcare community or public as an emerging threat.
- After presenting a series of HAI-related problems, the next *Vital Signs* presented a solution: promoting stewardship programs. This publication represented the first time that CDC clearly recommended antibiotic stewardship programs for all hospitals. DHQP worked closely with the American Hospital Association (AHA) and other partners to ensure that the publication was not isolated, but served to add CDC's voice to other partners' voices to facilitate implementation of stewardship programs.
- The next *Vital Signs* related to a coordinated approach to prevention, particularly the importance of working not only within but also across healthcare facilities to prevent the transmission of multidrug-resistant organisms (MDROs) and *C. diff*.

The most recent *Vital Signs* focused on integrating information from previous *Vital Signs* issues. The solutions proposed in the prior issues focused on programs and administrative strategies. This issue focused on resistant bacteria as a cause of HAIs. The publication described progress related to HAIs, but also noted that a large percentage of infections in healthcare are caused by resistant pathogens. The solutions require improvements in both horizontal strategies that are important for preventing a range of HAIs as well as vertical strategies aimed at preventing transmission of specific AR pathogens. This *Vital Signs* was aimed at informing the broad healthcare community beyond just infection control experts, , the general public, and policymakers.

Because the overall burden of AR needed to be defined, DHQP used available data to create the [“AR Threat Report.”](#) The report clarifies that the numbers are not precise and are a low estimate of the number of infections. The report was critical to highlight the magnitude of the AR problem for different groups, such as policymakers, and to engage them to be part of the solution. The solution involves not only the creation of new antibiotics. In addition, the report presented a framework for preventing infections, preventing the spread of infections, tracking infections, improving antibiotic use, and developing new drugs and new diagnostics.

DHQP works closely with federal partners and partner professional groups. The President’s Advisory Committee on Antimicrobial Resistance, which included public health and healthcare experts as well as other participants, created the [National Action Plan for Combating Antibiotic Resistant Bacteria \(CARB\)](#). The plan has five specific goals:

- Slow the emergence of resistant bacteria and prevent the spread of resistant infections
- Strengthen national one-health surveillance efforts to combat resistance
- Advance development and use of rapid and innovative diagnostic tests for identification and characterization of resistant bacteria
- Accelerate research to develop new antibiotics and alternative therapeutics and vaccines
- Improve international collaboration and capacities for disease prevention and surveillance and antibiotic research and development

CARB also has specific goals for reducing and preventing infections in the next five years. Monitoring progress toward these goals is important and helps to provide insight if certain goals are not being met. CDC’s role in CARB is to:

- Detect and respond to resistant pathogens
- Prevent the spread of resistant infections
- Encourage innovation for new strategies

CDC developed the [AR Solutions Initiative](#) and requested \$264 million to address the agency’s goals related to AR. CDC’s appropriation in FY ’16 was \$160 million which represents a significant increase over previous years. The FY ’17 budget includes an additional \$40 million for CDC to expand its programs further. It is important to note that the funding is not for new programs but instead will be used to expand existing programs that are making a difference. CDC’s overall approach incorporates urgent threats such as CRE, *C. diff*, and *Neisseria gonorrhoeae*, as well as strategies for serious infections such as Methicillin-resistant *Staphylococcus aureus* (MRSA) and other MDROs.

Regarding “detect and respond,” CDC’s approach includes laboratory as well as public health activities, and the response includes identification as well as containment of infections. “Prevent” focuses on a coordinated approach, and “innovate” includes new diagnostics and new ways to prevent HAIs.

The budget will support expansion of funding to state and local health departments. The Recovery Act allowed for the creation of HAI programs in state Health Departments, and they will continue to be funded through the Prevention Fund of the Patient Protection and Affordable Care Act (ACA). The support can be expanded to address AR. States will be eligible to receive

funding for more expertise in analyzing data and in responding to resistance issues at the state and local levels. State laboratories in all 50 states will be eligible to receive funding to improve capacity to detect CRE. Further, up to 25 states will receive additional funds to focus on prevention strategies with a coordinated approach. Data from the Prevention Epicenters show that if healthcare systems and facilities do not work together, then it is difficult to prevent HAIs. This work will take place with a network of facilities and expert groups and will be evaluated for its impact.

The laboratory network will also be expanded. Up to seven regional laboratories in the PulseNet regions will be funded to build capacity to address resistant pathogens. The work varies by pathogen and includes identifying mechanisms of resistance, as well as responding to outbreak events, implementing containment strategies, and screening patients. This support cannot be provided by hospitals or health departments; therefore, the regional laboratories will be funded to provide those services. The laboratories will work closely with academic centers and clinical laboratories on specific projects that respond to trends and problems.

The HAI Emerging Infections Program (EIP) also will expand to include more pathogens, including more multidrug resistant (MDR) gram-negatives. Additional settings will be included. For instance, work on MRSA work will expand to include community as well as healthcare settings. Plans for the future will incorporate assessments of extended spectrum beta-lactamases (ESBLs) and urinary tract infections (UTIs) in the community and their potential impact on healthcare. Pilots will be conducted in these areas before adding the work to the entire EIP. Annual prevalence surveys will continue not only in acute care, but also in long-term care. The HAI EIP will also work on sepsis. The EIP can add to understanding of risk factors and prevention strategies.

Innovation is critical for HAI prevention. Academic partners are vital to innovation. The Prevention Epicenters and other mechanisms provide opportunities to fund academic groups and healthcare systems to improve antibiotic use. Social networking tools will help implement coordinated approaches to stop the spread of AR. Other initiatives include improving sepsis recognition and early detection, particularly in partnership with SCCM and other partners. Electronic health records (EHRs) are potentially important tools to define appropriate use, and the healthcare environment can also play a critical role in the transmission and prevention of infections. The human microbiome is another innovative area for exploration.

The isolates housed at CDC can help industry and academic partners to develop new diagnostic tools, treatment tools, and vaccines. With the US Food and Drug Administration (FDA), the [AR Isolate Bank](#) has been developed. The US Department of Defense (DoD) also has a large collection of isolates, but the FDA-CDC bank is targeted for unique resistance that industry and academic partners can use. The bank has approximately 260 isolates.

Regarding implementing antibiotic stewardship programs and practices, new diagnostic tools are an important means for better detection of infections, improving use of antibiotics, and adding to knowledge regarding sepsis. CDC considers the entire spectrum of care to protect patients from infections, including HAIs, sepsis, and viral infections. Several healthcare systems receive CDC funding to implement strategies to improve use and improve outcomes. The systems are encouraged to use the antibiotic use ([AU](#)) module of the National Healthcare Safety Network (NHSN). In outpatient settings, stewardship work incorporates using the data and working with partners to implement concrete interventions. Stewardship efforts are just beginning in long-term care, but CDC is already working with partners to determine how best to

move forward with programs as well as concrete strategies to improve antibiotic use in those settings. CDC is funding healthcare systems, health departments, academic groups, and professional and public health organizations in these areas.

The concept of antibiotic stewardship also incorporates sepsis. The two issues have been perceived as contrary, but they should be messaged together. CDC is considering not only how to improve antibiotic use but also how to better detect infections and create strategies for reassessing antibiotic use. Education is important for patients, especially in the outpatient settings. It is also important for clinicians and a range of different groups to improve use.

CDC is building upon opportunities to work with different groups on the early detection and management of sepsis. Some professional organizations and groups have been working to improve antibiotic use and others have been working on early detection of sepsis. The work of these two groups may not have been optimally integrated in the past. There are opportunities to work on these issues holistically and to help patients. CDC is launching an educational campaign that unifies the messages of sepsis and appropriate antibiotic use:

- “Think sepsis”
- Collect laboratory cultures
- Encourage clinicians to “act fast”
- Encourage clinicians to reassess the need for a specific antibiotic, or for any antibiotic, 48-72 hours later
- Prevent future infections: if infections are prevented, there will be no sepsis

Based on the gaps identified by partners, the campaign considers the entire cycle. CDC and DHQP are conducting more activities related to sepsis, including the following:

- Better understand the epidemiology of the patient and the risk factors that can lead to better prevention, sometimes primary prevention
- Track sepsis infections for prevention activities to determine the impact of successful interventions
- Promote prevention, early recognition, and use of effective and appropriate antibiotics
- Work with various groups to conduct and refine campaigns, building on opportunities to help partners work together with facilities to implement infection prevention and stewardship activities

Discussion Points

There may be state-to-state and region-to-region variation in existing capacity. As CDC moves resources out, individual states’ ability to utilize the funding most effectively or to increase capacity may need to be assessed. For instance, the Targeted Assessment for Prevention (TAP) reports from NHSN focus on the most quickly and easily achievable goals that require limited effort and resources for preventing infections in hospitals. Nationally, it may be important to focus on geographic areas that are in most need of additional resources.

Dr. Cardo agreed that capacity varies by state. A group in DHQP is assessing state programs not only in terms of whether they prevent infections but also regarding the infrastructure that is needed to do the work. The health departments should work with academic centers in order not

to duplicate efforts and to leverage synergies. States can apply for direct assistance in making these connections and building capacity in prevention, detection, and response.

The overall program has aggressive targets. HICPAC asked about metrics. Some MDROs in institutions are real infections, while some results are related to testing behaviors and the type and sensitivity of diagnostics that laboratories use. The problem can be addressed with prevention and education of clinicians regarding appropriate testing.

Dr. Cardo said that the metrics for the budget initiative should be aggressive. Payment metrics are different. DHQP is setting goals for the national initiative to help assess where progress is being made and why targets are not being met. The evaluation will help to assess whether absence of progress around *C. diff.*, for example, reflects deficiencies around antimicrobial stewardship or increasing community transmission. Specific metrics for states may be developed at a later time.

FDA Device Updates: Flexible Endoscopes and Heater Coolers

Suzanne Schwartz, MD, MBA
Catherine Wentz, MS
Center for Devices and Radiological Health
US Food and Drug Administration

Dr. Suzanne Schwartz and Ms. Catherine Wentz updated HICPAC on FDA's ongoing efforts regarding the public health concern of Nontuberculous *Mycobacterium* (NTM) infections associated with heater-cooler devices. An FDA advisory committee meeting on this topic will be convened on June 2-3, 2016. They also updated HICPAC on FDA's work regarding flexible endoscopes. FDA welcomes HICPAC's input and advice regarding its multi-pronged approaches to these problems.

Dr. Schwartz explained that in May and June of 2015, based on early signals observed in Europe, CDC and its European counterpart reached out to FDA regarding a potential association between heater-cooler devices and NTM infections in patients who had undergone cardiac surgery. Reports to FDA regarding heater-cooler devices are classified into two areas: 1) patient infections, and 2) device contamination.

FDA receives user facility reports, voluntary reports, and manufacturer-submitted reports. When a safety notice is issued by FDA or its regulatory partners outside of the US, it is typical for reporting to increase due to increased awareness. Without this awareness in the healthcare provider community, FDA is handicapped by limited information, which in turn inhibits the agency's ability to ascertain the breadth and scope of the concern and to enact a timely investigation and response. FDA relies on the help of HICPAC and its partners, including professional societies based in hospitals, to raise the level of awareness to yield a fuller picture of a concern. FDA's approach to this investigation is broad. The investigation includes all heater-cooler devices that are regulated for use in cardiac surgery and is not focused solely on a single manufacturer's product.

Ms. Catherine Wentz is an engineer in FDA's Division of Cardiovascular Devices, which reviews heater-cooler devices and clears them for market. She described heater-cooler devices, which provide heated and/or cooled water to heat exchange devices for oxygenators and for cardioplegia heat exchanges. These devices can also provide temperature-controlled water to

heating and cooling blankets. The devices are FDA Class II and are cleared under two regulations:

- Thermoregulating devices, which include blankets
- Cardiopulmonary bypass temperature control devices, which feed temperature-controlled water to the heat exchangers in the bypass circuit

The heater-cooler devices are in the extracorporeal circuit and feed the two heat exchangers. The heater-cooler device is usually located close to the perfusion circuit, or heart-lung machine, which is within the operating room (OR), but outside the sterile field.

Heater-cooler devices have been on the market since the 1960s. For Class II devices, the sponsor must submit information to the FDA to demonstrate that the device can be compared to another device that is currently on the market, or the “predicate device.” The sponsor also must demonstrate that the device meets certain performance criteria called “special controls.” The FDA regulatory review for these devices generally includes:

- Review of device technology
- Performance and labeling as compared to the predicate device
- A determination of whether any differences between the devices can affect safety or effectiveness

The labeling review includes a review of the cleaning and disinfection procedure for the unit. Since the temperature-controlled water circuit of a heater-cooler device is a closed circuit with no intended patient contact and the device is not in the sterile field, the health risk associated with these devices for patients was considered to be low. As such, in the past, the disinfection procedures were not reviewed in detail; rather, the FDA relied on the Quality Systems Regulations in its Office of Compliance regarding validation of the procedures. The sponsor must have validated data in its files for these procedures. The possibility of aerosolization with heater-cooler devices was not a consideration until recently.

Since device contamination appears to be a recurring issue, FDA is actively working with manufacturers to appropriately validate their cleaning and disinfection procedures, taking into consideration issues relating to human factors, to demonstrate that the labeled procedures minimize contamination and that the procedures can be feasibly, consistently and effectively followed by the anticipated end user. It is important to note that the cleaning and disinfection of heater-cooler devices outside the manufacturer’s labeled procedures may result in a damaged device and is not recommended.

Mycobacterium chimaera is a relatively new species within the non-tuberculous Mycobacteria (NTM) grouping which consists of 150+ species. *Mycobacteria* can be divided into two groups: NTM and *Mycobacterium tuberculosis*. This investigation focuses specifically on *Mycobacterium chimaera* (*M. chimaera*) which is an NTM. While *M. chimaera* has been identified in many of the cardiac surgical patient infections to date, there also have been clusters of infections due to other NTM species such as *Mycobacterium abscessus* (*M. abscessus*).

NTM can be further categorized into rapid growers, which grow on solid media in 5 to 10 days, such as *M. abscessus*; and slow growers, which may grow on solid media in 6 to 8 weeks, such as *M. chimaera*. All of these waterborne bacteria have the ability to form biofilms. This point is

important to contamination, as once biofilm has formed inside the tank or the circuit, cleaning and disinfection of the device becomes difficult, if not impossible.

NTM is widespread in nature. It is found in natural and tap water, in soil, and even in some surgical solutions. Based on the infections being reported, NTM are likely being spread through aerosolization. Some predisposing patient factors that may contribute to the likelihood of infection include:

- Altered local or systemic immunity
- Structural factors, such as chronic obstructive pulmonary disease (COPD) or cystic fibrosis (CF)
- Surgical procedures with an open cavity, such as cardiopulmonary bypass or valve replacement

FDA's response has been multi-pronged over the past 10 months, given that an increasing number of NTM infections have been identified and reported by healthcare facilities through retrospective review of their patients who were exposed to contaminated heater-cooler devices during cardiac surgery. The reviews, in some cases, go back as many as four years and this extended scope in case finding is necessary because NTM infections can take years to develop into a symptomatic infection. FDA continues to receive reports of device contamination in spite of adherence to manufacturers' instructions for the cleaning and disinfection of these devices. The FDA response has incorporated research regarding:

- Design of the device
- Environment in which the device resides
- "Human factors" or usability aspects associated with cleaning and disinfecting

FDA has also conducted outreach to various organizations, agencies, and experts.

FDA has studied many facets of the surgical procedure, including:

- Water contamination
- Transmission of NTM into the OR
- Device design considerations
- OR design considerations
- Patient considerations

The investigations into water contamination focus on possible mechanisms that could enable NTM to reach the water tanks and contaminates the heater-cooler units.

- Tap water contains NTM naturally. These devices need to be filled, re-filled, rinsed, cleaned, and "topped off." If any of these steps utilize tap water rather than sterile water, NTM can be introduced into the device.
- The manufacturing line should be considered, as NTM could be in the water used to clean or rinse the devices as part of the manufacturing process.
- The devices are connected to external components, such as tubing and blankets, which may be reusable. Even if the heater-cooler device is disinfected, re-contamination will occur when it is reconnected to these reusable components if the circuit is contaminated.

- Access to the water tank and circuit may be limited. If full access is not possible, the tank may not be able to be physically scrubbed. If there is biofilm in the tank, mechanical scrubbing will most likely be necessary to eliminate the biofilm.
- FDA is addressing the cleaning and disinfection procedures proposed by the manufacturers to ensure that the procedures are adequate and validated to reduce contamination of the heater-cooler devices and aerosolization of organisms that can lead to patient infections.

One of the original papers suggesting aerosolization of NTM from heater-cooler devices was published by Dr. Hugo Sax in March 2015. Following that publication, a paper was published by Dr. J.O. Falkinham describing the hydrophobicity of NTM and its behavior in the context of heater-cooler devices. Dr. Falkinham cites a 1983 paper, which states that “hydrophobic mycobacterial cells are concentrated on the surface of air bubbles rising in water columns. When the air bubbles reach the surface, they burst, and water droplets are ejected into the air. Relative to the concentration of mycobacteria in the water, the concentration in the ejected droplets are 1,000 to 10,000-fold higher.” If there is aerosolization inside the water tanks and some communication between the tank and the OR, there is the potential for NTM to reach the OR environment.

FDA is pursuing a number of device design considerations that may contribute to tank contamination and/or aerosolization, including:

- Devices that use ice: is sterile water or tap water used to make the ice?
- Level of agitation inside the water tank creating air bubbles, including mixing components, pumps, and the return water circuit inlet back into the tank. The air bubbles collect hydrophobic NTMs, which burst upon reaching the surface of the water in the tank and create aerosolized NTMs within the tank.
- Water tanks are not usually sealed or airtight: depending upon the design of the unit, the aerosols in the water tank can find their way into the casing of the heater-cooler unit, where cooling fans located within the unit can facilitate their transmission of these aerosols into the OR
- The orientation of the vent(s) on the devices may or may not direct the fan exhaust toward the patient or the sterile field. The exhaust from cooling fans also may play a role in the airflow within the OR, possibly facilitating movement of the aerosolized NTM into the sterile field
- Access to the water tank and physical cleaning of the tanks prior to disinfection procedures that alone cannot remove biofilm may be necessary to assure proper disinfection of the tanks and internal water circuits.

In order to address these questions, FDA has sent information request letters to all manufacturers of these devices and is reviewing the information that has been returned. Regarding OR environment considerations, one limited study was conducted on one heater-cooler unit. It raised questions regarding the potential for the exhaust airflow from the heater-cooler unit to disrupt the protective laminar air flow above the patient in the OR. The study suggests that disruption of the protective laminar airflow may create a pathway for aerosolized NTM to find its way into the sterile field, and ultimately into the patient’s open chest cavity. While this study was limited, it does raise questions about other OR environmental factors, such as airflow, that may play a role in mitigating patient infections.

FDA is also consulting with epidemiologists who have studied the general effectiveness of infection control measures implemented in the OR during a surgical procedure, including:

- Laminar flow rate
- Positive pressure maintained during a procedure
- Cleaning of the OR between cases
- Infection control measures taken by the surgical team during the procedure

These areas could be reviewed and potentially improved. Patient considerations are also important. To date, most of the reported infections are in cardiothoracic or cardiovascular patients undergoing an open chest procedure requiring the use of an extracorporeal circuit. Many of these patients received a sterile implant, such as heart valve. The patients' general health may also contribute to infection susceptibility.

Many challenges are associated with this multi-factorial problem.

- It is not feasible for these devices to be sterile.
- There are many OR environment considerations as well as hospital infection control procedure and patient considerations.
- NTM is fairly ubiquitous and, locating the source of NTM leading to infection is challenging.
- It is not clear whether there is an acceptable level of contamination at which a device can still be used safely. For instance, if aerosols can be reduced or eliminated from the unit, can the circuit water safely maintain some level of contamination?
- There are challenges associated with validating the cleaning and disinfection procedures and what might represent "worst-case" testing. It is not clear how real-world use can be mimicked in laboratories for testing. Which microbe or microbes should be monitored and what is an acceptable output or contamination level?
- Heater-cooler units are a capital expense, currently with a service life of approximately 10 years. If they become contaminated beyond an acceptable level, alternatives are needed for these lifesaving devices. Unless contaminated units can be reliably disinfected, purchase of new units may be necessary.
- Patient notification is a challenge, including what patients should be told regarding the risks prior to a procedure and whether patients who have already undergone a cardiac surgery should be stratified and notified based on a reliable risk scale.

The FDA's ultimate objective is to protect patients from infection. Based on the investigations, theories, limited data, suppositions, and common sense, the agency has identified some short-, mid-, and long-term goals which are being pursued in parallel to reach the ultimate objective.

Short-Term Goals: Can be enacted immediately and reduce the possibility of infection without compromising device performance, device structural integrity, or patient safety:

- Location of heater-cooler devices in relation to the patient and sterile field
- Orientation of heater-cooler vents in relation to the patient and sterile field
- Directing or channeling the exhaust from heater-cooler device away from the patient and sterile field
- Performing an evaluation of the OR environment with respect to aerosol dispersion into the surgical field
- Review hospital infection control procedures for any improvements that can be made

Mid-Term Goals:

- Mitigation of aerosols from the heater-cooler devices into the OR. FDA is working with manufacturers on design aspects of their devices to prevent aerosolization of NTM into the OR.
- Studies to determine whether airflow in the OR can be manipulated to reduce the possibility of aerosols reaching the sterile field

Longer-Term Goals:

- Identifying cleaning and disinfection methods that will prevent biofilm formation and maintain contamination levels in the tank and water circuit at acceptable levels.

Dr. Schwartz commented on Dr. Cardo's emphasis on building coalitions and bridges and working collaboratively. Solving the problems associated with heater-cooler devices and NTM will require awareness and partnering across federal agencies as well as state, local, private sector, academic, and clinical partners. FDA has proactively engaged with different entities and organizations.

The Medical Product Safety Network (MedSun) through FDA's Center for Devices and Radiological Health (CDRH) brings opportunities for direct work and "deep dive" discussions with individual healthcare facilities that have been impacted by, or are concerned about possible impacts of, these issues. FDA also works with perfusionist societies, the Society for Healthcare Epidemiology of America (SHEA), the Infectious Diseases Society of America (IDSA), and other organizations. Other important partners include CDC, state departments of health, and regulatory agencies outside the US, particularly because of the lessons learned from signals observed overseas. The open exchange of information is critical to a multifaceted approach to the challenge.

In October 2015, FDA issued a safety communication that provided FDA's current understanding of the matter as well as short-term recommendations to provide immediate mitigation to reduce patient risk. FDA stands by the recommendations in that communication and is committed to revising and updating the recommendations as more information is gathered.

FDA has enforcement and compliance authority. As issues are identified related to lack of adherence to regulations and other problems, enforcement can occur. A warning letter was sent to one of the heater-cooler device manufacturers in December 2015. The warning letter, which is publicly available in redacted form on FDA's website, includes an import alert for that product, with an exemption for medical necessity. The problems with heater-cooler devices are potentially systemic; that is, the same concerns might involve the devices of other manufacturers.

A webpage on heater-cooler devices was released in March 2016. This approach allows FDA to provide updates in a timely manner and share them quickly with the public and healthcare provider communities. The agency is committed to maintaining those updates as more information is available. The page includes an information section for patients to help them make informed decisions and to provide guidance regarding conversations with their healthcare providers. The webpage is available at:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/default.htm>

The Medical Device Advisory Committee meeting is public and will convene on June 2-3, 2016. The standing Circulatory System Devices Panel which includes clinical experts in cardiovascular disease (e.g., cardiologists, cardiac interventionalists and cardiothoracic surgeons) is being expanded to assure that experts in infectious disease, infection control, and epidemiology, among others will contribute to the discussions, questions, and recommendations.

Some of the FDA recommendations in the Safety Communication and on the webpage include:

- Strictly adhere to the cleaning and disinfection instructions provided in the manufacturer's device labeling. Some facilities go above and beyond thinking that more is better but that approach is not advised, especially when parts of these devices are susceptible to corrosion and other related issues. Manufacturers' instructions and labels change frequently so should be monitored by the facility to ensure that they have the most recent version of the manufacturers' instructions and labeling.
- The heater-cooler device exhaust vent should face away from the surgical field in order to minimize the potential for patient exposure.
- Facilities should establish regular cleaning, disinfection and maintenance schedules for heater-cooler devices according to the manufacturer's instructions.
- Facilities should immediately remove from service any heater-cooler devices that show discoloration or cloudiness in the fluid lines/circuits, as it may be indicative of bacterial growth.
- Consider performing environmental, air, and water sampling and monitoring if heater-cooler contamination is suspected. There is variability across the country, however, regarding the feasibility and practicality of being able to carry out the sampling. The information that can be yielded from the tests is very helpful to FDA.
- If bacterial contamination of a heater-cooler device is suspected, or if there have been patient infections, facilities should not only notify the manufacturer, but also FDA through the MedWatch reporting system or other means. FDA seeks as much as information as possible, from across the country and from facilities that use different types of devices.

The main topic areas to be discussed at the upcoming advisory committee meeting include:

- Effectiveness of cleaning and disinfection methods for heater-cooler devices
- Premarket data and information needed in order to demonstrate validation of cleaning and disinfection of heater-cooler devices to support labeling and technical instructions
- Protective measures and risk mitigations that can improve upon and enhance patient safety during procedures where these devices are used, knowing that the devices are used in critical, often life-saving, procedures
- Identifying risk stratification schema that will help inform guidelines for notifying patients who may have already been exposed to NTM during prior cardiac surgeries

Flexible Endoscope Update

Dr. Schwartz reminded HICPAC that at the July 2015 meeting, she presented recommendations from FDA's May 2015 Advisory Committee meeting on concerns related to duodenoscopes. Since then, there has been a great deal of activity and action pertaining to duodenoscope reprocessing and instructions.

In August 2015, FDA issued a “supplemental measures” safety communication while the agency continued to work on the problem. This communication provided healthcare facilities with options to consider for enhancing and improving the safety margin for use of duodenoscopes for important endoscopic retrograde cholangiopancreatography (ERCP) procedures. FDA issued warning letters to all three duodenoscope manufacturers in the summer of 2015 and ordered all of the manufacturers to perform post-market surveillance studies. FDA continues to work with each of the duodenoscope manufacturers to ensure validation of their cleaning and high-level disinfection protocols for manual reprocessing. At this point, all three manufacturers have fully validated their reprocessing instructions and have issued safety communications with the new, revised instructions for use.

FDA has taken a parallel path to address the automated endoscope reprocessors (AERs) to ensure that the validation for use of those devices with duodenoscopes is equally as robust. FDA posted an AER webpage in February 2016 as work continues with each of the AER manufacturers. The webpage will continue to provide updates on which devices have completed testing, FDA review, and and noted to be adequate in passing acceptance criteria.

Recently, the 510(k) premarket notification for the Olympus TJF-Q180V closed elevator channel duodenoscope was cleared for marketing, along with a recall of the current Olympus TJF-Q180V duodenoscopes. Through this field safety correction, Olympus has committed to a phased approach to the recall over six months so that it will be completed by August 2016. The scopes that are in the market will be recalled so that the entire elevator mechanism can be replaced with the newly-designed mechanism that has been reviewed and approved by FDA. The devices will be redistributed. Olympus has also committed to annual servicing and testing of the devices.

Discussion Points

Regarding heater-cooler devices, HICPAC commented on anxiety regarding whether the short-term interventions will be adequate to prevent patients from ongoing exposure. Some of this anxiety is linked to a lack of understanding regarding the epidemiology. HICPAC asked whether specific information is available from FDA’s studies to date regarding why *M. chimaera* is a particular problem, whether the isolates are clonal, and evidence for contamination at the manufacturer level versus the point-of-care usage sites.

Dr. Schwartz answered that the epidemiology is the key question. FDA does not have a full picture to address the epidemiology and has embarked on the campaign to learn about what is happening within various clinical facilities inside and outside the US. More information will be publicly available by June 2016. The information that FDA has is driving the short-term mitigations, which the agency believes to be appropriate in recognition of anxiety about the devices. Patients should not be put at risk. There is a need to update and revise recommendations rapidly as more information comes to light. The device that has received the most attention has 80% to 90% of the global market share of these devices. Therefore, the detection associated with that device will automatically be higher. FDA does not have a sense whether facilities that use other devices are looking retrospectively to learn about contamination or infections associated with NTM in cardiac patients. The picture is not full enough to make epidemiologic associations. Help is needed from professional societies and others to “pull this picture together.”

It has become clear that case-finding, the critical first step in an outbreak investigation, is a major problem. Infectious disease and other clinicians do not routinely order acid-fast bacillus (AFB) cultures in patients based on a prior history of exposure to cardiac bypass. There is an “information vacuum” in terms not only of how extensive the problem is, but also for guidance on moving forward. HICPAC suggested that interim, tiered guidance is needed for institutions based upon whether they are conducting surveillance on their own heater-cooler units, whether they have detected contamination, whether the cultures have an acceptable negative predictive value, and suggesting next steps for patient notification. A uniform strategy for the country may be needed for case finding and patient notification. The “iceberg below the surface” of this problem is large and concerning.

In response to a question from HICPAC about the frequency and rate of infections, Dr. Schwartz answered that FDA does not have a sense of the frequency or rate of infections. Detection depends on facilities and organizations conducting and providing reports on retrospective evaluations that find links or associations. The reports often do not provide enough substantive information to understand the adverse event or injury. FDA is requesting to speak with the institutions that have voluntarily reported to fill the information gaps to patients’ backgrounds and medical histories and to understand whether the infections are related to infected valves, bypass procedures, or other events.

As one manufacturer represents the majority of the global market of heater-cooler devices, HICPAC asked whether the institutions where these infections have occurred have unique attributes, such as their water supplies and cleaning practices, that could shed light on the problem.

Dr. Schwartz answered that insufficient information is available to find a common thread among the institutions. Many facilities have reported because they have a heightened level of awareness and have chosen to conduct the retrospective evaluations. The European regulatory agencies have noted that the level of visibility of this issue is more heightened in certain countries. Most of the reporting has occurred in Europe, where coalitions of different organizations and entities have grown to ensure that the information is distributed and that facilities are doing their retrospective work.

Dr. Bell commented on the idea of observing cloudiness or discoloration in fluid in the system. The system is open and the reservoir is “topped off;” even if sterile water is used, there will be cloudy material in the device. He asked about the appropriate follow-up measures that the FDA guidance recommends after consulting with a hospital’s infection control officials.

HICPAC said that given what is known about these devices currently, the only way to keep patients completely safe is to remove the device from the OR in order to physically separate the air emitting from the device from the air that surrounds the patient. That separation presents a significant challenge, but the devices are lifesaving and required for the performance of cardiac surgery. There does not appear to be a good near-term solution to the problem. Variability around access to laboratories that can reliably identify *Mycobacterium* in hospitals’ water samples is a major limitation.

The US Department of Veterans Affairs (VA) commented on potential contamination of hospitals’ water systems with NTM. Hospital water safety is a hot topic, even more in Europe than in the US. These organisms are fairly resistant to chlorine. Many hospitals are re-oxidizing their water, so the number of *Mycobacteria* may be rising, putting higher concentrations of NTMs in ORs. Hospitals across the US are instituting NTM clinics in response to perceived

increases in disease incidence. The data are not clear, and it is not known whether the mitigation efforts will succeed.

HICPAC observed that heater-cooler devices have been used for decades. There may not be widespread knowledge about, or searches for, NTMs, but there is increased awareness. HICPAC asked about the rates of mortality and morbidity among patients whose cases have been detected. These rates may motivate hospitals to perform more active case finding.

Dr. Schwartz answered that there is not sufficient information to describe incidence. There are more reports of patient deaths outside the US than within the US. Given the denominator of the number of these procedures that are performed, the rate of postoperative NTM infections would be rather small. It is important to weigh the benefits and risks and not to deny patients critical lifesaving procedures. At this stage, there is not enough information to understand what is happening with these patients, some of whom may have undergone surgery years ago. They could have had a fever of unknown origin in the ensuing years and not have received a diagnosis or a workup to elicit the diagnosis of an NTM-related infection or sepsis. FDA looks toward partnering with others in the necessary descriptive epidemiology.

Regarding other types of endoscopes with elevator mechanisms such as endoscopic ultrasound devices, Dr. Schwartz said that FDA has not received reports of adverse events. Features of that device, such as the side-viewing elevator channel, have been a concern. FDA is monitoring other endoscopes carefully as well. In September 2015, FDA issued a safety communication regarding flexible bronchoscopes in response to a signal related to those devices. However, the situation was not entirely analogous to duodenoscopes. Other factors were related to the use of devices with mechanical defects. The design-related challenges of cleaning and reprocessing are not exactly the same for flexible bronchoscopes.

In response to a HICPAC question about the possibility of filtering the exhaust from heater-cooler devices as a short-term measure, Ms. Wentz said that FDA has considered such a strategy. From the FDA perspective, short-term recommendations should avoid device design issues. The agency cannot tell manufacturers how to design their devices and cannot give recommendations to redesign devices. FDA works with manufacturers to identify the design aspects which influence aerosolization. Filtering was discussed with the manufacturers, but it was deemed to be an impractical fix for devices currently in use. The size filter needed at the vent would not permit sufficient airflow to keep the device cool. There may be other alternatives, but adding a filter is not yet a possibility.

HICPAC commented that the field is clamoring for improvements in device design. The recommended short-term measures place the onus on the end user, as infection control departments must create risk mitigation strategies to address patient safety problems associated with an essential, lifesaving medical device that is known to be contaminated and is known to be re-contaminated even after certain mitigation measures. The situation is analogous to the endoscope elevator situation, and probably to other devices. Although the full picture of the epidemiology and of the number of people affected is not yet available, the evidence that is available is compelling. Infections are severe, and patients have died. The work with manufacturers should be accelerated, given that the device design is the root cause of the problem.

Dr. Schwartz said that manufacturers are not only required to address the appropriate validation of the cleaning and disinfection of devices that are in distribution, but also are required to

address device redesign approaches to eliminate or remediate concerns regarding aerosolization. Even if the process is expedited, the fix will not happen quickly. The new design will need to be validated. The different approaches are taking place in parallel. The lessons learned from these experiences will be incorporated into the pre-market evaluation process.

Regarding the idea of using sterile water to make ice, HICPAC noted that even if the ice is sterile, it is still important to follow recommendations to ensure that the ice machine is maintained and cleaned so that it does not become contaminated. That point should be explicit in the guidelines.

HICPAC asked about opportunities to set deadlines for manufacturers to redesign their devices. If there were an alternative, then the problem devices would be eligible for recall, and this would allow FDA to set a timeline to accelerate the redesign process.

Dr. Schwartz agreed, but pointed out that manufacturers need to be able to produce enough devices to satisfy the need. If there is a recall, then manufacturers need to be able to surge production to fill needs during the recall. These supply chain and shortage considerations are important. When FDA decides to remove a device from the market, there are downstream implications for patients. If enough devices are not available to fill the gaps, then short-term measures are needed to ensure that hospital operations can continue without interruption, particularly in case of lifesaving procedures.

The Council of State and Territorial Epidemiologists (CSTE) commented on the public health work of describing the epidemiology of NTMs. There have been dramatic increases of NTMs in recent years, and it is not clear how many of these involve respiratory isolates versus non-respiratory isolates. A pilot study to examine the epidemiology among the respiratory NTMs, working through state public health laboratories or EIP, could look at sterile site specimens with growth of NTM to assess possible etiologies for recent increases, including changes in water supply and the way that water is treated in hospitals.

Update on HICPAC Workgroup and Request for Guidance: Endoscope Reprocessing

Lisa Maragakis, MD, MPH
HICPAC Member
Co-Chair, HICPAC Endoscope Workgroup

Dr. Maragakis provided an update on the HICPAC Endoscope Workgroup's goal and charge as well as progress on drafting and revising an Essential Elements document. Endoscopes are high-risk medical devices. There have been outbreaks of bacterial infection associated with these devices, sometimes attributed to improperly reprocessed endoscopes related to the elevator design feature found on some endoscopes such as a duodenoscopes. Endoscope reprocessing is a highly complex and technical procedure with many potential risks for error.

At the November 2015 HICPAC meeting, HICPAC member Vickie Brown presented a summary of the current challenges that institutions on the front lines face when they try to implement and oversee endoscope reprocessing programs in a comprehensive, safe way that mitigates the associated risks for patients. As a result of that presentation and other discussions, HICPAC formed the Endoscopy Reprocessing Workgroup. The group's initial meetings focused on refining its goal and charge.

Goal

- To help healthcare facilities identify the key elements needed for a reliable, high quality system for endoscope reprocessing which minimizes infection risks.

Workgroup Charge

- To identify the elements that are necessary to achieve this goal, including risk assessment tools; training and competency assessments; measurement; and management of the endoscope reprocessing infrastructure.
- To deliver these draft elements/recommendations to HICPAC for deliberation and input in order to produce recommendations from HICPAC to CDC.

The workgroup is broadly inclusive of partners from the federal government, professional societies, CDC, HICPAC, and other relevant organizations. Because many groups have already done work in this area, an important goal is to avoid duplication of efforts and to generate a value-added set of recommendations and documents that will help facilities.

The group first convened in the fall of 2015 and has held biweekly conference calls since. They refined their goal, charge and scope and have delineated areas that are beyond their scope. The group's goal is to provide assistance to institutions that have endoscope reprocessing programs so that they have the appropriate elements in place to ensure patient safety. The group also identified gaps and priorities among the various activities associated with endoscope reprocessing. Their recent conversations have focused on drafting and revising an Essential Elements document, which had been submitted to HICPAC members and liaison members for their review and input.

The Essential Elements document is divided into the following categories:

Administrative: What does an institution need to have in place to have appropriate administration of an endoscope reprocessing program?

Accountable Leadership

- Resources and infrastructure should be available so that endoscope reprocessing can happen in a safe and comprehensive way.
- Leaders should be designated and given authority to oversee the program and oversee required changes

Policies

- Created with multidisciplinary input
- Address the selection, use, transport, reprocessing, storage of endoscopes in compliance with manufacturer instructions for use; training and competency assessment for all staff involved in the program; documentation that occurs during reprocessing; and quality assurance methods
- Consistent with all regulatory requirements, accrediting organizations, and standards and recommendations from professional organizations

Management

- Ensure that single-use devices are not reprocessed
- Ensure that occupational health protections for the workers who reprocess these devices are addressed, including their personal protective equipment (PPE), chemicals that are used, and other considerations
- Ensure that scheduling, staffing, and on-hand inventory allows adequate time for reprocessing
- Provide specific access to infection prevention knowledge and expertise

- Ensure adequate, ongoing training, education, and certification for all involved staff
- Ensure that water quality meets standards
- Ensure that appropriate documentation is kept at every stage of the reprocessing

Documentation

- Requirements may vary depending upon which endoscopes are being used, the method of reprocessing, the type of germicide, and other factors
- Endoscope and patient identifiers must be documented for traceability
- Times and dates for each step of the process should be included, including the pre-cleaning step, which incorporates point-of-use cleaning by those using the endoscopes and includes appropriate flushing of channels and appropriate cleaning so that the device does not sit for a long period of time before it is transferred to the reprocessing team
- Fluid tests of efficacy, appropriate concentrations, expiration dates
- Preventive maintenance and repair of devices, as lapses in maintenance play into risk
- Retain documentation of endoscopes, even those that are retired, as well as maintenance and repair of AERs, sterilizers, or other equipment

Inventory

- Identify all endoscopes by:
 - Make
 - Model
 - Location of use
 - Manufacturer instructions for use and reprocessing
 - Reprocessing equipment and personnel that are responsible for the device
 - Condition: this work is challenging because facilities are likely to use scopes in a wide range of outpatient and inpatient locations
- Ensure that each scope has a unique identifier for tracking

Physical Setting

- Separate, dedicated space for endoscope reprocessing
- One-way workflow that separates clean from dirty spaces
- If a separate room is used for manual cleaning, negative airflow should be present in that space
- Ensure proper ventilation, humidity, temperature
- Provide a clean hand washing sink with eyewash in addition to, and separate from, the reprocessing sink(s)
- Two sinks or a divided sink for washing and rinsing endoscopes
- Ensure that manufacturer instructions for use for endoscopes, AERs, and chemicals are available on site and that staff responsible for reprocessing the devices know where the instructions are and can easily access them

Training and Competencies

- Include the rationale for the reprocessing steps in training for front-line workers. The system will be more robust when the staff know why they are completing each of the steps, and there will be a better chance that they will recognize lapses
- Model-specific training and competency assessment based upon manufacturer instructions for use and equipment used

- Address the reprocessing of other reusable accessories that also break the mucosal barrier, such as biopsy forceps and other accessories that will be used with the endoscope
- Ensure that trainers and supervisors are also competent to reprocess endoscopes in order to train and assess the front line staff
- Assessment of staff competency:
 - Should be conducted upon hire and at least annually
 - Reassessment should occur when new equipment or chemicals are purchased and used and whenever manufacturer instructions for use change
 - Should include direct observation of reprocessing as well as paper-based competency assessment
 - Should include all steps of the process, from pre-cleaning to storage
 - Should include a review of manual reprocessing
 - Should include training on performing rapid verification tests when used by the facility

Quality Assurance (QA)

- Comprehensive gap analysis should occur, including all components, processes and equipment
- Periodic audits of documentation and observations of reprocessing should take place to identify risks and errors
- Risk assessment of any new supplemental measures should occur specific to the institution, equipment that is used, and other factors to determine which measures will be implemented
- Risk assessment should be conducted when the manufacturer instructions for use allow for intermediate reprocessing and use of a sheath to understand how best to utilize the sheath
- Gap analysis and risk assessment should be repeated periodically and when new equipment is purchased, manufacturer instructions for use change, or new recommendations and guidance are issued

The workgroup also discussed several other issues that they opted not to incorporate into the Essential Elements document, but to place in the “parking lot.” These topics are important but outside the scope of this document.

- Pre-market clearance processes
- Post-market regulatory activities
- Surveillance for post-procedure infections and MDROs
- Identification and reporting procedures for breaches in endoscope reprocessing protocols

The workgroup asked for HICPAC’s input on its work to date:

- Are there any additional considerations or feedback on the Endoscope Reprocessing Workgroup’s scope and charge?
- Is the Essential Elements document missing any important points?
- How much detail should the document include on the reprocessing process (i.e., should essential reprocessing steps [e.g., pre-cleaning, leak testing, manual cleaning with

brushes, quality monitoring of the disinfectant, scope storage principles] be included as a section of the document)?

- Are there elements in the document that require further elaboration?
- Should this document include some discussion of supplemental measures that endoscopy units can consider (e.g., microbial culturing, monitoring of manual cleaning using adenosine triphosphate (ATP) or other tests, repeat high-level disinfection (HLD))? If so, how should this be done (e.g., table of pros/cons)?
- Are there areas the document should highlight where additional research/ data is needed?

Discussion Points

HICPAC commented that the Essential Elements could apply to other devices, such as probes, that are also reprocessed. The workgroup discussed whether the focus should only be on duodenoscopes, scopes with elevators, all scopes, or other devices as well. The workgroup decided to focus on all channeled scopes at this point. The guidance is analogous to other devices, but there are implications to broadening its scope, which might not serve to move issues forward.

There was support among HICPAC for the structure of the Essential Elements document and its focus on key points. Some specific elements of the cleaning and disinfection process could be included. For instance, the document might highlight the importance of pre-cleaning, leak testing, and brush cleaning. Including discussion about supplemental strategies could imply endorsement of these practices but including a brief description of these supplemental practices in a table of “issues to consider” might be an option.

CSTE noted that additional detail regarding the essential reprocessing steps would be important to include. In terms of operationalization, it may be helpful to include a sample policy or example to illustrate the expected level of detail in a program. Smaller facilities may not have experienced infection preventionists, and an example could provide them with guidance in creating their own policies. Examples of risk assessments and gap analyses would also be helpful.

HICPAC suggested that including guidance regarding the management of a breach or problem in the Essential Elements document or a supplement could be useful. Local epidemiologists and infection preventionists may be insecure in this area. A thought process or algorithm of areas to consider, whom to contact, etc. would be helpful..

There was a question regarding facilities that outsource reprocessing and how to handle those responsibilities and arrangements.

The workgroup also discussed the available level of expertise outside acute care facilities. Most complicated procedures occur in hospitals, but an increasing amount of endoscopy is performed in ambulatory care facilities, outpatient surgical facilities, and the like. There was concern regarding whether the expertise to follow these detailed guidelines is available in these settings. While there are requirements for facilities to have an infection control presence, access to individuals with infection control and reprocessing expertise can be limited. Outside resources may be available in communities, such as through a local Association of Professionals of Infection Control and Epidemiology (APIC) chapter or other sources. The guidelines should take into account how a less-well-staffed, ambulatory facility in which one person may have many responsibilities can meet these requirements.

The workgroup also discussed how to incorporate the concept of certification without endorsing a specific certification or education opportunity.

HICPAC commented that certain infrastructure elements in the reprocessing environment can improve and sustain reprocessing reliability. The manufacturing sector and related sectors, for instance, post standard work steps, visual guidance, or video clips of procedures. HICPAC might make a statement about best practices in this area or highlight this area for further research.

Regarding dissemination and implementation of the guidance, CSTE observed that there would be value in ensuring that accrediting agencies and organizations are fully aware of the final document and can see them as part of their education efforts. The document could also serve as the basis for a checklist for implementation.

The VA cautioned that it should not be assumed that infection control staff know how to implement these guidelines. They understand the principles of the guidance but not necessarily the complexities of the work. Trying to “do the same thing all the time, every time” in this environment is challenging. There should be a Standard Operating Procedure (SOP) that can be posted in the area. An SOP has the advantage, especially in smaller places, of being available to support personnel who are trained in a process but who may not perform it every day. .

Many groups have done work on this issue. HICPAC discussed integrating the various groups’ products into this document. The workgroup representatives from professional societies were willing to share their work during the calls. A packet could be assembled of existing checklists, assessment surveys and other tools that facilities can adapt.

The Joint Commission agreed that it is important to consider human factors. In its courses on endoscope cleaning, the Joint Commission discusses human factors and SOPs. There is significant turnover in staff that perform the cleaning, making it all the more important to have SOPs and attention to human factors to avoid failures.

APIC concurred that infection preventionists are not necessarily experts in the actual processes of cleaning scopes. An SOP is critical. Infection preventionists may learn the steps from the individuals who do the work. With that in mind, the principles of infection prevention can be essential for responding to breaches. Infection preventionists should be well-versed in endoscope reprocessing but they should also make use of partnerships with the individuals who do the reprocessing work.

HICPAC noted that the brevity of the document makes it more useful. A toolkit could be developed around the document to provide examples of SOPs, management, or other relevant guidelines.

Dr. Bell asked whether the document can address the variability in automatic device reprocessors and equipment that all have different SOPs, and whether the document could suggest uniformity whenever possible. Such a statement would be helpful, but it may not be realistic, given the expense of the equipment and the investments that have already been made. The document can allude to the idea as an ideal as facilities make choices about equipment. The concept is important and a potential area for future research and work.

SCCM noted that the cleaning and reprocessing process is dictated by the manufacturer. In the event of a failure even when an organization follows all of the steps and audits full compliance, the document could offer recommendations for a process thereafter to inform the manufacturer and FDA that there is a problem with the stated reprocessing process.

Dr. Maragakis said that the workgroup will consider including that idea as well as the breach notification.

Devices in Healthcare Settings: Design Considerations for Infection Control

Michael Bell, MD

M. Shannon Keckler, PhD

Division of Healthcare Quality and Promotion

National Center for Emerging and Zoonotic Infectious Diseases

Centers for Disease Control and Prevention

Dr. Michael Bell said that in pursuing patient safety and infection prevention, groups that are normally targeted to receive information may not be the appropriate audience. For instance, staff in materials management, reprocessing, and environmental services play a crucial role in maintaining safety of devices. Further, the purchasing department has control over which devices are in the hospital. As a field, infection prevention may need to work more closely with purchasing departments.

A hospital that he recently visited has a system in which the environmental services lead and the materials management lead both have the authority to request different brands of devices if a certain brand is too difficult to clean or has other challenges. That empowerment and connection between the people who manage the materials and the people who are charged with purchasing the materials represents a critical innovation. Non-clinicians can be armed with guidance to help them make decisions.

Issues to consider for devices that require reprocessing include:

Cleanability

- Processes indicate that the devices must be cleaned, but it should be recognized that the device surface textures, seams, materials, and design elements may make it all but impossible to clean them effectively and consistently.

Assessability

- Is it easy to tell if the reprocessing was successful? Can colors and contrast be used more effectively to help users determine whether a device is clean or not? There may be new ways to utilize molecular indicators, color changes, or other approaches. Individuals doing this work on a daily basis experience high turnover and are likely to have a limited background in microbiology. If possible, it would be helpful to have clear indicators for them.

Similarity

- In general, the processes could be more consistent and the tools more familiar.

Issues to consider for equipment used in high-risk locations, based on where they are used as well as who might be exposed, include:

- Air current generation: devices that blow air should probably not be situated in high-risk locations
- Moisture retention or reservoirs: devices that use water will likely have NTMs, mold, and opportunistic pathogens that should be avoided

These categories can be useful for delivering this information to individuals who are not specialists in infectious disease, but who implement the actions. Other issues for consideration include:

- Porosity of surfaces and materials: for instance, foam insulation panels are not cleanable. Wooden surfaces should not be in ORs. Garments should not hang on the back of the door in a procedure room.
- Promoting innovative options, such as fanless cooling; retardant treatments to prevent the adhesion or formation of biofilms, such as are used in the shipping industry; microbicidal/static characteristics of equipment; and self-cleaning nano-coatings

Several draft documents are in development to describe “elements to avoid” in purchasing medical equipment, “elements of concern” that can guide purchasing and to stimulate innovation in industry, and high-risk locations to specify the zone of care that requires special treatment regarding medical devices.

Medical Device Purchasing
Infection Control "Red Flags"

DRAFT

Elements to Avoid	Elements of Concern	Extra Scrutiny Needed for devices and equipment used in:
<ul style="list-style-type: none"> • Fans • Motors/vibration sources • Condensation sites • Seams and porous surfaces • other...? 	<ul style="list-style-type: none"> • Water reservoirs • Moisture retention • Re-usable tubing • Splash potential • Inaccessible compartments open to environment • Complex cleaning procedures 	<ul style="list-style-type: none"> • NICU • Oncology • Transplant • Burn • OR • Sterile Processing

Discussion Points

Dr. Shannon Keckler added that CDC has approached this idea from a “bug-centric” point of view, focusing on HAIs and the ecology of how the microbes work. They welcome as much assistance as possible regarding this large topic area.

While it is important to articulate the factors that are important to assess, HICPAC expressed concern about placing the onus of responsibility to assess these factors on the purchasers, who are often reacting to specific requests from other groups within a hospital. It is a lot to ask them to assess products and compare them to others that are available. Further, purchasers are often bound by contractual agreements and may not necessarily have access to a full range of

products. HICPAC hoped that FDA could incorporate some of these concepts into the device review process.

HICPAC supported the idea of extra scrutiny in high-risk areas; however, at this point, high-risk patients are housed throughout a facility. It may not be beneficial to bring specific attention only to certain areas, as devices are used in many places.

There was support for issuing this guidance to motivate device manufacturers to invest effort into device redesigns that eliminate these problems. Purchasers are an appropriate pressure point. Purchasers could use explicit advice or a checklist from infection control regarding factors that should affect purchasing decisions. There may be issues regarding contracts, but if purchasers have power to choose equipment based on infection control criteria, then manufacturers may have the necessary incentive to fix the problems.

There are limitations to the success of this strategy, many of them associated with the purchasing process and by the ability and role of a purchaser to stand up for these concepts. If there are not alternatives to equipment, then facilities may be “stuck” with what is available, even if it is high-risk. The people who are trying to make these points at any level would find supportive documentation useful. Infection preventionists also find issues that arise because a piece of equipment did not need an infection prevention review. Information about medical device “red flags” could be distributed throughout an organization, including the supply chain and purchasing department, to provide a helpful structure.

AORN said that while the document is strong, it may not be practical to implement with purchasers. The document may need to be shared with manufacturers. There is a great deal of equipment in the OR, and nearly every piece of equipment has a fan to cool it. If alternative products are not available, then facilities may be caught in the middle. Pressure on manufacturers can be helpful, but it can still take years to arrive at solutions.

APIC supported articulating the “why” behind the elements to avoid, with data and elements of substance. Value analysis groups respond to robust information, and there are competing priorities for individuals who may want certain products.

IDSA said that there is no single, perfect strategy, but found this idea appealing. Purchasing decisions should come through a common pathway or gateway. Many institutions require construction projects to be reviewed by Infection Control but do not require similar review of equipment. The sensitivity and specificity may be adjusted according to the resources and priorities of the organization. This draft document is a strong starting point to set the standard that equipment should not be purchased by a hospital without presuming that it could cause infection.

Dr. Keckler asked about the usefulness of a tiered approach, with a basic level, a deeper level for the providers who want it, and an even-deeper level for manufacturers.

HICPAC said that the question is not whether steps should be taken in this direction, but rather how to take steps that will be most effective. Rather than a deeper approach, a more summative product might be helpful. If a purchaser is looking at two devices, each with “red flags,” he or she will need a tool to determine which to choose. Such a tool could rate devices on a scale of one to five stars, for instance. The Centers for Medicare and Medicaid Services (CMS) is

moving toward a star rating for all hospital quality. A similar approach could be utilized in this instance and serve as an effective communication strategy.

Additional benefit from this work could be additional pressure on the competitive marketplace for making medical devices. Simple changes could be instituted to remove the possibility of human error as people work with these complicated devices and equipment under a great deal of pressure. This information will illustrate the problems that hospitals and healthcare have identified and drive manufacturers to engineer out potential errors.

Dr. Bell thanked HICPAC for the helpful comments and input, noting that it will be more difficult to move quickly in some areas, while some areas may be amenable to prompt change.

Update on Pre-Market Notification Requirements Concerning Gowns Intended for Use in Healthcare

Terrell Cunningham, BSN, RN
Scientific Reviewer, Team Leader: Personal Protective Equipment
Infection Control Devices Branch
Office of Device Evaluation
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
Center for Devices and Radiological Health
United States Food and Drug Administration

Mr. Terrell Cunningham briefed HICPAC on the current status of FDA's review and regulation of surgical/isolation Gowns. These gowns are one of the primary product lines for which his branch is responsible.

FDA has enacted several key efforts regarding the regulation of surgical gowns, including the following:

- A draft guidance was published in June 2015
- The final guidance was published on December 8, 2015
- As a follow-up to allow for interaction with industry, a Webinar on the guidance was held on January 21, 2016 with approximately 200 attendees
- FDA will participate in the Association for the Advancement of Medical Instrumentation (AAMI)-Protective Barrier and American Society for Testing and Materials (ASTM) F23.40 Joint Meeting on April 19, 2016 in Bethesda, Maryland; this meeting represents an unusual opportunity to devote an entire day to one product line and is convened in response to the need to consider the status of gowns and to hold discussions with industry
- A Joint CDC/FDA Gown Workshop is proposed and will depend on the outcome of the AAMI/ASTM meeting
- The primary output of this collaboration will be an update of the 1993 Gown Guidance Document

Several factors affect FDA and its partners' work with surgical gowns. The 1993 document is quite old. In 2000, FDA down-classified isolation gowns from a Class II device to a Class I exempt product. In 2003, an AAMI PB70 document was established and published. It was recognized by FDA in 2004. In January 2015, the National Institute of Occupational Safety and Health (NIOSH) released results of a study of isolation gowns used in healthcare settings that

indicated a number of failures. These factors are signals to FDA that the product line should be examined closely.

Because the terminology used to describe gowns has evolved, it is important for industry and the users of gowns to have a clear and consistent understanding of the terms used to describe them. The goal of the guidance document is to provide clarification of what an isolation gown should be, and what manufacturers' claims involve. For all intents and purposes, a gown that is labeled "minimal" or "low" protection, or has an AAMI Level 1 or AAMI Level 2 PB70 claim, it is FDA's opinion that the product is Class I exempt. However, a gown that is labeled "moderate" or "high" level protection, or has AAMI Level 3 or Level 4 PB70 claim, it is FDA's expectation that the product has been reviewed and cleared prior to being released to market.

All surgical gowns are Class II devices subject to special controls and require 510(k) clearance by FDA. The primary function of a surgical gown is to act as a barrier. It is important to ensure that healthcare workers and patients are adequately protected. The recently-released guidance clarifies the performance testing needed to support liquid barrier claims for these gowns. The guidance also contains recommended labeling requirements and Manufacturer's Expectations.

The Manufacturer's Expectations include specific timelines for submission of 510(k) pre-market notifications within 60 days of publication. There is the expectation that the 510(k) will be accepted within 75 days. The only currently outstanding timeline is the 80-day requirement from publication to have cleared the 510(k). FDA is hopeful that many of the manufacturers have submitted 510(k)s. FDA is committed to working interactively with manufacturers to assist them with the review process. The review is required to be completed within 90 days. Thus far, six 510(k)s have been received. FDA's Office of Compliance is developing a plan for manufacturers who fail to comply with the Agency's recommendations.

FDA asks for HICPAC's assistance and feedback regarding some areas of concern, either in this meeting or at other venues and follow-up opportunities. The agency's objectives and questions are:

- To understand how the clinical use of surgical and isolation gowns has changed with the development of new technologies and terminology.
 - What are the clinically relevant performance parameters?
 - What exposure are gowns subjected to?
 - Are manufacturers and/or healthcare industry moving to a one-size-fits-all product line? If so, do variable exposure conditions matter?
- To determine whether the current performance standards are adequate, and if not, what are the appropriate, clinically relevant metrics for the current use paradigm?
 - Are the current performance tests appropriate for the intended use of the gowns?
 - American Association of Textile Chemists and Colorists (AATCC) 42 and 127
 - ASTM 1670 and 1671
 - Surgical versus non-surgical/isolation gowns
 - Should there be a review of all testing laboratories?
- To determine if the current sampling, validation, and monitoring ensures that existing performance standards are met or should measure be taken to improve compliance, if so, what can be done to improve that compliance?
 - Are the current sampling strategies prescribed in the standard(s) adequate? This area is a specific source of concern in the process of reviewing 501(k)s. The recommendation is clear that testing should take place on random samples from

- multiple lots. FDA is finding that there is difficulty in following the normal sampling plans and doubts that testing occurs from multiple lots or is random.
- Testing is typically performed in the design or production validation stage. Is there value in continuous or periodic testing in the post-production phase?
 - Are the current acceptable quality level (AQL) of 4% and rejectable quality level (RQL) of 20% adequate? It is the agency's position that they are not. The performance criteria, based on a test standard that was established in 2004, are not always what they should be. The reported results from recent isolation gown studies are an indication that there could be a problem with the accept/reject criteria. There is an obligation to consider established criteria for passing and failure to determine whether they are adequate.
 - To determine if there is a need to revise the definition of an isolation gown. Historically, FDA has never written a definition of an isolation gown; the agency has depended on standards organizations for the definition. FDA has accepted the definition in AAMI's PB70.
 - Should open-back gowns be included in the definition? One of the most significant expectations of an isolation gown is that it will provide full coverage; that is, 360 degrees of protection. Some healthcare workers may feel that the open-back gowns are cooler and provide extra air circulation. The primary question should be, should this product be identified as an isolation gown? If so, perhaps "isolation gown" should be redefined.

Discussion Points

Dr. Diekema reminded HICPAC of the upcoming meetings that will inform this discussion further and noted that a future meeting of HICPAC could delve more deeply into details.

Regarding the testing requirements, especially for surgical gowns, AORN expressed concern about the gowns' use, as they are sometimes worn for up to eight hours or longer during long surgical procedures. There is concern regarding how the gowns stand up over time. Post-product testing would be helpful. NIOSH conducts end-user product testing, and it would be valuable and comforting to know whether that testing occurs based on real-world use. Further, AORN stated that open-back gowns should not be included in the definition of an isolation gown.

Mr. Cunningham noted that an area of concern identified in a 2011 AORN user survey was end-user perception of an isolation gown and the important performance criteria for that product. End users felt that comfort and breathability were important factors related to gown performance. There is a direct correlation between the level of protection that a gown will afford and how comfortable and breathable it is. In order to pass the 1671 test standard, frequently a repellent surface is required that will repel fluids, but will not promote air circulation.

HICPAC commented on confusion regarding the standard, as it does not address surgical gowns made of totally impervious material.

Mr. Cunningham said that the term "impervious" was intentionally omitted from the guidance because when FDA recognized the PB70 in 2004, the agency moved forward with defining the level of performance as Level 3 or Level 4. That process attempted to bring consistent labeling to the market, as terms such as "slit resistant" and "impervious" are vague and mean different

things to different individuals. The terminology as defined in the AAMI PB70 document provides a “level playing field.”

APIC commented that it would be helpful to clearly define isolation barriers that are designed for MDR bacteria for contact precautions versus fluid-resistant barriers that are focused on bloodborne pathogens. This clarity would aid decision-making regarding which gowns to use in which circumstances.

Update on HICPAC Workgroup: Antimicrobial Stewardship Principles for Treatment Guidelines: Points to Consider

Dr. Jan Patterson
HICPAC member
Co-Chair, HICPAC Antibiotic Stewardship Workgroup

Dr. Patterson presented the progress of the HICPAC Antibiotic Stewardship Workgroup on antibiotic guidelines.

This workgroup came about because AR is a significant problem and antibiotic stewardship is an important part of controlling it. Discussion at the November 2015 HICPAC meeting led to the development of the workgroup to develop antibiotic stewardship considerations for organizations developing antibiotic treatment guidelines. The group met via teleconference and email. The document draft and editing was largely conducted via email.

The document’s introduction establishes the problem of AR and the role of antibiotic stewardship in controlling it. While current antibiotic guidelines are helpful for defining antibiotic use for prophylaxis and treatment of infections, they have not routinely incorporated antibiotic stewardship principles. With that introduction in mind, the workgroup generated six points for consideration to incorporate into guideline development.

- Determining the likelihood of a bacterial infection is important so that unnecessary antibiotics can be avoided. Cultures, such as for sepsis, and rapid diagnostic tests, when indicated, should be sent promptly to identify infections as specifically as possible.
- While empiric antibiotics may be needed when the clinical picture is uncertain, particularly at hospital admission, the likelihood of a bacterial infection should be reconsidered after cultures and diagnostic tests are available. Step-down therapy and culture-directed therapy should be used whenever possible.
- 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.
- Consider the most narrow-spectrum agent possible, because that approach will reserve the use of broader-spectrum agents.
- An antimicrobial stewardship program that incorporates the CDC Core elements should be cited in the guidelines as a valued resource for determining the optimal antibiotic selection, dose, route, and duration of treatment.

- Use diagnostic tests wisely to avoid unnecessary antibiotic therapy. For instance, do not perform a urine culture, rapid strep test, or *C. diff.* testing unless the patient has signs and symptoms of infection.

The primary reference was CDC's 2014 "Core Elements of Antibiotic Stewardship Programs." The workgroup also utilized additional resources from IDSA and SHEA, the National Quality Forum (NQF), the Society for Hospital Medicine (SHM), the *New England Journal of Medicine (NEJM)*, the Joint Commission, and the National Institute for Health and Care Excellence (NICE).

Dr. Patterson posed questions for HICPAC's consideration:

- To what groups should the Statement be distributed?
- Are there other points to consider?
- How specific should the document be regarding the principle of narrow-spectrum agent use?

Discussion Points

Dr. Cardo thanked the workgroup. The document will have an impact if the professional organizations that have guidelines about the use of antibiotics embrace it. Several of those organizations participate as liaisons to HICPAC. She hoped to hear from them on this point so that the document will be utilized.

SHM commented on the need to balance between the first and last recommendations; that is, the recommendation to identify infection early by testing as much as possible, and the recommendation to use diagnostic tests wisely. If a febrile patient presents, a pan-culture is often conducted. Empiric antibiotic therapy may begin while the results of the culture are pending. Sometimes, cultures are not helpful and yield false positives. Providers may struggle in these situations. There should be clarification regarding the clinical nuances associated with when to culture and when to use the tests wisely.

Dr. Patterson commented that the first recommendation states "where indicated," but suggested that the idea could be expanded. Many urine and sputum cultures are sent unnecessarily.

SCCM noted that critical care agrees that care should be tailored as much as possible, but there is also discussion regarding beginning narrow-spectrum antibiotics early. Antibiotics are lifesaving in sepsis when begun initially. Initiating broad-spectrum antibiotics early for sepsis is appropriate stewardship.

Dr. Patterson wondered whether an example could be presented regarding sepsis to emphasize this point. SCCM supported emphasizing the point. Because of the focus on stewardship, there is a perception that broad-spectrum antibiotics should not be initiated, even in the setting of sepsis. Because they are lifesaving, it is stewardship to initiate the appropriate antibiotics at the appropriate time.

HICPAC pointed out that stewardship encompasses more than limiting empiric antibiotics. De-escalation is an important component of stewardship as well.

HICPAC noted that the likelihood of bacterial infection is important to consider, but so are the clinical consequences of missing or delaying antibiotics in clinical context. The guidelines could incorporate the concept of the downsides of delaying antibiotics in the clinical context. In many situations, antibiotics are delayed even when the pre-test probability of bacterial infection is reasonably high. When delay is high-stakes, it should inform the approach to choosing appropriate empiric antibiotics..

Dr. Patterson said that the issue could be addressed by changing the order of the points of consideration so that the second point could be listed first. The guidelines regarding sepsis and use of antibiotics emphasize prompt initiation of antibiotics.

These considerations are not a guideline for treatment. They comprise a set of principles to support the writing of guidelines about treatment that incorporate stewardship principles. Some of the points that have been raised could be addressed by altering the language of the considerations to clarify that they are intended to serve as guidance to guideline developers and not to clinicians regarding testing.

The document encourages explicit thinking about re-evaluation of antibiotics after a time period and underscores the importance of testing promptly and early to gather information. Wording can be added to clarify that the first point is about testing and the second is about initiation of treatment. The sixth point could be rolled into the first point to illustrate the balance between the importance of early testing in situations of high acuity and of careful evaluation of which tests to administer, and when..

HICPAC appreciated the comments regarding the potential linkages between antimicrobial stewardship and sepsis. This balance requires considering not only initial treatment but also de-escalation and critical thinking using all clinical information available. Imbalance can lead to inappropriate and prolonged duration of antibiotics, especially in the absence of a plan regarding dose duration. This issue of the “why” could be incorporated into these considerations. Antibiotic stewardship occurs at the individual level, but it is also important to comment on audit and feedback across hospital and health systems that can drive differences in performance.

IDSA observed that the fifth point seems incongruous with the content in the other points, which focus on active statements about specifics and management. While CDC’s Core Elements document is the strongest and most concise statement available, other resources are available as well. It is unusual to name a specific element to be included. Some might interpret this point such that all parts of the Core Elements should be adopted.

There was discussion regarding whether HICPAC could provide guidance on specific drugs that may be either FDA-approved or listed in guidelines that are not appropriate. One example of this idea is the use of ertapenem for community-acquired pneumonia. The workgroup concluded that the guidelines should not refer to a specific drug that is not a first choice for community-acquired pneumonia, but asked for HICPAC’s feedback regarding whether more specific examples should or should not be included.

Dr. Cardo noted that this document is not primarily intended for clinicians, but rather for professional organizations that will recommend antibiotics. Guidance written by the professional organizations will recommend specific treatment recommendations

The National Association of County and City Health Officials (NACCHO) has three demonstration sites directly addressing antibiotic stewardship. At one site, even when certain drug routes or testing are not recommended, the cost base analysis indicates increased costs. These approaches are better for public health in the long-term, but they are not initially good for a facility's bottom line. This point is a struggle, as proper use of antibiotics will save money in the long run but is not immediately obvious.

CSTE suggested adding a statement regarding the importance of knowing what the likely pathogen is and the antibiotic susceptibility profile within the patient population, whether it is in the outpatient community or the hospital setting. The empiric antibiotic choice is influenced by these issues.

Dr. Diekema asked the HICPAC liaisons from societies that create guidelines if they feel that there are examples of current guidelines that incorporate some of these principles.

SHM relies on the CDC publications on core requirements. A resource list of potential documents for reference would be helpful.

NACCHO uses the CDC Core Elements and other CDC guidance resources. There is a gap associated with strategies for antibiotic stewardship and with localities having access to trained professionals to help implement the guidelines. Without a trained workforce to implement the guidelines, public health is not affected. NACCHO has asked for a document for training public health professionals on how to be knowledgeable on HAIs and antibiotic stewardship.

CSTE wondered about an opportunity to ensure that these principles are taught in medical and nurse practitioner schools. Many medical students are no longer taught about infectious diseases, and it is important that these principles of antibiotic stewardship are taught to the upcoming workforce.

Chlorhexidine Impregnated Dressing Recommendation Update

Erin Stone, MS
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

Ms. Erin Stone presented updated data and an updated draft recommendation regarding Chlorhexidine Gluconate-Impregnated (CGI) Dressings for Intravascular Catheter Exit Sites.

The 2011 CDC and HICPAC Bloodstream Infection (BSI) Guideline contained the following recommendation on CGI dressings:

- Use a chlorhexidine-impregnated sponge dressing for temporary short-term catheters in patients older than 2 months of age if the CLABSI rate is not decreasing despite adherence to basic prevention measures, including education and training, appropriate use of chlorhexidine for skin antisepsis, and maximum sterile barrier (MSB) precautions.
Category 1B
- No recommendation is made for other types of chlorhexidine dressings. **Unresolved Issue**

At the time the recommendation was made, evidence was available for the chlorhexidine-impregnated sponge dressing but not for the chlorhexidine-impregnated gel dressing. The recommendation is not stand-alone. It fits into the framework of the entire Guideline for Prevention of Intravascular Catheter-Related Infections, which outlines education, agents for skin antisepsis, and other considerations for prevention of intravascular-catheter related infections. This recommendation is the only one being updated, however.

The issue of chlorhexidine-impregnated dressings was presented to HICPAC in November 2015. The question was posited regarding whether CGI dressings should be considered a product class, including both the sponge and the gel, because of the availability of a study outlining benefits and harms of the gel dressing. HICPAC provided the following feedback:

To be considered a product class, the product should have:

- The same active agent
- The same site of action
- Local elution at the site
- The same mode of delivery
- A similar time span of delivery
- Clinical trials examining efficacy utilizing identical, or at least very similar, outcomes - including similar associated adverse events

Recommendations are formulated by looking at the overall quality grades of the evidence:

- A high-quality grade assigned to evidence indicates that further research is very unlikely to change confidence in the estimate of effect.
- Moderate-quality evidence means that further research is likely to impact confidence in the estimate of effect and may change the estimate.
- Low-quality evidence means that further research is very likely to impact confidence in the estimate of effect and is likely to change the estimate.
- Very low-quality evidence means that it could be any estimate of effect.

Regarding determinants of quality:

- Randomized controlled trials (RCTs) start as high-quality evidence.
- Five factors lower the quality of evidence:
 - Study quality
 - Inconsistency in the data
 - Indirectness of the data
 - Imprecision in the data
 - Publication bias
- Three factors can increase the quality of evidence:
 - Strength of association
 - Dose-response
 - Confounding

Several key inputs are considered when recommendations are formulated:

- Values and preferences used to determine the “critical” outcomes
- Overall Grading of Recommendations Assessment, Development and Evaluation (GRADE) of the evidence for the critical outcomes: the confidence in the estimate of effects for the grade of each outcome
- Net benefits, net harms, or trade-offs that result from weighing the “critical” outcomes

All Category 1 recommendations are strong recommendations.

- Category 1A: A strong recommendation supported by high- to moderate-quality evidence suggesting net clinical benefits or harms
- Category 1B: A strong recommendation supported by low-quality evidence suggesting net clinical benefits or harms, supported by low to very low-quality evidence
- Category 1C: A strong recommendation required by state or federal regulation
- Category 2: A weak recommendation supported by any quality evidence suggesting a trade-off between clinical benefits and harms, rather than a preponderance of one or the other
- Recommendation for further research: An unresolved issue for which there is low- to very low-quality evidence with uncertain trade-offs between benefits and harms

The key question regarding this recommendation was:

- For patients with temporary, short-term, non-tunneled catheters, how do CGI dressings compared to standard dressings impact the risk of catheter-related infections?
- Critical outcomes:
 - Infection such as catheter-related bloodstream infections (CRBSI),
 - Catheter-related infection (CRI), a composite outcome
 - Catheter-associated bloodstream infections (CABSIs)
 - BSI without a source
- Outcomes of interest:
 - Product-related adverse events
 - Chlorhexidine resistance

The CGI sponge label states that it is intended to reduce local infections, catheter-related bloodstream infections (CRBSI), and skin colonization of microorganisms commonly related to CRBSI, in patients with central venous or arterial catheters. Safety and effectiveness have not been established in children under 16 years of age. The label includes a warning not to use the sponge on premature infants. “Use of this product on premature infants has resulted in hypersensitivity reactions and necrosis of the skin.”

The CGI Gel dressing label indicates that it can be used to cover and protect catheter sites and to secure devices to skin. Common applications include securing and covering IV catheters, other intravascular catheters and percutaneous devices. Additionally, the label states: “Do not use chlorhexidine gluconate (CHG) gel dressings on premature infants. Current literature about

the use of CHG on premature infants suggests that use of chlorhexidine-impregnated gel dressings on infants with under-developed skin could result in hypersensitivity or necrosis of the skin.” At the time this label was designated by FDA, there was no benefit shown for reduction of CRBSI or infection outcomes. It states that although there are no studies on premature infants, data are extrapolated from the CGI sponge dressing to this situation.

After the updated literature search, title and abstract screen, full text review, and inclusion of the initial articles considered for the 2011 guideline, there were seven RCTs for consideration. Five of them evaluated populations of greater than 18 years of age, and two evaluated populations less than or equal to 18 years of age. The age break point was based on the FDA labels and on concern regarding lack of evidence in the pediatric population, as well as on the natural break point in the adult studies.

The evidence review shows benefit and reduction in CRBSI in this patient population. One of the studies was on the CGI gel dressing, and three of them were on the sponge. Regarding CRI, the two larger studies show benefit, and the two smaller studies show no difference. Therefore, the quality of evidence is moderate.

The two large, multi-center RCTs also evaluated patients according to an international contact dermatitis research group system and found significantly higher rates of abnormal scores in both RCTs. While allergy to chlorhexidine was typically an exclusionary criteria for these RCTs, the two studies that did not use it as an exclusionary criterion cited that no systemic adverse events associated with CGI dressings.

There are limitations to this evidence. In the table below, studies highlighted in yellow received industry funding. None of the RCTs was conducted in the US, and all were conducted in 2012 and earlier, with the majority of data collected before 2011 when the CDC-HICPAC BSI Guideline was released.

In order to obtain the needed power, the two larger studies included arterial and central venous catheters. They also included more than one catheter per patient. The smaller studies employed only central venous catheters and typically cited one catheter per patient. Skin antisepsis was not uniform across the studies. In all studies, antisepsis was the same between the study arms; however, the multi-center studies included some centers that use alcoholic CHG, some utilized alcoholic povidone iodine. All were within acceptable limits, but perhaps not per standard of care.

The Timsit 2012 study that using different skin antisepsis agents at different study centers conducted a sensitivity analysis that demonstrated that there was no difference in catheter related infection rates between alcoholic povidone iodine and alcoholic CHG. The rate of infections per arm stratified by skin antisepsis agent is unknown pending a reply from the corresponding author.

One of the 2011 Guidelines for the Prevention of Intravascular Catheter Related Infection recommendations is to avoid the femoral site. In the Timsit 2012 study population, there was no statistically significant difference in insertion site between the arms in either of the studies. Additionally, the 2012 study broke infection data down by central venous versus arterial catheters. Benefit was shown in a reduction of CRI and CR-BSI in central venous catheters, but no difference in catheter rates was seen in arterial catheters by dressing type. The study conducted a sensitivity analysis on the type of catheter and found no significant difference

between arterial and venous catheters in the outcome of CRI. Data were analyzed by arterial catheter site, including femoral and radial, and no difference was found. No statistically significant difference was found in the rate catheter related infection per insertion site of central venous catheters. It should be noted that in some of these outcomes, the 95% confidence interval crosses 1.

The two smaller studies also broke down infectious outcomes by insertion site. The Arvaniti 2012 study had high femoral insertion rates, almost 50% of the study, which could be why the CGI dressings did not show benefit. The Ruschulte 2009 study, conducted in a single-center hematology/oncology unit, showed a statistically significant benefit in the reduction of CR-BSI for the jugular site but not the subclavian site.

These limitations are important in considering whether these data are direct and apply to the current situation or are considered indirect. Indirectness would reduce the confidence in the estimate of effects seen in this data.

Only two RCTs address outcomes for patients less than 18 years of age. The quality of evidence is low to very low, largely because few RCTs look at these outcomes, and there are additional limitations to the data. Neither of the studies reported on chlorhexidine resistance. The neonatal study was conducted in the US, and the pediatric study was conducted in Israel. Neither addressed CHG gel dressings. Both studies were underpowered to detect a reduction in CR-BSI.

The pediatric study used aqueous povidone iodine for skin antisepsis. In the neonatal study, the intervention arm with the sponge used alcohol as a skin prep, where aqueous povidone iodine was used in the control arm. It is notable that the results are indirect and possibly not comparable. Further, the mean time in place for the lines and dressings was 4-5 days in the pediatric population, but higher in the neonatal population. Neither reported chlorhexidine bathing.

In summary, before considering limitations of the data, it appears that in populations greater than 18 years, there is evidence of benefit and not evidence of harm. In pediatric populations, there is evidence of no benefit, and there is evidence of harm in neonates.

After HICPAC's discussion, the next steps will be to review all of the HICPAC feedback, allow for a public comment period, and present public comments and an updated draft to HICPAC.

Discussion of Issues and Candidate Recommendations

Tom Talbot, MD, MPH HICPAC Member

Dr. Talbot thanked Ms. Stone for her work, noting that the issue became more complicated as the work progressed. He asked HICPAC to consider the framework for the CGI product class:

- How should comparable products be considered?
- What are criteria that would be acceptable for grouping them together?

Gel and sponge dressings were considered together because they deliver the same agent at the same site of action; with local elution at the site; with a similar time span; and trials have

been conducted to examine their efficacy. He asked HICPAC whether this framework still reflected the consensus opinion of the group and whether the rationale for grouping the products was still applicable.

The workgroup discussed what the recommendations should include, based upon the level of data. Earlier iterations of the recommendations had greater detail similar to the 2011 language regarding considering use if rates are not increasing despite the use of other practice. This language makes the recommendation somewhat confusing and variable. The candidate recommendations provide context about use that is not direct implementation guidance.

Candidate Recommendations: Adult Population

1. Use chlorhexidine gluconate impregnated dressings for the prevention of catheter related infections in patients with temporary, short-term, non-tunneled catheters older than 18 years. (Category IA)

OR

1a. Consider use of chlorhexidine gluconate impregnated dressings for prevention of catheter related infections in patients with temporary, short-term, non-tunneled catheters older than 18 years. (Category II)

Two possible recommendations are presented because the literature review revealed striking variability in the core practices of line insertion that many facilities utilize, particularly regarding the use of chlorhexidine as an antiseptic. The workgroup questioned whether this variability reduces the quality of the evidence. Similarly, chlorhexidine bathing is viewed as a standard for CLABSI prevention, but that practice was not in place during these studies. The workgroup discussed whether the lack of bathing downgrades the evidence.

In light of the issue of when to use the products when rates are not increasing, the workgroup turned to the SHEA Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals (“the Compendium”), which includes a useful flowchart regarding MRSA. The flowchart applies to implementation, but it also provides context for when special approaches should be used. It was suggested that the HICPAC guideline could incorporate a similar flowchart to provide guidance if the products are being considered:

The basic practices are based on the 2011 CDC-HICPAC guidelines and the SHEA Compendium. Notably, the basic practice of CHG bathing in the intensive care unit (ICU) is a Category 1A recommendation in the Compendium, but was not in the 2011 CDC-HICPAC guidelines. The flowchart is purposely vague in naming “benchmarks” so that facilities utilize their own performance standards. The flowchart also specifically states that practice should be observed before advancing to other strategies. If basic practices are intact, but benchmarks are still not reached, then special approaches should be considered.

The special approaches were not reviewed with the same level of evidence as the guidelines were, which is important to consider. The flowchart provides more context than “use” or “consider using.”

Candidate Recommendations: Patients 18 Years and Younger

Do not use CGI dressings for preventing CRI in neonates with temporary, short-term, non-tunneled catheters. **(Category 1A)**

No recommendation can be made about the use of CGI dressings for preventing CRI in pediatric patients 18 and younger with temporary, short-term, non-tunneled catheters. **(Unresolved issue)**

Dr. Talbot asked for HICPAC's input regarding which recommendation to make for adult populations; the practices used in the trials and whether they reflect current standard of care for line insertion and maintenance; potential problems where the recommendations in the Compendium do not mirror the CDC-HICPAC 2011 recommendations; and whether a certain order of the special approaches implies priority, which it should not.

Discussion Points

Dr. Diekema noted that public comment submitted by Patrick Parks at 3M relates to this issue, particularly to delivery to the skin and to clinical evidence that illustrates clinical value.

HICPAC asked about dressing change frequency, which is likely to be weekly. Ms. Stone said that there is no significant difference in rates of infection in the Timsit 2009 study based on the frequency of dressing change.

The issue of evaluating a practice in isolation in studies that may not have already been using the current standard of care is not unique to this area. This issue arose frequently during HICPAC's Surgical Site Infection (SSI) Guideline discussion. Some studies in the SSI Guideline development process did not follow the "standard bundle" of practices.

There was support among HICPAC for the first candidate recommendation:

A 1A recommendation appears to be appropriate in this case, partially due to the very low CLABSI rates in the control group, despite that some of the studies did not use chlorhexidine bathing. The practices of antiseptic use and insertion prep should also be considered.

HICPAC's recommendations are adopted widely, and facilities focus on the Category 1 recommendations. The Category 2 recommendations are often considered to be unnecessary, regardless of how HICPAC feels about the evidence. If a facility implements approaches sequentially and reaches zero infections, then the facility might perceive a Category 2 recommendation about dressings as not necessary and "backslide." If a facility has reached zero infections because a dressing was incorporated, but the dressing is not mandatory, the purchasing department may deem that it should not be used because it is expensive.

Covering the site with sterile gauze or sterile transparent adhesive dressing is a Category 1A recommendation in the 2011 guidance.

CHG dressing was not a Category 1A recommendation in the 2011 guidance, but it was that category in the Compendium.

The 2011 statement is essentially the same recommendation as the Category 1A recommendation proposed, with the addition of the gel dressings and a change of the age range. A Category 2 recommendation for both may be perceived as a downgrade from the 2011

1B recommendation. The move from Category 1 to 2 implies that additional data decreases the level of confidence that this intervention is one that ought to be used in all hospitals.

There was support for the second candidate recommendation:

Practices that are now considered standard of care that were not utilized in the studies. Concern was expressed about the differences between the skin prep between the control and intervention arms. That structure makes it more difficult to interpret the impact of the chlorhexidine dressing beyond the site prep and diminish enthusiasm about the strength of the recommendation.

The 2011 guideline includes chlorhexidine bathing as a Category 2 recommendation. If there is equivalence between the chlorhexidine dressing and bathing, if the question and data were not going to be revisited, then there is argument for a Category 2 recommendation.

In the past, recommendations have been downgraded to Category 2 if there are concerns regarding harms or the emergence of AMR. An ongoing argument regarding the many uses of chlorhexidine relates to concerns about losing it as a topical microbial because of overuse. If Category 2 is chosen, then the text should be explicit regarding the different methodologies.

Regarding concerns that facilities might not implement a recommendation if it is a Category 2, the problem may be associated with education and presentation. However, if the recommendation is Category 1, it indicates that facilities should implement the recommendation even if they are at zero infections. All facilities are expected to implement Category 1 recommendations. If a facility has reached zero infections, then a new Category 1A recommendation implies that the facility should still implement that recommendation, even when additional benefit is unlikely. This concern is significant, especially if the incremental benefit of these dressings added to other CLABSI prevention practices is unknown.

Dr. Diekema suggested that another option could be to append the statement to note that the recommendation is for sterile gauze or sterile transparent adhesive dressing, or CGI dressing. That combination does not address CGI dressing as an independent intervention, however.

There was discussion regarding whether the point might be a Category 1B recommendation, given that the supporting evidence may not be high. The alternative of revising the existing statement and keeping it as a Category 1B recommendation was posed. Ms. Stone pointed out that the overall confidence in the evidence of effect is moderate, based on the split in benefit versus no benefit. Taking a point off would make the recommendation Category 2.

While the concept of the flowchart is laudable, HICPAC pointed out that use of benchmarks as goals could cause hospitals to limit CLABSI prevention efforts once benchmarks are reached. Consumer advocates will push back against the aiming for a CLABSI target other than zero. The flowchart might be rewritten so that facilities constantly push toward reductions in rates. The writing group discussed this issue and considered specifying the 2020 goal, but many hospitals are far below that. At the same time, hospitals should not set their bar so that they look good. There may be a point at which facilities drive toward reduction and reach a point beyond which they cannot improve. Not all infections that are reported are truly preventable.

CSTE also expressed concern regarding the flowchart's referral to CLABSI rates being "better than benchmark." The language leaves the issue too open, and some facilities will not take

additional action. If there is an intervention that can affect CLABSI rates at relatively low cost, with few side effects in the adult population, then it is important.

The flowchart approach is consistent with the way that hospital settings evaluate risks and understand when certain measures should be applied. HICPAC cautioned against over-reliance on product-based solutions for elevated rates, as erosion of basic practices and changes of personnel are often at the root of these problems and should be considered at the root of the algorithm.

SHM said that it is known that alcoholic chlorhexidine is superior to alcoholic povidone-iodine. Chlorhexidine is used for line insertion, maintenance, and bathing. Good data are not available to suggest potential resistance to chlorhexidine, but there is concern about downsides to increasing exposure to it. More importantly, there are no clear data to suggest that adding CGI dressings on top of skin insertion is of value. These studies do not take peripherally inserted central catheter (PICC) lines into account. There are differences related to CLABSI, especially related to duration of onset, as the studies are short-term in ICU settings, with different patients. While some results may be transposed to a PICC, they are different from the lines in the studies.

SCCM added that there are differences between venous and arterial lines. Few studies compared the two, and the recommendation implies that the two should be handled in the same way. A slight change in the recommendation language could bring more clarity.

SHEA commented that listing bathing as a standard practice on the flowchart and not including dressings with the same degree of strength does not make clear sense. Both practices should be instituted when rates are not where a facility wants them to be. Most hospitals use chlorhexidine widely, but European colleagues believe that the widespread use of chlorhexidine is a mistake. Both are evidence-based procedures to prevent CLABSI with the same level of evidence, and both could be listed as basic practices or special approaches.

There was concern about including ICU bathing of all patients in the HICPAC CLABSI Prevention Guidelines as a line in the flowchart without explanation. Many facilities do this bathing already, but small hospitals with low CLABSI rates struggle with whether, and why, they should do chlorhexidine bathing daily on every ICU patient.

The flowchart is a helpful structure, but it may need to be more high-level, with nuanced discussion provided in accompanying text. This approach would allow for discussion of the different levels of literature review and not give the impression that the approaches received the same level of recommendation and data review that is implied by the HICPAC endorsement.

SHEA suggested that the flowchart may need to include the idea that chlorhexidine bathing may be needed for other reasons besides CLABSI prevention. The data suggest that it prevents MRSA and vancomycin-resistant *Enterococcus faecium* (VRE) spread as well.

There was discussion regarding cost considerations associated with using versus not using CGI dressings. Using the dressings may have an impact on budgets. A time series analysis of macro data received from different state agencies would be helpful. With this analysis, it is possible to see the differences when a step is added. RCTs are the standard, but it is known that bundles are effective. It is helpful for facilities to use their own benchmarks, and most want to reach zero. It is critical that each step is executed and validated.

Chlorhexidine bathing and dressing might be presented together. From an implementation standpoint, it is easier to teach someone how to apply a dressing correctly than to bathe with CHG correctly. There are many issues in the ICU setting, such as interactions with other necessary emollients, which inhibit consistent and correct CHG bathing.

The National Institutes of Health (NIH) suggested adding to the flowchart element, “ensure compliance with basic practices,” reference to minimizing “variation in line care practices.” Personnel tend to follow basic principles, but with variation.

It was suggested that HICPAC make a decision about CGI dressings in the context of revisiting the chlorhexidine bathing recommendation in the 2011 guideline. It was noted that CHG bathing has a number of other benefits, and considering it in isolation for CLABSI prevention would be a complex effort. Further, SHEA noted that the field looks to HICPAC for recommendations. It frequently takes a long time for a comprehensive guideline to be released. SHEA supported this attempt to answer a specific question within a guideline and urged HICPAC to move forward on the CGI dressing question. If the committee wishes to consider chlorhexidine bathing as a separate issue, it should do so, but delaying release of guidance does the public a disservice and affects HICPAC’s credibility.

An approach should be in place for ongoing antisepsis on the skin with chlorhexidine, whether with a sponge or a bath. There is no evidence for one or the other, and it is likely that there never will be such a trial.

HICPAC asked the writing group if further trials are unlikely to add additional knowledge regarding this issue, or whether it is possible that a large trial might change the point estimate sufficient to affect the committee’s opinion about the data. The writing group struggled with several issues. The evidence review focused on two devices that deliver chlorhexidine at the insertion site, and the practices of chlorhexidine at the insertion site and chlorhexidine bathing were not part of every trial. If both of those practices are in place, then does it matter if a CGI sponge is used as well? These practices have the same active agent, but delivered differently.

APIC said that the clarification will be important if the evidence is downgraded. It would be unfortunate for organizations that might be using CGI dressings that are struggling with CLABSI rates to discontinue the practice because it is a Category 2 recommendation that is perceived to have little to no benefit.

Dr. Talbot noted that the flowchart may help in that situation. The CGI dressings would be a special practice to employ. If a facility had high rates and dressings were part of the strategy to reduce them, then there may be less risk.

APIC said that the use of the flowchart should be stressed. There is significant associated cost with CGI dressing. Organizations and individuals may feel that the dressings are cumbersome and difficult to use, so if the evidence is not perceived to be strong, then the dressings might be eliminated.

Member Poll: Recommendations for the Use of Chlorhexidine Impregnated Dressings

Dr. Diekema proposed a poll of HICPAC regarding whether the evidence supports a Category IA or Category II recommendation for use of CGI dressings in patients over the age of 18. He reminded them that for Category IA, the current assessment is that the evidence is of moderate quality, suggesting net clinical benefits over harm. Category II would be the same quality evidence, but imply a trade-off between benefits and harms, with part of the concern related to AMR and topical agents. Issues regarding the language of the recommendation would be discussed separately. HICPAC determined the category to be IA with 10 members supporting a IA recommendation, 3 members supporting a IA recommendation with a caveat that the recommendation should be accompanied by guidance regarding appropriate terms of use for the CGI dressings, 0 in support of a Category II, 0 Abstaining, and 1 absent member. The disposition of the vote was as follows:

10 Supported Category IA: Brown, Fauerbach, Howell, Huskins, Janssen, Maragakis, Patterson, Rogers, Talbot, Tapper,

3 Supported Category IA with caveat describing terms of dressing use: Babcock, Diekema, Yokoe

0 Supported Category II: N/A

1 Absent Member: Chernetsky Tejedor

Dr. Diekema asked HICPAC to share concerns regarding the recommendations for pediatric populations. One recommendation is against use in neonates, and there is a “no recommendation” for children aged 18 and younger who are not neonates.

HICPAC observed that the harm data is primarily among neonates weighing less than 1000 grams. There was discussion regarding whether the rate of adverse event in the neonates weighing greater than 1000 grams is notably different from the rate among adults. It was suggested that the recommendation further define “neonate” according to body weight. Ms. Stone said that the package insert refers to “neonates.” HICPAC said that the recommendation as currently worded states that the dressings should not be used in any infant under 30 days of age. It is not uncommon to use these dressings in children of greater gestational and chronological age. A full-term infant at three weeks of age might have the dressing placed. Not all neonates are in neonatal intensive care units (NICUs). They might be in other units where the prevailing approach is to use a chlorhexidine-containing dressing. It is a potential problem to prohibit the use of the dressings in any infant when there are situations in which it might not be inappropriate. Such use is off-label, but the dressings are used off-label.

SCCM commented that the population described in the study is premature infants of very low birth weight. This group is different from a neonate. A full-term, 29-day-old infant in an ICU will likely receive this dressing. More precise language, such as reference to gestational age or birth weight, and elimination of the term “neonate,” might alleviate confusion.

HICPAC said that the recommendation should not exclude the use of CGI dressings in older children. The recommendation currently is “unresolved” for newborns up to age 18.

Dr. Diekema offered the option to vote on the recommendation as currently worded, or to amend the language to refer to neonates weighing less than 1000 grams. The argument to

leave the recommendation as written pertained to the information on the product insert and to the higher rate of contact dermatitis among the younger populations.

Ms. Stone added that age as well as weight is a confounding factor. The Garland study changed the enrollment criteria after conducting an interim analysis that found that seven out of 115 neonates randomized to the CHG arm in the first 15 months had severe contact dermatitis. All seven neonates had their lines and dressings placed on or before the eighth day of life. The study changed the enrollment criteria to include infants less than 26 weeks old only if the catheter was inserted after the first week of life.

Dr. Diekema proposed leaving the recommendation as it stands, which does not preclude future changes based on future, cumulative data.

HICPAC suggested that use of the term “premature” with explanatory text would alleviate the problem. No objections to this adjustment were voiced.

HICPAC discussed whether the recommendations would apply to arterial catheters as well as venous catheters. As it is written, many facilities would read the recommendation as applying to arterial catheters. The recommendation does not specify arterial lines, although some arterial line data were included in some of the studies. The recommendation does not distinguish in the CLABSI guidelines in general. The 2011 recommendation refers to central lines and specifies vascular or non-vascular percutaneous medical devices, with a series of examples.

HICPAC agreed that according to the evidence, there should be no recommendation for arterial catheters. The point is important because there may be as many, if not more, arterial catheters in ICUs. The evidence appears to be inadequate to make a Category 1A recommendation regarding arterial lines, particularly given that in the past year, a survey study has showed that only 15% of clinicians in the US report using full-barrier precautions for arterial lines. Therefore, the word “venous” should be inserted.

Dr. Diekema suggested that the Category 1A language could be amended to designate central venous lines. There was agreement among HICPAC.

Update of the Draft Guideline: Infection Prevention in Healthcare Personnel

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Dr. David Kuhar and Dr. Irwin presented an update on infection prevention in healthcare personnel.

The 1998 *Guideline for Infection Control in Healthcare Personnel* provided recommendations for reducing the transmission of infections among healthcare personnel and patients. This guideline is different from the guideline for isolation precautions, as it is aimed at occupational health providers working in healthcare facilities. It focuses on infections known to be transmitted in healthcare settings among personnel and patients and recommends strategies for preventing transmission, including those involved in the occupational health service, such as providing immunizations, education about isolation precautions, management of healthcare personnel exposures to infections, as well as infection personnel, including post-exposure prophylaxis (PEP) as well as work restrictions for infectious or ill personnel.

The guideline includes discussion on the infrastructure needed to provide infection prevention services to healthcare personnel, such as having identified the objectives of an occupational health service for providing infection prevention services, such as preventing exposures and managing ill or exposed healthcare personnel. It also provides the critical elements or infrastructure pieces that an occupational health service needs to deliver infection prevention services and that they are responsible for overseeing.

The 1998 guideline also provides in-depth discussion of selected infections transmitted among healthcare personnel and patients. For each disease, the guideline addresses epidemiology in healthcare settings, prevention strategies, immunization if available, the management of sick or exposed personnel including PEP, and work restrictions.

The 1998 guideline also separately discusses special populations that might have unique infection prevention service needs. These populations include pregnant personnel, laboratory personnel, and emergency response personnel. Latex hypersensitivity was a prevalent topic at the time and is included in the guideline. The Americans with Disabilities Act (ADA) is also discussed, particularly pertaining to its relevance to how services are delivered to personnel, such as the questions that can be asked about an employee's medical history.

At the time, the 1998 document was widely used. It not only provided needed information, but also compiled the information in a helpful way and in a helpful format. CDC has been encouraged to retain the scope of content that was useful in the original 1998 guideline. The primary audience for the updated guidance will be similar, but expanded, and CDC will modernize its delivery to the user community, publishing it as a living guideline on CDC's website. Complete sections will be published sequentially online, each with its own unique date and summary of updated information, to expedite the processing of getting timely information to readers. The organization of the document will be slightly revised to be more streamlined, and the scope will be expanded.

The updated guidance is currently planned to have at least two sections. The first section will be published ahead of the other sections and will address the necessary infrastructure and practices for provision of infection prevention services to personnel. 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 for infection prevention will either be addressed as part of each pathogen section or in a separate section. It is important to ensure that their needs are not overlooked in the presentation of information.

Section 1 is the first slated for updating. As healthcare services are increasingly provided outside of acute care hospitals, it is important to address the diversity in the settings in which occupational health services take place, including outpatient settings, clinics, and ambulatory settings. These issues incorporate consideration of how services are offered and delivered off-site. Overall, the guideline will still be aimed at occupational health providers and will target healthcare organization leaders who oversee occupational health services, as they provide the resources needed to deliver critical services.

The Section 1 update will utilize several methods to bring the critical recommendations forward. Therefore, the term “hybrid development methods” will be employed. Certain topics, such as immunizations, are addressed in other guidelines. This document will refer to those guidelines and not duplicate work that has already been done. New recommendations will be developed based upon research, program evaluation, other guidelines, theoretical rationale, and expert opinion. Recommendations will be categorized as a regulation or “recommended.” There is limited evidence regarding the needed infrastructure to provide optimal infection prevention services; therefore, this process is not amenable to GRADE.

Regarding the evidence base for the guideline, a systematic review was performed that identified approximately 310 articles related to the objectives, infrastructure, and elements for occupational health services for infection prevention. Approximately thirty related guidelines were identified, as well as twenty-five government and non-government websites.

The planned electronic format will allow for regular updates of even small subsections when needed without updating the entire guideline. The format also allows for more easily updated summary tables, which will ensure that they are useful for users. When one row or box is out of date, there will be the opportunity to correct it and extend the table’s longevity. There will be the opportunity to indicate dates of review and highlight when updates are made for certain subsections.

The writing group for Section 1 was reconvened in November 2015 and has met approximately every two to four weeks via teleconference. The group has used prior work on Section 1 and has completed the literature work. The rough draft of the section is being refined. The outline of Section 1 is:

- Introduction
- Methods for developing the recommendations
- Infection prevention objectives for an occupational health service
- Elements of infrastructure for an occupational health service to provide infection prevention services:
 - Leadership and management: quality improvement, performance measurement, conditions of participation, policy compliance
 - Collaboration and communication: infection prevention services and other departments, human resources when work restrictions are needed, health departments during outbreaks
 - Risk assessment in the healthcare facility and the importance of occupational health personnel participation in the assessment of infectious disease hazards related to the healthcare environment or risks related to using new devices, procedures, or policies
 - Pre-placement, periodic, and episodic medical evaluations, including counseling

- Health and safety education and training, which are critical for personnel to understand the rationale for procedures and to increase adherence
- Management of potentially infectious illnesses and exposures
- Records, data management, confidentiality, and reporting

The infrastructure of the update is similar to the 1998 guidance, with the addition of leadership and management as well as risk assessment in the healthcare facility. The 1998 version includes “health counseling,” which will be incorporated into “medical evaluations” in the update.

Each element of the updated guideline will be discussed in the following context, using the example of “records, data management, confidentiality reporting:”

- Definition: For example, maintenance of records refers to recording information on medical evaluations, evidence of immunity, and other such items.
- Purpose: Adhering to requirements, allowing for retrieving medical information when an exposure has occurred.
- Status of delivery and quality of the element: What are challenges in delivery? What do providers need to be aware of? For medical record-keeping, the guidelines should indicate the need to adhere to Occupational Safety and Health Administration (OSHA) requirements, such as the OSHA 300 log form when exposures occur.
- Interventions that could improve the delivery or the quality of the element will be discussed: how could the service best be delivered? For instance, perhaps an electronic medical record (EMR) could be used instead of a written record.
- Recommendations will include designing strategies after considering past experience. The guideline will refer to tables that include summaries of relevant literature identified from the systematic review to serve as a resource to readers.

Dr. Irwin described Section 2 of the guideline, which will begin with a review of the isolation precautions, which are a fundamental component of protecting healthcare workers and transmission of pathogens. It will then refer to specific pathogens.

Similar to Section 1, Section 2 will utilize a hybrid approach to developing the updated recommendations. Pathogens that have been assigned to DHQP will be addressed by a writing group drawn from experts within the division and external experts from other divisions at CDC or outside the agency. The literature review will emphasize new issues, and many issues in the 1998 guidance will need to be revisited. A standard outline will be applied that will be amenable to updates, using a modular approach. Standard categorization recommendations similar to those used in 1998 will be used. Hyperlinks will be provided to supplemental documents, especially those that change often. These recommendations will be vetted with HICPAC and the public.

The leadership for some pathogens is assigned to other divisions within CDC, such as tuberculosis (TB), hepatitis, and influenza. In these cases, the writing group will be drawn from those divisions’ experts, plus DHQP staff and external experts. Hyperlinks to those divisions’ latest guidance regarding infection control and healthcare workers will be important. The links will be paired with an alert to readers that the non-DHQP guidelines might have used different development methods, a different evidence base, different recommendation categories, and stakeholder vetting.

The outline for each of the pathogen subsections will be similar to the 1998 document:

- Overview of the pathogen and clinical manifestations
- Epidemiology, with an emphasis on recent data regarding transmission in healthcare settings
- Methods to prevent and control transmission, including new vaccination strategies
- Individual risk assessment, screening, and diagnosis of healthcare workers
- Post-exposure management
- Illness management
- Management of outbreaks
- Hyperlinks to implementation resources
- References

The format will be a “living guideline.” The electronic, iteratively updated series of documents is intended to provide the latest federal guidance on a given topic and exploits the Web format that allows for hyperlinks to standalone documents that can be updated more easily than a full guideline. The format also reduces the burden on division staff to update, reformat, and clear a series of large, complete guidelines with fully updated components. It relies on experts and external stakeholders and guideline development methods that have been used in other divisions. This format has been used by other federal agencies.

The approach requires important resources for formatting of the guideline, prominent posting of updates, flagging new information with icons, and committing DHQP staff to check the links to non-DHQP guidelines and to update the compiled tables as evidence changes over time. HICPAC’s feedback was requested regarding Sections 1 and 2 of the updated guideline.

Discussion Points

Regarding occupational health, the VA noted that the question of dual capacity frequently arises, especially as it pertains to treatment. Non-occupationally-related diseases are not supposed to be treated beyond stabilization and moving a person on to the next step. Otherwise, occupational health becomes a person’s doctor, which is problematic. There are settings in which occupational health personnel provide treatment, when issues are part of a person’s occupational duties, but in a case such as a person with sinusitis, occupational health might provide treatment in the immediate term but should not treat beyond that. People in occupational health want to help, and the guideline should be cognizant of these issues.

Dr. Irwin said that it will be clear that the scope of the guideline is the management of occupationally-related illnesses and exposures. The coverage of healthcare for healthcare workers has evolved; many healthcare workers are insured by their facility, so they are a patient as well as an employee. The guideline will make it very clear how that type of coverage relationship affects access to records as well as the obligation to provide onsite versus referred treatment.

CSTE commented on guidance for providing screening for employees. Some of the topics in the proposed guideline merit additional detail. For instance, does the health and safety education and training include a “cheat sheet” for employees to help them understand conditions that should be reported to occupational health to prevent spread?

Dr. Kuhar answered that such items might be addressed in the discussion of individual pathogens, especially those associated with acute gastrointestinal illness. The specificity of

criteria can be controversial, and there is a great deal of gray area. While there is a need to create criteria to guide personnel, it should be considered carefully.

CSTE added that the guidance should be clear regarding to whom it applies: only employees versus licensed, independent practitioners, volunteers, and students; only personnel with direct patient contact; personnel who work off-site; and so on. Regarding the immunization program, the guideline should address how to handle people who refuse to be vaccinated.

APIC agreed and added that the issue of returning to work is important to include. Infection prevention departments are frequently consulted by their occupational health colleagues regarding return-to-work scenarios for a variety of these illnesses.

Dr. Irwin assured HICPAC that the guideline has a definition of “healthcare personnel” that includes employees, volunteers, and trainees. Further, return to work is part of the exposure management section of the guideline. The topic can be complex and controversial. The guideline will make a strong recommendation on the importance of training healthcare workers about reporting conditions and exposures that they may have. There should be a constructive, positive environment for peers and supervisors to encourage that reporting. Training, decision support tools, and checklists that may describe elements of training curricula will likely be hyperlinked support documents rather than included in the main guideline.

NACCHO reiterated the importance of defining “healthcare personnel,” particularly in the context of outbreak management. For example, the public health unit does not consider information technology staff as healthcare personnel, even though they work throughout the unit. This issue arises in discussions about exclusions and preventative measures. Further, a definition of what is considered a “healthcare facility” is important to include. Regarding records and data management, the timeliness of occupational health’s reporting to public health can be an issue, especially in an emergency context.

HICPAC noted that the guideline refers to workers outside the US and wondered whether it will address the issue of returning workers that may have had potential exposures to various pathogens. It would be helpful to provide links to guidelines in this area. Dr. Irwin answered that the guideline will address both healthcare workers who practice outside the US and their pre-departure evaluation, preparation, and immunizations as well as returning healthcare workers.

AORN pointed out that at times, physicians do not consider themselves “healthcare personnel,” which can hinder efforts. She praised the living document format, which will speed up the process of bringing guidance to practice.

Regarding Section 2, Dr. Irwin noted that HICPAC has provided input regarding the pathogens that may be of highest priority for the update:

- *Staphylococcus aureus*, including methicillin-susceptible *Staphylococcus aureus* (MSSA) and MRSA
- *Streptococcus* (group A)
- Hepatitis C
- *C. diff*

The guidance will likely include hyperlinks to existing guidance regarding agents of bioterrorism or high-consequence pathogens such as Ebola. CSTE suggested adding Middle East Respiratory Syndrome Coronavirus (MERS Co-V) and related pathogens.

Public Comment

Pat Parks Medical Director, 3M

Pat Parks is the Medical Director for the area of 3M that addresses vascular access and associated problems. He thanked HICPAC for considering the note that he submitted prior to the meeting regarding chlorhexidine dressings. He appreciated HICPAC's deliberations, which help guide 3M's efforts to develop meaningful clinical research. He understood that there is a category of CGI for which local elution of chlorhexidine is important. He emphasized this clinical meaningful event and understood that the recommendation does not incorporate a comment to include local elusion. Such a comment may not be necessary, as the point is included in the preface.

Drs. Diekema and Talbot indicated that the point was correct.

Renee Odehnal Manager of Professional Education, Ethicon© BIOPATCH© Registered Nurse

Ms. Renee Odehnal thanked HICPAC for its deliberations and expressed pleasure that the committee supported a 1A recommendation regarding the CGI dressings. BIOPATCH®, Tegaderm™ CHG, and CHG dressings have been an integral part of central venous catheter dressing regimes for some time and have likely contributed to decreases in BSI. There is no "silver bullet" that will prevent all BSIs. Everything that can be done to reduce them will be important. It would be ideal to go back to the basics and for everyone to do what he or she is supposed to do, every time; however, this is unlikely due to staff turnover, experience, and human nature. A device that can save lives should be used to give an extra edge. Right now, there is only one gel on the market. That might not be the case in six months or a year. There is more than one sponge currently on the market. Other sponges have come to market with some degree of CHG that may or may not be released from the sponge, delivered to the skin, or have any effect on BSIs. She urged HICPAC to consider this issue as a general recommendation is released for CHG dressings. Unfortunately, the market profits on some of the HICPAC recommendations by meeting the bare minimum of what the recommendation states. Some products may only contain some CHG, and products such as sprays or powders may be developed in the future. She urged HICPAC to consider this issue.

Liaison / Ex Officio Reports

NIH

The NIH report focuses on Ebola, VRE, and what the agency now calls Carbapenemase-producing organism (CPOs), because the term CRE is no longer relevant: a range of plasmid organisms have been found. NIH continues whole-house surveillance in its unique hospital. Twenty-five isolates have been identified since the cluster in 2011-2012. All of them are genetically different.

Agency for Healthcare Research and Quality (AHRQ)

AHRQ continues to support CARB through reducing the transmission of resistant infections; improving antibiotic use; encouraging conducting antibiotic stewardship; and reducing resistant

infections. The agency is testing an antibiotic stewardship guide for nursing homes, which is slated for completion in Fall 2016. AHRQ will hold a joint conference with CDC in June 2016 to address knowledge gaps in this area. The agency continues its safety programs to reduce HAIs through the use of a comprehensive, unit-based safety program. Notably, the program for reducing catheter-associated urinary tract infection (CAUTI) in hospitals found an 11% reduction in CAUTI in all units across the safety program in the fall of 2015. CAUTI rates decreased by 30% in non-ICU settings, and there was no significant change in ICUs.

CMS

CMS has begun an infection control pilot to improve infection prevention and control assessment during the survey process. The purpose of the three-year pilot is to develop and test new surveyor tools and products based on the proposed new. The agency will conduct educational surveys, which carry no citations for facilities. This point is particularly important for nursing homes, as many of them are not up-to-date regarding the new regulations. Ten nursing home surveys will be performed in 2016 to begin testing the newly-developed tool. In 2017 and 2018, 40 hospital and 40 nursing home surveys will be conducted. The pilot focuses on three areas:

- Assessing a nursing home's infection prevention and control
- Updating the hospital infection control worksheet
- Assessing for infection prevention during transitions of care; this area is new for CMS

There is benefit in this work, especially for the nursing home industry. The tools for ambulatory surgery center and hospital surveys provide transparency so that the industry knows what to expect when CMS conducts a survey. A new surveyor infection control worksheet for nursing homes will be generated, and it will be clear regarding what the nursing homes need to do in order to be in compliance after the rule is finalized and implemented. CMS will provide more information later in 2016 and plans to release a draft of the worksheet.

FDA

FDA is planning a heater/cooler meeting that will be held in Maryland June 2-3, 2016. FDA is working actively with CDC and standards organizations on gowns that have been brought for regulatory review if manufacturers make Level 3 or Level 4 performance claims. FDA is actively working with duodenoscope and AER manufacturers to review for clearance all devices that sterilize, clean, and reprocess medical devices. The agency is reviewing validation data related to scopes that are on the market, and manufacturers have been asked to make changes with some of them.

Health Resources and Services Administration (HRSA)

No report

SHM

SHM has been busy with a number of HAI-associated projects. SHM has completed work with several hundred hospitals regarding CAUTI in the acute care setting and has now expanded to long-term care facilities. That multifaceted intervention has yielded impressive data on catheter use, catheter culture rates, and CAUTI. SHM has begun an ambitious project with the Health Research and Educational Trust (HRET) to address low-performing hospitals with respect to four HAIs: MRSA, *C. diff*, CLABSI, and CAUTI. The work will consider the factors leading to poor performance and will put into place interventions and measure efficacy. The "Fight the Resistance" campaign is a targeted social media campaign that reaches core front-line

hospitalists with case examples of using mindfulness or techniques for using antibiotics. The campaign includes colorful posters and campaigns to encourage participation from front-line clinicians. SHM is in the process of writing guides and modules for education and development of best practice. A call has been sent out to front-line clinicians to submit cases for educational purposes. HICPAC's feedback on this grassroots effort is appreciated and will be shared with SHM as a whole.

Surgical Infection Society (SIS)

SIS's upcoming annual meeting will include a number of oral and non-oral presentations. The most commonly-discussed issue in the world of surgical infection is the role of the microbiome and dysbiosis in terms of post-operative infections as well as infections that surgeons commonly treat. In the next few months, SIS will publish updated intra-abdominal infection guidelines, which has a surgical perspective. IDSA is also working on a set of recommendations that analyze these infections in a different manner. SIS continues to partner with CDC to help understand specific areas that are unique to surgeons, including a curriculum for quality officers in hospitals and its relationship to postoperative infections. SIS is also working on a project to use patient-gathered data, such as imaging, to follow patients postoperatively and to help diagnose postoperative infections.

SHEA

SHEA is holding its annual spring meeting in Atlanta, Georgia. In addition to the usual courses, the meeting will include an added course on antimicrobial stewardship. SHEA has three expert guidance papers and programs in process:

- Duration of contact precautions
- Infection prevention practices in anesthesia
- Initiation of antibiotics in long-term care

Guidance from the day's HICPAC discussion will be shared with those writing groups. SHEA has been busy in advocacy and public policy, issuing statements on the FY 2017 budget; medical devices, Institutional Review Boards (IRBs) and human protection; and antimicrobial stewardship in long-term care and other settings.

SCCM

SCCM and the European Society of Intensive Care Medicine (ESICM) recently published the third international consensus definition for sepsis in the *Journal of the American Medical Association (JAMA)*. The associated commentaries are valuable. A joint SCCM-ESICM effort is focusing on the development and publication of a pediatric sepsis guideline. SCCM has completed "Spotlight on Success," a booklet containing initial experiences of health systems and hospitals that participated in an 18-month Quality Improvement (QI) program and implementation project funded by the Moore Foundation to improve early detection of sepsis outside the ICU.

American College of Surgeons (ACS)

Regarding HAIs, ACS is focused on surveillance and maintenance registries. The ACS National Quality Improvement Program® (NSQIP®) is its flagship registry, but the group also maintains a bariatric registry, trauma registry, and pediatric ACS NSQIP®, all of which incorporate HAI 30-day surveillance. There are plans to launch a new pilot for transplant 30-day outcomes, which will include HAI surveillance. ACS continues to monitor the accuracy of the data, training of abstractors, and data audits. As of January 2016, the UTI definitions were harmonized with

NHSN to streamline processes for hospitals. The largest efforts are underway to focus on automating and harnessing EHRs for data fields in the registries. ACS is moving all of its registries to a single vendor to facilitate automation at the hospital level. Additionally, ACS supports QI collaboratives related to patient populations, procedures, or processes to help hospitals improve.

AORN

AORN has a new award, the Go Clear Award, that will roll out at the April 2016 conference. The award is a surgical smoke-free recognition program. The sponsor is the AORN Foundation. The award will include education regarding compliance with evacuating smoke in ORs, gap analysis, and other issues. AORN guidelines for hand hygiene will be open for public comment through May 22, 2016. The guideline addresses basic hand hygiene and includes references to CDC, the World Health Organization, and SHEA Compendium guidelines. It refers to surgical hand antisepsis and nail polish and shellac polish. Guidelines are forthcoming regarding energy devices, including guidance specific to electrocautery devices and lasers. The smoke information will be pulled from those guidelines and incorporated into a new guideline on smoke safety, which will be released for public comment in the summer of 2016 with guidelines on minimally-invasive surgery and positioning. AORN has been working on a Heating, Ventilating, and Air Conditioning (HVAC) task force with AAMI and the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE), harmonizing their temperature ranges and considering design versus operational parameters. When the task force determines operational ranges for temperature and humidity in the OR, AORN will update its guidelines for environment of care and submit that section for public comment. The goal is for the guidelines to be easier for practice to use.

APIC

APIC released a position paper on safe injection practices in January 2016. It is available on the APIC website. APIC has also launched a Fellows Program that gives distinction to infection preventionists who are not only advanced practitioners in the field, but also leaders. APIC is working on a “dos and don’ts” resource for wearing gloves in the healthcare environment, focusing on education healthcare workers on the different types of gloves in the healthcare environment and their proper application and use.

Association of State and Territorial Health Officials (ASTHO)

ASTHO has a number of ongoing HAI-related activities. ASTHO is preparing to launch a Web-based toolkit to support health departments in accessing EHRs in the investigation of healthcare-associated outbreaks. ASTHO also supports state health agencies as they conduct Ebola and infection control assessments through the federal Epidemiology and Laboratory Capacity (ELC) supplemental funding. Those activities include conducting site visits in select states to understand the impact of that funding. ASTHO is convening two meetings, one in Atlanta, GA, and one in Salt Lake City, Utah, to explore the lessons learned about the ELC supplemental funding activities. ASTHO is assembling an HAI Outbreak Council, co-chaired by ASTHO and CSTE, to improve practices and policies for detection, investigation, control, and prevention of HAI outbreaks and emerging infectious disease threats. The council met in December 2015.

CSTE

CSTE will hold its annual conference in Anchorage, Alaska, in June 2016. The CDC/CSTE Antimicrobial Resistance Surveillance Task Force is a core group that has been meeting for two to three hours per week. SHEA and APIC members will be invited to join the group, and a task

force meeting will be held in late summer or early fall 2016. The Council of Outbreak Response, Healthcare Associated Infections, and Antimicrobial Resistance Pathogens has issued letters of invitation to SHEA and APIC. The CSTE conference will include discussion of three position statements:

- Prioritization of CAUTI surveillance and using NHSN to maximize prevention efforts
- Recommendations for the selection and implementation of SSI reporting for NHSN
- Inter-facility communication to prevent and control HAIs and AR pathogens

IDSA

The priorities and main thrust of IDSA's work parallels the HICPAC guidance that has been discussed, with a focus on antimicrobial stewardship and MDRO prevention, as well as work on duodenoscopes. In the domains of advocacy and awareness, IDSA is bringing forward new guidelines about antimicrobial stewardship and *C. diff* infection. IDSA's legislative work includes close coordination with Senator Patty Murray's office on legislative proposals related to tracking scopes. IDSA is coordinating feedback to the Joint Commission on accreditation standards for antimicrobial stewardship. IDSA is engaged in ongoing advocacy related to research and development and establishing a more reliable pipeline for new antimicrobial therapies.

NACCHO

NACCHO has been conducting a number of HAI activities, including applying information gleaned from the Ebola structure to other infectious disease threats. Three sites, in Florida, Illinois, and Pennsylvania have been funded to continue antibiotic stewardship efforts. Information from these sites is being utilized to develop an HAI guidance document for local health departments to engage in HAI prevention activities. NACCHO is meeting and collaborating with many agencies regarding how to implement HAI activities at the local level. NACCHO has updated its position statement on increasing local health department access to HAI data through NHSN. NACCHO approved a new policy on addressing AMR and promoting antibiotic stewardship. NACCHO submitted a comment letter to HHS regarding the proposed rule for the protection of human subjects and signed a letter urging finalization and release of the CARB Economic Incentive Working Group recommendations. Recent NACCHO publications include Antimicrobial Resistance and Stewardship: Local Efforts on a Global Issue. The publication addresses the role of local health departments in combating resistance.

Public Health Agency of Canada (PHAC)

Two relevant PHAC guidelines are currently in development:

- Guideline on the prevention of transmission of bloodborne pathogens from infected healthcare workers: the final draft is expected by the end of 2016, and the product will be distributed to stakeholders in early 2017.
- Infection prevention control guidelines for personal services: this guideline pertains to tattooing, piercing, and related services.

PHAC is also starting to work on revisions to a 2002 document on occupational infections in healthcare.

America's Essential Hospitals (AEH)

AEH brought awareness of Patient Safety Week events through its website. Content has also been posted on the AEH website about CDC-sponsored Twitter chats and webinars to educate members about medication and diagnostic errors and infections in care transitions. AEH called members' attention to CDC's launch of the new Web application, Antibiotic Resistant Patient

Safety Atlas, featuring interactive data on HAIs caused by AR bacteria. AEH keeps members updated with revised instructions validated by FDA for proper cleaning and high-level disinfection and sterilization of devices. AEH has created an online Zika resource page for member hospitals and others with an interest in this emerging issue. The response page is updated regularly with new information related to clinicians, infants, pregnant women, and travel.

Summary, Work Plan, & Adjourn

Daniel Diekema, MD Co-Chair, HICPAC

Dr. Diekema commented that several active HICPAC workgroups are moving forward on guideline development and other issues. HICPAC will be tasked with developing an approach to reviewing existing guidelines and prioritizing them according to which are in the greatest need of updating, based upon how outdated they are or on new evidence. He thanked HICPAC members, CDC personnel, HICPAC liaison representatives and *ex officio* members, the content experts who continue to contribute to the cause of making healthcare safer, and Dr. Yokoe, HICPAC co-chair.

The next HICPAC meeting will be held July 14-15, 2016. With no additional comments or questions, the HICPAC meeting adjourned at 5:23 p.m.

Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the March 31, 2016 meeting of the Healthcare Infection Control Practices Advisory Committee, CDC are accurate and complete.

Date

Daniel Diekema, MD or Deborah Yokoe, MD, MPH
Co-Chair, Healthcare Infection Control Practices
Advisory Committee, CDC

Attachment #1: Acronyms Used in this Document

Acronym	Expansion
AAMI	Association for the Advancement of Medical Instrumentation
AATCC	American Association of Textile Chemists and Colorists
ACA	(Patient Protection and) Affordable Care Act
ACS	American College of Surgeons
ADA	Americans with Disabilities Act
AEH	America's Essential Hospitals
AER	Automated Endoscope Reprocessor
AFB	Acid-Fast Bacillus
AHA	American Hospital Association
AHRQ	Agency for Healthcare Research and Quality
AMR	Antimicrobial Resistance
AORN	Association of periOperative Registered Nurses
APIC	Association of Professionals of Infection Control and Epidemiology
AQL	Acceptable Quality Level
AR	Antibiotic Resistance
ASHRAE	American Society of Heating, Refrigerating, and Air-Conditioning Engineers
ASTHO	Association of State and Territorial Health Officials
ASTM	American Society for Testing and Materials
ATP	Adenosine Triphosphate
AU	Antibiotic Use
BSI	Bloodstream Infection
<i>C. diff.</i>	<i>Clostridium difficile</i>
CABSI	Catheter-Associated Bloodstream Infection
CARB	(National Strategy for) Combating Antibiotic-Resistant Bacteria
CAUTI	Catheter-Associated Urinary Tract Infection
CDC	Centers for Disease Control and Prevention
CDRH	Center for Devices and Radiological Health
CF	Cystic Fibrosis
CGI	Chlorhexidine Gluconate-Impregnated
CHG	chlorhexidine gluconate
CLABSI	Central Line-Associated Bloodstream Infection
CMS	Centers for Medicare and Medicaid Services
COPD	Chronic Obstructive Pulmonary Disease
CRBSI	Catheter-Related Bloodstream Infection
CRE	Carbapenem-Resistant <i>Enterobacteriaceae</i>
CRI	Catheter-Related Infection
CRO	Carbapenemase-Producing Organism
CSTE	Council of State and Territorial Epidemiologists
DFO	Designated Federal Official
DHQP	Division of Healthcare Quality Promotion
DoD	(United States) Department of Defense
ECMO	Extracorporeal Membrane Oxygenation
EHR	Electronic Health Record
EIP	Emerging Infections Program
ELC	Epidemiology and Laboratory Capacity

Acronym	Expansion
EMR	Electronic Medical Record
ERCP	Endoscopic retrograde cholangiopancreatography
ESBL	Extended Spectrum Beta-Lactamase
ESCIM	European Society of Intensive Care Medicine
FDA	(United States) Food and Drug Administration
FY	Fiscal Year
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HAI	Healthcare-Associated Infection
HHS	(United States Department of) Health and Human Services
HICPAC	Healthcare Infection Control Practices Advisory Committee
HLD	High-Level Disinfection
HRET	Health Research and Educational Trust
HRSA	Health Resources and Services Administration
HVAC	Heating, Ventilating, and Air Conditioning
ICU	Intensive Care Unit
IDSA	Infectious Diseases Society of America
IRB	Institutional Review Board
JAMA	<i>Journal of the American Medical Association</i>
<i>M. abscessus</i>	<i>Mycobacterium abscessus</i>
<i>M. chimaera</i>	<i>Mycobacterium chimaera</i>
MDR	Multidrug-Resistant
MDRO	Multidrug-Resistant Organism
MedSun	Medical Product Safety Network
MERS-CoV	Middle East Respiratory Syndrome Coronavirus
MMWR	<i>Morbidity and Mortality Weekly Report</i>
MRSA	Methicillin-resistant <i>Staphylococcus aureus</i>
MSB	Maximum Sterile Barrier
MSSA	Methicillin-Susceptible <i>Staphylococcus aureus</i>
NACCHO	National Association of County and City Health Officials
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NEJM	<i>New England Journal of Medicine</i>
NHSN	National Healthcare Safety Network
NICE	National Institute for Health and Care Excellence
NICU	Neonatal Intensive Care Unit
NIH	National Institutes of Health
NIOSH	National Institute of Occupational Safety and Health
NQF	National Quality Forum
NSQIP®	National Quality Improvement Program®
NTM	Nontuberculous <i>Mycobacterium</i>
OR	Operating Room
OSHA	Occupational Safety and Health Administration
PEP	Post-Exposure Prophylaxis
PHAC	Public Health Agency of Canada
PICC	Peripherally Inserted Central Catheter
PPE	Personal Protective Equipment
QA	Quality Assurance
QI	Quality Improvement

Acronym	Expansion
RCT	Randomized Controlled Trial
RQL	Rejectable Quality Level
SCCM	Society of Critical Care Medicine
SHEA	Society for Healthcare Epidemiology of America
SHM	Society of Hospital Medicine
SIS	Surgical Infection Society
SOP	Standard Operating Practice/Procedure
SSI	Surgical Site Infection
TAP	Targeted Assessment for Prevention
TB	Tuberculosis
UTI	Urinary Tract Infection
UV	Ultraviolet
UVDI	UltraViolet Devices, Inc.
VA	(United States Department of) Veterans Affairs
VRE	Vancomycin-Resistant <i>Enterococcus faecium</i>
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: March 31, April 1, 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:
<ul style="list-style-type: none">• APIC launches new Fellow of APIC advanced designation program. The 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.• Resource in development: “Do’s and Don’ts for wearing gloves in the healthcare environment,” aimed at educating healthcare workers on the different types of gloves encountered in the healthcare environment and the importance of their proper use. Seeking input from CDC and others on content.
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:
The APIC Position Paper: Safe Injection, Infusion, and Medication Vial Practices in Health Care was approved and published in January 2016. It is an update to the 2010 paper.
Legislation/Regulation:
<ul style="list-style-type: none">• Endorsed the Preventing Superbugs and Protecting Patients Act (S. 2503)• Joined coalition efforts to support federal funding for a myriad of programs, including programs supporting the effort to combat antibiotic resistance, domestic TB programs, emergency funding for Zika.• Joined allied organizations to support consideration of the Promise for Antibiotics and Therapeutics for Health (PATH) Act in the Senate.• Submitted comments to FDA on Draft Guidance for Industry on labeling injectable medical Products packaged in multiple-dose, single-dose, and single-patient-use containers.• Submitted comments to AHRQ on the draft technical brief on resident safety practices in nursing homes.• Submitted comments to CMS on revisions to discharge planning requirements for hospitals, CAHs, and HHAs.• Submitted comments to HHS on revisions to Federal policy for the protection of human subjects.• Provided input to CMS on draft infection control surveyor worksheet for nursing homes.• Submitted comments to NIOSH on the information collection project “Monitoring and Coordinating Personal Protective Equipment (PPE) in Healthcare to Enhance Domestic Preparedness for Ebola Response.”
Campaigns and related activities:

APIC has developed a plan to promote CDC TAP Reports and infuse APIC resources with information about the reports.

Press activities:

- Issued press statements related to key infection prevention milestones and initiatives:
 - [Press statement](#): CDC's March *Vital Signs* report on antibiotic resistant HAIs, Antibiotic Resistance HAI Patient Safety Atlas, and National and State HAI Progress Report
- Issued press releases on new APIC resources and programs:
 - Fellow of APIC: A new designation for advanced infection preventionists
 - Central Line-Associated Bloodstream Infection APIC Implementation Guide
- Issued press releases on key articles in APIC's scientific journal *AJIC*. Topics included:
 - A pilot study into locating the bad bugs in a busy intensive care unit
 - Factors influencing nurse compliance with Standard Precautions
 - Visitor characteristics and alcohol-based hand sanitizer dispenser locations at the hospital entrance: Effect on visitor use rates
 - Cross-sectional survey of infection prevention, hand hygiene, and injection safety in outpatient safety in outpatient settings utilizing medical student observers

Publications:

- Consumer e-bulletins focused on:
 - December: [World AIDS Day](#)
 - January: [Fecal Transplants](#)
 - February: [Zika virus](#)
 - March: Strep
 - March: Norovirus
- Spring issue of *Prevention Strategist* featured articles on models for successful antimicrobial stewardship programs, unique staffing for infection prevention programs, conflict resolution for infection prevention program success, the horizontal approach to infection prevention, rehab hospital creativity for infection prevention programs, *Streptococcus pyogenes*, and more.
- Summer issue of *Prevention Strategist* will feature articles on how infection preventionists can use statistics to improve their programs, the IP's role in design and construction, Zika virus, Rotovirus, collaboration between IPs and EVS personnel, and more.

Other items of note:

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

Meeting Date: March 31, 2016

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison name: Elizabeth Wick

Organization represented: American College of Surgeons

Interim activities and updates:
The ACS continues to support multiple surgical registries which all include HAI surveillance (ACS NSQIP, MBSAQIP, TQIP, Peds ACS NSQIP). There are plans to trial a new registry for transplant – TRANSQIP. HAI rates are exceptionally accurate – abstractors are trained through a central program and data is audited periodically to ensure accuracy. As of Jan 2016, the UTI definition was changed to harmonized with NHSN. Efforts continue to automate data fields to decrease the labor required for registry participation. Epic currently supports automation through an uploader in Optime. This approach will be trialed with other vendors in the upcoming year. ACS continues to support quality improvement collaboratives with one of the most robust being related to geriatric surgery but others are convened around specialties (HPB, emergency, general surgery, etc.) or processes (enhanced recovery).
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.
None
Position statements:
None
Legislation:
None
Campaigns and related activities:
None
Press activities:
None
Publications:
Multiple publications related to HAIs are published each year with ACS registry data.
Other items of note:

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

Meeting Date: March 31, 2016

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison name: Michael McElroy, MPH, CIC

Organization represented: America's Essential Hospitals

Interim activities and updates:
National Healthcare Safety Network (NHSN) annual training course – America's Essential Hospitals communicated to all members the benefits of registering for this year's course, having particular focus on revisions and updates to the NHSN Patient Safety Component Manual.
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.
None
Position statements:
None
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:
<p>Patient Safety Awareness Week (PSAW) – America's Essential Hospitals used social media and other communication through its website to bring awareness of the various events for this year's PSAW. Outreach included content posted to the association's website about CDC sponsored twitter chats and webinars to educate members about medication and diagnostic errors, infections, and care transitions.</p> <ul style="list-style-type: none"> • <i>Vital Signs</i> and CDC's Antibiotic Resistance Patient Safety Atlas – America's Essential Hospitals called our members' attention to CDC's launch of the new web application—Antibiotic Resistant Patient Safety Atlas—featuring interactive data on HAIs caused by antibiotic-resistant bacteria. • Reprocessing – America's Essential Hospitals continues to keep its members updated with revised instructions, validated by the FDA, for the proper cleaning, high-level disinfection, and sterilization of devices such as the PENTAX ED-3490TK video duodenoscope.
Publications:
<ul style="list-style-type: none"> • Zika – America's Essential Hospitals has created an online Zika resource page for its member hospitals and other 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. • Highland Hospital (member of Alameda Health System) (Oakland, CA) – use of CDC recommendations to develop a Zika protocol for Maternal & Child Health for at risk pregnant and delivering patients
Other items of note:

Ex-Officio Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)

Centers for Disease Control and Prevention

Meeting Date: March 31, 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)

The CARB National Action Plan calls on AHRQ to support research to develop improved methods and tools for combating antibiotic resistance and conducting antibiotic stewardship activities in long-term care, ambulatory care, and acute care hospitals. In FY 2015, AHRQ more than doubled its investment in CARB-related research as compared to FY 2014. Research funded in 2015 included projects focused on:

- Transmission of resistant infections:
 - Reducing transmission of MRSA in households
 - Evaluating the effectiveness of universal glove and gown to decrease transmission of carbapenem-resistant gram-negative bacteria
 - Utilizing systems engineering to reduce *C. difficile* transmission
- Improving antibiotic use and ways to conduct antibiotic stewardship:
 - Promoting appropriate antibiotic use in dialysis units
 - Identifying and disseminating the most effective methods of antibiotic stewardship in nursing homes
 - Using technology to personalize antibiotic stewardship to the hospital patient
 - Promoting appropriate antibiotic use for urinary tract infections in nursing homes using a multi-faceted intervention
- Reduction of resistant infections:
 - Applying universal decolonization to reduce resistant infections in long-term care facilities
 - Using antiseptic bathing to reduce resistant infections in hospitals
 - Evaluating strategies to reduce MRSA in long-term care

In early FY 2016, AHRQ funded a project which aims to improve antibiotic prescribing in nursing homes. Previous AHRQ-supported research in this area has produced significant results: e.g., funding a study, conducted collaboratively with CDC, that demonstrated the most effective method for preventing MRSA transmission in ICUs, and the production of a toolkit for antibiotic stewardship programs to prevent *Clostridium difficile* infections. AHRQ has also developed a guide for implementing antibiotic stewardship programs in nursing homes based on previous research, which is currently being field-tested and is expected to be widely available in late 2016. AHRQ and CDC are planning a June meeting of experts and stakeholders to identify knowledge gaps for preventing antibiotic-resistant healthcare associated infections (HAIs) and to identify potential interventions. In addition, AHRQ, CDC, CMS, and OASH are collaborating in an Agency Priority Goal effort to accelerate the implementation of antibiotic stewardship programs in hospitals.

AHRQ Safety Program for Reducing CAUTI in Hospitals

AHRQ's 4-year project to promote the nationwide implementation of the Comprehensive Unit-based Safety Program (CUSP) to reduce catheter-associated urinary tract infections (CAUTI) reached completion in August 2015. 1266 hospitals across 42 states, the District of Columbia, and Puerto Rico participated in the project. Overall, NHSN CAUTI rates decreased by 11% (p=0.03) and catheter

utilization decreased by 5% ($p < 0.001$). CAUTI rates decreased by 30% ($p < 0.001$) in 701 non-ICU units, while in 509 ICUs no significant change in CAUTI rates was seen.

AHRQ Safety Program for Surgery

This 4-year project to promote implementation of a surgical unit-based adaptation of CUSP to reduce surgical site infections and other surgical complications reached completion in September 2015. This project recruited 5 cohorts comprising 197 hospitals and 376 surgical teams across 37 states.

Included in the project is an ethnographic study which qualitatively examines the factors associated with successful implementation of a safety improvement program in the surgical environment.

Results are currently being finalized, and an implementation toolkit will be available later this year.

AHRQ Safety Program for Mechanically Ventilated Patients

This 3-year project applies 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 thus far recruited 255 units in 200 hospitals across 34 states, Puerto Rico, and Saudi Arabia and will complete in Fall 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 thus far recruited 662 centers in 46 states including one cohort specifically focused on endoscopy centers. Two issues that will be addressed for the endoscopy cohort are adequacy of scope cleaning and safety of sedation/anesthesia. This project will reach completion in Fall 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. To date, more than 500 long-term care facilities across the United States are participating. The project will also reach completion in Fall 2016.

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

Initiated in September 2015, this 1.5 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 will be developed, including a modified set of CUSP training resources.

Position statements:

Legislation:

Campaigns and related activities:

Press activities:

Publications:

Calderwood, M. S., L. E. Vaz, A. Tse Kawai, R. Jin, M. D. Rett, P. S. Grant and G. M. Lee (2016). "Impact of Hospital Operating Margin on Central Line-Associated Bloodstream Infections Following Medicare's Hospital-Acquired Conditions Payment Policy." *Infect Control Hosp Epidemiol* 37(1): 100-103.

Carter, E. J., D. J. Pallin, L. Mandel, C. Sinnette and J. D. Schuur (2016). "Emergency Department Catheter-Associated Urinary Tract Infection Prevention: Multisite Qualitative Study of Perceived Risks and Implemented Strategies." *Infect Control Hosp Epidemiol* 37(2): 156-162.

Cocoros, N. M., K. Kleinman, G. P. Priebe, J. E. Gray, L. K. Logan, G. Larsen, J. Sammons, P. Toltzis, I. Miroshnik, K. Horan, M. Burton, S. Sims, M. Harper, S. Coffin, T. J. Sandora, S. N. Hocevar, P. A. Checchia, M. Klompas and G. M. Lee (2016). "Ventilator-Associated Events in Neonates and Children- A New Paradigm." *Crit Care Med* 44(1): 14-22.

Jones, K., J. Sibai, R. Battjes and M. G. Fakih (2016). "How and when nurses collect urine cultures on catheterized patients: A survey of 5 hospitals." *Am J Infect Control* 44(2): 173-176.

McAlearney, A. S. and J. L. Hefner (2015). "Getting to Zero: Goal Commitment to Reduce Blood Stream Infections." *Med Care Res Rev*.

Meddings, J., H. Reichert, M. T. Greene, N. Safdar, S.L. Krein, R.N. Olmsted, S.R. Watson, B. Edson, M. Leshner, and S. Saint (2016). "Evaluation of the Association Between the Hospital Survey on Patient Safety Culture Measures and Catheter-Associated Infections: Results of Two National Collaboratives." *Infect Control Hosp Epidemiol* (*in press-exp. pub. 3/29/16*).

Other items of note:

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

Meeting Date: March 31, 2016

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison name: Amber Wood

Organization represented: AORN

Interim activities and updates:
<p><u>Hot Topics</u></p> <ul style="list-style-type: none"> • Public Comment on Guideline for Hand Hygiene, April-May • HVAC Task Force (AAMI ST79, ASHRAE 170) proposed changes to operational temperature ranges in perioperative setting. AORN Guidelines will be updated and up for public comment based on task force findings. <p><u>Upcoming Events</u></p> <ul style="list-style-type: none"> • AORN Surgical Conference & Expo 2016, April 2-6, Anaheim, CA <ul style="list-style-type: none"> ○ OR Executive Summit™/Leadership Development Summit™ • Guideline Implementation Workshops, Sept-Nov 2016, multiple dates and cities
<p>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.</p> <ul style="list-style-type: none"> • AORN guidelines are available in print and through electronic access (e-subscription and e-book). • 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 in development: Information Management, Hand Hygiene, Energy Devices, Smoke Safety, Minimally Invasive Surgery, and Positioning
Position statements:
Position Statements
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
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: March 31, 2016

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison name: 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 is preparing to launch 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.

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:
 - Conducting site visits in select 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.
 - Convening state teams meetings to explore lessons learned regarding ELC supplemental funding activities. The meetings will be held in two different locations and dates – April 13-14 in Atlanta, and May 24-25 in Salt Lake City – to maximize participation. Invitations have been sent out to HAI coordinators in participating jurisdictions.
 - Assembling an HAI outbreak council, co-chaired by ASTHO and CSTE 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 identified a central challenge, strategic priorities and objectives.
 - Launching a website to share infection control & outbreak information, tools and resources. The *Healthcare and Infection Control Gateway* is available at: www.astho.org/programs/infectious-disease/healthcare-associated-infections/
 - Developing and testing public health communications tools
 - Facilitating a workshop with insular jurisdictions to strengthen infection control outbreak response infrastructure in the context of HAI/AR programs.

Ongoing:

ASTHO monitors developments in HAI-related policies and initiatives, shares this information with members, represents the state health agency perspective, and enhances collaboration with partners. ASTHO participates on the Safe Injection Practices Coalition, CSTE HAI Subcommittee and HAI Standards Committee, and National Healthcare Safety Network Steering Committee Workgroup.

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 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 <i>State Public Health Weekly</i> newsletter.
Press activities:
Publications:
ASTHO's HAI Publications are available online.
Other items of note:

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

Meeting Date: March, 2016

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Ex-officio name: Daniel Schwartz, MD

Organization represented: CMS

Interim Activities and updates:
S&C: 16-05-ALL: Infection Control Pilot Project
Position statements:
S&C-15-32 Hospitals/CAHs/ASCs: Alert Related to Outbreaks of Carbapenem-Resistant Enterobacteriaceae (CRE) during gastrointestinal endoscopy, particularly Endoscopic Retrograde Cholangiopancreatography (ERCP) S&C: 15-43-ASC: Update to Ambulatory Surgical Center (ASC) Infection Control Surveyor Worksheet (ICSW)
Legislation:
LTC NPRM has a new Infection Control Condition of Participation requiring a designated infection prevention and control officer (IPCO) and antibiotic stewardship.
Campaigns and related activities:
S&C: 16-06-ALL: Medicare Learning Network (MLN) Infection Control Courses
Press activities:
Publications:
Other items of note:
S&C Memos can be found online

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

Meeting Date: March 31, 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 will be held in Anchorage, Alaska, June 19-23; Abstracts close Jan 6, additional information is online.
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.
<ul style="list-style-type: none"> • CSTE Survey was sent out to state HAI coordinators to better understand healthcare-associated infection (HAI) program's infection prevention and control and drug diversion investigation resources, capacity and experience. The information will be used to determine your state HAI program's needs and interest in expanding activities in these areas and to identify gaps. These data are currently being analyzed • 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." Has been meeting regularly since December 2015 is currently on a fact finding mission, with regular 2-3 hour conference calls per week. Core group members include Gus Birkhead, CSTE consultant (former deputy state epidemiologist, NY State), Dan Pollock (CDC/DHQP, Wes Kennamore (APHL), Jeff Engel (CSTE) and Marion Kainer (TN DOH). The new taskforce likely will have liaison positions with professional societies such as SHEA, APIC, APHL. Anticipate a meeting in late summer or early fall • There is a new Council for Outbreak Response: Healthcare Associated Infections and Antibiotic Resistant Pathogens (exact name and acronym under discussion). This Council is similar to the Council to Improve Foodborne Outbreak Response (CIFOR). A strategic planning meeting for the Council for Outbreak Response: HAI/AR was held in December 2015; the governance structure and bylaws are being worked on; the mission and vision statements are being finalized. The Council is being co-chaired by CSTE and APHL. Expect to reach out to professional organizations such as APIC and SHEA to be partners of the council and/or to participate in workgroups.
Position statements :
3 position statements were submitted for consideration by CSTE membership for the annual meeting in June 2016. <ul style="list-style-type: none"> • Prioritizing Catheter-Associated Urinary Tract Infections (CAUTI) Surveillance utilizing the National Healthcare Safety Network (NHSN) to maximize prevention efforts. • Interfacility Communication to Prevent and Control Healthcare Associated Infections and Antimicrobial Resistant Pathogens across Healthcare Settings • Recommendations for the Selection and Implementation of Surgical Site Infection Reporting in the National Healthcare Safety Network
Legislation:
Campaigns and related activities:

Press activities:
Publications:
Other items of note:
In fiscal year (FY) 2016, Congress appropriated \$160 million for CDC to fight antibiotic resistance (AR) , a testament to the urgent AR threat and highest levels of support for the ambitious public health actions outlined in the <i>National Action Plan for Combating Antibiotic-Resistant Bacteria</i> . This is a substantial opportunity for state and local public health to expand capacity to detect and respond to AR threats in healthcare and communities, protect patients, and save lives. CDC plans to distribute the largest extramural portion of this funding through the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement (Funding Opportunity Number CK14-1401PPHF), primarily to support all 50 state health departments, the 6 largest local health departments (Chicago, the District of Columbia, Houston, Los Angeles County, New York City, and Philadelphia), and Puerto Rico. Please See attachment of the FY 2016 AR Project opportunities for further details.

CSTE Attachment

FY 2016 AR Project Opportunities*: Please see project attachments¹ for detailed strategies and activities. CDC will make available a limited number of Direct Assistance (DA) positions. ELC applicants may request CDC to provide DA in the form of federal personnel as part of their award under projects K1, K2, K7, and K8.

Build state capacity to detect, respond to, and protect against emerging healthcare-associated infections (HAI)/AR threats and improve antibiotic use, building on existing HAI/AR programs and Ebola-funded activities:

1. **HAI/AR Detection and Response Infrastructure:** Sustain and expand capacity to track and respond to HAI/AR threats and implement HAI/AR prevention efforts (\$20,000,000 total estimate available; 57 awards; average award \$350,000; see Attachment K1 on page 94)²
2. **HAI/AR Coordinated Prevention:** Establish State HAI/AR Prevention Programs to scale up evidence-based interventions for reducing inappropriate antibiotic use and preventing the spread of common HAI/AR threats. Grantees can use resources to expand AR data collection from NHSN as well as other data systems such as NNDSS to address AR prevention priorities. (\$18,900,000 total estimate available; up to ~25 awards; average award \$750,000; see Attachment K2 on page 100)²
3. **Educational Efforts to Promote Appropriate Antibiotic Use:** Implement health communication programs and behavioral interventions to promote appropriate antibiotic use and prevent AR spread (\$430,000 total estimate available; 7 awards; average award \$60,000; see Attachment J on page 90)

Expand nationwide laboratory capacity to detect emerging HAI/AR threats:

4. **State CRE Laboratory Capacity:** Increase state public health laboratory capacity to detect and confirm the nightmare bacteria, carbapenem-resistant Enterobacteriaceae (CRE) (\$4,750,000 total estimate available; ~57 awards; average award \$83,000; see Attachment K6 on page 118)
5. **AR Regional Laboratory Network:** Support AR Regional Laboratories to serve as a national resource for gold-standard laboratory capacity to characterize emerging AR (\$16,250,000 total estimate available; up to 8 awards; average award \$1,500,000 plus additional average awards \$150,000–\$500,000 for optional testing; see Attachment K7 on page 121)²

Expand detection, response, and prevention efforts to address community AR threats:

6. **AR Gonorrhea (GC) Rapid Detection and Response:** Support rapid GC detection and response capacity to better monitor GC treatment in high-risk jurisdictions and ultimately reduce spread of drug-resistant GC (\$7,500,000 total estimate available; up to 9 awards; average award \$800,000; see Attachment K8 on page 129)²
7. **OutbreakNet Enhanced:** Improve state and local capacity to fully investigate and respond to enteric disease outbreaks (\$2,700,000–\$2,900,000 total estimate available; ~18-20 awards; average awards \$100,000–\$175,000 in addition to OutbreakNet/NORS funding; see Attachment I1 on page 46)
8. **Integrated Food Safety Centers of Excellence (CoE):** Improve tools, information, and training for practicing veterinarians to prevent AR and promote antibiotic stewardship (\$2,500,000–\$3,000,000 total estimate available; 6 awards; average award \$300,000–\$600,000; see Attachment I3 on page 62)
9. **National Antimicrobial Resistance Monitoring System (NARMS) Surveillance:** Expand whole genome sequencing of *Salmonella* and other enteric AR threats (\$10,500,000 total estimate available; 21 awards; average award \$500,000; see Attachment I8 on page 85)

* Access Funding Announcement Number “CDC-RFA-CK14-140102PPHF16” at www.grants.gov.

¹ A limited number of Direct Assistance (DA) positions will be available under projects K1, K2, K7, and K8.

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

Meeting Date: March 31, 2016

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:
<ul style="list-style-type: none">• IDSA Comments to PACCARB. IDSA presented comments at a public meeting of the Presidential Advisory Council on Antibiotic-Resistant Bacteria (PACCARB). IDSA applauded the PACCARB for its work so far on the five goals of the National Action Plan for Combating Antibiotic Resistant Bacteria, and highlighted specific recommendations to advance each of the goals in the National Action Plan. (3/21/16)• IDSA and Pew Call on Health Spending Panel Leaders to Fund Antibiotic Resistance Proposals. IDSA and the Pew Charitable Trusts wrote to leaders of the House and Senate subcommittees charged with appropriating funding for health agencies to fully fund the President's plan to combat antibiotic resistance. (11/9/15)• IDSA Response to ID Match for Appointment Year 2016. Attracting the best and brightest to ID is a top priority for IDSA. The recent results of the ID Match for Appointment Year 2016, which were released on December 2, 2015, reaffirm the importance of the Society's ongoing efforts to promote the specialty. (12/15/15)
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: <ol style="list-style-type: none">1. Implementing an Antimicrobial Stewardship Program2. <i>Clostridium difficile</i> (Update) - Joint w/SHEA3. Hospital-acquired, ventilator-acquired pneumonia (Update) - Joint w/ATS4. IV Catheter Management (Update)5. Outpatient Parenteral Anti-Infective Therapy (OPAT) - (Update)6. Vancomycin - (Update) Joint w/ASHP/SIDP/PIDS Approved, to be Published <ol style="list-style-type: none">1. Candidiasis Link to other guidelines on website: http://www.idsociety.org/IDSA_Practice_Guidelines/
Position statements:
<ul style="list-style-type: none">• IDSA Responds to The Joint Commission's Proposed Standards for Antimicrobial Stewardship for Various Types of Healthcare Facilities. IDSA responds to The Joint Commission's Proposed Standards for Antimicrobial Stewardship for various types of healthcare facilities that include Ambulatory Health Care Centers, Critical Access Hospitals, Hospitals, Nursing Homes, and Office-based Surgical Centers. Please review The Joint Commission's Proposed Standards for Antimicrobial Stewardship to provide context to our comments. (12/30/15)
Legislation:
<ol style="list-style-type: none">1. IDSA Supports Senate Committee Effort to Address CRE Outbreaks from Duodenoscopes. Sen. Patty Murray (D-WA), has released a report on carbapenem-resistant Enterobacteriaceae (CRE) outbreaks associated with contaminated duodenoscopes. The report includes recommendations to provide a clear and timely path for reporting new infections that stem from medical devices. At the

request of Sen. Murray’s staff, IDSA’s Public Health Committee provided feedback on the initial recommendations and subsequent bill. The legislation would require the FDA to publish a list of reusable devices that would need to provide proposed cleaning instructions as part of a pre-market submission process. Manufacturers of the devices on this list would also need to provide FDA with validation data showing that proposed cleaning instructions are effective. IDSA and several other organizations formally supported the bill.

2. IDSA Engages Senate Health Committee Ahead of Key Biomedical Innovations Mark-Up. As the Senate’s health committee prepared to begin considering bills included in their biomedical innovations package, IDSA wrote to leaders in support of those that promote the research workforce and slow the spread of infectious diseases.

3. IDSA Encourages Members to Take Action to Support New Antibiotic Pathway Bill. The Promise for Antibiotics and Therapeutics for Health (PATH) Act, introduced on Jan. 16 by Sens. Orrin Hatch (R-UT) and Michael Bennet (D-CO)—would establish a new limited population approval pathway at the Food and Drug Administration (FDA) for antibacterial drugs to treat serious or life-threatening infections where there exists

Campaigns and related activities:

Key areas of IDSA focus related to infection prevention and control remain:

- New antibiotic development ([10 x '20 initiative](#)):
- [Antimicrobial resistance and stewardship](#)
- [Infection prevention and control](#)

Press activities:

[Selected news releases](#) from:

- IDSA and its Center for Global Health Policy applaud the White House release of its National Action Plan for Combating Multidrug-Resistant Tuberculosis. (12/22/15)

Publications:

[Selected publications](#) from IDSA Journals

- Shortages of key antibiotics, including gold-standard therapies and drugs used to treat highly resistant infections, are on the rise, according to a new study of shortages from 2001 to 2013 published in *Clinical Infectious Diseases* and available online.

Other items of note:

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

Meeting Date: March 31, 2016

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison name: Sarah Matthews, Florida Department of Health in Orange County, FL

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 developed 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
- November 2015: Attended the CDC ELC HAI and Ebola Grantees' meeting
 - Two NACCHO representatives and three local health department representatives from Dallas County Health and Human Services, Florida Department of Health in Orange County, and Philadelphia Department of Public Health attended
- November 2015: Updated the HAI chapter of NACCHO's internal Strategic Messaging Guide, which staff use as a reference in developing external facing materials to ensure consistency and clarify in messages
- December 2015: Attended the two-day HAI outbreak detection and response council kick off meeting hosted by CDC, ASTHO, and CSTE
 - Two NACCHO representatives and two local health department representatives from Los Angeles County Department of Public Health and Barren River District Health Department attended

- December 2015: Participated in a call with Dr. Nimalie Stone and Taitainia Williams of the CDC to explore HAI activities and opportunities to partner more closely to advance shared priorities surrounding antimicrobial stewardship and long-term care facilities
- December 2015: Released a funding opportunity for local health departments seeking to enhance local public health’s infection control preparedness and response to HAI outbreaks, Ebola, and other infectious diseases through strengthening organizational capacity and partnerships
 - Recipients for this funding opportunity are being finalized and the work will embark in March and conclude at the end of June
 - January 2016: Participated in a call with representatives from the New York Department of Health to explore HAI activities; their work with long-term care facilities and implementing the Core Elements of Antibiotic Stewardship for Nursing Homes; and opportunities to partner more closely to advance shared priorities surrounding antimicrobial stewardship and long-term care facilities
 - March 2016: Participated in a call for the HAI outbreak detection and response council
 - Two NACCHO representatives and three local health department representatives from Dallas County Health and Human Services, Florida Department of Health in Orange County, and Philadelphia Department of Public Health participated
 - 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
 - Council of State and Territorial Epidemiologists (CSTE) HAI Standards Committee calls
 - Ongoing: Participated in conference calls with ASTHO and CSTE to discuss HAI 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.

- Ongoing: Developing an HAI guidance document for local health departments to engage in HAI prevention activities – it will be 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

Position statements:

- November 2015: Updated policy statement on increasing local health departments’ access to healthcare-associated infection data through the National Healthcare Safety Network
 - Worked in partnership with NACCHO’s Infectious Disease Prevention & Control Workgroup to update policy statement
 - Emphasized the importance of inclusion and support of local health departments in accessing NHSN and the relationship to antimicrobial stewardship
- November 2015: Approved new policy statement on increasing federal, state, and local collaboration in addressing antimicrobial resistance and promoting antibiotic stewardship
 - Worked in partnership with NACCHO’s Infectious Disease Prevention & Control Workgroup and

<p>other local health department representatives to develop policy statement</p> <ul style="list-style-type: none"> ○ Emphasized importance of inclusion and support of local health departments and encourage state health departments to engage and establish relationships with their local health departments in antimicrobial resistance prevention and antibiotic stewardship <ul style="list-style-type: none"> ● November 2015: Submitted a comment letter to DHHS on the Proposed Rule for the Protection of Human Subjects <ul style="list-style-type: none"> ○ Described the surveillance activities local health departments perform to detect and prevent the spread of disease ○ Described the public health quality improvement activities local health departments utilize to improve and enhance the services they deliver ○ Recommended the publication of information gleaned from normal public health activities be permitted ● December 2015: Signed onto letter urging finalization and release of CARB Economic Incentives Working Group recommendations
Legislation:
N/A
Campaigns and related activities:
N/A
Press activities:
N/A
Publications:
<ul style="list-style-type: none"> ● November 2015: Published a fact sheet on “Antimicrobial Resistance and Stewardship: Local Efforts on a Global Issue” about the role of local health departments in combatting resistance and NACCHO’s demonstration site projects
Other items of note:

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

Meeting Date: March 31, 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:
<ul style="list-style-type: none"> • Since the previous HICPAC meeting, the NIH has continued to communicate with DHHS and other federal Agencies about Ebola. While there are no patients on the immediate horizon, we have taken this opportunity to make modifications to 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. We are watching the current cases in Guinea with renewed interest. • Work is ongoing evaluating the transmission of Vancomycin-resistant <i>Enterococcus faecium</i> (VRE) in our hospital environment using whole-genome sequencing and detailed epidemiological information; a manuscript describing a cohort study of 350 patients were found to have either VRE colonization or infection. More than a fifth ultimately met criteria for decolonization. More than 2/3 remained decolonized for the duration of the study. • In addition, studies of carbapenemase producing organisms (CPO) transmission are also continuing. We have stopped using the term “CRE” because plasmid-mediated carbapenemase is much more epidemiologically significant than for example, accumulated porin mutations producing carbapenem resistance. Further, the ‘E’ in CRE is less appropriate because KPC and other carbapenemases have been found in <i>Pseudomonas</i>, <i>Acinetobacter</i>, <i>Aeromonas</i> and others. We continue to employ aggressive microbial surveillance for MDR gram-negatives. We perform about 150 surveillance cultures a week, or 600-700 a month. • We obtain surveillance cultures at the time of admission, then twice weekly in ICU, and once weekly on the infectious diseases/immunodeficiency unit. We also conduct whole hospital surveillance once a month (excluding the behavioral health units). Those who meet CDC high risk criteria – inpatient in US healthcare facility in past week or hospitalized abroad in past 6 months – are identified by Admissions Office, empirically isolated and undergo two swabs before isolation discontinued. We have 40x the rate of positivity in cultures from that high-risk group than the rest of the patient population. • Since July 2012, we have not detected transmission of any CPO isolates, but have detected 25 new CPO colonized patients, all unrelated to the outbreak strain – all of which are genetically dissimilar to each other. Of these, identified 25 CPO colonized patients: 21 had the KPC gene, 3 NDM-1, 1 OXA-48. Two of the 25 were identified initially from urine cultures and one from a perirectal abscess – the rest all from perirectal surveillance cultures.
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, *in press*.
2. Hughes H, Henderson DK. Post-exposure prophylaxis after Hepatitis C occupational exposure in the interferon-free era. *Curr Opin Infect Dis* 2016, *submitted*.
3. 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.
4. 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.
5. Uyeki TM, Mehta AK, Davey RT Jr, Liddell AM, Wolf T, Vetter P, Schmiedel S, Grunewald 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.
6. Chertow DS, Palmore TN, Masur H. Critical Care Medicine After the 2014-2015 Ebola Outbreak: Are We Ready If It Happens Again? *Crit Care Med*. 2016 Mar;44(3):457-9.
7. Chertow DS, Nath A, Suffredini AF, Danner RL, Reich, DS, Bishop R, Childs RW, Arai AE, Palmore TN, Lane HC, Fauci AS, Davey RT. Severe Meningoencephalitis in a Case of Ebola Virus Disease. *Ann Intern Med*, accepted.

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

Meeting Date: March 31, 2016

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison name: Laurie O'Neil

Organization represented: Public Health Agency of Canada (PHAC)

Interim activities and updates:
<p>Agency response related to emerging pathogens: <i>Infection Prevention and Control Guidance for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in Acute Care Settings</i> http://www.phac-aspc.gc.ca/eri-ire/coronavirus/guidance-directives/nCoV-ig-dp-eng.php Guidance is going through final stages of review and consultation prior to French translation.</p>
<p>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.</p>
<p>Ebola virus disease guidance document awaiting release: <i>Infection Prevention and Control Measures for Prehospital Care and Ground Transport of Patients with Suspected or Confirmed Ebola Virus Disease</i> Guidance is in process of approval for release.</p> <p>Core IPC guidelines and HAI surveillance reports currently under development: <i>Guideline on the Prevention of Transmission of Bloodborne Pathogens from Infected Healthcare Workers</i> A final draft of the guideline is expected in this calendar year. <i>Infection Prevention and Control Guidance for Personal Services: Risks, Principles, and Recommendations</i> A working draft of the guidance is expected by the end of calendar year.</p> <p>Antimicrobial resistance surveillance documents recently released: <i>Canadian Antimicrobial Resistance Surveillance System Report 2015</i> http://healthycanadians.gc.ca/publications/drugs-products-medicaments-produits/antibiotic-resistance-antibiotique/antimicrobial-surveillance-antimicrobioresistance-eng.php <i>Human Antimicrobial Drug Use Report – 2014</i> (released November 2015 as part of the Global AMR Twitter Chat and National Antibiotic Awareness Week) http://healthycanadians.gc.ca/publications/drugs-products-medicaments-produits/human-antimicrobial-use-2014-utilisation-antimicrobiens-humains/index-eng.php http://canadiensensante.gc.ca/publications/drugs-products-medicaments-produits/human-antimicrobial-use-2014-utilisation-antimicrobiens-humains/index-fra.php</p> <p>Foundational IPC Guideline document identified for development: <i>Prevention and Control of Occupational Infections in Health Care, 2002</i> To initiate work on updating the guidance document.</p>
Position statements:
<p>Public Health Agency of Canada – Infection Control Notice. <i>Recommended Practices for the Prevention of Endoscopy - related Infections</i> Awaiting approval for release.</p>
Legislation:
Campaigns and related activities:

Press activities:
Publications:
<p><i>Determinants of Outcome in Hospitalized Patients With Methicillin-Resistant Staphylococcus aureus Bloodstream Infection: Results From National Surveillance in Canada, 2008-2012</i> Andrew E. Simor, Linda Pelude, George Golding, Rachel Fernandes, Elizabeth Bryce, Charles Frenette, Denise Gravel, Kevin Katz, Allison McGeer, Michael R. Mulvey, Stephanie Smith, Karl Weiss, the Canadian Nosocomial Infection Surveillance Program Infection Control & Hospital Epidemiology , Volume 37 , Issue 04 , April 2016, pp 390 - 397 doi: 10.1017/ice.2015.323 (About doi) Published Online on 19th January 2016</p>
Other items of note:

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

Meeting Date: March 31, 2016

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison name: Craig M. Coopersmith, MD, FACS, FCCM

Organization represented: Society of Critical Care Medicine

Interim activities and updates:
<ul style="list-style-type: none"> • CAUTI/CLABSI: The SCCM is collaborating with the American Hospital Association serving as content experts for the On the CUSP reduction of CLABSI and CAUTI in intensive care units. The AHA held a boot camp at the Society’s 45th annual Congress with approximately 125 attendees. The project runs through the end of 2016. • SCCM provided comment on changes to Common Rule impacting definitions of research and human subjects. • Collaboration will begin on multi-stakeholder feedback to Centers for Medicare and Medicaid on antibiotic table 5.0 contained within the SEP-1 measures. • SCCM and the European Society of Intensive Care Medicine (ESICM) will fund the development and publication of a pediatric sepsis guideline. Work is anticipated to begin later in 2016. • A multi-disciplinary meeting was held at the CDC on February 4th to begin work on an implementation guide for sepsis screening on medical-surgical-telemetry units in hospitals. Follow up on that work is ongoing. • The SCCM produced, “Spotlight on Success” a booklet containing the experiences of health systems and individual hospitals during the 18-month quality implementation program funded by the Gordon and Betty Moore Foundation to improve early detection and intervention of septic patients on wards in hospitals. • SCCM and EISCM published The Third International Consensus Definition for Sepsis. More information can be found on the SCCM website. • The Surviving Sepsis Campaign provided a statement related to the consensus definition paper:
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.
<ul style="list-style-type: none"> • Work continues on the revision of the Surviving Sepsis Campaign guideline anticipated publication in late 2016. There are 6 translations for the 2012 guidelines: Chinese, Portuguese, German, Spanish, French and Japanese. • Guidelines for the Provision and Assessment of Nutrition Support Therapy in the Adult Critically Ill Patient: Society of Critical Care Medicine (SCCM) and American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Crit Care Med: February 2016 – Volume 44 – Issue 2 – p 390-438. • Guidelines for the Appropriate Use of Bedside General and Cardiac Ultrasonography in the Evaluation of Critically Ill Patients. Crit Care Med: November 2015 – Volume 43 – Issue 11 – p 2479-2502. Part I: General Ultrasonography. Now available on Guidelines Clearinghouse website.
Position statements:
Legislation:
Campaigns and related activities:
The Surviving Sepsis Campaign has completed an 18 month collaborative working to assist hospitals in early detection and treatment of sepsis patients on inpatient wards. A manuscript of results is being

submitted for publication. Spotlight on Success Books are available to feature some of the many gains made by this effort. A session was held at the SCCM Congress available on the [Surviving Sepsis Campaign YouTube playlist](#):

The Society of Critical Care Medicine continues to offer educational content and resources for intensive care unit teams on how to reliably incorporate spontaneous awakening and breathing trials as a component of the ABCDEF bundle. [The ICU Liberation Campaign](#) which supports this work offers videos, podcasts, team training materials and other resources at both the Surviving Sepsis Campaign and the ICU Liberation Campaign have received funding from the Gordon and Betty Moore Foundation.

Press activities:

[Press activities](#):

Publications:

A selection of recent infection-prevention-related and antimicrobial studies in Critical Care Medicine and Pediatric Critical Care Medicine the principal journals of the Society of Critical Care Medicine:
Pediatric CCM:

1. Reduction of Broad-Spectrum Antibiotic Use in a Tertiary Children’s Hospital Post Antimicrobial Stewardship Program Guideline Implementation. Pediatric Crit Care Med: March 2016 - Volume 17 - Issue 3 - p 187–193
2. An Evaluation of Various Ventilator-Associated Infection Criteria in a PICU. Pediatric Crit Care Med: January 2016 – Volume 17 – Issue 1 – p 73-30.
3. Comparison of the New Adult Ventilator-Associated Event Criteria to the Centers for Disease Control and Prevention Pediatric Ventilator-Associated Pneumonia Definition (PNU2) in a Population of Pediatric Traumatic Brain Injury Patients. Pediatric Crit Care Med: February 2016 – Volume 17 – Issue 2 – p 157 – 164.

CCM:

1. Critical Care Medicine After the 2014-2015 Ebola Outbreak: Are We Ready If It Happens Again? Crit Care Med: March 2016 – Volume 44 – Issue 3 – p 457-459.
2. Duration of Antimicrobial Treatment for Bacteremia in Canadian Critically Ill Patients. Crit Care Med: February 2016 – Volume 44 – Issue 2 – p 256-264.
3. Ventilator-Associated Events in Neonates and Children – A New Paradigm. Crit Care Med: January 2016 – Volume 44 – Issue 1 – p 14 – 22.
4. A Multicenter Evaluation of Prolonged Empiric Antibiotic Therapy in Adult ICUs in the United States. Crit Care Med: December 2015 – Volume 43 – Issue 12 – p 2525 – 2704.
- 1) 5. 5. Antibiotic-Induced Within-Host Resistance Development of Gram-Negative Bacteria in Patients Receiving Selective Decontamination or Standard of Care. Crit Care Med: December 2015 - Volume 43 – Issue 12 – p 2582 – 2588.

• Other items of note:

- Sepsis Redefined (Free Webcast) Recording 3/29/2016 available on SCCM YouTube channel
- Surgical Fires are Preventable Medical Errors ([Free Webcast](#))
- [Electronic Distraction in the ICU: An Impediment to Patient Safety](#)
- [Hot Topics and Late Breaking Science: Sepsis Redefined Town Hall at SCCM Congress](#)
- Team work [instructional videos and associated teaching guide](#) related to implementation of the ABCDEF bundle of care (pain, agitation, delirium, mobility and family)
- SCCM Pod-310 [Evidence-Based Pediatric Outcome Predictors to Guide the Allocation of Critical Care Resources in a Mass Casualty Event](#)
- Margaret Parker, MD, MCCM, speaks with Philip Toltzis, MD, about the article, “Evidence Based Pediatric Outcome Predictors to Guide the Allocation of Critical Care Resources in a

Mass Casualty Event,” published in the September 2015 issue of Pediatric Critical Care Medicine. Dr. Toltzis is Professor of Pediatrics at Case Western Reserve University School of Medicine and formerly was the Medical Director of the Pediatric ICU and Division Chief of Pediatric Critical Care Medicine at Rainbow Babies and Children’s Hospital in Cleveland, Ohio. In this article, Dr. Toltzis and coauthors devise a Crisis Standards of Care triage allocation scheme specifically for children. *Pediatr Crit Care Med.* 2015; 16(7):e207-e216. Released: 2/18/16

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

Meeting Date: March 31, 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 will be held on May 18 – 21st in Atlanta, GA.

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

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). Beginning in mid-February, SHEA will be offering 4 MOC Points for this online course.

Certificate Track Recordings

At the SHEA Spring Conference 2015, the Post-Acute & Long-Term Care and SHEA/CDC Healthcare Epidemiology Certificate Tracks were recorded. SHEA has launched the online purchase of these track recordings with PowerPoint presentations. The Post-Acute and Long-Term Care Certificate track was co-sponsored with the Society for Post-Acute and Long-Term Care Medicine (AMDA).

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. Bearman and Banach)
 - PICO-style questions being finalized and voted upon
 - MeSH and other search terms being finalized and voted upon
- Expert Guidance: Infection Prevention Practices in the Anesthesia Work Area (Chair Dr. Munoz-Price)
 - Environmental scan being conducted of current guidelines by AANA, ASA, and USP<797> to help set scope
- Expert Guidance: Initiation of Antibiotics in Long-Term Care (Chair Dr. Christopher Crnich)
 - Scope finalized
 - Collaborators invited (Dr. Mark Loeb, representatives from AMDA and AMMI-Canada)

Based on the SHEA Choosing Wisely released in October 2015, representatives of the GLC are working with Consumer Reports to develop patient materials focused on the recommendation:

Don't continue antibiotics beyond 72 hours in hospitalized patients unless patient has clear evidence of infection. Antibiotics are often started when a patient is possibly infected. After three days, laboratory and radiology information is available and antibiotics should either be deescalated to a narrow-spectrum antibiotic based on culture results or discontinued if evidence of infection is no longer present. Lessening antibiotic use decreases risk of infections with *Clostridium difficile* (*C. difficile*) or antibiotic-resistant bacteria. A final draft is under review.

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)
- The "[Handbook for SHEA-Sponsored Guidelines and Expert Guidance Documents](#)," written last year by a subgroup of the committee known as the "Methodologies Task Force" to guide the process of writing guidelines and expert guidance papers in a systematic and transparent way, has been published on the SHEA website. The webpage has been reorganized to divide the guidelines into "current," "under review," and "retired."

Position statements:

Legislation:

FY 2017 Budget and Appropriations

SHEA is working with a number of coalitions to advance its interests in President Obama's budget request and in the upcoming congressional budget and appropriations process. SHEA partners with the Coalition for Health Funding, the CDC Coalition, the Friends of AHRQ, and S-FAR on a number of joint and sign on letters. We provided support for the S-FAR Advocacy Hill Day on February 18 and are participating in a number of similar Hill events. SHEA will be collaborating with APIC to jointly draft outside witness testimony for submission to both the House and Senate Appropriations Committees.

Support for Bill to Improve Medical Device Oversight

SHEA in collaboration with APIC is actively advocating for the passage of S. 2503, the Preventing Superbugs and Protecting Patients Act, a bill that would establish requirements for manufacturers of reusable medical devices to submit proposed cleaning and disinfection instructions and validation data to FDA before marketing the devices. It would also clarify for device manufacturers when they must seek and obtain FDA clearance before marketing modified devices. The bill follows a report of an investigation led by Sen. Patty Murray (D-WA) and an outbreak of multi-drug resistant organism infections from contaminated duodenoscopes that are difficult to clean due to its modified design. SHEA and APIC jointly submitted a letter of support for the bill in early February.

Contaminated Heater-Cooler Units

SHEA is exploring a new 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. Similar to the case of duodenoscopes, it was discovered that water used in certain heater-cooler units during cardiothoracic surgery could become contaminated with difficult to detect bacteria such as *M. chimaera*, which is then aerosolized by a fan on the device making patients vulnerable to infection through direct exposure. Cases of these infections date back to exposures that took place as far back as 2010, with many more potential unidentified cases. SHEA is working with other organizations and agencies to better raise awareness of the problem, and is also exploring options for changes in federal policies to help prevent problems like these and to allow FDA to move more quickly to mitigate patient exposure.

Comments on the Federal Common Rule for the Protection of Human Subjects

SHEA submitted comments January 6th in response to the federal policy for the protection of human subjects, or the "Common Rule." In our comments, SHEA recommends OHRP take steps to provide better clarity on the intent of the exclusion provisions of the Common Rule and to verify the ability of healthcare facilities, as well as regional, state, and national public health agencies and quality improvement organizations to conduct quality improvement activities within the scope of healthcare operations, and that these activities do not require IRB oversight. SHEA recommends the exclusion provision exempt all aspects of quality improvement activities from IRB oversight which includes measuring the effectiveness of these activities on patient-centered outcomes within the scope of healthcare facility operations. The scope of the exemption provision should also allow public health agencies the ability to evaluate risk factors for adverse outcomes in assessing the impact of diseases of public health importance.

Comments on The Joint Commission's Proposed Antibiotic Stewardship Standard

SHEA submitted comments at the end of December responding to The Joint Commission's call for public comment on its proposed new standard for antibiotic stewardship for a variety of healthcare settings. In the submission SHEA recommends The Joint Commission move forward with finalizing the components of the standard that would apply to inpatient hospitals, critical access hospitals, and long-term care facilities. However SHEA does not recommend The Joint Commission finalize the standard to include ambulatory and outpatient settings. While SHEA recognizes the need for optimizing the use of antimicrobials in ambulatory and outpatient settings, SHEA recommends

suspending the finalization of a standard for these settings until more research and work can be done on developing data to identify the most effective approaches to implementing antibiotic stewardship programs in these settings.

SHEA Convening LTPAC Stakeholders

SHEA convened in January a teleconference of staff representatives from the long-term/post-acute care, infectious diseases community, and CDC to discuss implementation of the CDC's Core Elements of Antibiotic Stewardship in Nursing Homes guidance published in September. Chief among the concerns and observations made by members of the LTPAC community was the high variability of access to resources for nursing homes seeking to implement the core elements. Because there is no "one size fits all" approach to implementation of antibiotic stewardship in nursing homes, the LTPAC representatives expressed a need for collaboration around identifying and sharing success stories of antibiotic stewardship in different types of long-term care facilities, and the need for state and regionally-based supports and services. Finally, the LTPAC stakeholders made clear the need for access to ID-trained clinicians to assist with implementation and maintenance of antibiotic stewardship activities in the nursing home settings. SHEA will continue to lead these discussions on behalf of the LTPAC and infectious diseases communities.

California exploring bill requiring ASPs for outpatient healthcare facilities

SHEA is working with office of California State Sen. Jerry Hill to explore potential new legislation that would require antibiotic stewardship programs for outpatient and ambulatory healthcare settings. Sen. Hill successfully introduced legislation that was signed into law by the governor requiring antibiotic stewardship programs in acute and long-term care facilities. SHEA is convening a group of California members to assist the senator with developing legislative language.

Expansion of the SHEA Grassroots Network

In 2015, SHEA rolled out its grassroots program for members by introducing the SHEA Grassroots Network. The network successfully executed a campaign to fund the Agency for Healthcare Research and Quality (AHRQ), which was in danger of being terminated through the FY 2016 federal appropriations process. In the first quarter of 2016, SHEA has begun the build out of the network's infrastructure using MySHEA, SHEA's member only social network platform. MySHEA now houses the Healthcare Epi Policy News and Updates community, where members of the Grassroots Network can stay informed on priority issues on SHEA's policy agenda. In the coming weeks, the SHEA Action EpiCenter will go online in MySHEA to support calls to action for SHEA members.

Campaigns and related activities:

[SHEA Awards](#)

SHEA opened SHEA Career Awards for IDWeek2016 in February 2016. These awards are non-abstract driven. Applications are due to SHEA May 2, 2016. The awards include:

- SHEA Mentor Scholar Award
- SHEA Senior Scholarship Award
- SHEA Pediatric Scholarship Award
- SHEA Mid-Career Scholarship Award
- SHEA International Scholarship Award
- SHEA Advanced Practice IP Award

More information can be found online.

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

02/02/16 - Antiseptic Baths to Prevent Infections Deemed Effective for Long-Term Use

12/09/15 - U.S. Capability for Treating Ebola Outbreak Appears Sufficient but Limited

11/23/15 - Complex Hospital Infection Data Confuses Consumers
11/16/15 - Antibiotic-Preserving Strategies Must Be Implemented to Battle Resistance
11/04/15 - SHEA Applauds Congress on the Passage of the Bipartisan Budget Act of 2015
10/27/15 - Diabetes Identified as a Risk Factor for Surgical Site Infections
10/13/15 - Drug-Resistant E.coli Bacteria Increasingly Found in Community Hospitals
10/01/15 - Infection Control Experts Announce Recommendations to Reduce Overuse in Medicine
09/16/15 - Dominant Strain of Drug-Resistant MRSA Decreases in Hospital Settings But Persists in the Broader Community
09/15/15 - Ensuring Appropriate Antibiotic Use in Long-Term Care Settings to Improve Patient Care
[SHEA continues to collaborate with Medscape](#) submitting expert commentaries and contributing select articles from Infection Control and Hospital Epidemiology. The SHEA page is available online: 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/SHEAPreventingHAls

Publications:

Infection Control and Hospital Epidemiology (ICHE)

In 2015, submissions to ICHE increased over the previous year to 935 submissions. SHEA is looking at our current editorial structure to better triage the review process as we continue to grow. This will be a part of Dr. Suzann Bradley's contract renewal in 2016 – her anticipated new term will be 2017 – 2021.

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 kweinschel@shea-online.org.

Other items of note:

Research

SHEA Annual Epi Project Competition Review

SHEA's Research Committee has suspended the annual Epi Project Competition for the 2016 cycle in order to make recommendations for improvements to the event. 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 \$20,000. The successful proposal is carried out as a research project supported by the SHEA Research Network. The Research Committee is doing a review of all aspects of the competition and is considering making changes to some aspects of the event including eligibility of proposal submitters, criteria for judging proposals, and parameters of the award. The competition will be re launched at the 2016 Spring Conference with the announcement of revised competition criteria and a call for proposal submissions.

International Research - MDRO Survey Manuscript

The committee is finalizing the manuscript for the MDRO survey conducted in 2015. The paper will be submitted to ICHE for publication in the coming weeks.

Methodologies Paper Series

Members of the Research Committee and other members have collaborated to develop 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. The final drafts of these manuscripts are currently under development and will be submitted to ICHE for review and publication on a staggered scheduled beginning in June 2016 through August 2016. The papers will also be presented at the SHEA Spring Conference this year.

SHEA Research Network (SRN)

The SRN membership application has been condensed, and member institutions will be contacted in the next month with the request to update their information to ensure an accurate database.

Open projects:

- Knowledge and information sharing for emerging infectious diseases

In queue:

- Activities of the World Health Organization (WHO) against antimicrobial resistance (AMR)
- Evaluating current infection prevention practices in the cardiac electrophysiology laboratory

Recently completed:

- 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: March 31, 2016

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison name: Vineet Chopra, MD

Organization represented: The Society of Hospital Medicine

Interim activities and updates:
<ul style="list-style-type: none"> • SHM is working with HRET on Catheter Associated Urinary Tract Infection (CAUTI) and Hospital Associated Infection (HAI) prevention and best practices regarding the Comprehensive unit-based safety program model (CUSP) <ul style="list-style-type: none"> ○ SHM facilitates coaching calls and has actively supported four cohorts for the project to assist long term care facilities (LTCFs) with implementing cultural and technical interventions in order to reduce CAUTI/HAI rates; SHM is currently executing the final option year of the program and managing five physician experts in the program; SHM began serving as an organizational lead for 13 LTCFs in the program in December 2015 • SHM is working with HRET to identify strategies for reducing MRSA, CAUTI, C.Diff and CLABSI in several hundred United States hospitals. • SHM is a partner to HRET to reduce CAUTI in ICUs. • SHM is developing an antimicrobial stewardship implementation guide and educational modules for hospitalists regarding the implementation of antimicrobial stewardship programs in the hospital <ul style="list-style-type: none"> ○ The guide and modules are currently in production and will be completed by January 2017 • SHM continues to promote its Fight the Resistance Campaign dedicated to promoting awareness and behavior change related to antimicrobial stewardship and appropriate prescribing practices <ul style="list-style-type: none"> ○ SHM will deploy a follow-up survey to all members on antimicrobial stewardship in April 2016; the baseline survey was disseminated in August 2015 and we are measuring the impact of SHM's Fight the Resistance campaign ○ A call for antimicrobial stewardship case studies has been sent to all SHM membership on implementing antimicrobial stewardship programs in hospitals led by hospitalists; success stories; barriers to success; and tips on implementation
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.
None at this time
Position statements:
None at this time
Legislation:
SHM added its name to the sign-on letter in support of antimicrobial resistance funding in the FY17 Labor-HHS Appropriations bill.
Campaigns and related activities:
SHM's Fight the Resistance Antimicrobial Stewardship campaign is ongoing. Several campaign resources may be accessed online
Press activities:
None at this time
Publications:
<ul style="list-style-type: none"> • Performance of processes of care and outcomes in patients with Staphylococcus aureus bacteremia

- [Fecal microbiota transplantation for the treatment of Clostridium difficile infection](#)
- [Barriers to guideline-concordant antibiotic use among inpatient physicians: A case vignette qualitative study](#)
- [Impact of antibiotic choices made in the emergency department on appropriateness of antibiotic treatment of urinary tract infections in hospitalized patients](#)
- [Infectious Diseases Society of America 2014 Practice Guidelines To Diagnose, Manage Skin, Soft Tissue Infections](#)

Other items of note:

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

Meeting Date: March 31, 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 has been planned and finalized. It is set to take place from May 19-21 in Palm Beach, FL. 48 oral presentations and 44 poster presentations will be given, as well as several focused symposia.
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.
<p>Guidelines in process: The members of the Guidelines and Therapeutics Committee are conducting the following systematic reviews:</p> <ol style="list-style-type: none"> 1. Antibiotics for facial trauma <ol style="list-style-type: none"> a. October 2015: completion of analysis b. December 2015: manuscript submission to <i>Surgical Infections</i> 2. Revision of 2010 Guidelines for the management of intra-abdominal infections <ol style="list-style-type: none"> a. August 2015 Review literature b. November 2015 Complete analysis c. March 2016 Submit manuscript 3. Guidelines for the management of acute appendicitis <ol style="list-style-type: none"> a. May 2016 Review literature b. August 2016 Complete analysis c. November 2016 Submit manuscript 4. Guidelines for the management of the open abdomen <ol style="list-style-type: none"> 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 <ol style="list-style-type: none"> 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:
<p>REVIEWS Severe Acute Pancreatitis: Gut Barrier Failure, Systemic Inflammatory Response, Acute Lung Injury, and the Role of the Mesenteric Lymph</p>

Per Landahl, Daniel Ansari, Roland Andersson
Surgical Infections. Nov 2015, 16(6): 651-656.

Alcohol Consumption Increases Post-Operative Infection but Not Mortality: A Systematic Review and Meta-Analysis

Daniel Mønsted Shabanzadeh, Lars Tue Sørensen
Surgical Infections. Nov 2015, 16(6): 657-668.

Infection of Penile Prosthesis in Patients with Diabetes Mellitus

Michelle Christodoulidou, Ian Pearce
Surgical Infections. Jan 2016, 17(1): 2-8.

Duration of Antimicrobial Therapy in Treating Complicated Intra-Abdominal Infections: A Comprehensive Review

Massimo Sartelli, Fausto Catena, Luca Ansaloni, Federico Coccolini, Salomone Di Saverio, Ewen A. Griffiths
Surgical Infections. Jan 2016, 17(1): 9-12.

Mesh Infection and Hernia Repair: A Review

Bárbara Pérez-Köhler, Yves Bayon, Juan Manuel Bellón
Surgical Infections. Mar 2016, 17(2): 124-137.

Reducing Surgical Site Infections in Abdominal Surgery: Are Ring Retractors Effective? A Systematic Review and Meta-Analysis

Khalid Ahmed, Khalid Bashar, Tara T.M. Connelly, Tom Fahey, Stewart R. Walsh
Surgical Infections. Mar 2016, 17(2): 138-151.

Prevention of Surgical Site Infections in Joint Replacement Surgery

Camelia E. Marculescu, Tad Mabry, Elie F. Berbari
Surgical Infections. Mar 2016, 17(2): 152-157.

Is Staphylococcal Screening and Suppression an Effective Interventional Strategy for Reduction of Surgical Site Infection?

Charles E. Edmiston Jr, Nathan A. Ledebor, Blake W. Buchan, Maureen Spencer, Gary R. Seabrook, David Leaper

Other items of note:

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.