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 (HICPAC)

Meeting

July 16-17, 2015
Atlanta, Georgia

Meeting Summary Report

Available from: https://www.cdc.gov/hicpac/minutes.html

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Meeting Agenda

Healthcare Infection Control Practices Advisory Committee

July 16-17, 2015
Centers for Disease Control and Prevention
Tom Harkin Global Communications Center (Building 19, Auditorium 3)
1600 Clifton Road NE, Atlanta, GA

Thursday, July 16, 2015

Time	Topic	Purpose	Presider/Presenter
9:00	**Welcome and Introductions**	Information	Dan Diekema (HICPAC Chair) Jeff Hageman (HICPAC DFO)
9:15	CDC Updates: National Center for Emerging and Zoonotic Diseases (NCEZID) and Division of Healthcare Quality Promotion (DHQP)	Information	Beth Bell (NCEZID,CDC) Michael Bell (DHQP, CDC)
9:45	Draft Guideline to Prevent Surgical Site Infections	Information Discussion	Erin Stone (DHQP, CDC)
10:45	**Break**		
11:00	Healthcare Antimicrobial Resistance and Stewardship: DHQP Updates, Stewardship Technical Package	Information Discussion	Michael Craig (DHQP, CDC) Arjun Srinivasan (DHQP, CDC)
12:15	**Lunch**		
1:30	International Infection Prevention Control	Information	Ben Park (DHQP, CDC)
2:00	Medical Device Reprocessing: Duodenoscope Update, Duodenoscope Culture Methods Update, Ensuring Training and Competency of Staff – Facility Perspective	Information Discussion	Suzanne Schwartz (FDA) Angela Coullitte (DHQP, CDC) Vickie Brown (HICPAC)
3:15	**Break**		
3:30	Ventilator-Associated Events: CDC Updates, VAE from the ICU's Point of View – Implementation Lessons, Pivoting to Prevention, and the Research Agenda	Information Discussion	Shelley Magill (DHQP, CDC) Michael Howell (SCCM Liaison)
4:15	Public Comment		
4:30	**Liaison/*Ex officio* reports**		
5:00	**Adjourn**		

Friday, July 17, 2015

Time	Topic	Purpose	Presider/Presenter
9:00	Draft Guideline to Prevent Surgical Site Infections	Vote	Dan Diekema (HICPAC Chair)
9:15	Research Framework for Environmental Infection Control: Environmental Surfaces	Information Discussion	Sujan Reddy (Emory University)
10:15	**Break**		
10:30	Infection Prevention and Control Guidelines: Experience of the Public Health Agency of Canada	Information Discussion	Toju Ogunremi (PHAC Liaison)
11:10	Public Comment		
11:30	Summary and Work Plan		
12:00	**Adjourn**		

List of Participants

Thursday, July 16, 2015

HICPAC MEMBERS

Dr. Daniel Diekema, Chair
Ms. Vickie Brown
Dr. W. Charles Huskins
Ms. Lynn Janssen
Dr. Lisa Maragakis
Dr. Jan Patterson
Ms. Gina Pugliese
Dr. Selwyn Rogers
Dr. Tom Talbot
Dr. Michael Tapper
Dr. Deborah Yokoe

EX OFFICIO MEMBERS

Ms. Elizabeth Claverie-Williams, Food and Drug Administration
Dr. David Henderson, National Institutes of Health
Ms. Jacqueline Taylor, Health Resources and Service Administration

LIAISON REPRESENTATIVES

Elizabeth Wick (American College of Surgeons (ACS))
Akin Demehin (American Hospital Association (AHA))
Amber Wood (Association of periOperative Registered Nurses (AORN))
Michael Anne Preas (Association of Professionals of Infection Control and Epidemiology (APIC))
Emily Lutterloh (Association of State and Territorial Health Officials (ASTHO))
Marion Kainer (Council of State and Territorial Epidemiologists (CSTE))
Lisa McGiffert (Consumers Union)
Stephen Weber (Infectious Diseases Society of America (IDSA))
Jennifer Gutowski (National Association of County and City Health Officials (NACCHO))
Toju Ogunremi (Public Health Agency of Canada (PHAC))
Michael Howell (Society for Critical Care Medicine (SCCM))
Vineet Chopra (Society of Hospital Medicine (SHM))
Robert Sawyer (Surgical Infection Society (SIS))

CDC REPRESENTATIVES

Ms. Jessica Adam, CDC/DHQP
Dr. Matt Arduino, CDC/ DHQP
Dr. Beth Bell, CDC/ DHQP
Dr. Michael Bell, CDC/ DHQP
Mr. James Baggs, CDC/DHQP
Ms. Catherine Capers, CDC/DHQP
Dr. Bryan Christiansen, CDC/ DHQP
Ms. Danielle Coker, CDC/DHQP
Ms. Nicole Coffin, CDC/ DHQP
Ms. Angela Coulliette-Salmond, CDC/ DHQP
Mr. Michael Craig CDC/DHQP
Mr. Jonathan Edwards, CDC/DHQP
Dr. Lauren Epstein, CDC/ DHQP
Dr. Ryan Fagan, CDC/ DHQP
Ms. Angela Fisher, CDC/ DHQP
Dr. Tony Fiore, CDC/ DHQP
Dr. Scott Fridkin, CDC/DHQP
Dr. Carolyn Gould, CDC/ DHQP
Dr. Nicole Gualandi, CDC/DHQP
Ms. Stephanie Gumbis, CDC/ DHQP
Mr. Jeff Hageman, CDC/ DHQP
Dr. Alison Halpin, CDC/DHQP
Ms. Heather Hastings, CDC/ DHQP
Ms. Carmen Hazim, CDC/ DHQP
Dr. Rita Helfand, CDC/ DHQP
Dr. Susan Hocevar, CDC/ DHQP
Ms. Bette J. Jensen, CDC/DHQP
Dr. Alex Kallen, CDC/ DHQP
Dr. Rebecca Konnor, CDC/ DHQP
Ms. Paulette Knights, NCEZID/OD
Ms. Rachel Kossover, CDC/ DHQP
Ms. Denise Leaptrot, CDC/ DHQP
Ms. Nancy Levine, CDC/DHQP
Dr. Ulzii Luvsansharav, CDC/DHQP
Dr. Meghan Lyman, CDC/ DHQP
Dr. Cliff MacDonald, CDC/ DHQP
Mr. Randy McCray, CDC/ DHQP
Dr. Shelley Magill, CDC/ DHQP

Dr. Duc Nguyen, CDC/ DHQP
Dr. Judith Noble-Wang
Ms. Amanda Overholt, CDC/ DHQP
Ms. Rose Pecoraro, CDC/ DHQP
Mr. Austin Penna, CDC/DHQP
Dr. Kiran Perkins, CDC/ DHQP
Dr. Joe Perz, CDC/DHQP
Ms. Ruby Phelps, CDC/ DHQP
Ms. Rose Reilley, CDC/ DHQP
Dr. Melissa Schaefer, CDC/ DHQP
Dr. Issac See, CDC/ DHQP
Ms. Kathy Sieber, CDC/ DHQP
Ms. Ami Shah, CDC/ DHQP
Ms. Aditya Sharma, CDC/ DHQP
Ms. Erin Stone, CDC/ DHQP
Dr. Nimalie Stone, CDC/ DHQP
Dr. Nicola Thompson, CDC/ DHQP
Ms. Abbigail Tumpey, CDC/ DHQP
Ms. Katharina van Santen, CDC/DHQP
Ms. Isata Ward, CDC/ DHQP
Dr. Cindy Weinbaum, CDC/ DHQP
Ms. Tahainia Williamson, CDC/DHQP
Ms. Sarah Yi, CDC/ DHQP

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Mr. Terrell Cunningham, Food and Drug Administration
Dr. Suzanne Schwartz, Food and Drug Administration
Ms. Shani Haugen, Food and Drug Administration
Ms. Elaine Mayhall, Food and Drug Administration

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Dr. Jim Arbogast, Gojo
Ms. Kay Argroves, American Association of Nurse Anesthetists
Mr. Dale Bratzler, OU Physicians
Dr. Russ Castioni, 3M
Ms. Kendra Cox, Cambridge Communications, Training, and Assessments
Dr. Paul Edwards, Merck
Mr. Hudson Garrett, PDI
Ms. Kristin Hake, Emory Healthcare
Ms. Nancy Hailpern, Association of Professionals in Infection Control
Ms. Amna Handley, GA Pacific
Ms. Lori Harmon, Society of Critical Care Medicine
Ms. Eve Humphries, Society of Healthcare Epidemiologist of America
Ms. Shirley Jankelevoch, All Children's Hospital
Ms. Jane Kirk, Gojo Industries
Ms. Rachel Long, Carefusion/ Bard
Ms. Valerie Lowe, Dignity Health
Ms. Donna Marshall, Johnson & Johnson
Ms. Renee Odehnal, Ethicon
Ms. Silvia Quevedo, Association of Professionals in Infection Control
Dr. Sujan Reddy, Emory University
Mr. Stephen Rothensburger, Ethicon
Ms. Maria Rodriguez, Xenex
Mr. Ben Russo, Ethicon
Ms. Penny Smalley, International Council on Surgical Plumes
Dr. Michelle Stevens, 3M
Ms. Rachel Stricof, Council of State and Territorial Epidemiologists
Ms. Brenda Ulmer, International Council on Surgical Plumes
Mr. Tim Waitkus, Bard

July 17, 2015

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Ms. Angela Coulliette-Salmond, CDC/ DHQP
Ms. Shani Doss, CDC/DHQP
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Dr. Scott Fridkin, CDC/DHQP
Dr. Carolyn Gould, CDC/ DHQP
Mr. Jeff Hageman, CDC/DHPQ
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Executive Summary

The US Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on July 16 – 17, 2015, in Atlanta, Georgia. The Designated Federal Official (DFO) and Chair confirmed the presence of a quorum of HICPAC voting members and ex officio members on both days of the meeting. The meeting was called to order at 9:12 a.m. on July 16, 2015.

Drs. Beth Bell and Michael Bell provided updates from the NCEZID and DHQP.

Ms. Erin Stone presented, and HICPAC discussed, the draft recommendation in the Draft Guideline to Prevent Surgical Site Infections: How safe and effective are antimicrobial-coated sutures, and when and how should they be used?

Michael Craig and Dr. Arjun Srinivasan presented activities at DHQP and beyond related to healthcare antimicrobial resistance and stewardship. The topics included the recent White House Antibiotic Stewardship Forum and stewardship work in hospital, as well as other, settings. HICPAC's input was requested regarding antibiotic stewardship approaches at CDC.

Dr. Benjamin Park described experiences in international infection prevention and control, particularly regarding the Ebola outbreak in West Africa.

Dr. Suzanne Schwartz, US Food and Drug Administration (FDA), Dr. Angela Coullitte, DHQP, and Vickie Brown, HICPAC member, presented updates and challenges associated with medical device reprocessing, including culturing devices and training and competency of staff.

Dr. Shelley Magill, DHQP, updated HICPAC on new definitions pertaining to Ventilator-Associated Events (VAEs). Dr. Michael Howell, HICPAC liaison representative, Society of Critical Care Medicine (SCCM), described lessons learned and perspectives at the facility level regarding VAE, including challenges associated with automation and data availability; the active move toward prevention instead of surveillance; and the response of the critical care community to the changes.

HICPAC liaison groups provided written and verbal updates. HICPAC stood adjourned from 4:49 p.m. on July 16 until 9:13 a.m. on July 17, 2015.

HICPAC voted on and approved the language in the Draft Guideline to Prevent Surgical Site Infections.

Dr. Sujan Reddy, Emory University, presented a draft research framework for environmental infection control of surfaces.

Ms. Toju Ogunremi, HICPAC liaison member, Public Health Agency of Canada (PHAC), shared PHAC's experience regarding the development of Infection Prevention and Control Guidelines.

HICPAC stood in recess at 11:31 a.m. on July 17, 2015. The next HICPAC meeting will be held in Atlanta, Georgia on November 5-6, 2015.

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)

July 16-17, 2015
Atlanta, Georgia

Meeting Summary Report

The United States Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on July 16 and 17, 2015 at the Tom Harkin Global Communications Center at the Centers for Disease Control and Prevention, 1600 Clifton Road NE, Atlanta, Georgia.

Thursday, July 16, 2015

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 9:12 a.m. He welcomed HICPAC members and liaison representatives and introduced Dr. Daniel Diekema as the new Chair of HICPAC.

Daniel Diekema, MD
Chair, HICPAC

Dr. Daniel Diekema greeted the group and introduced new HICPAC members:

Vickie Brown, RN, MPH, CIC, Director of Infection Prevention and Control, WakeMed

Lisa Maragakis, MD, MPH, Associate Professor of Infectious Diseases and Epidemiology, Johns Hopkins University; Senior Director of Healthcare Epidemiology and Infection and Control, Johns Hopkins Health System; Hospital Epidemiologist and Director, Department of Hospital Epidemiology and Infection Control, Johns Hopkins Hospital

Jan Patterson, MD, MS, FACP, FIDSA, FSHEA, CPE, FACHE, Professor of Medicine, Infectious Diseases, and Pathology; Associate Dean for Quality and Lifelong Learning; Director, Center for Patient Safety and Health Policy, University of Texas School of Medicine

Dr. Diekema conducted a roll call of HICPAC members, *ex officio* members, and liaison representatives. A quorum was present. HICPAC members disclosed the following conflicts of interest:

Dr. Diekema has received research funding from bioMérieux.

Dr. W. Charles Huskins serves on the Advisory Board of Genentech.

Ms. Lynn Janssen's department receives program funding from CDC. Her spouse works for Dynavax Technologies, which develops immunological products, including vaccines.

Dr. Lisa Maragakis receives research funding from Clorox for a study of ultraviolet (UV) light devices.

Dr. Tom Talbot's spouse receives research funding from Gilead Sciences, Inc., Teva Pharmaceutical Industries, Inc., Sanofi Pasteur, MedImmune, and Novartis for vaccine research.

Dr. Michael Tapper was recently a visiting professor at the University of Panama and serves as a consultant at Tulane University.

CDC Updates: National Center for Emerging and Zoonotic Infectious Diseases

Beth Bell, MD, MPH
Director
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Dr. Beth Bell welcomed the group and provided an update on activities within NCEZID. NCEZID's budget appropriation for fiscal year (FY) 2015 was $405 million, including a $352.99 million budget authority and $52 million in the Prevention and Public Health Fund (PPHF). The center's budget supports activities focused on the following:

Foodborne / Waterborne Illnesses

Healthcare-Associated Infections (HAIs)

Antibiotic-Resistant Infections

Deadly Diseases (e.g., anthrax, smallpox, Ebola)

Zoonotic Diseases

Vector-Borne Diseases

Illnesses That Affect Immigrants, Migrants, Refugees, and Travelers

The President's Budget Request for NCEZID for FY 2016 includes a $264 million increase for antibiotic resistance (AR) and a $14 million increase for the National Healthcare Safety Network (NHSN).

NCEZID has broad infectious disease responsibilities. The center publishes the Yellow Book and the *Emerging Infectious Diseases* journal. The center is responsible for NHSN and the Laboratory Response Network (LRN), a network of public health laboratories in all state health departments and other areas. The LRN is able to test for biothreat agents using standard protocols and assays that are developed and distributed by CDC.

The center is responsible for the platform cooperative agreement that supports all state health departments and six of the largest local health departments for "bread and butter" epidemiology and laboratory work. The platform funds more than 20 specific disease areas, including influenza and foodborne diseases. The center provides cross-cutting support for infectious disease epidemiology, laboratory, and health information systems capacity in state health departments. State budgets have decreased in recent years, and an increasing proportion of funding to support infectious disease work in state and local health departments has been provided by CDC.

NCEZID conducts a great deal of outbreak response. EpiAids are official outbreak investigations. Investigations in the past year have focused on duodenoscopes and Carbapenem-resistant Enterobacteriaceae (CRE) and a number of foodborne outbreaks, including a surprising and large botulism outbreak.

Response to the Ebola outbreak has been a primary activity of the center for over a year. There have been more than 10 times as many cases of Ebola during the current epidemic than in all other outbreaks combined. Over 11,000 deaths have been reported. The Ebola response is the largest emergency response in CDC history. The Emergency Operations Center (EOC) has been activated for over a year. Over 3000 CDC staff have been involved in the response, including hundreds who have deployed to West Africa. At times, 20% of the NCEZID staff was working on the Ebola response. Over 6800 communications products and 360 scientific documents have been produced. There have been over 35,000 responses to Ebola-related inquiries and over 1000 responses to calls about patients with possible Ebola. CDC has trained over 150,000 US healthcare workers via webinars. The video on personal protective equipment (PPE) has been viewed almost 450,000 times.

The current focus of the Ebola response is "getting to zero." The work in Ebola is far from over even as the situation has improved. The work includes difficult, meticulous contact tracing and core public health field work in West Africa. Cases are still being reported in Sierra Leone and Guinea at a rate of approximately 24 per week. At the end of June 2015, a new case was detected in Liberia and a small cluster was identified.

There has been a great deal of national momentum on AR since the publication of CDC's *Antibiotic Resistance Threat Report*. The National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB) was released on March 27, 2015. It follows on the National Strategy that was released in the fall of 2014 and outlines steps to implement the strategy and recommendations from the President's Council of Advisors on Science and Technology (PCAST) report. The plan includes significant, hard outcomes that are expected by 2020. All of the activities are consistent with the investments proposed in the President's FY 2016 Budget. A companion Tuberculosis (TB) Action Plan is currently under development.

The activities in the Strategy and in the Action Plan focus on prevention and slowing the emergence of AR and include state programs and stewardship, surveillance, diagnostics, research, and international collaboration. The President's Budget Request for CDC in AR is $264 million, which is a large budget request for the agency. AR is one of CDC's two highest priorities for FY 2016, and the work is in three general categories:

Detect and Respond

Regional laboratories

Expansion of the Emerging Infections Program (EIP), which conducts gold-standard surveillance and special population-based projects

Expansion of the National Antibiotic Resistance Monitoring System (NARMS), which monitors enteric antibiotic resistant organisms

Protect
Building state AR programs

Meaningful stewardship in facilities and communities

Innovate
Projects focusing on the microbiome

Operational research through the Prevention Epi-Centers

Chikungunya is a mosquito-borne disease that has been recognized in Asia and Africa, but did not appear in the Western Hemisphere until the fall of 2013. The first cases were detected on the islands of St. Martin in the Caribbean. Since then, 44 countries or territories in the Western Hemisphere have reported over 1.5 million cases of Chikungunya. The outbreak is expected to continue and to spread to new countries. Over 2700 travel-associated cases of Chikungunya have been reported in 47 US states in 2014. This number represents a large increase. There were also 11 locally-acquired cases in Florida. Because of the distribution of the two competent vectors, *Aedes aegypti* and *Aedes albopictus*, which are present in the US, particularly in the South, locally-acquired cases and potential small outbreaks are expected to continue. Chikungunya has also appeared on the México side of the US-México border. CDC is working with the border states to gear up their ability to detect and to respond. CDC has also worked with the Pan-American Health Organization (PAHO) for several years on diagnostics, surveillance, education, and supply of reagents.

The Advanced Molecular Detection (AMD) initiative at CDC was first funded in FY 2014. The initiative brings the benefits of next-generation sequencing to public health. It does not focus on creating new, high-tech methods, but on applying methods to public health. CDC works in a number of areas to improve capabilities and upgrade systems. An example of this work is in the foodborne area. CDC is in the middle of a pilot project in partnership with the US Food and Drug Administration (FDA), the National Institutes of Health (NIH), and some state public health departments. The project sequences in real time all *Listeria* isolates from patients and from food. So far, the project has sequenced over 1000 isolates. The cluster detection method used for molecular epidemiology is pulsed-field gel electrophoresis (PFGE), a technology that is over 20 years old. Whole genome sequencing (WGS) detects clusters faster than PFGE, speeding up investigations and allowing clusters to be more specific and to exclude cases that share PFGE patterns but are not related to each other. Conversely, WGS can identify new clusters and help determine sources. These efforts will broaden in the future.

Culture-independent diagnostic tests are another important part of WGS. The advent and spread of these tests in the foodborne arena clearly provide clinical benefits; however, the tests also present short-term problems for public health, as public health relies on cultures for all cluster detection and laboratory-based surveillance. Approaches to encourage clinical laboratories to perform reflex testing to send specimens to state public health laboratories include FDA labeling and Centers for Medicare and Medicaid Services (CMS).

The Global Health Security Agenda (GHSA) is a major initiative for the US government that is gathering momentum. The agenda focuses on recognizing risks in the global arena, including emerging organisms, drug resistance, and the intentional creation of threats. There are a number of opportunities in this area pertaining to new technologies and societal commitment. The Ebola epidemic has illustrated that the world is not well-prepared to respond to risks and threats. The GHSA includes priorities to prevent problems where possible, to detect problems rapidly, and to respond to problems effectively.

CDC received $1.2 billion in FY 2015 to build core public health capacities around the world and to create an environment in which an event such as the Ebola epidemic and its resulting problems does not happen again. Of the FY 2015 allocation, approximately $600 million is allocated for Global Health Security (GHS) and $600 million is designated for emergency funding for the Ebola response. CDC's GHS work includes AMR and infection control. Globally, the Ebola epidemic has brought into sharp focus the importance of infection control and prevention and protecting people from infectious diseases. The epidemic has also shown that the world is behind in ensuring that facilities and Ministries of Health (MoHs) are equipped, even at a basic level, to respond to Ebola or other problems.

CDC Updates: Division of Healthcare Quality Promotion

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

Dr. Michael Bell described some of the downstream effects of the Ebola outbreak. The event has clarified national and global capabilities for controlling infections. While Ebola has disappeared from the press, the work is not complete. There is ongoing transmission in parts of West Africa, new clusters are being recognized, and international travel still occurs. Travel is particularly challenging, as health departments, hospitals, emergency departments, and the CDC must remain vigilant. There is fatigue in the field, particularly regarding issues such as travel screening, which is a challenging reminder of the work that remains.

From an infection control perspective, there are deficits in adherence and training. Underlying those deficits is a deficit in understanding infection transmission. This lack of understanding is manifested in the fear and uncertainty that characterize the Ebola response. There are opportunities for the large investments in Ebola to address these issues in a larger context, particularly regarding daily harms that occur to patients and healthcare personnel if infection control is not carried out well.

CDC's efforts and investments with partners related to Ebola infection control fall into four major categories:

Strengthening State HAI Programs

Increasing the ability to conduct targeted assessments of healthcare facilities in partnership with state authorities to identify gaps in infection control

Bolstering ability at the state level to provide training and assist with the implementation of infection control practices that address those gaps

Improving the coordination of healthcare and public health; the two have not always been linked well: healthcare personnel often are not aware of real-time issues, and public health authorities may not have a clear understanding of what happens in hospitals; CDC investments in many locations have led to closer relationships between healthcare facilities and public health leadership.

Accelerating Implementation of State/Local Prevention Activities

Working with partner organizations to create model policies for implementing infection control to foster consistency

Providing technical assistance to help state HAI programs, hospitals, and other healthcare facilities to grow the necessary capabilities to implement good infection control

Infection Control Training

Providing Ebola-specific training in partnership with facilities that have been leaders in containing similar infections in healthcare settings

Sharing standardized infection control curricula across multiple partners that reflect not only CDC guidelines, but also provide clear rationales pertaining to disease transmission

Revisiting risk assessment in infection control, which is an important component of infection control that may have been minimized by approaches that utilize checklists and bundled practices

Supporting innovations in infection control by funding research and demonstration projects

Consider new ways to reduce infectious material in the environment

Improve the design and utility of infection control equipment

Find new interventions that can prevent the transmission of pathogens

The goal of this work, which combines innovation and implementation, is to ensure that the US is better-connected and ready to address infectious disease situations ranging from Ebola-like illnesses to resistant pathogens that spread throughout communities.

Discussion Points

HICPAC supported the idea of revisiting the risk assessment. Many infection prevention programs are overwhelmed by meeting the bundled elements that are mandated. The periodic risk assessments conducted by hospitals have gone by the wayside. This work presents a tremendous opportunity to strengthen the infection control infrastructure within hospitals, states, and nationally.

Dr. Michael Bell said that DHQP is ahead of the curve with the “Essential Practices” document that HICPAC has been instrumental in guiding. That kind of clarity and focus on routine practice will be helpful. In addition, it will be helpful to work with HICPAC regarding what risk assessment means and who needs to be engaged in it. There is a tendency for frontline healthcare staff to focus on tasks and perhaps not to think about risks on a minute-by-minute basis. It is not realistic to think that all healthcare workers will do this work at a high level, but there are certain aspects of risk assessment, such as syringe re-use, that can permeate all levels of the healthcare workforce. The field of infection prevention has an opportunity to re-grow that capacity and that role within healthcare facilities. In the past, there was a stronger presence of individuals focused on risk assessment on wards and at bedsides. Now, demands are tremendous on limited staff. Additionally, HICPAC can advise the division on future goals in terms of better ways to structure healthcare. The current model has evolved for recognized reasons, but an additional voice could articulate what healthcare could look like if staff and resources were supported and arranged differently.

Travel screening presents a significant opportunity not only in hospitals, but also in outpatient and ambulatory settings. Every point of risk should have a standardized approach for assessing risk, particularly regarding pathogens and their relationship to travel history.

Dr. Michael Bell agreed that the field has a rare opportunity not only in resources, but also in a willingness to consider different approaches. For instance, national training centers for Ebola infection are now accepted ideas. However, healthcare facilities are still being built according to 1930s medical practices, and new facilities are designed to look like hotel lobbies rather than being designed to prevent infection transmission or to keep patients safe. Conversations are underway regarding what healthcare should look like. Why are there waiting rooms at all in hospitals when pager systems or cell phones could be utilized? There are opportunities to build ambulatory centers to self-triage so that potentially infectious patients do not mix with other people. These approaches include material and process innovations as well.

Draft Guideline to Prevent Surgical Site Infections

Erin Stone, MS
Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases Centers for Disease Control and Prevention
Member, Surgical Site Infection Guideline Writing Group

Ms. Stone provided an overview of the complex and iterative Guideline Development Process. The topic of antimicrobial coated sutures has been in front of HICPAC several times as the topic has undergone abstract and full-text screening; data extraction and synthesis; draft recommendation formulation and presentation; and re-analysis, followed by the process again.

The creation of a guideline begins with the establishment of a writing group. The core writing group consists of DHQP Staff, CDC subject matter experts (SMEs), method experts, HICPAC members, and external experts. The Surgical Site Infection (SSI) Guideline group includes a large group of professional surgical co-authors.

The writing group utilizes guideline methods established with the 2010 Umscheid, et al, *American Journal of Infection Control* (*AJIC*) paper. The methods involve HIPCAC input throughout the process. Guideline creation frequently begins with a search of relevant guidelines to identify gaps and questions. The SSI Guideline is intended to be a targeted update to HICPAC's 1999 Guideline to Prevent Surgical Site infections. The writing group reviewed the 1999 guideline and generated a preliminary list of key questions. The questions were submitted to content experts who provided feedback and identified additional topics of interest. The key questions were established after vetting with the surgical co-authors and HICPAC members.

Using these questions, the literature search was developed and executed and a bibliography was created. The bibliography was sent to the co-authors and content experts to ensure that no important papers were missed. The original literature search identified 5487 articles. An additional 104 articles were suggested by the content experts. Including the 168 studies cited in the 1999 Guideline, 5759 studies underwent title and abstract screening. After exclusions at this phase, 896 articles underwent Full Text Review. After that phase, 170 studies were extracted into the evidence tables and synthesized into the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Tables for evaluation.

The GRADE Tables are used as a foundation for drafting recommendations. This process is iterative, with draft GRADE Tables and draft recommendations being presented to HICPAC for input, revised, and presented again.

When HICPAC and co-author input is incorporated, the resulting draft recommendations, as well as the narrative and appendices, including the supporting tables, are presented as a draft document. The draft is submitted to CDC clearance, and any revisions are incorporated. The draft is submitted to the *Federal Register* for the Public Comment period. The public comments are received, consolidated, and reviewed at a HICPAC Meeting. Changes based on public comments are incorporated into the draft document for a final draft. HICPAC provides input and votes on the recommendations. CDC can incorporate or not incorporate HICPAC input, which then finalizes the draft, and it is submitted to final CDC clearance before publication.

The SSI Guideline process began in June 2010. The process included two public comment periods, ending in May 2014. One of the major topics from the public comment period was that the literature search was outdated. The literature search was updated and the results were incorporated and presented to HICPAC in December of 2014. 2015 began with conducting analyses suggested by HICPAC at the December 2014 meeting. During this time, surgical co- author feedback was obtained and incorporated and a series of methodologic reviews were conducted. A public call was conducted on May 11, 2015, to present this work. Transcripts for this call and minutes from all of the meetings can be found on the HICPAC website. Feedback received during the public call resulted in a tabling of the antimicrobial-coated sutures topic pending further review.

The draft guideline started with over 600 questions with input received from the surgical co- authors. These questions were narrowed down with input from HICPAC to 20 topics and 27 subtopics. The updated literature search identified new studies in the eleven highlighted topics. Most of those topics were finalized at the December 2014 HICPAC meeting. Additional analyses were requested by HICPAC at that meeting on antimicrobial sutures and oxygenation. The results of the additional analyses were presented during the May 2015 public call. Oxygenation meta-analyses were presented to HICPAC, which voted to approve the public comment version of the draft recommendations for this section.

At the start of the SSI Guideline process, a decision was made by the writing group to limit the studies used to determine the quality of supporting evidence to randomized controlled trials (RCTs) for questions within the Core Section but to allow consideration of other study types for questions within the Prosthetic Joint Arthroplasty Section. Several factors can impact the level of the quality of evidence assigned to each reviewed study.

Factors that can lower the quality of evidence include:

Study quality, or risk of bias

Study limitations

Inconsistency, indirectness, or imprecision of the data

Publication bias

Factors that can increase the quality of evidence include:

A large magnitude of effect

Dose-response

Confounding

The outcomes that are critical to formulating a recommendation are typically determined at the outset of the guideline. The nature of these outcomes, however, may be reassessed during the course of the guideline creation, potentially after extraction. Some outcomes or their importance may not be known until after the evidence review

and analysis. At that time, these outcomes may be added or removed, or deemed critical, or downgraded from critical to important. This process is another example of how iterative the guideline process is. The critical and important outcomes are not determined by what is measured in the studies; rather, outcomes and their determination are based on what is considered important by HICPAC, the writing group, and the surgical co-authors.

Several key inputs contribute to the recommendation formulation:

Values and preferences used to determine the "critical" outcomes

Overall GRADE score of the evidence for the "critical" outcomes; that is, the confidence in the estimate of effects as determined by the lowest GRADE for all critical outcomes

Net benefits, net harms, or trade-offs that result from weighing the "critical" outcomes

The overall quality grades are as follows:

High: Further research is very unlikely to change confidence in the estimate of effect

Moderate: Further research is likely to impact confidence in the estimate of effect and may change the estimate

Low: Further research is very likely to impact confidence in the estimate of effect and is likely to change the estimate

Very low: Any estimate of effect

HICPAC recommendations are either for or against, and either strong or weak:

Category IA: A strong recommendation based on high- to moderate-quality evidence with a net benefit or a net harm

Category IB: A strong recommendation based on low- to very low-quality evidence, or currently an established practices. HICPAC has modified the GRADE process for the SSI Guidelines in this area

Category IC: A regulatory recommendation with high- to very low-quality evidence. This area represents another modification of the GRADE process

Category II: A conditional or weak recommendation; this category is based on interventions with trade-offs of benefits and harms and is based on high- to very low-quality evidence

No Recommendation/Unresolved Issue: There are uncertain tradeoffs between benefits and harms, and it is typically based on low- to very low-quality evidence

Before the public call in May 2015, publication bias was assessed. A review of the directionality of the studies in the context of their conflict of interest disclosures was conducted. Funnel plots for the larger meta-analyses were also reviewed. No suggestion of publication bias was observed. Risk of bias assessments were reviewed at both the individual study and the aggregate study levels. This review resulted in no changes to the recommendations. For the meta-analysis review, all confidence intervals were reviewed and all heterogeneity assessments were assessed and included in the grade tables.

Since the public call, the writing group has conducted a review of study characteristics, including:

Baseline infection risks across studies

Publication date or study age

Study country of origin: US, non-US, or non-Western

This review was conducted for all topics across the SSI Guideline. The group also conducted a brief literature review of harms associated with triclosan-coated sutures in observational studies. No harms were found. The group also reviewed:

Extracted data to include in GRADE tables

All critical outcomes across all of the interventions

The level and direction of the evidence in relation to the strength of recommendation across the guideline

The final issue put before HICPAC for the SSI Guidelines is:

> How safe and effective are antimicrobial coated sutures and when and how should they be used?

The evidence base for this question consists of 14 RCTs. They all consider absorbable triclosan-coated sutures versus absorbable non-antimicrobial-coated sutures. All of the studies utilized triclosan-coated sutures, most on deep and/or fascial layers. Two of the RCTs were mixed surgical populations using the sutures in different layers, and four of the RCTs used them at subcutaneous layers as their primary consideration. An additional four RCTs utilized them in both the subcutaneous or fascial layer, and additionally the cutaneous layer for closure. One of the studies used them at the cutaneous layer in both the intervention and control groups. Only one of the studies that utilized triclosan-coated sutures in the superficial layer analyzed superficial SSI as an outcome. One study utilized triclosan-coated sutures were used in all steps that were possible. That study did not conduct any sub-analysis by SSI type.

In organ space SSI, where triclosan-coated sutures are not typically utilized, four RCTs with 1081 patients report on this outcome with low-quality evidence. A statistically significant benefit was not detected, the heterogeneity was high, and the confidence interval was wide.

Two studies utilized triclosan-coated sutures in the deep and/or fascial layers. One of the studies was in open abdominal surgeries, and the other was in appendectomies. Only one of the studies defined deep SSI and utilized the CDC definitions. No statistically significant benefit was seen for the use of triclosan-coated sutures on prevention of deep SSI. This body of evidence was rated overall as moderate-quality because of a wide confidence interval that did not reach statistical significance.

For the outcome of superficial SSI, four RCTs with 1922 patients yielded high-quality evidence of no benefit. Only one of the four RCTs utilized triclosan-coated sutures in the superficial layer, and it was defined according to CDC definitions. The evaluation of the evidence in this section comes down to a trade-off between benefit in all SSI outcome and no benefit in the deep SSI outcome, the layer most important to the evaluation of where these sutures have primarily been utilized.

Surgical co-author input resulted in a deeper assessment of harms, with some surgeons suggesting that AR and wound dehiscence should be critical outcomes. There was discussion about the possibility that the use of triclosan-coated sutures could lead to resistance to triclosan or impact resistance to other antimicrobials. None of the studies reported specific testing for triclosan resistance. However, this evaluation is limited by the absence of standardized methods for determining triclosan resistance.

Low-quality evidence from eight RCTs offered some assessment of antimicrobial-resistant bacteria and suggests no difference between groups in the follow-up period. For the outcome of adverse product related events, four RCTs suggested no difference between groups. Three RCTs were available to meta-analyze for wound dehiscence. The studies had low-quality evidence, high heterogeneity and a wide confidence interval. They suggested no difference between groups.

To summarize, there is high-quality evidence of benefit across procedures for closure primarily at the deep and fascial layers with absorbable triclosan-coated sutures versus absorbable coated sutures without triclosan for the critical outcome of all SSI. There is moderate-quality evidence of no benefit for the critical outcome of deep SSI, the primary layer of use for triclosan- coated sutures in the studies. There is low-quality evidence of no benefit in the important but non-critical outcomes of organ space SSI, and there is high-quality evidence of no benefit in superficial SSI. There is low-quality evidence of no harms. Suture appropriateness and suture selection were not assessed beyond the impact of the triclosan coating. Further, not all sutures that a surgeon might utilize have a triclosan-coated option. The uncertainty of benefit for this intervention results in the following proposed draft recommendation:

Consider use of triclosan coated sutures for the prevention of SSI. **(Category II)**

Discussion Points

HICPAC thanked the writing group and Ms. Stone for the hard work they devoted to the SSI Guideline. The vote on the proposed recommendation would be held the next day.

Mr. Dale Bratzler said that the surgical co-authors have met and reviewed all of the work. They were troubled with some of the outcomes. Some of the individual studies were well-done, but outcomes were not reported well in others. For instance, one of the critical harm outcomes was wound dehiscence. Some studies did not report it or eliminated it from the analysis for unexplained reasons. The group decided on a moderate level of evidence of benefit because of the impact on deep SSIs, which was deemed a critical outcome. All studies used the sutures in this way, where benefit would be expected. The surgical co-authors strongly support the Category II draft recommendation.

Regarding the depth of infection, it is often challenging to discern superficial from deep SSI in the operational application of surveillance. Because the delineation is difficult, it may be problematic to anchor onto deep versus superficial SSI, particularly since the studies are retrospective chart reviews to study documentation of depth of infection. There is a struggle even within facilities to ensure that personnel apply the preset case definitions provided by HICPAC and NHSN in defining what a SSI is. Documentation varies considerably in medical records regarding criteria that meet those definitions. Anytime the outcome measure is a certain category of SSI that is a critical component of any study, there may be unreliability in data depending upon the case definitions used to define SSI.

HICPAC stated that another potential harm is associated with opportunity costs. As a broad category, any coated tool or device may be seen as a “magic bullet” product that could, by itself, have a significant impact on HAI reduction. It is important to think carefully and critically about the evidence and to consider it in the context of all of the other best practice, basic interventions available.

HICPAC asked whether the authors of studies that did not report the depth of SSI were contacted to determine whether they could report that data. Ms. Stone answered that the writing group maintained the methods used throughout the guideline, which were to not contact the study authors.

While the overall benefit for combined all-SSI outcome, across surgeries has high-quality evidence, the confidence in these results, or the overall quality of evidence appears to be moderate. This means another study might change the confidence associated with the data. Another study showing no benefit might change the upper limit of the confidence of the interval, pushing it over 1 and changing the level of evidence.

Ms. Stone replied that the GRADE table in the presentation includes the grade of the individual comparator and the grade of the overall quality of evidence. It does not list the overall GRADE based for the section, which is moderate, based on deep SSI. There is moderate confidence in the high-quality evidence. Ultimately, the category has moderate quality evidence, but individually, the evidence is high-quality because no points were deducted for a wide confidence interval or heterogeneity. Mr. Bratzler added that in this instance, the quality of the evidence was based purely on the GRADE table. There was low heterogeneity in the studies and the confidence intervals were relatively narrow. For an all-SSI composite outcome, the GRADE table lists high-quality evidence.

Category II also implies that there are unclear benefits or a trade-off between potential benefits and harms. HICPAC discussed whether the distinction for this question was made based on the amount of benefit, or whether harms were considered in delineating a Category II. Ms. Stone replied that harms were considered, and no differences were found in harms. The question was whether benefits were detected. In this case, the suggestion to assign Category II was based on unclear benefits.

Regarding the application of the GRADE approach to making a recommendation, one of the critical outcomes, all SSI, shows benefit. It appears, however, that the critical outcome of deep SSI is more important than the all-SSI critical outcome, which therefore changes the way that the benefit is viewed. Ms. Stone said that both outcomes are critical. The values and preferences of the writing group, the surgical co-authors, and HICPAC affect the recommendation. The GRADE methodology utilizes the lowest-quality evidence of all critical outcomes within any comparator as the overall GRADE for the outcome. Mr. Bratzler agreed and noted there was extensive discussion by the surgical co-authors on this point. They agreed that deep SSI should be considered as a critical outcome since this is the surgical level where triclosan-coated sutures are typically used. It was troubling that there was no benefit seen for deep SSI

HICPAC suggested that the focus on deep SSI may not be useful because the pathogenesis of SSI is not well-understood. Prevention efforts have been based on killing all bacteria, and it is likely that the issue focuses more on how the ambient microbiome is altered and changed into a pathobiome. The use of triclosan-coated sutures at the deep organ level may affect likely bacteria at other levels; however, that claim cannot be made now based on the available science. Defining SSIs and applying SSI definitions to surveillance continue to pose many challenges.

At one point, the recommendation was slated to be separated according to different benefits of the coated sutures for different procedures. Because the other core recommendations included in this guideline do not focus on specific procedures, the decision was made to eliminate that element.

There was HICPAC concern that dehiscence was not considered as an outcome for any other of the key questions in the SSI Guideline. If it is considered to be an infection marker, then it should be applied as an outcome across the guideline rather than in a single question in order to be consistent. It was noted that wound dehiscence was

raised as a concern for a potential harm for these sutures, not necessarily as a primary outcome across the entire guideline. The evidence may be difficult to assess. If this recommendation were focused on a different intervention that had as many RCTs with the same strength of effect, it may not have been rated a Category II. HICPAC discussed a possible bias against coatings, which may lead to an over- reliance on technology and less focus on the basics.

Mr. Bratzler said that there were substantial challenges with the quality of some of the studies that concerned the surgical co-authors. Many studies did not report how they conducted surveillance for SSIs. Some did not conduct intention to treat analyses and some did not report on, or excluded, patients with outcomes such as burst abdomen or dehiscence. Some studies did not indicate which patients were in the coated-suture group or the non-coated suture group. These challenges made the co-authors uncomfortable with making a strong recommendation that the coated sutures should always be utilized. Based on the moderate level of evidence regarding the critical outcome and the concerns associated with the quality of the individual studies that were reviewed, at one point the co-authors considered issuing a "no recommendation." The co-authors felt that the evidence supports recommending considering using the triclosan-coated sutures, but they did not have confidence that additional research will not change the strength of the recommendation. There was concern among the group that additional studies could easily change the quality of the evidence.

HICPAC stated the meta-analyses for this recommendation included a large number of patients. As long as those studies are included in future analyses, it is unlikely that the results will change substantively. The issue concerns not the outcomes, but assessing the impact of the intervention on specific subgroups within individual studies for which these studies are often underpowered. . Point estimates are more relevant in this case, and the consistency of point estimates remaining less than 1 throughout is more supportive than the confidence interval.

There are limitations associated with GRADE and its focus on confidence intervals, but very few studies showed outcomes. The chances of finding a significant result are quite low.

Over the past decade, the critical care societies have learned that when a group does not feel strongly confident about a recommendation, it is advisable to make the recommendation in a softer rather than a harder way.

There was some disagreement among HICPAC with assigning the recommendation to Category II as opposed to Category IA. Based on the "all SSI" benefit and the absence of any clear harm, a Category IA is justified.

The use of "consider" as opposed to "recommend" is appropriate because of the properties of triclosan, which carries potential risk for resistance. This risk cannot be evaluated based on studies that have been conducted. It was noted that the coated suture being introduced into tissue is not normally colonized with bacteria, but there is bioaccumulation in the environment, so the concern is beyond the setting of the suture itself.

From an implementation perspective, there are challenges associated with surveillance for different types of SSIs and the amount of time that infection preventionists (IPs) devote to that work. A number of penalties are associated with having those SSIs. It would be helpful to provide explanation and guidance to those who interpret and operationalize the recommendation, particularly around Category II recommendations.

Dr. Michael Bell commented on the difference between a practice and a product. The field of infection prevention is still evolving regarding how to embrace innovative products. The ones that work should be embraced and used consistently when it is appropriate, but there can be shifts in recommendations. He is sensitive to the fact that the

HICPAC and CDC recommendations can sway purchasing significantly at the facility level, and they have an obligation to be aware of the difference between a practice and a product. As the field shifts to more sophisticated products and devices, these issues will be revisited several times.

Dr. Diekema reminded HICPAC that the vote on the draft recommendation as written would take place on the next day, and that unanimity would not be required.

Healthcare Antimicrobial Resistance and Stewardship: DHQP Updates

Michael Craig, MPP
Senior Advisor for Policy and Communications Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Mr. Michael Craig provided HICPAC with an overview of the White House Antibiotic Stewardship Forum, which was held in June 2015. The genesis of the forum was tied to the Obama Administration's CARB initiative as well as the National Action Plan, released in March 2014, and the National Strategy, released in September 2014. During the process of developing the action plan and the strategy, the White House asked the federal agencies that were developing and would implement the plan and strategy about Executive Actions that could be taken to accelerate progress or to highlight important issues.

CDC's Dr. Arjun Srinivasan suggested that the White House convene a meeting to focus on the importance of antibiotic stewardship across the continuum. The resulting forum included both human and veterinary medicine. CDC led outreach to human health entities, and the US Department of Agriculture (USDA) reached out to veterinary medicine entities. Their charge was to seek organizations that are involved in antibiotic stewardship and to secure commitments from them to improve antibiotic stewardship over a five-year period. The National Action Plan is a five-year plan, and the organizations were asked to accelerate progress on, or help achieve, the activities under it.

Over 150 organizations across the spectrum of human and animal health participated in the forum. Each organization committed to antibiotic stewardship in some manner. The forum was divided into an opening plenary session with speakers and a panel discussion chaired by Dr. Tom Frieden, CDC Director. The discussion included representatives from leading organizations and large companies associated with animal and human health. The day was then divided into breakout sessions devoted to human and animal health. CDC personnel moderated the human health breakout sessions, which included: Inpatient Settings, Outpatient Settings, Long-Term Care Setting, and New Tools for Stewardship. The breakout sessions yielded discussion on substantive issues. The White House intended for the forum to identify needs and challenges associated with implementing antibiotic stewardship across the continuum. Some challenges are shared across settings, while others are unique to different settings. The following themes are important to recognize:

Follow-Up Opportunities in Inpatient Settings

Increase implementation of hospital antibiotic stewardship programs based on CDC's Core Elements for Hospital Antibiotic Stewardship Programs. How are they put into practice at the facility level?

Work with clinical societies to ensure that guidelines related to prescribing are up-to-date, evidence-based, and promote appropriate use. Is the public health perspective represented, or are clinical societies making recommendations for treatment that are specific to their groups and practice without taking larger, related issues regarding other antibiotic use in other settings into account?

Increase hospital antibiotic use (AU) data reporting to NHSN. Many of the large health systems and data systems in attendance committed to this reporting. CDC is leading the effort to follow up with those systems and organizations to support them in achieving their commitments.

Outpatient Setting Follow-Up Opportunities

Improve stewardship education to largest outpatient prescriber segments.

Work with clinical societies to ensure that provider specific guidelines related to prescribing are evidence-based and promote appropriate use.

Organizational Commitments

The largest provider prescribers made commitments to improve outreach and education.

The groups that account for the most outpatient prescriptions are family practice, pediatrics, internal medicine, dentistry, physicians' assistants, nurse practitioners, and emergency medicine. These groups were actively engaged in discussions to understand how their guidelines and recommendations are used in a larger context and impact more than their practice.

There was a great deal of interest among long-term care setting organizations in implementing CDC's forthcoming Core Elements in Long-Term Care. CMS released a Condition of Participation (CoP) for long-term care that requires those settings to have an antibiotic stewardship program. There will be ongoing collaboration between CDC and CMS to help implement this CoP as the rulemaking process moves forward and is finalized. Further, the agencies will work together so that the Core Elements dovetail with CMS requirements and expectations.

The breakout session on new technologies included pharmaceuticals and a focus on diagnostics. There was a robust discussion regarding opportunities and exciting work in diagnostics that have the potential not only to improve the practice of medicine, but also to affect antibiotic stewardship programs across care settings. It is recognized that more thought should be devoted to how the new diagnostics come to the market to improve care practice and antibiotic stewardship efforts. The session also considered how to move this work forward and how to work with companies to test and pilot new diagnostics as they might apply to stewardship.

Discussion Points

Regarding plans to collaborate with clinical societies regarding stewardship issues, Mr. Craig said that CDC is following up with organizations that participated in the forum to determine the areas that they most want to address. The clinical societies will vary, but many commitments from the societies related either to updating their guidelines or working to improve the stewardship applications of their guidelines. Other commitments related to improving the education of their members related to appropriate prescribing. There are also opportunities regarding how some of the societies can work collaboratively on issues that cross-cut their guidelines. There will

be positive impacts if each of the societies knows what other societies are recommending and know about the application of antibiotics across settings, especially in some settings where patients receive a great deal of antibiotics.

Healthcare Antimicrobial Resistance and Stewardship: Stewardship Technical Package

CAPT Arjun Srinivasan, MD
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Centers for Disease Control and Prevention

Dr. Arjun Srinivasan updated HICPAC on ongoing antibiotic stewardship efforts pertaining to inpatient, particularly hospital, settings. A great deal of activity is also ongoing in outpatient and long-term care settings. There is significant momentum in antibiotic stewardship, and work should take place quickly to capitalize on that momentum.

The fundamental goal of hospital stewardship programs is that every hospitalized patient gets optimal antibiotic treatment. Further, every hospital in America should have an active antibiotic stewardship program to accomplish that goal. Every stewardship program should ensure that proven best practices are being implemented. In order to accomplish these goals, a National Program for Antibiotic Stewardship is needed, built on the same pillars that characterize the successful HAI prevention efforts, including: Education, Measurement, National Goals, National Policies, and Research.

Measurement surrounding antibiotic stewardship has been a historic challenge. AU and the appropriateness of AU should be better measured. Additionally, stewardship programs need to be measured. It is not clear how many hospitals have these stewardship programs, and it is not clear what these programs include. To address these questions, CDC added questions regarding antibiotic stewardship programs in hospitals to the annual facility survey of the NHSN in 2015. The questions are based on CDC's Core Elements that are essential to the success of a hospital-based antibiotic stewardship program, including leadership commitment from administration; single leader responsible for outcomes; single pharmacy leader; antibiotic use tracking; regular reporting on antibiotic use and resistance; educating providers on use and resistance; and specific improvement interventions.

Twelve questions on the survey gathered information on implementation of the seven core elements on hospital . Responses were received from 4091 acute care hospitals that currently participate in NHSN:

Element	N	%
Leadership	2457	60.1
Element	N	%
Accountability	2949	72.1

Drug Expertise	3566	87.2
Act	3844	94.0
Track	3211	78.5
Report	2767	67.6
Educate	2827	69.1

Most of the hospitals have implemented individual core elements. Of the respondents, 1740 (42.5%) indicated that they have all seven of the core elements in place. This result is encouraging and fairly consistent with other survey results:

Count of Elements	N	%
0	103	2.5
1	160	3.9
2	279	6.8
3	324	7.9
4	359	8.8
5	441	10.8
6	685	16.7
7	1740	42.5

The leadership element refers not to leadership of the antibiotic stewardship program, but to leadership from the hospital administration: Is there written or fiscal support of the stewardship efforts? Commitment from the facility administration is critical for any activity in a hospital. Increasing commitment from that level will help accomplish additional stewardship goals.

Implementation of the core elements varies by bed size. Stewardship programs are more common in larger hospitals, and smaller hospitals are less likely to have implementation of all of the elements:

0-50 beds: 25%

51-200 beds: 43%

>201 beds: 59%

The responses were analyzed in terms of the implementation of all seven core elements based on hospitals indicating salary support for their antibiotic stewardship program versus hospitals that did not have salary support:

Hospitals with salary support: 76%

Hospitals without salary support: 27%

Leadership commitment, the least implemented element, was analyzed according to written support, indicated in 53% of the respondents, and to salary support, indicated only in approximately one-third of the hospitals. Among the specific actions to improve antibiotic use, there was fairly broad uptake of the most effective approaches:

Facility-specific guidelines: 77%

Audit with feedback: 74%

Prior approval: 63%

The NHSN includes the option to report AU within the Antibiotic Use and Resistance module. A total of 116 facilities have submitted at least one month of data, and DHQP hopes for more participation. A variety of facility types have submitted reports. The US Department of Veterans Affairs (VA) is committed to ensuring that all of its hospitals report through the AU Option. Other facility types include small hospitals, children's hospitals, and an oncology hospital. The facilities are located in 25 different states and submit via four different pharmacy vendor programs, as well as a variety of direct submission approaches.

DHQP is actively working to expand enrollment in the AU Option. There is limited experience with AU data, which hinders understanding of how to interpret and use the data. A Funding Opportunity Announcement (FOA) was released to support the AU and AR components of the module. CDC has an ongoing partnership with the VA as its facilities come online. New partnerships with large healthcare systems are being explored as well.

CDC's proposed risk-adjusted measure of use in the AU option, the Standardized Antibiotic Administration Ratio (SAAR), answers the need to conduct risk-adjusted benchmarking of AU at the facility or unit level. Similar approaches have been effective for infection control. A number of different partners have worked with CDC to develop the SAAR, which is similar to the Standardized Infection Ratio (SIR). It includes an observed and expected amount of AU, risk- adjusted for facility characteristics. A measure proposal was submitted to the National Quality Forum (NQF) Patient Safety Committee in the spring of 2015 and was endorsed for approval.

The measure is now open for public comment before a vote of the full NQF membership in the fall of 2015. This measure represents an important first step toward having a risk-adjusted benchmark measure to help facilities improve AU.

Work is continuing with partners because it is important not only to have the risk-adjusted benchmark, but also to use the benchmark. CDC is eager to work with facilities that are submitting to AU to produce a SAAR value and to help the facilities understand what the value means for their stewardship efforts. If it does not help identify areas for improvement in AU, then it can be adjusted and improved so that it does.

CMS posted proposed revisions to the CoP for long-term care facilities. The infection control condition now includes a requirement for antibiotic stewardship programs. CMS has expressed an interest in moving in a similar direction for inpatient facilities. The hospital conditions are under review and revision.

In summary, the survey results are encouraging. Many hospitals have implemented many, if not all, of the core elements. There is less implementation of all of the core elements in smaller hospitals, however. DHQP's next steps will be to:

Validate the results. Feedback has indicated that the surveys may have been sent to the infection preventionist in a facility and may not have reached the antibiotic stewardship personnel. The NHSN administrator is often an infection preventionist.

Explore implementation in smaller hospitals. Talk to smaller hospitals to learn from how they are successfully implementing the core elements.

Explore ways to understand not only implementation of the elements, but also optimal implementation of the elements.

Implementation may be aided by the development of a Technical Package for Antibiotic Stewardship. A technical package is a group of interventions that help attain a goal. The technical package can help facilities operationalize elements such as "leadership." This concept is promoted by CDC. Many hospitals understand and agree with the core elements, but need assistance with the steps of implementation.

Another critical area is engaging bedside nurses in stewardship. These nurses administer every dose of antibiotics and seem to be in a good position to help improve use. They have been critical in infection control, helping with checklists and remaining at the front end of this work.

Questions for HICPAC are:

What can DHQP do to help hospitals implement the stewardship core elements, and implement them effectively?

Are there good resources already available that people can be directed to in an organized way?

Are there things that need to be developed to help with implementation?

Specifically, how can DHQP help with the implementation of high-yield interventions for certain conditions and antibiotics? For instance, over half of all antibiotic use in hospitals is for three conditions: pneumonia, urinary tract infections (UTIs), and skin and soft tissue infections. There are many studies available on these issues and many opportunities for improvement.

How might the NHSN antibiotic stewardship facility survey results be validated?

How can key implementation successes and barriers, especially in small hospitals, be explored?

How can bedside nurses best be engaged in stewardship?

Discussion Points

Mr. Hageman said that if there is a continued need for discussions on antibiotic stewardship, HICPAC can form a working group to bring discussion points to the larger committee.

Leadership support is crucial for antibiotic stewardship. Hospital leadership tends to listen to groups that speak at their levels, such as the American Hospital Association (AHA). The AHA could send a letter to hospital Chief Executive Officers (CEOs) and ask for a response that requires a CEO's signature, with a list of activities and resources. Dr. Srinivasan replied that DHQP is working in those areas. AHA has been very supportive of, and engaged in, the effort. AHA has identified antibiotic stewardship as one of their top five resource utilization improvement areas to highlight for their members. AHA developed a toolkit for their membership in collaboration with a number of different societies and groups. These leaders were part of the White House Forum and have included antibiotic stewardship in their communications to their members.

It is important to reach out to medical, nursing, and pharmacy schools so that antibiotic stewardship and appropriate use are included as people are trained in antimicrobials. The problems of stewardship and resistance must be built into education and repeated. Residency may be too late to receive these lessons. Educational requirements should also continue, perhaps through continuing education mechanisms. Dr. Srinivasan said that the American Council on Graduate Medical Education (ACGME) and pharmacy groups committed at the White House Forum to helping integrate education on AU and stewardship principles earlier in medical training.

HICPAC encouraged reaching out to hospitalist groups as well, as hospitalists have an impact on antimicrobial use in healthcare. Hospitalists are sometimes pressured to facilitate a more rapid resolution of a clinical problem. The

Society of Hospital Medicine (SHM) has recognized that the solution must come from within the society, with respect to competing priorities and to education and defining scalable interventions. Dr. Srinivasan has been a key partner to SHM on a demonstration project in Michigan, with 48 hospitals working together to address this problem. The project is collecting data prospectively, submitting it to NHSN, and running it through hospital medicine programs to determine what works and what does not work, as well as to consider the culture of hospital medicine with respect to antimicrobial stewardship. Without internal effort, the problem will not be solved. Dr. Srinivasan noted that these internal efforts are especially important in smaller hospitals that may not have Infectious Disease (ID) pharmacists or doctors. Many of the smaller hospitals have hospitalists and a critical access model in which the hospitalist is the IP and the antimicrobial steward.

There was support for the idea of including nurses at the point of care as additional antibiotic stewards. HICPAC hoped, however, that CDC and its partners would think critically about how that idea will be implemented. Issues of culture, power, and differential knowledge should be considered. Doing this work well will require tact, but it represents a novel approach to a persistent problem. Dr. Srinivasan agreed and said that no one should be put in an undesirable position, and it is important not to overburden an already-overworked staff. At the same time, there is a critical opportunity in working with bedside nurses. Nurses in this country are now empowered to stop doctors who are putting in central lines. This dynamic would have been unimaginable 10 years ago. Antibiotic stewardship efforts can capitalize on this culture change, but it is important to work carefully and considerately, engaging with nurses as opposed to imposing on them.

California passed a law in 2014 requiring all hospitals to have antimicrobial stewardship programs effective July 1, 2015. The HAI program at the state health department has been involved in this work, and 150 hospitals voluntarily participate in a collaborative group to share implementation guidance. The state health department is currently administering a voluntary survey to California's 400 hospitals to learn whether they are measuring antimicrobial use and what their informatics capability is to implement the NHSN AU. The health department is also educating its own staff to use the NHSN platform to benchmark hospitals. If hospitals will use the AU data and measures, it is of concern that only 116 hospitals are participating as the expected levels of AU are being developed. Any work that HICPAC or CDC can do to create the component of the technical package that describes how the 116 hospitals have been able to implement the core elements will be helpful. Further, state health departments would benefit from guidance regarding how best to engage hospitals and bring them together, even before the CMS mandate. Dr. Srinivasan agreed and said that CDC is creating materials such as one- pagers and fact sheets to share with partners and leaders. Engagement with health departments will be critical for promotion and for helping to improve understanding.

HICPAC described the proposed technical package as sounding like a "bundle" and should include concepts such as revisiting training and capacity regarding risk assessment. There are implications in several areas, including the measure itself, which must be accurate. Facility-level data, especially if it is drawn from a small, non-random set of facilities, could have unintended implications later. Regarding leadership, it is important to recognize that antimicrobial stewardship will not stand alone from infection prevention for the individuals who create budgets. As valuable as stewardship is, it should not be framed separately from infection prevention, lest they run the risk of depleting infection prevention budgets to support antimicrobial stewardship programs.

Dr. Srinivasan said that in partnership with the Pew Research Center, CDC is developing an assessment tool for facilities. It is important for facilities to understand what their SAAR number means, how antibiotics are used in their facilities, and where there may be opportunities to improve. High SAAR values may be justified, such as in

facilities with many patients with infections. The SAAR number will be a tool to help facilities determine where antibiotics are not used well. Risk assessment has been historically difficult. It is not easy to assess appropriate use. The partnership between infection control and antibiotic stewardship is critical and should be cohesive. Further, stewardship and infection control must fit into the broader quality arena, which is their budget area. Understanding the relationships within quality and bringing cohesion to the quality domain is important as hospitals balance their initiatives in other areas. They must use resources well so they are not duplicating different pieces of quality improvement.

Hospitalists have provided guidance in these areas.

State and local health departments are important contributors to this work. Work with the National Association of County and City Health Officials (NACCHO) and the Philadelphia Department of Health has included leadership of a regional collaborative. Facilities need technical support. Large academic institutions have become mentors for the region, and they are willing to share what they have learned. This work that crosses organizations is ongoing in other places, and CDC can help organize the efforts, helping state and local health departments to organize the partnerships and create simple methods that can be shared with facilities. Some facilities have indicated that they are willing to mentor smaller hospitals. The technical package can help smaller facilities with "low-hanging fruit" and determine where they can start to promote stewardship.

A technical piece advising hospital leadership of exact expectations will be important. The Chief Medical Officer (CMO) Society in Tennessee has been supportive of antimicrobial stewardship. Giving them tools and exact expectations will be very valuable. Engaging with this group in addition to AHA will be helpful, as CMOs may understand antimicrobial stewardship to a greater degree than CEOs do. The Council of State and Territorial Epidemiologists (CSTE) held a forum for CMOs, pharmacists, and others describing reporting requirements to NHSN. There has been commitment from CMOs to reporting to NHSN, even from relatively small facilities. Engaging with them on a national level would likely be helpful.

Now is an exciting time for antimicrobial stewardship. Regarding finding synergy between infection prevention and stewardship, UTI represents a potential focus area. Catheter- Associated Urinary Tract Infection (CAUTI) rates continue to be a struggle, and UTI rates are also high. Many of these high rates are driven by inappropriate testing, but it is difficult to measure the harm accurately. Additional harm is being inflicted, because if the diagnosis is made, then antibiotics are administered. Educating and working with front-line providers, many of whom are residents and a wide array of other providers, who send urine cultures when they are not indicated or who treat asymptomatic bacteria, could be highly beneficial. The same testing behavior is observed with *Clostridium difficile* (*C. difficile*), and the behavior is contaminating publicly-reported infection rates and leading to overuse of antibiotics.

Dr. Srinivasan agreed that there are good opportunities in this area. A paper was recently published regarding a program at the VA. The program educates personnel about the criteria for sending urine cultures. The study demonstrated that when individuals go through a thought process before sending a culture, the number of cultures that are sent drops and antibiotic use drops correspondingly. This intervention is interesting and could be applied in other settings.

Regarding bedside involvement, the process measures have been effective in Central Line- Associated Bloodstream Infection (CLABSI) control. Providers feel empowered. There has been discussion for several years regarding the five "rights" of medication administration. One individual cannot be responsible for medication

administration. It is a system issue. Human factors and engineering can improve the system. A sixth "right" could be added to the list: Is this the right reason?

HICPAC asked whether Electronic Medical Record (EMR) providers and software programs that collect antibiotic use data could be used to calculate SAAR values. As with audit feedback, receiving the data sooner can change behavior sooner. Dr. Srinivasan said that they are not working with EMR providers to calculate the SAAR specifically. Their work with those providers focuses on enrolling them and enabling them to submit data to NHSN. The SAAR calculation will be built into NHSN so that SAAR values can be fed directly to facilities. A number of reports will be available from the AU option.

HICPAC appreciated the explanation of the core elements and the links to the research that supports each one and its sub-elements. However, the links require individuals to reference the articles themselves. Many people trying to implement antimicrobial stewardship programs are looking for a technical package. Regarding antibiotic use in the three main areas, CDC has an assessment tool for antibiotic use, but it is a checklist that does not provide rationales. Either CDC or a partner group could assemble information into one place so that providers have a narrative to support and explain the guidelines. Such a "Reader's Digest" of the issues could be provided to a front-line worker, and more detail could be provided as needed.

The issue of cost was raised at a recent antimicrobial meeting. Programs that are funded have better outcomes. At this meeting, the participating hospitals indicated their struggle with identifying the cost associated with antibiotic stewardship. It is challenging to quantify the results of reducing antibiotic use, for instance. The cost of the antibiotic is saved, but there are also savings that result from the steps in the process. A means for making those calculations could be included in the technical package to help hospitals think about the money that they are saving, which could be reinvested in the overall program.

If the survey is administered again, HICPAC hopes to learn more about the degree of salary support for antimicrobial stewardship and whether there is a difference between facilities that support a pharmacist or physician.

Moving stewardship into the quality area is important. The "Choosing Wisely" campaign of the American Board of Internal Medicine (ABIM) campaign focuses on inappropriate laboratory testing and could present an opportunity for discussing stewardship. In December 2014, a paper was published on core competencies for stewardship leadership. The Spring 2016 Society for Healthcare Epidemiology of America (SHEA) meeting in Atlanta, Georgia will include a stewardship basic training course, which will include linkages with long-term care groups. They hope to make this training course sustainable. SHM's Version Two of "Choosing Wisely" is being considered now. Antimicrobial stewardship and responsible prescribing are important topics. Discussions are also ongoing regarding the issue of diagnostic certainty, particularly a Bayesian approach. Dr. Srinivasan replied that they have been talking with the individuals who created "Choosing Wisely" and are exploring other opportunities to work with them. SHEA is submitting a list of their "Choosing Wisely" recommendations for the next release, and the list includes several stewardship-focused items.

The definitions are not intuitive. Surgeons may prescribe antibiotics for asymptomatic bacteria or for SSIs, and it is not clear how to treat these problems. This issue also applies to advanced- practice nurse practitioners. Clarity will help reduce usage. There is a fundamental misunderstanding that every culture has to be treated. This idea is well-known to the infectious disease world, but it is out of the context of other medical providers not to treat cultures immediately. There is a great deal of pressure to move patients through the system, which results in conflict of

interest that must be weighed carefully. The possibility of point of care tests was raised regarding how to better diagnose true infection.

HICPAC suggested engaging with microbiologists. In the United Kingdom and other countries, clinical microbiologists conduct most of the antimicrobial supervision. The American Society for Microbiology (ASM) is engaged in some work in this area. ASM has multiple regional chapters and is another potentially important group for engagement.

Robust stewardship programs require information technology (IT) support so that the front-line pharmacists and clinicians can look at patients in real time to make the "bug-drug" match and to make recommendations. Facility leadership must recognize the importance of spending money to provide IT to staff so that they can develop and sustain stewardship. IT vendors were key invitees to the White House Forum.

AHA has appreciated collaborating with CDC on this important issue. A great deal of work remains, and AHA looks forward to continuing the journey. A section of AHA's membership is specific to critical access hospitals and small, rural hospitals, including finding ways to reach those facilities with good case studies of how other small hospitals have progressed with their antibiotic stewardship programs. AHA also has a group of clinical leaders comprised of CMOs and Chief Nursing Officers. This group has already engaged on this issue. Regarding the AU module within NHSN, there is some uncertainty pertaining to reporting of the AU measure.

There may be concerns because the measure reports the level of use but does not necessarily indicate whether the level is appropriate. Part of the intent of the module is to build baseline data that could be used to help make those determinations in the future, but it could be made more explicit how facilities can use the results of the measure now to support stewardship efforts. This understanding will help facilities understand why the resources needed to collect the measure are worthwhile.

There has been progress, but as is often the case from the consumer perspective, "we want more than we have, and we want it to happen now." CDC should continue to move aggressively. More needs to be learned about how to measure AU and what SAAR measures, but the necessary first steps are being made. Reaching the leadership is critical for making progress, and leaders are often reached when issues affect the money that their organization receives. The sooner these measures can be tied to how hospitals are paid, the faster leadership will engage.

The American Nurses Association (ANA) and the American Association of Critical-Care Nurses (AACN) are powerful groups that are influential with beside nurses. Their members may receive messages best from their own organizations. Dr. Srinivasan agreed. Those organizations are strong potential partners, but they are large, and he hoped to determine who within each organization would fit with the stewardship efforts. The Association of periOperative Registered Nurses (AORN), as a technical affiliate of ANA, could create a technical expert panel on this topic.

A presentation at a recent SHEA meeting focused on asymptomatic bacteria treatment. The work focused on nurses in long-term care facilities, where doctors are not present every day. In these facilities, nurses often call doctors to request or suggest cultures. This work is an example of working collaboratively and successfully with nurses.

Stewardship is also a key priority for the Public Health Agency of Canada (PHAC). There was discussion regarding guidance or tools for discontinuation of precautions related to antibiotic use when a patient is discharged from a

hospital to a home or community setting. Dr. Srinivasan said that the transition of care is an important area for several reasons. In pneumonia, for instance, studies show that patients often receive a full treatment course with the guideline- recommended duration of therapy and a prescription for another full treatment course at discharge. This approach is significant post-discharge over-treatment. There are similar issues with intravenous (IV) antibiotics. In a substantial percentage of these cases, antibiotics are not needed after discharge. Colonized patients with antimicrobial resistance need to understand that they are colonized, not infected. They do not need antibiotics to treat colonization.

There was discussion regarding research studies on duration of therapy. Studies such as the recent Study to Optimize Peritoneal Infection Therapy (STOP-IT) trial and older studies helped to reduce duration for ventilator-associated pneumonia. Obvious sources for this funding are not clear, and duration of therapy should be better defined. Dr. Srinivasan said that this area is important for the Antibacterial Research Leadership Group (ARLG) of NIH. Studies of the duration of therapy is one of their domains, and they have some active studies in this area and are continually soliciting applications for studies. ARLG has taken on this important area of research investigation. These studies are expensive, and NIH may be the only funder with sufficient resources to support them.

International Infection Prevention and Control

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Dr. Ben Park described DHQP's international investments in infection prevention and control. Work is ongoing in Ebola, and there will be other, broader investments in the future. Work in the countries affected by Ebola could be classified as response or recovery. Response focuses on addressing an active outbreak, where recovery focuses on health systems strengthening and rebuilding. Response and recovery are related to each other. Response incorporates coordination of partners and development of guidelines, as well as training. A number of CDC teams conducted facility assessments and improvements, identifying key gaps in areas that could be impacted and helping to make facilities safer. Recovery incorporates standard operating procedures (SOPs) and national policies. It has been important to establish Infection Prevention and Control (IPC) specialists at facilities at the district and national levels. Recovery also incorporates the concept of reporting and accountability for data, which was new for many of the affected countries.

The response efforts in Liberia were termed "Keep Safe, Keep Serving." This motto galvanized workers and reminded them that their focus was to keep themselves safe so that they could keep serving during the outbreak. Sick people could present to an Ebola Treatment Unit (ETU). The units were constructed with vinyl sheeting and occupied by non-governmental organizations (NGOs). The ETUs performed case isolation and treatment. Care was usually provided by NGO staff and sometimes by a mixture of local and MOH staff.

The ETUs were considered high-risk areas for Ebola, but many people presented to a regular doctor, hospital, or clinic when they became sick. Those facilities are staffed by local providers who do not have training on Ebola-specific issues. The facilities also lack quality assurance and PPE. CDC focused on general healthcare facilities, as most healthcare workers were becoming ill in them and the risk of nosocomial transmission was high.

Early in the outbreak, many clusters were in healthcare facilities. In certain areas, 30% of the cases were among healthcare workers. Often, these high rates were attributable to poor knowledge and adherence to IPC practices. There was no concept of infection control and no understanding of germ theory. As a result, there was facility transmission, and healthcare workers brought Ebola back to their communities. The death of many healthcare workers was extremely problematic due to the relatively low numbers of doctors in these countries. When some of the facilities had to close, there was an interruption in healthcare services.

Several IPC partners were at work in the three affected countries early in the Ebola outbreak. There was little, if any, coordination among them. Sometimes, multiple NGO partners were helping the same healthcare facilities and communities, and sometimes there were gaps in assistance. Messaging was inconsistent as well, because all of the NGOs were providing training and support, but the groups were not consistent. There was no national plan or SOPs.

In Liberia, CDC helped to create the National IPC Task Force early in the Ebola. The task force was a Ministry-led activity that was supported by the international community, including CDC and the World Health Organization (WHO). The activities included providing technical assistance (TA) to the MOH and developing infection control curriculums and training personnel to train other healthcare workers on infection control. This group also coordinated healthcare facility assessments and conducted investigations of healthcare-associated Ebola. The group also estimated PPE needs that could be purchased with donor funds.

Perhaps the most important function of the task force was to coordinate and provide oversight for partners. As a result, there were new guidelines and SOPs. Because Ebola and infection control were both new in these countries, SOPs for almost every situation needed to be created. Guidelines were created for communities, but the important focus was on healthcare centers, hospitals, and clinics. When the MOH approved the SOPs, then training could begin.

CDC developed two different training courses. The course for front-line healthcare workers focused on the specifics of the IPC recommendations, including hands-on scenarios, donning and doffing PPE, and patient-related scenarios in emergency departments. The IPC specialists received a longer course that focused on the recommendations and their underlying principles. That course included basic germ theory and the chain of disease transmission and what it means for people in healthcare settings. The course also taught supervision skills and the concepts of quality assurance and quality improvement. The courses included exercises on appropriate PPE use, making chlorine, hand hygiene, needle safety, and more. Almost 25,000 healthcare workers were trained directly, and many more trainings probably occurred ad hoc or with various partners. Many of these workers were cleaners, ambulance drivers, or others who were affiliated with healthcare beyond direct providers. The massive training effort took place from the fall of 2014 until January 2015.

The roles of these specialists in facility safety were new concepts in the affected countries. The ideas of designating a person to oversee healthcare worker behavior, facility controls, and PPE were new. Additionally, CDC introduced the idea of personnel at higher levels who could provide assistance. Liberia had the “Imbedded TA Program,” which included 20 doctors whose post-graduate education was interrupted due to the Ebola outbreak. They were trained to support the county health teams. Only one or two specialists were available per county, initially for a one or two weeks each and then for a few months. Their job was to facilitate the implementation of IPC and to provide and coordinate healthcare worker training. They used standardized forms to audit facility safety. Between November and December of 2014, these specialists were able to help institute significant change. Patients being screened according to protocols increased, correct use of PPE by staff increased dramatically, and

standard guidelines were posted more. Redemption Hospital, one of the largest hospitals in Monrovia, Liberia, had an exceptional turnaround and now as an infection control committee. Improvements have been documented in many non-ETU facilities in the affected countries, and healthcare worker infections declined as a result. A number of efforts in different areas of the healthcare sector were taking place, and many of CDC's interventions led to improved safety.

A key issue in Sierra Leone was to develop sustainable improvements in the overall healthcare structure. Part of that effort included the establishment of a National IPC Unit. It sits at the MOH and oversees IC from a national perspective. The unit appoints focal personnel at district hospitals and supports the development of IPC guidelines and SOPs. The position of IPC Coordinator was created in February 2015. The person reports directly to the CMO, which brings visibility to the issue. IC is one of four key priorities in the Presidential Recovery Plan.

The president of Sierra Leone was requested updates in IC on a regular basis. The framework in Sierra Leone incorporates personnel collecting data on a routine basis at facilities and reporting the data up the chain to district supervisors, and eventually to a national unit. Each step in the chain is important and is an opportunity to take action, using the data to institute change. The IPC focal personnel are responsible for developing their own skills and to provide healthcare worker training at their facilities. CDC has worked with the Infection Control African Network on teaching technical aspects of training and on mentoring skills. This approach is an important part of the overall healthcare system recovery.

It is not enough to train personnel on IPC. It is important to have supportive supervision. NGOs are mentoring the IPC focal personnel. The Ebola Response Consortium is a consortium of eight NGOs, led by the International Rescue Committee (IRC), which provides a mentor for each focal person. It has been important to provide MOH-led IPC guidelines that can be used for training and can be utilized as SOPs by all healthcare workers.

There are a number of lessons learned from the Ebola outbreak experience. Infection control is about human capacity, not just PPE and supplies. The most important work at general healthcare facilities was ensuring that the personnel had the know-how to use the supplies and oversee their use. It is extremely challenging and daunting to institute infection control rapidly in a place that did not have it previously. This lesson is particularly important for emerging diseases. Having national staff focus on infection control was a critical aspect of the Ebola work in Africa. There are limited staff and competing priorities in these countries. Overall, a culture of safety needs to be fostered across the healthcare system. This work can only be accomplished through the long-term presence of specialists in infection control.

From an infection control perspective, "getting to zero" and "staying at zero" will require consistent adherence to the guidelines and practices. There are issues associated with healthcare worker complacency. When an area "gets to zero," it is important to maintain a level of heightened awareness. This approach will be important until the entire region is Ebola-free. Additionally, critical supplies are a key element for the long-term. In particular, maintaining access to the supplies when the spotlight from Ebola is gone.

The long-term picture also requires investment in infrastructure and capacity. This work is not only relevant for Ebola, but also for other health security issues. Many emerging threats with communicable aspects will go through the healthcare system. It is also important to think about prioritizing infection control in the GHSA, not only with ministries and WHO, but also with international partners and donors. This point is important to private industry as well, as solutions could be developed through advanced technology or industry. Many countries need cost-effective solutions.

Discussion Points

HICPAC asked whether the IPC model will be sustainable after the Ebola crisis and can be expanded to other resource-limited countries, and who will take the lead in this effort. It is also a challenge in the US to improve baseline infection control practices in a sustainable way. Dr. Park answered that the three Ebola-affected countries have clearly seen the importance of infection control and there is a great deal of political will in the countries to address it. The countries understand that their healthcare systems need strengthening and that infection control is key to this work, in addition to elements such as running water, electricity, and sewers.

Political will is the most important aspect of sustainability. There is a great deal of investment in recovery now, and as long as infection control is prioritized by MOHs, there is a good chance that it will be sustained. CDC and other partners need to consider how to help the countries ensure that infection control is self-sustaining and their assistance translates into long-lasting change. The investment must be long-term in order to succeed.

The focus in Ebola-effected countries was on acute care facilities, triage facilities, and hospitals. However, much of the transmission occurred at the community level and was related to unsafe care practices and unsafe burial practices. HICPAC wondered about a long-term plan to share basic knowledge about these practices into communities and to identify community leadership. These elements were extremely important as the epidemic progressed to ensure that case finding and contact tracing could take place. The concerns are beyond issues of PPE and appropriate care in healthcare facilities, which may be easier settings for this work.

Dr. Park agreed that while the work is not easy, it is easier to focus on healthcare settings than the community. There is a laundry list of issues and places for work. A great deal of healthcare takes place outside hospitals, at clinics and with traditional healers. Maternity and obstetric care occurs at Peripheral Health Clinics, another type of facility with personnel that may or may not have advanced levels of training. There are many areas for intervention, and it remains to be seen how this work will take shape in the long-term. Work in hospitals may be easier to sustain, but there are issues everywhere.

Dr. Michael Bell agreed that a great deal of work needs to be done in the communities, particularly regarding food sources. DHQP is not responsible for all of that work. Many other partners within CDC and elsewhere are addressing these issues. DHQP focuses on healthcare aspects of recovery. The Ebola outbreak occurred in three urban centers. This setting was different from previous Ebola outbreaks. The urban centers have crowding and travel, but they can receive resources and attention in a ways that does not happen when an outbreak occurs in a small, remote, rural village. The urban environment represents a unique opportunity.

Frequently in situations like the Ebola outbreak, international organizations deliver resources and effort until the outbreak is quelled, and then they leave. Because sustainability may not have been addressed, there is no evidence of their efforts after they leave. It is not realistic to expect that the all healthcare can be made safe at every level in these countries, but there are opportunities to focus investments in a way that changes how these countries and their MOHs interact with donor organizations so that the conversation is not just about one-time fixes, but about sustaining quality if not across the entire healthcare system, then at least in locations that can serve as ongoing resources for the next wave of disease. Ebola is an endemic organism and it will return. In an event of this magnitude, a number of well-intentioned people and groups want to help. These people and groups may not be organized to do the work, and the likelihood that workers return home with infections increases. People who want to help should be prepared consistently and tracked when they return home.

Complacency and fatigue are significant enemies. As people are trained, fatigue must be considered. A trained observer should be involved in every aspect of care.

Medical Device Reprocessing: Duodenoscope Update

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Dr. Suzanne Schwartz provided HICPAC with an update from FDA's May 2015 Advisory Committee meeting that addressed issues of endoscopic retrograde cholangiopancreatography (ERCP)-related infection and duodenoscope reprocessing. She also shared information regarding concerns that the infection control community has pertaining to reprocessing challenges. HAIs are not only related to medical devices. The concern is related to broader issues such as AR and infection practices in the US. Reducing the risk of exposure to improperly reprocessed devices is a shared responsibility that includes FDA, healthcare facilities, manufacturers, standards organizations, professional societies, federal, state, and local governments, and others.

FDA has been concerned for years with patient safety with regard to undergoing procedures that involve reprocessed medical devices. FDA is actively engaged with stakeholder groups to minimize patient exposure to infections that result from inadequately reprocessed devices. Over time, FDA's focus has shifted. FDA provides regulatory oversight over manufacturers of reusable medical devices. They are reviewing pre-market and post-market. They communicate regulatory requirements and work with manufacturers to address public health concerns that arise after a device enters the market.

Prior to 2013, breaches observed in end-user adherence to manufacturers' reprocessing instructions in the labeling emerged as the root cause of transmission of bacteria. FDA's engagement in this issue before 2013 falls into three categories: Guidance Documents, Safety Communications, and Public Meetings. Since 1992, FDA has issued seven guidances related to sterilization, disinfection, and reprocessing. In 2011, FDA published a draft guidance document on reprocessing medical devices in healthcare settings. It was finalized in early 2015. Regarding safety communications, in November 2009, FDA issued a joint safety communication with CDC and VA which cautioned healthcare facilities, hospitals, ambulatory care facilities, and private practices about the risks for patients if flexible endoscopes and their accessories are not cleaned properly. FDA recommended steps to reduce those risks. The FDA held two events in 2011: a public workshop that focused on factors affecting reprocessing and reusable devices, and a joint summit with the Association for the Advancement of Medical Instrumentation (AAMI) to further identify key challenges and priority actions.

In September 2013, CDC alerted FDA to a potential association between multidrug-resistant (MDR) bacteria and duodenoscopes. The cases of infection were occurring despite confirmation that users were following proper manufacturer cleaning and disinfection sterilization instructions. After this point, FDA focused on assessments of the characteristics of the duodenoscopes as well as the Automated Endoscope Reprocessors (AERs) used for reprocessing duodenoscopes. From the fall of 2013 through the winter of 2014, FDA worked with federal partners, manufacturers, and other stakeholders to better understand the critical factors contributing to the

infections and how best to mitigate them. The outbreak investigation included identifying and studying the devices in question; gathering and reviewing information from facilities that were experiencing infections and outbreaks; and evaluating information about documented and potential infections from multiple sources, including medical device adverse event reports that are submitted to the FDA, the medical literature, the healthcare community, medical professional societies, and CDC.

When FDA had a good understanding of these issues, in February 2015 they published a Safety Communication warning that it is difficult to effectively clean and disinfect duodenoscopes and providing recommendations to help mitigate the risk associated with infection transmission. The communication also stated that the risk of CRE to patients following ERCP is low. For most patients, the benefits of the procedure outweigh the risks of infection. FDA continues to stand by that recommendation.

Activities and communications continue as FDA's investigation progresses, including guidance, Safety Communications, and public meetings. The Final Reprocessing Guidance was issued in March 2015 after incorporating comments from the public comment period and feedback obtained at the 2011 workshop. The guidance outlines general considerations for the design of all reusable medical devices and recommendations regarding important elements to include in reprocessing instructions to ensure that they are understood and correctly followed.

FDA issued a second Safety Communication in March 2015. It encourages users of the 180V duodenoscope to employ the manufacturer's new instructions for reprocessing and recommends that facilities train staff on the new instructions and implement them as soon as possible. FDA continues to work with industry to validate reprocessing instructions for all duodenoscopes. FDA convened an Advisory Committee Meeting in May 2015 to seek expert, scientific, and clinical opinion to generate evidence-based recommendations regarding duodenoscope reprocessing. In partnership with the Joint Commission, FDA provided a live webinar in June 2015 to help care facility stakeholders on duodenoscope reprocessing.

Activities and collaborations are ongoing. FDA is working with industry as manufacturers modify and validate their reprocessing instructions to show that they can effectively clean and disinfect duodenoscopes. The partners include the three companies that manufacture duodenoscopes and the companies that manufacture the AERs used to reprocess them. FDA works with these companies on their test methodology and cleaning and high-level disinfection protocols. This work will continue until a reliable safety margin can be demonstrated. FDA is also evaluating information about infection from various sources, including medical device adverse event reports, the healthcare community, and CDC. FDA collaborates with other federal agencies to assess AR organisms' susceptibility to different high-level disinfectants. FDA works with many other groups, such as international regulatory agencies, state and local governments, and professional societies. FDA is exploring with CDC the utility of duodenoscope microbiological surveillance testing to reduce the risk of infections. FDA is working with hospital representatives to understand their experiences implementing reprocessing protocols; obtain feedback on AERs; learn about ethylene oxide sterilization; learn about surveillance sampling capabilities hospitals; and discuss the use of high-level disinfectants and detergents.

Talking to hospitals has been beneficial in better understanding the challenges, bottlenecks, hurdles, and concerns associated with these issues. A number of common themes emerged from the May 2015 Advisory Committee Meeting. Reducing patient exposure is a national healthcare priority that involves multiple stakeholders with overlapping responsibilities. Many of these stakeholders convened at the meeting to generate the following evidence-based recommendations

Manual cleaning is clearly a critical component of the reprocessing process, and it must continue. Efforts must be focused on this step to ensure that it is done comprehensively, vigilantly, and accurately.

A factor of this element could be the inclusion of human factors testing within the development of reprocessing instructions as part of FDA's pre-market assessment and review.

Another way to ensure user adherence to the instructions could be through competencies and training

Some panelists recommended a move from high-level disinfection toward sterilization. However, participants recognized the large economic impact and burden associated with this shift.

The panel concluded that the type of surveillance is important. More data and validation testing are needed before implementing a universal surveillance culture program.

Regarding device design and maintenance, the panel recommended that scopes should have disposable parts or be disassembled to allow for easier and thorough cleaning. The panel also discussed that scope maintenance schedules and the lifetime of the device should be defined by industry.

The next steps for FDA in this area are to:

Continue to assess strategies that FDA can implement within its regulatory parameters in order to reduce the risk of infection following procedures with reprocessed medical devices. Considering the feedback from the committee meeting, FDA will be able to assess how the panel recommendations can inform its approach to reviewing reprocessing information from manufacturers.

Investigate the association between reprocessed medical devices and cases of bacterial infection in US healthcare facilities. Foster dialogue with outside regulatory agencies to understand the international front as well.

Work with industry as they validate their reprocessing instructions.

Collaborate with international, federal, and state partners to develop strategies to further reduce infection risk and improve the safety margin associated with ERCP procedures and duodenoscopes.

Share information and recommendations as the investigations progress to help further reduce the incidence of infection.

When device issues occur, FDA encourages reporting of any events when there is transmission of an infection due to an inadequately cleaned duodenoscope, or when a scope remains contaminated after it undergoes the cleaning process.

Discussion Points

In this situation, there were numerous steps along the way at which federal, state, and local levels, as well as agencies, hospitals, and manufacturers could have changed the outcomes if they had acted appropriately in their oversight roles. The situation illustrates drawbacks in the way medical devices are approved in the US. The FDA is not able to ask companies to demonstrate that their cleaning processes work before a product goes to market. The majority of the public does not understand this important gap in providing safety to consumers. There are repeated, continual, and recurrent efforts to weaken oversights even further. There was discussion regarding whether the companies have been able to demonstrate that their cleaning processes effectively work.

Dr. Schwartz said that FDA works with each of the three duodenoscope manufacturers and with the AER firms to demonstrate more robust protocols for cleaning and high-level disinfection that is held to a high bar regarding worst-case testing. The Olympus 180 scope issued revised instructions for use in March 2015, and FDA released a Safety Communication indicating that they had reviewed the robust validation testing for cleaning and high-level

disinfection, and it met FDA's acceptance criteria. FDA is working with the other two manufacturers to do the same. The demonstration of cleaning and high-level disinfection is being held to a much higher bar, and the definition of worst-case testing is more rigorous than in the past. FDA is shifting its expectations with regard to reprocessed medical devices, particularly duodenoscopes and some of the other types of devices that have been called out in the March 2015 guidance.

Regarding the move from cleaning and high-level disinfection to sterilization, Dr. Schwartz noted that scopes are not merely cleaned. They are cleaned and then decontaminated via another process. Throughout the instances of infections and outbreaks, additional supplementary procedures have been undertaken by some hospitals aimed at eradicating the potential for infection. These measures may include ethylene oxide sterilization. There was discussion at the panel meeting regarding whether there should be a move toward revisiting the classification of these devices from "semi-critical devices" to "potentially critical devices," which would put them in a different category for moving to sterilization from high-level disinfection. A verdict on this point was not reached. Several experts felt that this direction should be undertaken over a course of years. In the short term, however, the ability to increase the safety margin to a level of public health confidence for patients can be achieved through cleaning and high-level disinfection. While FDA is working with manufacturers on revised instructions for use, the agency will work in parallel to consider the need for a move to sterilization in the future. There has also been discussion that a scope can be sterilized, but if it has not been cleaned appropriately and meticulously, the organisms will not be eradicated and the device will remain contaminated. The issue must be considered in a multifaceted way. There is not a single panacea. All particulates and debris should be removed as a primary, critical step.

HICPAC asked whether the endoscope manufacturers indicated that these issues were prevalent in other countries. HICPAC wondered about ways to incorporate this knowledge into the vetting process and to require manufacturers to report outbreaks outside the US that might impact products that are used in the US.

Dr. Schwartz replied that the issues were not known at the time, but they are known now. Many lessons have been learned. There is a need to develop relationships with partnering regulatory agencies outside the US so that there are signals or signs of issues or concerns regarding medical devices used in the US. Manufacturers are required to submit reports for adverse events that occur outside the US if the devices are used in the US. Reporting failures have to be addressed.

Medical Device Reprocessing: Duodenoscope Culture Methods Update

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Dr. Coullitte-Salmond described laboratory efforts as part of CDC's duodenoscope surveillance activities within the Clinical and Environmental Microbiology Branch (CEMB) laboratory, which has two arms. The Antimicrobial Resistance and Characterization Laboratory, led by Dr. J. Kamile Rasheed, performs core activities such as reference identification and surveillance. The Environmental Applied and Microbiology Team, led by Dr. Judith Noble-Wang, engages in a variety of healthcare and environmental research activities, including biofilm research and outbreak response. The team aims to understand how microbes survive and attach to different healthcare

surfaces and devices within healthcare facilities. The team worked with DHQP's Prevention and Response Branch to develop the CDC Interim Duodenoscope Surveillance Protocol, which includes sampling and culture methods.

The CEMB laboratory involvement in these issues increased in the peak year of 2013. The CDC Interim Protocol was developed and released in 2015, which led to participation in workshops, meetings, advisory committees, and other organized working groups. The duodenoscope activities can be viewed in two areas: Protocol Development and Stakeholder Engagement.

The first outbreak response was in Illinois in 2013, where there were 39 case patients positive for New Delhi metallo-β-lactamase (NDM)-producing *Escherichia coli* (*E. coli*). CDC engaged after the first case patient was identified. The scope was sent to the CDC laboratory, which used primary rigorous methods to recover bacteria. They used broth and a brush to sample the channel, and broth with sonication and a brush to sample the distal end. The laboratory found *Klebsiella pneumoniae* carbapenemase (KPC)-positive as well as NDM-producing *E. coli* two months after the scope's last use.

The next response was in Washington, where a more refined sampling and culturing protocol was used to investigate a cluster of MDR-*E. coli* in 32 case patients associated with the use of contaminated scopes. Four of the eight scopes were positive with the same clonal strains of hyper ampC *E coli*. During this outbreak response, CDC collaborated with the facility to produce a more refined sampling protocol that was more field-friendly that a facility could do on its own. Epidemic Intelligence Service (EIS) officers were deployed to Washington. They used a targeted protocol that focused on flushing channel with a sterile solution. The distal end was swabbed and brushed, with elevator forceps up and down as well as the elevator recess. The samples were sent back to CDC, where the laboratory was only able to detect gram-positive bacteria; however, the facility had already changed its practices when the samples were collected.

The team conducted a literature review in addition to the outbreak response. The review is ongoing. Historically, in the 1970s, channels were flushed with a sterile solution. There is also documentation of using a swab to sample the distal end as well as external surfaces of the duodenoscope. The first validated sampling procedure for endoscopes was published in the 1980s, but it only included to viruses. In the 1990s, Michelle Alfa, a well-known expert, adjusted the Hansen model for identifying bacteria from flexible endoscopes.

Recent literature has revealed common approaches for sampling and culturing flexible endoscopes. The channel is the most common sampling location, but the distal end has been a focus of recent studies. Flushing the channel is a more common sampling technique, as well as using a brush to sample within the channel or scrubbing the distal end. The most common sampling medium was a type of sterile water or saline solution. Regarding the concentration and processing of samples, researchers who wanted to detect low numbers of organisms utilized centrifugation or membrane filtration. A wide variety of culture media are documented in the literature; however, a majority of studies used blood or selective media, such as MacConkey. To quantify the bacteria detected, a majority of studies counted the colonies to determine the Colony Forming Unit (CFU). The common bacteria detected are *Pseudomonas* and *Staphylococcus*.

Based on the outbreak response activities, working with the facilities about their protocols, and the literature review, CEMB formulated a new protocol. A draft protocol has been circulated to national and international SMEs. It also refers to other guidances, including from the New Zealand, Australian, and Canadian public health agencies, regarding these medical devices.

The protocol highlights forceps at the distal end of the device, sampling above, below, and within the elevator recess. A brush is used on the distal end, and the channel is flushed. The samples could be consolidated. The culturing process will focus on high-concern organisms, such as gram-negative bacteria, *E. coli*, *Klebsiella* (*K*), *Staphylococcus aureus* (*S. aureus*), and *Enterococcus*.

The interim protocol also provides an algorithm with a means of interpreting results and remedial actions, depending on the number of organisms that are found. For low-concern organisms, the action level is above 10 CFU per scope. If more than 10 are found, the duodenoscope needs to return for reprocessing. For high-concern organisms, there is a zero- tolerance level. If a facility chooses to use a qualitative method, if the sample is turbid, then the scope should be reprocessed.

A survey was conducted through the Emerging Infections Network (EIN) to gauge feedback on general practices regarding duodenoscope surveillance, if any. The survey distributed to EIN and was open for a few weeks to physicians who had an interest in IC and/or were members of SHEA. Of the facilities, 31% either performed no cultures at all, were performing clinical cultures, or were conducting some type of surveillance cultures. The most common surveillance culture approach was flushing the channel. The second most common was the CDC recommendations. The remaining facilities used a modification of what is available.

Since then, CEMB has engaged with multiple stakeholders on current duodenoscope surveillance efforts. A great deal of feedback and inquiry has resulted from the sharing of the interim protocol. CEMB has developed a Frequently Asked Questions (FAQs) document that is available online. The protocols have been updated to incorporate feedback from stakeholders. Conversations are ongoing with healthcare facilities and their personnel in clinical laboratories regarding their surveillance experience and whether they are using the CDC protocol or a modification of it. Pilot studies may be needed to answer questions where more research is needed. CEMB continues to assist healthcare facilities with handling transmission clusters and providing environmental laboratory assistance to reprocessing personnel and clinical laboratories. The protocols are being amended and will be published on the internet, with additional talking points in the FAQ document.

Regarding the next steps, as noted by the FDA, work with manufacturers to create validated reprocessing procedures is crucial to assure that reusable devices are safe for patients. Due to the design complexity of these devices, such as their microscopic crevices, as well as innate human error within the meticulous reprocessing procedures, quality control through microbial surveillance is essential. There are limitations associated with the CDC protocol. It represents one approach for facilities to use as a starting point. CEMB is encouraging efforts to move forward toward acceptance. CDC and other clinical microbiologists and SMEs are participating on the FDA-led working group, which will lead to an agreement or consensus for facility buy-in.

Discussion Points

HICPAC asked whether manufacturers are considering other technologies or different ways to address some of the design elements of the scopes that are so difficult to clean. Dr. Schwartz said that manufacturers within and outside the US are evaluating new scope designs. FDA has encouraged those manufacturers to provide their design and early pre-submissions so that they can work together. FDA cannot mandate a new scope design, however.

Dr. Michael Bell asked how FDA communicates a desire to see design changes. Dr. Schwartz answered that FDA speaks publicly about those needs. There is not a mechanism for making those solicitations formal, but there are

opportunities in building relationships with partners, professional societies, and other organizations. If there is an understanding of needs and gaps, then that innovation can be encouraged.

Facilities think of ERCP scopes and endoscopic ultrasound scopes as two different species. HICPAC asked whether the devices carry similar or differential risk. This question is important operationally. Dr. Coullitte-Salmond answered that some facilities are beginning to combine them and consider sampling both as part of their surveillance protocol. Dr. Schwartz added that from a design and engineering perspective, the scopes are considered to be very similar.

Regarding potential vulnerabilities or weaknesses associated with cleaning and disinfecting them, those scopes are in the same category as duodenoscopes. Ms. Elizabeth Claverie-Williams, FDA liaison representative to HICPAC, said that on the pre-market side, when FDA is consulted regarding any scope, they ensure that manufacturers utilize the same type of reprocessing. All scopes are considered in the same way for infection control purposes.

Human factor elements are significant in device use and reprocessing. Fatigue is a major consideration, and expecting a group of individuals to be as meticulous as needed 100% of time is asking a lot, especially considering that these individuals are likely to be paid at some of the lowest levels. Sampling is not intuitive for every healthcare facilities, or even for laboratories that will potentially run the samples. There are elements of human factors in sampling as well. If the sampling is not done correctly, then it will always yield negative results. It is challenging to reconcile those issues with these devices. Making advances in design may be more productive.

Many hospitals struggle to know whether/how to incorporate culture protocols in a non-outbreak setting. The work is labor-intensive, and it is easy to get false results. Most clinical microbiology laboratories are not equipped to do that kind of microbiologic culturing. Hospitals would benefit from guidance regarding whether they should be doing this work routinely, and how often.

HICPAC discussed how many of their hospitals are conducting culturing of endoscopes as routine surveillance outside an outbreak or cluster investigation. One facility has begun culturing on a limited schedule, using an outside environmental laboratory for the hospital system. The hospital takes the cultures, but the specimens are processed by the environmental laboratory.

Dr. Coullitte-Salmond said that the CDC protocol indicates that the facility has the option to reprocess after every procedure, once a month, or after every 60 procedures. Facilities have options. They understand the concerns that this protocol is new and the structure may not be in place to implement it. The process is organic and they are working with facilities and hospitals to determine how best to move forward.

There are significant challenges associated with implementing the protocol beyond not having the infrastructure. Facilities may have to triple the fleet size of their scopes. The time and resources involved are enormous on the microbiology laboratory, the investment in equipment, and the staff time. One of the research gaps is associated with how more feasible technologies, such as ChannelCheck^{TM} and Adenosine TriPhosphate (ATP), might correlate with culture results. Regarding a question about continuing evaluation work in this area, Dr. Coullitte-Salmond said that open discussions are ongoing about the possibilities.

Outbreaks at the local level have been investigated in which hospitals have detected a positive scope, but there is no linkage to the patient. This situation is difficult, as hospitals wonder whether they should continue to culture

the scope after every use when it has been detected to be positive once. It is difficult to provide a straightforward answer regarding routine sampling frequency or sampling a scope that has been positive.

Medical Device Reprocessing: Ensuring Training and Competency of Staff – Facility Perspective

Vickie Brown, RN, MPH, CIC
HICPAC Member

Ms. Brown offered comments related to the reprocessing of endoscopes and other medical devices that require a process that is frequently performed in healthcare facilities called "high- level disinfection." A reusable medical device is an instrument used during a diagnostic or treatment procedure that a healthcare provider can use for more than one patient. These devices include ultrasound probes and endoscopes. Reprocessing is a multi-step process for cleaning, disinfection, or sterilization of a reusable medical instrument. High-level disinfection is a process that involves exposing an instrument to a disinfectant at a sufficient concentration and exposure time to kill all microorganisms except for large numbers of bacterial spores. The basic steps of high-level disinfection are:

Pre-Clean: Wipe or rinse the external surface. Flush internal channels with the appropriate detergent solution or water, followed by air. Remove and discard any disposable valves and attachments. For endoscopes, pre-cleaning is performed in the procedure room immediately after completion of the procedure and before it is ever taken out of the room into another room for reprocessing.

Leak Test: Performed on the device in the first area of the reprocessing room. The leak test checks for possible openings that would allow fluid into the internal body of the scope. It involves immersing the entire scope in water and observing for air bubbles.

Manual Clean: There is a thorough washing, brushing, and rinsing of all external and internal components of the scope.

Disinfection: The entire instrument and internal channels are exposed to a chemical disinfectant for a designated time and temperature. This process may be done manually or by use of an automated reprocessor. Use of the automated reprocessor requires the use of correct adaptors to connect the channels to the reprocessor ports. There have been errors made when technicians are not well-trained and do not realize that connectors need to attach to the scope in order for the fluid to reach the internal channels of the device.

Rinse: Removes the chemical that was used to disinfect from the device. Rinsing may be done manually or by the use of an automated reprocessor.

Dry: The external surface is wiped with a clean, lint-free cloth. Channels are flushed with alcohol to aid drying. Some automated reprocessors include the alcohol flush cycle.

Storage: Endoscopes are hung vertically in a clean, vented cabinet that allows for air circulation around the scope. The distal tip of endoscope needs to hang freely.

Devices that undergo the process of high-level disinfection vary in complexity. They may be as simple as a solid vaginal ultrasound probe that has no internal channels and is relatively easy to clean and reprocess, or complicated such as a duodenoscope. In her system, which includes 900 beds across three hospitals, 159

endoscopic devices are in current use. Endoscopic devices and other devices that require high-level disinfection for reprocessing are used in multiple sites within a healthcare facility. For example, in her system these devices are used in 27 different locations or sites within the organizations. Most of the devices are reprocessed within the service or facility in which they are used. A variety of healthcare personnel perform this task, including Registered Nurses, Licensed Practical Nurses (LPN), Surgical Technicians, Radiology Technicians, Nursing Assistants, and Medical Assistants. All of these individuals receive on-the-job training for reprocessing medical instruments. There is also a variety of ways in which high-level disinfection is performed, including the following:

Entirely manually, using detergents, water, and liquid germicide an immersing the device in a basin or soak station

A combination of a manual pre-clean followed by cleaning and reprocessing using an automated scope washer

Automated scope reprocessor

Different germicides are used in the disinfection process, such as glutaraldehyde, orthophthaldehyde, hydrogen peroxide

There are a number of challenges associated with having trained and competent staff to perform the task of high-level disinfection. Many endoscopes are being used in multiple locations, and they are disinfected and reprocessed by different categories of healthcare worker. Staff with different medical backgrounds and responsibilities are reprocessing these instruments. There is a large variety of instruments that vary from solid probes to multi- channeled endoscopes. Reprocessing occurs at multiples sites and locations within a facility. There are multiple ways in which reprocessing is performed. There is a lack of a standardized approach to training and competency assessment for individuals performing this critical task.

References for high-level disinfection include the following:

HICPAC Recommendations for Cleaning, Disinfection, and Sterilization

Recommendations from AORN for the reprocessing of endoscopic devices

Guidelines from the American Society for Gastrointestinal Endoscopy (ASGE)

All of these guidelines are excellent; however, they are not device-specific. They should only be used in conjunction with the manufacturer's instructions for use.

HICPAC's 2008 Guideline for Disinfection and Sterilization in Healthcare Facilities provides fairly broad steps regarding cleaning:

> **Immediately after use, meticulously clean the endoscope** with an enzymatic cleaner that is compatible with the endoscope. Cleaning is necessary before both automated and manual disinfection.
>
> **Disconnect and disassemble endoscopic components** (e.g., suction valves) as completely as possible and completely immerse all components in the enzymatic cleaner. Steam sterilize these components if they are heat stable.
>
> **Use cleaning brushes appropriate for the size of the endoscope channel or port** (e.g., bristles should contact surfaces). Cleaning items (e.g., brushes, cloth) should be disposable or, if they are not disposable, they should be thoroughly cleaned and either high-level disinfected or sterilized after each use.

Discard enzymatic cleaners (or detergents) after each use because they are not microbicidal and, therefore, will not retard microbial growth.

Steps for cleaning provided by a manufacturer may look like the following:

Pre-Clean

Immerse distal tip in clean water.

Turn light source on.

Suction water.

Suction air.

Turn light source off.

Flush detergent, then water, then air thru channels.

Disconnect removal parts and immerse in detergent.

Manual Clean

Brush channels, ports, distal end of scope. Clean brush and continue brushing until all debris removed.

Attach to suction: Flush channel with detergent and water for X amount of time.

Detach from suction and remove suction tube.

Completely immerse scope and suction tube in detergent.

Personnel who work with front-line staff to train and ensure their competency must become knowledgeable about the manufacturers' instructions for use to move beyond basic guidelines. Nevertheless, many human factors can affect and impact the quality of staff training and performance regarding high-level disinfection:

The staff assigned to perform high-level disinfection usually have many other responsibilities, particularly within an endoscope unit.

Persons being trained may have limited educational background and minimal medical training.

Staffing limitations may not allow time for sufficient training.

Clinical staff may not be aware of accessory items that are needed for reprocessing (e.g., leak tester, lint-free wipes, storage cabinet).

Technicians and nursing assistants are paid a low wage that may affect their motivation and engagement.

Too few staff and staff turnover can lead to inadequately trained staff and then errors in reprocessing.

Staff may perform high-level disinfection infrequently, affecting their competence. In some cases, a weekend on-call nurse must reprocess the scope. Without this approach, then issues regarding delayed reprocessing are important.

Competency assessments may be inadequate or not done at all.

The IP staff may be insufficient to oversee high-level disinfection activities as well as training and competency.

The following environmental factors can also affect training and competency:

Facilities may have limited space and the wrong configuration so that there is not a clear workflow from dirty to clean and there are opportunities for cross-contamination.

Facilities may lack necessary supplies such as the correct size brushes, the correct size syringe for flushing, a timer, a measuring device for detergent, and space for appropriate device storage.

Sinks may be limited. Facilities may use the hand-washing sink for cleaning a device in the procedure or exam room.

A dedicated sink may be too small or too shallow to immerse the entire device completely into a solution.

There can be minimal counter space for instruments and for documentation and records.

Several issues are related to competency assessments, such as the following:

There is no standardized approach to assessing competency of individuals across and within facilities.

The frequency of assessments is variable.

Assessments may not be specific to the types of devices that are reprocessed. In response to the outbreaks related to ERCP scopes, her organization revisited its tools for assessing the competency of technicians reprocessing the endoscopes. Because of the variety of scopes used within the facility, they developed six separate assessment tools in order to appropriately assess each individual responsible for reprocessing the different types of endoscopes. The manufacturers' instructions were married to the assessment tool so that staff understood the process for each device.

Competency assessments may not include direct observation of the person performing the task.

In certain types of facilities, the person conducting the assessment may not have ever performed reprocessing.

Beginning steps to address these issues may include the following:

Each facility should identify the different models of endoscopes and other instruments requiring high-level disinfection where they are used, and who is responsible for reprocessing them.

Educate Directors, Vice Presidents, and Managers to improve their understanding of why devoting resources to training and assessing the competency of the staff is so important:

The importance of high-level disinfection and risk to patients when not done correctly.

Competency outweighs any negative impact on patient flow and therefore compensation.

The value of trained staff and need to allot time for adequate training.

The importance of necessary supplies, space, and time for high-level disinfection.

The need for a comprehensive written training and competency assessment policy.

The following key elements for training and competency assessment should be considered:

All steps of the cleaning and disinfection process must follow the manufacturer's instructions for use. The different types of instructions may not be a complete match to the type of automated scope washer or reprocessor in a facility. The equipment being used must be assessed, and the manufacturers' instructions could be reconciled with the available guidelines and recommendations so that individuals are taught correctly and their competency is assessed properly.

New hires should be supervised until they successfully demonstrate competence.

Competency assessments should be completed upon the initial hire and at least annually thereafter.

Annual assessments should include a demonstration; they should not be limited to a written or verbal test.

Training and assessment should be required for all new products, devices, and changes in manufacturer's instructions for use. The company educators and representatives should be consulted for the assessment tools and to reinforce training.

Individuals should have the opportunity to attend a refresher class when desired.

An additional step to ensuring trained and competent staff is to provide a basic mandatory training class conducted by hospital epidemiologists or IPs for staff responsible for high-level disinfection. The class should:

Provide background on disinfection and sterilization and the importance of adhering to the manufacturer's instructions for use.

Build rapport with front-line staff.

Provide an opportunity for two-way learning. Front-line staff can identify weaknesses in current procedures and lessons learned from their experiences.

Provide custom online training modules for review and reference by staff that are relevant to the environment in which they work.

Hold the on-site supervisors, managers, and medical provider responsible for oversight of staff performance. Providers that use these devices want to feel confident that the scopes have been reprocessed, but they can be disengaged with the reprocessing work.

IPs or liaisons should audit sites performing high-level disinfection frequently and provide feedback to front-line staff and leadership. It is not adequate to visit these areas one or two times per year. More time should be devoted to visiting and observing these areas. At Ms. Brown's facility, the areas are audited at least once every three months and the scores are shared with facility leadership.

Discussion Points

HICPAC thanked Ms. Brown and observed the significant challenges associated with high-level disinfection. There was discussion regarding how HICPAC can help in the process, given that a number of stakeholders are already involved, and whether a White Paper or other product would be useful for individual facilities in helping them get their processes under better control.

Ms. Brown answered that HICPAC can be of great value in sharing the daily challenges associated with having competent staff. A workgroup or White Paper to consider these issues could be helpful. Many IP staff need guidance and information, including example tools to use in their facilities to ensure that the work is being done correctly. When these tools are endorsed by HICPAC and CDC, it will elevate IPs' ability to get the attention of leadership to ensure that progress is made.

Ventilator-Associated Events: CDC Updates

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Dr. Magill explained the following three definitions within ventilator-associated events (VAEs), which build on each other:

Ventilator-Associated Condition: based on changes in Positive End-Expiratory Pressure (PEEP) and FiO2. Each VAE must meet the VAC definition.

Patients who meet the VAC definition and also have general evidence of infection, such as an elevated or low white blood cell count or elevated temperature, plus a new antibiotic starts, are defined as having Infection-Related Ventilator-Associated Complication (IVAC).

Patients who meet the IVAC definition and have laboratory evidence of pneumonia would have Possible Ventilator-Associated Pneumonia (PVAP). In the first two years of surveillance, there were both Possible and Probable Ventilator-Associated Pneumonia (VAP) definitions; the two have since been consolidated.

VAE surveillance was first implemented in NHSN in January 2013. It underwent some changes in the subsequent months, including changes to the PEEP criteria and the foundational VAC definition. Adjustments were made to the types of antimicrobials eligible for making an IVAC determination. Additional guidance was provided regarding microbiological criteria in the VAP aspect of the algorithm. In January 2015, the PVAP tier was consolidated and an optional denominator was added regarding episodes of mechanical ventilation that could be used in addition to the traditional ventilator-day denominator. Organism exclusions were added to the PVAP definition. VAE has been included in the CMS long-term care hospital quality reporting program, with data collection to begin in 2016.

Updates are available to the preliminary data that were presented at IDWeek in 2014 from facilities that are reporting "in plan," VAE to NHSN using the surveillance protocol. There was a small increase in the number of facilities reporting between 2013 and 2014, with a total of 2017 facilities reporting in 2013 and/or 2014. The majority of the facilities are general hospitals, and approximately 7% are long-term care acute hospitals. Critical access hospitals and other types of facilities are reporting as well. Regarding the distribution of types of locations reporting in-plan VAE data, there have been 68,695 location months of VAE surveillance data reported in the first two years from 3927 unique locations. Of the reporting locations, approximately half are either medical-surgical intensive care units (ICUs) or medical ICUs. A number of units that report are non-ICU locations as well.

Information about preliminary rates is being shared with the community so that those who conduct surveillance have comparisons. Data are available by the location type and the number of units of that location type that have reported data. The rate distribution is included for units that reported at least 50 ventilator days during the year. Long-term acute care hospital ICU locations have the lowest pooled mean rates, and the trauma ICUs have a pooled mean rate of almost 12 events per 1000 ventilator days. Approximately 63% of the events that are reported to NHSN meet only the VAC definition. Approximately 21% meet the IVAC definition, and about 16% meet one of the VAP definitions. Together, IVAC and the VAP definition events are called the "IVAC Plus" events. There are two ways to meet the VAC definition: 1) Using the PEEP criterion, an increase in the amount of PEEP that the patient requires that is sustained over a period of two days; and 2) having an increase in the FiO2 over two days. Most of the events are reported using only the PEEP criteria, 22% use only the FiO2 criterion, while 10% of the events meet both criteria. In medical cardiac ICUs, 67% of events are VAC, and 33% are infection- oriented events. At the other end of the spectrum in the trauma ICU, there is a more even spread, with 54% VAC events compared to 46% IVAC Plus events.

The data also examine the time from intubation or mechanical ventilation initiation to VAE. Users have expressed concern about patients who meet the definition early in the course of hospitalization and mechanical ventilation. Approximately 35% of events occur early in hospitalization, with the earliest onset of VAE on Day 3 of mechanical ventilation and full meeting of the definition on Day 4. Of the events, 39% occur by Days 5 and 9, and 25% occur on or after Day 10. Patients who met the definition after relatively few days on mechanical ventilation were considered regarding how far they were into their hospital stay. Of those patients, 60% were early in the course of their hospital stay, and 40% had been in the hospital for five or more days at the time of VAE onset. VAEs in patients who were in the hospital for less than five days and were on the ventilator for less than five days comprise 32% of all VAEs, compared to 68% of VAEs in patients who had been in the hospital or on the ventilator for at least five days. Most of the events occur on or after Day 5 of mechanical ventilation or hospitalization, suggesting that most of them are healthcare-associated. The distribution of the VAC and IVAC-Plus events differs by ICU type, which probably reflects that VAEs capture a variety of different conditions in patients on mechanical ventilation that could be more or less common, depending on the types of patients that are cared for in different units. Additional work is needed regarding the following:

The distribution of clinical conditions resulting in VAEs in different patient populations;

Why the specific event distributions are different in different unit types;

The clinical correlates of the early-onset VAEs; and

The difficulty with the current VAC definition, because a VAE can be detected in situations where there is a PEEP/FiO2 trade-off, when PEEP may be increasing at the same time the FiO2 is decreasing. In this situation, a patient is not clinically worsening, but the parameters are being modified to reduce the FiO2.

Few definition changes are planned for 2016. Some of the more recently approved antimicrobial drugs will be added to the list of those drugs that will be eligible for meeting the IVAP and PVAP definitions. Regarding Pediatric VAE, a Neonatal and Pediatric Working Group was convened a few years ago, but that group went on hiatus while additional data were gathered. There has been some recent work exploring potential pediatric VAE-like definitions, and that work has been presented at SHEA. The Workgroup will reconvene in September 2015, with the hope of implementing a pediatric definition in 2017.

Regarding IT-oriented updates, a synthetic data set is available. An Electronic Health Record (EHR) vendor wants to automatically detect VAE within its data can use the CDC protocol to develop an algorithm for detecting VAEs. There needs to be a way to validate the results and electronically confirm that they are detecting and applying the definitions accurately. A synthetic data set can help with that effort. Files are available with sample patient records with various VAEs imbedded in them. Vendors can import the files into their systems and run them through their implementation of the VAE algorithm. The results can be compared to the correct results.

A web service is available for vendor systems or individual users can submit de-identified data and receive VAE determinations to enter into NHSN. This tool is for detecting events, not for electronically reporting to NHSN. There are different file formats and a number of different data elements showing what needs to be submitted to get the VAE determinations. The tool assumes that the user has determined the daily minimum PEEP and FiO2 level accurately.

The synthetic data set has been provided to the vendor community. It can be obtained upon request. The web service is in the beta testing phase and is expected to move into production in the fall of 2015.

Ventilator-Associated Events: VAE From the ICU's Point of View: Implementation Lessons, Pivoting to Prevention, and the Research Agenda

Dr. Michael Howell
Associate Chief Medical Officer for Clinical Quality University of Chicago
HICPAC Liaison Representative, SCCM

Dr. Howell addressed the issues of VAEs from his perspective as an ICU doctor and a Chief Quality Officer. He has been involved in VAP and VAE work for several years and is a health sciences researcher with experience using large data sets. Some of the work he shared was funded by CDC. He noted that his remarks did not represent SCCM positions, but reflected his work. SCCM has been closely involved with the work and is supportive of it.

It is not possible to identify VAP with any reasonable consistency either in the real world or for surveillance. Studies 14 years ago in the Surgical Intensive Care Unit (SICU) showed that using some different definitions led to 12-fold variability in VAP ascertainment. In 2010, work in a single health system with people trained in the same manner indicated that individuals had 82% variability. From a clinical standpoint, if autopsy is the gold standard of whether pneumonia was present or absent, the different clinical definitions had different specificity. One had 16% specificity, another had 36% specificity, and a more standardized way of looking at infection had poor performance characteristics. The clinical abstraction of the cases and chest X-ray interpretation can be subjective, but a 2014 study that enrolled 43 randomly-selected centers found that the person who conducted VAP ascertainment for the hospital, when given vignettes, returned rates from 0% to 100%; that is, the results were the same as if they had been random.

A number of research projects have focused on automated VAE algorithms. Dr. Howell has worked in this arena in two different EMRs in two different locations. One of the studies, funded by CDC in Boston, considered 26,000 patients, approximately 11,000 of whom were ventilated. Because a synthetic dataset was not available, the investigators conducted a careful hand review of over 1200 cases and validated them by hand-entry into the CDC VAE calculator. The study determined that the algorithm was valid. Two cases were not identified, but they were not charted as having an airway type. This issue becomes a recurring problem.

The University of Chicago uses a Measure Matrix to determine, operationally, how the facility is graded. There are approximately 500 measures in the inpatient setting and a few hundred in the outpatient setting. The institution also has internal priorities. They track 148 measures, including VAE, every two weeks and keep a score card. The institution's EMR vendor does not provide this measure tracking, so the University of Chicago uses its own algorithm. Approximately half of their patients' VAEs are non-infectious.

Implementation is complicated. Determining who is on a ventilator is one of the most difficult aspects of the work. Documentation of ventilator start and stop times is not perfect. In particular, determining who is on a mask and who is on invasive ventilation is difficult, because all patients have PEEP and FiO2, and they often use the same ventilator. The electronic footprint can look the same for those patients. Further, integrating medication, laboratory, and microbiology data can be challenging. It can be more than an order of magnitude more difficult if,

like many institutions, legacy systems have different formats and may be integrated into the overall clinical data repository in ways that are not easy to use. The scale of data is impressive. In one year at the University of Chicago, even using a relatively narrow set of data parameters, 2.5 million pieces of data result.

In shifting from surveillance to prevention, three national resources will be important: 1) Compendium of Strategies to Prevent HAIs; 2) Comprehensive Unit-based Safety Program (CUSP) from the Agency for Healthcare Research and Quality (AHRQ), which has a mechanical ventilation program that is largely the implementation of elements of the Compendium; and 3) ICU Liberation effort with implementation tools, which SCCM supports.

One intervention trial is directly applicable to these issues. It was a 20-center trial that implemented turning off sedation and turning off the ventilator. It had no effect on the way that VAEs started being measured, but showed a 37% reduction in the VAEs per episode of mechanical ventilation. The results of the trial match the primary RCT that preceded it. The University of Chicago conducted many of the primary RCTs that had uptake into the Compendium, CUSP, and the Epicenter's Wake Up and Breathe Trial. Early mobility can be shocking for people when they see it the first time, and it nearly doubles a patient's chance of being able to care for himself at the end of 30 days. It is not a typical infection control approach for prevention, but it is important. The spontaneous awakening trials (SATs) are now 15 years old, and the University of Chicago is systematically approaching them and spontaneous breathing trials (SBTs). Some patients have been moved into complete sedation elimination.

RCT data supports this approach. The University is evaluating subglottic suction tubes but has not deployed them. The institution is not actively de-implementing approaches to prevent VAP.

The work at the University of Chicago has shown that clinicians and IPs do not have a framework to talk about VAC or IVAC. It seems that no individual in medical school today learned about VAC. VAEs are not discussed; rather, there is a focus on pneumonia, nosocomial acute respiratory distress syndrome (ARDS), heart failure, and other issues. VAE has not been incorporated into work at the bedside. Improvement focuses on process measures. The infrastructure has been built to follow through to outcome measures without requiring bedside data collection.

Some individuals in the critical care community have been supportive of VAE, but it has not been welcomed with completely open arms. One well-read paper in the critical care community stated that "Incidence and associated mortality of VAE were susceptible to small differences in electronic implementation." Another paper from the trauma literature stated that "The applicability of the new National Healthcare Safety Network categories of VAE to critically ill surgery patients is limited. Agreement between Probable Ventilator-Associated Pneumonia (PrVAP) and clinical VAP in SICU patients is poor." That paper recommended finding another definition. Another commonly-read paper concluded that "The National Health Safety Network ventilator-associated event/ventilator-associated condition constructs … were susceptible to manipulation." Other articles in the critical care literature addressed challenges related to VAE implementation.

Dr. Howell believes that general issues, such as "what is a VAC," will be resolved. He worries, however, about the following issues:

The possible spread of VAE to areas where there is no evidence supporting its use, such as long-term care: As the conversations about antimicrobial stewardship progress, it is important to attend to the fact that concepts may generalize to areas where they were not intended to apply.

The potential to unintentionally penalize antibiotic de-escalation: Eliminating some antibiotics such as vancomycin and others would be beneficial, but new antibiotics may not be the answer.

The possibility of unintentionally penalizing early and aggressive extubation: Multiple RCTs show the benefit of SBTs, and 14% of those patients will be re-intubated. Nearly all of those patients will "trip" VAE. Clinicians may be incented, consciously or unconsciously, to extend intubation. Marginal patients may remain on a SBT for two hours, but their minimum daily PEEP will lower, and if the level increases, then the patient will "trip" a VAE.

Will rates go up if a lot of noninvasive ventilation is used to prevent intubation?

How much gaming is possible to minimize reported VAE without improving outcomes, and how will we inadvertently change ventilator management practices?

Dr. Howell offered the following four areas of thought as VAEs move forward: **What are all of these noninfectious VAEs?**

Approximately 40% to 60% of VACs are non-infectious. Increasing understanding about them will open the door to new interventions to help patients.

There is substantial literature on hospital-acquired ARDS. The literature shows overlap in terms of worse oxygenation after 48 hours, and after 48 hours there is a four-fold increase in the risk of death. It seems likely that nosocomial ARDS and non-infectious VACs have a great deal of overlap.

Some is known about the cause of hospital-acquired ARDS: high tidal volume, transfusion, high fluid balance, and other elements that need to be understood regarding whether they help prevent VACs.

Can we use supervised or unsupervised large data methods to detect gaming?

A number of members of the critical care community are worried about gaming.

Gaming can be intentional or inadvertent, but it can still have large impacts. The Cleveland Health Quality Choice Program is a strong example of how deaths were shifted from inpatient to outpatient across a city for approximately a decade because of public reporting.

Source data density makes it possible to use novel methods for gaming detection. There are a number of potentially promising methodologies, including discrete event simulation or Markov models to predict ideal gaming strategies, as well as regression discontinuity to detect potential gaming.

New evidence is needed for VAE-specific prevention techniques.

It is uncomfortable to recommend prevention techniques based on VAP trials in which it cannot be discerned who had VAP. The *Compendium* did its best to "thread this needle," and the Epicenters Wake-Up and Breathe trial is very important in this context.

New prospective interventional trials are needed.

Are there opportunities for secondary analysis of existing RCT datasets, perhaps from primary mechanical ventilation management trials?

How will the CDC partner with other federal agencies with overlapping topics?

The National Heart, Lung, and Blood Institute (NLHBI) has funded the Clinical Trials Network for the Prevention and Early Treatment of Acute Lung Injury (PETAL Network);

CMS is working on developing a measure for accountability related to ARDS;

There are questions regarding using VAE/IVAC/PVAP for trial enrollment and other primary VAP trials. The University of Chicago submitted a U01 application to the National Institute of Allergy and Infectious Diseases

(NIAID) that proposed using real-time VAE/IVAC/PVAP to detect patients. They are anxious regarding whether the definition has penetrated other federal agencies.

In summary, Dr. Howell expressed his approval of moving on from VAP. Challenges remain for automation, especially in terms of data availability, which patients are on ventilators, and other issues. There is an active move toward prevention instead of surveillance, but the language of this shift is troubling. The critical care community has had some positive response, and some less-positive response, to the changes.

Discussion Points

HICPAC emphasized the critical care community response to VAE and noted some concerns among the IP community as there is movement toward VAE prevention. Many VAEs are not infectious, and IPs may not have the necessary content expertise about fluid and ventilation management to understand what is involved with surveillance and to dialogue with critical care physicians who are well-versed in those strategies. It is important to build partnerships so that the individuals who are monitoring the events are not put in an awkward position. VAEs present an opportunity for the IP field to expand beyond infectious outcomes and quality improvement, but it will be challenging because the strategies to prevent VAEs are not in the traditional categories of infection control and prevention.

There was discussion regarding opportunities to exclude VACs that occur early in the process in order to focus on the important VACs. Dr. Howell said that the former definition began at the first minute after intubation, so many individuals in the critical care community are happy to have the 48-hour window where they cannot occur. Dr. Magill added that CDC has heard both criticisms:

1) because the definition cannot be met until Day 4, events may be missed; and 2) at the same time, there is concern that the early events represent patients who are admitted with problems and have not had an opportunity to stabilize. The definition walks a fine line, and knowing more about what VAEs are will help them make decisions about adjusting time frames.

HICPAC thanked Dr. Howell for raising questions that many practitioners have, and to which they do not have answers. The presentation serves as a warning as more metrics will be imposed by CMS and other agencies. It is important to think through and understand what is being measured. The definition is better since the revision, but the field still struggles with this entity. It is not good for a patient to get it, but it is not known how to prevent, measure, or treat it. As with other interventions they have discussed, there are issues associated with the ease of "gaming the system" and the pressure from different areas within hospitals. It is not always easy to defend a VAE versus pneumonia. Dr. Howell agreed and said that the Epicenters trial showed that one-third of the events can be prevented. The field has been pleased that CDC has continually innovated on this definition. The field is learning together, and his conversations with IPs have been useful. He hoped that as nosocomial ARDS is a disease, CDC will prevent it as well. Some issues still remain, however.

Public Comment

At 4:25 p.m., Mr. Hageman called for public comment. Hearing none, they proceeded to the next agenda item.

Liaison/*Ex Officio* Reports

The Association of Professionals of Infection Control and Epidemiology (APIC): APIC's annual conference was recently held and was successful. APIC has launched three new publications, updated the Certification Study Guide, updated the manual for Infection Prevention During Construction and Renovation, and updated the Hand Hygiene Guide. APIC launched the mega- survey with 15,000 IPs to gather baseline data on the current state of the professionals and their organization. A new certification exam and road map for novice ITs are available, which is timely given HICPAC's discussion of risk assessment and its challenges.

The Association of State and Territorial Health Officials (ASTHO): ASTHO is finalizing a web- based toolkit to support health departments in accessing EHRs for healthcare-associated outbreak investigations. This toolkit is based on an assessment of the experience of several states. A report has been prepared regarding how to develop or enhance antimicrobial stewardship policies. ASTHO convened a meeting with state health officials, HAI coordinators, and state epidemiologists on AMR on June 18-19, 2015. The purpose of the meeting was to share best practices and to develop state strategies and actions to address resistance. In recognition of the White House Forum on Antibiotic Stewardship, ASTHO committed to supporting the state and territorial health agency role to operationalize the White House five- year National Strategy for combating AR bacteria. The ASTHO AMR and Stewardship position statement is available on the website.

Council of State and Territorial Epidemiologists (CSTE): CSTE released three position statements of importance to HICPAC. They were part of eight position statements passed at the CSTE conference in Boston, Massachusetts:

Recommendations for strengthening antibiotic stewardship in veterinary medicine and animal agriculture, the role that state health departments and the HAI programs can play, and how they can collaborate.

Recommendations for the surveillance and reporting of HAI in long-term care facilities and how state health departments can assist in enrollment of long-term care facilities into NHSN in their cities.

A standardized definition for CRE for reporting out by state health departments: the definition is the same as the new NHSN LabID Event definition. It includes the *Enterobacteriaceae*, *E. coli*, and *K* and is resistant to any carbapenem, including ertapenem, without regard to any third-generation cephalosporins. The definition allows for sub- categorization into likely carbapenemase producers, likely non-carbapenemase producers, or not sufficient information. The secondary sub-classification is complex, particularly regarding the evidence that is needed for it.

Infectious Diseases Society of America (IDSA): No fewer than 25 IDSA guidelines are in development, and antimicrobial stewardship in different healthcare settings is a particular emphasis area. IDSA made a number of stewardship commitments in advance of the White House Forum. Work continues regarding stewardship in many areas, including food-producing animals and new diagnostic tests and tools. The society continues to focus on new antibiotic development with the "10x20" initiative. There are important statements and long-term concerns to express regarding the decline of physician trainees choosing the field of infectious diseases.

Society of Critical Care Medicine (SCCM): SCCM is rolling out the "ICU Liberation" campaign that may help prevent VAE. The society is supporting a program called Thrive, which is focused on reducing long-term complications from critical illness, including post-traumatic stress disorder (PTSD), and is testing different models of patient and family support. This work has a particular focus on minimizing sedation and deliriogenic medications, which are related to VAE. SCCM has been a partner in CAUTI work with CUSP with AHA, AHRQ, and SHM. That collaborative is coming to a conclusion and the results are being collected. SCCM became involved in CUSP through a connection made at a HICPAC meeting. SCCM and the European Society for Intensive Care Medicine are completing revised sepsis definitions which will be quite different from the 2001 definition. They hope to partner with CDC in this effort.

Surgical Infection Society (SIS): At the recent SIS meeting in California, approximately half of the research presentations related to clinical, surgical infections most commonly related to the abdomen, skin, and pneumonia. The other half of the presentations focused on basic science aspects of the surgical patient population, given that there are sometimes unique sets of patients who are iatrogenically injured by surgeons. The major themes remain. What happens to the microbiome in terms of surgical injury versus traumatic injury, and the host response in immediate and long-term persistent inflammation, immunosuppression and catabolism syndrome (PICS)? PICS is seen in patients who remain in the ICU perhaps because they do not get up soon enough, and they do not get better. SIS is working on guidelines and several review publications. The STOP-IT trial, a randomized study of duration of antibiotic therapy for intraabdominal infection, was published in May 2015. The trial suggests that a short course of four days of antibiotic therapy is equivalent to a longer course. Widespread adoption of this approach will reduce antibiotic pressure in the patient population.

Society of Hospital Medicine (SHM): SHM continues work in CAUTI with a partnership with the Health Research and Educational Trust (HRET). A third cohort now incorporates all 50 states looking specifically at implementation of best practice. This work is becoming concrete with an infection prevention fellowship within SHM called a CAUTI Fellowship. It focuses on implementation science and the basics of implementation. This work is extending to long-term care facilities through another project in partnership with a number of other organizations for implementation at the front lines. Another area of interest is CLABSI in non-ICU settings. SHM focuses specifically on the use of peripherally inserted central catheters (PICCs) in hospitalized medical patients. This work has been conducted through a partnership with the Michigan Hospital Medicine Safety Consortium and looks not only at patterns, prevalence, and predictors of CLABSI, but also at the appropriateness of the use of a PICC in a hospitalized medical patient. Recommendations from a multidisciplinary panel will be published soon regarding when it is appropriate or not appropriate to use a device. Antimicrobial stewardship is a key priority area for SHM, which has created an Antimicrobial Stewardship Committee within the national organization that reports up to the Healthcare Quality and Patient Safety Committee. The antimicrobial stewardship campaign extends across all 14,000 SHM members. A recent conference call was held to ask SHM members to pledge to change behavior with two key strategies to incorporate into their decision-making.

Public Health Agency of Canada (PHAC): PHAC is updating the Middle East Respiratory Syndrome Coronavirus (MERS-CoV) guidelines. An interim guideline was developed in 2013, and upon review of evidence from the recent outbreak, there will be no change in the recommendations because there does not appear to be a change in the mode of transmission. PHAC has been working on many Ebola Virus Disease (EVD) guidelines, ensuring that there is consistency among the agency's recommendations. There is a national case definition as well as the IPC recommendations for healthcare settings and a triage algorithm for screening and assessment. PHAC created an advice document on managing EVD-associated waste in Canadian healthcare settings, looking at public health

management of cases and contacts of human illness associated with EVD. Those documents are available online. Some documents are under development. One document is considering IPC measures for pre-hospital care and is intended for pre-hospital personnel, including medical first responders. The document also relies on liaisons with pre-hospital organizations for education and training. Another document focuses on safe cleaning, disinfection, and terminal cleaning of large, reusable equipment.

Regarding surveillance, the Canadian Antimicrobial Resistance Surveillance System (CARSS) was created by PHAC as the focal point for AMR and AU surveillance. An Antimicrobial Resistant Organism (ARO) surveillance report is posted online. The IPC section of the PHAC website describes two core guidelines that are under development: one on the prevention of transmission of bloodborne pathogens from infected healthcare workers to patients, and one on IPC guidance for personal services such as tattooing and piercing. PHAC's scope has expanded in these areas. The Prevention and Control Occupational Infections Guideline, originally posted in 2002, will be updated.

National Association of County and City Health Officials (NACCHO): NACCHO has been busy supporting local health departments in preparation for HAI outbreaks in outpatient settings as well as preparing for and responding to Ebola through a modified incident command structure. NACCHO is continuing a multi-year HAI demonstration project, which includes the Philadelphia Health Department as well as the state of Florida and DuPage County in Illinois. The project this year has focused on antibiotic stewardship efforts, a major recent focus for NACCHO. In addition, NACCHO also supported participants to attend the SHEA and APIC conferences. In conjunction with supporting the HAI project, NACCHO is developing an HAI guidance document for local health departments to engage in HAI prevention efforts. The guidance will be nationally available for other local health departments. NACCHO is developing a policy statement on increasing federal, state, and local collaboration to address AMR and to promote stewardship.

Association of periOperative Registered Nurses (AORN): AORN is updating guidelines regarding endoscope reprocessing, specifically flexible endoscopes. The document will be available for public comment before the next HICPAC meeting. Another pertinent guideline focuses on preventing patient hypothermia, which will be called thermoregulation. It will be available on the AORN website for public comment in the coming weeks. AORN has addressed clinical issues associated with ultraviolet (UV)-cured nail polishes, such as gels and shellacs, in an FAQ on the website. AORN has partnered with APIC's Practice Guidance Committee to state that there is insufficient evidence regarding these polishes, and because of their similarity to artificial nails, AORN recommends taking an abundance of caution and does not recommend them being worn in the perioperative setting. A Clinical Issues peer-reviewed expert opinion paper on the topic is available. The Guidelines Advisory Board chair from AORN and the liaison from SHEA are working on a research study to generate evidence on this issue.

American Hospital Association (AHA): AHA's work is ongoing on antibiotic stewardship. In addition to participating in the White House Forum, AHA continues to share information with the field. AHA was pleased that Dr. Frieden, CDC Director, was a plenary speaker at the annual meeting. His presentation focused on the rise of AR and it was well-received by the AHA membership. AHA closely monitors and responds to proposals related to the use of NHSN measures in federal programs. Most recently, CMS proposed the expansion of the use of CAUTI and CLABSI measures by using all-unit data as opposed to ICU-only data. AHA is largely supportive of this change as it is incorporated into pay-for-performance programs in the future. AHA undertook a process in conjunction with its membership to identify high-priority issues for quality improvement and measurement. The hospital CEOs who responded to and participated in the exercise identified patient safety as the top priority, with HAIs at or near the

top of the priority list. HICPAC's work dovetails with that priority, and there will be more work in this area in the future.

American College of Surgeons (ACS): Most of ACS's work on HAIs is focused on registries. ACS's National Surgical Quality Improvement Program® (NSQIP®) is a robust registry that includes a range of procedures and has voluntary participation from approximately 600 to 700 hospitals. It won the Eisenberg Award in 2015. HAI definitions are harmonized with NHSN. SSI- 1 has always been harmonized, and the UTI definitions are in the process of being updated.

Other registries modeled on NSQIP® include the bariatric registry, which also has 30-day outcomes in HAIs, and now there is a trauma 30-day outcome registry. The Surgeon-Specific

Registry is a voluntary reporting of surgeon outcomes. Soon there will be a compendium to the other registries that will add to 30-day transplant outcomes that will include HAIs.

Food and Drug Administration (FDA): FDA's on IC was presented previously by Dr. Schwartz. The work includes developing a guidance document related to the reprocessing of medical devices.

National Institutes of Health (NIH): NIH has been involved in the care of patients who have Ebola. The experience was both educational and illustrative. The agency is still processing the lessons learned from the four patients that have been cared for in the hospital, two of whom had disease and two of whom did not have disease, but were exposed. Even well-thought-through plans may not work in practice, and so it is important to "triangulate on the fly." Five Phase II-III clinical trials of Ebola vaccines are ongoing in Western Africa. One of the vaccines was developed by NIH, and one was developed in Canada. The trials are struggling be there are not enough cases to show definitive efficacy. It is possible to show immunological impact. The CDC deserves great credit for its work in Western Africa, and Dr. Henderson thanked his CDC colleagues for that work.

Dr. Diekema directed the group's attention to the liaison reports from the representative groups that were not in attendance at the meeting. He thanked them for their attention and adjourned the meeting for the day. HICPAC stood in recess at 4:49 p.m.

Friday, July 17, 2015

The second day of the HICPAC meeting was called to order at 9:13 a.m. on Friday, July 17, 2015. A roll call was conducted to establish quorum. HICPAC members restated their conflicts of interest.

Draft Guideline to Prevent Surgical Site Infections

Dr. Diekema presented the draft recommendation for the SSI Guideline for the question:

> How safe and effective are antimicrobial sutures and how and when should they be used?

The draft recommendation is:

> Consider use of triclosan-coated sutures for the prevention of surgical site infection (Category II).

Dr. Tapper moved to approve the recommendation as written. Ms. Janssen seconded the motion. The motion carried with 9 in favor and 2 opposed. There were no abstentions.

Dr. Huskins and Dr. Talbot disapproved of the recommendation because they believe that the data support a stronger category of recommendation based on the quality of evidence supporting benefit for preventing all categories of SSI.

Mr. Hageman provided a potential timeline for the SSI Guideline's next steps. The approved draft recommendation will be incorporated into the overall draft of the SSI Guideline. All GRADE tables, evidence tables, and references will be updated to reflect the final draft recommendation. The document will be re-read and submitted to the surgical co-authors with the final draft recommendations for their review and approval. When the surgical co-authors approve the draft, it will be submitted to CDC clearance. Following CDC clearance, there will be an opportunity for liaison organizations to endorse the document officially if they choose to do so as the document is being prepared for posting and publication. The document will be posted on CDC's website and, in partnership with the surgical co-authors, in the literature.

Discussion Points

Mr. Hageman indicated that because the document is a CDC guideline, it does not require approval from federal agency partners. Input and discussion with other federal agencies that have responsibility in the health arena at HICPAC meetings are worthwhile aspects of the development process. If there are potential regulatory or other issues for agencies within HHS or the VA, then they will be aware of those throughout the development process. The public comment period also captures input broadly. Liaison organizations also provide input through HICPAC so that confusion or concerns can be discerned during development and so that the guideline can be communicated clearly in partnership with those organizations. The goal of the guideline is to work with partners to implement the recommendations to improve patient safety.

Proposed Framework for Environmental Infection Control Research: Focus on Non- Critical Surfaces

Sujan Reddy, MD, MSc Emory University
Division of Healthcare Quality Promotion
National Center for Emerging Zoonotic and Infectious Diseases Centers for Disease Control and Prevention

Dr. Reddy explained that the proposed framework is a draft research proposal involving CDC and partners for work in the area of environmental infection control. The role of non-critical surfaces in the transmission of pathogens in healthcare facilities has been debated for several decades. Prior to the 1970s, healthcare facilities frequently cultured healthcare surfaces, which were thought to play an important role in the transmission of pathogens. In the 1970s and 1980s, evidence emerged that these surfaces may not play a significant role in the transmission of pathogens. This evidence led to sampling methods falling out of favor as controlling for contamination of surfaces received less attention.

In the last decade, an abundance of evidence has shown that non-critical surfaces may play a role in pathogen transmission. The strongest evidence relates to same-room transmission, in which a patient's risk of colonization or infection is related to the colonization or infection of the prior occupants of the same room. This finding suggests that there is a reservoir for pathogens in the healthcare environment. The findings have been shown for Methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant *enterococcus* (VRE), and *C. difficile* as well as with some viruses.

The landscape is changing regarding cleaning and disinfecting environmental surfaces. There are emerging technologies for reducing and preventing contamination, such as no-touch cleaning and disinfection modalities; enhanced wipes, mops, and cloths; and enhanced surface coatings that may prevent contamination. There are also emerging technologies for monitoring cleaning and disinfection. These technologies can be low-tech, such as observation and feedback, or can use fluorescent markers and ATP bioluminescence. Even though the field is aware of the problem and modalities to address it, there is limited evidence guiding facilities on how to minimize contamination.

A draft Technical Brief on Environmental Cleaning from AHRQ addresses challenges regarding environmental cleaning. AHRQ performed a systematic review and key informant interviews on the following topics: Cleaning and Monitoring Practices, Practice Implementation, Knowledge Gaps, and Research Challenges. The overall conclusions in the draft document are that: 1) there is limited evidence on how the clean the environment, mainly due to weak study designs and non-clinical outcomes in many of the studies; and 2) there is a lack of consensus pertaining to key concepts such as cleanliness thresholds and the delineation of high-touch surfaces.

The draft document suggests the following six key areas for future research, which DHQP used to inform the suggested research framework:

Focus on the comparative effectiveness of emerging technologies for cleaning and monitoring.

Engage in implementation and process research.

Examine thresholds for cleanliness.

Focus on patient-centered outcomes.

Identify high-touch and high-risk surfaces.

Control for confounders and multi-component interventions in the move to patient-centered outcomes.

The research setting of the suggested research framework is geared toward CDC and its partners. There are many recently completed, ongoing, and proposed projects related to environmental infection control. The goal of the framework is to integrate these projects, understanding that there will be overlap in some areas, and to guide future projects toward a shared objective. The framework focuses on non-critical surfaces as defined by Spaulding

criteria and on contamination with potential nosocomial pathogens, perhaps including multidrug resistant organisms (MDROs) and emerging pathogens such as Ebola. The initial focus will be on adult acute care facilities. The chief interest will be in ICUs and wards, but there is also interest in the role of emergency rooms services and operating rooms. The framework focuses on single-patient rooms as opposed to multi-patient rooms. The findings in this setting may be applicable to other healthcare settings.

The two main objectives of the research framework are to:

Determine the public health significance of non-critical environmental surface contamination, which addresses the historical backing of the issue and sets the stage for investing resources in improving surface contamination; and

Provide evidence to healthcare facilities to reduce the contamination of non-critical environmental surfaces reliably in order to improve patient safety.

Four specific aims support the framework objectives, which are to:

Understand the transmission dynamics of nosocomial pathogens in relation to non-critical environmental surface contamination in healthcare facilities;

Determine the bioburden levels of these surfaces as they are associated with transmission of pathogens and patient outcomes such as HAIs;

Compare methods for reducing or preventing contamination as well as methods for monitoring cleaning and disinfection of non-critical surfaces; and

Though the focus is on adult acute care facilities, understand the differences in transmission dynamics and bioburden levels in different settings.

The conceptual framework focuses on three topics, including: Transmission of Pathogens in Healthcare Settings; Surface Exposure Factors that May Influence Transmission Events; and Focus on Both Bioburden Levels and Patient Safety Outcomes.

The historical interest in transmission of pathogens in healthcare settings has been in healthcare workers that are contaminated by infected or colonized patients. The healthcare worker then transmits the pathogen to the next patient, causing an HAI. This research framework, however, focuses on the role of the environment. There is an interaction with the environment as patients acquire infections from others who have been in the same room. There is also interaction between the healthcare worker and the environment, which may play a key role in causing HAIs. The healthcare worker may contaminate the environment, and the environment may contaminate the healthcare worker as well.

In focusing on the link between the environment and HAIs, the research must consider potential confounders to the interaction. Direct patient-to-patient contact may be important in certain settings, such as pediatric or long-term care facilities. Air and water contamination also play an important role in patient-to-patient transmission. Air and water contamination may also play a role in environmental contamination. Hand hygiene rates are another potential confounder.

Understanding these dynamics helps focus models on understanding the association between nosocomial transmission and surface exposure. The models also have to take into account host factors of colonized patients and susceptible patients.

The following four key elements influence surface exposure:

Bioburden, including total microbe level and the current composition of the microbiota.

Transfer efficiency from the surface to the patient and from the patient to the surface. This point relies on the type of surface, such as whether it is porous or not porous, or has been exposed to enhanced products. It also relies on the type of pathogen and how it transfers from the patient to the surface. The type of human exposure, such as skin, gloves, or PPE, is also a consideration.

Frequency of exposure, focused on high-touch surfaces, as transfer efficiency and frequency describe the risk of a surface, not just touch itself.

Time is an important variable, not just in terms of frequency of touches and the number of total touches, but also regarding the survivability and persistence of pathogens on the surfaces, as well as the duration of cleaning. The impact of contaminated surfaces in transmission likely has more to do with an area under the curve, and duration between cleaning, from terminal to routine cleaning, likely plays a role in the transmission of pathogens.

The outcomes of the research framework focus on bioburden levels and on patient safety. Both are needed. Studies focused on bioburden levels may examine the methods of assessment, the association of bioburden and pathogens, and how to reduce bioburden levels. Understanding bioburden levels may be insignificant in isolation. The link between bioburdens and patient safety needs to be established. Research methodology can be a concern related to patient safety. Baseline infection rates are important as well to determine whether research results will be generalizable to other research settings. Studies should also control for other confounders, such as hand hygiene rates and air and water contamination. The process between bioburden levels and patient safety is iterative.

The first aim of the research agenda is to understand the following transmission dynamics:

What proportion of transmission events involve surface contamination? This addresses the public health significance of the issue and may require multiple studies. An important question to ask is: How many hospital-acquired infections can be prevented by decreasing surface contamination? Stating this aim guides future study topics, the development of the studies, and integrating different studies.

How do environmental surfaces become contaminated? This aspect of the work addresses direct patient or healthcare worker contact, as well as indirect contact via air handling or splash zones. Microbial factors affect contamination and incorporate questions of persistence and survivability, biofilm formation, and matrix effects.

Which non-critical surfaces are most important? This question incorporates surfaces that are frequently touched as well as their transfer efficiencies, how they are touched, and which pathogens are of concern. This question also includes the characteristics of surfaces that influence survivability and persistence as well as duration between cleaning, terminal and routine cleaning, and how they affect re-contamination rates.

The second aim of the research agenda is focused on determining bioburden levels and associating them with outcomes:

What are the best methods for assessing bioburden? There are many methods, and it is important to understand the performance characteristics of the different strategies. It is also important to understand the role of non-culture based methods in sampling. Ideally, there will be a standardization of protocols for sampling in order for effective study comparison. There are differences between composite and multi-site site sampling strategies, and different surface types are sampled differently. The feasibility of strategies also plays an important role, as research sampling strategies are different from strategies that facilities may be able to accomplish. Total bioburden levels should be associated with microbial composition, particularly pathogen burden, and with different surrogate markers.

What influences the bioburden of surfaces in healthcare settings? How does the microbiota of a room change over time? Do pathogens survive or persist on surfaces differently?

What influences the non-pathogenic bioburden? How much is air-derived or water-derived, and are there differences among surfaces?

How do bioburden levels impact patient safety? What are the appropriate research methods to link bioburden to patient-centered outcomes? How does one control for other elements that contribute to surface exposure in addition to bioburden, such as surface type, pathogen type, and duration between cleaning?

Are certain bioburden levels associated with clinical outcomes? These issues are related to hand contamination rates, patient colonization rates, and patient infection rates. Overall, the research should demonstrate whether reducing bioburden actually reduce HAIs and whether non-culture based approaches can aid in evaluating this risk.

The third aim addresses comparing the methods:

Multiple studies will be needed to understand the effectiveness of the methods for reducing contamination and understanding the modalities of cleaning and disinfection as well as the role of terminal versus daily cleaning.

What is the effectiveness of methods for preventing contamination? This issue incorporates enhanced surface coating methods.

What are methods for monitoring cleaning and disinfection, and how can surrogates be associated with outcomes?

Implementation and process research will also be important. The baseline of environmental surface hygiene in US hospitals needs to be established, as well as the length of time required to adequately clean and disinfect surfaces using currently available technologies. The research should assess factors that affect real-world implementation, such as human factors, competency of workers performing the cleaning and disinfection, and the role of education and training.

The interventions will not occur in isolation; there will be multi-component interventions for cleaning and disinfection, and they need to be studied to decrease transmission events.

The fourth aim is related to understanding how transmission dynamics and bioburden levels change in other facilities, such as long-term care facilities; high-turnover ambulatory care settings such as infusion centers and dialysis centers; inpatient radiology; and multiple patient rooms. There are likely to be different strengths of association that will change based on the healthcare setting.

DHQP is currently engaged in research related to environmental infection control. One project is an assessment of overall and MDRO bioburden levels on environmental surfaces. The DHQP laboratory in Atlanta assessed 11 hospitals or long-term care facilities from four states, conducting environmental sampling of MDRO isolation rooms for: *Acinetobacter baumannii*, *Clostridium difficile*, *Klebsiella pneumoniae*, MRSA, and VRE. A total of 375

composite samples were collected via sponge from 170 rooms. Samples were taken from surfaces close to the patient and slightly farther from the patient. The toilet area was also sampled for *C. difficile*. The study compared composites from routinely cleaned rooms and terminally cleaned rooms.

Several factors were determined to be associated with higher bioburden levels:

Routine cleaning had higher levels than terminal cleaning.

The use of quaternary ammonium product had higher levels than rooms that were cleaned with bleach products.

Objects closer to the patient had higher bioburden levels than objectives that were farther from the patient.

Some factors were associated with recovering an MDRO:

Having a high total room microbial burden of over 10^3 CFU/100cm^2 was associated with recovering an MDRO.

The use of quaternary ammonium products were associated with finding an MDRO compared to the use of bleach products.

The MDRO that was recovered was not always the same as the MDRO for which the patient was isolated. There is probably contamination of the environmental surfaces other than the prior occupant.

DHQP and its partners are actively involved in multiple studies regarding the environmental infection control of surfaces. The objectives of the research framework are to describe the public health significance of non-critical environmental surface contamination; and provide further guidance to facilities to help reduce contamination of these surfaces reliably in order to improve patient safety. The research agenda is in draft form, and DHQP hopes for HICPAC's feedback regarding areas that are missing or need additional elaboration.

Discussion Points

HICPAC commented on the tension regarding the threshold issue. There are bacteria all around us, and the threshold issue and its link to outcomes is important in hospitals. The research agenda might focus on that issue above all others while also focusing on the issue of human factors. Who is cleaning the environment, and how is it being done and monitored? What is the role of surveillance cultures? These questions are the most important links to patient outcomes.

The research agenda needs additional emphasis and elaboration on the human factors aspects of the problem. Before delving into bioburden and important questions about it, it should be recognized that institutions are struggling with the basics. Strategies that are known to be effective are not being applied on a reliable, sustainable basis. This problem is related to human factors, including training and competency. The environmental care worker is a critical component of the conceptual models. There are daunting questions to address, such as education level, workforce engagement, and the connection of their role in healthcare facilities to infection prevention. There is not a roadmap for this work, but it may not be possible to consider the bioburden issues adequately because of known failures. As the question of human factors is examined more closely, it will become evident that there are a number of pressures on environmental service workers to turn over rooms rapidly. These pressures fall on disempowered and poorly trained individuals. Environmental factors also affect their job. They may not have the best equipment and tools, they may use compounds with a 10-minute wet time, which is difficult to achieve and maintain when a room is turned over rapidly. These issues can be improved upon to support their work and ensure that terminal and routine cleaning of patient rooms is

performed appropriately. Regarding human factors and engineering, there is tremendous turnover expected of environmental services workers. Any steps that can be taken to help them avoid errors will be helpful. New technologies and advances may help, but there are barriers associated with their availability. One of the ultimate outcomes is reducing infections in patients. Given the fact, however, that there has been recent progress in reducing HAIs, it may be difficult to show a real difference. Surrogate markers such as acquiring colonization may be needed.

HICPAC suggested considering viruses more strongly in the research agenda. Past and current experience would argue that the transmission of respiratory viruses to both patients and healthcare workers represents a greater risk than some of the other factors described in the research agenda.

Genome sequencing has helped shape the idea of what is and is not important regarding environment surfaces. The transmission is clearly not solely patient-to-patient. CRE is in the sink traps in ICUs and can infect patients. It is likely that a species of bacteria lives in the environment, and something happens to turn it from commensal to pathogenic and invasive, when it infects a patient. It may, therefore, not be as important for the research agenda to emphasize overall bioburden, as individual bacterial species and their particular state may be more important. Sequencing will shed light on that transition.

This process is dynamic. The work will focus on the environment, but people come in and out of it. These dynamic questions have not been addressed in a formal way. Certain flora are endogenous in institutions. CRE is in drain traps in many facilities. NIH has been sequencing isolates frequently and has found 23 genetically different isolates. Where are they coming from? NIH conducts whole-house surveillance. Some of the infections are HAIs among ICU patients who have been in the hospital for two months, with multiple negative surveillance cultures and no other connection. Many bacteria strains live in drain traps. They pass plasmids back and forth and move from species to species.

Regarding a timeframe for the research and who will be supported to conduct it, Dr. Michael Bell is in the process of reviewing implementation guidance in hospitals outside the US that are responding to grim situations. In the 1970s, the hospital environment was important because it was filthy. A great deal of progress has been made since then. At some point, the focus shifted from the environment to other areas with high-severity outcomes, such as catheters or ventilators. They were points of systematic intervention. That work has gone on for some time, and the focus is returning to the environment, where looking and smelling clean is not sufficient. The rationale for the research agenda is to drive implementable solutions. There are fascinating questions associated with the genetic aspects of the organisms, and there are pragmatic questions associated with splash zones and biofilms. There is good evidence that the solenoid- activated valve of touchless faucets actually is associated with biofilm in the tap water that can lead to infection and colonization. Design issues are part of the agenda. Groups are being funded to do work on sink galleries that can be disassembled to assess for colonization.

Understanding what to do with the information is the next step. Recommendations, such as not to install touchless faucets in patient areas, can be created. Solutions related to engineering and facilities management can be created to address how the environment is related to infection risk, but the evidence described in this research agenda is needed to push the field.

AORN's updated guideline on environmental cleaning in the perioperative setting addresses many of the issues. There have been relatively few studies conducted in the operating room (OR) setting. Contamination of an OR is different from contamination of a patient room.

Efficiency and human factors are also important, given that some facilities only have one environmental services worker assigned to the OR, and there is rapid turnover of the room. Work needs to be done in education and to standardize this process across all personnel. Empowering the environmental services team and incorporating the concept of team training in the OR will be important steps.

Concerns outside the OR, such as nearby construction, can deflect attention away from basic infection control practices. There are no sterile environments, but there are ways to work in a less microbial environment. It is important not to risk emphasizing that the environment is a main cause of infection when opportunities remain with the basics.

HICPAC asked about plans for air sampling, which may be perceived not to have benefit, except for certain pathogens. It may be important to determine whether the air is important or less important related to hard surface bioburden. Dr. Reddy said that there are many important transmission dynamics. In considering the full bioburden, it is important to understand what comes from the air and what can be reduced.

Dr. Michael Bell said that much of the bioburden work focuses on creating an engineering intervention that makes it less likely that human factors will result in bad outcomes. It is not possible to eliminate human factor problems, but if the environment friendly and conducive to being free from pathogens, then mistakes are less likely to have bad outcomes. In terms of respiratory pathogens, air handling and displacement strategies could lead to less cross-transmission in hospitals and could have a benefit. It is challenging that surveillance is not conducted for all of the specific respiratory pathogens. There is not a systematic means for tracking them, but engineering solutions for air handling could make a big difference. Gathering data to make the business case for facility-level construction or renovation is challenging, as the data needs to be robust in order to convince a healthcare system to make these investments.

There are gaps in knowledge related to the value and role of laminar air flow. It is important to understand what needs to be done regarding air, as pressure to control the air is a burden on personnel in the environment. There are many unknowns in this area, such as whether surgical smoke contaminates the environment, whether the air contaminates the sterile field and causes SSIs.

Some facilities seem more eager to invest in technology than in people. Because of successes in other areas, infection rates are lower and it is difficult to generate data using hard outcomes of HAI. The ability to demonstrate effectiveness is being outstripped by the availability of new technology, such as antimicrobial-coated surfaces or UV robots. Purchasing decisions and decisions about improving patient safety related to environmental risk are being made in the absence of data. This research agenda is critical.

There was discussion regarding examining beyond healthcare facility onset, as many patients may be colonized, get discharged, and then present with the infection. Ignoring this portion of the situation may ignore a large proportion of the burden of disease. The issues are complex to capture, but community-associated HAIs are important.

Comments were provided regarding conducting this research within outbreak settings in which all human factors have been addressed and there are questions regarding what in the environment caused the outbreak. This work could be helpful in providing structure to future outbreak investigations regarding what should be sampled.

The aspects of curtains and water were raised. Institutions are concerned about the intersection between water and surface, such as splash zones. Dr. Reddy said that water plays an important role in how a surface becomes contaminated, especially regarding splash zones. The draft research agenda represents a starting point. As evidence is gathered and sampling methods are understood, they may be utilized in other settings as well. Dr. Michael Bell noted that the research agenda is a starting point for the hard surfaces in a patient care environment. A body of work has been accumulated on premise plumbing and water supplies within healthcare facilities. There is a growing arena of biofilm research regarding what that plumbing is contributing to infection. There is a significant challenge associated with eradicating or reducing Legionella. The options are not optimal now, whether they relate to point-of-use filtration or waiting for a cluster before acting. Waterborne issues tend to be more well-defined in patient care, whether the patients are on dialysis or ventilators. This research agenda represents a first step in addressing the issues associated with surfaces that are less well-defined.

IDSA is involved in a Hospital Microbiome Project that incorporated different disciplines. This holistic view could have an impact on this work. It is reassuring that this work is not just a series of one-off projects or risks, but apply across the spectrum of facilities as the work focuses on living, breathing organisms in that larger context.

Dr. Reddy agreed and noted that the project helps to illustrate that CDC does not have to do all of the work. The framework can be informed by other projects.

Infection Prevention and Control Guidelines: Experience of the Public Health Agency of Canada

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Ms. Ogunremi shared background on the geography and demographics of Canada, which is a Federated state with 10 provinces, 3 territories, and 1 federal government. The country is the second-largest land mass in the work, at approximately 10 million square kilometers in area and spanning six time zones. The population is approximately 35 million, 20% of which is foreign- born and 4% of which is aboriginal. Although Canada is a multicultural country, the official languages are English and French. The population is not evenly distributed: 90% of Canadians live within 160 kilometers of the US border; 75% of Canadians live in Ontario, Quebec, and British Columbia. The largest cities in Canada are Toronto, Montreal, and Vancouver; 80% of Canadians live in urban areas; and .3% live in territories, and half of that population are people of aboriginal descent.

Regarding the roles and responsibilities of Canada's healthcare system, by constitution, healthcare service delivery is primarily a provincial responsibility. Under the Canada Health Act, provinces receive federal funding for healthcare through the Canada Health Transfer. The federal government provides healthcare and public health services to specific populations, such as First Nations populations who live on reserves and the Canadian forces. Public health responsibility is shared across jurisdictions. The federal health portfolio is led by the Minister of Health and is composed of 5 departments. The Canadian Institutes of Health Research is the government's health research agency and includes 13 institutes. It is responsible for creating new scientific knowledge, knowledge

transfer and exchange (KTE), and studying more effective health services and products. Health Canada is responsible for helping Canadian people maintain and improve their health. PHAC is led by a President and a Chief Public Health Officer. They report to and advise the Minister of Health on public health issues. The work of infection prevention and control fits within the Infectious Disease Prevention and Control Branch in PHAC. The other two agencies are the Patented Medicine Prices Review Board, an independent, quasi-judicial body established to protect the interests of Canadian consumers by ensuring that the prices of patented medicines sold in Canada are not excessive; and the Canadian Food Inspection Agency, which focuses on food safety and zoonotic disease.

The mission of PHAC is to promote and protect the health of Canadians through leadership, partnership, innovation, and action in public health. Its mandate includes health promotion; prevention and control of chronic and infectious diseases; and preparing for and responding to public health emergencies. PHAC serves as the central point for sharing Canada's public health expertise with the rest of the world and applies international research and development to Canada's public health programs. It also strengthens inter-governmental collaboration on public health and facilitates national approaches to public health policy and planning.

The Pan-Canadian Public Health Network was established in 2005 as a key mechanism to strengthen and enhance Canada's public health capacity; enable the federal, provincial, and territorial governments to work better together; and anticipate and prepare for public health events and threats. The network is comprised of individuals from across Canada from various backgrounds, including academia, government, NGOs, research, and health professionals. It is governed by a 17-member Council composed of federal, provincial, and territorial government officials, including the Chief Public Health Officer. The Council is accountable to the Conference of federal, provincial, and territorial Deputy Ministers of Health. The work of the network is managed by three steering committees that are accountable to the Council. Each steering committee has two co-chairs: one federal, and one provincial. The committees are able to establish time-limited task groups to address specific issues or projects. The talent pool of expertise allows for access to the nation's best available public health expertise, and they contribute to the work of the network.

Each province and territory has a Chief Medical Officer of Health. Along with other senior agency officials, they make up the Council of Chief Medical Officers of Health (CCMOH), which is a forum for communication with a broad range of stakeholders for collaboration and the exchange of ideas. CCMOH may provide guidance and direction to the work done by the network and the Council. CCMOH also reports to the Council.

Key drivers for guidance development include: ministerial priority, public health emergencies, or items that are prioritized by provinces or territories. Some guidelines have more than one trigger. PHAC produces a wide range of guidelines that can be classified into four types:

Comprehensive guidelines are long and exhaustive documents. Examples of these guidelines include the Hand Hygiene Guideline and Routine Practices and Additional Precautions.

Targeted guidelines are more concise and specific. For example, there is a *C. Difficile* Guideline.

Interim guidelines usually focus on emerging pathogens. The MERS-CoV guideline is an example of an interim guideline.

Companion tools can be quick reference guides or educational material developed to support the more elaborate or comprehensive guidelines.

PHAC has worked on a Guideline Transformation Initiative for approximately a year. This process has included guideline producers from every group within the agency and has been a productive and worthwhile exercise. Internal drivers of guideline production include the agency's federal role and mandate as well as core business. External drivers include stakeholders, professional organizations, and the community of practice.

One of the first steps in guideline creation is a needs and risk assessment for the agency. It considers whether the topic is within the scope and priorities of the agency as well as the timeliness, feasibility, and resources required to create the guideline. The assessment takes into consideration stakeholder concerns, policy and legal implications, and the risk of developing or not developing the guideline. Three main models are used to develop guidelines: 1) collaboration between PHAC and another group; 2) outsourcing the development; and 3) in- house guideline development.

Collaboration on guideline development could be with provincial or territorial jurisdictions. PHAC's guidelines are not legally binding or enforceable. They are not intended to supersede provincial or territorial guidelines. Ownership of the guidelines varies and is negotiated, but that decision is made before the guideline produced. Outsourcing provides funding to a third party to develop the guidelines. These guidelines are owned by the responsible external party and are shared via website cross-linkages. An example of an outsourced guideline is the Ebola Clinical Care Guidelines, which were funded by PHAC and developed by the Association of Medical Microbiology and Infectious Disease (AMMI) Canada. When guidelines are created internally to PHAC, they may be created by employees of the agency working with an external working group or task group, or they could be written by experts with or without a contract in place. These guidelines belong to PHAC.

The Infection Prevention and Control Guidelines have evolved over the years. They are now administered by an expert working group, having previously been governed by a National Steering Committee. The group is recruited through a transparent nomination process and enters into a voluntary membership agreement. Group members are selected for subject matter expertise. The group currently has 60 members, including seven practicing physicians specializing in infectious disease, medical microbiology, occupational health, and public health. The group includes six infection prevention and control professionals with expertise in acute care, long-term care, home care, and public health. It also includes three other healthcare professionals with expertise in medical nursing education, remote community health, and medical instrument and device processing. The manager of the PHAC HAI IPC group co-chairs the group with an IPC expert. The group is balanced by geographical jurisdiction and by official languages. The group provides technical expertise on the development, dissemination, evaluation, and implementation of the IPC guidelines and recommendations. They also provide timely technical expertise on current or emerging IPC issues. The meetings can be scheduled or can be ad hoc consultations.

The guideline development methodology was created to reflect the way that guidelines are produced throughout PHAC. The IPC Guideline process is similar to HICPAC's SSI Guideline process:

Topic selection, including key drivers, a needs assessment, and an environmental scan.

Key questions are developed by the expert working group using the Participants, Interventions, Comparisons, and Outcomes (PICO) criteria.

A literature search is performed in-house, working with the agency librarians.

Eligible studies are extracted and synthesized into an evidence summary table. For grading of the evidence, the IPC Guidelines utilize an agency-developed critical appraisal tool (CAT). In the past, critical appraisal was conducted by the task group and expert working group, but the appraisal is currently performed in-house.

There are groups within PHAC that use GRADE as their appraisal tool. Most of those guidelines are clinical practice guidelines.

Recommendations are formulated by the task group or expert working group. Where evidence is limited, the agency may seek additional expert opinions. For example, the development of the Ebola IPC Guideline included experts from Médecins Sans Frontières (MSF) and Emory University Hospital. They were involved in weekly teleconferences for several months.

Consensus is reached on the final recommendations. In-house agency IPC staff write the guidelines.

Following approval of the guideline by the expert working group, there is a series of internal agency approvals.

The dissemination plan for guidelines includes development of KTE tools or mobile applications.

The guidelines are evaluated to assess their uptake.

Consultations with the expert working group and any relevant stakeholders continue throughout the guideline development process. This approach increases the timeliness of reaching a final product and group consensus. A lack of consensus is addressed early in the process, so the final document can move forward. The expert group conducts a line-by-line review of the guideline, and several teleconferences and one or two face-to-face meetings during the development process. The group considers draft recommendations and their working, the grading of the evidence, and the rationale for the grades. PHAC factors translation into its timeline for guideline development. If there are challenges with technical terminologies, then the agency utilizes consultants.

PHAC uses an in-house developed CAT. In 2007, the expert working group was developing two major guidelines: Hand Hygiene and Routine Practices and Additional Precautions. The group identified concerns that were reported in the literature regarding the paucity of RCTs in IPC research, mainly due to feasibility and ethical concerns. At that time, there were approximately six CATs available, and the group had difficulty choosing the right tool. There was a lack of clarity, detailed explanations, and common language in the available tools. This area of critical appraisal has progressed significantly in recent years. Whether the expert group used the same tool or different tools, there was not consensus regarding the grading of the evidence and the recommendations. There was strong expertise in IPC, but the expertise in research methods and appraisal was variable, and training was needed.

The quality assessment section of the critical assessment tool was based on a standard, validated quality assessment form, the Effective Public Health Practice Project Quality Assessment Tool, which was developed in 2003. It was deemed suitable and to have content and construct validity. The PHAC tool was developed by a small group of individuals led by a working group member with expertise in research methods, critical appraisal, Cochrane reviews, and epidemiology. They gave consideration to the need to assess evidence from both strongly-designed studies such as clinical trials and from studies with weaker designs, such as observational or time series studies.

The analytic CAT can be used to analyze RCTs, non-RCTs, observational studies, and interrupted time series studies. A descriptive CAT can be used to assess cross-sectional studies, ecologic studies, and case series. A literature review tool can be used to assess the quality of a systematic review, a meta-analysis, or a narrative review. The document includes supporting tools, such as four algorithms to help identify the study design, select the appropriate tool, and provide background on statistical tests. It also contains a glossary of terms. Results from the critical appraisal of individual studies are compiled into an evidence summary table, which is similar to a GRADE

table and allows for review of the body of evidence. The body of evidence is then rated using the grading system within the tool.

Although the tool is complementary to GRADE, the question that PHAC is asked the most is how the tool is different from GRADE. Different groups within the agency use different tools depending on the type of guideline that is being created. The key differences between GRADE and PHAC's CAT are:

Study Types: GRADE focuses on the strongest study types, such as RCTs. The CAT allows for assessment of other types of studies. More recently, GRADE has been applied to observational studies.

Risk of Bias: The CAT does not assess risk of bias at the outcome level. If there is a small pool of studies on a given issue, enough of them need to report on a specific outcome do this assessment.

Criterion Scoring: Both tools are similar in that they assess individual studies. They also both assign a grade to the body of evidence.

Explanations for Users: The expert working group felt at the time that there was not sufficient direction and clear instructions for using GRADE. There were brief descriptions of criteria, sometimes in a number of different publications, and insufficient guidance. The CAT consolidates all explanation and criteria into a single document that is user-friendly. A dictionary allows for its use by novices as well as experts in critical appraisal.

Grading Evidence: GRADE grades evidence as high, moderate, low, or very low. The recommendations are graded separately. The CAT grades evidence as strong, moderate, or weak. The recommendations are not graded. The rationale for not grading the recommendation is based on the strength of the available evidence, which changes, as opposed to the strength of the recommendation. The guidelines provide a rating for the recommendations, but the ratings are linked to the quality of the evidence that informs them.

The PHAC HAI and IPC group initially focused on nosocomial infections and has now transitioned to focusing on HAIs and IPC. Its website will be upgraded during a move to a single Canadian government website. All IPC documents can be found on the PHAC website. Many lessons were learned in the IPC Guideline development process, including the following:

Using different models allows for selecting the optimal approach for the scope and type of product.

Previously, much of the guideline writing was conducted by external experts. The IPC Guidelines were written in-house, which allows for more training for staff and the ability to respond to requests and questions regarding the guideline.

A byproduct of the Guideline Transformation Initiative has been further clarity on federal, provincial, and territorial roles in guideline development. There is a more coordinated effort to maximize resources for guideline development.

The target audience for IPC Guidelines is chiefly health professionals, so the products are evidence-based. PHAC's sister agency, Health Canada, regularly conducts consultations with the public and other interested stakeholders. These consultations provide the agency with an opportunity to hear what Canadians are thinking on an issue. Input is obtained during these interactions that influence policies and legislation. A limited number of public health agency guidelines include public consultations, but there are avenues for the public to advocate with the Minister's office. PHAC is also expected to respond to questions from the public within a specified timeline.

The expert group has moved from a single chair, who was always an external expert, to a co-chair approach. This change has enhanced the ability to meet requirements of the federal government and of stakeholders during

the guideline development. Those requirements are usually defined in an early stage of guideline development, such as during the needs assessment, when key stakeholders are engaged.

PHAC's guidelines are non-prescriptive, with a focus on critical thinking and risk assessment.

The challenges associated with guideline development have changed over the years, including the following:

The expanded scope of the HAI program can be considered a challenge. The subject matter included has been broadened and now overlaps with community settings.

There has been an increase in IPC issues and the numbers of guidelines that are developed.

Resources are a challenge. Like CDC, PHAC uses the same IPC resources in an emerging event such as H1N1, Ebola, or MERS-CoV, which causes challenges and affects the timelines of document release.

Guideline development is resource-intensive. Currently, the PHAC staff consists of 5.8 full- time employees.

Surveillance support comes from the PHAC HAI Surveillance Section, but they also have challenging timelines, as they administer the National Nosocomial Surveillance Program.

Guideline evaluation and maintenance involves revision and archiving. There are challenges associated with migrating to a new website and with responding to the need for access to social media and mobile apps.

Discussion Points

The PHAC approach is similar to AORN's Evidence Appraisal and Grading Model. AORN incorporates qualitative literature because much of the nursing literature is qualitative. AORN assigns two individuals to each article, and they come to consensus on it. The tools have been published in the AORN journal and are being revised to be more detailed, including the addition of more quality points. The revision is being submitted for publication and should be available soon.

Ms. Ogunremi said that in the PHAC process, two individuals conduct every critical appraisal. If they do not come to consensus, then a third person reviews the article to achieve consensus. The timeline for updating guidelines is under discussion as part of the Guideline Transformation Initiative. There is wide variation among the guidelines. An Occupational Health Guideline that was developed in 2002 has been flagged for revision for some time, but there are competing priorities and other reasons that the revision has not yet begun. Ideally, guidelines will be revisited every three to five years, but they work with the resources they have. When there is an event such as MERS-CoV, there is an assessment of changes in the evidence and whether there is a need to update guidelines. The revision process requires resources.

Ms. Ogunremi said that there are limited CATs for qualitative studies. The PHAC tool would not be the best tool for that work. If there are enough RCTs to inform a quantitative assessment, then GRADE is a better tool to use.

The PHAC tool grades the quality of evidence but does not provide a strength of recommendation. HICPAC asked how decisions are made regarding what to include within the guideline and whether the decision is solely based on the quality of the evidence, or whether it includes recommendations have low-quality evidence that are based on consensus.

Ms. Ogunremi said that the PICO criteria eliminate some studies. The evidence summary tables categorize the studies by the question or recommendation that they are informing. Frequently, a specific recommendation does

not have enough evidence to back it, but the recommendations clearly state the grade of the evidence and the limitation associated with making the recommendation. This topic is related to the discussion of evidence-based versus evidence- informed: the guideline is evidence-based in terms of what qualifies to be a part of the document, but no tool provides steps for writing recommendations. The grading of the strength of a recommendation is related to the level of confidence that the recommendation will change based on a change in the evidence. The guideline development group opted to make it clear when the evidence is graded and expert opinion has been incorporated to generate that recommendation.

HICPAC has struggled in identifying key questions that are important for the field but that have little strong evidence. In this situation, HICPAC may ultimately provide no recommendation. Ms. Ogunremi said that PHAC does not have an option not to provide a recommendation. It may take a long time to create a recommendation, but without a recommendation, there is pushback from the practice community that asks for guidance. Some jurisdictions within Canada fully rely on the federal government for guidance because they do not have the capacity to produce recommendations. Because of this need, giving no recommendation does not help practices.

PHAC therefore decided to make recommendations and to be clear about the limitations of the recommendations and the strength of the evidence.

AORN has reached the same conclusion. AORN uses a rating model modified from the Oncology Nurses Society and the Johns Hopkins Evidence-Based Practice Model. AORN translates the scores in able to make recommendations based on benefits balanced with harms when there is a lack of evidence. The practice needs guidance.

Dr. Michael Bell visited PHAC during the guideline evaluation and evidence review processes and was impressed with the rigor and thoroughness with which PHAC approached them. He was struck by the extent to which the challenges in the US are mirrored across the border. He said that the step of translation into French adds another challenging layer to guideline development. Substantial time and financial resources are necessary to produce high-quality guidelines and to maintain a process so that the guidelines can be updated appropriately and respond to changing needs. CDC is looking at lessons learned from Canada and is reaching out to colleagues in England to consider ways to build a sustainable system. Similar to historic sways back and forth in IP in general, the guideline production process continues to evolve. At first, recommendations were unreferenced. There was then a phase of textbook-like recommendations and massive guidelines. From a sustainability and responsiveness perspective, that approach has to change. Mr. Hageman and others in DHQP are considering how to move to an evidence review process that can embrace a broader swath of evidence and not be limited by a process that may be a better fit for a different kind of literature. DHQP is also considering how to grow its in-house capacity. For instance, a person who is trained in methodology for evidence review is an important investment.

HICPAC noted the goal of updating guidelines every three to five years as well as the need to be able to edit guidelines in response to changing conditions. Ms. Ogunremi said that PHAC is moving in the direction of periodic, real-time updating of guidelines as data are released that may provide practice-changing evidence. One of their collaborative projects was to update a 1996 TB IPC Guideline. Before writing began, the Canadian Thoracic Society indicated that they were ready to update their Canadian TB Standards, which address every aspect of TB from IPC to epidemiology. PHAC's needs assessment showed that the Canadian TB Standards was the top resource referenced by Canadian practitioners looking for recommendations in TB. PHAC decided that rather than devoting resources into updating the 1996 guideline, they could collaborate with the Canadian Thoracic Society. PHAC

wrote the chapter on IPC in the book and did not update its 1996 guideline. The book is evergreen, and PHAC has made changes in the chapter since the book was released a year ago. This mechanism has been successful.

Public Comment

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

Phil Carling
Boston Medical Center

Dr. Carling said that a decade ago, when it was discovered that the healthcare patient environment was not being cleaned by the environmental services personnel in the way they thought it was being cleaned, Boston Medical Center convened a group to develop guidance for the evaluation and monitoring of environmental hygiene. The guidance evaluated practices objectively and provided education and feedback to the individuals who were involved. During this process, a new world of technology emerged, including non-touch technologies and approaches to kill pathogens on surfaces. Hospitals have spent millions of dollars in this area without much objective, scientific, non-industry-based input. He wondered whether HICPAC found this area to be of concern and whether it should be addressed by the committee.

Discussion Points

Dr. Diekema thanked Dr. Carling and said that he could not speak for HICPAC, but he feels that is an area of concern. The issue lends increased urgency to the need for the research agenda presented by Dr. Reddy. The only way to provide more evidence-based approaches is to have the evidence.

Dr. Michael Bell added that innovation and encouraging new approaches that will make the process of care safer are important, but the field should be consistent in demanding a certain level of evidence. Marketing cannot drive implementation. Many of these approaches are not inexpensive, so hospitals are rigorous in deciding to purchase them. Framing these decisions in the context of good science is key.

Summary and Work Plan

Dr. Diekema thanked the meeting attendees for their participation during the meeting and recognized the success of moving the SSI Guidelines forward. HICPAC will form working groups on stewardship and on endoscope reprocessing.

HICPAC members volunteering to participate on the stewardship working group include:

Ms. Janssen

Dr. Tapper

Dr. Patterson

HICPAC members volunteering to participate on the endoscope reprocessing group, which may also address reprocessing more broadly, include:

Dr. Hilary Babcock, who was not present at the meeting but who had expressed interest in participating

Ms. Brown

Mr. Hageman thanked the presenters and new and existing HICPAC members and liaison representatives.

Dr. Diekema adjourned the meeting at 11:31 a.m.

Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the July 16-17, 2015, meeting of the Healthcare Infection Control Practices Advisory Committee, CDC are accurate and complete.

_____ _____

Date

Daniel Diekema, MD
Chair, Healthcare Infection Control Practices Advisory Committee, CDC

Attachment 1: Acronyms Used in this Document

Acronym	Expansion
AACN	American Association of Critical-Care Nurses
AAMI	Association for the Advancement of Medical Instrumentation
ABIM	American Board of Internal Medicine
ACGME	American Council on Graduate Medical Education
ACS	American College of Surgeons
AER	Automated Endoscope Reprocessor
AHA	American Hospital Association
AHRQ	Agency for Healthcare Research and Quality
AJIC	*American Journal of Infection Control*
AMD	Advanced Molecular Detection
AMMI	Association of Medical Microbiology and Infectious Disease
AMP	Antimicrobial Prophylaxis
AMR	Antimicrobial Resistance
ANA	American Nurses Association
AORN	Association of periOperative Registered Nurses
APIC	Association of Professionals of Infection Control and Epidemiology
AR	Antibiotic Resistance
ARDS	Acute Respiratory Distress Syndrome
ARLG	Antibacterial Resistance Leadership Group
ARO	Antimicrobial Resistant Organism
ASGE	American Society for Gastrointestinal Endoscopy
ASM	American Society for Microbiology
ASTHO	Association of State and Territorial Health Officials
ATP	Adenosine TriPhosphate
AU	Antibiotic Use
AUR	Antimicrobial Use and Resistance
C. difficile	*Clostridium difficile*
CARB	(National Action Plan for) Combating Antibiotic-Resistant Bacteria
CARSS	Canadian Antimicrobial Resistance Surveillance System
CAT	Critical Appraisal Tool
CAUTI	Catheter-Associated Urinary Tract Infection
CCMOH	Council of Chief Medical Officers of Health
CDC	Centers for Disease Control and Prevention
CEMB	Clinical and Environmental Microbiology Branch
CEO	Chief Executive Officer
CFU	Colony-Forming Unit
CLABSI	Central Line-Associated Bloodstream Infection
CMO	Chief Medical Officer
CMS	Centers for Medicare and Medicaid Services
CoP	Condition of Participation
CRE	Carbapenem-Resistant Enterobacteriaceae
CSTE	Council of State and Territorial Epidemiologists
CUSP	Comprehensive Unit-based Safety Program
DFO	Designated Federal Official

Acronym	Expansion
DHQP	Division of Healthcare Quality Promotion
E. coli	Escherichia coli
EHR	Electronic Health Record
EIN	Emerging Infections Network
EIP	Emerging Infections Program
EIS	Epidemic Intelligence Service
EMR	Electronic Medical Record
EOC	Emergency Operations Center
ERCP	Endoscopic retrograde cholangiopancreatography
ETU	Ebola Treatment Unit
EVD	Ebola Virus Disease
FAQ	Frequently Asked Question
FDA	(United States) Food and Drug Administration
FiO2	Fraction of Inspired Oxygen
FOA	Funding Opportunity Announcement
FY	fiscal year
GHS	Global Health Security
GHSA	Global Health Security Agenda
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
HRET	Health Research and Educational Trust
ICU	Intensive Care Unit
ID	Infectious Disease
IDSA	Infectious Diseases Society of America
IP	Infection Preventionist
IPC	Infection Prevention and Control
IRC	International Rescue Committee
IST	Systemic Immunosuppressive Therapy
IT	Information Technology
IV	Intravenous
IVAC	Infection-Related Ventilator-Associated Complication
K	Klebsiella
KPC	Klebsiella pneumoniae carbapenemase
KTE	Knowledge Transfer and Exchange
LPN	Licensed Practical Nurse
LRN	Laboratory Response Network
MDR	Multidrug-Resistant
MDRO	Multidrug-Resistant Organism
MERS-CoV	Middle East Respiratory Syndrome Coronavirus
MoH	Ministry of Health
MRSA	Methicillin-resistant Staphylococcus aureus
MSF	Médecins Sans Frontières
NACCHO	National Association of County and City Health Officials
NARMS	National Antibiotic Resistance Monitoring System
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases

Acronym	Expansion
NDM	New Delhi metallo-β-lactamase
NGO	Non-Governmental Organization
NHLBI	National Heart, Lung, and Blood Institute
NHSN	National Healthcare Safety Network
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NQF	National Quality Forum
NSQIP®	National Surgical Quality Improvement Program®
OR	Operating Room
PAHO	Pan-American Health Organization
PCAST	President's Council of Advisors on Science and Technology
PEEP	Positive End-Expiratory Pressure
PETAL Network	Clinical Trials Network for the Prevention and Early Treatment of Acute Lung Injury
PFGE	Pulsed-Field Gel Electrophoresis
PHAC	Public Health Agency of Canada
PICC	Peripherally Inserted Central Catheter
PICO	Participants, Interventions, Comparisons, and Outcomes
PICS	Persistent Inflammation, Immunosuppression and Catabolism Syndrome
PJA	Prosthetic Joint Arthroplasty
PPE	Personal Protective Equipment
PPHF	Prevention and Public Health Fund
PrVAP	Probable Ventilator-Associated Pneumonia
PTSD	Post-Traumatic Stress Disorder
PVAP	Possible Ventilator-Associated Pneumonia
RCT	Randomized Controlled Trial
S. aureus	Staphylococcus aureus
SAAR	Standardized Antibiotic Administration Ratio
SAT	Spontaneous Awakening Trial
SBT	Spontaneous Breathing Trial
SCCM	Society of Critical Care Medicine
SHEA	Society for Healthcare Epidemiology of America
SHM	Society of Hospital Medicine
SICU	Surgical Intensive Care Unit
SIR	Standardized Infection Ratio
SIS	Surgical Infection Society
SME	Subject Matter Expert
SOP	Standard Operating Procedure
SSI	Surgical Site Infection
STOP-IT	Study to Optimize Peritoneal Infection Therapy
TA	Technical Assistance
TB	Tuberculosis
USDA	United States Department of Agriculture
UTI	Urinary Tract Infection
UV	Ultraviolet
VA	(United States Department of) Veterans Affairs
VAC	Ventilator-Associated Condition

Acronym	Expansion
VAE	Ventilator-Associated Event
VAP	Ventilator-Associated Pneumonia
VRE	Vancomycin-Resistant Enterococcus faecium
VTE	Venous Thromboembolism
WGS	Whole Genome Sequencing
WHO	World Health Organization

Attachment 2: Liaison Reports

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention
Meeting Date: July 16-17, 2015
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:

America's Essential Hospitals commented on FY 2016 IPPS proposed rule:

In our comments to CMS on its proposed refinement to the measures included in the Hospital Acquired Conditions (HAC) Reduction Program for FY 2018, America's Essential Hospitals urged CMS not to expand the CAUTI and CLABSI measures to select ward (non-ICU) locations until FY 2019.

CDC will be updating the standard population data to use CY 2015 as the "new standard population data" for HAI measures. CMS anticipates that the new standard population data will affect the HAC Reduction Program beginning in FY 2018; however, CMS intends to postpone the use of the new standard population data until FY 2019 in the VBP Program. In our comments to CMS, America's Essential Hospitals urged CMS to also postpone the new standard population data until FY 2019 in the HAC Reduction Program, to avoid confusion among hospitals and maintain consistency in the application of the new baseline across programs.

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.

Campaigns and related activities:

America's Essential Hospitals runs a Hospital Engagement Network as part of the Partnership for Patients (PfP). In our work through the Essential Hospitals Engagement Network (EHEN), America's Essential Hospitals' staff members visited all EHEN hospitals for site visits to discuss best practices and interventions on healthcare-associated infections, along with the other PfP conditions. We reported, at the December 2014 HICPAC meeting, the findings from our latest EHEN performance period of May '14-July '14.

We are pleased to report close to 80% of original EHEN has recommitted to working around these issues, and we are working to keep the network engaged as we await announcement by CMS of awardees for new HEN contract.

Press activities:

America's Essential Hospitals was pleased to participate in the June 2nd White House Antibiotic Stewardship Forum. The active discussions highlighted the need to work across sectors and take a comprehensive approach to improve antibiotic stewardship in human health

Publications:

December 2014 – publication of research brief - **HAC Reduction Program Penalties: An Undue**

Burden on Essential Hospitals?

Ex-Officio Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention
Meeting Date: July 16-17, 2015
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA Ex-officio name: William B. Baine, M.D.
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 is doubling its investment in CARB-related research. Previous AHRQ-supported research in this area has produced significant results: e.g., collaborating with CDC on a study 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 is currently developing a guide for implementing antibiotic stewardship programs in nursing homes. In addition, AHRQ is planning to apply its powerful behavior change vehicle, the Comprehensive Unit-based Safety Program (CUSP), to the challenge of promoting the adoption of antibiotic stewardship programs in multiple healthcare settings. AHRQ, CDC, CMS, OASH, and NIH are collaborating to accelerate the implementation of antibiotic stewardship programs in hospitals and advance research to combat antibiotic resistance.

CUSP for CAUTI Nationwide Implementation Project

AHRQ's four-year project to promote the nationwide implementation of CUSP to reduce catheter-associated urinary tract infections (CAUTI) will reach completion in August 2015. Some 1595 inpatient units in 955 hospitals across 40 states, the District of Columbia, and Puerto Rico, as well as 397 intensive care units and 371 emergency departments, have participated in the project. Preliminary data show promising results. Final results will be announced in September 2015.

AHRQ Safety Program for Surgery

This four-year program to foster development of a surgical unit-based safety program to reduce surgical site infections and other surgical complications will reach completion in September 2015. This project has recruited five cohorts comprising 272 hospitals and 381 surgical teams across 36 states. Included in the project is an ethnographic study that qualitatively examines the factors associated with successful implementation of a program to improve safety in the surgical environment.

AHRQ Safety Program for Mechanically Ventilated Patients

This three-year project aims 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 157 hospitals and will reach completion in Fall 2016.

AHRQ Safety Program for Ambulatory Surgery

This is a project extending over four years to improve safety and reduce complications, including surgical site infections, in ambulatory surgery centers. There are 538 centers in 46 states already recruited to participate.

The project is currently recruiting a special cohort of endoscopy centers. Two issues that are under consideration for this cohort are adequacy of endoscope cleaning and safety of sedation and anesthesia.

Position statements:

n/a

Legislation:

n/a

Campaigns and related activities:

n/a

Press activities:

n/a

Publications:

Roghmann MC, Johnson JK, Sorkin JD, Langenberg P, Lydecker A, Sorace B, Levy L, Mody L. Transmission of methicillin-resistant *Staphylococcus aureus* (MRSA) to healthcare worker gowns and gloves during care of nursing home residents. Infect Control Hosp Epidemiol. 2015;26:1-8. [Epub ahead of print]

Schweizer ML, Chiang HY, Septimus E, Moody J, Braun B, Hafner J, Ward MA, Hickok J, Perencevich EN, Diekema DJ, Richards CL, Cavanaugh JE, Perlin JB, Herwaldt LA. Association of a bundled intervention with surgical site infections among patients undergoing cardiac, hip, or knee surgery. JAMA. 2015;313:2162-71.

Scheck McAlearney A, Hefner JL, Robbins J, Harrison MI, Garman A. Preventing central line-associated bloodstream infections: a qualitative study of management practices. Infect Control Hosp Epidemiol. 2015;36:557-63.

Other items of note:

This report has been prepared by Melissa Miller, M.D., who is the alternate *ex-officio* representative for AHRQ, in consultation with James I. Cleeman, M.D., Director, Division of Healthcare-Associated Infections, Center for Quality Improvement and Patient Safety.

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention
Meeting Date: July 16-17, 2015
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA Liaison name: Amber Wood
Organization represented: AORN

Interim activities and updates:

Hot Topic

UV-Cured Nail Polish (eg, gel, shellac):

Gel and shellac nail polish should not be worn in the perioperative setting. Due to the lack of evidence on these types of nail polish, and their chemical similarities to artificial nail compounds, an abundance of caution

should be taken until research evidence on gel and shellac nail polish is available and demonstrates their safety. http://www.aorn.org/clinicalfaqs/handantisepsis/

Wood, A, & Van Wicklin, S. Ultraviolet (UV)-cured nail polish. [Clinical Issues]. AORN Journal. 2015;101(6):701-708. http://www.aornjournal.org/article/S0001-2092(15)00247-1/pdf Upcoming Events

AORN Surgical Conference & Expo 2016, April 2-6, Anaheim, CA

OR Executive Summit™/Leadership Development Summit™

Poster abstracts accepted through 10/2/15

Emerging Leaders Financial Management Seminars, multiple dates and cities TeamSTEPPS Master Training Course, October 22-23, Denver, CO

New Publication

AORN Guidelines and Tools for the Sterile Processing Team Crosswalks from the AORN Guidelines to the AAMI standards

Guidelines and Guidance:

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

AORN guidelines are available in print and through electronic access (e-subscription and e- book). Information on how to obtain can be found at www.aorn.org.

The 2015 Guidelines for Perioperative Practice include 8 new evidence rated guidelines: Safe Environment of Care Part 2, Specimen Management, Preoperative Patient Skin Antisepsis, Surgical Attire, Care and Cleaning of Surgical Instruments, Surgical Tissue Management, Local Anesthesia, and Complementary Care Interventions.

Available electronically now (will be in 2016 book): Radiation Safety

Guidelines in development: Thermoregulation, Prevention of Retained Surgical Items, Flexible Endoscopes, and Moderate Sedation.

Position statements:

Available at http://www.aorn.org/Clinical_Practice/Position_Statements/Position_Statements.aspx

Legislation:

The AORN legislative priorities for 2015 are RN as circulator, preserving and protecting the Perioperative Registered Nurse's scope of practice, supporting workplace safety and patient safety initiatives, and advancing positive health care improvements.

Campaigns and related activities:

Sharps Safety Campaign

Press activities:

Recent AORN press releases can be accessed at www.aorn.org.

Publications:

2015 Guidelines for Perioperative Practice, AORN Journal, Periop rative Job Descriptions and Competency Evaluation, & Perioperative Policies and Procedures

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention
Meeting Date: July 15-16, 2015
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 finalizing a web-based toolkit to support health departments in accessing electronic health records for healthcare-associated outbreak investigation. The toolkit, which will be released in Summer 2015, is based on an assessment of experiences and tools from twelve states. ASTHO presented preliminary assessment findings at the Council of State and Territorial Epidemiologists (CSTE) annual meeting in June 2015.

ASTHO released a report on antimicrobial stewardship that describes current state activities and presents a range of opportunities for health agencies to develop or enhance stewardship policies and activities (http://www.astho.org/Antimicrobial-Stewardship/). The report presents the results of a survey of HAI coordinators, findings from three state capacity building projects, and recommendations, tools and examples for states looking to initiate or enhance stewardship activities. ASTHO facilitated a roundtable on state stewardship activities at the CSTE annual meeting in June 2015.

ASTHO convened a meeting with state health officials, HAI coordinators, and state epidemiologists on the topic of antimicrobial resistance. The June 18-19 meeting was designed to identify capacity needs at the state level, share best practices to elevate HAI/antimicrobial resistance priorities, and develop state strategies and action steps to address resistance.

In recognition of the White House Forum on Antibiotic Stewardship, ASTHO committed to supporting the state and territorial health agency role in operationalizing the White House's five- year National Strategy for Combating Antibiotic-Resistant Bacteria. ASTHO published a blog post about the commitment and the state public health role in addressing resistance (http://www.astho.org/StatePublicHealth/State-Health-Agencies-Play-Critical-Role-in- Addressing-Antimicrobial-Resistance/6-2-15/).

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:

Antimicrobial Resistance and Stewardship Position Statement, available at http://www.astho.org/Policy-and-Position-Statements/Position-Statement-on-Antimicrobial-Resistance/

ASTHO's Antimicrobial Resistance and Stewardship Position Statement affirms the need for an ongoing public health commitment to support state health agency roles and ensure adequate capacity to address antibiotic resistance – including sound surveillance methods; effective education of healthcare workers and the public; and stable funding streams for health agencies.

Legislation:

Ongoing: Real-time state HAI legislative tracking on ASTHO's website, available at www.astho.org/state-legislative-tracking/

Campaigns and related activities:

Ongoing: ASTHO provides information to health officials on pertinent HAI issues through conference calls (All S/THO Call) and the *State Public Health Weekly* newsletter.

Press activities:

n/a

Publications:

ASTHO's HAI Publications are available at www.astho.org/Programs/Infectious-Disease/Healthcare-Associated-Infections/

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention
Meeting Date: July 2015
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Liaison name: Lisa McGiffert
Organization represented: Consumers Union, the advocacy arm of Consumer Reports

Interim activities and updates:

Consumer Reports has launched a major initiative on antibiotic resistance that covers antibiotic use in health care and in food animals. The initiative includes print and online publications, national polling, videos, social media and advocacy to change policies regarding oversight of the use of antibiotics and the outcomes of that use. The Safe Patient Project will be covering the health care related issues to include ensuring the President's National Action Plan for Combatting Antibiotic Resistance and improving state/local responses to infection outbreaks.

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.

Campaigns and related activities:

Consumer Reports continues to be actively engaged in the Choosing Wisely initiative. Our role is to inform consumers and we have numerous materials on our Consumer Health Choices page at http://consumerhealthchoices.org/depth-antibiotics/.

Publications:

Consumer Reports magazine series on antibiotic resistance. The first one, **already published,** was a primer on antibiotic resistance and focused on outpatient issues. The second will come off embargo on July 23 will focus on hospital infections, including hospital ratings. And, a third article will cover use of antibiotics in food animals. All articles will be posted at http://www.consumerreports.org/cro/health/the-rise-of-superbugs/index.htm?utm_source=dlvr.it&utm_medium=twitter

Other items of note:

In a national poll, we found:

3 in 10 (30%) of adult consumers got an antibiotic prescription during the past year. Of those, half (52%) got it at a retail pharmacy, while 31% received the medicine at the doctor's office. Those over age 35 (61%) were more likely than other age groups to get the antibiotics at a pharmacy.

Around one-fifth (21%) of consumers who received antibiotics asked the clinician to write the prescription, with men (28%) more likely than women (17%) to make the request.

The leading reasons that patients received antibiotics, by roughly 1 in 10 or more, were:

Sinus infection (15%)

Urinary tract infection (11%)

Before a medical or dental procedure (10%)

Cough or cold (9%)

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention
Meeting Date: July 16-17, 2015
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:

2015 annual conference held in June in Boston. Lots of presentations on HAI and antimicrobial resistance, as well as Ebola. Expect archive of conference presentations to be available at: http://www.csteconference.org/ in near future.

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.

In development: a survey 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.

Position statements :

8 position statements passed at the 2015 conference:

15-ID-01: Standardized surveillance and case definition for acute flaccid myelitis

15-ID-02: Recommendations for strengthening antimicrobial stewardship in Veterinary Medicine and Animal agriculture

15-ID-03: Revision of case definition for Hepatitis C for National Notification

15-ID-04: Recommendations for Surveillance and Reporting of Healthcare Associated Infections in Long Term Care Facilities

15-ID-05: Standardized Definition for Carbapenem Resistant Enterobacteriaceae (CRE) and Recommendation for Sub-classification and Stratified Reporting

15EB01: Common Data Structure for National Notifiable Diseases15-CD-01: Revision to the National Oral Health Surveillance System (NOHSS) Indicators 15-EH-01: Public Health Reporting and National Notification for Elevated Blood Levels The position statements are currently being formatted and will be available at the following

URL the week of July 20, 2015. http://www.cste.org/?page=PositionStatements

Definitions (if changed) take effect January 1, 2016.

Legislation:

n/a

Campaigns and related activities:

n/a

Press activities:

n/a

Publications:

Report that Assesses State Activities in Non-Infectious Environmental Health Exposure Monitoring and Investigations is available at:
http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/EnvironmentalHealth/CSTE_Sentinel_Assessment_Fin.pdf

Charting a future for epidemiologic training:
http://www.cste2.org/Publications/Brownson_Futureofepitraining_AnnEpi_2015.pdf

Applied Epidemiology Scientific Writing Trends, Needs and Recommendations, 2014: available at: http://www.cste2.org/Publications/CSTE-Applied_Epi_Scientific_.pdf

CSTE 2013 National Assessment of Epidemiology Capacity: http://www.cste2.org/2013eca/CSTEEpidemiologyCapacityAssessment2014-final2.pdf

Other items of note:

n/a

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention
Meeting Date: July 16-17, 2015
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Liaison name: Stephen Weber, MD
Organization represented: Infectious Diseases Society of America

Interim activities and updates:

IDSA Submits Testimony to Congress Urging Better Investments for Seasonal and Pandemic Influenza Preparedness (February 2015) - IDSA testimony highlighted the importance of building a strong public health infrastructure to protect the public from severe illness and death.

IDSA Spearheads Advocacy Effort for Antibiotic Resistance Funding (March 2015) – IDSA was joined by 56 other groups in a letter to congressional appropriators calling for funding to address antimicrobial resistance

IDSA Leadership and Staff Engage in White House Forum on Antibiotic Resistance (June 2015) – President Stephen Calderwood spoke on the final panel and highlighted ID physicians as critical leaders of stewardship programs and also discussed the need to stimulate the research, development and appropriate use of rapid diagnostics.

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.

In development:

Aspergillosis (Update) Asymptomatic Bacteriuria (Update)

Bone and Joint Infections in Children - *joint w/PIDS*

Candidiasis (Update)

Clostridium Difficile (Update) - *Joint w/SHEA*

- Coccidiomycosis (Update)

Community-acquired pneumonia - (Update) - *Joint w/ATS*

Cysticercosis

Diarrhea (Update)

- Drug Resistant TB – Joint w/ (led by) ATS

Encephalitis (Update)

Hospital-acquired, ventalator-acquired pneumonia (Update) - *Joint w/ATS*

Influenza (Update)

Intra-Abdominal Infections (Update)

IV Catheter Management (Update)

Leishmaniasis

LTBI Diagnosis Joint w/ ATS, CDC and IDSA

LTBI Treatment Joint w/ ATS, CDC and IDSA

Lyme Disease Joint with AAn and ACR

MRSA (Update)

Nosocomial Meningitis

NTM (Update) Joint w/ (led by) ATC, ECMID, ERSA and IDSA

Outpatient Parenteral Anti-Infective Therapy (OPAT) - (Update)

Pain Management in HIV

Vancomycin - (Update) *Joint w/ASHP/SIDP/PIDS*

Approved, to be Published

Vertebral Osteomylitis (Approved, to be Published)

Link to other guidelines on website: http://www.idsociety.org/IDSA_Practice_Guidelines/

Position statements:

IDSA Stewardship Commitments for the White House Forum on Antibiotic Stewardship (6/2/15): http://www.idsociety.org/View_All_Statements_on_Antimicrobial_Stewardship/

Legislation:

IDSA Supports Passage of 21st Century Cures Act in the House (July 2015) - IDSA strongly supports swift passage of the 21st Century Cures Act (H.R. 6), which includes important provisions to spur antibiotic development, including the Limited Population Antibacterial Drug.

The bill also includes increased mandatory funding for NIH and an increase in the NIH loan repayment maximum.

IDSA Members Urge Increased NIH Funding on Capitol Hill (June 2015) **-** IDSA leaders met with more than 20 congressional offices, primarily to support funding increases for NIH.

IDSA Endorses Medicare Coverage of Home Infusion Therapy Bill (February 2015) - In a letter to House and Senate sponsors, IDSA addressed the gap that private insurers typically cover such services, but Medicare does not.

IDSA Supports the Preventing Antibiotic Resistance Act of 2015 (March 2015) – The bill focuses on antibiotic use in food-producing animals

Campaigns and related activities:

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

Antimicrobial Stewardship in Different Healthcare Settings

New antibiotic development (10 x '20 initiative): http://www.idsociety.org/10x20/

Ebola and emerging infection readiness: http://www.idsociety.org/Biothreat_Policy/

Antimicrobial resistance and stewardship: http://www.idsociety.org/AR_Policy/ Infection prevention and control: http://www.idsociety.org/Infection_Control_Policy/ Immunizations and vaccinations: http://www.idsociety.org/Immunization_Policy/

Press activities:

Selected news releases from: http://www.idsociety.org/News_Releases/

White House Antibiotic Stewardship Forum (6/4/15)

IDSA: National Action Plan for Combating Antibiotic Resistant Bacteria (CARB) (3/27/15) Infectious Diseases Experts Stress Effectiveness and Safety of Vaccination During Measles Outbreak (2/10/15)

IDSA Applauds Focus on Antibiotic Resistance in Presidents FY 2016 Budget Request (2/2/15)

Publications:

Calderwood SB. IDSA Response to Factors Contributing to the Decline of Medical Residents Choosing the Field of Infectious Diseases. Clin Infect Dis. 2015;60(11):1724.

Other items of note:

n/a

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention
Meeting Date: July 16-17, 2015
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA Liaison name: Jennifer Gutowski, Philadelphia Department of Public Health, PA
Organization represented: National Association of County and City Health Officials (NACCHO)

Interim activities and updates:

August 2014 – March 2015: Planned, in collaboration with the City of Milwaukee Health Department and CDC's Division of Healthcare Quality Promotion, a tabletop exercise for local Milwaukee healthcare partners and other stakeholders that featured an HAI outbreak in an outpatient setting

The tabletop exercise aimed to increase awareness among local healthcare partners and other stakeholders of the roles they and local and state health departments play in responding to and addressing reports of communicable disease outbreaks in outpatient settings

The exercise also enabled a discussion on how various roles, policies, and approaches help or hinder the prevention, investigation, response, and control of outbreaks in these settings 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 is planned for 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 include CDC and ASTHO and invitees include federal, state, and local representatives, as well as partner organizations

April 2015 – present: Started new fiscal year of multiyear HAI demonstration site project and this year focuses on local health departments' antibiotic stewardship efforts; the three funded demonstration sites are:

Florida Department of Health in Orange County – Orlando, FL: Launched a partnership with the state's Department of Health to collaborate in 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

May – June 2015: Supported funded HAI demonstrate sites, as well as other local health departments and partnering long-term care facilities, in sending staff to the Society for Healthcare Epidemiology of America (SHEA) Spring 2015 Conference and the Association for Professionals in Infection Control and Epidemiology (APIC) 2015 Annual Conference for informational and training purposes

June 2015: Participated in the White House Forum on Antibiotic Stewardship, which brought together key human and animal health stakeholders who are eager to take positive action to improve antibiotic use and prescribing in the U.S.

Statement submitted to the White House outlines NACCHO's commitment to sustaining or expanding existing demonstration projects that enable local health departments to engage with local healthcare partners and other stakeholders to improve antibiotic stewardship and address resistance

Published blog featuring NACCHO's participation in the event and snapshots of the three HAI demonstration sites NACCHO is supporting

June 2015: Presented at the Michigan Department of Community Health Carbapenem-Resistant *Enterobacteriaceae* (CRE) Surveillance and Prevention Initiative Educational Conference on the role of local partners in preventing CRE and other HAIs

Ongoing: Participated in the following meetings, conference calls, and committees related to (1) obtain updates on HAIs, injection safety, antimicrobial resistance, and infection control; and (2) determine 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: Shared HAI prevention and infection control news and resources via NACCHO's regular communication channels

Upcoming: Will be initiating work with local health departments on infection control

A funding opportunity will be released in August that seeks 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

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:

Upcoming: Developing policy statement on increasing federal, state, and local collaboration in addressing antimicrobial resistance and promoting antibiotic stewardship

Working in partnership with NACCHO's Infectious Disease Prevention & Control Workgroup and other local health department representatives to develop policy statement

Will emphasize 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

Legislation:

N/A

Campaigns and related activities:

N/A

Press activities:

N/A

Publications:

N/A

Other items of note:

N/A

Ex-Officio Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)

Centers for Disease Control and Prevention
Meeting Date: July 15-16, 2015
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:

Since the previous HICPAC meeting, the NIH has continued to engage with DHHS and other federal Agencies to address various aspects of the Ebola epidemic in West Africa. The Clinical Center has provided care for four patients – one a Maryland physician who sustained a high risk occupational exposure, another the first of the two intensive care unit nurses from Dallas who became ill after providing care for Thomas Eric Duncan, the Liberian man who was the first person to be diagnosed with Ebola in the US, the third a healthcare worker who sustained an occupational exposure, and the fourth a healthcare provider who developed severe Ebola illness. Managing these patients in the sophisticated clinical research environment of the Clinical Center makes implicit sense and offers a substantial opportunity for us to learn about the disease's unique pathophysiology, as well as the optimal approaches to the management of patients who have this disease. All these patients were discharged home.

NIH is working hard to contribute both to the understanding of EVD as well as strategies for preventing its spread. For example, NIAID has nearly completed a Phase 1 study of a new candidate Ebola Virus Vaccine at the NIH Clinical Center; NIAID intramural scientists developed this vaccine. The vaccine employs a replication incompetent chimpanzee adenovirus vector carrying the gene for the ebola coat glycoprotein. The vaccine uses a 'prime-boost' strategy, with the primary inoculation being made with the chimp adenovirus vector with a modified vaccinia Ankara boost. The vaccine demonstrated protective efficacy in a Rhesus macaque model – protecting 4/4 macaques from lethal Ebola inoculation The Phase I trial in humans required twenty volunteer participants; all 20 have been vaccinated.

No adverse events were observed, and we are awaiting the immunological results, which should be available within a week or so. A second study began earlier this month evaluating another candidate Ebola vaccine. This second vaccine study is also taking place. This vaccine is being jointly developed by the Department of Defense and Canadian collaborators. This vaccine employs a replication-competent horse vesicular stomatitis virus vector. Phase I trials are underway at the Clinical Center and at several other sites in the US, Canada, Europe, and Africa.

Work is ongoing evaluating the transmission of Vancomycin-resistant *Enterococcus faecium* (VRE) in our hospital environment using whole-genome sequencing and detailed epidemiological information..

In addition, studies of CRE transmission are also continuing. We continue to aggressive microbial surveillance for CRE and other MDR gram-negatives and are focusing now on the presence of these organisms in our environment. Since July 2012, we have not detected transmission of any CRE isolates, but have detected 23 new isolates of CRE – all of which are genetically dissimilar to our epidemic strain and to each other. Two of these isolates harbored the New Delhi Metallo-beta-lactamase-1 gene.

Campaigns and related activities:

n/a

Press activities:

n/a

Publications:

Palmore TN, Barrett, K. Davey RT, Henderson DK. Challenges in managing patients who have suspected or confirmed Ebola Virus infection at the National Institutes of Health. *Infect* Control Hosp Epidemiol 2015;36(6):623-6.

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention
Meeting Date: July 16-17, 2015
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA Liaison name: Toju Ogunremi
Organization represented: Public Health Agency of Canada

Interim activities and updates:

Agency response related to emerging pathogens:

Interim Infection Prevention and Control Guidance for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in Acute Care Settings*:*

http://www.phac-aspc.gc.ca/eri-ire/coronavirus/guidance-directives/nCoV-ig-dp-eng.php Guidance is currently being updated mainly for clarity, user-friendliness, and to reflect current outbreak. No change in recommendations as evidence on mode of transmission remains the same.

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.

EBOLA VIRUS DISEASE (EVD) GUIDANCE DOCUMENTS RELEASED:

National Case Definition: Ebola Virus Disease (EVD): http://www.phac-aspc.gc.ca/id-mi/vhf- fvh/national-case-definition-nationale-cas-eng.php

Infection Prevention and Control Expert Working Group: Advice on Infection Prevention and Control Measures for Ebola Virus Disease in Healthcare Settings: http://www.phac- aspc.gc.ca/id-mi/vhf-fvh/ebola-ipc-pci-eng.php

Algorithm for Screening and Assessment for Ebola Virus Disease (EVD) in Persons Presenting to Healthcare Settings: http://www.phac-aspc.gc.ca/id-mi/vhf-fvh/ebola-ipc-pci/algo-triage-eng.php http://www.phac-aspc.gc.ca/id-mi/vhf-fvh/ebola-ipc-pci/algo-triage-eng.php

Infection Prevention and Control Expert Working Group: Advice on the Management of Ebola Virus Disease-associated Waste in Canadian Healthcare Settings: http://www.phac-aspc.gc.ca/id-mi/vhf-fvh/ebola-ipcw-pcid-eng.php

Public Health Management of Cases and Contacts of Human Illness Associated with

Ebola Virus Disease (EVD): http://www.phac-aspc.gc.ca/id-mi/vhf-fvh/cases-contacts-cas-eng.php

ADDITIONAL EVD RELATED DOCUMENTS UNDER DEVELOPMENT:

Infection Prevention and Control Measures for Prehospital Care and Ground Transport of Patients with Suspected or Confirmed Ebola Virus Disease

Safe Cleaning, Disinfection and Terminal Cleaning of Large Reusable Equipment Used for Patients with Suspected or Confirmed Ebola Virus

HEALTHCARE ASSOCIATED INFECTIONS SURVEILLANCE DOCUMENTS RECENTLY RELEASED:

Canadian Antimicrobial Resistance Surveillance System Report 2015: http://healthycanadians.gc.ca/publications/drugs-products-medicaments-produits/antibiotic-%20%20%20resistance-antibiotique/antimicrobial-surveillance-antimicrobioresistance-eng.php

Antimicrobial Resistant Organisms (ARO) Surveillance Report - 2009-2014: http://www.phac-aspc.gc.ca/nois-sinp/projects/aro-mra-eng.php

CORE IPC GUIDELINE DOCUMENTS CURRENTLY UNDER DEVELOPMENT:

Guideline on the Prevention of Transmission of Bloodborne Pathogens from Infected Healthcare Workers

Infection Prevention and Control Guidance for Personal Services: Risks, Principles, and Recommendations

CORE IPC GUIDELINE DOCUMENT IDENTIFIED FOR DEVELOPMENT:

Prevention and Control of Occupational Infections in Health Care***: Guidance document (2002) to be updated.***

Position statements:

n/a

Legislation:

n/a

Campaigns and related activities:

n/a

Press activities:

n/a

Publications:

n/a

Other items of note:

n/a

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention
Meeting Date: 7/16-17/2015
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA Liaison name: Michael D. Howell, MD MPH
Organization represented: Society of Critical Care Medicine

Interim activities and updates:

ICU Liberation Campaign: ABCDEF Bundle

SCCM in collaboration with the Gordon and Betty Moore Foundation, has launched an ICU improvement collaborative to integrate the recently revised A (assess, manage & prevent pain) B (SBT & SAT trials) C (choice of analgesia & sedation) D (delirium assess, prevent & manage) E (early mobility and exercise) F (family engagement and empowerment). 77 ICUs in total have signed agreement letters: 69 adult and 8 pediatric ICUs from across the U.S. representing community hospitals through large academic institutions for the 18 month activity. Special initial focus will be to create teams of trainers for each hospital ICU who will focus on team communication, synergistic care plans, integration of validated assessment tools and reductions in ICU length of stay and ICU ventilator hours. Data collection will be accomplished through REDCap. Three collaborative groups will meet in the Southeast, Midwest, and West regions beginning in August and September 2015. A multi-talented inter-professional faculty team has been assembled including advanced practice and clinical nurse specialists, respiratory therapists, physical and occupational therapists, pharmacists and an advisory clinical psychologist. The collaborative will conclude in early 2017. Additionally a simulation course, *"ICU Liberation and Animation: Implementing the Guidelines"* is being offered in collaboration with Vanderbilt University Medical Center in September, 2015.

Thrive

The SCCM council has allocated nearly $1M dollars over three years to launch a patient and family support program to raise awareness and provide tools focused on post ICU syndrome including PSTD. A SCCM sponsored white paper inclusive of 50 professionals from various organizations across the United States served as the basis for a proposal and approved funding. The Thrive program will support 5 seed sites to test various models of patient and family support, the SCCM patient and family website "MyICUCare" will be updated with information for patients and their loved ones, and connections will be made back to the ICU Liberation initiative to bring clinicians to a new understanding of the sometimes long-term consequences of ICU care. A special emphasis on controlled delirium, reduction of sedative use and early mobilization will be featured as a part of this interlinked project. Additional focus will be placed on comprehensive care plan development for patients as they are transferred from the ICU to next step care settings.

Catheter-Associated UTI – On the CUSP Stop HAI Program

SCCM subcontracted with the AHA/AHRQ to conduct an improvement collaborative with an aim is to reduce CAUTI rates via the *On the CUSP* program in ICUs (cohort 9). ICUs in Georgia, North Carolina, South Carolina and Virginia along with state hospital associations began work in October 2014. A boot camp program with several hundred clinicians in attendance was offered at the 44th Annual SCCM Critical Care Congress in Phoenix, Arizona. SCCM leads William Miles, MD and Diane Byrum, CCRN, CNS headed up the ICU improvement effort. Device assessment and use, days of catheterization, proper culturing techniques, use of bladder ultrasound and other methods to reduce potential infection were undertaken by ICU participants. Data analysis will be underway as the collaborative comes to a close this month. Collaborative participants experienced a shared learning model through both in-person and virtual meetings.

Surviving Sepsis Campaign (SSC)

SCCM is concluding an 18 month improvement collaborative with 63 hospitals on screening and early intervention for sepsis on inpatient hospital wards. Collaboration with the ED and ICU rapid response teams using a model of screening every patient, every day, every shift yielded identification of patients in early sepsis and targeted those who had progressed to severe sepsis or septic shock. A combination of training, EHR alert systems in some institutions and application of the Surviving Sepsis Campaign bundles in early data analysis is showing trending of reduced mortality over time. This activity was a joint project with the Gordon

and Betty Moore Foundation and faculty from the Society of Hospital Medicine. Final data is due on August 15, 2015 with a subsequent findings paper to be published in *CCM*.

The Hellman Foundation and the European Society of Intensive Care Medicine (ESICM) have provided grant funding to the SSC to conduct a pilot project in Gitwe, Rwanda to educate clinicians on early recognition of sepsis in pediatric and adult patients in community clinics and doctor's offices. IRB approval has been completed at the Gitwe Hospital. The database is now being built by the research team at the Beth Israel Deaconess Hospital.

In collaboration with the Johns Hopkins School of Medicine, SCCM is offering, "Sepsis Without Walls: Ensuring All Patients Receive Optimal, Time-Sensitive Care" on September 25 in Baltimore, MD.

Sepsis Definitions

The SCCM and ESICM funded an update to the 2001 published sepsis definitions paper. Experts from across the globe assembled to review current literature and analyze data from the largest data sets on sepsis available. The manuscript has been completed and is now entering a phase of distribution to the organizations that reviewed and endorsed the 2012 Surviving Sepsis Campaign guidelines. These organizations will be offered an opportunity to comment and then if in agreement to endorse the document. It is anticipated that the new definitions document will be published and subsequently available to clinicians in early in 2016.

Ebola Webcast

The SCCM in collaboration with the World Health Organization (WHO) delivered a webcast entitled, *Ethics of Outbreaks* on 07/07/2015. Dr. Marie-Paule Kieny, Assistant Director and Dr. Abha Sacena, Coordinator for Global Health for the WHO were featured speakers. The webcast will be available on the SCCM You Tube channel as an enduring material.

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.

Work has begun on revision of the Surviving Sepsis Campaign guideline anticipated publication 2016. There are now 6 translations for the 2012 guidelines: Chinese, Portuguese, German, Spanish, French and Japanese.

SCCM has been in close contact with the CDC to discuss and collaborate on a pending revision of the definition of sepsis. A meeting is planned at the CDC in September.

SCCM is now entering the final year of an AHRQ grant (Project Dispatch) with a focus on dissemination of patient-centered outcomes programs and projects.

Publications:

A selection of recent infection related studies in *Critical Care Medicine (1-6)* & *Pediatric Critical Care Medicine*, the principal journal of the Society of Critical Care Medicine:

The Association Between Colonization With Carbapenemase-Producing Enterobacteriaceae and Overall ICU Mortality: An Observational Cohort Study; June 2015 - Volume 43 - Issue 6 - p 1170–1177 Lessons Learned: Critical Care Management of Patients With Ebola in the United States; June 2015 - Volume 43 - Issue 6 - p 1157–1164

Editorial: Bad Bugs, No Drugs: Are We Part of the Problem, or Leaders in Developing Solutions? Critical Care Medicine; June 2015 - Volume 43 - Issue 6 - p 1153–1155

The Role of Systemic Antibiotics in Acquiring Respiratory Tract Colonization with Gram-Negative Bacteria in Intensive Care Patients: A Nested Cohort Study; April 2015 – Volume 43 – Issue 4 – p774-780

The Impact of Hospital and ICU Organizational Factors on Outcome in Critically Ill Patients: Results From the Extended Prevalence of Infection in Intensive Care Study; March 2015 – Volume 43 – Issue 3 –p519-526

Invasive Candida Infections and the Harm From Antibacterial Drugs in Critically Ill Patients: Data From a Randomized, Controlled Trial to Determine the Role of Ciprofloxacin, Piperacillin-Tazobactam, Meropenem, and Cefuroxime; March 2015 – Volume 43 – Issue 3 – p594-602

Longer RBC Storage Duration is Associated With Increased Postoperative Infections in Pediatric Cardiac Surgery; March 2015 – Volume 16 – Issue 3 – p227-235

Editorial: Outcomes and Risk Factors in Pediatric Ventilator-Associated Pneumonia: Guilt by Association; March 2015 – Volume 16 – Issue 3- p299-301

Other items of note:

Journal of Critical Care Medicine

Management of the Potential Organ Donor in the ICU: Society of Critical Care Medicine/American College of Chest Physicians/Association of Organ Procurement Organizations Consensus Statement; June 2015 - Volume 43 - Issue 6 - p 1291–1325

At journal awaiting publication: Guideline for Stress Ulcer Prophylaxis; Guideline for appropriate use general and cardiac ultrasound by the Intensivist in the evaluation of critically ill patients

In development/update:

- Clinical practice guidelines for support of the family in the patient-centered ICU
- Surviving Sepsis Campaign
- Clinical Practice guidelines for the management of pain, agitation and delirium (ICU Liberation)
- Management of critically ill patient with liver disease
- Guidelines for the provision and assessment of nutrition support therapy in adult critically ill patient (SCCM & A.S.P.E.N)
- Clinical parameters for hemodynamic support of newborn and pediatric septic shock
- Recommendations for the Diagnosis and Management of Corticosteroid Insufficiency in Critically Ill Patients – Consensus Statements for International Task force
- Implementing Shared Decision-Making in the ICU (SCCM and ATS)Guideline for Admission and Discharge for the Pediatric ICU and Levels of Care
- Medication Use Safety
- Guidelines for ICU Admission, Discharge and Triage

Pediatric and Neonatal Analgesia and Sedation in the ICU

Journal of Pediatric Critical Care Medicine

Pediatric Acute Respiratory Distress Syndrome: Consensus Recommendations From the Pediatric Acute Lung Injury Consensus Conference; June 2015 - Volume 16 - Issue 5 - p 428–439

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention
Meeting Date: July 16-17, 2015
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA Liaison name: Mark Rupp, MD
Organization represented: SHEA

Interim activities and updates:

Education

SHEA Spring 2015 Conference: Science Guiding Prevention (May 14-17, 2015)

Under the leadership of Co-Chairs, Drs. Eli Perencevich and Susan Huang, the SHEA Spring 2015 conference was just held on May 14- 17th in Orlando, FL to a record number of attendees; 683.

Building on the success of past Spring Meetings, SHEA added several new enhancements, these include:

- Focused scientific abstracts related to healthcare epidemiology, surveillance, implementation science and patient safety, and prevention strategies
- Traditional healthcare-associated infection tracks PLUS sessions on multi-disciplinary and integrated approaches involving implementation science and prevention across the range of healthcare facilities, including hospital-based, community-based, and post-acute and long term care settings
- Certificate Courses
- SHEA/CDC Training Certificate Course in Healthcare Epidemiology
- Post-Acute and Long Term Care Certificate Course
- Poster and oral abstract awards for diverse professional fields related to healthcare epidemiology for all career levels
- 4th Annual SHEA Epi Project competition for Fellows and junior faculty

Expanded networking and mentoring opportunities

IDWeek 2015

SHEA is pleased to be joining with IDSA, PIDS and HIVMA once again for IDWeek 2015. Drs. Charlie Huskins and Arjun Srinivasan are serving as SHEA's Chair and Co-Chair, respectively. This year SHEA will have 1 Pre-Meeting workshop, 6 MTPs, 11 Symposiums, 1 Interactive Session and 2 Cross-Cutting Sessions.

Primer on Healthcare Epidemiology, Infection Control and Antimicrobial Stewardship SHEA has launched its Online Primer on June 1st. 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, we anticipate this to be 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). SHEA is grateful for the financial support offered by IDSA as well.

Guidelines, Expert Papers and Compendium

SHEA Guidelines Committee

Under the goal of sustaining development and dissemination of expert guidelines addressing healthcare-associated infections:

The SHEA Expert Guidance: Isolation Precautions for Visitors was recently published in ICHE. Both the Animals in Healthcare and the Isolation Precautions for Visitors guidance documents have been converted into pocket guides.

http://www.shea-online.org/GuidelinesResources/Guidelines.aspx
http://www.shea-online.org/GuidelinesResources/SHEAPocketGuidelines.aspx

SHEA has commissioned a "Methodologies Task Force" to review prevailing methodologies in guidelines development and to further codify SHEA's guidelines and expert guidance literature review and grading process. The task force is being chaired by Drs. Kristina Bryant and Deborah Yokoe.

A subgroup of the Guidelines Committee developed comments presented on May 14 to the FDA regarding SHEA's positions on reprocessing and culturing scopes. The SHEA comments address the interim CDC guidance on culturing and focusing on premarket instructions for use so that the onus does not fall on healthcare facilities to determine how to reprocess the equipment.

Policy

SHEA Participation in White House Forum on Antibiotic Stewardship

SHEA was represented at the June 2 White House Forum on Antibiotic Resistance by SHEA President Anthony Harris, MD. Dr. Harris was also an invited speaker on a panel discussion on inpatient prescribing practices and the impact on antibiotic resistance. Additionally, SHEA submitted to the White House a formal commitment to actively contribute to achieving the President's goals outlined in the Combating Antibiotic Resistant Bacteria (CARB) initiative.

SHEA's commitments span all five main goals of the CARB initiative. Of note, SHEA is convening a multi-stakeholder human health antibiotic stewardship working group organized under the auspices of the Stakeholder Forum for Antibiotic Resistance (S-FAR). The work group will be comprised of organizations committed to the CARB initiative and identify opportunities for collaboration, identify gaps, and challenges in achieving goals. Copies of SHEA's full commitment letter are available upon request.

Budget and Appropriations Advocacy

SHEA is collaborating with a variety of partners and coalitions to support the President's 2016 budget request in support of programs for improving antibiotic stewardship, strengthening antibiotic resistance risk assessment, surveillance and reporting capabilities, and driving research innovation in the human health sector. SHEA supports the House and Senate's proposed increase funding certain programs run by NIH, CDC and other agencies with programs directed at combatting antibiotic resistance. SHEA is opposed to eliminating AHRQ as proposed by the House, and cutting overall funding to CDC as proposed by the Senate.

CMS and ONC Proposed Regulations on Meaningful Use and HIT Certification Criteria

SHEA submitted comments to the Centers for Medicare & Medicaid Services' (CMS') proposed rule for Stage 3 of the Electronic Health Record (EHR) Incentive Program and the Office of the National Coordinator's (ONC's) proposed rule for the 2015 Edition Health IT Certification Criteria. SHEA's comments were coordinated with IDSA and APIC and are available upon request.

CMS Inpatient Prospective Payment System Proposed Rule

SHEA submitted comments to the CMS's annual proposed rule for the Inpatient Prospective Payment System for Acute Care Hospitals. SHEA's comments were coordinated with APIC. SHEA has developed a summary of its comments for quick reference, which can be made available upon request along with SHEA's full comment document.

CMS Outpatient Prospective Payment System Proposed Rule

SHEA is in the process of evaluating CMS's annual proposed rule for the Outpatient

Prospective Payment System and Quality Incentive Program.

CMS Annual End Stage Renal Disease Payment and Quality Incentive Program

SHEA is in the process of evaluating CMS's annual proposed rule for the End Stage Renal Disease Payment System and Quality Incentive Program.

FDA Proposed Rule for Healthcare Antiseptics

SHEA will submit comments in response to an FDA proposed rule to reevaluate the safety and effectiveness of over-the-counter healthcare antiseptics containing certain ingredients and to amend the tentative final monograph (TFM) for these products. SHEA issued a statement April 30 in reaction to the proposed rule when it appeared on the Federal Register Inspections Desk.

AHRQ Comments re: Interventions to Improve Appropriate Antibiotic Use for Acute Respiratory Tract Infections

SHEA submitted comments March 9 providing feedback on a draft AHRQ report that provides an analysis on current interventions and prescribing practices related to the treatment of acute respiratory tract infections.

State Legislation

SHEA has been communicating with the office of California State Senator Jerry Hill [D-13] regarding a bill he introduced in February that would require skilled nursing facilities to implement antibiotic stewardship policies. The bill, SB 361, mirrors a similar piece of legislation for acute care facilities signed into law September 2014. With support and input from SHEA and other long-term/post- acute care stakeholder organizations, SB 361 continues to progress through the California Senate. SHEA expects SB 361 to be signed into law this September.

SHEA Grassroots Network

SHEA is the process of developing and rolling out a new Grassroots Network program for members. The network will establish a new framework for SHEA members to become actively engaged in SHEA's Policy and Practice initiatives, and in advancing the Society's policy goals.

Research

The Research Committee recently deployed an international survey to better understand the capabilities of infection prevention teams globally, related to prevention of multidrug resistant organisms. The survey will gather data exclusively from international sites, and will assess respondents' current practices in terms of infection prevention and control staffing, policies and resources, as well as those related to antimicrobial stewardship, laboratory testing, and information technology. Barriers to optimal infection prevention and control will also be assessed. Initial deployment went to SHEA international members; a secondary deployment will expand beyond this pool.

SHEA Research Network

The SHEA Research Network (SRN) has released three projects to its membership. The first by PI Dr. Susan Huang seeks to define research quality improvement in the context of when patient consent is needed, the second by Dr. Jason Lempp, winner of the 2014 Epi Competition, seeks to apply the Washington state CLABSI validation method to national standards, and the third, by Dr. David Yassa addresses practices related to ERCP. Two projects in queue for release address use of antibiotics in acute care settings and defining healthcare-acquired influenza.

Press activities:

Activities/Media Coverage

SHEA has released several press releases outside of ICHE related to Antibiotic Stewardship. 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 www.shea-online.org/JournalNews/PressRoom/PressReleaseArchives.aspx

06/02/15 - SHEA Applauds Administration's Continued Support to Combat Antibiotic Resistance

05/28/15 - High Rates of MRSA Transmission Found Between Nursing Home Residents and

Healthcare Workers

05/18/15 - Diagnostic Errors Linked to High Incidence of Incorrect Antibiotic Use

04/30/15 - APIC and SHEA statement on FDA proposed rule on safety and effectiveness of healthcare antiseptic products

04/29/15 - Drug Resistant Bacteria Common for Nursing Home Residents with Dementia 04/10/15 - New Guidance on Contact Precautions for Hospital Visitors

04/01/15 - Ebola Planning Created Need for Unprecedented Preparedness in Hospitals 03/30/15 - Endoscopes Linked to Outbreak of Drug-Resistant E.coli

03/27/15 - SHEA Applauds Strategies Outlined in National Task Force for Combating Antibiotic- Resistant Bacteria Plan

03/09/15 - International Infection Experts Selected to Support Global Efforts to Reduce Healthcare Associated Infections

03/02/15 - Infection Control Experts Outline Guidance for Animal Visitations in Hospitals 02/24/15 - APIC and SHEA statement on infections associated with duodenoscope procedures SHEA continues to collaborate with Medscape submitting expert commentaries and contributing select articles from Infection Control and Hospital Epidemiology. The SHEA page is available at: www.medscape.com/partners/shea/public/shea SHEA is working with Medscape to develop a presentation of key elements of the compendium to draw attention to these critical documents. SHEA also has an active social media presence which you can follow:

LinkedIn – The Society for Healthcare Epidemiology Group Twitter: @SHEA_Epi

Facebook: www.facebook.com/SHEAPreventingHAIs

Publications

Publications/ICHE

The ICHE transition to Cambridge continues to go well. Submissions to ICHE are up overall and the time to online view of an article has reduced. SHEA staff will meet with Cambridge Staff and the Editor at Large in June for a strategic planning session to address outstanding issues and ideas moving forward.

SHEA is starting work on updating our textbook, the Practical Healthcare Epidemiology, 4th Edition expected to make its debut in 2016.

Other items of note:

SHEA Awards

SHEA slightly tweaked awards this year in order to enable a broader pool of applicants and renamed our awards to end some confusion with IDWeek Awards. Applications for the following SHEA Awards presented at IDWeek were due June 5, 2015. Award selection will occur in late June/early July. More information is available here: http://www.shea-online.org/About/SHEAAwards.aspx.

SHEA Mentor Scholar Award

SHEA Senior Scholarship Award

SHEA Pediatric Scholarship Award

SHEA Junior Scholarship Award

SHEA International Scholarship Award

SHEA Advanced Practice IP Award

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention
Meeting Date: July 16-17, 2015
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:

SHM has been working with HRET on Catheter Associated Urinary Tract Infection (CAUTI) prevention and best practices regarding the Comprehensive unit-based safety program model (CUSP)

SHM has facilitated coaching calls and actively supported three cohorts for the project in order to assist hospitals with implementing cultural and technical interventions in order to reduce CAUTI rates; Data collection is complete for cohort 8

The CAUTI Fellowship, Project Protect: Infection Prevention Fellowship, completed in March 2015 and The Hospitalist Blog highlighted one of SHM's faculty and his mentee

SHM is completing Option Year 3 of the contract; Currently, HRET is exploring opportunities to help hospitals implement sustainable strategies

Received notification of award for additional subcontract to work in partnership with HRET to reduce CAUTI in the long term care setting; Currently executing Option Year 1 of the contract SHM recruited four faculty experts who are responsible for developing content and coaching organizations enrolled in the program to reduce CAUTI in long term care facilities (LTCFs) The program is also assisting facilities in developing their culture of safety and working on additional safety issues such as falls and antimicrobial stewardship

SHM served as an organizational lead for the South Dakota facilities participating and assisted with content development for specific learning sessions and coaching calls

We currently have three faculty experts participating in cohort 2, and three faculty experts for cohort 3. The fourth cohort for the project has been recruited and we anticipate having three of our faculty participating

HRET is currently recruiting for cohort 5

March 2015- SHM's HQPS Committee introduced the Antimicrobial Stewardship Subcommittee recognizing that hospitalists are well positioned to impact the improvement of antimicrobial use, implement appropriate prescribing and appropriately address antimicrobial resistance

June 2, 2015- SHM was invited to participate in the White House Forum on Antibiotic Stewardship

The forum brought together key human and animal health constituencies involved in the development, promotion and implementation of activities to improve antibiotic stewardship nationwide.

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.

SHM is working in conjunction with the Society for the Advancement of Blood Management, Inc (SABM) on an Anemia Prevention and Management Implementation Guide

SHM has recruited three faculty experts to assist with the production of a repository of materials to assist clinicians and facilities who are interested in improving the care of patients with anemia in the hospital setting as well as preventing transfusion overuse in anemia patients

SHM participated in the American Board of Internal Medicine's (ABIM) *Choosing Wisely* Campaign, which subsequently identified blood transfusion as a common, but inappropriately utilized intervention for anemia

SHM in partnership with the ABIM's *Choosing Wisely* initiative previously published two recommendations that will guide hospitalists toward high-value care pertaining to blood transfusions and lab testing.

Position statements:

SHM signed on to letter urging the Congress to provide resources to support the recommendations made by the President's Council of Advisors on Science and Technology to combat antibiotic-resistant bacteria

Support federal funding for antimicrobial resistance activities

Legislation:

n/a

SHM will target its membership of 14,000 members through a targeted Antimicrobial Stewardship Campaign created within its Center for Hospital Innovation and Improvement

The campaign will include targeted messages that address appropriate antimicrobial prescribing practices and key strategies to reduce spread of antimicrobial resistance

SHM will rely on multiple venues to introduce and conduct the campaign including social media, email and its Hospital Medicine Exchange interactive site

SHM will ask members to sign a formal commitment to modify two key behaviors associated with antimicrobial prescribing

Press activities

n/a

Publications

Time to clinical stability among children hospitalized with pneumonia

Prior pneumococcal and influenza vaccinations and in-hospital outcomes for community- acquired pneumonia in elderly veterans

Hospital outcomes associated with guideline-recommended antibiotic therapy for pediatric pneumonia

Development, implementation, and impact of an automated early warning and response system for sepsis

A nurse-driven screening tool for the early identification of sepsis in an intermediate care unit setting

The association of patient complexities with antibiotic ordering

Other items of note:

n/a/

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention
Meeting Date: July 16-17, 2015
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 was held April 15-16 in Westlake Village, California. The meeting started with a half-day review course, and was followed by two more days of that included 44 oral papers, 58 posters, and three update symposia. The annual invited William A. Altemeier Memorial Lecture was entitled "Evolving Epidemiology of MOF into PICS," and was given by Frederic Moor, MD, Professor of Surgery, University of Florida School of Medicine.

Guidelines and Guidance:

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

1. Guidelines in process

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

Antibiotics for facial trauma

October 2014: completion of analysis

December 2014: manuscript submission to *Surgical Infections*

Revision of 2010 Guidelines for the management of intra-abdominal infections August 2014 Review literature

November 2014 Complete analysis

July 2015 Submit manuscript

Position Statements:

n/a

Legislation:

n/a

Press activities:

Philip S. Barie, MD and Giana Davidson, MD quoted in NY Times article on antibiotics for appendicitis.

http://www.nytimes.com/2015/05/19/health/antibiotics-resurface-as-alternative-to-removing-appendix.html

Recent Publications:

REVIEWS

Necrotizing Pancreatitis: New Definitions and a New Era in Surgical Management Full Access Andrew Rosenberg, Elizabeth A. Steensma, Lena M. Napolitano

Surgical Infections. February 2015, 16(1): 1-13.

Skin Preparation Before Surgery: Options and Evidence Full Access Feroze Sidhwa, Kamal M.F. Itani

Surgical Infections. February 2015, 16(1): 14-23.

Gastrointestinal Mucormycosis Requiring Surgery in Adults with Hematologic Malignant Tumors:

Literature Review Full Access

Joseph D. Forrester, Venita Chandra, Andrew A. Shelton, Thomas G. Weiser

Surgical Infections. April 2015, 16(2): 194-202.

The Challenge of Antimicrobial Resistance in Managing Intra-Abdominal Infections Full Access Massimo Sartelli, Fausto Catena, Salomone di Saverio, Luca Ansaloni, Federico Coccolini, Cristian Tranà, James Kirkby-Bott

Surgical Infections. June 2015, 16(3): 213-220.

Perioperative Skin Preparation and Draping in Modern Total Joint Arthroplasty: Current Evidence Full Access

Konstantinos Markatos, Maria Kaseta, Vasileios S. Nikolaou Surgical Infections. June 2015, 16(3): 221-225.

Trial of short course antimicrobial therapy for intra-abdominal infection.

Sawyer RG, Claridge JA, Nathens AB, Rotstein OD, Duane TM, Evans HL, Cook CH, O'Neill PJ, Mazuski JE, Askari R, Wilson MA, Napolitano LM, Namias N, Miller PR, Dellinger EP, Watson CM, Coimbra R, Dent DL, Lowry SF, Cocanour CS, West MA, Banton KL, Cheadle WG, Lipsett PA, Guidry CA, Popovsky KA. N Engl J Med 2015;372: 1996-2005.

Other items of note:

n/a

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention
Meeting Date: July 16-17, 2015
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Liaison name: Margaret VanAmringe
Organization represented: The Joint Commission

Interim activities and updates:

The recent Ebola crisis in West Africa led to an unprecedented call for preparedness by U.S. hospitals. To date, the impact on our country's hospitals is unknown. Researchers from the Society for Healthcare Epidemiology of America and The Joint Commission began in June to conduct an important study that will provide estimates of the costs and benefits of Ebola Virus Disease preparedness to hospitals. This national snapshot will inform key stakeholders and better enable preparedness for future challenges.

Guidelines and Guidance:

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TJC is in the process of revising its National Patient Safety Goal (NPSG) on CAUTIs to harmonize with the 2014 infection control Compendium for Hospitals. The revised NPSG will also be field tested for our Nursing Care Center accreditation program which currently does not have a CAUTI NPSG.

Position statements:

Campaigns and related activities:

TJC attend the June White House Forum on Antibiotic Stewardship that brought many stakeholders together to further the president's action plan in this area. TJC made commitments to strengthen its various programs and tools around stewardship, including looking at standards and revising its current AS toolkit.

Publications:

The Joint Commission disseminated our recent CDC/NIOSH-supported monograph on hospital respiratory protection programs jointly with OSHA's toolkit press release in May. Results are expected around the end of the year. Our document has been viewed approximately 1300 times since March. We will do additional dissemination via webinars and conferences.

Other items of note:

TJC is evaluating changes to its accreditation standards for hospitals and home health based pharmacies that could lead to incorporating more standards relevant to sterile compounding.